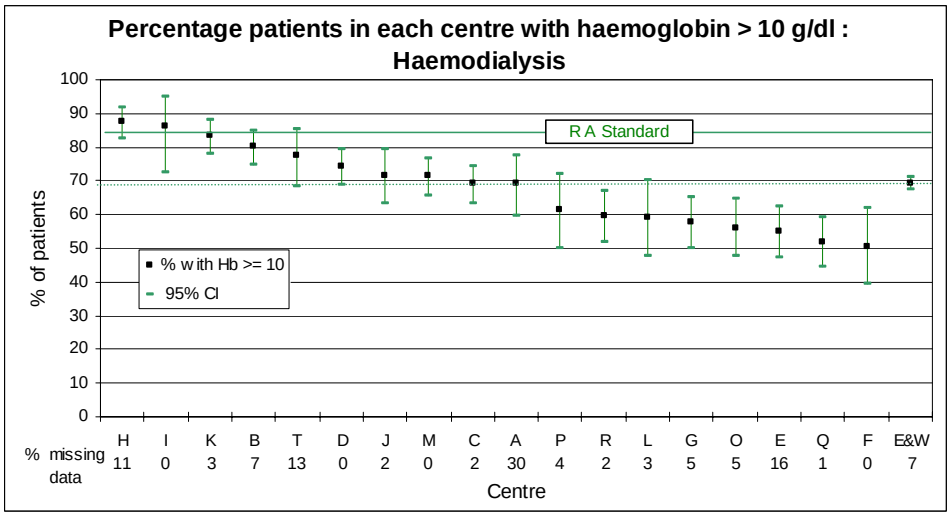
The Second Annual Report

The
UK Renal Registry

December 1999



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Copies of this report are provided as a service by the Renal Association

We would like to thank Dr A J Williams for editorial consultation

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Chapter 1: Summary

- The 1999 UK Renal Registry report refers to activity in 1998. The proportion of the UK adult population covered has risen from 16% to 43%, and all of Scotland is included. Data is presented from 15,000 patients on renal replacement therapy.

- During 1998 the 31 units contributing to the Registry started 2,304 patients on renal replacement therapy, with a median age of 63, giving an estimated take-on rate of 92.2 patients per million population per year. Diabetic nephropathy is the most common single cause of end stage renal failure (16% of the total).

- There were 1,229 deaths on renal replacement therapy in Registry units in England and Wales in1998 compared with 1,788 new patients. This leaves 549 additional patients being treated, a 5.3% increase. One year survival is well within the national recommended standard.

- There is a continuing rise in the proportion of dialysis patients receiving haemodialysis. Haemodialysis is now the modality of 64% of all prevalent dialysis patients, is the first elective modality in 60% of new patients, and is used even more frequently in elderly patients. Although popular in some centres, automated peritoneal dialysis was only used in 2% of Registry dialysis patients.

- Several centres reported that funding restrictions limited haemodialysis to twice weekly or inappropriately short hours. Overall 8% of patients receive haemodialysis only twice a week. The percentage of hospital haemodialysis patients with a urea reduction ratio of greater than 65%, (the minimum recommended Standard) was 70% in Scotland. In England and Wales it averaged 57%, but varied between renal centres from 97% to 28%.

- The data show a progressive improvement in the haemoglobin of dialysis patients for England & Wales through 1997 to 1999, but there was wide variation between the centres. The achievement of the Renal Association Standard was 69% for haemodialysis patients and 78% for peritoneal dialysis patients. Many units reported funding restrictions limiting use of erythropoietin.

- Haemodialysis patients in the first few months of renal replacement therapy have a higher rate of anaemia. The adequacy of haemodialysis appeared to be related to haemoglobin, but variations in iron stores did not seem to be a determining factor influencing variations in haemoglobin.

- The haemoglobin of individuals showed marked volatility through the year. Better understanding of these changes and the factors influencing them would enable better protocols for intervention and prevention of anaemia to be developed.

- Measurement of serum albumin remains a complex methodological issue in renal failure and also creates interpretative difficulties with calcium measurement. As a result of Registry activity the Association of Clinical Biochemists has instigated a national audit of laboratory reference ranges to address these problems.

- There has been no change over 2 years in the percentage of haemodialysis patients with high serum phosphate. Only 30% of haemodialysis patients and 40% of peritoneal dialysis patients complied with the recommended Standard for serum phosphate. All Centres had difficulty reducing high serum phosphates.

- Many centres may feel that the Renal Association Standard for serum phosphate is unachievable and has little evidence based justification. The Registry data is indicating a higher risk of death for patients with a serum phosphate above 2.1 mmol/L, but no indication that reducing serum phosphate below 1.70 mmol/L, as suggested by the Renal Association Standards document, is beneficial.

- The one year survival of patients with renal transplants established for at least 6 months is not less than 97%. Despite the high incidence of cardiovascular disease in transplanted patients, good control of blood pressure and serum cholesterol is frequently not achieved.

- The most pressing need for the Registry is to improve the returns of co-morbidity data from patients starting renal replacement therapy. Without this the value of the Registry database will be greatly reduced.

- A database for collection of data on children on renal replacement therapy has been successfully established.

- It is hoped the publication of this report will be of use to patients, physicians, surgeons, commissioners of care, and the Department of Health, and will further the aim of the Registry to help improve the quality and efficiency of renal care in the UK.

Chapter 2: Introduction to the 1999 report

Introduction

The primary intention of the UK Renal Registry is to carefully monitor the quantity and quality of renal care in the UK, and thus to improve the quality and efficiency of this care. This report is provided to facilitate that process. It will enable internal audit within renal centres, support comparative audit, and provide information to stimulate and inform the process of improving protocols of care.

The UK Renal Registry is part of the pioneering work of the Renal Association in support of clinical governance. The process was initiated by the Renal Association with the publication of the document on "recommended standards and audit measures for the treatment of adults with renal care". The audit and research work of the registry is essential for closing the audit loop and implementing those recommendations.

The 1999 UK Renal Registry report refers to activity in 1998 and covers 43% of the UK adult population. Many more renal units have joined the Registry since then. In total 31 Renal Units have contributed to the report, including all 12 Units in Scotland and 19 of the 63 Units (30 %) in England and Wales (Table 2.1). The English and Welsh units cover 38% of the population of 52.2 million.

	Included in the Renal Registry		
	England & Wales	**Scotland**	**Total**
No. of units	19	12	31
No.of patients (31/12/99)	10,510	2,956	13,466
Population (m)	19.9 (of 52.2m)	5.1	25.0
Patients (pmp)	528	580	539
Patients per unit	553	246	434

Table 2.1 Summary of adult patients registered and total population covered

The participating centres are listed in Table 2.2; the areas represented are shown in Figure 2.1.

			Population (millions)
England & Wales		**Total**	**19.9**
Birmingham	Heartlands Hospital		.60
Bristol	Southmead Hospital		1.50
Carlisle	Cumberland Infirmary		.32
Carshalton	St Helier Hospital		1.80
Cardiff	University of Wales Hospital		1.30
Coventry	Walsgrave Hospital		.85
Exeter	Royal Devon and Exeter Hospital		.85
Gloucester	Gloucester Royal Hospital		.55
Hull	Hull Royal Infirmary		1.02
Leeds	St James's Hospital		1.45

Leicester	Leicester General Hospital	1.80
Middlesborough	South Cleveland Hospital	1.00
Nottingham	Nottingham City Hospital	.86
Oxford	Churchill Hospital	1.80
Plymouth	Derriford Hospital	.45
Sheffield	Northern General Hospital	1.75
Stevenage	Lister Hospital	1.25
Sunderland	Sunderland Royal Hospital	.34
Wordsley	Stourbridge Hospital	.42
Scotland	**Total**	**5.10**
Aberdeen	Aberdeen Royal Infirmary	
Airdrie	Monklands District General Hospital	
Dunfermline	Queen Margaret Hospital	
Dumfries	Dumfries & Galloway Royal Infirmary	
Dundee	Ninewells Hospital	
Edinburgh	Royal Infirmary	
Glasgow	Glasgow Royal Infirmary	
	Stobhill General Hospital	
	Western Infirmary	
Kilmarnock	Crosshouse Hospital	
Inverness	Raigmore Hospital	

Table 2.2 Participating adult centres

Most of this report concerns adults on renal replacement therapy. All the paediatric renal units in the country participate in a paediatric registry which is linked with the adult registry. A separate paediatric chapter is included.

The following centres have since joined the Registry, or are in the process of doing so.

Bradford	Bradford Royal Infirmary	.60
Liverpool	Royal Infirmary	1.75
London	Guys and St Thomas Hospital	
London	Kings College Hospital	.81
London	St Mary's Hospital	.64
Leeds	Leeds General Infirmary	.75
Preston	Royal Preston Hospital	.95
Portsmouth		2.00
Rhyl		
Southend		.35
Swansea	Morriston Hospital	1.00
Wolverhampton	Newcross Hospital	
Wrexham	Maelor General Hospital	.32
York		.25

Tables 2.3 New units joining the Registry

The catchment populations quoted are estimates provided by each individual unit, and only include areas for which a total renal replacement therapy service is provided. For the transplant units providing a transplant service to other renal units the additional transplant population is not included in the population served. As the Registry grows and covers large contiguous areas, errors due to cross-boundary flow of patients will become insignificant. It will then be possible to estimate prevalence and incidence of

renal replacement therapy by geographical areas, such as Health Authorities, using postcodes of individual patients.

It is difficult to estimate the growth of the UK renal replacement therapy program. Some indication is given by the fact that at the end of 1997 the Registry had data from 9 units, all in England, on 5,057 live patients. In the subsequent 12 months the number of patients receiving all forms of renal replacement therapy in these units has increased by 5.6 %.

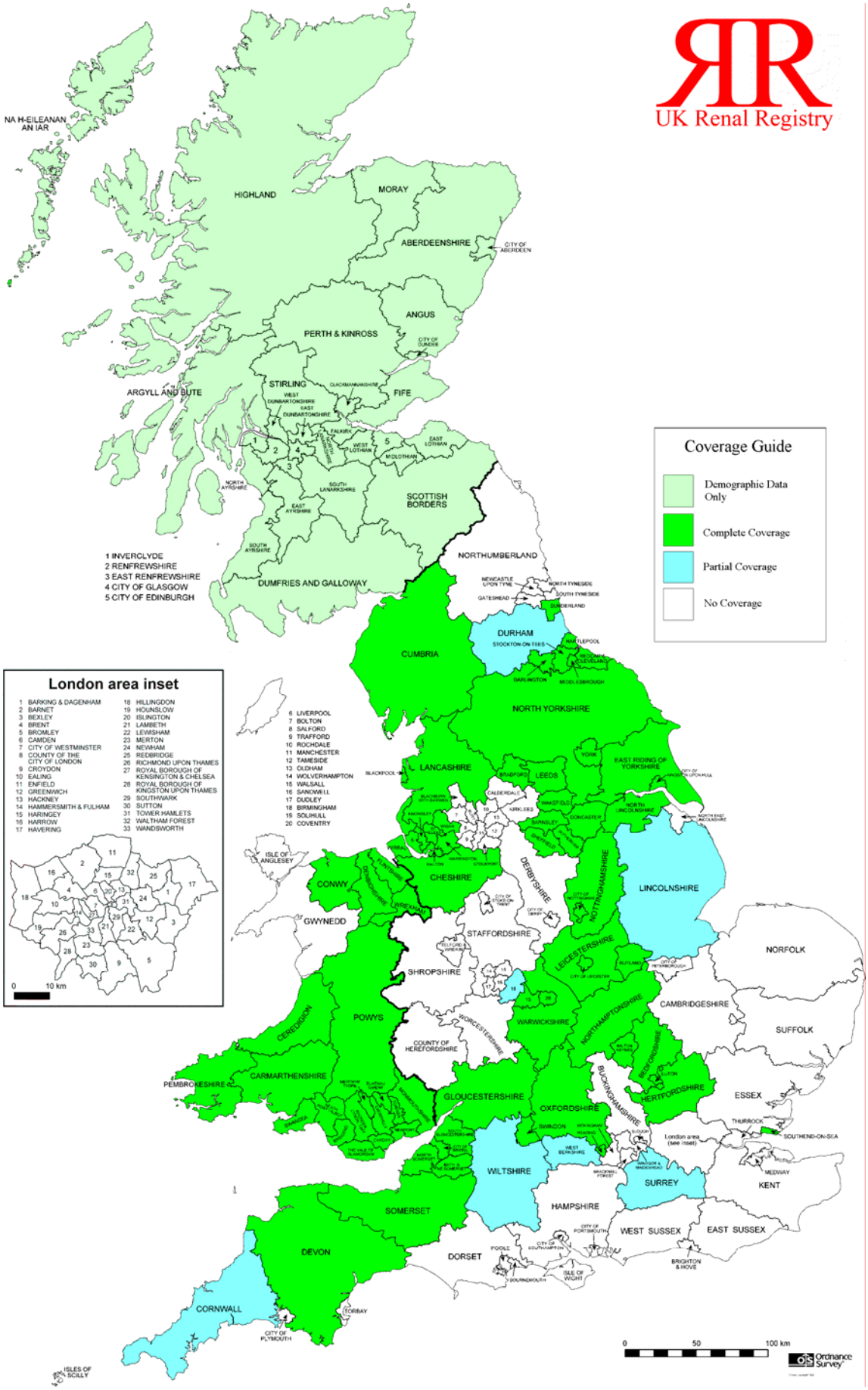


Figure 2.1 Geographical location of Units contributing to the Renal Registry

Recommended Standards of renal care and the Renal Registry

The UK Renal Association, together with the Royal College of Physicians of London, has produced a comprehensive document of recommended standards and audit measures for the treatment of adult patients with renal failure. Much of this report will assess compliance with these standards and guidelines.

Many national and regional renal registries provide data on the acceptance of patients for renal replacement therapy, the stock of patients, treatment modalities and survival. The unusual feature of the UK Registry is the collection of sequential quarterly data on all patients related to the quality of care. Such data include adequacy of dialysis, haemoglobin, blood pressure, and many biochemical variable such as serum albumin, phosphate and cholesterol. It is the collection of this data which allows audit against the national recommended standards.

The UK Renal Registry

The UK Renal Registry was established by the Renal Association, with support from the Department of Health, the British Association for Paediatric Nephrology, and the British Transplantation Society. It has close links with the Scottish Renal Registry.

The initial development of the Registry was financed by grants from the Department of Health and from industry. Continuing activity is largely funded through payment by participating renal units of an annual fee per patient registered. In this way the Registry will be able to remain an independent source of data and analysis on national activity in renal disease.

Participation in the Renal Registry is voluntary but the expectation is that all United Kingdom renal and transplant units will ultimately take advantage of the opportunities offered by the Renal Registry database. Ability to participate could be limited by the individual centre's information technology and data quality

A more full explanation of the Registry is contained in the document 'The Registry Rationale' in Appendix A.

Anonymity and confidentiality

Centre anonymity has been carefully maintained, in accordance with the wishes of some participants. Neither the Chairman of the Registry nor the subcommittee members are aware of the identity of the centres within the analysis. Only the Renal Registry director, data manager and statistician are able to identify the centres. This identification is necessary so that any issues raised, and discrepancies in the analysis, can be discussed with the relevant centre.

It may be possible to identify a centre by the number of patients; for this reason throughout this report the analyses which compare centres do not show actual numbers of patients in each centre.

Outline of Report

This report will concentrate on the following areas :-

1. Analysis of new patients and all other patients receiving renal replacement therapy, and their short term survival
2. A comparison of adequacy of haemodialysis, using urea reduction ratio.
3. Analysis of haemoglobin, serum ferritin, and use of erythropoietin, including analysis of sequential changes in individuals
4. Analysis of biochemical indicators of quality of care
5. Blood pressure control
6. Renal transplantation
7. Paediatric renal replacement therapy
8. A summary of comparative standards of care measured against the Renal Associations Standards Document.

Statistical Interpretation of the Report

In this years report the 95% confidence interval is shown for compliance within a Standard. Calculation of this confidence interval takes into account the number of patients within the Standard and the number of patients with data. The 95% confidence interval provides an indication of how the result might vary if the measurement was repeated a short time later, or if patients with missing data were included.

Although the results have been ranked according to their achievement of the Standard, the 95% confidence interval indicates that their positions may vary if the measurement was repeated or patients with missing data included. It is possible to provide the 95% confidence interval on prediction of the rank order for each centre, though this has not been included this year.

To assess whether there is overall significant variation among the percentage reaching the Standard between centres, a chi-squared test has been used. Caution should be used when interpreting "no overlap" of 95% confidence interval between centres in the presentations. When comparing data between many centres, it is not necessarily correct to conclude that two centres are significantly different if their 95% confidence intervals do not overlap. In this process the eye compares centre X with the other 18 centres and then centre Y with the other 17 centres. Thus 35 comparisons have been made and if using a hypothesis test at least 2 are likely to be "statistically significant" by chance, at the commonly accepted 1 in 20 level. If 19 centres were compared with one another, then 171 individual comparisons would be made, and one would expect to find 9 "statistically significant" differences. To test for significance between individual centres to see where the differences lie would require multiple testing in this way and therefore was not performed by the Registry.

In addition, the Registry has not tested for significant difference between the highest achiever of the Standard and the lowest achiever, as these centres were not known in advance of looking at the data, which then invalidates the test.

References

Essential references have been included at the end of each chapter of this report.

Distribution of Report

The Renal Association has made a grant towards part of the report cost to allow distribution to all members of the Association. The report will also be distributed to Health Authorities.

Further copies of the report will be sent to individuals or organisations on request and a donation towards the £12 cost of printing and postage would be appreciated

The full report will also appear on the Registry web site – ***www.renalreg.com***

Chapter 3: New Adult Patients Accepted For Renal Replacement Therapy In 1998

Introduction

During 1998 the 31 units contributing to the Registry started 2304 patients on treatment for end-stage renal failure. The figures are summarised in Table 3.1. Since all Scottish units contribute to the Registry the acceptance rate per million population can be given more accurately than for England & Wales, where only 30% of the units contribute and the catchment areas are estimates provided by the units themselves.

This analysis only includes adult patients (aged over 18) starting end stage renal replacement therapy for the first time as defined in appendix B, and does not include patients who transferred into centres participating in the Registry who had previously started on therapy elsewhere.

	England & Wales	Scotland	Total
No. of units	19	12	31
No. of new patients	1,788	516	2,304
Catchment population million	19.9	5.1	25.0
New patients p.m.p.	89.8	101.2	92.2
(95% C.I.)	(85.7 – 94.1)	(92.6 – 110.4)	(88.4 – 96.0)
New patients per Unit	94	43	

Table 3.1 Summary of new patients accepted during 1998

The Renal Association standards document recommends ***a minimum annual acceptance rate of new patients with renal failure of 80 per million population, adjusted upwards as necessary for ethnic and age distribution of the population.***

Interpretation of apparent of the acceptance rates for individual units is very difficult for the following reasons :-

1. The catchment populations are ill-defined, the Registry relies on each unit's own estimation of its catchment area.
2. In large conurbations there are significant cross-boundary flows of patients.
3. The demand for treatment will vary with the age and ethnicity characteristics of the population served.
4. There variation in definition of "chronic renal failure", some units including patients others would define as "acute".
5. Resource constraints have significant effects. One of the centres with a low acceptance rate has lacked facilities for more patients and has been referring patients to nearby units. Thus the population has been served, but not by its local unit.

It is therefore not surprising that the calculated acceptance rates vary between the units from 50 to 150 patients per million population per year. This variation is illustrated in figure 3.1. As the Registry grows to cover larger contiguous areas of the UK, cross

boundary flows will become less significant. Analysis of treatment rates, on the basis of postcodes, will be performed for each health authority for next year's report.

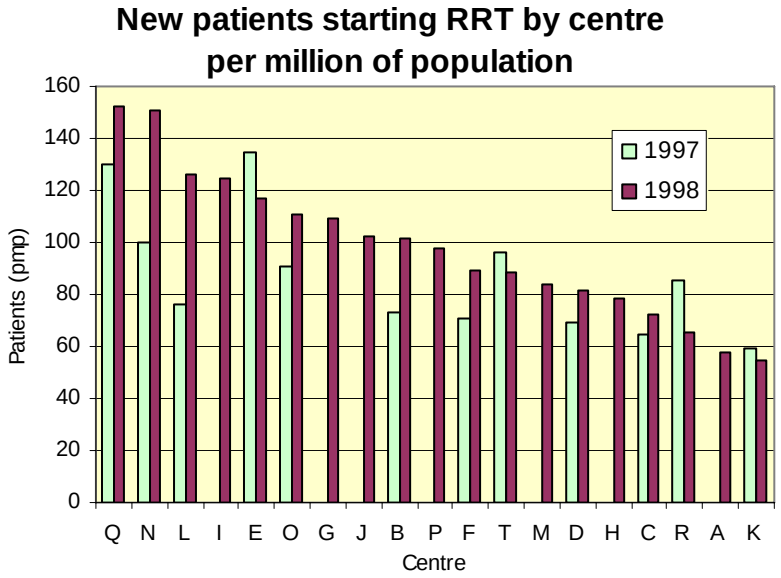


Figure 3.1 New patients starting RRT by centre per million of population

Age of new patients

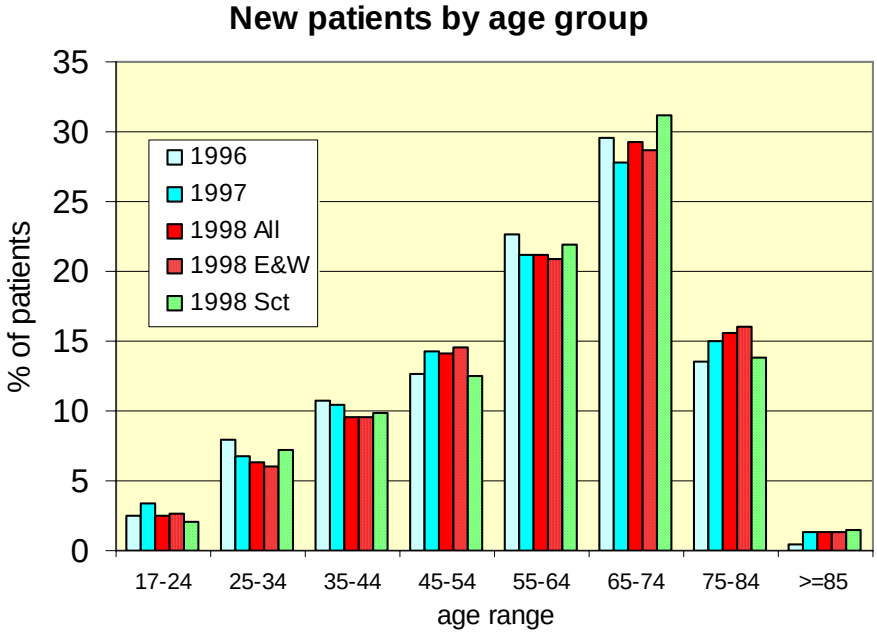


Figure 3.2 New RRT patients by age group

The age distribution of new patients is illustrated in figure 3.2. The high incidence of end-stage renal failure in older age groups is demonstrated. At the start of treatment 46% of patients were aged 65 or more. This has slowly increased in recent years: in 1997 43% were aged 65 or over, compared with 41% in England in 1995, and 37% in 1993. There was little difference between England & Wales and Scotland in 1998. In

1998 33% of all new patients were aged 70 or over compared with 29% for England and Wales in 1997. Although the catchment populations for these figures differ, there appears to be a continuing trend for accepting older patients.

The median age for the UK was 63 years (63 for England & Wales; 64 for Scotland) - with a surprising degree of variation between units from 55 to 71 years (Figure 3.3). The median age of new patients differed significantly between the centres for England & Wales (Kruskal Wallis test, X^2=79, d.f=18, p<0.0001. although there was no significant difference between centres in Scotland (X^2=18, d.f=10, p<0.0634).

Without knowledge of the age and ethnicity of the individual catchment areas and of local policies and constraints it is not possible to analyse the reasons for this variation in England & Wales. Nevertheless these variations are greater than would be expected from known variations in the age distribution of UK populations, and do not appear to relate to the ethnic distribution of patients accepted for treatment. It thus seems that differences in referral patterns and acceptance policies play some part in these observed variations.

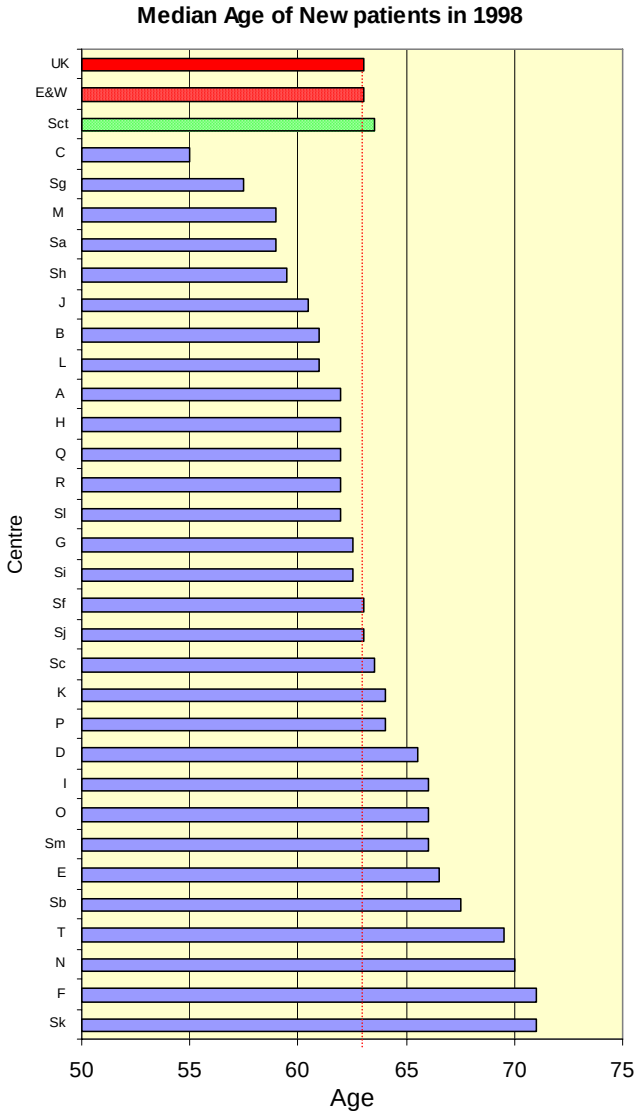


Figure 3.3 Median age of new patients in each unit

The relationship between the median age and acceptance rates for individual units is shown in Figure 3.4.

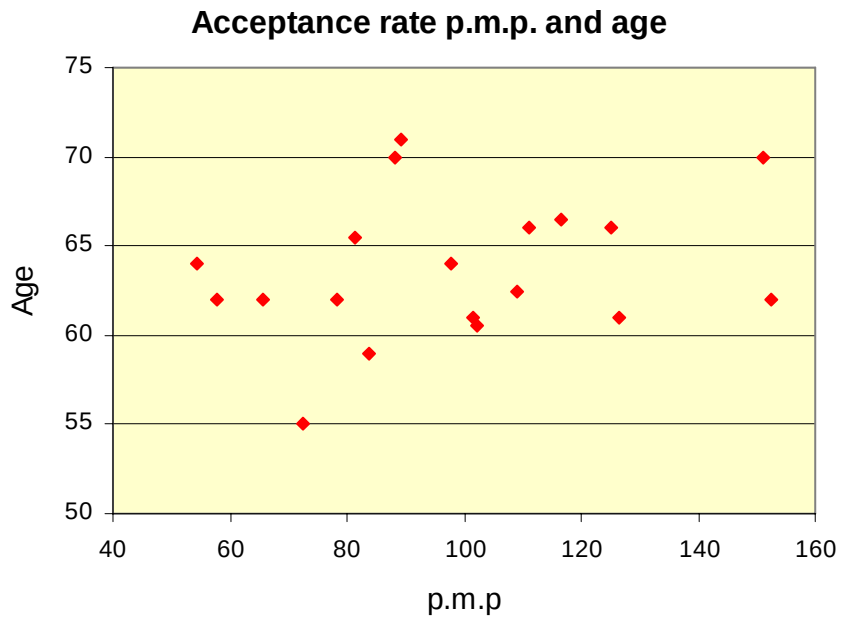


Figure 3.4 Acceptance rate p.m.p. and age

As discussed earlier, the acceptance rate for an individual renal unit is due to a combination of factors. Patient age, ethnicity and cross boundary flow due to lack of dialysis capacity influence this.

Gender

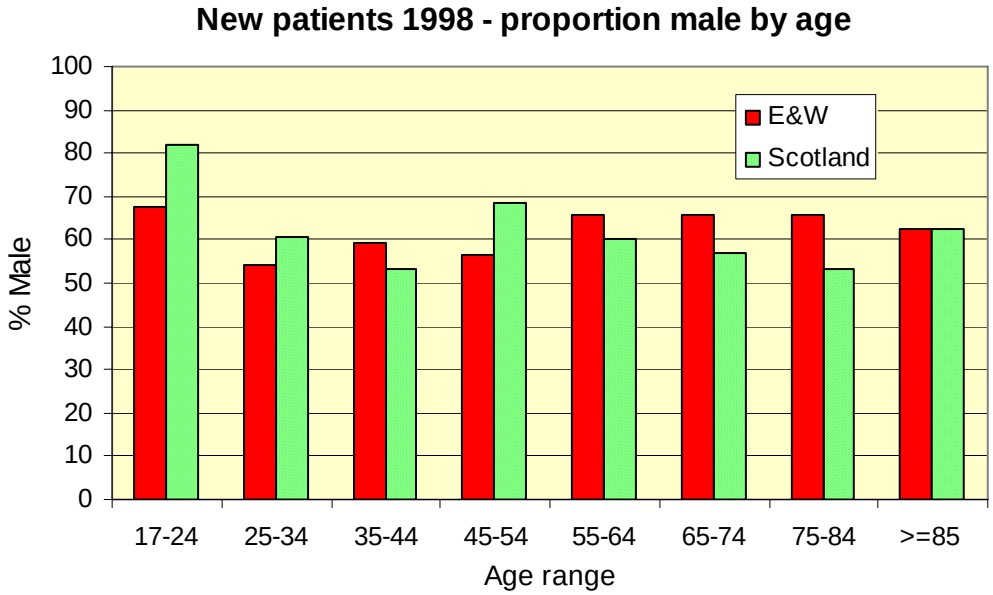


Figure 3.5 New patients 1998 – proportion male by age

The 11-24 age group contains few patients: no significance can be attached to the apparent high percentage of males in this age group for Scotland.

The male to female ratio for new patients was 1.64 (1.71 for England & Wales; 1.45 for Scotland). Despite the increasing preponderance of females in the older age groups in the general population, the proportion of males starting renal replacement therapy in the older groups does not reduce.

The variation between units in male to female ratio with age is illustrated in Figure 3.6.

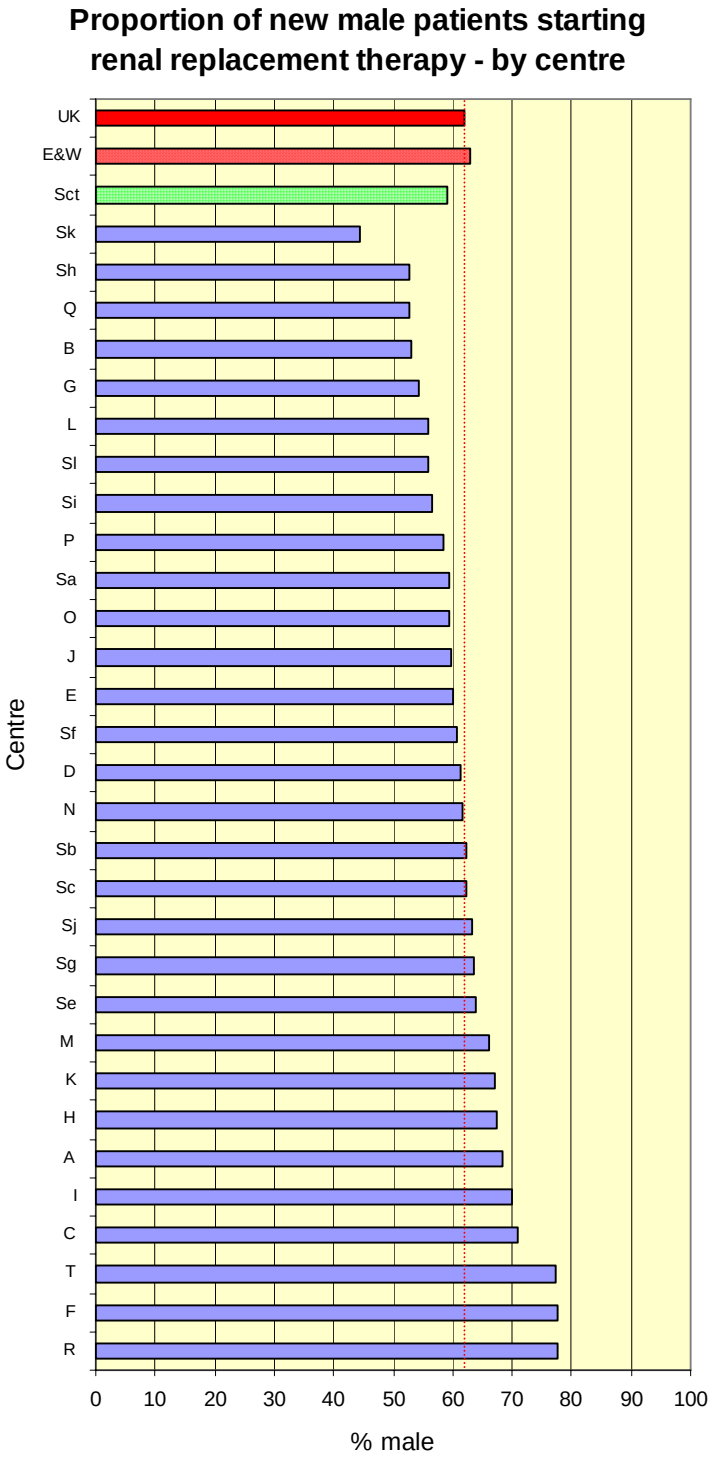


Figure 3.6 Variation between units in new male patients

Ethnicity

Ethnicity was recorded in 58% of patients who started treatment in 1998 in England and Wales, compared with 66% and 76% from the much smaller 1997 and 1996 cohorts. It is not yet requested for the database in Scotland. Of the 19 units from England & Wales, 6 units sent no ethnicity data at all, but data from 5 units had greater than 90% completeness. Of the 11 units with ethnicity data on at least 75% of their patients, the combined proportion of Asian and Black patients together varied from none to 27% of the new patients accepted for treatment (Table 3.2a).

	% with data complete	% White	% Black	% Asian	% Chinese	% Other
Birmingham	100	75.7	8.6	15.7		
Plymouth	100	100				
Sunderland	98	95.2	4.8			
Nottingham	96	87.3	5.6	7.1		
Gloucester	94	100.0				
Leicester	89	82.1	1.9	13.6	0.6	1.9
Bristol	83	91.1	5.0	3.0		1.0
Middlesborough	77	96.5		3.5		
Coventry	76	71.2	7.6	19.7	1.5	
Wordsley	76	100.0				
Carshalton	75	69	3	3	.	.
Leeds, St James's	49	87.2	5.1	7.7		
Exeter	4					
Cardiff	0					
Carlisle	0					
Hull	0					
Oxford	0					
Sheffield	0					
Stevenage	0					
E & W	**58**	**89.2**	**3.2**	**7.0**	**0.3**	**0.4**

Table 3.2.a Ethnicity by centre

Excluding centres with less than 85% completeness of ethnicity data, the most common cause of renal failure amongst the Black / Asian cohort is diabetes

	White	Black /Asian
No	450	50
Median age	64	61
% diabetic *	20.1%	38.9%

* only includes centres with > 85% completeness of ethnicity

Table 3.2b Ethnicity, age and diabetes

Primary Renal Disease

The details on diagnosis are summarised in Table 3.3. Information on diagnosis was missing in 14% of patients (17% from England & Wales; 6% from Scotland) compared with 7% of the new patients reported in 1997 (and it is absent in only 3.4% of prevalent patients).

	% All	% Age < 65	% Age ≥ 65	M:F ratio
Aetiology uncertain*	24	19	30	1.88
Diabetes	16	19	11	1.31
Glomerulonephritis	9	12	6	2.89
Pyelonephritis	9	9	8	1.74
Polycystic kidney	6	9	3	0.94
Hypertension	5	5	5	2.53
Renal vascular disease	6	2	10	2.05
Other	12	13	11	1.27
Not sent	14	12	16	1.53

* Includes those listed as glomerulonephritis without biopsy

Table 3.3 Primary renal disease

"Aetiology uncertain" was recorded in 24% overall, and 30% in those over 65 years old. Diabetes was the single most common diagnosis reported (16% of all patients) whereas for prevalent patients diabetes comprises 9.5%. For prevalent patients the single most common diagnosis is glomerulonephritis (15.7%) closely followed by pyelonephritis (15.5%). Of all the diabetics starting treatment in 1998, 66% were under 65 years of age, whereas 79% of prevalent diabetics are under 65.

Treatment modality

Many patients, especially those referred late to a renal unit, undergo a brief period of haemodialysis before being established on peritoneal dialysis. As an indication of elective treatment modality, the established modality at 90 days is a more clearly defined figure which is easier to derive: this has been used in subsequent analysis of elective modality of treatment of new patients.

On day 90 of treatment, 60% of patients were on haemodialysis. Table 3.4 shows that the proportion treated by haemodialysis was higher in Scotland than in England & Wales. It was also higher in older patients: 76% of dialysis patients in Scotland who are over 65 receive haemodialysis on day 90.

	% of dialysis patients on HD at day 90		
	All ages	< 65	≥ 65
U.K.	60	52	69
England & Wales	57	49	67
Scotland	67	60	76

Table 3.4 Dialysis modality

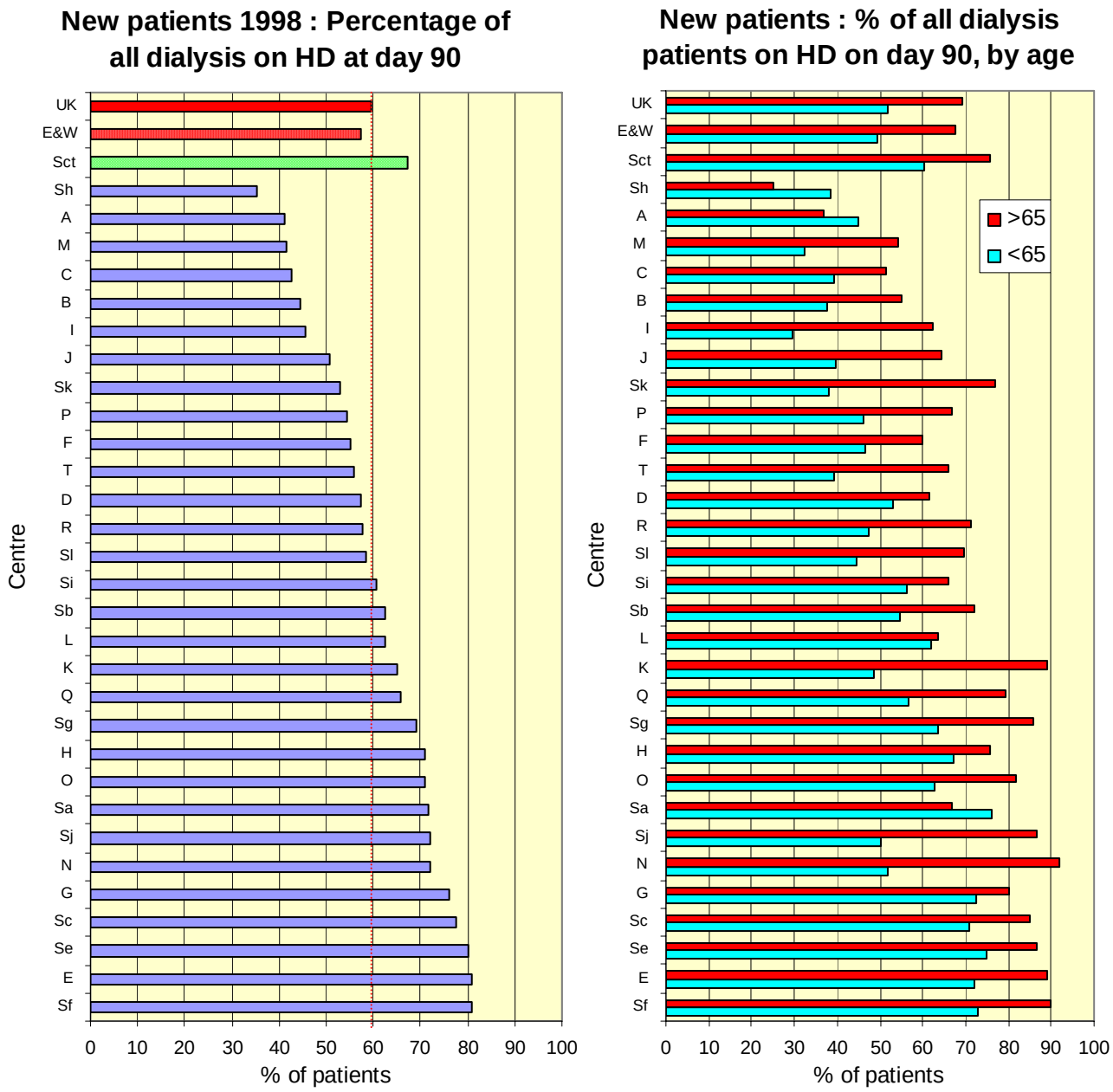


Figure 3.7 % of patients established on HD at day 90 by centre and by age

There does not seem to be any systematic gender bias in choice of modality (Fig 3.7)

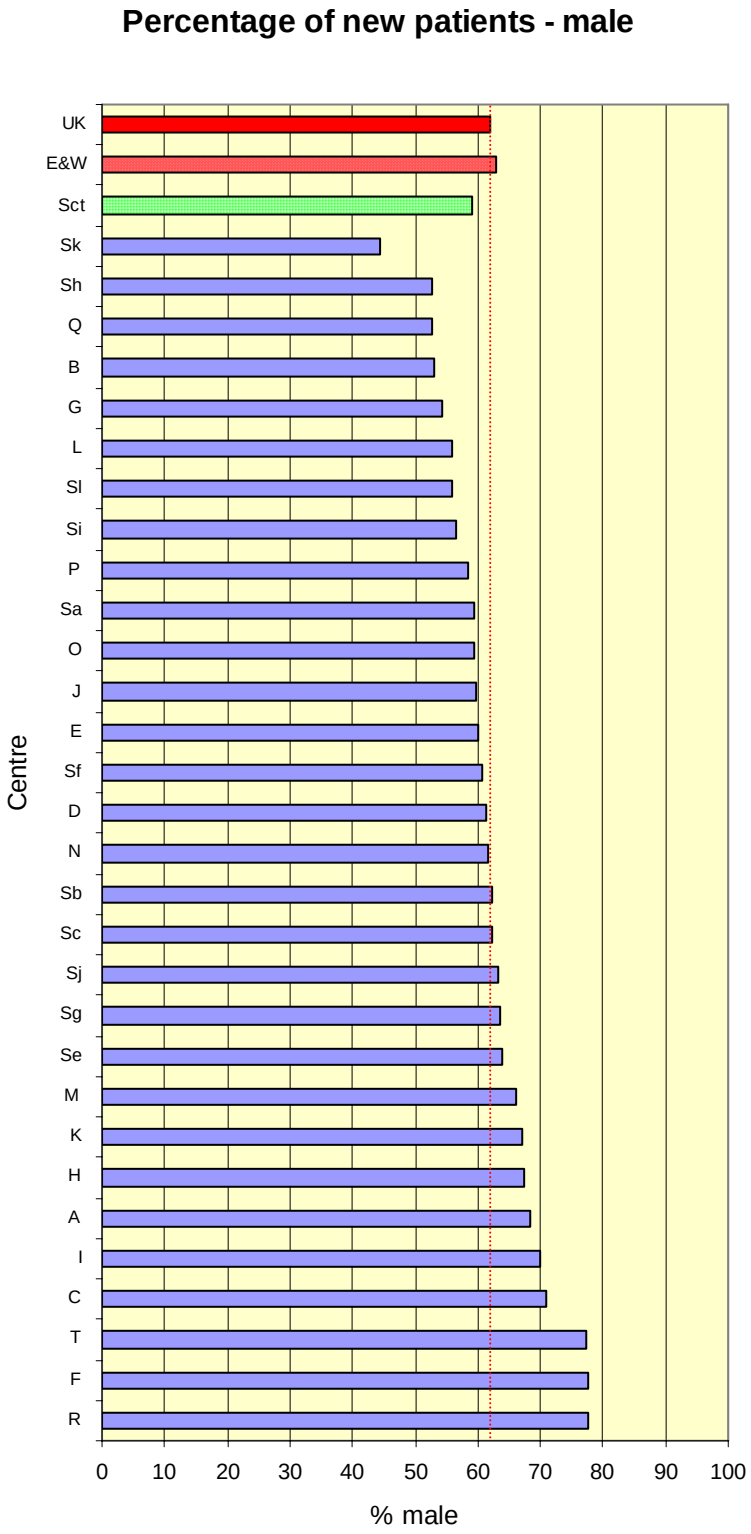


Figure 3.8 Percentage of male patients on each modality of dialysis

The first change of treatment modality

Criteria for analysis

The first change in treatment modality from the established modality at 3 months of therapy was analysed. The following criteria were applied:

1. A patient was classified as having changed to transplantation even if the transplant only lasted one day.

2. If a patient changed from haemodialysis to peritoneal dialysis the patient was classified as changed to peritoneal dialysis, independent of the subsequent length of time on peritoneal dialysis.

3. Patients on peritoneal dialysis who changed to haemodialysis for less than 31days before changing back to peritoneal dialysis were classified as remaining on peritoneal dialysis. Those remaining on haemodialysis for more than 30 days and then changing back to peritoneal dialysis were classified as having changed to haemodialysis.

4. Patients who transferred out to a centre not on the Registry were categorised as unknown.

Change of treatment modality in the first year

This analysis includes the 912 patients from 12 centres sending data to the Registry in 1996/7 who started renal replacement therapy between 1/10/96 and 31/9/97, and analyses the first change of modality in 12 months from the established modality at 90 days of treatment.

The results are shown in table 3.5a and 3.5b.

Haemodialysis		
Modality	**% all patients**	**no. of patients**
Remains on haemodialysis	68	329
Changed to PD	6	29
Transplanted	5	23
Transferred out elsewhere	.6	3
Recovered	`	6
Died (no change in modality)	19	98

Table 3.5a HD patients at 90 days: changes in modality in subsequent year

Peritoneal Dialysis		
Modality	**% all patients**	**no. of patients**
Remains on PD	63	190
Change to haemodialysis	17	50
Transplanted	10	31
Transferred out elsewhere	1	3
Recovered	0.7	2
Died (no change in modality)	9	26

Table 3.5b PD patients at 90 days: changes in modality in one year

It is possible that some of the changes from haemodialysis to peritoneal dialysis were "elective", some patients not having been established on their elective treatment modality by 90 days.

First modality change over 2 years

This analysis includes the 480 patients from 4 centres with returns from 1995/6 who started RRT between 1/10/95 and 31/9/96, and analyses the first change of modality in 2 years from the established modality at 90 days of treatment.

Patients who were on haemodialysis after the first 90 days

There were 225 patients on haemodialysis after 90 days of renal replacement therapy.

	At end of 1 year		At end of 2 years	
First Change in Modality	**No. of Patients**	**% of Patients**	**No. of Patients**	**% of Patients**
Remains on haemodialysis	150	67%	105	47%
Changed to PD	11	5%	13	6%
Transplanted	21	9%	40	18%
Transferred out	1	0.5%	5	2%
Stopped Treatment (died)	5	2%	5	2%
Died (with no change in modality)	37	17%	57	25%
Total	225		225	

Table 3.6 Changes in modality over the first 2 years for patients on HD

Patients who were on peritoneal dialysis after the first 90 days

There were 201 patients on peritoneal dialysis after the first 90 days of treatment.

	At end of 1 year		At end of 2 years	
First Change in Modality	**No. of Patients**	**% of Patients**	**No. of Patients**	**% of Patients**
Remains on PD	133	66%	84	42%
Changed to haemodialysis	23	11%	40	20%
Transplanted	23	11%	41	20%
Transferred out	1	0.5%	2	0.5%
Recovered	2	1%	2	0.5%
Stopped Treatment (died)	0	0	0	0%
Died (with no change in modality)	19	9%	32	16%
Total	201		201	

Note that patients are classed as 'died with no change in modality' if they died within 30 days of changing to haemodialysis: this applies to 13 patients.
3 additional patients died more than one month after changing to haemodialysis.

Table 3.7 Changes in modality over the first 2 years for patients on PD

Comment

These data demonstrate the large number of changes of modality which occur in individuals, even during the first and second year of treatment.

There is a high rate of transfer from peritoneal dialysis to haemodialysis in the first year, which appears to continue through the second year. From the smaller early cohort, of those established on peritoneal dialysis 20% changed to haemodialysis within 2 years. However, of the larger recent cohort, 17% had already changed to haemodialysis within one year. In contrast, there are few changes from peritoneal dialysis to haemodialysis, and these virtually cease after the first year. In addition 6% of all peritoneal dialysis patients (68% of those that died) had a brief period of haemodialysis immediately prior to death. These figures emphasise the need for an adequate haemodialysis program to support peritoneal dialysis.

No significance can be attached to the higher death rate amongst haemodialysis patients as they are an older group of patients, and allocation to modality is not random.

New patient survival

The only recommendation in the Renal Association Standards document is for a limited group of patients. The document recommends the following provisional targets may be set for mean survival:

For all patients with 'standard' primary disease aged 18-55 years:
1 year >90%; 5 years >80%.

Analysis criteria

Patients who later recovered renal function were excluded from the analysis.

Patients who transferred out of a Renal Registry centre without later transferring into another Renal Registry centre were censored when they transferred out.

To relate to the recommendations these analyses only considered patients who were aged between 18 and 55 when they started renal replacement therapy.

Analysis of patients with 'Standard Primary Renal Disease' only included those patients with EDTA codes between 0 and 49 for their primary cause of ESRF.

Analysis of patients with 'All Diseases Except Diabetes' also excluded patients with a diagnosis of 'Not Sent'.

Analysis of 'All treatments' did not censor patients when they were transplanted or changed dialysis modality.

For the analysis by modality of patients on haemodialysis and peritoneal dialysis, patients were censored when they changed treatment modality - even if the change in treatment modality only lasted a day. Patients were classified according to their starting

treatment modality – even if they only remained on their starting treatment modality for a day. Note that if a patient transfers out and then back into the centre later then it is assumed that the patient has remained on the same modality unless the timeline shows otherwise.

The Kaplan – Meier Method was used to estimate the percentage of patients surviving more than a year.

Comparison with the Standard recommendation

One year patient survival was calculated for the groups of patients to whom the Standard applies.

This analysis considers patients starting renal replacement therapy treatment in 1997 from 12 Renal Units. These 12 Renal Units are the 9 Renal Units considered in the 1998 Report together with Hull, Sunderland and Exeter. Patients starting in 1996 at the 4 Renal Units for which 1996 data was also collected are also included.

	Patients 18-55 - One Year Survival [95% CI]			
First Treatment	**Standard Primary Renal Disease**		**All Diseases Except Diabetes**	
	Survival	**No. of deaths**	**Survival**	**No. of deaths**
All	97.2 [95.3 – 99.1]	8/284	94.4 [92.1 – 96.7]	22/393
Haemodialysis	96.8 [93.8 – 99.9]	4/173	92.2 [88.4 – 96.0]	15/244
Peritoneal dialysis	97.5 [94.1 - 100]	2/101	95.3 [91.3 – 99.3]	5/132

Note that the numbers are small when split by treatment modality. As the number of deaths are small and the numbers surviving are close to 100% some of the 95% CI are likely to be approximate and are most likely to be too narrow.

Table 3.8 One Year Patients Survival – patients age 18-55

These results fall well within the recommended standard.

Survival of all new patients

The death rate per 100 patient years was calculated by counting the number of deaths and dividing by the person years exposed. This includes all patients, including those who died within the first three months of therapy. The person years at risk was calculated by adding up for each patient the number of days at risk (until they died or transferred out) and dividing by 365.

Results are shown in tables 3.9 and 3.10.

90 day survival

The 90-day survival is shown in table 3.9. The probability of a new patient aged under 65 surviving the first 90 days is 95%, compared with 81% for those aged 65 or over.

There is a relatively high early death rate. Of those who die in the first year, 50% die within three months. This is more marked in the older patients (54% deaths in 3 months) than in the younger patients (43%).

	Deaths No of Patients	KM Survival Analysis	K-M 95% Confidence Interval
< 65	29/547	0.95	0.93 – 0.97
≥ 65	81/437	0.81	0.78 – 0.85
All	110/984	0.89	0.87 – 0.91

Table 3.9 Ninety day survival of new patients

One year survival

	At 3 months	At one year			
	Deaths No of Patients at 3/12	Deaths No of Patients	KM Survival Analysis	K-M 95% Confidence Interval	Death Rate Per 100 Patient Years
< 65	29/547	68/547	0.87	0.85 - 0.90	13.6
≥65	81/437	151/437	0.65	0.61 - 0.70	45.7
All	110/984	219/984	0.78	0.75 - 0.80	26.3

Table 3.10 One year survival of new patients, by age at start of therapy

Two year survival

This was studied for the small cohort of 446 patients from 4 units recorded by the Registry as starting renal replacement therapy during 1996. Statistical techniques used are similar to those described for the one year survival estimates. There was a similar trend in early deaths. One year survival was similar to the larger 1998 cohort. Although it appears slightly better, with such a small number of patients in this cohort confidence intervals are wide and the differences are not significant.

	Deaths / No of Patients			KM Survival Analysis		K-M 95% Confidence Interval
	3/12	1 year	2 years	1 year	2 year	2 year survival
< 65	7	22	43/252	91.2	0.83	0.78 –0.87
≥ 65	31	62	92/194	67.8	0.52	0.45 – 0.59
All	38/446	84/446	135/446	81	0.69	0.65 – 0.74

Table 3.11 Two year survival of new patients

Comment

The death rate for diabetic patients has not been analysed separately, as there were insufficient numbers to draw any conclusions. In future Registry reports when larger numbers of patients will be included, analysis of survival by diagnosis and other means of stratification, including co-morbidity and gender, will be possible. It will also be possible to study survival of new patients in smaller age bands.

The figures produced here are not comparable with those reported by the United States renal data system (USRDS) which excludes patients dying within the first 90 days of renal replacement therapy. The USRDS is unable to collect data with regard to the first 90 days of treatment as much of their data is collected by billing systems, and patients are not eligible for Medicare payment until 90 days of therapy have passed.

Chapter 4: All Patients Receiving Renal Replacement Therapy In 1998

Introduction

This chapter provides information on the demography of the 13,466 patients on the Registry who were alive on 31/12/98 with details of diagnosis and treatment. It also includes the one-year survival rate for patients who were alive on 1/1/98. All 12 units in Scotland (population 5.1 m) are included and the 19 participating units in England and Wales, as detailed in the introduction. However the population served by the units in England and Wales is derived from estimates made by the individual centres; until all units contribute it is important to note that the accuracy of calculations based on population cannot be assured. The prevalence of patients in England and Wales is similar to that in Scotland (table 4.1).

	England & Wales	**Scotland**	**Total**
No. of units	19	12	31
No. of patients	10,510	2,956	13,466
Population (m)	19.9* (of 52.2m)	5.1	25.0*
Patients (pmp)	528*	580	539*

* = estimated figures

Table 4.1 Summary of adult patients registered and total population covered

For the transplant units providing a transplant service to other renal units the additional transplant population is not included in the population served. As the Registry grows and covers large contiguous areas, errors due to cross-boundary flow of patients will become insignificant. It will then be possible to estimate prevalence and incidence rates of renal replacement therapy for health authorities and regions using postcodes of individual patients.

Age

The median age for all patients alive on 31/12/98 was 54 years with 26.6% of patients over 65 and 16.8% over 75 years. As might be expected the median age was less for those with working transplants followed by patients on peritoneal dialysis and then haemodialysis (table 4.2). The wide variation in median age of dialysis patients between the different renal units is illustrated in Figure 4.1. It is not possible to say from the currently available information to what extent this is a reflection of differences in when a unit was established, policies on referral / acceptance for treatment, age of local population, funding, or survival rates.

	Median Age			
	Transplants	**Peritoneal dialysis**	**Haemodialysis**	**All**
England & Wales	49	59	62	54
Scotland	46	57	59	52

Table 4.2 Median age and treatment modality

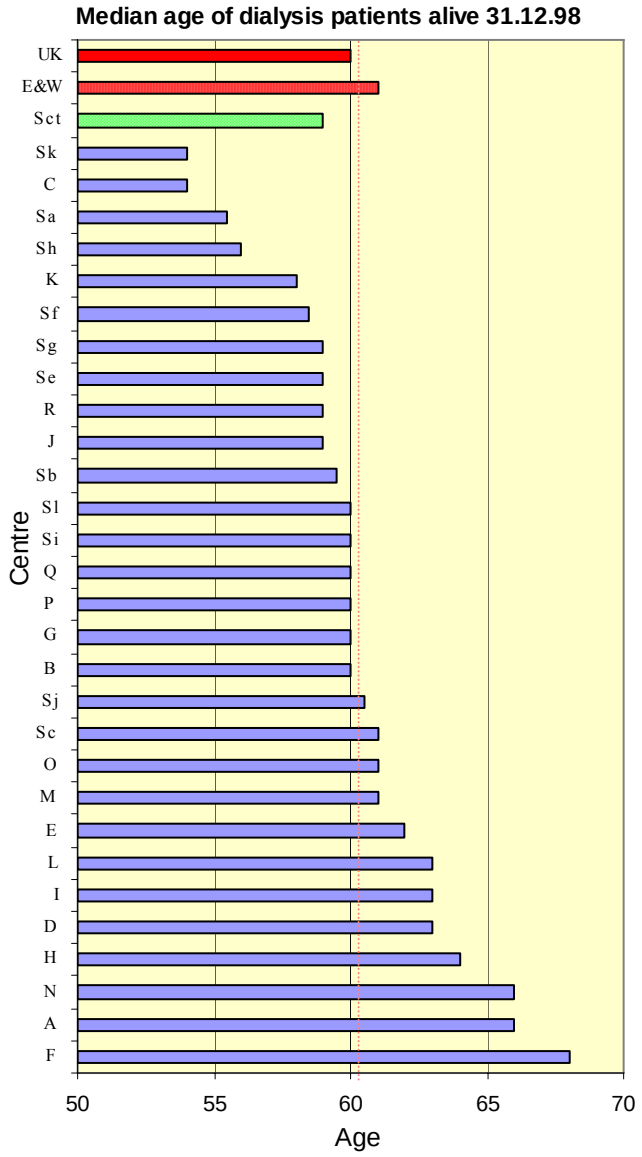


Figure 4.1 Median age of dialysis patients by Centre

Gender

Overall 61% of patients on Renal Replacement Therapy were male (62% in England and Wales; 58% in Scotland). The male preponderance was present in all age groups (Figure 4.2), and was greatest in the oldest group despite the greater proportion of women in the older general population.

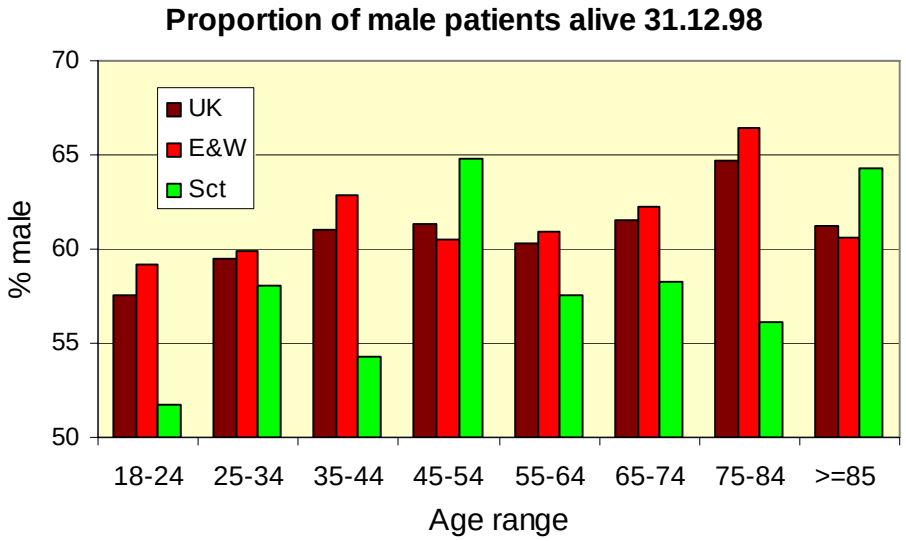


Figure 4.2 Gender distribution by age

Ethnicity

Ethnicity was recorded in 61% of the patients from the contributing Units in England and Wales. Ethnicity information was provided for at least 90% of patients by nine centres whereas in six centres this was either not recorded at all or very rarely. As yet ethnicity has not been requested in the data set for Scotland. The data available demonstrated a wide variation in the percentage of Black and especially of Asian patients (Table 4.3). As Registry coverage becomes more complete, with large contiguous areas covered, it will be possible to relate these figures to the ethnicity of the local population, and hence derive ethnic specific prevalence rates.

	% with data complete	% White	% Black	% Asian	% Chinese	% Other
Plymouth	100	99			1	1
Birmingham	99	77	5	17	1	1
Sheffield	99	94	1	3	1	1
Sunderland	97	99	1	0	0	0
Coventry	96	81	3	16	1	0
Middlesborough	96	96	0	3	0	0
Bristol	95	94	3	2	1	1
Gloucester	91	100	0	0	0	0
Wordsley	90	91	2	6	0	0
Nottingham	89	89	5	6	-	0
Leeds, St James's	83	91	1	7	-	-
Leicester	80	80	2	14	0	3
Carshalton	76	89	5	6	1	-
Cardiff	15	*	-	*	-	-
Exeter	4	*	-	-	-	-
Carlisle	0	-	-	-	-	-
Hull	0	-	-	-	-	-
Oxford	0	-	-	-	-	-
Stevenage	0	-	-	-	-	-
E & W	**61**	**90**	**2**	**7**	**0**	**1**

* - completeness of data returns too small to for reliable estimate.

Table 4.3 Ethnicity

Primary Renal Disease

Details of primary renal disease are shown in Table 4.4. These definitions are based on the original EDTA codes. Outflow obstruction is included in "pyelonephritis". The category "glomerulonephritis not histological proven" has been included in "aetiology uncertain". The diagnosis was given in all but 3.4% of patients. Missing information was more common in patients over 65 years (6.0% compared with 3.0% in the younger patients). More of the older patients were categorised as "aetiology uncertain" (33% compared with 23%). The male preponderance was greater in those whose diagnosis was given as hypertension, glomerulonephritis, and reno-vascular disease and not present in pyelonephritis and polycystic kidneys. Diabetic nephropathy contributed a similar proportion to both age groups.

Diagnosis	All patients	Age < 65 On 31/12/98	Age > 65 On 31/12/98	M : F ratio	Inter unit range
Aetiology uncertain *	25.2	22.5	32.5	1.75	13-45
Glomerulonephritis**	15.7	18.1	9.4	2.43	8-23
Pyelonephritis	15.5	17.0	11.6	1.09	8-25
Diabetes	9.5	9.7	9.2	1.56	6 –16
Type I	6.8	7.9	4.0	1.57	4-11
Type II	2.7	1.7	5.2	1.54	0- 7
Polycystic Kidney	9.3	9.7	8.1	1.03	4 -14
Hypertension	5.3	4.9	6.3	2.56	1 - 13
Renal Vascular disease	2.6	1.2	6.5	1.96	0 - 7
Not sent	3.4	2.6	5.7	1.81	0 -17
Other	13.5	14.2	10.7	1.30	2 - 20
All Patients Total	13026	9513	3513	1.57	

* - includes patients listed as "glomerulonephritis not biopsy proven".
** - biopsy proven.

Table 4.4 Primary renal disease in all patients and according to age and gender

Diabetes

Diabetic renal disease was recorded in 9.5% of patients (inter Unit variation 6-16%). Overall, patients with diabetics were the group with the highest proportion treated by peritoneal rather than haemodialysis (Table 4.5).

Proportion of patients on PD by diagnostic category	
Diagnosis	**% treated on PD**
Diabetes	42.3
Aetiology uncertain *	36.9
Glomerulonephritis	36.8
Polycystic Kidney	33.2
Pyelonephritis	32.2
Hypertension	29.4
Renal Vascular disease	24.1
Other	28.7

* - includes patients listed as "glomerulonephritis not biopsy proven".

Table 4.5 Proportion of patients on PD by diagnostic category

Of all patients with diabetic nephropathy causing end stage renal failure, 31% had working transplants, 29% were on peritoneal dialysis and 40% on haemodialysis. Further details of patients with diabetic nephropathy in relation to Type I and Type II and age and modality of treatment are shown in Tables 4.6a and 4.6b. It is acknowledged that the categorisation of diabetes may show variation between units, some type II diabetics requiring insulin being included as type I.

4.6a	**Type I**	**Type II**	**Non-Diabetics**
Number	891	350	11,338
M : F ratio	1.6	1.5	1.6
Median Age on 31/12/98	50	65	53
Median Age started ESRF	45	63	45
Median days on treatment	995	598	2,014
% HD	33	57	32
% PD	29	30	16
% transplant	37	13	51

4.6b	**Type I < 65**	**Type II < 65**	**Non-diabetics < 65**	**Type I ≥ 65**	**Type II ≥ 65**	**Non-diabetics ≥ 65**
Number	752	166		139	184	
% HD	27	46	25	67	67	53
% PD	30	32	14	25	28	22
% transplant	43	22	61	8	5	25

Tables 4.6a and 4.6b Type of diabetes – age, sex ratio, treatment

At all ages diabetics are less likely to have a functioning transplant. This is most marked for type II diabetics, who are also more likely receive haemodialysis than peritoneal dialysis.

Modalities of Treatment

The relationships between age and treatment are shown in Figures 4.3 and 4.4, which emphasise the predominance of transplantation in younger patients and of haemodialysis in the elderly. More patients were treated by haemodialysis than PD in all age groups, but the preference for haemodialysis is more marked with increasing age. This is important for future planning, as the predicted increase in the dialysis population will be mainly in the older age group.

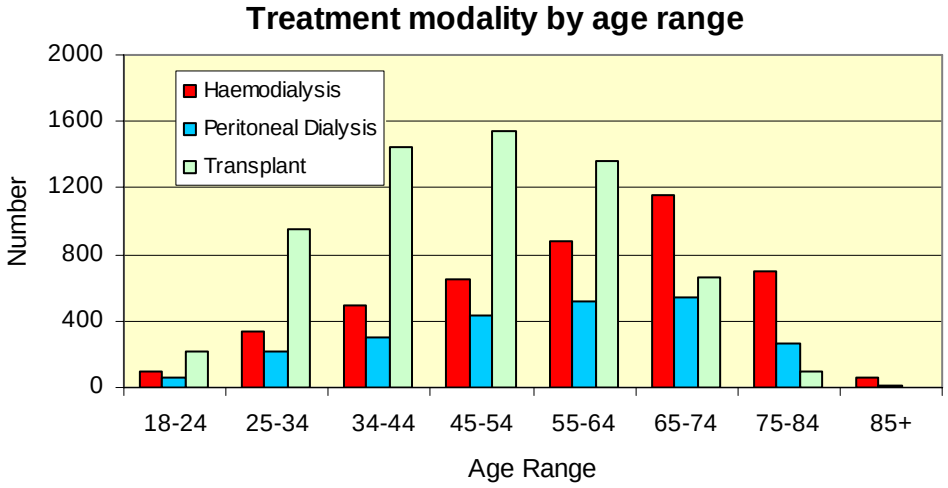


Figure 4.3 The number of patients treated by the three modalities in each age group

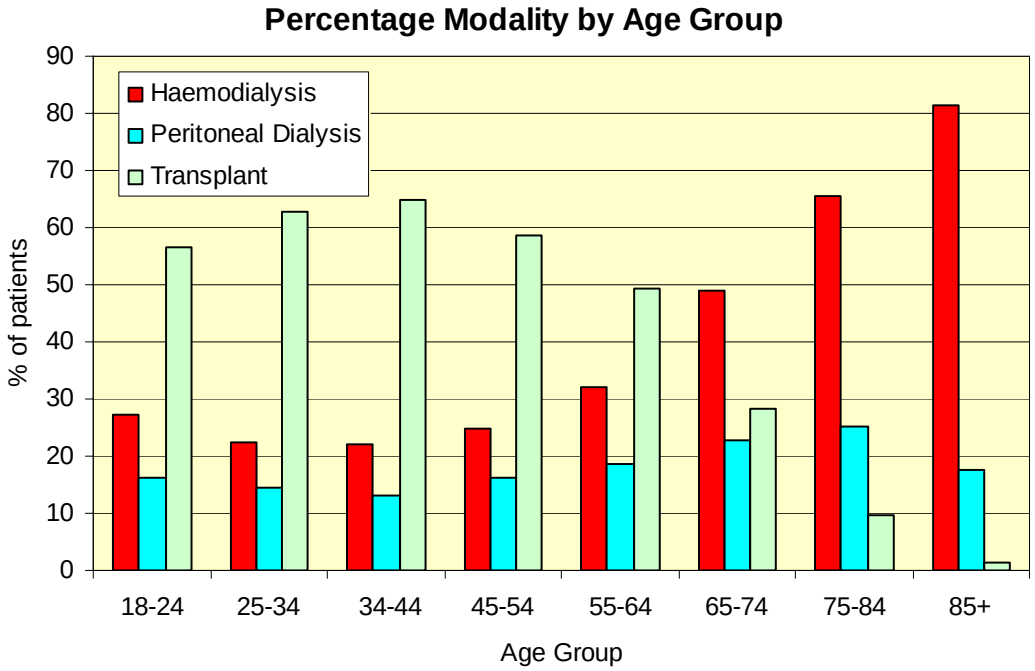


Figure 4.4 For each age group, the percentage of patients on each modality of treatment

The proportion of patients treated by the different types of haemodialysis and peritoneal dialysis is shown in Figure 4.5.

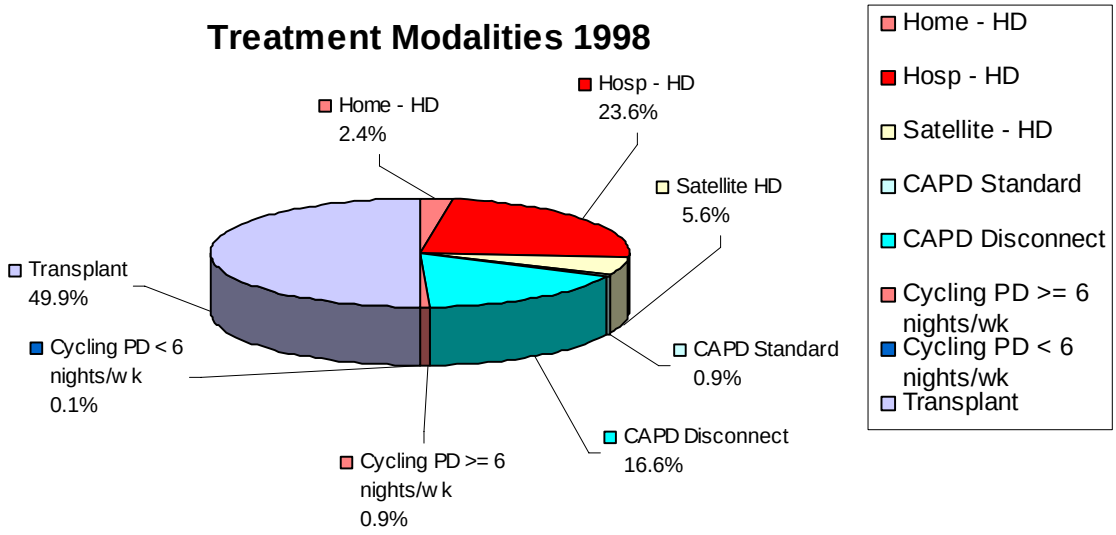


Figure 4.5 Treatment modalities of patients alive 31/12/98

Peritoneal dialysis

Only four centres K, T, F and D, had patients on "standard" CAPD – consisting of 1,4, 5, and 14% of their dialysis patients respectively. In the case of the latter centre this was nearly twice the number on disconnect CAPD.

The frequency of use of cycling PD varies widely. All Scottish units make some use of cycling PD, two centres, Sj and Sf, had more patients on cycling PD than on continuous PD. Sj has 16% of dialysis patients on cycling PD compared with 6% on continuous PD, Sl has 11 compared with 16% on CAPD, and Sh has ten compared with 42%. Of the 19 English units contributing to the Registry only one has a significant use of cycling PD, and eight of the 19 English units do not use this form of therapy.

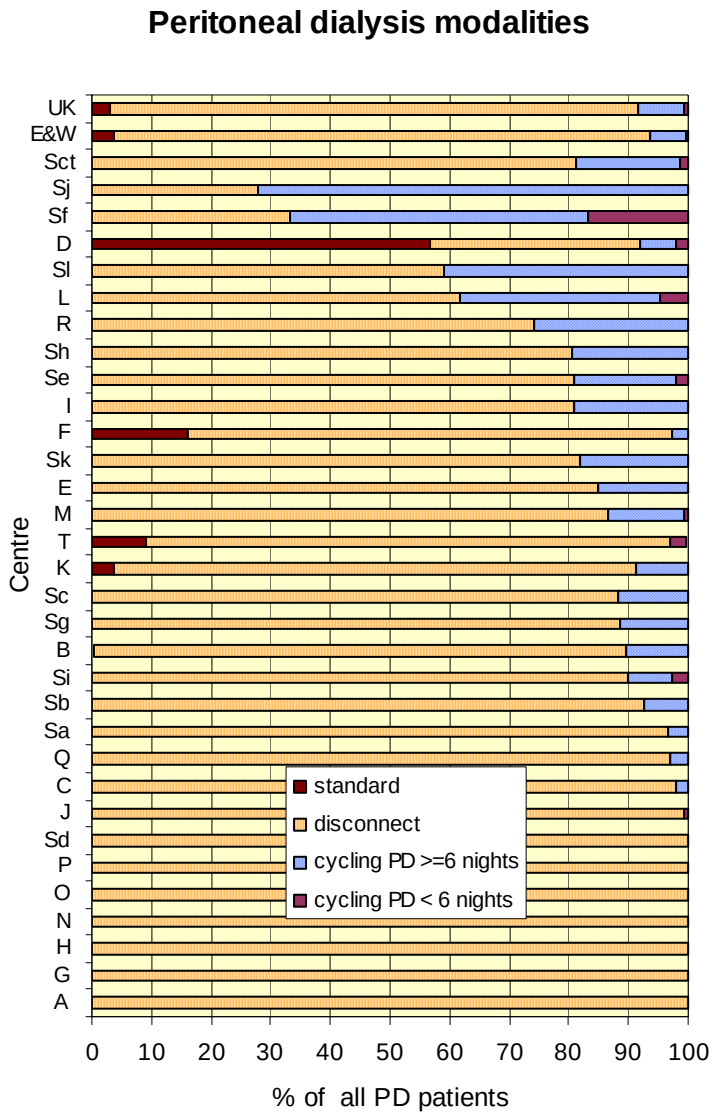


Figure 4.6 Peritoneal dialysis modalities

Haemodialysis

Figure 4.7 shows a wide variation in the proportion of patients treated by haemodialysis (almost two fold) which is not explained by age alone. Figure 4.8 demonstrates the limited role of home haemodialysis in most units, and the importance of satellite units in some.

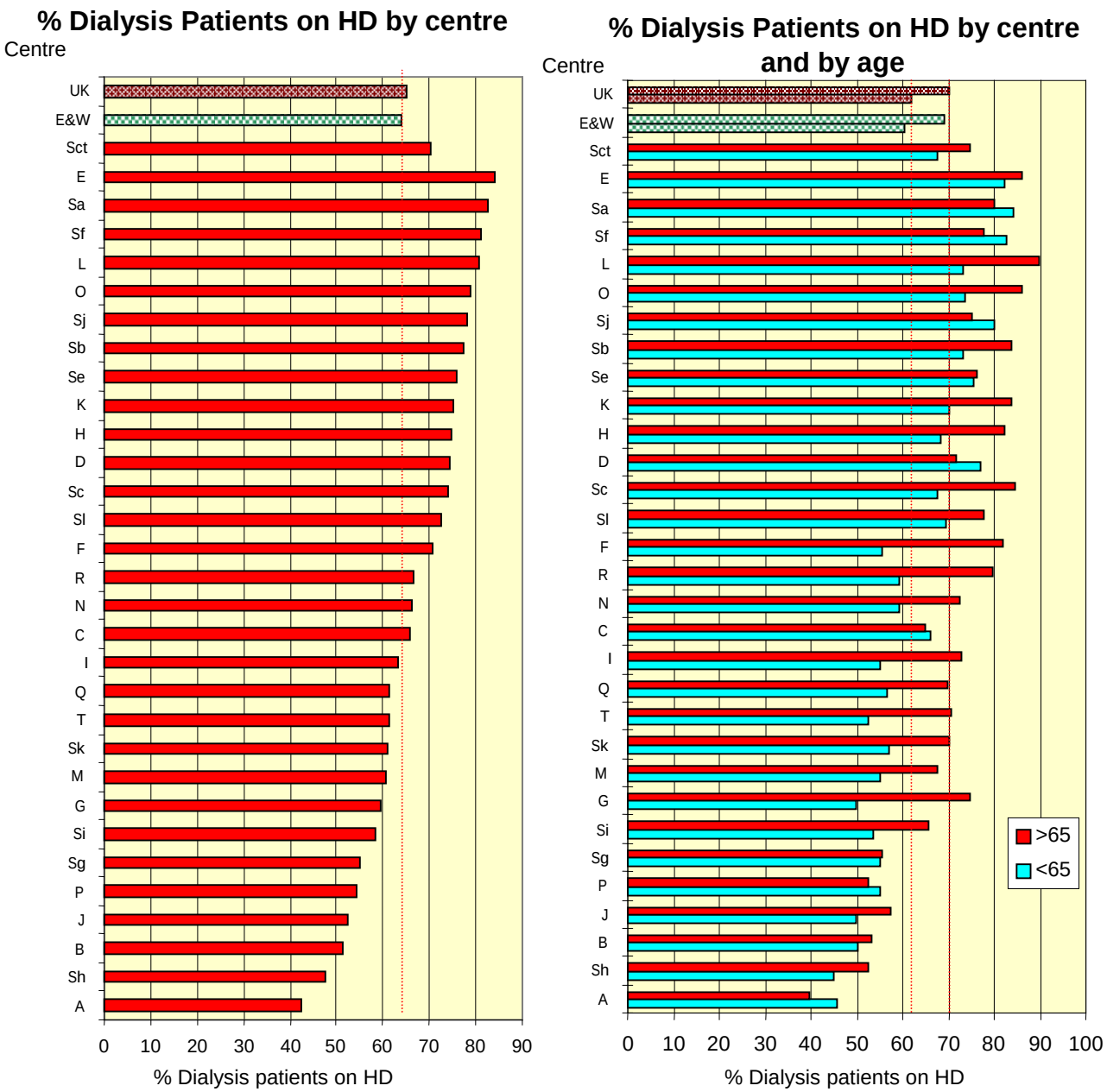


Figure 4.7 Percentage of dialysis patients on HD by centre and by age

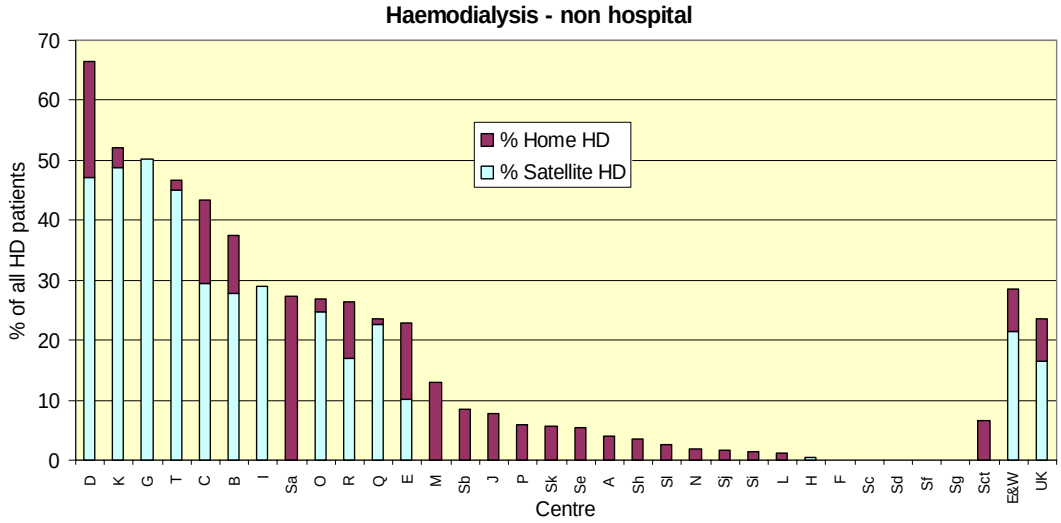


Figure 4.8 Percentage of HD patients on satellite and home HD

Change in treatment modalities 1997 – 98

As there are many more units included in this Registry report than previously figures for the total Registry are not directly comparable with last year. Trends can be identified from the 11 units participating in the Registry throughout 1997-1998. Tables 4.7 and 4.8 show that for these units the proportion of patients with a functioning transplant fell from 49% to 47%. This reflects an increase in the dialysis population rather than a fall in the transplant population. This is due to relatively static rates of transplantation, increasing rates of acceptance for RRT, and the increase in acceptance of older patients and others with more co-morbidity who are not suitable for transplantation. The absolute number of patients with a functioning transplant rose from 2654 to 2808 (2.5 % in 12 months).

	% HD Home	% HD Hospital	% HD Satellite	% HD Total	% PD standard	% PD Disconnect	% PD cycling	% PD Total	% with Transplant
1st qtr 1997	3.5	22.3	7.9	33.7	1.5	14.9	0.9	17.3	49.0
1st qtr 1998	3.3	22.8	8.6	34.7	1.5	14.5	1.4	17.4	47.9
4th qtr 1998	3.1	23.5	9.3	35.9	1.1	14.4	1.5	17.0	47.0

Table 4.7 Proportion of patients with different modalities of RRT 1997 and 1998

	HD Home	HD Hospital	HD Satellite	HD Total	PD standard	PD Disconnect	PD cycling	PD Total	Transplant
1st qtr 1997	187	1206	430	1823	81	807	51	939	2654
4th qtr 1997	182	1291	479	1952	89	819	70	978	2739
1st qtr 1998	192	1320	495	2007	87	840	81	1008	2772
4th qtr 1998	184	1403	558	2145	66	862	88	1016	2808

Table 4.8 Number of patients with different modalities of RRT 1997 and 1998

The number of patients on home haemodialysis is static. There has been an increase in the number of patients treated at hospital and satellite haemodialysis units (a combined annual increase of 9.9%). The overall number of patients on PD has increased through

1997–1998 from 939 to 1016 (3.9 % in 12 months) although the rate of increase slowed during 1998. There was a reduction in the use of Standard CAPD in these centres.

Long term trends

Sequential figures on modalities of renal replacement therapy from the same population are not available. However reviewing data drawn from different sources (table 4.9) it is clear that haemodialysis is increasing as a proportion of total dialysis therapy.

	England		England and Wales			Scotland		
	1991	1995	1996	1997	1998	1991	1996	1998
% on haemodialysis	52	56	64	66	62	49	67	70

Table 4.9 Proportions of dialysis patients on haemodialysis, UK, 1991 – 1999

Survival on renal replacement therapy

The survival data below is for England and Wales only, with Scotland excluded from this analysis because of technical problems which occurred with the data during transfer between systems and was only highlighted during the analysis. The data presented are those on survival during 1998 of those patients alive on renal replacement therapy on 1/1/98. Patients who had been transplanted in the six months before 1/1/98 were excluded because post-operative mortality would distort the survival statistics for each modality.

	No. of patients	No patients died	Death rate (95% CI)	K-M 1 yr survival (95% CI)
Dialysis	4554	706	17.8 (16.5 - 19.1)	83.8% (82.6% - 84.8%)
Transplant Censored at dialysis	4853	121	2.6 (2.1- 3.1)	97.4% (97.0% - 97.9%)
Transplant Inc. dialysis return	4853	141	3.0 (2.5 –3.5)	97.1% (96.6% - 97.5%)

Table 4.10 Survival during 1998 of patients on RRT on 1/1/98

The analysis was repeated separately for patients aged under 65 on 1/1/1998 and for patients aged 65 or more on 1/1/1998 (table 4.11).

Age on 1/1/1998	No. of patients	No patients died	Death rate (95% CI)	K-M 1 yr survival (95% CI)
< 65	2695	253	10.6 (9.3 – 12.0)	89.9% (88.7% - 91.0%)
≥ 65	1859	453	28.5 (26.0 – 31.3)	75.2% (73.3% - 77.2%)

Table 4.11 Survival during 1998 of dialysis patients by age

At the English and Welsh units there were 35 patients who died in 1998 who were aged less than 35.

The one-year survival of diabetic and non-diabetic patients over 65 (table 4.12) was similar, although the confidence intervals are much wider for the smaller number of diabetic patients. However mortality was higher in diabetic than for non-diabetic patients in those under 65 years. Patients with no primary renal diagnosis have been excluded from the analysis.

Age	Primary Diagnosis	No. of patients	No. patients died	Death rate (95% CI)	K-M 1 yr survival (95% CI)
<65	Diabetic	362	65	21.3 (16.4 - 27.1)	80.5% (76.2% - 84.8%)
	Non-Diabetic	2279	182	8.9 (7.7 – 10.3)	91.4% (90.2% - 92.6%)
≥65	Diabetic	173	44	29.5 (21.5 – 39.6)	74.5% (67.9% - 81.0%)
	Non-Diabetic	1624	374	26.7 (24.1 – 29.6)	76.6% (74.5% - 78.7%)

Table 4.12 Survival during 1998 of dialysis patients by age and diagnosis

Age	No. of patients	No. patients died	Death rate (95% CI)	K-M 1 yr survival (95% CI)
<55	1527	85	6.2 (5.0 – 7.7)	93.9% (92.7% - 95.2%)
55-64	752	97	14.4 (11.7 – 17.5)	86.6% (84.1% - 89.1%)
65-74	979	194	22.9 (19.8 – 26.4)	79.7% (77.1% - 82.2%)
≥75	645	180	32.4 (27.9 – 37.5)	72.0% (68.6% - 75.5%)

Table 4.13 Survival during 1998 of non-diabetic dialysis patients by age

Statistical methodology of mortality analysis

Patients have been classified as 'Scottish' or 'English or Welsh' according to where they were receiving treatment on the 1/1/1998. Patients who moved from Scotland to England or Wales or vice versa, have therefore not been censored but have been classified according to where they were receiving treatment on the 1/1/1998.

Dialysis patients

The mortality rate was defined as :-

$$\frac{\text{the number of deaths on dialysis}}{\text{the number of patient years at risk.}}$$

It was calculated according to the following rules. Note that the number of patients years at risk is the sum of the number of days each individual patient was at risk of dying divided by 365 (the number of days in a year).

1. For patients who were transplanted, the number of days at risk is censored on the date of transplant i.e. patients are counted as at risk until they have their transplant.

2. For patients who transfer out, and do not transfer back into another Renal Registry Centre, the number of days at risk is censored on the date of transfer out.

3. For patients who transfer out, but transfer back into another Renal Registry centre on transplant, the number of days at risk is censored on the date of transfer out.

4. Patients are not censored if they transfer out, but transfer into another Renal Registry centre on dialysis. Similarly patients are not censored if patients transfer into another Renal Registry centre on 'treatment unknown' as it is assumed if the patient had a transplant then it would be recorded.

5. If patients die on the day of transplant, then the death is not counted, and the number of days at risk is censored on the date of transplant.

6. If a patient transfers out and has a transplant, then the patient is censored on the date of the first event.

7. Patients who died, received a transplant, or transferred out on the 1/1/1998 were included and were counted as being at risk for one day.

8. Patients who stopped treatment have not been censored, even if they did not die within the next few days.

9. The one year survival estimates were calculated using the Kaplan Meier method.

Transplant

The same rules were applied except survival was calculated both censoring at return to dialysis or by not censoring at return to dialysis

Comments

1. Compared with the 1998 Registry report the proportion of the population of the UK covered by the Registry has increased substantially from about 16% to about 43%. It is thus likely that any extrapolations made from Registry data in respect of the whole UK will be more accurate.

2. There were 1229 deaths in England and Wales 1998 compared with 1788 new patients. This leaves 549 additional patients being treated for ESRF, a 5.3% increase. This requires additional financial resources year on year even if the take on rate remains stable.

3. To enable the Registry to provide more meaningful data on prevalence of RRT in relation to local populations renal units will need to provide more complete data on ethnicity.

4. Although a diagnosis was given in most patients it is widely agreed that there is room for discussion of the definition of some categories– especially hypertension, vascular disease, pyelonephritis, outflow obstruction, and glomerulonephritis without biopsy.

5. For the centres on the Registry in 1997, there was an annual increase of **10%** in the number of **haemodialysis** patients, **4%** in **peritoneal dialysis** patients and **2.5%** in **transplant** patients providing an overall **5.3%** increase in the **total** number of patients on renal replacement therapy

Chapter 5: Adequacy of haemodialysis

Haemodialysis frequency

The Standards document states ***"Twice weekly haemodialysis is not recommended except where there is good preservation of renal function."***

The majority of patients in Registry units (92%) receive thrice weekly dialysis. Many units have a small proportion of patients (<8%), often with some residual renal function, who dialyse twice weekly, but some units have disproportionately large numbers of patients on twice weekly treatments. These latter units have informed the Registry that the high proportion on twice weekly dialysis is due to limited facilities and financial resources.

Solute clearance Standards

The Renal Standards Document recommends that all patients stable on three times a week haemodialysis should show :

A urea reduction ratio > 65%
Or ***Kt/V > 1.2 (dialysis and residual renal function)***

The Standards document considers both Kt/V and Urea Reduction Ratio (URR) as indicators of adequacy of haemodialysis. Several different methods are in use for calculating Kt/V and they give results which vary significantly. For meaningful comparisons, the Registry would need to calculate Kt/V by a single method from the raw data. This would require, as a minimum were the Daugirdas formula used for example, knowledge of pre and post dialysis weights and duration of treatment. This information is not available from many units. The simpler calculation of URR, the percentage fall in blood urea during a dialysis session, is possible and has been used again by the Registry. This has been shown to correlate with patient survival (Owen, Held).

Centre achievement of the Standard

The data below excludes patients known to be on home haemodialysis or dialysing less than three times per week.

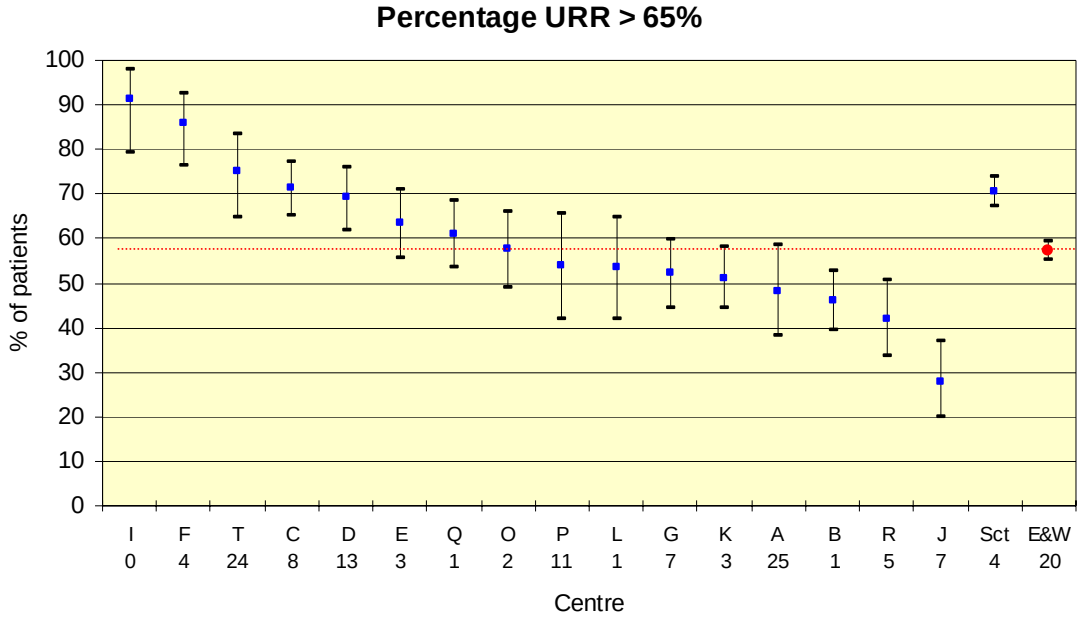


Figure 5.1 Percentage patients with URR > 65%

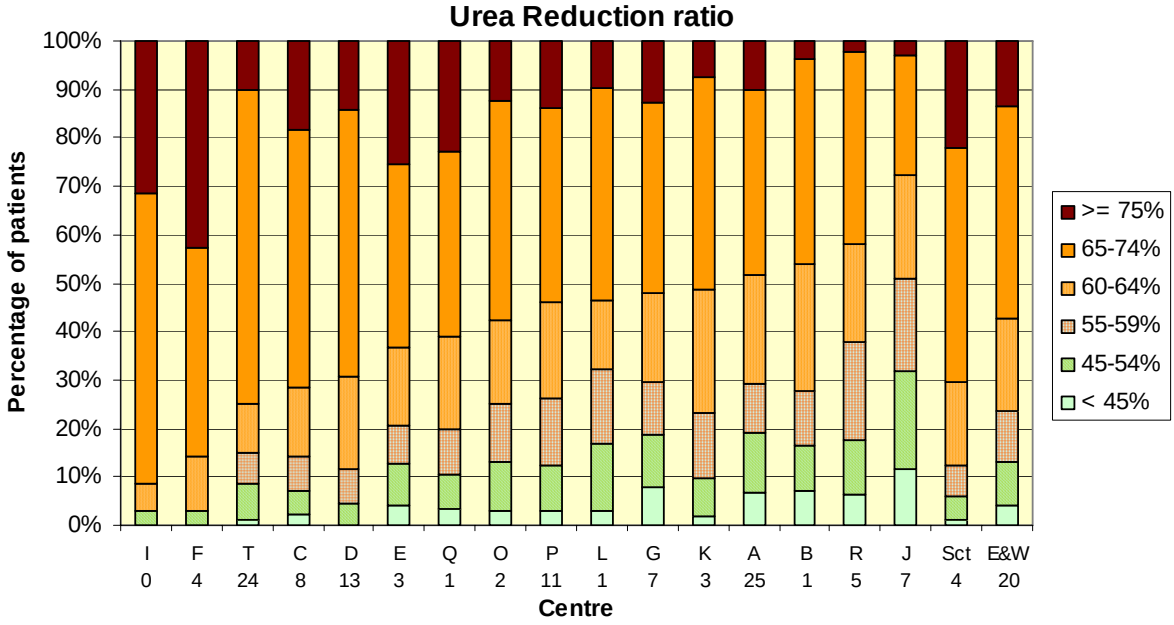


Figure 5.2 Urea reduction ratio

Interpretation of results

Urea rebound and timing of blood samples

The URR, like all methods of calculating haemodialysis adequacy, requires a precise and reproducible method of pre-dialysis, and more importantly, post-dialysis blood sampling. The standardisation of post-dialysis blood sampling is critical to limit the overestimation of urea removal that is inevitable if no account is taken of post-dialysis urea rebound. The dilutional effects of access recirculation (in patients dialysing using arterio-venous fistulae), and cardiopulmonary recirculation cease within a few minutes

of stopping haemodialysis. The remaining rebound is due to intercompartmental urea disequilibrium, with equilibration taking 30-45 minutes. The percentage increase in urea after 30 minutes may be as much as 17 – 45% (Abramson).

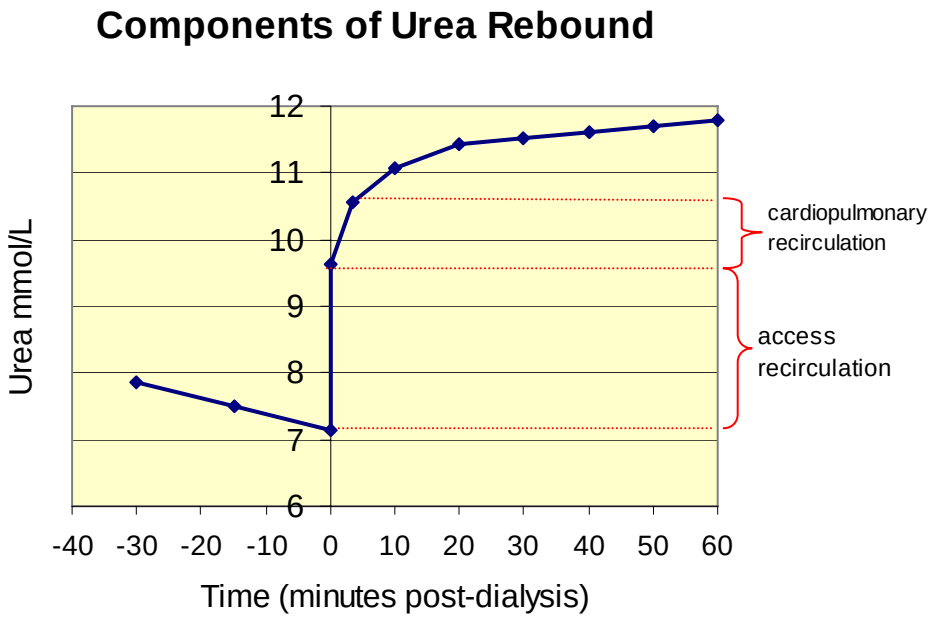


Figure 5.3 Components of urea rebound (from the DOQI report)

Practical problems of timing of blood samples

It is not practical to ask patients to wait for such a delayed blood sample to be taken and estimations of this late rebound are often used. Methods of sampling are considered in some detail in the Standards document (page 98). The Renal Association and National Kidney Foundation Dialysis Outcomes Quality Initiative (DOQI) guidelines currently advise "slow flow methods" of post-dialysis blood sampling since they negate the effects of access recirculation and allow partially for cardiopulmonary recirculation (Renal Association Standards document). However both of these methods involve four steps and require accurate timing of blood samples during the early period of most rapid urea rebound: this may be difficult to achieve in a busy renal unit. In North America dialysis centres have revealed that at least 20 methods of post-dialysis blood sampling were recently in use and more than 40% of the haemodialysis centres used a method of post-dialysis sampling that did not attempt to allow for the effects of access and cardiopulmonary recirculation (Beto et al).

The observation that patient survival in the USA improves as URR increases up to 60% was made using undefined post-dialysis sampling methods which are likely to have been similar to the post-dialysis methods described more recently in North American haemodialysis facilities.

Current UK practice in blood sampling

An informal survey by the Registry of the methods of post-dialysis sampling used by participating UK renal units has shown a wide range of sampling techniques in use. Many units obtain the post-dialysis blood sample immediately at the end of the dialysis session with no "slow flow" period. A similar observation was made in a survey of all adult renal units in Scotland in early 1998 (Mactier). This widespread use of immediate post-dialysis sampling will overestimate urea removal during dialysis and hence the URR, as the sample is diluted by access recirculation of 'just dialysed blood', and there is no account of cardiopulmonary recirculation and the disequilibrium component of the urea rebound.

For good comparative audit, it is essential that a standardised post dialysis sampling technique is used which is simple and reproducible.

In the absence of a formal programme of standardisation of dialysis methods in the UK only one method of sampling has been in evaluation. In the past year all the renal units in Scotland, and some in England, have utilised a standardised method of post-dialysis blood sampling from any point in the extracorporeal circuit 5 minutes after stopping the dialysate flow while the dialyser blood flow rate remains unchanged (Traynor et al). This "stop dialysate flow" method does not require exact timing of blood sampling, permits blood sampling from the arterial or venous limbs of the extracorporeal circuit and is practical to perform in a busy unit. This has proved reproducible, allowing for both access and cardiopulmonary recirculation, if not for the disequilibrium component of urea rebound. This technique has been verified in 117 patients. During the same haemodialysis session the URR was 69.1 (s.d. 9.3%) when using the "stop dialysate flow" method compared with 71.7 (s.d. 8.3%) when blood sampling was performed immediately at the end of haemodialysis ($p < 0.0001$). The method is being further evaluated. It should be noted that the extent of urea rebound depends on the intensity of dialysis in terms of K/V and t, so that a wide range of treatment conditions are required to validate any sampling method. The 'stop dialysate flow method is not suitable for conversion to estimate Kt/V, unlike versions of 'slow flow', so that international and historical data comparisons may be compromised by concentration on this method.

Implications for URR results calculated by the Renal Registry

Without a standardised post dialysis sampling technique in use by all units, it must be accepted that many units will be overestimating URR by taking immediate "no slow flow" samples. This is part of a wider problem with URR, however, because it takes no account of urea removal by ultrafiltration. This distorts the equivalence of URR 65% and Kt/V 1.2, which is further flawed because of the effects of variable dialysis time, t. For these reasons URR is not a reliable indicator of haemodialysis dose, despite its relationship to outcomes.

This is particularly important when the distribution of unit results clusters around the Standard 65% value, because even a small bias in the data will profoundly shift the percentage compliance with Standard. Values well above (or below) the Standard will be scarcely affected. There are several examples of this from Figs 5.1 and 5.2, where it is clear that a very small change in median URR achieved can make a profound difference to the compliance with the Standard.

However, any attempt to increase URR values will tend to increase delivered dialysis doses. In very large scale mortality studies these niceties appear to be less relevant. It should be stressed again that the observation that patient survival in the USA improves as URR increases up to 60% was made using undefined post-dialysis sampling methods.

Results of UK comparative audit

There is wide variation between units, in the proportion of patients who achieve the current minimum Standard URR. For England and Wales, the percentage of hospital haemodialysis patients with a compliant URR (>65%) averaged 57% in all of the 16 units but varied from 97% in centre F to 28% in centre J. Discussions with centre J indicate most patients are on 3 hours dialysis due to lack of funding. In 1999 these hours are being increased.

In the early cycles of the hospital haemodialysis audit reported by the Scottish Renal Registry from 1994 to 1998, when the total number of hospital haemodialysis patients almost doubled, the proportion of patients in Scotland with a URR above 65% increased from 42% to 75%, whilst in one unit the percentage of patients with URR greater than 65% rose from zero to 85%. This suggests a benefit from such regular comparative audit, although during this period attitudes changed in the nephrology world as a whole, with clinicians accepting the need for an increase in the haemodialysis prescription. In other studies the most important feature has been the lack of aspiration in prescription of haemodialysis, rather than underperformance of the technique or other social factors [Seghal) The 95% confidence intervals for the % URR above 65% shown in figure 5.1, indicate that there are true differences of achievement between the units sampled here.

Higher urea reduction ratios have been associated independently with older patients, females and lower body weight. Centre F has the oldest median age of haemodialysis patients (70) while Centre J with the lowest performance against the Standard has a combination of the youngest patients (median age 58) and the highest proportion of males (69%). Centre F has all patients on at least 4 hours dialysis. Centre C is probably performing very well as the median age is 54 with 66% males.

Centre	Median age	% Male	M:F ratio
A	64	61	1.66
B	60	63	1.69
C	54	66	1.95
D	62	62	1.65
E	63	63	1.71
F	70	64	1.78
G	64	58	1.39
H	66	67	2.09
I	66	62	1.65
J	58	69	2.26
K	61	62	1.65
L	65	65	1.84
M	64	64	1.81
N	69	63	1.68
O	63	52	1.08
P	59	65	1.90

Q	61	59	1.42
R	61	61	1.54
T	67	76	3.21
Scotland	59	60	1.48
E&W	62	63	1.72
UK	62	62	1.66

Table 5.1 Median age and M:F ratio by centre

The URR results of three of the units, N, M and H, may not have been representative since a substantial proportion of the patients had no data recorded, and have not been included in the
analysis.

Change in URR during 1998

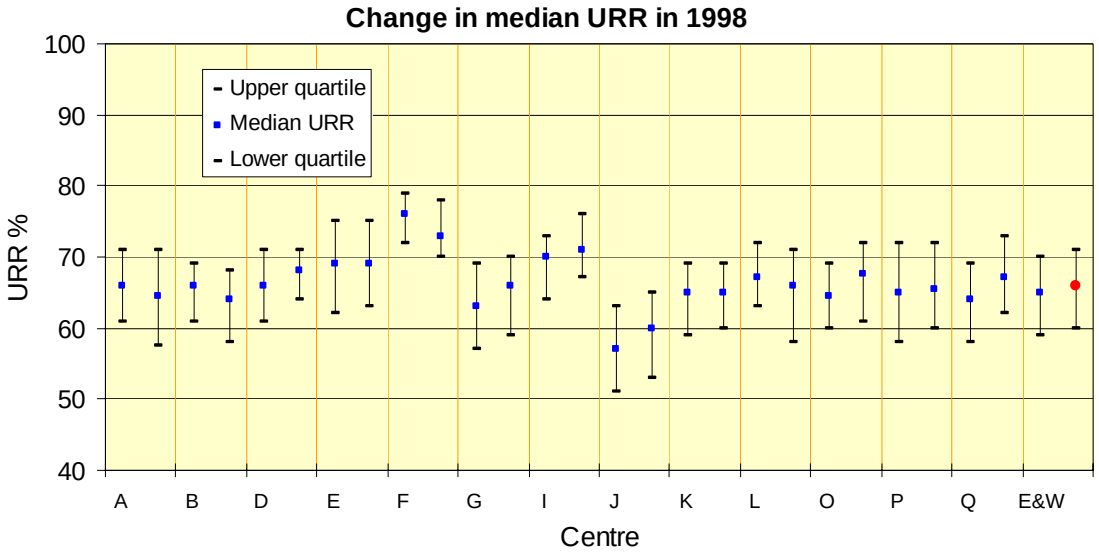


Figure 5.4 Change in median URR in 1998

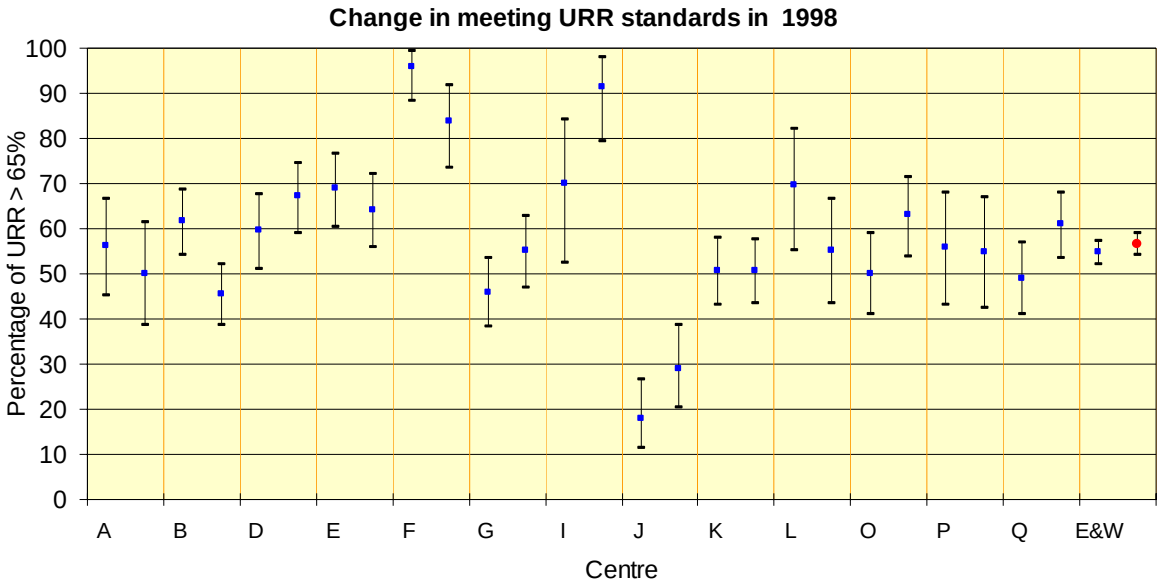


Figure 5.5 Change in meeting URR Standard in 1998

The stability of URR distributions in most units across 1998 suggests that no major programme of change was introduced in them

If full KT/V values including residual renal function are calculated, in some patients with significant residual function dialysis may be reduced. As the URR calculation does not include any allowance for residual renal function, estimation of dialysis clearance will underestimate the true clearances in such patients where this approach is used. Registry enquiries have found only one current registry unit where there is widespread use of this approach.

Conclusions

A standardised method of measuring the URR is required to permit meaningful comparative audit among participating renal units. This will need to be addressed in the Renal Association Standards Group, but as yet there has been no formal programme in the UK to study this problem. The Renal Registry data demonstrate that 'adequate' URR results can be achieved in most patients in some centres. It is hoped that the wide variation in URR achieved in these early cycles of audit of hospital haemodialysis will decrease as the beneficial effects of re-audit are seen, together with a shift in perception of satisfactory dose regimens.

References

1. Abramson F, Gibson S, Barlee V, Bosch JP: Urea kinetic modelling at high urea clearances: Implications for clinical practice. Advances in Renal Replacement Therapy 1:5-14, 1994

2. Beto JA, Bansal VK, Ing TS, Daugirdas JT. Variation in blood sample collection for determination of haemodialysis adequacy. Arner J Kid Dis 1998; 31: 135-141.

3. Clinical practice guidelines for haemodialysis adequacy. National Kidney Foundation Dialysis Outcomes Quality Initiative (DOQI). 1997; 25-61.

4. Clinical practice guidelines of the Canadian Society of Nephrology for the treatment of patients with chronic renal failure. J Am Soc Nephrol 1999; 10: S307.

5. Held PJ, Port FK, Wolfe RA, Stannard DC, Carroll CE, Daugirdas JT, Greer JW, Hakim RM: The dose of hemodialysis and patient mortality. Kidney Int 50:550-556, 1996

6. Leblanc M, Charbonneau R, Lalumiere G, Cartier P, Deziel C: Postdialysis urea rebound: Determinants and influence on dialysis delivery in chronic hemodialysis patients. Am J Kidney Dis 27:253-261, 1996

7. Owen WF, Lew NL, Liu Y. Lowrie KG, Lazarus JM. The urea reduction ratio and serum albumin as predictors of mortality in patients undergoing haemodialysis. N Engl J Med 1993; 329: 1001-1006.

8. Treatment of adult patients with renal failure. Recommended standards and audit measures. The Renal Association 1998; 21 -22.

9. Traynor J. Geddes CC, Walbaum D, MacGregor M, Allam B. Fox JG, Mactier RA. A new method of post-dialysis blood sampling: the "stop dialysate flow" method. Nephrol Dial Transplant 1999; 14: 2063A.

10. The Scottish Renal Registry. Audit of quality of hospital haemodialysis in Scotland. Nephrol Dial Transplant 1997; 12: 29-32.

11. The Scottish Renal Registry. The quality of hospital haemodialysis in Scotland - improvement with audit. Health Bulletin 1999; 57: 237-240.

12. Seghal AR, Snow RJ, Singer ME, et al. Barriers to Adequate Delivery of Hemodialysis. Am J Kidney Dis 1998;31:593-601

Chapter 6: Haemoglobin and related variables

This chapter describes the position at the end of 1998 for all units from England and Wales on the Registry.

The Renal Association Standards document 1997 which recommends that ***"a target haemoglobin concentration of 10g/dl should be achieved in 85% of patients after 3 months on dialysis."***

Inclusion criteria

Patients were included in this analysis if they had been stable at the same centre, on the same modality of dialysis for 3 months. The last available haemoglobin from each patient in the last quarter of 1998 was used in the analysis.

Data from centres were only included for statistical analysis if there was more than 75% data completeness. Centres with less than 50% completeness of data were not shown on the graphs. No laboratory harmonisation is required for haemoglobin.

Haemoglobin achievement by dialysis units

The data for haemoglobin concentrations has been presented in a variety of ways. This has enabled comparison with the Renal Association Standard for haemoglobin achievement but also provides units with their median haemoglobin. The spread of haemoglobin concentrations may help determine why the Standard is not being met and is also a marker of success in targeting particular haemoglobin levels. The data for haemodialysis and peritoneal dialysis patients is presented in figures 1- 6 and tables 1 and 2.

A higher proportion of patients on peritoneal dialysis achieved the Renal Association Standard than on haemodialysis. In 1998 78% of peritoneal dialysis patients and 69% of haemodialysis patients in England and Wales had haemoglobin of 10g/dl or more (76% and 62% respectively in 1997).

Two centres achieved the Standard for patients on haemodialysis compared with none last year. For three additional centres, the 95% C.I. also included the 85% achievement Standard. Of those centres on the Registry in 1997 centre K achieved the greatest improvement in haemoglobin.

Five centres achieved the haemoglobin Standard for patients on peritoneal dialysis with an additional eight centres having a 95% C.I which includes the Standard. In 1997 for patients on peritoneal dialysis, only one of the nine centres achieved the Standard.

Units with good results for HD (I, H, B, K, M, D) also appeared to perform well for PD. This suggests that some units have haemoglobin management strategies that are effective in both dialysis modalities.

A chi-squared test was used to determine whether the percentage of patients with haemoglobin over 10g/dl differed between centres. A significant difference was found between centres in both haemodialysis (X^2 = 164.0, d.f. = 17, p<0.001) and peritoneal dialysis (X^2 = 64.5, d.f. = 18, p<0.001).

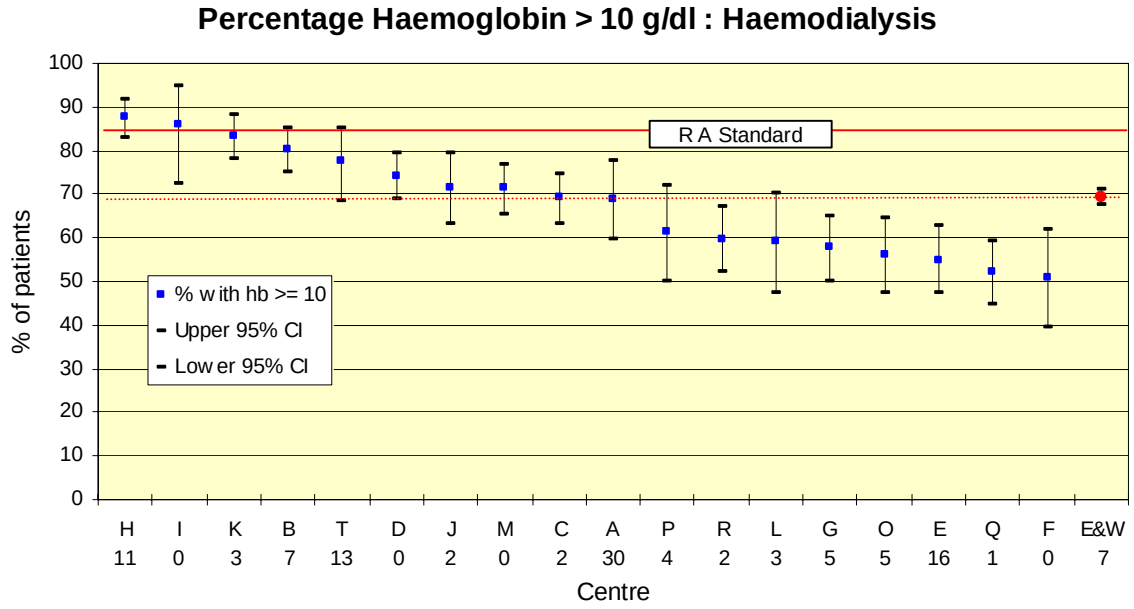


Figure 6.1 Haemoglobin Percentage of HD patients achieving the RA Standard

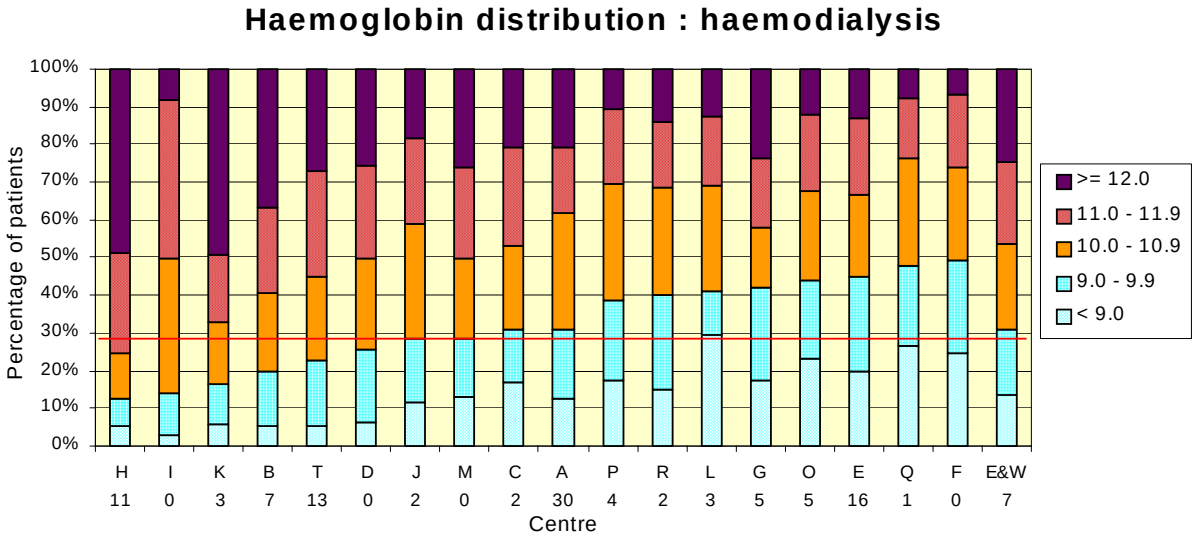


Figure 6.2 Haemoglobin for patients on HD by 1g/dl bands

Figure 6.2 shows the spread of data by 1g/dl bands. The centres are ordered by increasing percentage with a haemoglobin > 10 g/dl, with centres to the left having the highest percentage. These bands give a clearer representation of the distribution of the data by centre than the cumulative frequency distribution plots presented in the 1998 report.

Centre	% data return	Median Hb g/dl	90% range	Quartile range	% Hb ≥ 10g/dl	Mean Hb	Standard deviation	% Hb ≥10 without epo
A	70	10.5	8.4-13.5	9.7-11.7	69	10.7	1.5	*
B	93	11.3	8.9-14.3	10.3-12.6	80	11.4	1.7	11
C	98	10.8	8.0-13.2	9.6-11.8	69	10.7	1.6	22
D	100	11.0	8.7-13.6	9.9-12.0	74	11.0	1.6	14
E	84	10.1	8.1-13.7	9.3-11.3	55	10.3	1.6	17
F	100	10.0	7.9-12.1	9.0-11.0	51	10.0	1.3	*
G	95	10.5	7.8-13.8	9.3-11.9	58	10.6	1.8	*
H	89	11.9	8.9-14.3	11.0-12.8	88	11.8	1.6	*
I	100	11.0	9.0-12.8	10.3-11.5	86	10.9	1.1	*
J	98	10.7	8.0-13.6	9.8-11.5	72	10.7	1.6	8
K	97	11.9	8.7-14.4	10.4-12.8	83	11.7	1.8	*
L	97	10.1	7.1-12.6	8.8-11.4	59	10.0	1.7	1
M	100	11.0	8.0-13.5	9.7-12.0	71	10.9	1.8	*
N	48	*	*	*	*	*	*	*
O	95	10.2	6.9-12.8	9.0-11.2	56	10.2	1.4	5
P	96	10.2	7.8-12.6	9.2-11.1	61	9.9	1.7	*
Q	99	10.0	7.4-12.5	8.8-10.9	52	10.3	1.4	*
R	98	10.4	7.9-12.6	9.3-11.3	60	11.0	1.4	*
T	87	11.1	8.6-13.2	10.2-12.0	77	10.8	1.7	*
E & W	**93**	**10.8**	**8.0-13.7**	**9.7-11.9**	**69**	10.8	1.7	**12**

* insufficient data

Table 6.1 Haemoglobin data for patients on haemodialysis

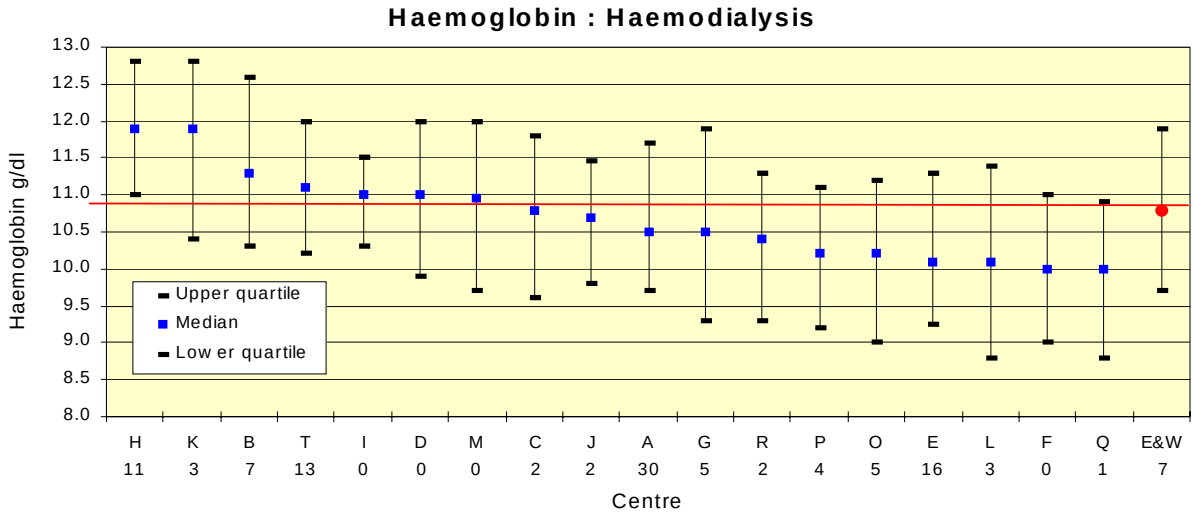


Figure 6.3 Haemoglobin median and quartile range for haemodialysis patients

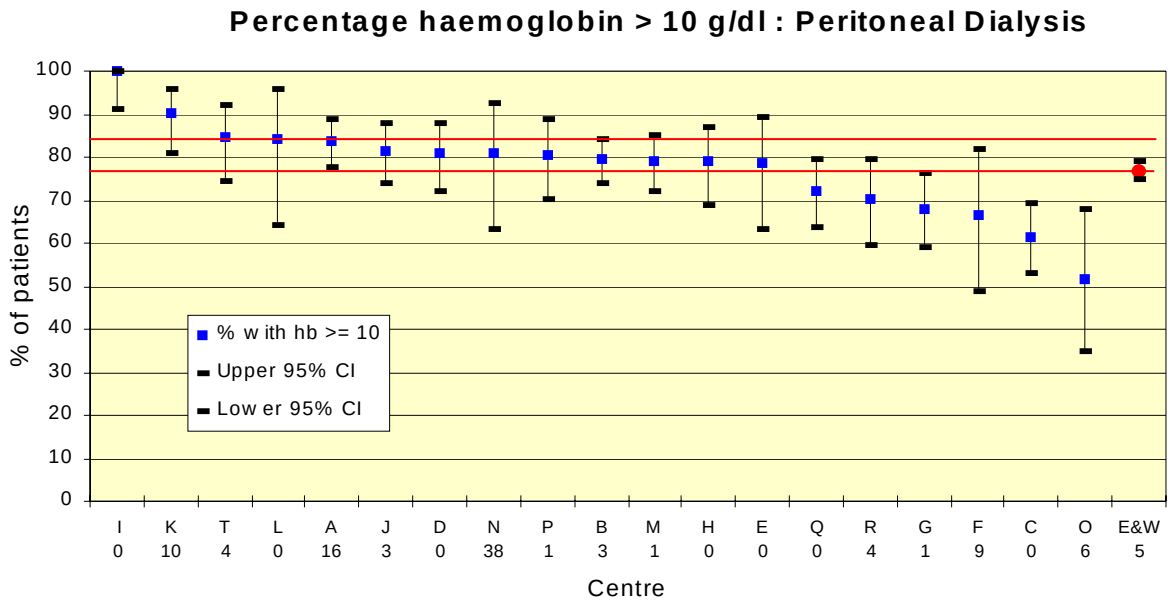


Figure 6.4 Percentage haemoglobin > 10 g/dl on peritoneal dialysis

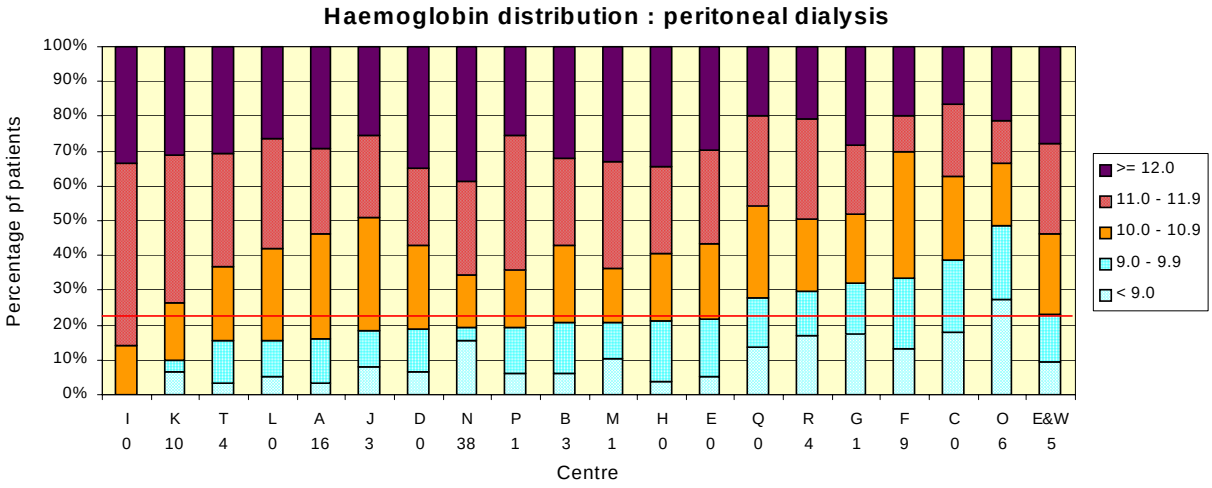


Figure 6.5 Distribution of haemoglobin for patients on PD by 1g/dl bands

Centre	% data return	Median Hb g/dl	90% range	Quartile range	% Hb ≥ 10g/dl	Mean Hb	Standard deviation	% Hb ≥10 without epo
A	84	11.2	9.3-13.8	10.3-12.1	84	11.3	1.5	*
B	97	11.2	8.6-13.8	10.2-12.3	79	11.2	1.7	25
C	100	10.4	7.6-13.1	9.3-11.5	61	10.4	1.6	43
D	100	11.2	8.9-13.8	10.1-12.2	81	11.2	1.5	34
E	100	11.6	8.8-13.2	10.1-12.2	78	11.1	1.4	*
F	91	10.5	8.0-12.1	9.6-11.2	67	10.4	1.3	40
G	99	10.8	8.0-14.1	9.6-12.3	68	10.8	1.9	*
H	100	11.3	9.0-13.6	10.1-12.3	79	11.3	1.5	*
I	100	11.5	10.4-14.2	11.0-12.3	100	11.9	1.4	*
J	97	10.9	8.6-13.5	10.2-12.0	82	11.1	1.4	33
K	90	11.4	8.8-14.2	10.9-12.1	90	11.6	1.5	*
L	100	11.7	8.9-15.4	10.5-12.4	84	11.6	1.7	16
M	99	11.4	8.2-13.8	10.5-12.4	79	11.2	1.7	*
N	62	11.6	8.0-13.0	10.7-12.2	81	11.1	1.6	*
O	94	10.1	6.8-14.1	8.9-11.4	52	10.3	2.2	27

Centre	% data return	Median Hb g/dl	90% range	Quartile range	% Hb ≥ 10g/dl	Mean Hb	Standard deviation	% Hb ≥10 without epo
P	99	11.2	8.9-13.0	10.2-12.0	81	11.2	1.3	*
Q	100	10.8	7.8-13.1	9.8-11.7	72	10.7	1.7	*
R	96	10.9	8.5-12.9	9.3-11.6	70	10.8	1.7	*
T	96	11.4	9.1-13.8	10.5-12.0	85	11.4	1.5	*
E & W	**95**	**11.1**	**8.4-13.7**	**10.0-12.0**	**77**	11.1	1.6	**32**

* insufficient data

Table 6.2 Haemoglobin data for patients on peritoneal dialysis

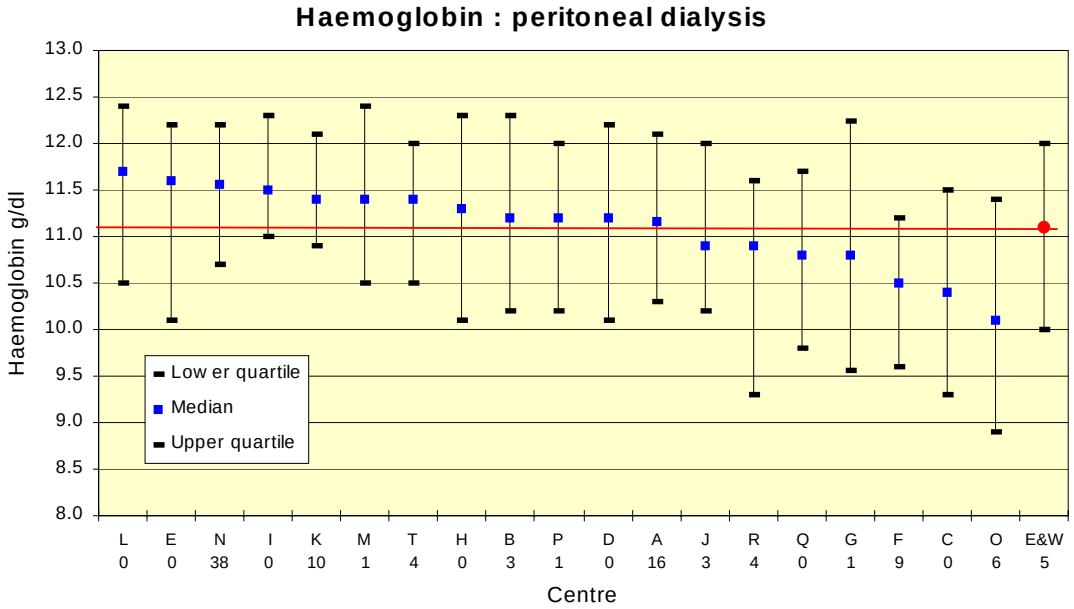


Figure 6.6 Median haemoglobin on peritoneal dialysis

Factors influencing haemoglobin

Haemoglobin concentration is influenced by several factors, for example erythropoietin prescription and iron stores. Other influences are less certain. Interpretation of factors influencing haemoglobin is rendered difficult by lack of information on prescription of erythropoietin, which is a major determining factor of haemoglobin achieved. It is important for more centres to facilitate the collection of erythropoietin data in their renal systems.

Tables 6.1 and 6.2 report (where available) the percentage of patients in each unit that achieved a haemoglobin concentration greater than 10 g/dl without the prescription of erythropoietin. This may be an indicator of whether overall management within a centre is conducive to high haemoglobin. As expected fewer patients on peritoneal dialysis require erythropoietin than haemodialysis.

Haemoglobin and serum ferritin

The Renal Association does not set a Standard for serum ferritin but it is known that individuals do not respond well to erythropoietin without adequate iron stores. Centres use different variables as measures of iron stores: Serum ferritin is the one most commonly used. For this report, serum ferritin levels have been analysed and are shown in tables 6.3 and 6.4. As with haemoglobin the distribution of serum ferritin concentrations is represented by the inter-quartile and 90% ranges. The percentage with serum ferritin over 100 mcg/l can be compared between units using 95% confidence intervals.

A chi-squared test was used to determine whether the percentage of patients with ferritin over 100 mcg/dl differed between centres. A significant difference was found between centres in both haemodialysis ($X^2 = 352.1$, d.f. = 17, $p<0.001$) and peritoneal dialysis ($X^2 = 93.7$, d.f. = 18, $p<0.001$).

Centre	% data return	Median ferritin	90% range	Quartile range	% ferritin ≥ 100µg/l	95% CI % ferritin ≥ 100
A	63	315	128-976	185-548	98	93-100
B	96	210	50-871	129-365	84	79-88
C	99	413	42-1263	255-630	92	88-95
D	99	251	32-866	114-399	78	72-82
E	83	135	26-602	68-248	65	57-72
F	100	233	32-846	130-348	90	82-96
G	90	467	116-1660	239-840	98	95-100
H	69	350	28-1188	175-570	87	81-91
I	100	373	190-1103	297-453	100	95-100
J	98	189	33-975	106-379	77	69-84
K	97	392	133-729	251-504	98	95-99
L	93	314	81-1041	182-561	93	85-97
M	93	104	20-652	56-187	53	46-59
N	49	*	*	*	*	*
O	93	292	56-1699	130-566	84	77-90
P	96	258	32-771	102-416	76	66-85
Q	98	346	117-1055	233-463	96	82-98
R	97	421	71-1080	300-556	93	88-96
T	85	225	44-976	126-444	79	70-87
E & W	**90**	**285**	**41-987**	**140-482**	**84**	**83-85**

* insufficient data

Table 6.3 Ferritin concentrations in haemodialysis patients

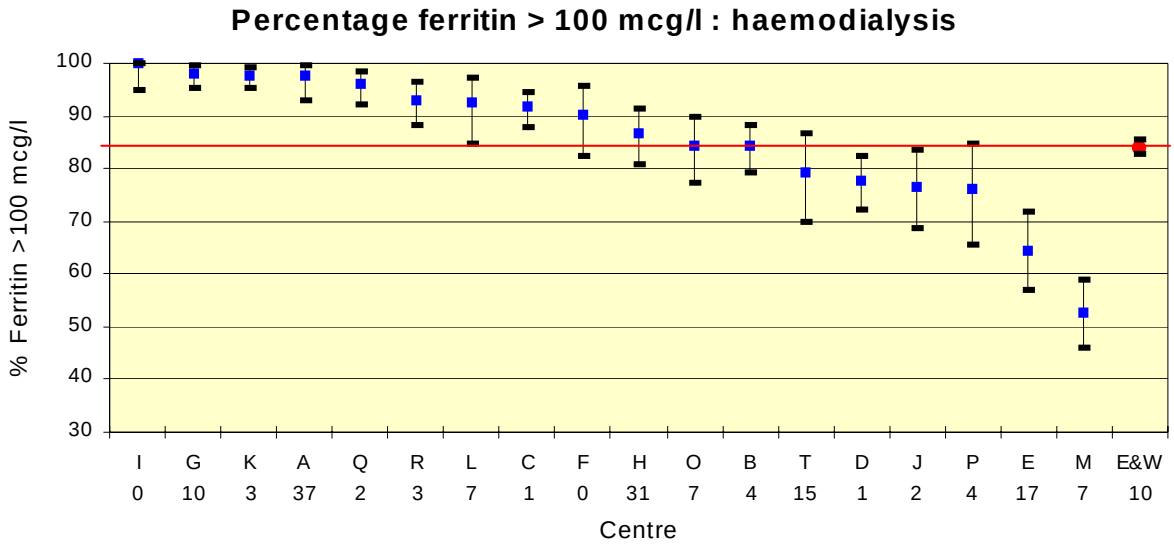


Figure 6.7 Percentage ferritin > 100 mcg/l on haemodialysis

The numbers under each centre on the graph show the percentage of missing ferritin data over 9 months, for that unit. Error bars represent 95% confidence intervals.

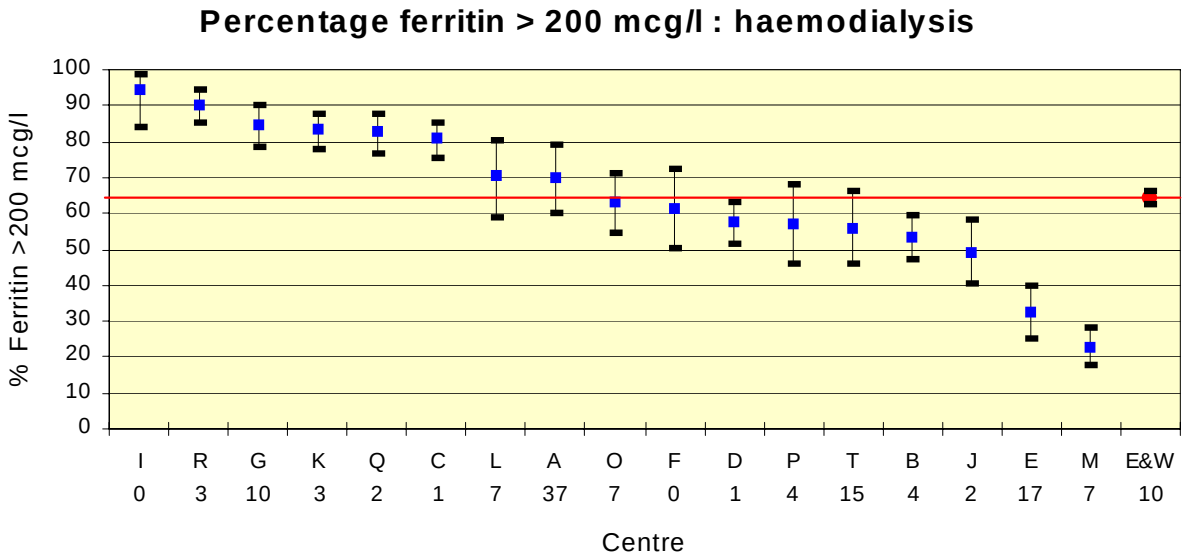
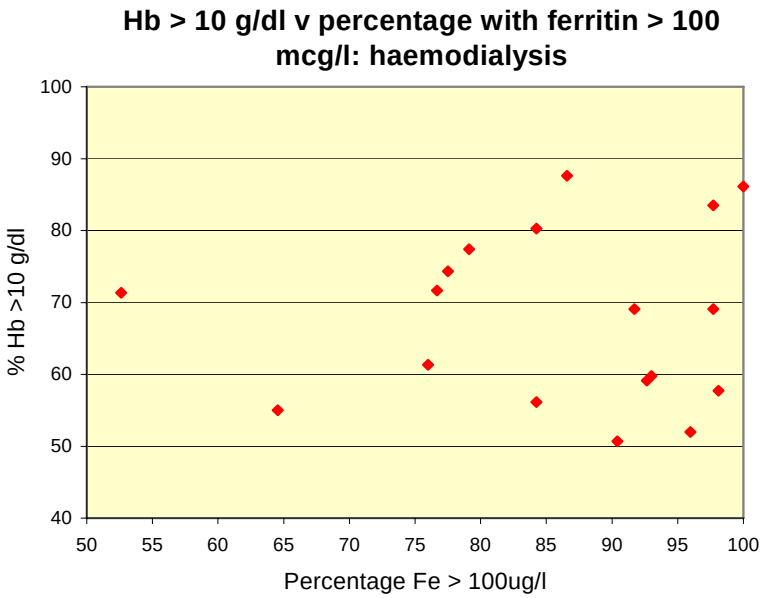


Figure 6.8 Percentage ferritin > 200 mcg/l on haemodialysis



Centre	% with ferritin ≥ 100	% with Hb ≥ 10
A	98	69
B	84	80
C	92	69
D	78	74
E	65	55
F	90	51
G	98	58
H	87	88
I	100	86
J	77	72
K	98	83
L	93	59
M	53	71
O	84	56
P	76	61
Q	96	52
R	93	60
T	79	77
E&W	**84**	**69**

Figure 6.9 Haemoglobin > 10 g/dl vs. ferritin > 100 mcg/l on haemodialysis

Centre	% data return	Median ferritin µg/l	90% range	Quartile range	% ferritin > 100µg/l	95% CI for % ferritin > 100µg/l
A	79	266	58-901	175-392	89	83-93
B	97	266	56-1330	148-468	85	80-89
C	100	322	81-1060	178-566	91	86-95
D	99	229	47-783	136-371	81	72-88
E	97	181	23-377	131-262	89	76-96
F	55	119	26-696	84-169	61	38-81
G	68	179	20-1065	99-359	75	65-84
H	89	199	57-686	104-372	76	66-85
I	100	265	65-793	147-373	81	61-94
J	74	133	27-758	75-292	60	50-70
K	88	239	58-584	174-377	87	77-94
L	100	516	101-930	240-660	100	90-100
M	88	149	32-927	78-251	64	56-72
N	64	142	41-984	69-256	59	41-76
O	86	239	50-1089	114-326	93	81-99
P	90	252	54-686	134-395	84	73-91
Q	96	216	61-722	123-387	85	78-91
R	99	222	49-696	135-350	84	74-91
T	90	257	48-532	156-382	87	77-94
E & W	**88**	**229**	**45-879**	**122-389**	**81**	**79-83**

Table 6.4 Ferritin concentrations in peritoneal dialysis patients

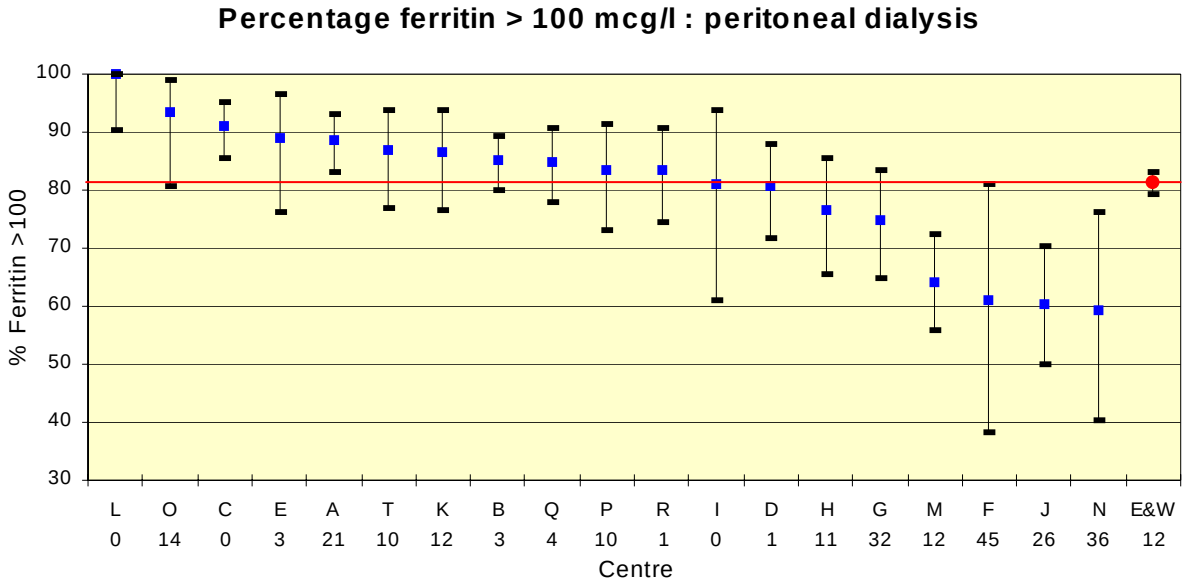


Figure 6.10 Percentage ferritin > 100 mcg/l on peritoneal dialysis

The numbers under each centre on the graph show the percentage of missing ferritin data over 9 months, for that unit. Error bars represent 95% confidence intervals.

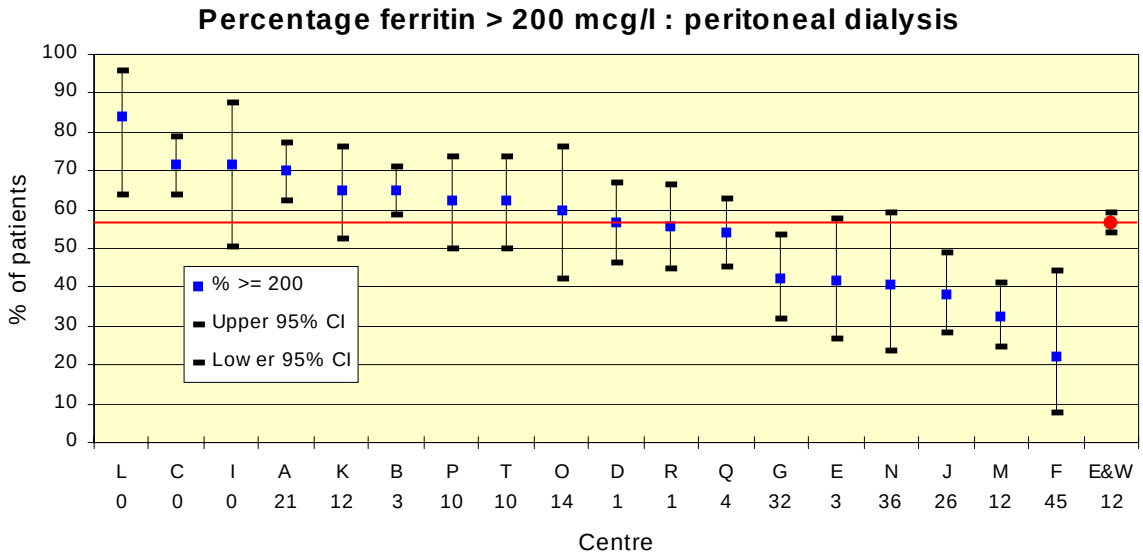
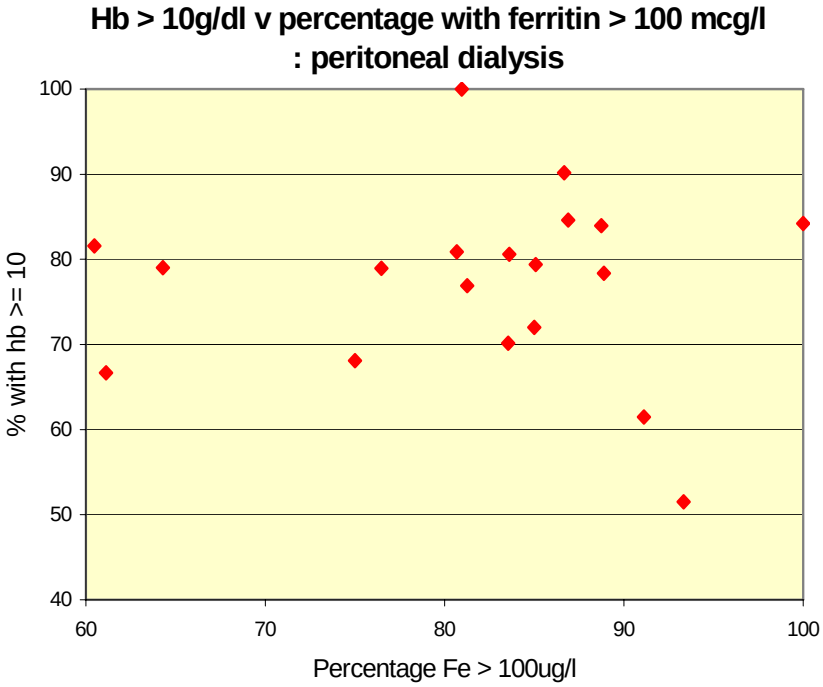


Figure 6.11 Percentage ferritin > 200 mcg/l on peritoneal dialysis

The numbers under each centre on the graph show the percentage of missing ferritin data over 9 months, for that unit. Error bars represent 95% confidence intervals.



Centre	% with ferritin ≥ 100	% with Hb ≥ 10
A	89	84
B	85	79
C	91	61
D	81	81
E	89	78
F	61	67
G	75	68
H	76	79
I	81	100
J	60	82
K	87	90
L	100	84
M	64	79
N	59	81
O	93	52
P	84	81
Q	85	72
R	84	70
T	87	85
E&W	**81**	**77**

Figure 6.12 Haemoglobin > 10 g/dl vs. ferritin > 100 mcg/l on peritoneal dialysis

There was no clear correlation between the percentage of patients with serum ferritin over 100 mcg/l and achievement of the Standard haemoglobin in either haemodialysis or peritoneal dialysis patients (figures 6.6 and 6.9). This suggests that variations in iron stores are not a major determinant of the differences in haemoglobin achieved between units.

Intravenous iron usage

Syner-Med collect data on intravenous iron used in centres which exclusively use their preparation. The company made available to the Registry data from some of the centres on calculated intravenous iron usage per dialysis patient. The centres have been classed as high, medium or low users of intravenous iron to preserve confidentiality.

Intravenous iron use	Centre
Low	B,M,T
Medium	C,R
High	G, I, L,O

Low usage of intravenous iron is correlated with a lower percentage of patients having a serum ferritin above 200 mcg/L. Usage of intravenous iron is not correlated with achievement of the haemoglobin Standard. Centre B, a low user has 80% of haemodialysis patients with a haemoglobin above 10 g/dl. Centres G, L, and O are high users although only 58, 59 and 56% of their haemodialysis patients have haemoglobins above 10 g/dl. The iron usage by these centres has not changed in the last 1- 2 years.

Haemoglobin and erythropoietin

Although the Registry is able to accurately collect laboratory data from centres, many renal units do not record erythropoietin usage on their renal IT systems. Some centres only record partial erythropoietin data and this has been identified during the analysis, confirmed with the centre and excluded from the erythropoietin analysis. This limits conclusions that can be drawn from this data. Most centres only record whether an individual was prescribed erythropoietin and failure to record is assumed to mean that erythropoietin has not been prescribed. The rates of prescription of erythropoietin are shown in table 6.5.

Data from the Health Care Finance Association in the USA shows a much higher usage, with 96% of haemodialysis patients on erythropoietin. The importance of erythropoietin is illustrated by centre Q in which 48% of HD patients have haemoglobin < 10g/dl as this centre is not adequately funded for erythropoietin treatment. If centres work to a minimum haemoglobin of 10g/dl then it might be presumed that patients with a haemoglobin less than this level will be prescribed erythropoietin. Rates of erythropoietin prescription to patients with haemoglobin less than 10g/dl are reported in table 5 and may be useful in determining whether there are specific groups to which there is a relative reluctance to prescribe erythropoietin. For example although patients on peritoneal dialysis have higher haemoglobins and lower erythropoietin requirements than haemodialysis patients, there is a smaller proportion of those with haemoglobin less than 10 g/dl that are prescribed erythropoietin.

	Haemodialysis				**Peritoneal dialysis**			
Centre	**% on EPO**	**Mean dose for pats on EPO**	**Median dose pats on EPO**	**Hb<10g/dl % on EPO**	**% on EPO**	**Mean dose pats on EPO**	**Median dose pats on EPO**	**Hb<10g/dl % on EPO**
B	88	6791	6000	98	69	4762	4000	74
C	70	6126	6000	72	36	5885	6000	46
D	83	6389	6000	71	61	4444	4000	71
F	85	6121	6000	92	45	3467	4000	70
J	86	6962	6000	82	57	5716	6000	57
L	97	6958	8000	97	84	3438	3000	100
N	*			*	79			
O	81			77	51			63
E & W	**81**			**84**	**59**			**62**

* insufficient data

Table 6.5 Erythropoietin prescribing in dialysis patients

Despite the known importance of erythropoietin and iron stores the measured variables do not fully explain the differences in haemoglobin achievement between units. In centre F 49% of HD patients did not achieve the Standard although 85% of patients were treated with EPO and 92% of patients with a haemoglobin of < 10 g/dl were on EPO. Serum ferritins were high in this centre.

Influence of demographics on haemoglobin concentration

Regression analysis adjusted for treatment centre effect, has been used to describe the relationship between haemoglobin and continuous variables. Statistical significance has been defined as $p<0.05$.

Haemoglobin and age

Patients' age on 31/12/98 was analysed against latest haemoglobin in the previous 6 months.

Haemodialysis

Data from 2694 patients was analysed from a total of 2823 patients in the centres with more than 75% data return. A significant negative association was found between age and haemoglobin. A 10-year increase in age was associated with a 0.047g/dl decrease in haemoglobin (95% CI: 0.008-0.087, F=5.5, p=0.0187). Data for erythropoietin prescribing is shown in table 6 indicating no consistent effect of age on spontaneous haemoglobin over 10g/dl without erythropoietin or on rates of erythropoietin prescription.

Age group (years)	18-34	35-44	45-54	55-64	65-74	75+
% on EPO	89 (106)	81 (129)	69 (134)	77 (202)	85 (271)	83 (182)
% Hb >10 no EPO	8 (9)	13 (19)	23 (42)	15 (36)	8 (22)	8 (15)
% Hb <10 on EPO	97 (30)	86 (37)	78 (39)	79 (57)	86 (85)	85 (47)

Brackets indicate total numbers.

Table 6.6 Erythropoietin prescription by age in haemodialysis patients

Peritoneal dialysis

Data from 1598 patients on peritoneal dialysis was analysed from a total of 1660 patients in the centres with more than 75% data return. A significant positive association was found between age and haemoglobin. A 10-year increase in age was associated with a 0.096g/dl increase in haemoglobin (95% CI: 0.043 – 0.148, F=12.9, p=0.0003). Data in table 6.7 suggests a relative reluctance to prescribe erythropoietin to elderly anaemic patients on peritoneal dialysis although numbers are too small for formal analysis.

Age group (years)	18-34	35-44	45-54	55-64	65-74	75+
% on EPO	63 (47)	65 (57)	62 (84)	59 (97)	53 (83)	56 (48)
% Hb>10 no EPO	24 (7)	26 (21)	32 (41)	36 (54)	33 (49)	36 (25)
% Hb<10 on EPO	70 (19)	75 (24)	76 (22)	64 (18)	36 (13)	50 (7)

Brackets indicate total numbers

Table 6.7 Erythropoietin prescription by age in peritoneal dialysis patients

Haemoglobin and time on renal replacement therapy

The number of days on renal replacement therapy on 31/12/98 was analysed. Since the time distribution was skewed the data was log transformed for regression analysis. The data is shown in table 6.8.

	no of patients with data	total patients in included centres	change in Hb for 10 fold increase in days on dialysis	95% CI	F
Haemodialysis	2463	2632	+0.33 g/dl	+0.19 to +0.47	21.4 (p<0.0001)
Peritoneal dialysis	1417	1468	- 0.12 g/dl	- 0.31 to +0.07	1.6 (p=0.2117)

Table 6.8 Haemoglobin and time on dialysis

No significant relationship was found between haemoglobin and time on renal replacement therapy in peritoneal dialysis patients. For haemodialysis patients there was a significant relationship between haemoglobin and time on dialysis. The cross section of patients who had been on dialysis for a short time had lower haemoglobin than those who had been dialysed for some years. One interpretation of this would be that patients with low haemoglobins have increased mortality and therefore drop out from data on the long-term survivors. The relationship is most easily demonstrated graphically. Figure 6.10 shows the relationship for one particular centre. The regression line is derived from the relationship described for the whole population in table 6.8 and the haemoglobin distribution in that centre. The data suggest that centres with a high proportion of new patients will find it difficult to achieve the Renal Association Standard at three months. Data from the USA also show early anaemia reaching a plateau by about one year. The characteristics of patients early in their treatment history may be difficult for a centre to influence if referrals are received late. The rapid increase in haemoglobin during the first year suggest that it would be more appropriate to judge a centre's performance by haemoglobin levels at a later time point after starting renal replacement therapy.

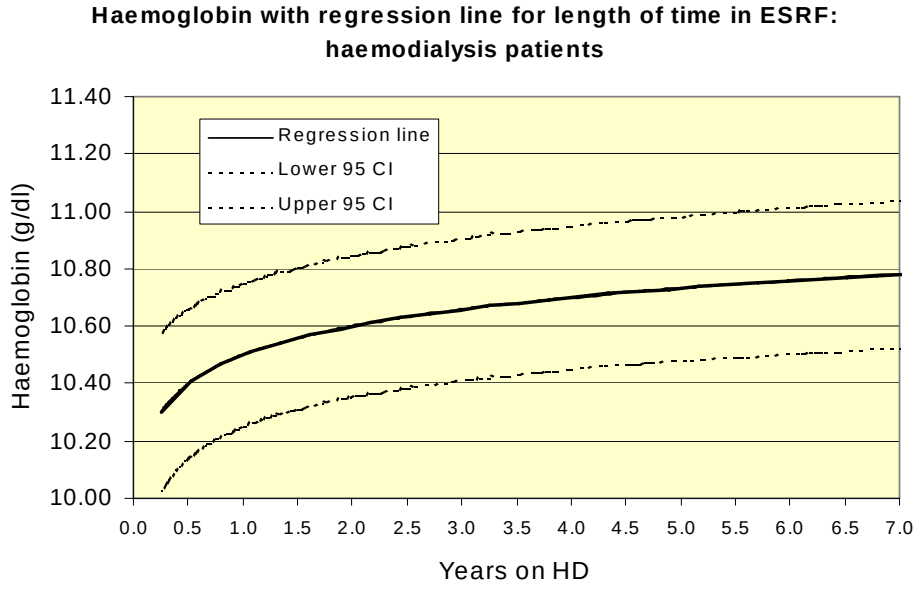


Figure 6.13 Haemoglobin regression line by length of time in ESRF

Haemoglobin and gender

The mean haemoglobin of men and women was compared by analysis of variance and adjusted for treatment centre effect.

Haemodialysis

Haemoglobin data was available for 2692 patients (1702 males and 990 females) from a total of 2823 in the included centres. Data on erythropoietin prescribing was available for 800 males and 468 females in the included centres.

Gender	mean Hb g/dl	Standard deviation	% on EPO	% Hb < 10 g/dl on EPO	% Hb>10g/dl without EPO
Male	10.9	1.78	77 (617)	80 (173)	15 (108)
Female	10.6	1.62	87 (406)	91 (122)	8 (35)

Numbers in brackets are the total number of patients

Table 6.9 Haemoglobin and gender in HD patients

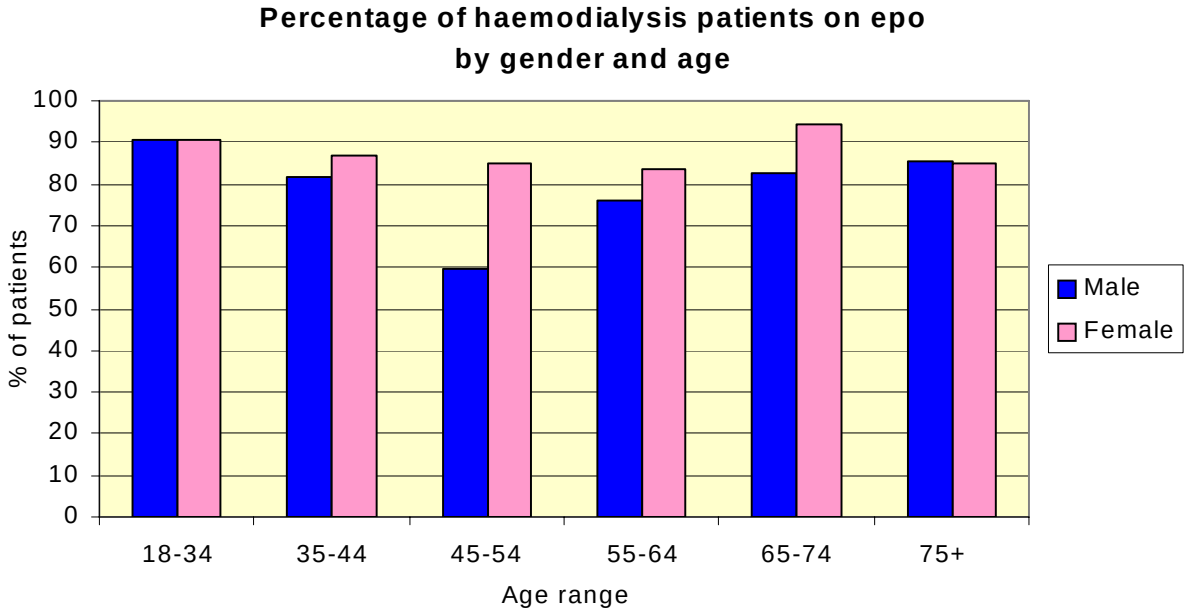


Figure 6.14 Percentage of haemodialysis patients on EPO by age

The mean haemoglobin of men on haemodialysis was significantly higher than women (Difference 0.25g/dl, 95% CI 0.13-0.38g/dl, F=15.1, p<0.0001).

Peritoneal dialysis

Haemoglobin data was available for 1598 patients (960 males and 635 females) from a total of 1660 in the included centres. Data on erythropoietin prescribing was available for 430 males and 276 females in the included centres.

Gender	mean Hb g/dl	s.d.	% on EPO	Hb < 10 g/dl % on EPO	% Hb>10g/dl without EPO
Male	11.2	1.65	56 (240)	66 (57)	37 (146)
Female	10.8	1.61	64 (176)	58 (46)	24 (61)

Numbers in brackets are the total number of patients

Table 6.10 Haemoglobin and gender in peritoneal dialysis patients

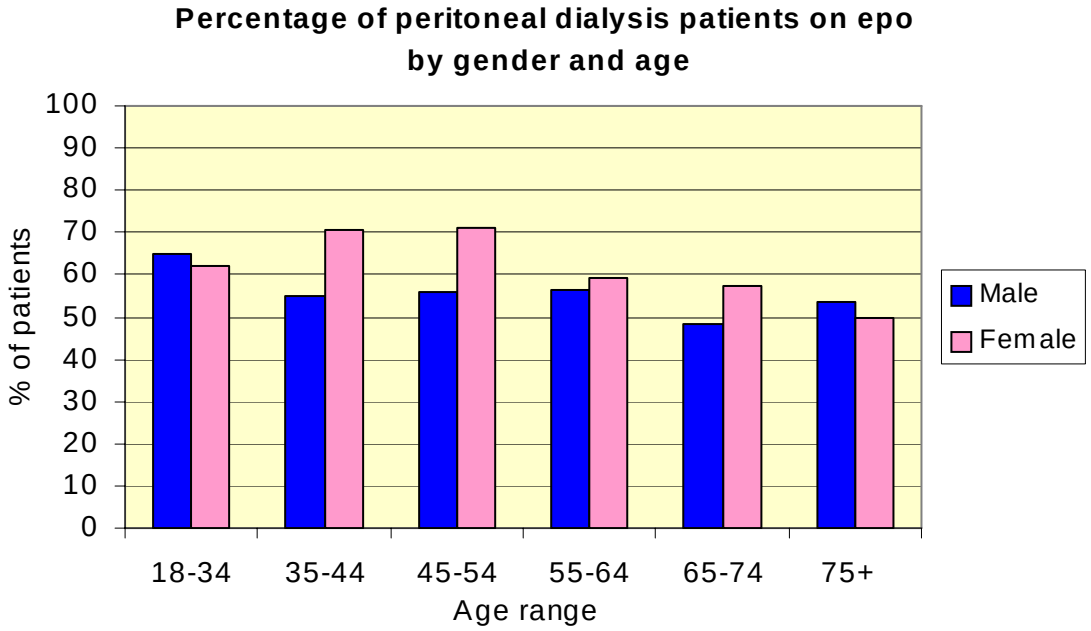


Figure 6.15 Percentage of peritoneal dialysis patients on EPO by age

The mean haemoglobin of men on peritoneal dialysis was significantly higher than women (Difference = 0.36g/dl, 95% CI 0.20-0.52, F=19, p<0.0001)

The percentage of patients with haemoglobin greater than 10g/dl, without requiring erythropoietin, was higher in men than women in both dialysis modalities. Despite their lower mean haemoglobin, a higher proportion of women were being treated with erythropoietin. Amongst patients on haemodialysis with a haemoglobin less than 10 g/dl men were less likely to be on erythropoietin than women (p=0.011). For patients on peritoneal dialysis there was no significant difference in erythropoietin prescribing to men and women with haemoglobin less than 10 g/dl (p=0.43) although numbers were small.

Haemoglobin and hyperparathyroidism

The most recent PTH value from the last three-quarters of 1998 was used for analysis. The PTH value was accepted even if the patient had subsequently changed modality. PTH follows a skewed distribution and hence the log of PTH was used for regression analysis.

Haemodialysis

Sufficient data on PTH was only available from 8 centres. 1209 patients were included from a total of 1300 in the analysed centres. No significant association between log

PTH and haemoglobin was found in haemodialysis patients. There was a non-significant decrease in haemoglobin of 0.14g/dl (95% CI –0.01 to 0.29g/dl, F=3.4, p=0.0637) for a ten-fold increase in PTH. This significance may change with increased patient numbers.

Peritoneal dialysis

Data was analysed for 846 patients out of a total of 944 from the 10 centres with sufficient data return. No significant association between log PTH and haemoglobin was found in peritoneal dialysis patients (decrease in haemoglobin for a ten-fold increase in PTH =0.15g/dl 95% CI –0.05 to 0.35g/dl, F=2.1, p=0.1447).

Haemoglobin and URR in haemodialysis patients

Haemoglobin and URR data were taken paired from the same quarter in the last 6 months of 1998. Patients on home haemodialysis or those known to be on twice or four times weekly dialysis were excluded. Data were available from 1868 patients from the total of 2075 patients in the centres with adequate data return. URR was significantly associated with a linear increase in haemoglobin (p=0.0143). The increase though, was only small with a 10% increase in URR from 60% to 70% associated with an increase in haemoglobin of 0.10g/dl (95% CI: 0.02-0.18g/dl).

Haemoglobin and cause of renal failure

In both haemodialysis and peritoneal dialysis the diagnosis of polycystic kidney disease was associated with higher haemoglobin than other causes of renal failure. The mean haemoglobin of haemodialysis patients with a diagnosis of polycystic kidney disease was 0.5g/dl higher than patients with other diagnoses (ANOVA 95% CI: 0.27-0.74g/dl, F=18, p<0.0001). The mean haemoglobin of peritoneal dialysis patients with a diagnosis of polycystic kidney disease was 0.7g/dl higher than patients with other diagnoses (95% CI: 0.36-1.04g/dl, F=16.2, p<0.0001).

Compliance with Renal Association recommendations and Renal Unit Median Haemoglobin

The current data confirm the linear relationship of median centre Haemoglobin and percent compliance with a minimum value of 10g/dl demonstrated in the 1998 Report, for both forms of dialysis (Figs 6.16/6.17). This association depends on the uniformity of the range of results (Standard Deviation, shown in Tables 6.1 and 6.2). Because of the apparently inevitable spread of outcome values a considerable over-achievement is necessary for compliance with the Standard.

It would be expected that a successful policy of targeting a particular haemoglobin concentration would result in narrowing of the spread of haemoglobins as shown by the standard deviation from the mean. This would indicate economic use of erythropoietin, with little wastage stimulating excessive haemoglobin concentrations, and may protect patients from the possible risks to vascular access of high haemoglobin. It is difficult

from a single year's data to comment on the targeting policy of individual centres, but the spread of data in most centres is similar regardless of median haemoglobin achieved. Some differences between centres are noted. For instance 86% of haemodialysis patients in Centre I achieved a haemoglobin > 10 g/dl with a median haemoglobin of 11.0 g/dl whilst centre H with 88% above 10 g/dl had median haemoglobin of 11.9 g/d, and many patients with high haemoglobin. The standard deviation for Centre I was 1.1 compared with 1.6 for Centre H, though the smaller number of patients in Centre I would have been expected to increase the standard deviation. The influence of explicit treatment strategies (e.g. 'Target' values) is uncertain from these data but will be reviewed with individual centres as part of the evaluation exercises undertaken by the Registry.

It is only by comparing data in subsequent years that it will become clear whether these differences are consistent or are a statistical anomaly of the 1998 data.

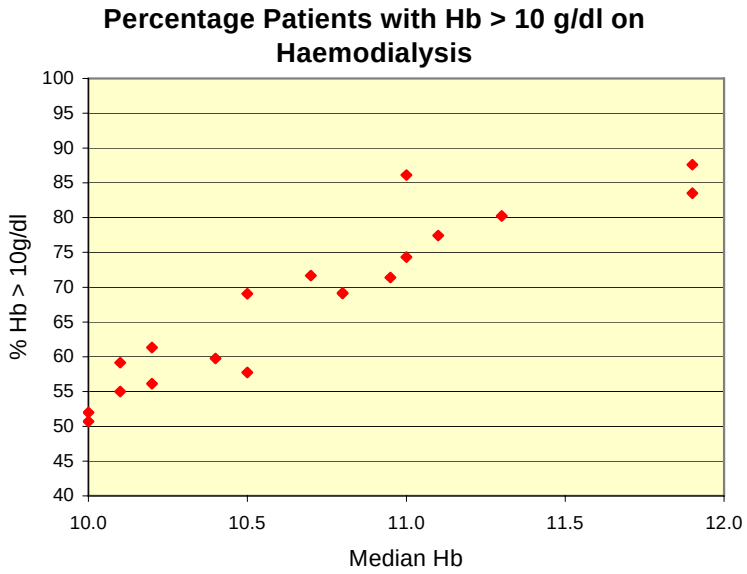


Figure 6.16 Individual centres achievement and median haemoglobin on HD

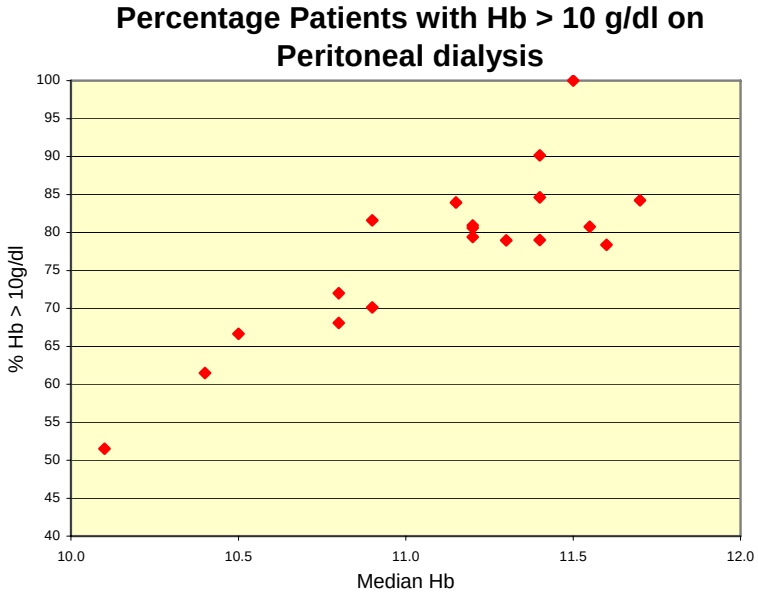


Figure 6.17 Individual centres achievement and median haemoglobin on PD

	Haemodialysis		Peritoneal Dialysis	
Centre	**Median Hb**	**% with Hb ≥ 10**	**Median Hb**	**% with Hb ≥ 10**
A	10.5	69	11.2	84
B	11.3	80	11.2	79
C	10.8	69	10.4	61
D	11.0	74	11.2	81
E	10.1	55	11.6	78
F	10.0	51	10.5	67
G	10.5	58	10.8	68
H	11.9	88	11.3	79
I	11.0	86	11.5	100
J	10.7	72	10.9	82
K	11.9	83	11.4	90
L	10.1	59	11.7	84
M	11.0	71	11.4	79
O	10.2	56	10.1	52
P	10.2	61	11.2	81
Q	10.0	52	10.8	72
R	10.4	60	10.9	70
T	11.1	77	11.4	85
E&W	**10.8**	**69**	**11.1**	**77**

Table 6.11 Percentage patients with Hb ≥ 10 g/dl on haemodialysis and peritoneal dialysis

Conclusion

More than 75 % return of haemoglobin data was achieved in all but 2 centres for haemodialysis and all but 1 centre for peritoneal dialysis. High rates of return were also achieved in the majority of centres for serum ferritin. The data for erythropoietin prescribing was only available from 8 centres and was less robust since failure to record prescription was assumed to mean that no prescription was made rather than as a failure to return the data. There was a wide range of median haemoglobin in the different centres and a wide range of achievement of the Renal Association Standard. The linear relationship of compliance with Standard and Median Haemoglobin was confirmed, although less consistent at higher values.

Haemodialysis patients in the first few months of renal replacement therapy have a higher rate of anaemia. It may be more appropriate to address the current standard to those on renal replacement therapy for at least six months or possibly one year.

There were different practices between centres with respect to prescribing erythropoietin and iron. As noted in the 1997 report anaemic patients on peritoneal dialysis were less likely than those on haemodialysis to be prescribed erythropoietin. The adequacy of haemodialysis appeared to be related to the achieved haemoglobin. The proportion of women on haemodialysis prescribed erythropoietin is higher than men, for a haemoglobin outcome that is less satisfactory. From the variables that have been measured it is often not possible to determine the reasons for differences in haemoglobin achieved in different centres.

These data show a progressive improvement in the haemoglobin of dialysis patients for England & Wales through 1997 to 1999.

Chapter 7: Changes in Haemoglobin over Time

This chapter examines the changes in haemoglobin which occur over time in individuals and the variations with time in achievement of the Renal Association Standard by Centres.

Data selection

At the end of each quarter of the calendar year the Registry collects the most recent haemoglobin data for each patient.

For the analysis relating to the start of dialysis, data used are, for each new patient in 1998, the haemoglobin recorded during the quarter in which renal replacement therapy by dialysis started. The measurement was thus made within 1 to 90 days of starting dialysis.

For al other data points there had been no change of treatment modality in the previous 3 months and there had been no transfer between centres in the previous 3 months. Data from centres are shown if there was more than 50% completeness, though centres were only included in the statistical analysis if there was greater than 75% completeness.

Haemoglobin at start of dialysis

Centre	% data return	Median Hb g/dl	Quartile range	% Hb > 10g/dl	95% CI for %Hb > 10
A	66	10.6	9.2-11.6	61	49-72
B	93	10.1	9.2-11.1	56	49-63
C	95	9.3	8.2-10.4	39	45-66
D	100	9.7	8.9-10.9	45	40-70
E	76	9.0	8.4-10.0	28	47-63
F	90	9.4	8.9-10.6	30	37-57
G	94	9.1	8.1-9.8	24	36-54
H	94	9.9	8.7-11.0	47	30-48
I	100	10.1	9.0-11.4	55	23-53
J	91	10.2	9.3-11.0	56	25-49
K	92	9.4	8.4-10.5	34	24-46
M	93	10.1	9.0-11.2	55	17-44
O	96	9.7	7.2-9.3	37	17-41
P	93	9.1	9.1-10.6	28	20-36
Q	99	9.6	8.0-10.1	36	17-32
R	87	9.5	8.7-10.7	41	8-21
E&W	**89**	**10.6**	**8.6-10.8**	**61**	**38-43**

Table 7.1 Haemoglobin at start of dialysis

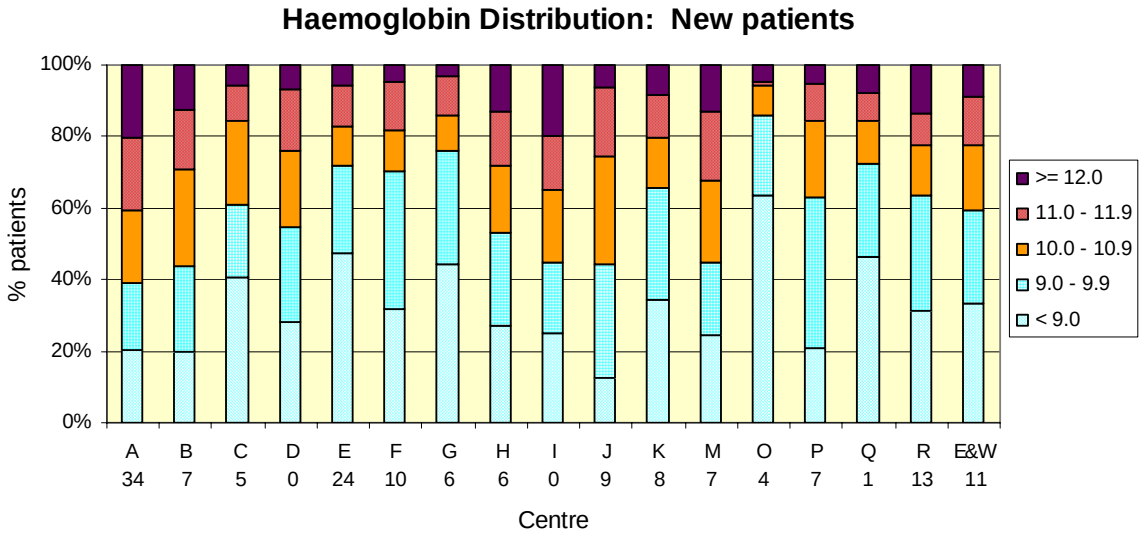


Figure 7.1 Haemoglobin distribution at start of dialysis

At the start of dialysis there was a wide range of median haemoglobin between centres from 8-9.8 g/dl. The percentage haemoglobin greater than 10.0g/dl varied from 15-43% in the centres with greater than 75% completeness. For the new patients the median haemoglobin and achievement of the Standard were both lower than for contemporaneous prevalent haemodialysis patients in the 1st quarter of 1998 (figure 7.2).

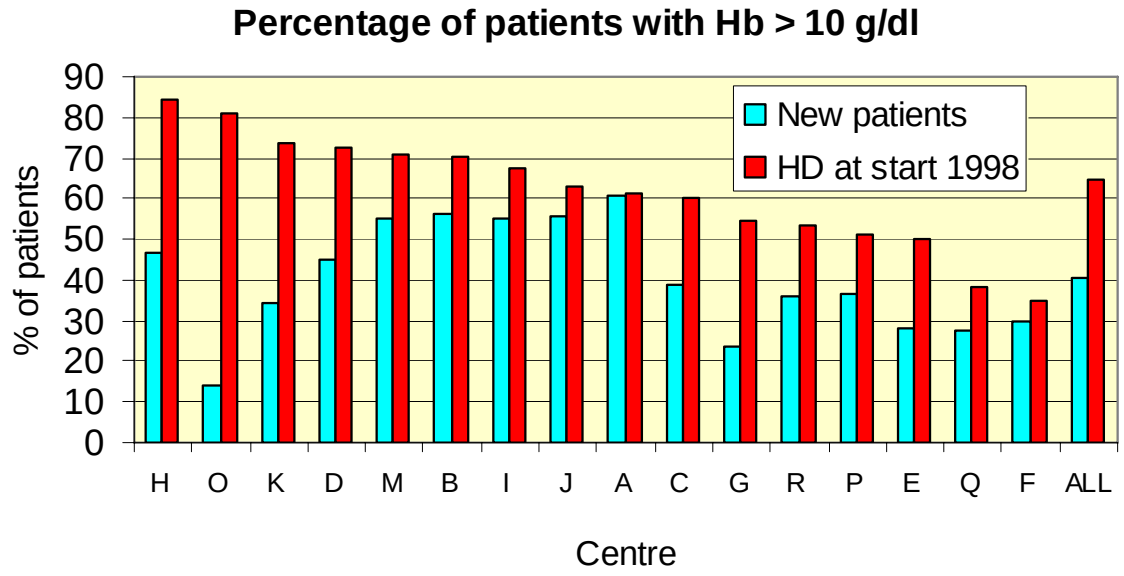


Figure 7.2 % with haemoglobin>10 g/dl: new and all prevalent patients

Changes in haemoglobin of individuals in the first year of dialysis

For the cohort of patients recorded by the Registry as starting renal replacement therapy in 1997 changes in haemoglobin during the first year on dialysis were monitored. These are shown in figure 7.3, which includes both haemodialysis and peritoneal dialysis patients. The Renal Association Standard includes patients after 3 months of treatment but this data indicates that haemoglobins do not plateau until after a year. Although the effect may be exaggerated by the fact that median haemoglobin of all prevalent patients on the Registry is increasing year on year, the cross-sectional analysis presented in chapter 6 also confirms that patients in the first few months of renal replacement therapy by dialysis have lower haemoglobin than those established on treatment for one year or more.

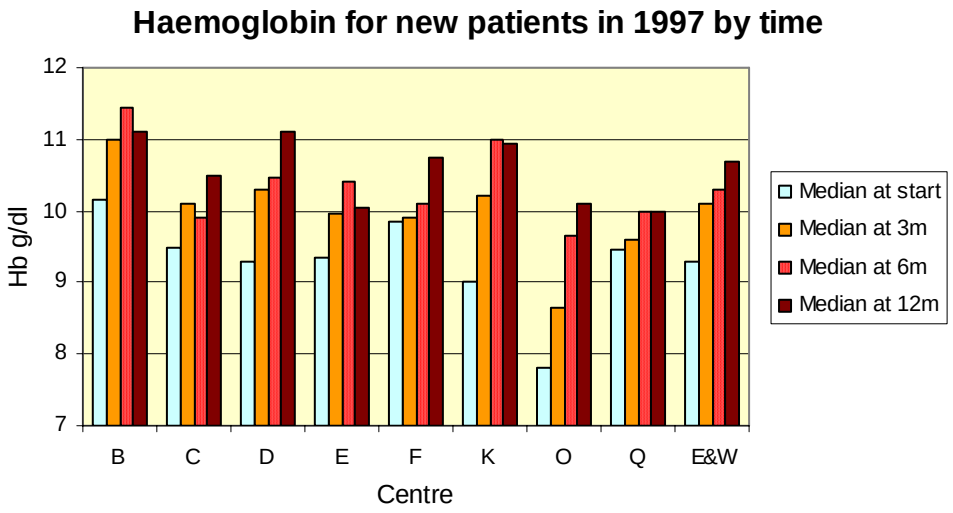


Figure 7.3 Change in haemoglobin for new patients.

Changes in haemoglobin of prevalent patients 1997-1998

This data relates to all patients alive on dialysis at selected time points. Data over 2 years is available from centres which sent returns to the Registry in 1997.
The data are summarised in table 7.2

	Mean	s.d.	Median	90% Range	Quartile Range
Haemodialysis					
Qtr 1 1997	10.2	1.6	10.2	7.6-13.0	9.1-11.2
Qtr 1 1998	10.6	1.7	10.5	7.7-13.5	9.3-11.7
Qtr 4 1998	10.8	1.7	10.8	8.0-13.7	9.7-11.9
Peritoneal dialysis					
Qtr 1 1997	10.8	1.7	10.7	8.2-13.7	9.7-11.8
Qtr 1 1998	10.8	1.7	10.7	8.1-13.6	9.7-11.9
Qtr 4 1998	10.9	1.7	10.9	8.2-13.6	10.0-12.0

Table 7.2 Change in Hb for all centres in 1st qtr. of 1997, 1998 and 4th qtr. of 1998.

In the following figures data presented for each centre are, in sequence, from the end of 1st quarter 1997, 1st quarter 1998 and the 4th quarter 1998.

Haemodialysis

Adequate data on haemodialysis patients was available from eight centres

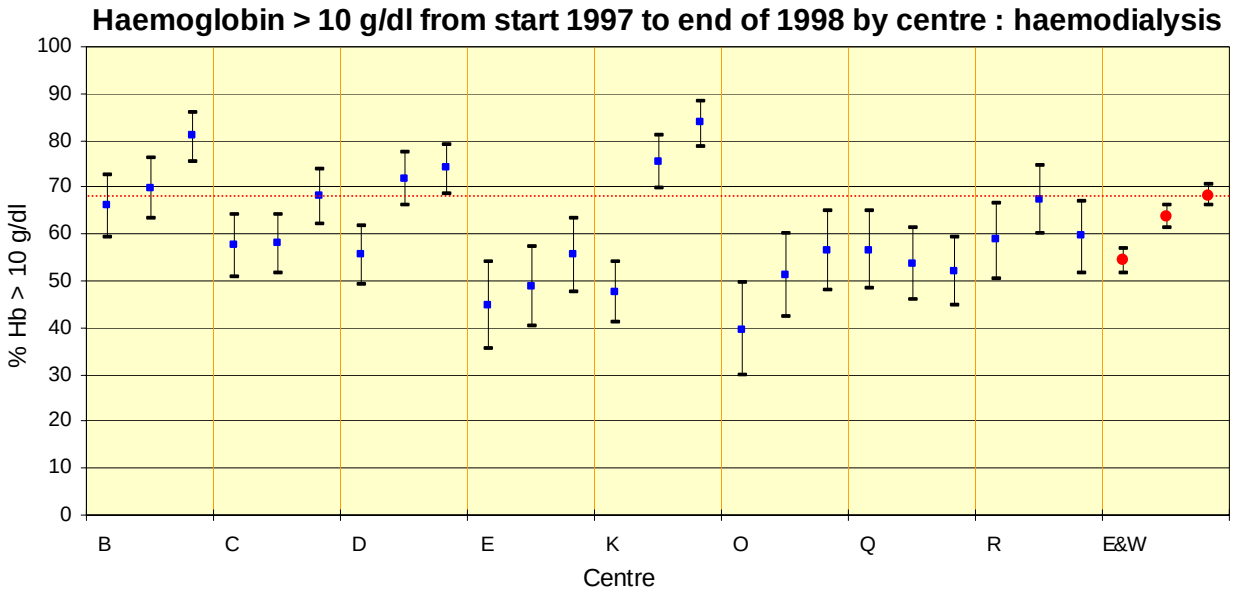


Figure 7.4 Hb > 10 g/dl from 1997 to end 1998, on haemodialysis
Data presented for each centre are, in sequence, from the end of 1st quarter 1997, 1st quarter 1998 and the 4th quarter 1998

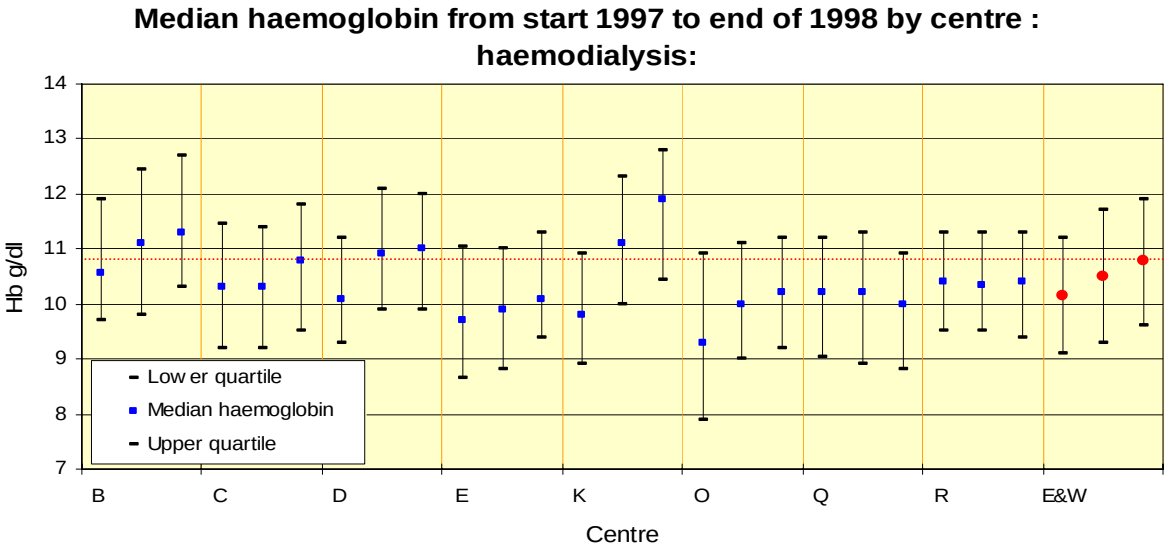


Figure 7.5 Median haemoglobin 1997-1998 on haemodialysis
Data presented for each centre are, in sequence, from the end of 1st quarter 1997, 1st quarter 1998 and the 4th quarter 1998

Comparing the 1st quarter of 1997 with the 4th quarter of 1998 showed that 7 out of the 8 centres recorded an increase in achievement of the Renal Association Standard for haemodialysis patients. Only centre Q, which has no funding for erythropoietin and makes frequent use of blood transfusion to maintain haemoglobin, showed a decline. Centre K has made the largest improvement. Overall in these units there was a

significant increase from 53% to 68% in the percentage of patients reaching the Renal Association Standard.

Peritoneal dialysis

Adequate data for peritoneal dialysis were available from 9 centres

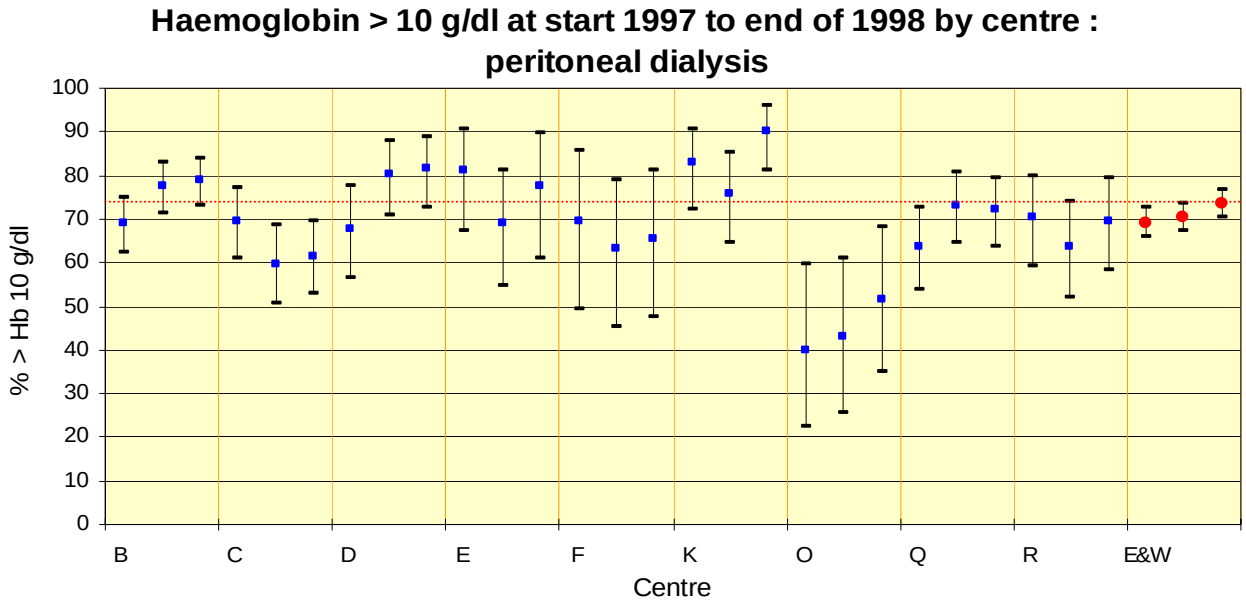


Figure 7.6 Percentage with Hb ≥ 10g/dl 1997 to end 1998, on Peritoneal dialysis
Data presented for each centre are, in sequence, from the end of 1st quarter 1997, 1st quarter 1998 and the 4th quarter 1998

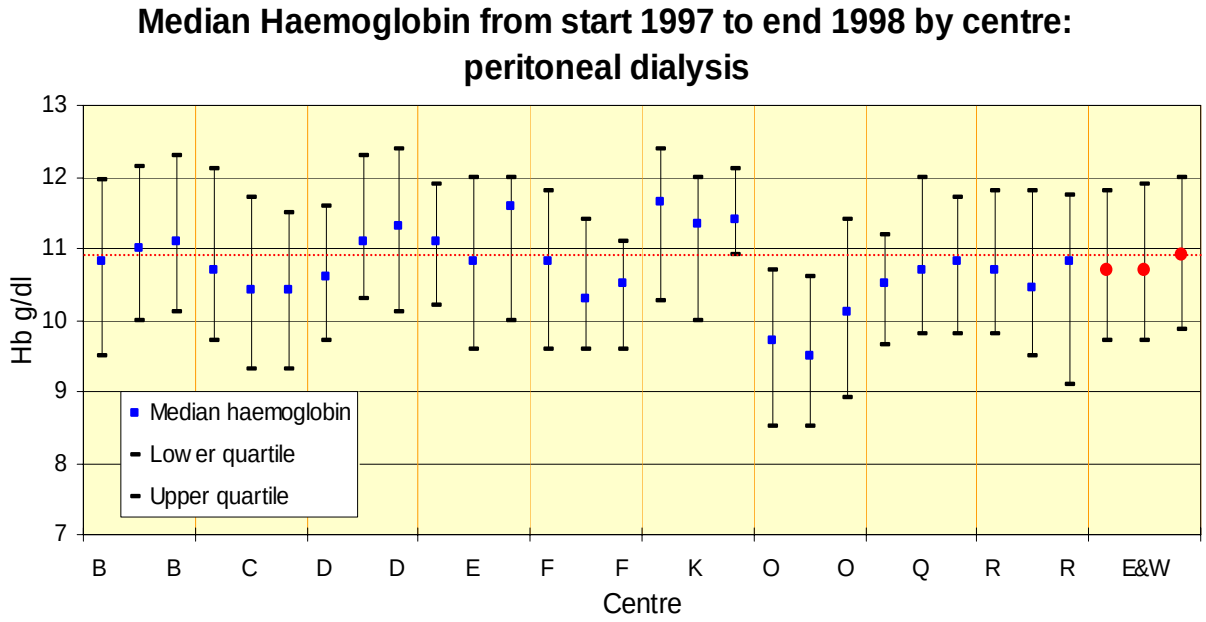


Figure 7.7 Median haemoglobin 1997- 1998 on peritoneal dialysis
Data presented for each centre are, in sequence, from the end of 1st quarter 1997, 1st quarter 1998 and the 4th quarter 1998

Patients on peritoneal dialysis started with higher haemoglobins than haemodialysis patients, and changes through 1997-1998 were smaller and more variable. Overall in these units there was a trend upward from 70% to 74% of patients with haemoglobin above the Standard.

Comment

The difference between haemodialysis patients and peritoneal dialysis patients narrowed in this time. At the start the achievement of the haemoglobin Standard was 56% for haemodialysis compared with 70% for peritoneal dialysis, and at the end 68% compared with 74%

In most centres there is no evidence of a reduction in spread of data to suggest an improvement in targeting over the two year time period. Centre K for patients on haemodialysis, has an asymmetric quartile range with a smaller upper quartile. This may indicate a more selective management of patients with higher haemoglobins and requires further investigation.

Change in haemoglobin achieved through 1998

This data relates to all patients alive on dialysis at selected time points. Sixteen centres returned sufficient haemoglobin data in both the first and fourth quarters of 1998 for analysis of both haemodialysis and peritoneal dialysis patients. (figures 7.8-11).

The data are summarised in table 7.3.

	Mean	s.d.	Median	90% Range	Quartile Range
Haemodialysis					
Qtr 1 1998	10.6	1.7	10.5	7.7-13.5	9.4-11.7
Qtr 4 1998	10.8	1.7	10.8	8.0-13.7	9.7-11.9
Peritoneal dialysis					
Qtr 1 1998	10.9	1.7	10.8	8.1-13.8	9.8-12.0
Qtr 4 1998	11.0	1.6	11.1	8.4-13.7	10.0-12.0

Table 7.3 Change in Hb for all centres returning data in 1st and 4th quarter of 1998.

The median haemoglobin in the centres over the time period is shown below (figures 7.9, 11). A reduction in the spread of data shown by reduction in the inter-quartile range may indicate success in targeting a particular haemoglobin concentration. There is a suggestion of narrowing of the range in peritoneal dialysis patients in centres I and K (figure 7.11) The spread of data for patients in all centres is shown in table 7.3.

Haemodialysis

During 1998 14 of 16 centres recorded an increase in the percentage of haemodialysis patients with haemoglobin of 10g/dl between the 1st and 4th quarters
In peritoneal dialysis patients 13 of 16 centres recorded an increase in the percentage of patients reaching the Standard haemoglobin between the 1st and 4th quarters of 1998.

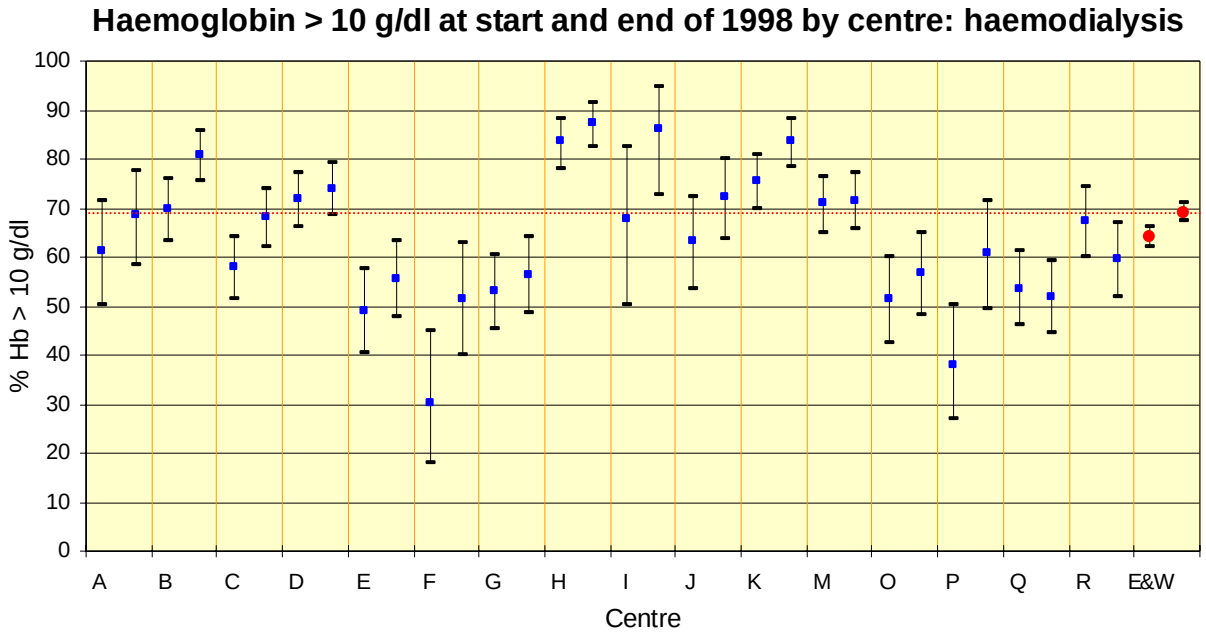


Figure 7.8 Hb > 10g/dl at start and end of 1998, on Haemodialysis
Data from each centre are from the end of the first and fourth quarters of 1988

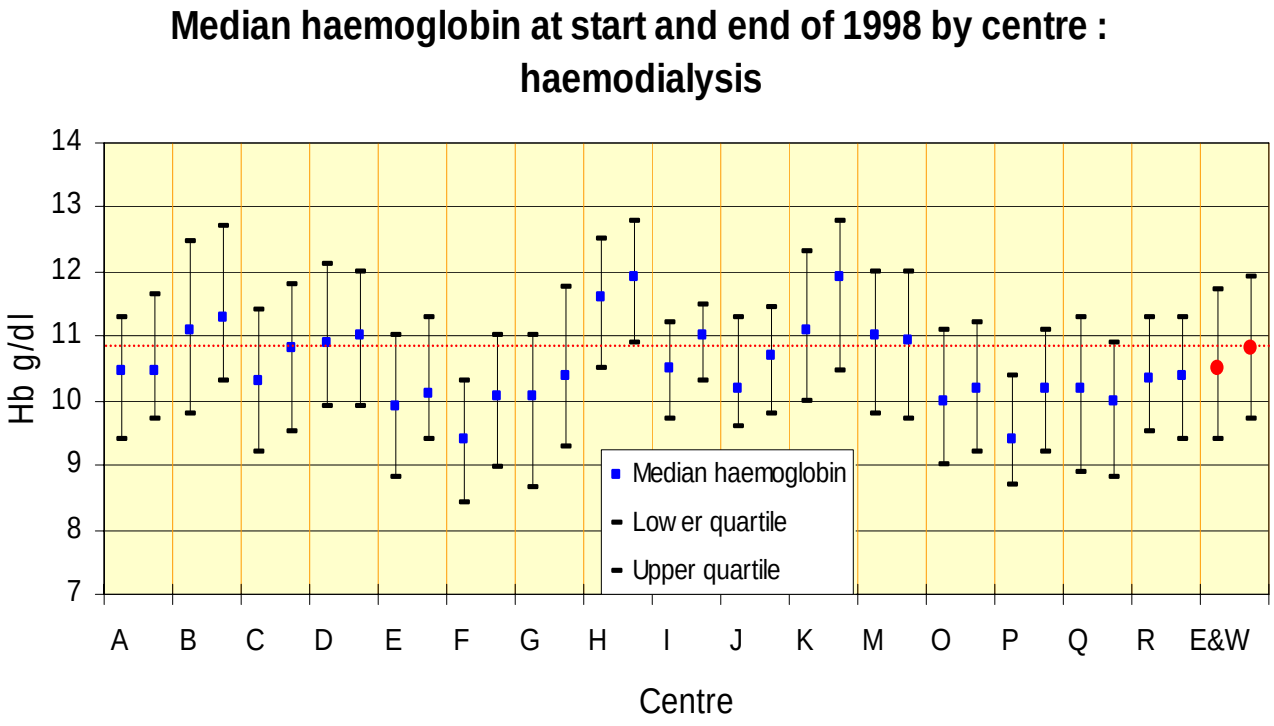


Figure 7.9 Median Haemoglobin, Haemodialysis, start and end of 1998
Data from each centre are from the end of the first and fourth quarters of 1988

Peritoneal dialysis

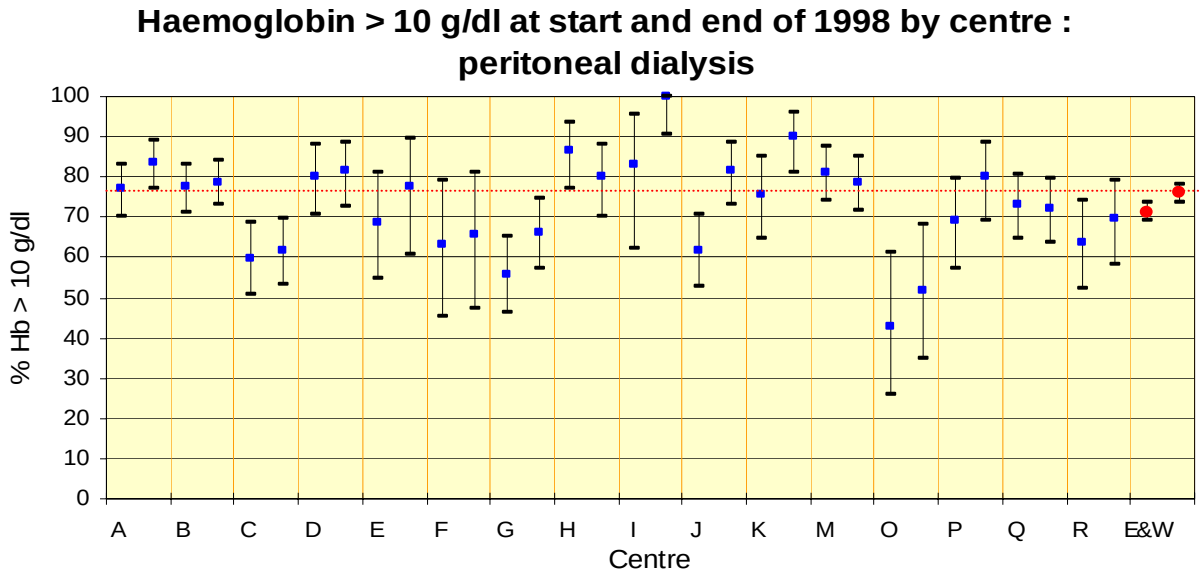


Figure 7.10 Hb > 10g/dl at start and end of 1998, on Peritoneal Dialysis
Data from each centre are from the end of the first and fourth quarters of 1988

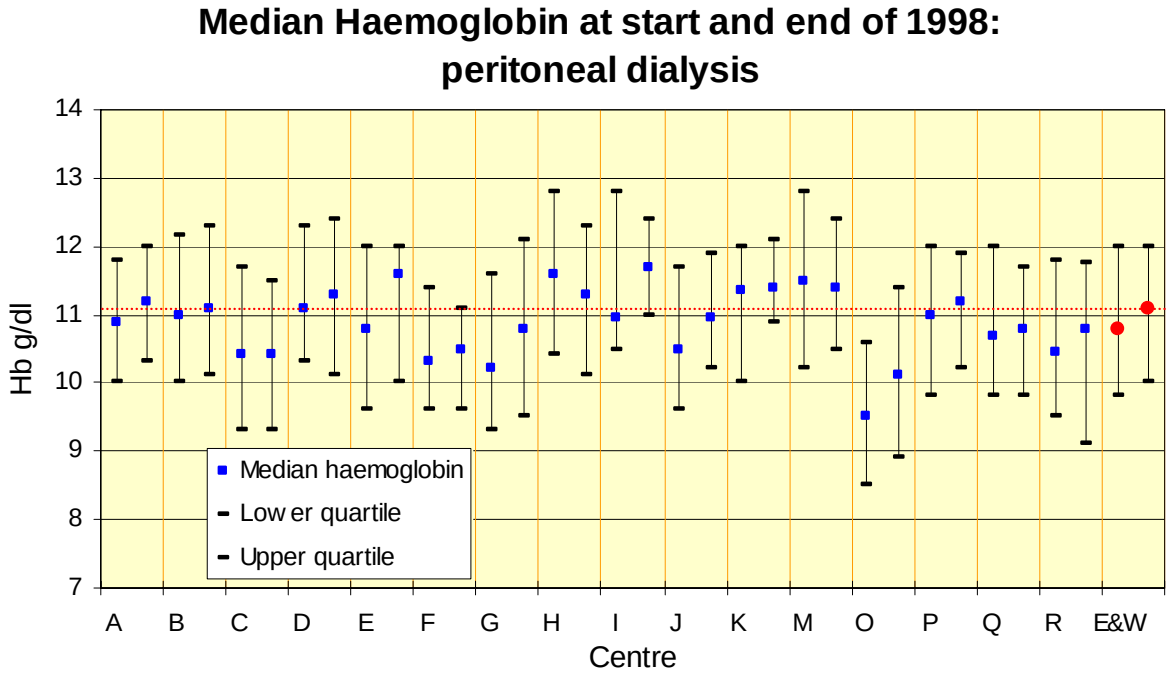


Figure 7.11 Peritoneal Dialysis results at start and end of 1998
Data from each centre are from the end of the first and fourth quarters of 1988

Analysis of changes in haemoglobin of individuals during 1998

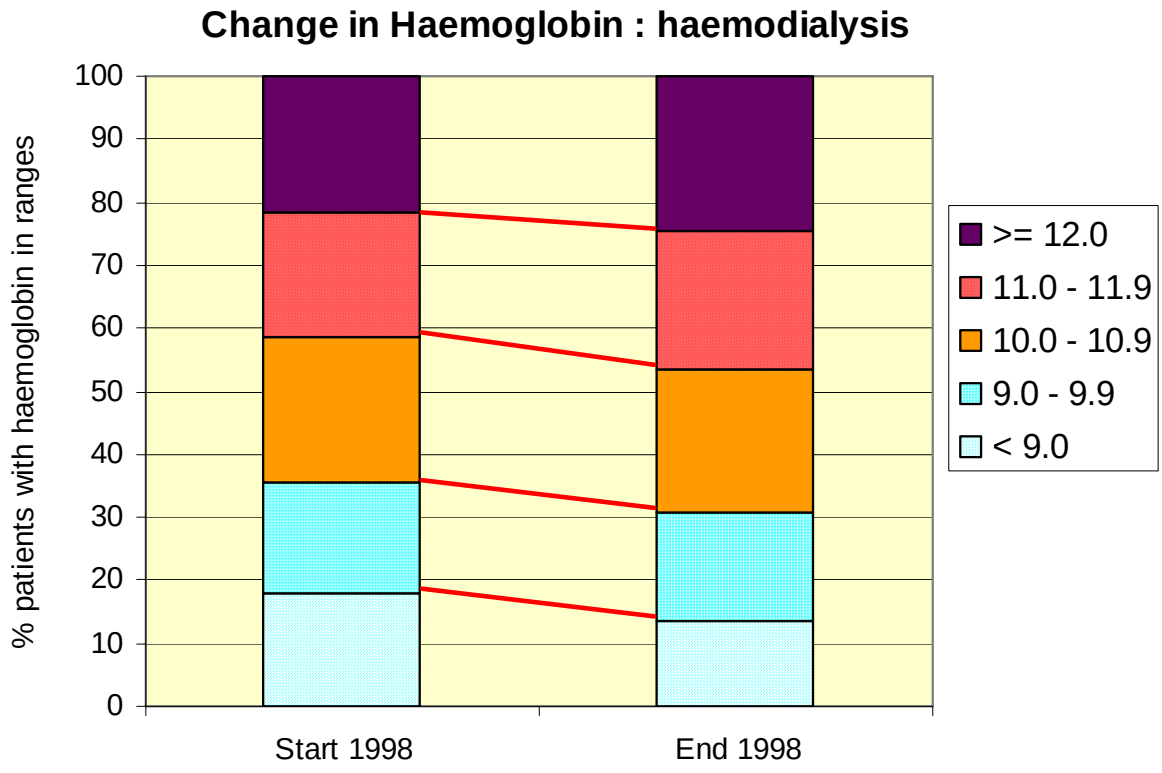


Figure 7.12 Change in haemoglobin distribution through 1998
All patients on the Registry at end of first and last quarters of 1998

Analysis of the haemoglobin distributions in populations at different time points masks significant volatility in the haemoglobin of individuals. Thus considering figure 7.12, the proportion of Registry patients in each haemoglobin band at the beginning and end of 1998 is similar and there appears to be little movement taking place. This is very misleading as the two populations of patients are different: some have died or been transplanted and new patients have started dialysis. By tracking the sequential haemoglobin changes of individual patients it becomes clear that the populations in each haemoglobin band at the two time points is quite different. This is illustrated in figure 7.13.

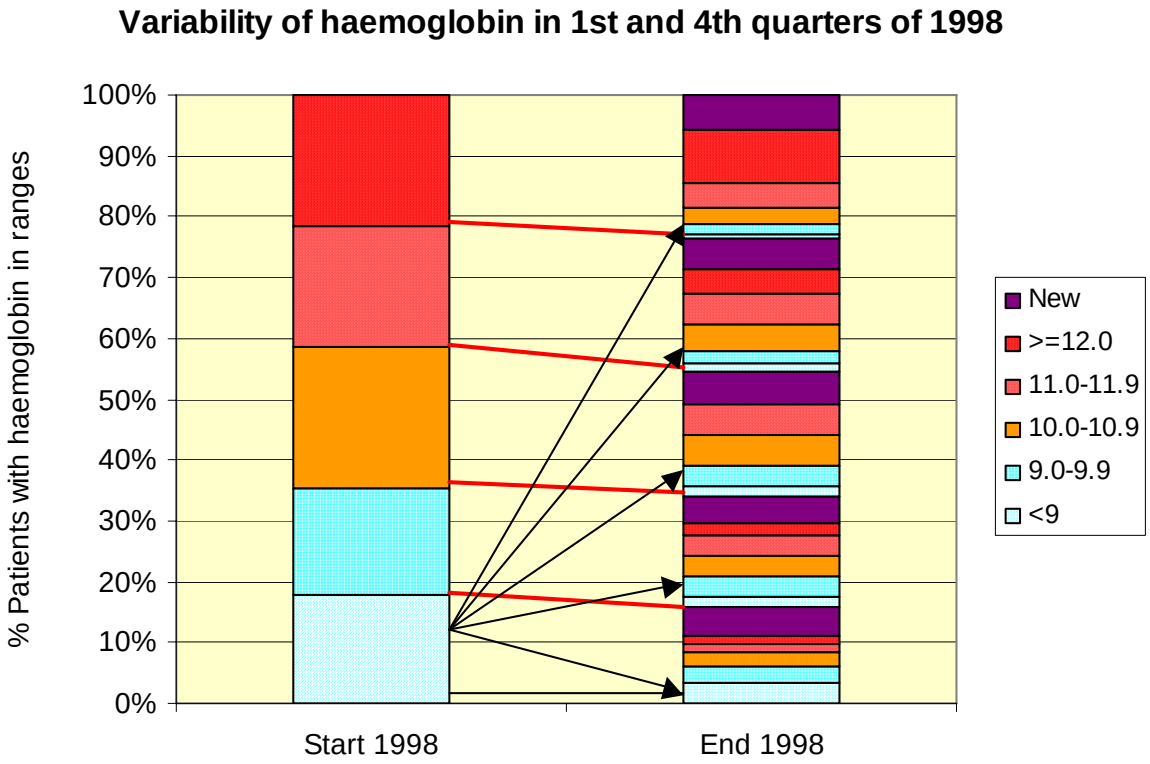


Figure 7.13 Change of haemoglobin in individuals from 1st to 4th quarters of 1998

Figure 7.13 is complex. The left column represents the proportion of patients in each haemoglobin band in the first quarter of 1998. The heavy lines linking this column to the right column define the same haemoglobin bands in the right column, which shows the situation at the end of 1998. The individual patients retain their shading code from the first quarter. It can be seen for example, that patients who are severely anaemic with haemoglobin less than 9 g/dl at the beginning of the year appear in all bands at the end of the year (illustrated by light linking lines). Likewise patients with the higher haemoglobins at the start of the year are distributed throughout the range by the end of the year.

From further study of figure 7.13 it is clear that a minority of patients in any haemoglobin band at the end of the year were in that category at the beginning of the year. New patients (those starting RRT or returning to dialysis after a failed transplant or transferring in to the centre) also comprise a large proportion of patients in each category at the end of the year.

Significant proportions of patients did start and end the year with low haemoglobin. If there is to be an improvement in the percentage of patients with acceptable haemoglobin, it is important to understand more of the characteristics of these patients and reasons for their failure to improve. However it is equally important to understand more about those patients who become anaemic from an initially satisfactory position, and to develop protocols for early recognition and prevention of this.

Determinants of haemoglobin variability

To investigate factors influencing haemoglobin change, individuals were divided into four groups described below.

Group A (remains anaemic) = Hb < 10g/dl in 1st and 4th quarter of 1998
Group B (Hb improves) = Hb < 10g/dl in 1st quarter and ≥ 10g/dl in 4th quarter
Group C (Hb falls) = Hb ≥ 10g/dl in 1st quarter and < 10g/dl in 4th quarter
Group D (Hb in Standard) = Hb ≥ 10g/dl in 1st and 4th quarter

1850 patients were on **haemodialysis** in both the first and fourth quarters of 1998 and 1705 had haemoglobin data available at both time points (table 7.4).

Group	No. of patients	% of patients
A	231	13.5
B	326	19.1
C	207	12.1
D	941	55.2

Table 7.4 Haemodialysis patients

966 patients were on **peritoneal dialysis** in the first and fourth quarters of 1998 and 857 had haemoglobin data at both time points (table 7.5).

Group	No. of patients	% of patients
A	103	12.0
B	136	15.9
C	113	13.2
D	505	58.9

Table 7.5 Peritoneal dialysis patients

The data suggest similar levels of volatility between patients on haemodialysis and peritoneal dialysis. In both modalities 12-15% of patients remained anaemic throughout the year, and 12-13% of patients developed anaemia during the year

Haemoglobin variability and age

Analysis of variance was used to compare the mean ages in each group and the data are shown in Table 7.6.

Group	No of patients	Mean age	Standard deviation
A	359	55.1	15.9
B	484	57.0	15.6
C	349	57.3	16.1
D	1481	58.1	15.6

Table 7.6 Haemoglobin variability and age

There was no significant variation in the mean age of patients in the four groups after adjusting for treatment centre (F=2.1, p=0.096).

Haemoglobin variability and ferritin

This analysis used the most recent ferritin in a 6-month period and the corresponding haemoglobin for that period. Analysis of variance was used to compare the log ferritin in the 4 groups adjusting for treatment centre. Centres G, H and J were excluded due to less than 75% data completeness. The results are shown in table 7.7

Group	No of patients	Log ferritin	S.D. log ferritin	Geometric mean ferritin
A	283	2.53	0.42	343
B	363	2.41	0.38	257
C	275	2.52	0.40	334
D	1104	2.33	0.41	215

Table 7.7 Haemoglobin variability and serum ferritin

A statistically significant variation was found between the four groups ($F = 32.1$ $p<0.0001$).

Differences in the geometric means of the groups are shown below after adjusting for treatment centre (table 7.8). The Bonferroni correction has been applied to p-values and 95% confidence intervals. This correction is used when performing multiple tests to take into account the increased probability of a result being significant by chance. The disadvantage of this test is that it is too conservative. It is possible to have a statistically significant F test value from ANOVA, but to have no individual means that differ significantly after applying the Bonferroni correction. Nevertheless there are highly significant differences between the groups.

Comparison	Ratio of Geometric means	95% confidence interval for ratio	p-value
A with B	1.37	1.14-1.65	<0.0001
A with C	1.00	0.83-1.22	1.0000
A with D	1.57	1.35-1.84	<0.0001
B with C	0.73	0.61-0.88	<0.0001
B with D	1.15	1.00-1.32	0.0564
C with D	1.57	1.34-1.83	<0.0001

Table 7.8 Comparison of groups by ferritin concentration

The data shows that those with persistently low or falling haemoglobin have higher serum ferritin than those with stable high or rising haemoglobin. Factors possibly explaining this include inability to utilise iron stores in those with low or falling haemoglobin, to repeated iron infusion in patients with other factors inhibiting haemoglobin response, or a raised ferritin associated with an illness that causes a fall in haemoglobin.

Haemoglobin variability and gender

The Mantel-Haenszel General Association statistic was used to test for an association with gender adjusting for treatment centre (table 7.9).

Group	% (N) Male	% (N) Female
A	56% (202)	44% (157)
B	58% (282)	42% (202)
C	59% (207)	41% (142)
D	64% (946)	36% (533)

Table 7.9 Haemoglobin variability and gender

A statistically significant association was found with gender (Q_{GMH} = 10.4, d.f = 3, p=0.015.) A logistic regression analysis was used to obtain odds ratios comparing each of the three groups with group D for males compared with females as shown below (table 7.10).

Comparison	Odds ratio [95% CI]	p-value
A with D	0.73 [0.57-0.93]	0.0101
B with D	0.77 [0.62-0.96]	0.0177
C with D	0.82 [0.64-1.04]	0.1077

Table 7.10 Comparison of groups with group D for gender

The data would suggest that females form a higher proportion of those with persistently low haemoglobin than they do of those with stable high haemoglobin. Taken with data presented in the previous chapter this again suggests that reaching the Standard haemoglobin in females may be more difficult than for males.

Haemoglobin variability and parathyroid hormone

The analysis used the most recent iPTH value over a 9-month period. The distribution of iPTH is skewed so the log iPTH was used in analysis of variance. Data from centres H, J, K, M, P and Q were excluded since there was less than 75% data completeness. Results are shown in table 7.11.

Group	No . of patients	Mean log iPTH	S.D. log iPTH	Geometric mean iPTH
A	183	1.28	0.59	18.8
B	269	1.16	0.65	14.4
C	185	1.18	0.64	15.0
D	656	1.16	0.62	14.5

Table 7.11 Haemoglobin variability and parathyroid hormone

There was no statistically significant variation in log iPTH between the 4 groups (F=1.2, p=0.3099).

Haemoglobin variability and time on treatment

Analysis of variance was used to compare length of time on dialysis in the 4 groups adjusting for treatment centre. Length of time on dialysis follows a skewed distribution

and the data was therefore log transformed. Length of time on treatment in days on 31st December 1998 was used. Results are shown in table 7.12.

Group	No of patients	Mean log days on treatment	S.D. Log days	Geometric mean years
A	355	3.14	0.38	3.87
B	472	3.14	0.37	3.89
C	345	3.15	0.33	3.95
D	1444	3.14	0.34	3.87

Table 7.12 Haemoglobin variability and time on treatment

No statistically significant difference was found in log time on treatment between the groups (F=0.05, p=0.9863).

Haemoglobin variability and urea reduction ratio

Only in-centre haemodialysis patients on thrice weekly dialysis were included in the analysis. Data from centres C, D, G, H, J and M were excluded from the analysis due to less than 75% completeness. Analysis of variance was used to compare the 4 groups adjusting for treatment centre. Results are in table 7.12.

Group	No of patients	Mean URR	Standard Deviation
A	101	65.2	10.8
B	132	66.4	9.0
C	84	62.9	10.1
D	365	65.0	8.6

Table 7.13 Haemoglobin variability and urea reduction ratio

A statistically significant association was found between the groups and urea reduction ratio (F = 2.7, p=0.0437). The differences between the groups are shown in table 7.14, together with p-values following application of the Bonferroni correction.

Comparison	Difference in Mean URR	95% confidence interval	p-value
A with B	-2.1	-5.3 - +1.0	0.4206
A with C	+1.1	-2.4 - +4.5	1.0000
A with D	-1.2	-3.9 - +1.5	1.0000
B with C	+3.2	-0.1 - +6.5	0.0563
B with D	+0.9	-1.5 - +3.3	1.0000
C with D	-2.3	-5.2 - +0.5	0.1907

Table 7.14 Comparison of groups for urea reduction ratio

Most of the difference is accounted for by lower URR in those with a falling haemoglobin (group C) than those with a rising haemoglobin (group B), but this does not reach statistical significance. Because of applying the Bonferroni correction, the individual means do not appear to be significant but this may be an over conservative interpretation.

Conclusion

There is wide variation between centres in the haemoglobin concentration of patients on starting dialysis. Factors influencing this may include differences in prescription of erythropoietin to predialysis patients, and differences in time of referral before dialysis. It currently takes up to 12 months after starting dialysis for many patients to reach the desired haemoglobin concentration. Most centres are seeing increasing achievement of the Renal Association Standard for haemodialysis patients. Even for Centres not participating in the Registry in 1997, there was probably an increased awareness of comparative audit and the Standards achieved from the published report. The picture is more mixed for peritoneal dialysis patients.

The headline figure for the percentage achieving the target haemoglobin within a unit disguises volatility haemoglobin concentrations of individuals. Significant proportions of dialysis patients (12-13%) did start and end the year with low haemoglobin. If there is to be an improvement in the percentage of patients with acceptable haemoglobin, it is important to understand more of the characteristics of these patients and reasons for their failure to improve. However it is equally important to understand more about those patients who become anaemic from an initially satisfactory position, and to also develop protocols for early recognition and prevention of this. The data presented here offer some help to better understanding of these changes.

Chapter 8: Calcium, Phosphate and Parathyroid Hormone

Overview of presentation

In the following section the figures use a common modified box-plot format with data presented separately for haemodialysis and peritoneal dialysis. The figures showing the percentage of patients reaching the Renal Association Standard include the 95% confidence interval calculated for this figure. Where medians are displayed, the 25th and 75th centiles for the unit are included. Figures showing the percentage within a range (as defined by the Renal Association Standard or a Renal Registry defined range) also include the 95% confidence interval calculated for this figure. Data completeness is indicated by the "percentage missing" figure below the unit code letter.

Harmonisation of laboratory data between hospitals

In 1998 the Renal Registry joined with the Association of Clinical Biochemists (ACB) to investigate methods to compare laboratory results between hospitals.

With the use of local reference ranges, the result for a sample analysed in one laboratory using one analytical method may differ significantly from that generated by another laboratory using another method. For many analytes, the local laboratory reference range is mainly derived from a population distribution. For some analytes (e.g. iPTH), this may be variably derived from a reference textbook, or the manufacturer's kit specification (which would be derived from a US population distribution). While the laboratory data is both appropriate and valid for use within the local hospital environment it is possible that the ability of a Unit to meet the Renal Association Standard may be compromised not only by its clinical efficiency or case mix but also by the derivation of the local reference range.

Clinical Laboratories are all required to participate in national external quality assessment schemes, in which samples are distributed to all participating laboratories for analysis. The results are compiled by organisations such as UK NEQAS to evaluate the degree of agreement between methods and between laboratories. These schemes act as an objective management tool for maintaining and improving professional standards, analogous to the Registry's own aims.

On behalf of the ACB the Clinical Biochemistry laboratories contributing results to Registry linked Renal Units were approached for permission to look at their External Quality Assessment data, access to which is only given if permission is granted. This resulted in harmonisation factors being produced from UKNEQAS. Where the Renal Standards document specifies a range of values for a standard, harmonisation is achieved by using an adjustment for that laboratory from UKNEQAS, against the all laboratory mean for that method held by UKNEQAS. Where the Renal Standards document specifies that the local reference range should be used to define a standard, the percentage of patients achieving the standard was calculated without using the laboratory harmonisation factor produced for the Registry by UKNEQAS.

Calcium

Measurement of serum calcium

Centre	Method	Uncorrected range	Corrected range	Correction formula
A	CPC	2.20-2.60	2.20-2.60	+0.02(40-Alb)
B	Arsenazo	Not Reported	2.10-2.60	+(40-Alb)/40
C	Arsenazo	2.20-2.60	Not Reported	+0.0175x(40-ALb)
D	CPC	2.10-2.65	Not Reported	+0.02(40-Alb)
E	CPC	2.05- 2.60	2.05- 2.60	+0.025(40-Alb)
F	Electrode	2.13-2.63	Not Reported	+0.02(40-Alb)
G	CPC	2.20-2.60	Not Reported	+0.02(40-Alb)
H	Arsenazo	2.20-2.63	Not Reported	+0.025(40-Alb)
I	Arsenazo	2.10-2.60	2.10-2.60	+0.02(40-Alb)
J	Arsenazo	2.22-2.58	2.22-2.58	+0.0116(40.1-Alb)
K	CPC	2.20-2.60	2.20-2.60	+0.016(46-Alb)
L	CPC	2.12-2.65	Not Reported	Not Reported
M	Arsenazo	2.12-2.62	Not Reported	Not Reported
N	CPC	2.12-2.55	2.12-2.55	+0.025(40-Alb)
O	Arsenazo	2.10-2.60	Not Reported	+0.02(40-Alb)
P	Arsenazo	2.20-2.60	Not Reported	Not Reported
Q	CPC	2.20-2.60	2.20-2.60	+0.017(43-Alb)
R	Electrode	2.20-2.60	2.20-2.60	+(-0.016 xAlb)+0.59
T	Arsenazo	2.20-2.62	2.20-2.62	+0.02(40-Alb)

Conversion factor for calcium mg/dl = mmol/L x 4

Table 8.1 Laboratory methodologies for serum calcium

There are many different formulae to calculate total calcium, taking the measured value and correcting for serum albumin. The specific formula used varies from site to site (table 8.1). For comparison it is important that the same formula is used for all centres. Wherever possible the Renal Registry has collected the calcium data from centres uncorrected for albumin and then applied the same correction formula throughout. Some laboratories only supply corrected calcium values to the renal units and for these centres the corrected calcium was taken and a derived uncorrected value was calculated using the locally used formula supplied by each centre, in conjunction with the albumin (non-laboratory harmonised) measured.

The Renal Registry has applied a standard formula to all the calcium data of :-

$$\text{Corrected calcium} = \text{uncorrected calcium} + ((40 - \text{albumin}) \times 0.02)$$

The correction formula applies a laboratory harmonisation value to both the uncorrected calcium and the albumin.

The value for corrected calcium is therefore dependent on the local method for measuring albumin. Centre Q and J use the BCP method for measuring albumin, and this reads 2-5 g/L lower than the other sites using the BCG method. Corrected calcium values for this site will therefore be slightly high, rendering comparison with other centres invalid.

A range of 2.25 – 2.65 mmol/L was defined by the Registry for corrected calcium, as locally defined normal ranges are no longer applicable after the Registry correction. Because of all these variations, a chi-squared test for significance was not performed.

The Renal Standards document recommends that ***total calcium should fall within the normal range quoted by the local pathology laboratory, corrected for serum albumin concentration.***

Haemodialysis

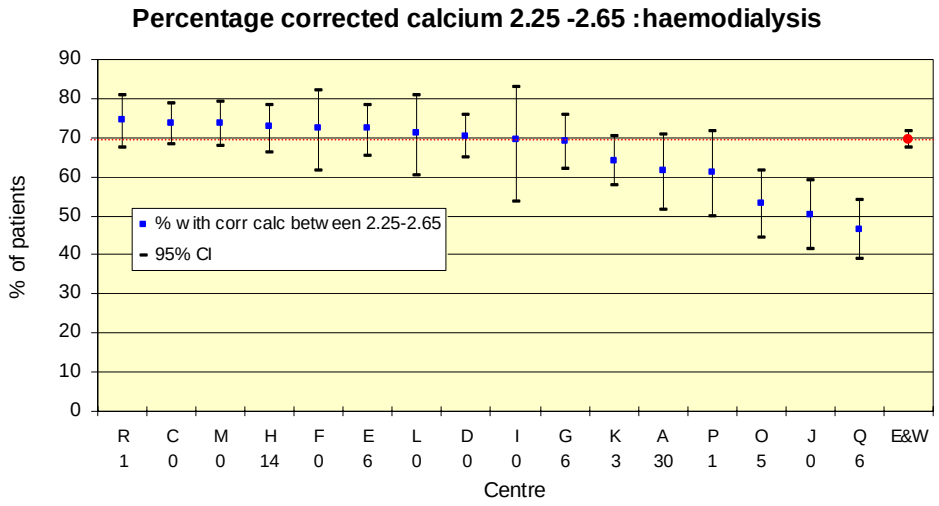


Figure 8.1 Percentage corrected calcium within 2.25-2.65 mmol/L on haemodialysis

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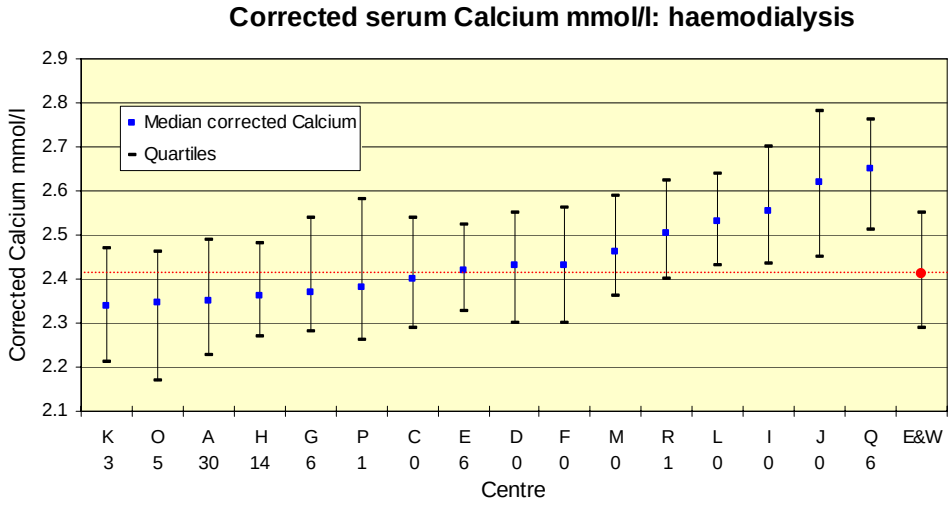


Figure 8.2 Median corrected calcium on haemodialysis

In figures 8.2 and 8.4, Centres J and Q (both use the BCP albumin method) have very high median corrected serum calcium on both haemodialysis and peritoneal dialysis. The differences are less marked in figures 8.5 and 8.6 when using the uncorrected values. This may indicate that albumin correction may be inadequate for centres using the BCP method to measure albumin.

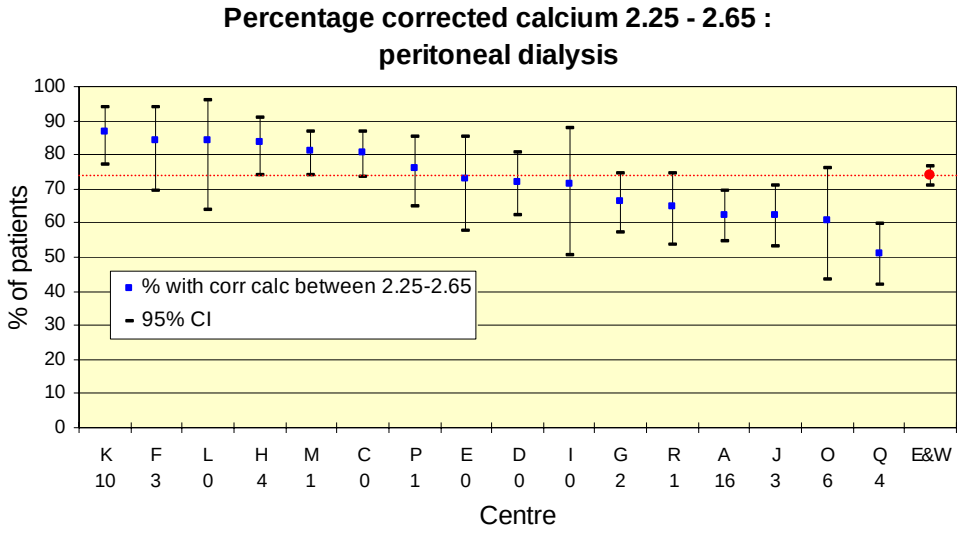


Figure 8.3 Percentage corrected calcium in range 2.25-2.65 mmol/L on peritoneal dialysis

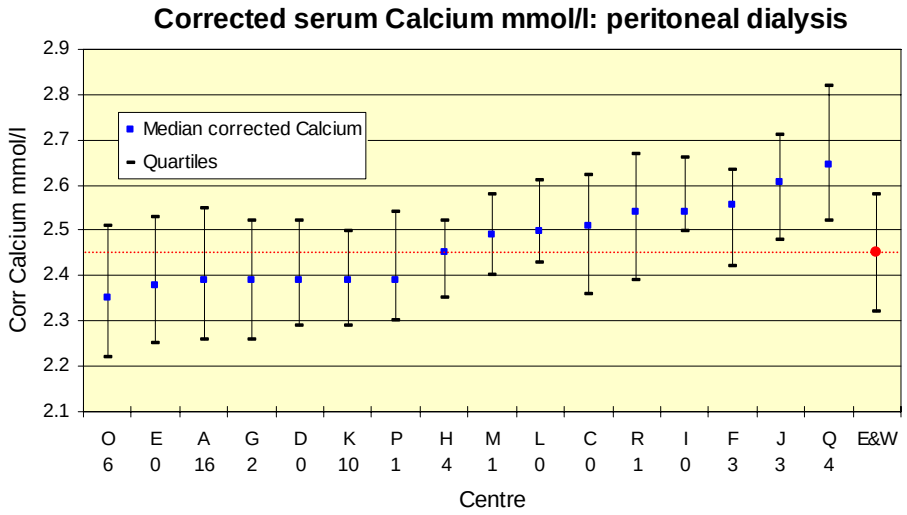


Figure 8.4 Median corrected calcium on peritoneal dialysis

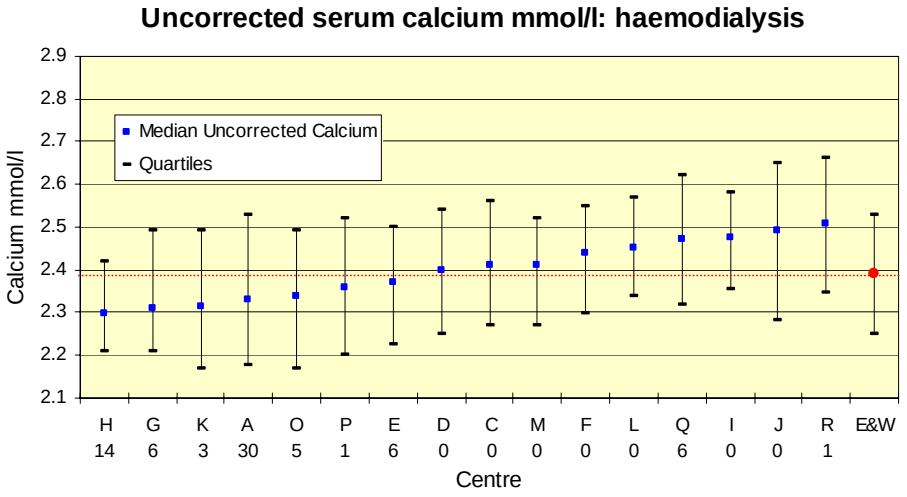


Figure 8.5 Median uncorrected serum calcium on haemodialysis

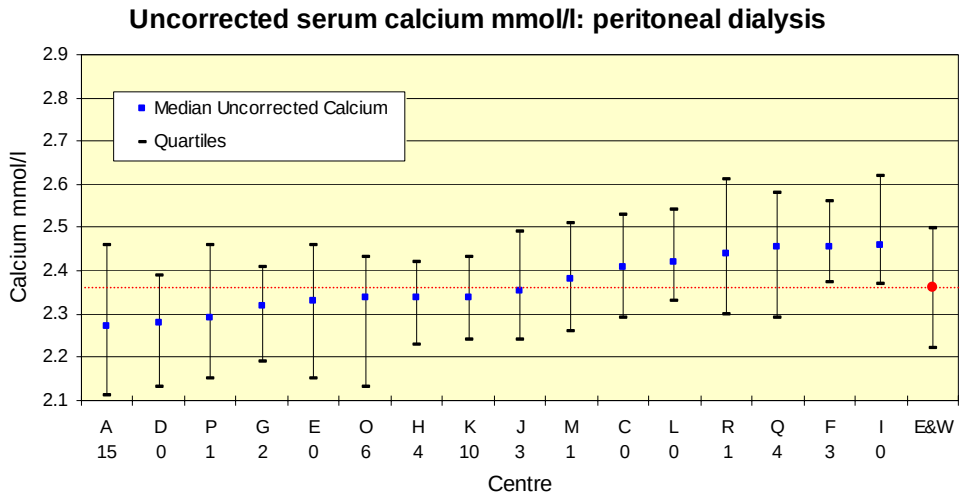


Figure 8.6 Median uncorrected serum calcium on peritoneal dialysis

Phosphate

An analysis of serum phosphate and outcome is included at the end of this chapter.

Measurement of phosphate

Centre	Methodology	Lab reference Range mmol/L	harmonisation factor (multiplier)	Derivation of ref Range
A	PMb	0.80-1.40	0.964	Manufacturer
B	PMb	0.80-1.40	0.996	Local
C	Fish/Sub	0.80-1.40	Not available	Not available
D	PMb	0.75-1.35	0.954	Not available
E	PMb	0.80-1.45	0.984	Text book
F	PMb	0.82-1.55	Not available	Text book
G	PMb	0.80-1.45	1.024	Local
H	Fish/Sub	0.75-1.36	1.011	Manufacturer
I	PMb	0.90-1.50	1.011	Local
J	PMb	0.75-1.40	1.003	Local
K	PMb	0.80-1.30	1.007	Local
L	PMb	0.80-1.40	Not available	Not available
M	PMb	0.80-1.45	0.960	Local
N	PMb	0.80-1.40	1.009	Manufacturer
O	PMb	0.74-1.40	0.971	Local
P	Fish/Sub	0.80-1.40		Local
Q	PMb	0.80-1.40	1.010	Local
R	PMb	0.70-1.40		Local
T	PMb	0.80-1.45		Text book

Conversion factor mg/dl = mmol/L x 3.1

Table 8.2 Phosphate methodologies

The comparative phosphate data is laboratory harmonised where available. There is variation of the upper reference range from 1.30 to 1.55 mmol/L (table 8.2). This variation in range does not correlate with UKNEQAS harmonisation factors that have been applied and does not appear to be related to the achievement of the Standard.

Haemodialysis

The Renal Standards document recommends ***a target range for predialysis serum phosphate of 1.2 –1.7 mmol/L.***

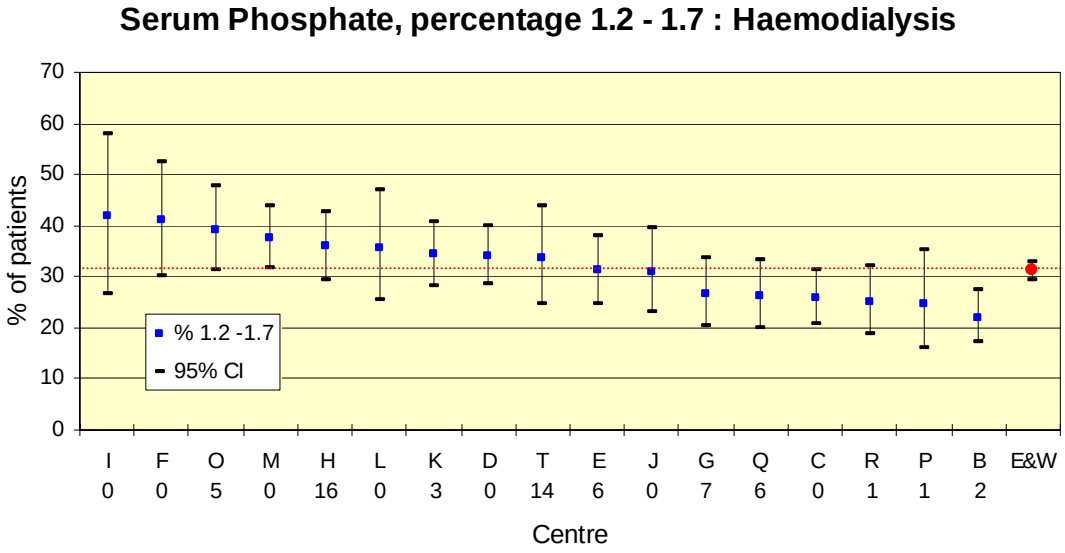


Figure 8.7 % patients with serum phosphate between 1.2 and 1.7 mmol/L on haemodialysis

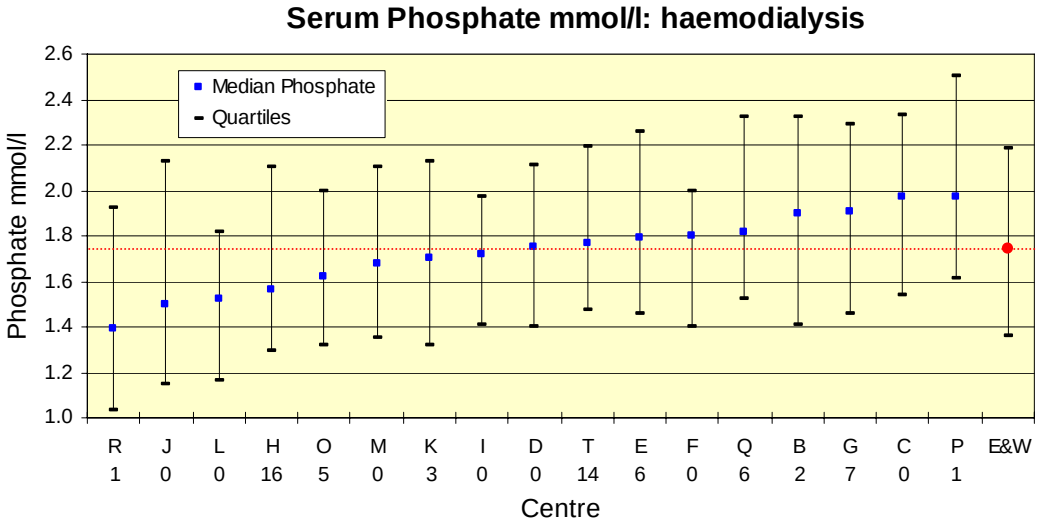


Figure 8.8 Median serum phosphate on haemodialysis

A chi-squared test was used to determine whether the percentage of patients on haemodialysis with phosphate ≤ 1.70 differed between centres. For these patients the percentage with phosphate ≤ 1.70 differed significantly between centres (X^2 = 100.7, d.f. = 16, p<0.001).

Only 31% (95% C.I. 29-33%) of serum phosphates are within the Standard and achievement of the Standard ranged from 22% to 42%. The Standard for phosphate is clearly very difficult to achieve, although centres may be influenced by the recent USA study which indicates that mortality is only increased for serum phosphate >2.1 mmol/L (Block et al).

Peritoneal dialysis

The Renal Standards document recommends ***a target range for serum phosphate of 1.1 –1.6 mmol/L.***

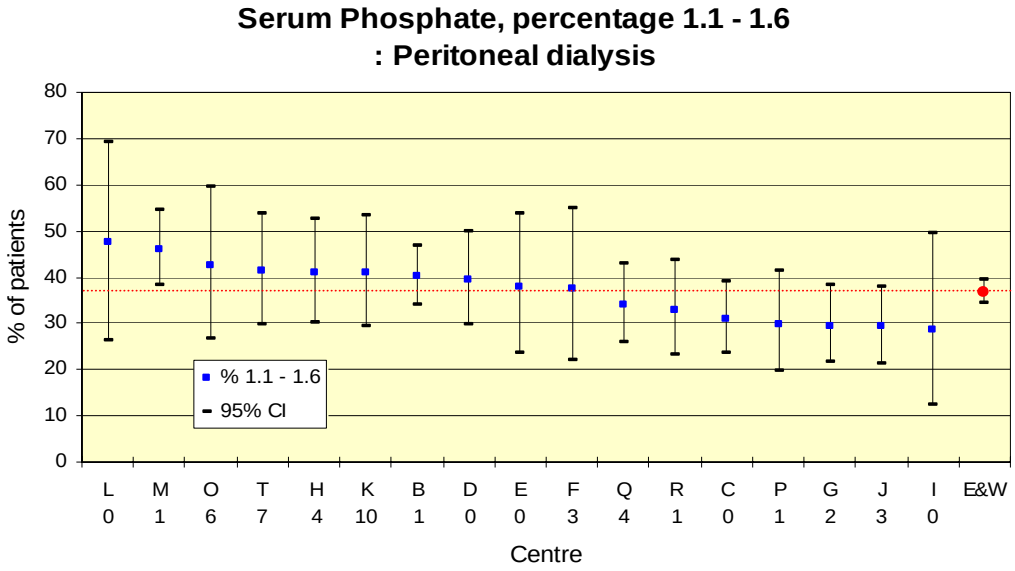


Figure 8.9 % patients with serum phosphate between 1.1 and 1.6 mmol/L on peritoneal dialysis

A chi-squared test was used to determine whether the percentage of patients on peritoneal dialysis with phosphate ≤ 1.60 differed between centres. For these patients, the percentage of patients with phosphate ≤ 1.60 differed significantly between centres ($X^2 = 34.4$, d.f. = 16, p=0.005).

Achievement of the Standard in peritoneal dialysis patients ranges from 29% to 49% with even greater overlap of the 95% confidence interval (caused by smaller numbers of patients) than in haemodialysis patients. The overall achievement of the Standard for England and Wales is 37%.

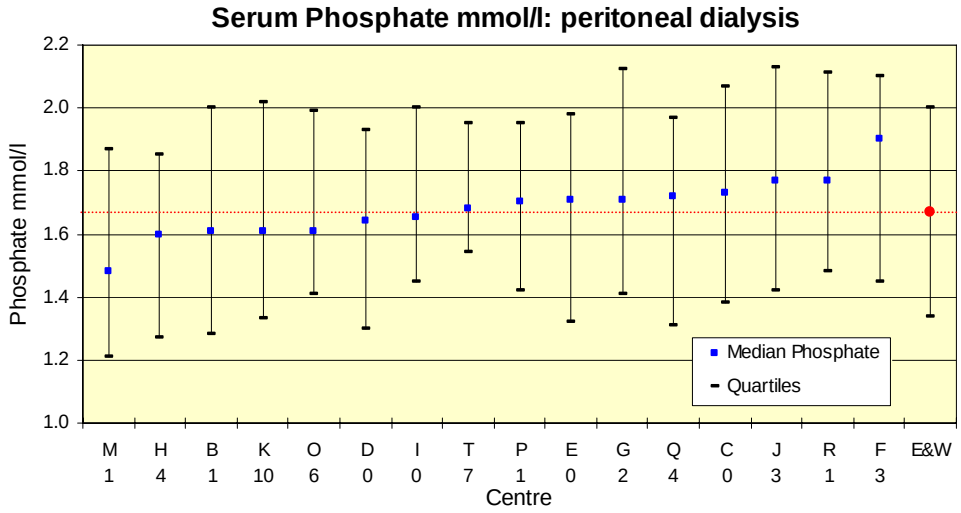


Figure 8.10 Median serum phosphate on peritoneal dialysis

Changes in serum phosphate 1997 – 1998

The changes in serum phosphate have been analysed over a two year period for the nine renal unit with data available for 1997 and 1998. The three time points displayed are 1st quarter 1997, 1st quarter 1998, 4th quarter 1998.

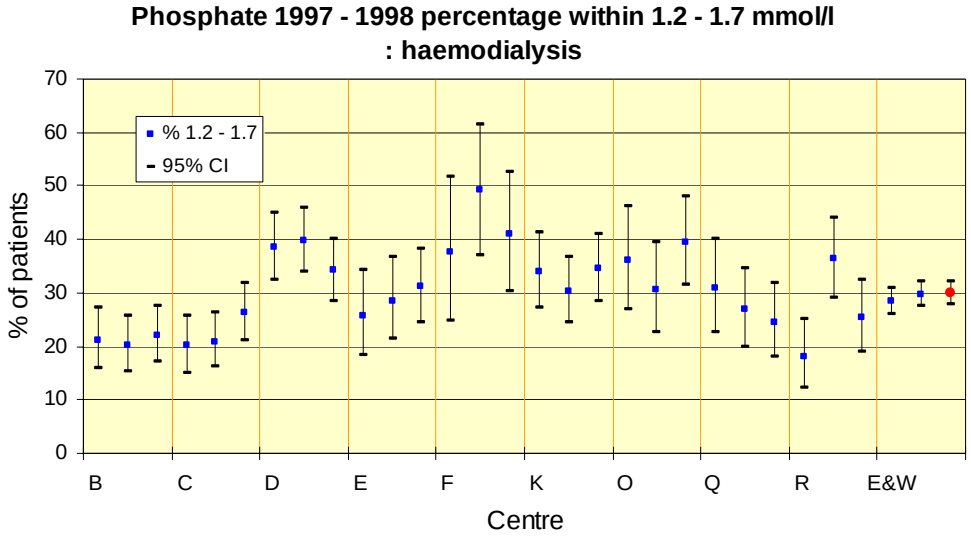


Figure 8.11 Change in % phosphate 1997 – 1998 in range 1.2-1.7 mmol/L on HD

Figure 8.12 shows the proportion of patients at these time points with serum phosphate concentration banded into 3 ranges above the upper limit of the Standard. Although centre B shows little change in compliance wihin the Standard, there has been a consistent decrease in the percentage of patients with serum phosphate above 1.7, especially in the 2.1 - 2.9 mmol/L range. This must have therefore been accompanied by an increase in patients with low serum phosphate.

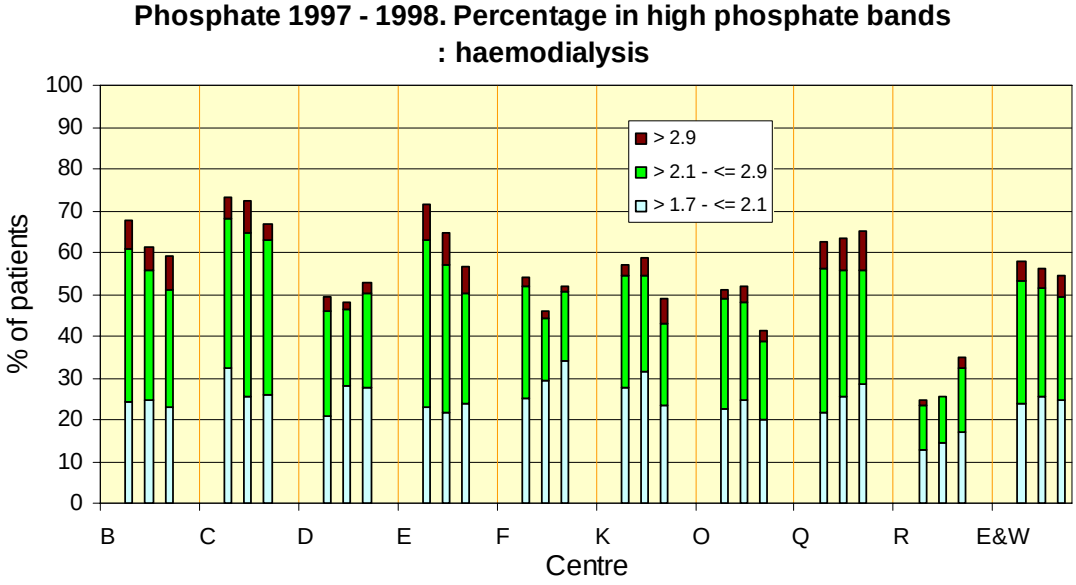


Figure 8.12 Change 1997-1998 of percentage in high phosphate bands on HD

Centre E shows a reduction in the higher serum phosphate levels but with an overall increase in the number of patients within the Standard. Within 1998 centre K and O also appear to show a reduction in patients with high serum phosphate. The reduction for centre F in the 2.1-2.9 mmol/L band is matched by an increase in the lower 1.7 –2.1 band.

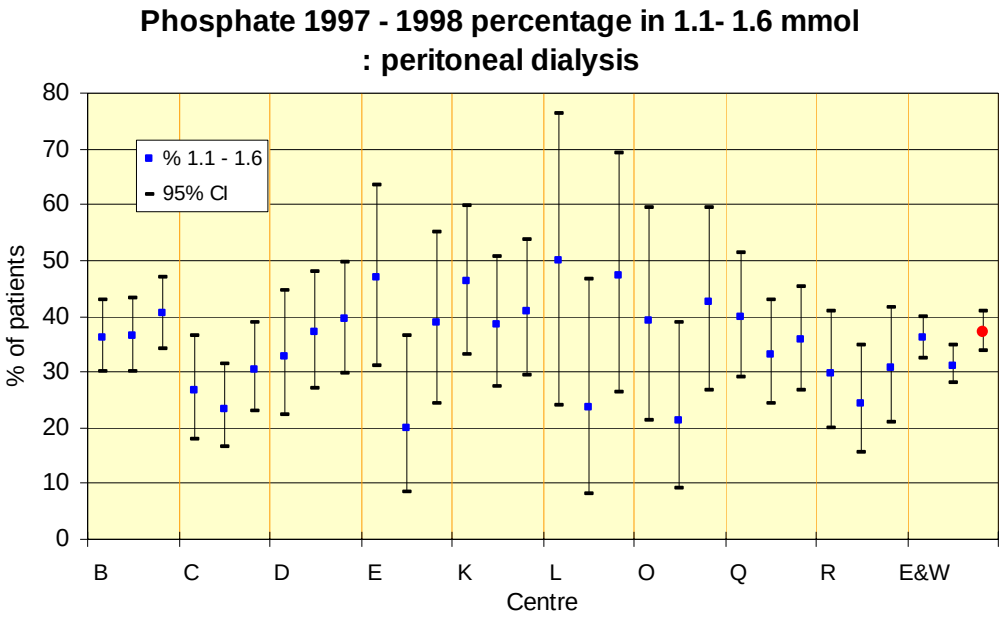


Figure 8.13 Change in phosphate 1997-1998 between 1.1 and 1.6 mmol/L on PD

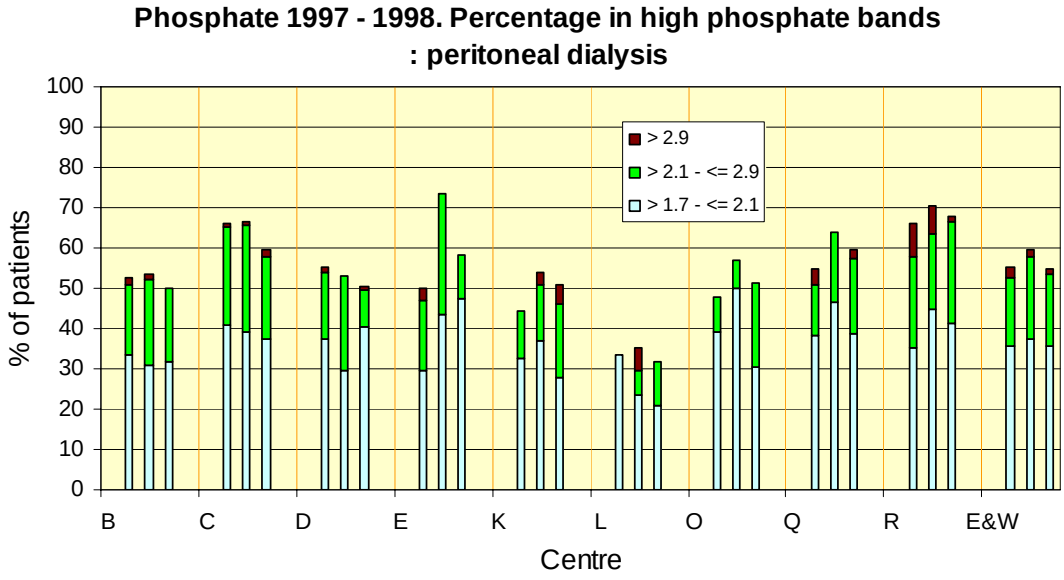


Figure 8.14 Change 1997-1998 of percentage in high phosphate bands on PD

Centre L consistently has the lowest percentage of peritoneal dialysis patients with high serum phosphate although this centre has a very small number of patients on peritoneal dialysis. The percentage of patients with phosphates above 2.1 mmol/L varied between centres from 10 – 25%. The increased compliance with the Standard for centre D is not just due to a reduction in high serum phosphate but also an increase in low serum phosphate.

Changes in serum phosphate during 1998

For 14 centres serum phosphate was available for haemodialysis patients for both the 1st quarter 1998 and the 4th quarter 1998. There were 16 centres with serum phosphate data for patients on peritoneal dialysis.

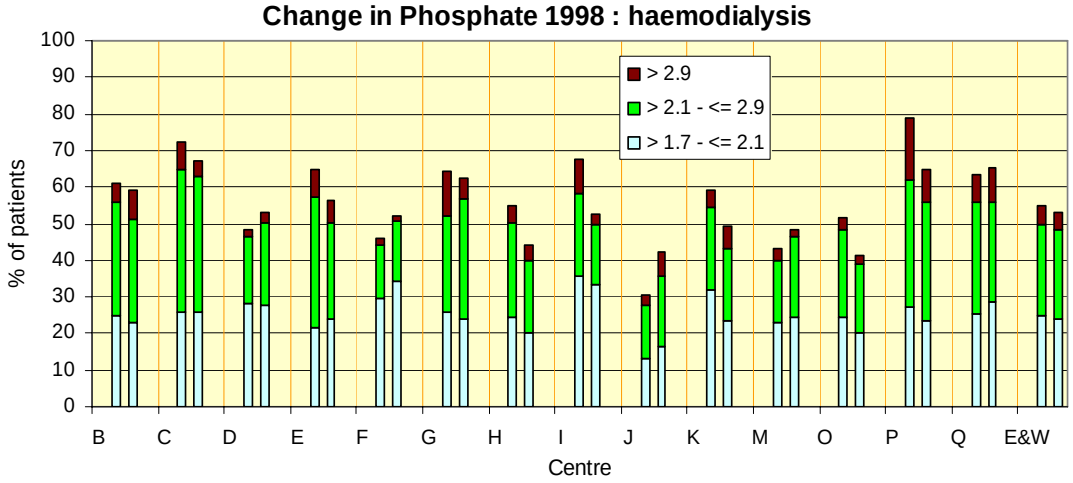


Figure 8.15 Change in phosphate in 1998 on haemodialysis

For England and Wales as a whole there has been no change in the percentage of dialysis patients with a high serum phosphate during 1998, but the time course is short.

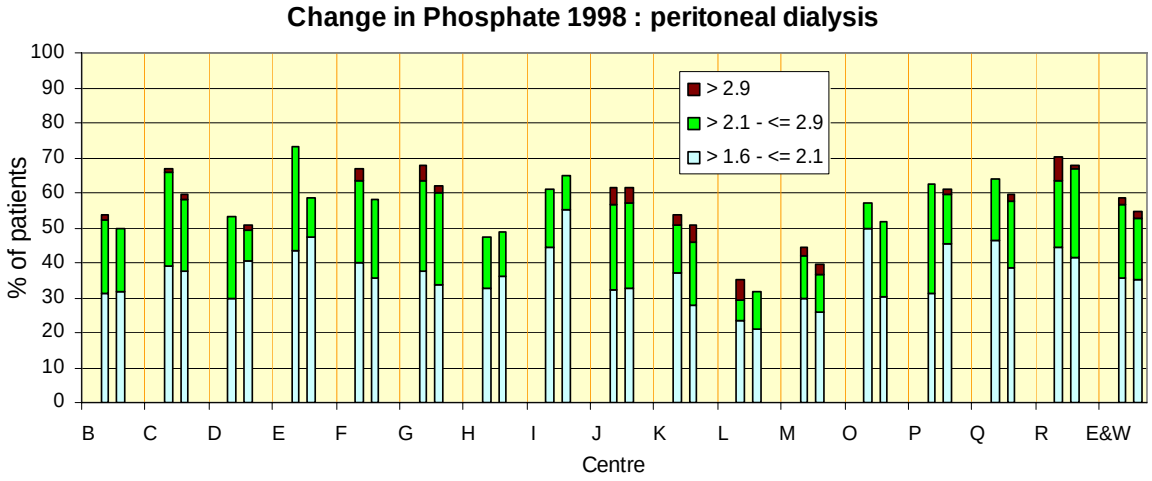


Figure 8.16 Change in phosphate in 1998 on peritoneal dialysis

Parathyroid hormone

Parathyroid hormone is defined as missing if it has not been measured within the previous 9 months.

The Renal Standards document recommends ***that iPTH (intact hormone assay) should be maintained at between 2 and 3 times the local normal range***

As discussed in the 1998 Report, the local reference range is variable even between laboratories using the same methodology (table 8.3.). This gives a variation in the upper limit for the Standard varying between 12 – 22.8 pmol/L. For comparative purposes the Registry has used the most widely quoted upper limit of 22.8 pmol/L., but acknowledges that there is no other specific reason for preferring this value.

Centre	Methodology	Lab ref Range	3 x upper ref. Range	Derivation of ref Range
A	DPC	0.9 – 6.8 pmol/L	20.4	
B	DPC	0.9 - 5.4 pmol/L	16.2	
C	Chiron	0.9 – 6.8 pmol/L	20.4	Manufacturer
D	Chiron	< 4.0 pmol/L	12.0	Local
E	DPC	1.3 – 7.6 pmol/L	22.8	Manufacturer
F	Chiron	0.8 -5.4 pmol/L	16.2	Manufacturer
G	Chiron	0.8 - 5.4 pmol/L	16.2	Manufacturer
H	INCSTAR/DPC	0.9 – 6.5 pmol/L	19.5	Manufacturer
I	Nichols	0.9 – 6.8 pmol/L	20.4	Manufacturer
J	DPC	1.3 – 7.6 pmol/L	22.8	Manufacturer
K	Nichols	0.9 – 6.8 pmol/L	20.4	Manufacturer
L	DPC	1.3 - 7.6 pmol/L	22.8	Manufacturer
M	Nichols	1.0 - 6.1 pmol/L	18.3	
N	DPC	1.3 – 7.6 pmol/L	22.8	Manufacturer
O	DPC	1.3 – 7.6 pmol/L	22.8	Manufacturer
P	DPC	1.3 - 7.6 pmol/L	22.8	Manufacturer
Q	DPC	1.3 – 7.6 pmol/L	22.8	Manufacturer
R	DPC	1.3 – 7.6 pmol/L	22.8	Manufacturer
T	INCSTAR	0.8 - 4.8 pmol/L	14.4	Manufacturer

conversion factor ng/L = pmol/L x 9.5

Table 8.3 Laboratory methodology for serum iPTH

Centre H has changed its methodology within the year form DPC to Incstar. Data is not shown for this centre as more than 50% was missing.

Haemodialysis

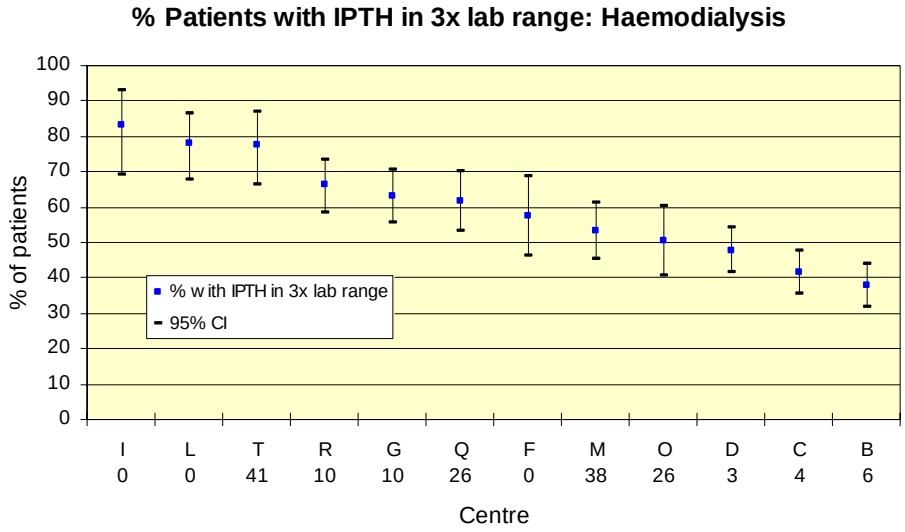


Figure 8.17 Percentage patients with iPTH in 3x lab range on haemodialysis

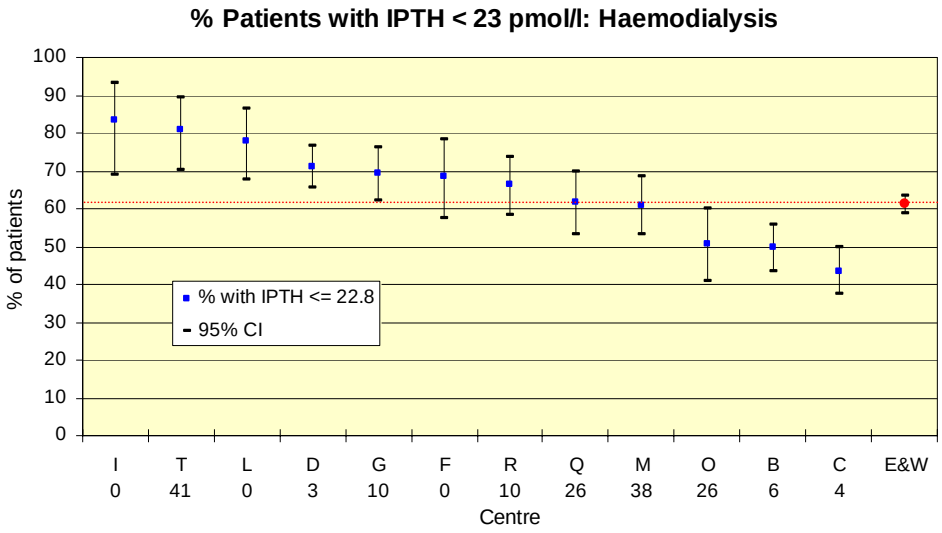


Figure 8.18 Percentage patients with iPTH < 23 pmol/L on haemodialysis

A chi-squared test was used to determine whether the percentage of patients with laboratory harmonised iPTH ≤ 22.8 differed between centres. For patients on haemodialysis, the percentage of patients with iPTH ≤ 22.8 differed significantly between centres ($X^2 = 96.7$, d.f. = 11, $p<0.001$).

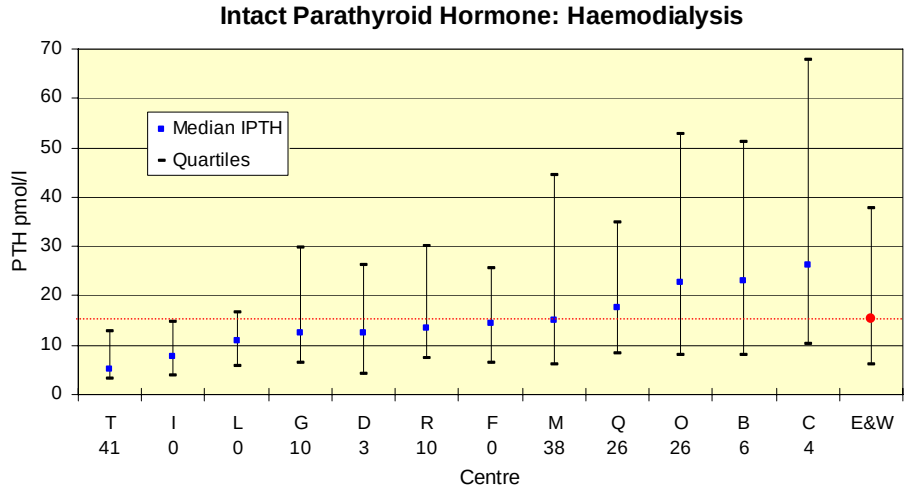


Figure 8.19 Median intact parathyroid hormone on haemodialysis

The variation in approach is more clearly seen by looking at the quartile range. For centre I 50% of patients have iPTH between 4 – 15 pmol/L while at centre C 50% are between 10 – 68 pmol/L.

Peritoneal dialysis

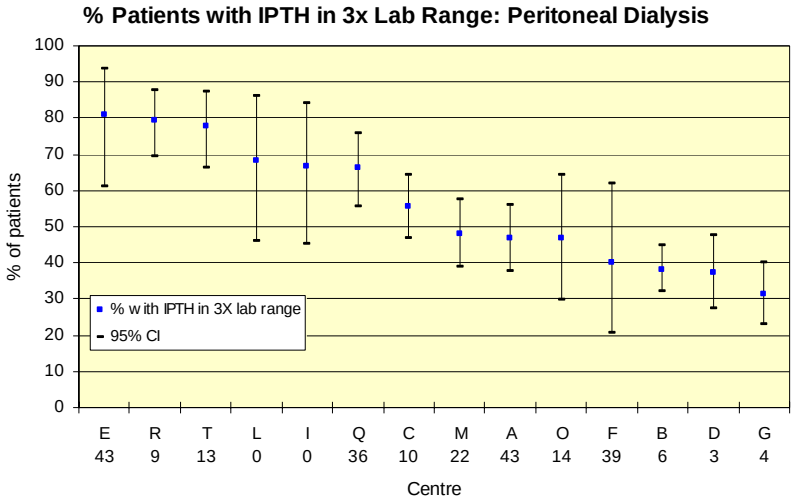


Figure 8.20 Percentage patients with iPTH in 3x lab range on peritoneal dialysis

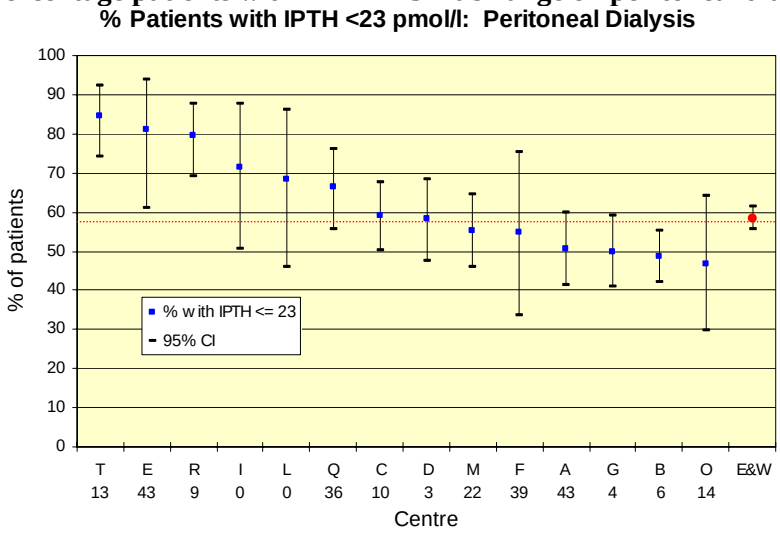


Figure 8.21 Percentage patients with iPTH < 23 pmol/L on peritoneal dialysis

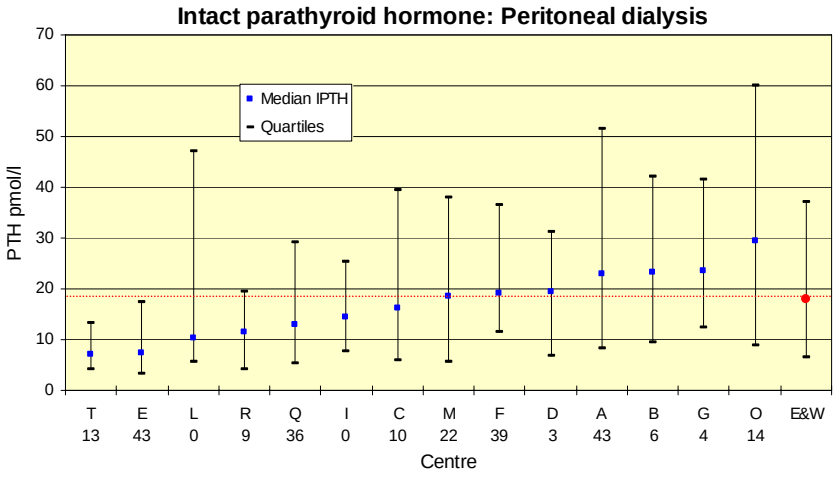


Figure 8.22 Median intact parathyroid hormone on peritoneal dialysis

For patients on peritoneal dialysis, the percentage of patients with iPTH ≤ 22.8 differed statistically significantly between centres ($X^2 = 55.9$, d.f. = 13, $p<0.001$).

At least one centre has a policy of only measuring iPTH when there are other indicators of hyperparathyroidism. This might cause a bias in the results, with a high proportion of iPTH levels being recorded from these centres. However there was no correlation between the percentage of missing data and compliance with the Standard.

Conclusions

1. Algorithms used to correct serum calcium concentration for serum albumin concentration measured may not be appropriate when BCP methods are used to measure serum albumin.

2. All Centres had difficulty reducing high serum phosphates. Many centres may feel that the Renal Association Standard for serum phosphate is unachievable and has little evidence based justification. Using the best current evidence some Centres may only be trying to control serum phosphate to below 2.1 mmol/L.

3. There has been no change over 2 years in the percentage of haemodialysis patients with high serum phosphate.

4. Figures showing compliance with a Standard (e.g. for serum phosphate) may mask change if the whole population shifts so that although more patients in the upper limit have moved into range, patients may drop below the lower limit.

5. There are varying practices between centres in the management of secondary hyperparathyroidism and many centres have a high proportion of missing data.

Serum Phosphate and Mortality

Introduction

In 1997 there were 11 centres on the Registry. This analysis relates serum phosphate of patients in 1997 to their risk of death through 1998.

Lowrie et al in 1990 reported a relationship between serum phosphate and mortality using data from 1987-88 from the National Medical Care database. Block et al confirmed this in 1998 using data collected from the 1990 Case Mix Adequacy Study and 1993 Dialysis Morbidity and Mortality Study.

Since the data for the above studies were collected there has been a general move in the USA and the UK towards improved dialysis clearance. This may have reduced the average serum phosphate of prevalent patients, and could have altered the relationship between serum phosphate and mortality. To investigate this the Registry compared distribution of serum phosphates from two centres in the UK for the years 1990, 1993, and 1997.

Sample population

Patients who were on dialysis on 1/1/1998, at one of the 11 centres on the Renal Registry database with quarterly data for 1997 were included. Patients on renal

replacement therapy for less than a year on the 1/1/1998 were excluded from the analysis. Patients were included in the analysis, regardless of their previous renal replacement therapy modality.

Patients at Centres L and N on the 1/1/1998 were excluded from the analysis, as some of the serum phosphates measured in those centres were post dialysis.

The analysis excluded patients who transferred out in 1998 to a non-Renal Registry site or received a transplant in 1998. This methodology is similar to Lowrie et al.

Statistical methods

The outcome analysed was patient death in 1998. A logistic regression analysis was used to examine the association between serum phosphate and risk of death, adjusting for age, length of time on renal replacement therapy, a primary diagnosis of diabetes and the treatment centre. These methods are similar to those used by Lowrie et al. Age and length of time on renal replacement therapy were entered into the model as continuous variables. The length of time on renal replacement therapy was measured in days on the 1/1/1998 and its log transform was used in the logistic regression model. In the adjusted analysis, patients who had been on renal replacement therapy for an unknown duration and those with a primary diagnosis of 'Not sent' (as adjustment factor includes diabetes) could not be included.

The 1997 serum phosphate data were used in the analysis without being harmonised for inter-laboratory variation. Patients had differing total numbers of serum phosphate readings for 1997, ranging from 1 to 4 values. For the analysis mean serum phosphate throughout 1997, the serum phosphate from the first quarter of 1997, and the serum phosphate from the last quarter of 1997 were each related to outcome in 1998. Patients with fewer than three quarterly values of serum phosphate available were excluded.

First quarter 1997 serum phosphate was studied, as all patients in this analysis would have survived at least 9 months from this measurement. Last quarter 1997 data might include terminally ill patients who could have a higher serum phosphate from reduced dialysis prior to death or a catabolic state, or a low serum phosphate from reduced nutritional intake prior to death. These results may be predictive of death in the next quarter, but would not indicate the contribution of serum phosphate control to mid or long-term outcome.

The analysis was first carried out categorising the serum phosphate as ≤ 1.70mmol/L, 1.71 – 2.10 mmol/L and ≥ 2.11mmol/L. These ranges were chosen since ≤ 1.70mmol/L coincides with the Renal Association Standard for haemodialysis patients, and Block et al found an increased risk of death for those with a serum phosphate greater than 2.1mmol/L (6.5mg/dL). Block et al categorised the serum phosphate into quintiles. The analysis was therefore repeated using quintiles derived from UK Registry data. The quintiles used were from the mean serum phosphate throughout 1997. The ranges were: ≤ 1.47mmol/L, 1.48-1.73mmol/L, 1.74-1.96mmol/L, 1.97-2.23mmol/L and ≥ 2.24mmol/L.

The results have been described in terms of odds ratios. The reference category chosen for the first analysis was < 1.71mmol/L. For the analysis using UK Registry quintiles, the serum phosphate reference category was 1.48-1.73mmol/L.

In this context, for someone with a serum phosphate of 1.71-2.10mmol/L the odds of dying are the

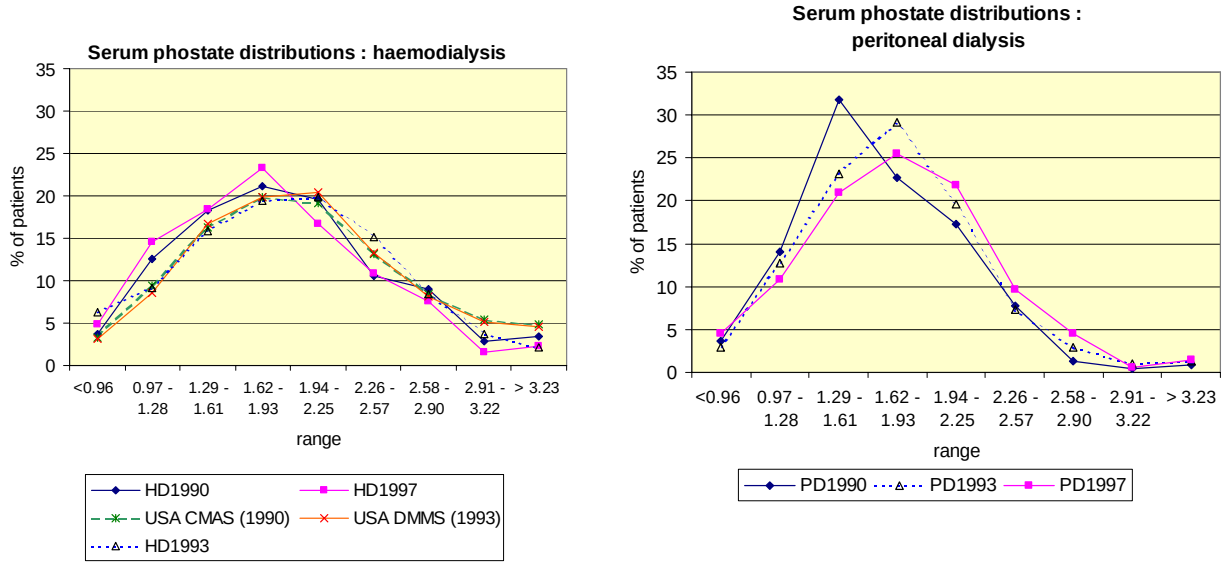
$$\frac{\text{probability of dying for someone with serum phosphate 1.71–2.10 mmol/L}}{\text{probability of surviving for someone with serum phosphate 1.7–2.10 mmol/L.}}$$

The **odds ratio** for someone with a serum phosphate of 1.71-2.10mmol/L is the odds of dying for someone with a serum phosphate of 1.71 – 2.10mmol/L divided by the odds for someone in the reference category.

Results

1. Distribution of serum phosphates 1990 – 1997

These bands were chosen to compare the published USA data.



Formula to convert from mmol/L to mg/dl is: - **mg/dl = mmol/L x 3.1**

Figure 8.23 Serum phosphate distribution by year

These results demonstrate that for patients on haemodialysis, the serum phosphates from 2 centres in the UK in 1990 and 1993 were similar to the USA data in those years. The 1997 distribution of haemodialysis serum phosphate data appears to have changed with more patients in the lower 0.97 – 1.93 bands.

For patients on peritoneal dialysis there is a shift in 1997 towards higher serum phosphates, with more patients in the 1.62 –2.90 bands.

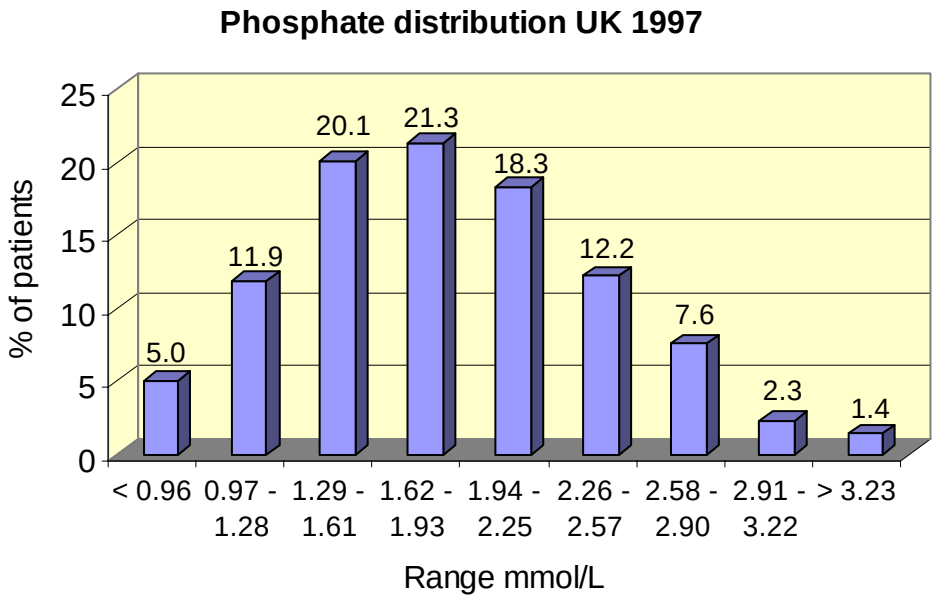


Figure 8.24 Serum phosphate distribution last quarter 1997 - all modalities

Figure 8.24 shows the serum phosphate distribution from the last quarter of 1997 for all units on the Registry. This 1997 data was used in the analysis.

2. Results using the mean serum phosphate throughout 1997

For mean serum phosphate throughout the year, the three ranges ≤ 1.70mmol/L, 1.71 – 2.10 mmol/L and ≥ 2.11mmol/L were not significantly associated with risk of death either unadjusted (n=1358, p= 0.1486) or adjusted (n = 1330 p = 0.1004)

The analysis was also repeated including patients who had a transplant in 1998 to ensure that bias did not arise from excluding possibly healthier patients. Again the effect did not reach statistical significance (p=0.1584).

Mean serum phosphate was also not significantly associated with risk of death when categorised by UK quintiles unadjusted (n=1330 p=0.6272) or adjusted (n=1330 p=0.2681)

3. Results using the serum phosphate from the fourth quarter of 1997

The fourth quarter serum phosphate when categorised as ≤ 1.70mmol/L, 1.71 – 2.10 mmol/L and ≥ 2.11mmol/L was not significantly associated with risk of death either unadjusted (n=1368, p= 0.2617) or adjusted (n = 1340 p = 0.0927)

The 4th quarter serum phosphate was also not significantly associated with risk of death when categorised by UK quintiles unadjusted (n=1368 p=0.4924) or adjusted (n=1340 p=0.1897)

4. Results using the serum phosphate from the first quarter of 1997

Phosphate from First Quarter of 1997	Unadjusted Analysis (n = 1328) O.R. [95% CI]	Adjusted Analysis (n = 1299) O.R. [95% CI]
≤ 1.70mmol/L	REF	REF
1.71 – 2.10mmol/L	0.63 [0.43 – 0.92]	0.70 [0.46 – 1.03]
≥ 2.11mmol/L	0.94 [0.67 – 1.32]	1.20 [0.84 – 1.72]
X^2	6.1	6.6
d.f.	2	2
p-value	0.0475	0.0367

Table 8.4 Results using serum phosphate from 1997 first quarter

The unadjusted analysis showed a significant **reduced** mortality for patients with serum phosphates in the 1.71 – 2.10 band compared with the reference range. This just failed to reach significance in the adjusted analysis.

In the adjusted analysis patients with serum phosphates > 2.11mmol/L had an **increased** risk of dying compared to patients with serum phosphates between 1.71 – 2.10mmol/L. The odds ratio was 1.73 [95% CI 1.13 –2.67]

The 1st quarter serum phosphate was also not significantly associated with risk of death when categorised by UK quintiles unadjusted (n=1328 p=0.1113) or adjusted (n=1299 p=0.1599).

Discussion

Since 1993, there has been a reduction in the percentage of patients on haemodialysis with very high serum phosphate. This may be due to improved dialysis adequacy, but there may also have been changes in nutritional status and use of phosphate binders in that period. There are fewer peritoneal dialysis patients in the lower serum phosphate bands. This may relate to changes in nutritional status, in the population of PD patients, or in dialysis technique. In the UK, there is now a greater proportion of dialysis patients on haemodialysis.

A logistic regression was used, as this was comparable to the analysis by Lowrie et al. A survival analysis, using Cox Proportional Hazards would enable patients who had transferred out, or been transplanted, to be included and to contribute information until they were censored. The interpretation of the results would be different since the hazard ratios obtained from Cox regression would relate to whole survival experience until the end of the follow up period, where as the odds ratios obtained by logistic regression relate to the risk of dying within a year.

Block et al. combined data from two haemodialysis patient cohorts, one studied in 1990, the other in 1993. There were a total of 6,340 patients. Using a single predialysis serum phosphate measurement from each patient they demonstrated an increase relative risk of death of 1.18 (95% C.I. 1.02-1.36, p=0.03) with serum phosphate between 2.1 – 2.59 mmol/L compared with serum phosphate of 1.4 – 1.7mmol/L. The risk increases to 1.39 (95% C.I. 1.19-1.58, p=<0.0001) with serum phosphate higher than this

The 1997 UK data suggests a relationship between serum phosphate in the first quarter of 1997 and the risk of death in 1998. There was an increased risk of death for patients with serum phosphate > 2.11 mmol/L when compared to those with serum phosphate between 1.71 –2.10 mmol/L although not when compared with serum phosphate < 1.71 mmol/L. This relationship was not significant when using serum phosphate data from the fourth quarter of 1997, which includes serum phosphate of patients who died within the next 3 months of this measurement. This may be due to the effects of terminal illness on serum phosphate. There is a suggestion that patients with serum phosphate between 1.71 – 2.10 mmol/L have a better prognosis than those with a lower serum phosphate. This elevated serum phosphate may reflect better nutritional status.

The risk of death was not significantly associated with serum phosphate for any of the other analyses. This may be due to the limited number of patients (1400) compared with the USA studies. This analysis will be repeated in next Registry report, which will include serum phosphate data from 6000 patients. The two year risk of death of the 1997 cohort will also be studied.

Conclusion

The results are very dependent upon the way in which serum phosphate is categorised and upon the summary statistic used. The Registry data is indicating a higher risk of death for patients with a serum phosphate above 2.1 mmol/L confirming the both the Lowrie and Block data. There is currently no indication that reducing serum phosphate below 1.70 mmol/L, as suggested by the Renal Association Standards document, is beneficial.

References

1. Block GA, Hulbert-Shearon TE, Levin NW, Port FK. 'Association of Serum Phosphorus and Calcium * Phosphate Product With Mortality Risk in Chronic Haemodialysis Patients: A National Study'. American Journal of Kidney Diseases. Vol. 31, No 4, 1998: 607-617.

2. Lowrie EG, Lew NL. 'Death Risk in Haemodialysis Patients: The Predictive Value of Commonly Measured Variables and an Evaluation of Death Rate Differences Between Facilities'. American Journal of Kidney Diseases. Vol. 15, No 5, 1990: 458-482.

Chapter 9: Bicarbonate, albumin, cholesterol

Overview of presentation

In the following section the figures use a common modified box-plot format with data presented separately for haemodialysis and peritoneal dialysis. The figures showing the percentage of patients reaching the Renal Association Standard include the 95% confidence interval calculated for this figure. Where medians are displayed, the 25th and 75th centiles for the unit are included. Figures showing the percentage within a range (as defined by the Renal Association Standard or a Renal Registry defined range) also include the 95% confidence interval calculated for this figure. Data completeness is indicated by the "percentage missing" figure below the unit code letter.

Albumin

Albumin measurement

Albumin measurement is complicated by the use of two different methodologies, bromocresol green (BCG) and bromocresol purple (BCP). As discussed in 1998 Registry report, the BCG method, unlike BCP, measures some immunoglobulin along with albumin. In non-uraemic sera, BCP is clearly the preferred method, however in uraemic sera there appears to be some interference with the BCP method. The difference in readings between the two methodologies varies across the range, with a greater discrepancy at lower albumin values (up to 5g/L) than high values.

	Method	Ref Range g/L	Derivation of ref Range
A	BCG	35-50	Manufacturer
B	BCG	35-55	Local
C	BCG	36-50	Not available
D	BCG	35-50	Text book
E	BCG	35-48	Text book
F	BCG	35-53	Manufacturer
G	BCG	35-50	Local
H	BCG	35-50	Manufacture
I	BCG	36-47	Local
J	BCP*	34-48	Local
K	BCG	37-49	Local
L	BCG	34-50	Not available
M	BCG	35-50	Local
N	BCG	35-50	Manufacturer
O	BCG	35-50	Text book
P	BCG	35-47	Local
Q	BCP*	30-52	Local
R	BCG	36-50	Local
T	BCG	30-48	Text book

Conversion g/dl = g/L x 0.1

Table 9.1 Methods and ranges of albumin measurement

Reference ranges for albumin vary widely and this is in part due to the use of different information sources for its derivation (table 9.1).

Centres J and Q use BCP and centres B, D (haemodialysis only) and T have a variable percentage of patients results supplied from both BCP and BCG laboratories. Although centre J uses BCP its laboratory still quotes a locally derived reference range of 34-48 g/L: this leads to low achievement of the Standard. Centre T does well in achieving the Standard as defined: this is due to a wide local reference range of 30-48 g/L. This wide albumin range was literature based and was not specifically set to 'include' both BCP and BCG methods.

The figures showing the percentage in 35 –50 g/L are laboratory harmonised and in addition use a range 30-45 g/L for the centres on BCP. No adjustment can be made for the two centres with results measured by both methodologies. Although centre J improves, it is still one of the centres with relatively low achievement of the Standard.

The percentage within range for England and Wales has been calculated excluding data from B, J, Q and T.

Haemodialysis

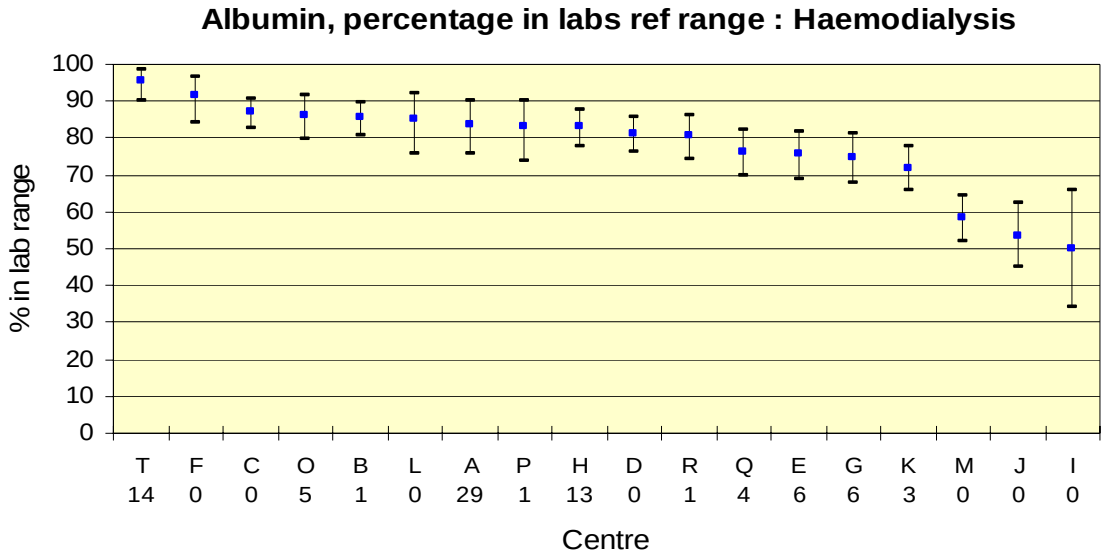


Figure 9.1 Percentage albumin in laboratory reference range on haemodialysis

The Renal Association Standard for albumin is that ***all patients should be within the local normal range***

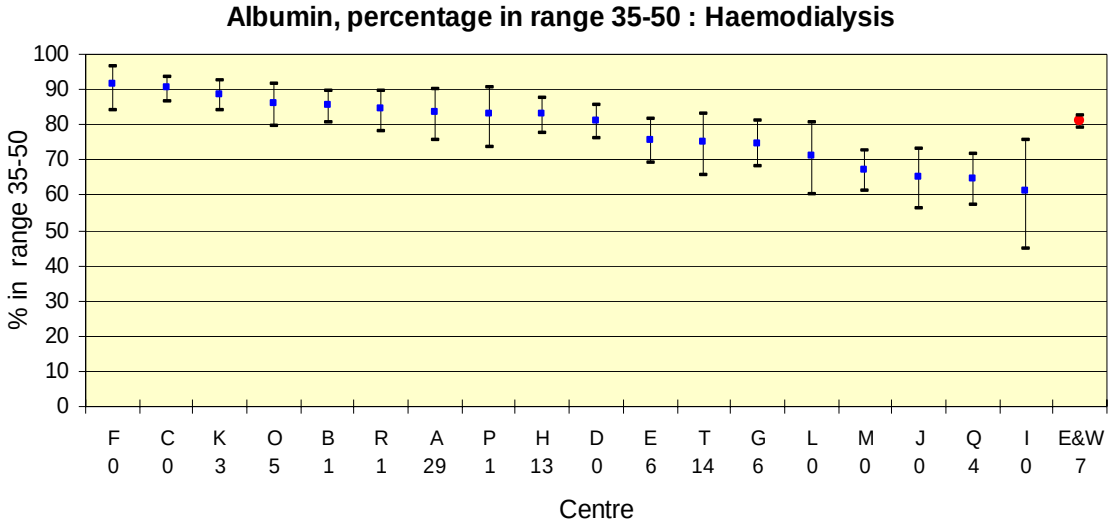


Figure 9.2 Percentage albumin in range 35-50 g/L on haemodialysis

A chi-squared test was used to determine whether the percentage of patients with albumin below and greater than or equal to the laboratory's lower reference range limit differed between centres. Centres using the BCP method to measure albumin have been included in the analysis since the local laboratory reference range has been used in the analysis. For patients on haemodialysis, the percentage of patients with albumin greater than or equal to the laboratory's lower reference range limit differed significantly between centres ($X^2 = 184.2$, d.f. = 17, $p<0.001$).

Centre K achieves the Standard poorly, but their laboratory lower reference range is the highest at 37 g/L and this has been locally derived. When comparing the centre using a range of 35-50 88% of patients are within this range.

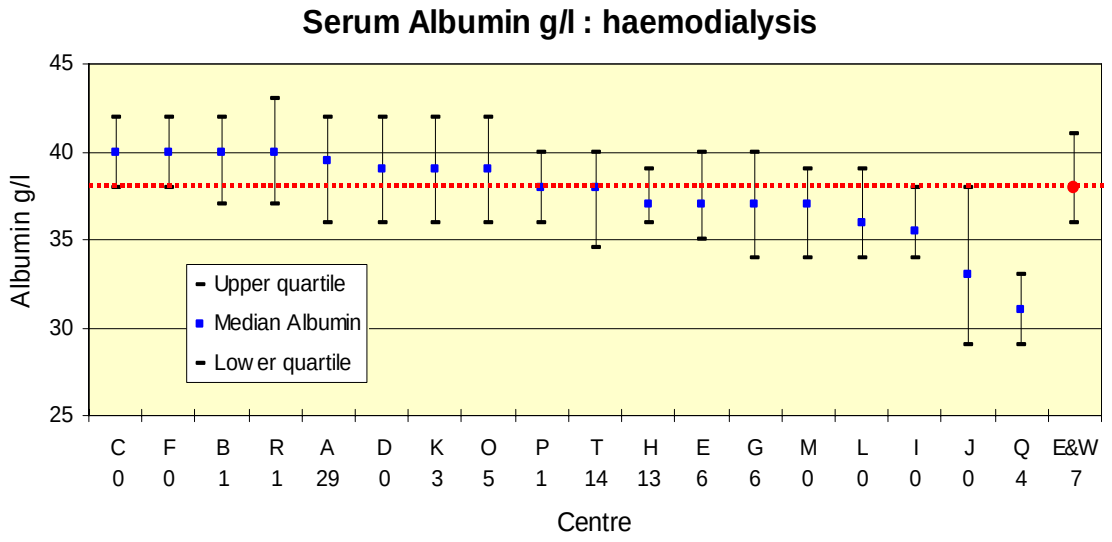


Figure 9.3 Serum albumin on haemodialysis

In figure 9.2 and 3, centres F and I are at either extreme of the albumin range and their 95% C.I. do not overlap, though both are the highest achievers of dialysis adequacy. Centre I also has the greatest percentage of patients with haemoglobin above 10 g/dl

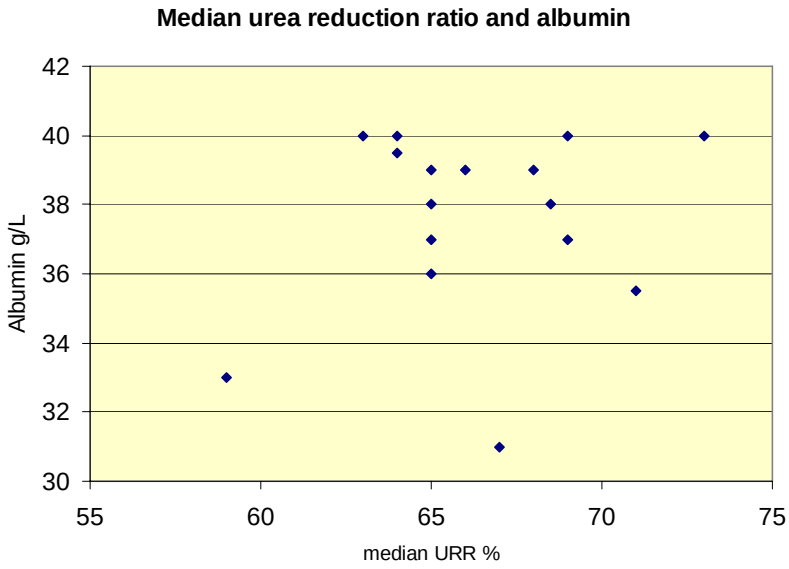


Figure 9.4 Median urea reduction ratio and albumin

The figure above shows a scatter plot of median URR achieved at centres against albumin. Even excluding the two centres on BCP with a median albumin of 31 and 33 g/L respectively, there does not appear to be any relationship. Analysing the data for percentage of albumin with a reference range of 35 –50 (30 – 45 BCP) g/L also showed no relationship for individual centres.

Peritoneal dialysis

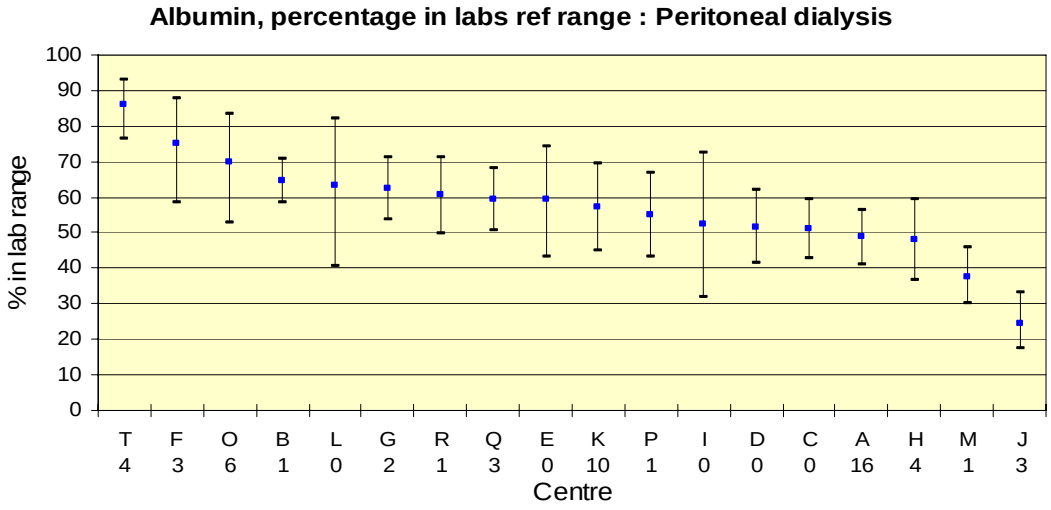


Figure 9.5 Percentage albumin in laboratory reference range on peritoneal dialysis

The R.A Standard for peritoneal dialysis is that ***70% of patients should be within the local reference range***.
This was achieved by 3 centres with 5 others whose upper 95% C.I. included this value. The mix of laboratory methodology for centre T may account in figure 9.7 for the skewing of the data with very asymmetric upper and lower quartiles.

For patients on peritoneal dialysis, the percentage of patients with albumin greater than or equal to the laboratory's lower reference range limit differed significantly between centres ($X^2 = 113.2$, d.f. = 17, $p<0.001$).

When analysed by a range of 35 – 50 g/dl there are still 3 centres within the Standard but T has dropped out. An additional 6 centres (R,I,B,G,E) also have a 95% C.I. which includes the 70% Standard.

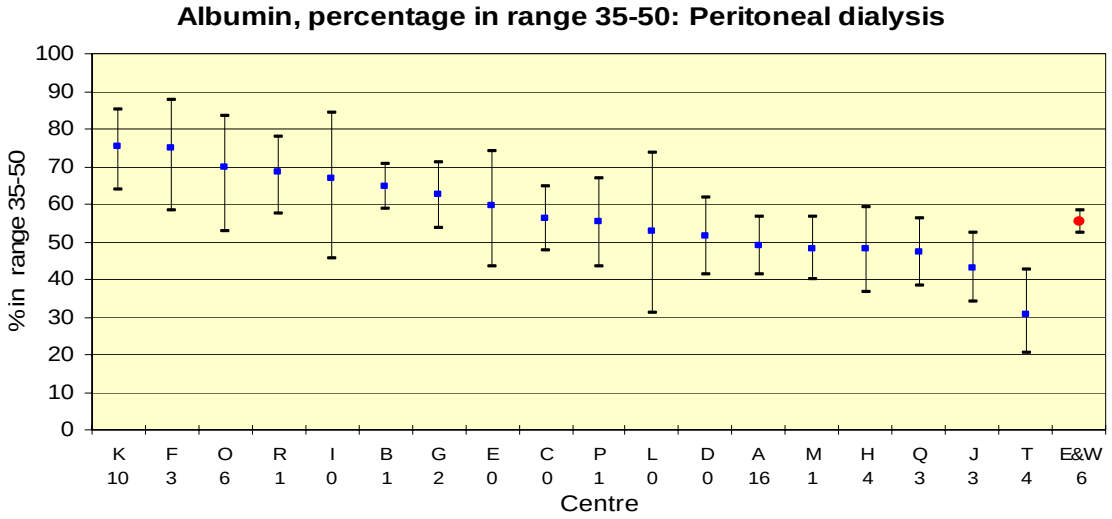


Figure 9.6 Percentage albumin in range 35-50 g/L on peritoneal dialysis

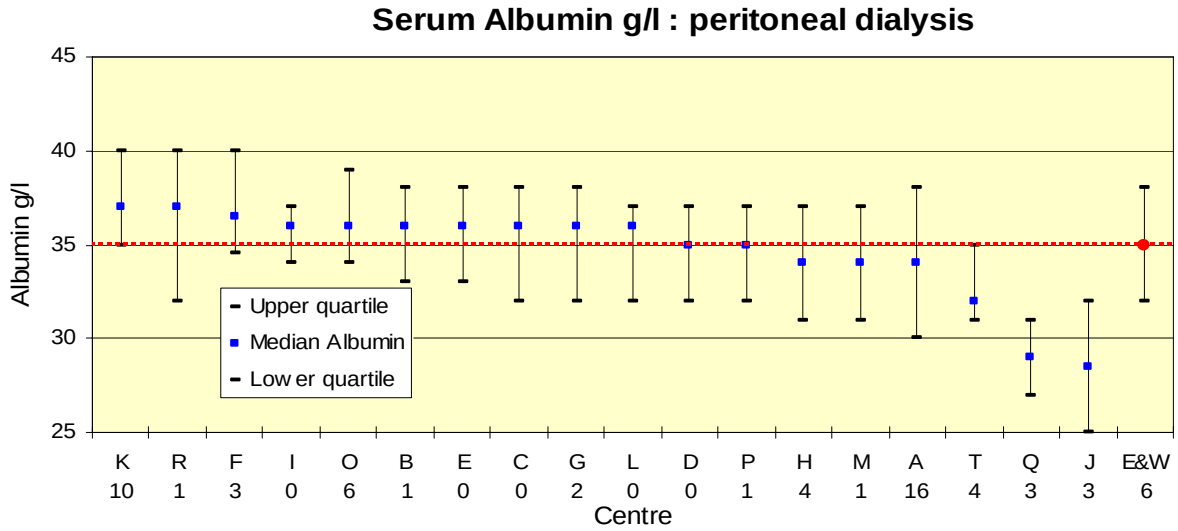


Figure 9.7 Serum albumin on peritoneal dialysis

The median albumin for BCG centres ranged from 34-37 g/L on peritoneal dialysis compared with 36 – 40g/L on haemodialysis. The centre variation in median albumin using BCG is small, although there are significant variations between centres in meeting the Standard or in achieving the 35 – 50 g/L range.

Changes in albumin 1997 – 1998

The three time points on the figures are 1st quarter 1997, 1st quarter 1998 and 4th quarter 1998

Haemodialysis

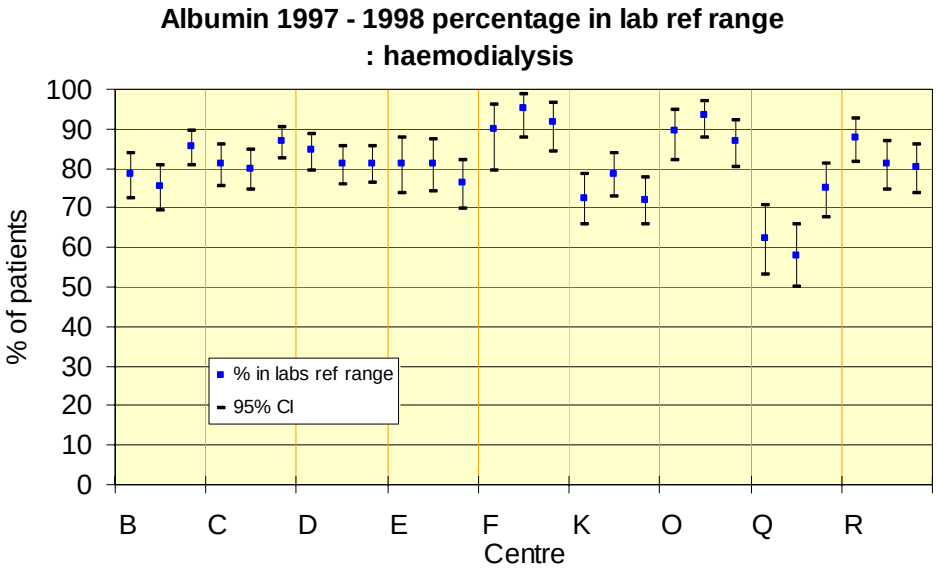


Figure 9.8 Percentage albumin in laboratory reference range on haemodialysis, 1997-1998

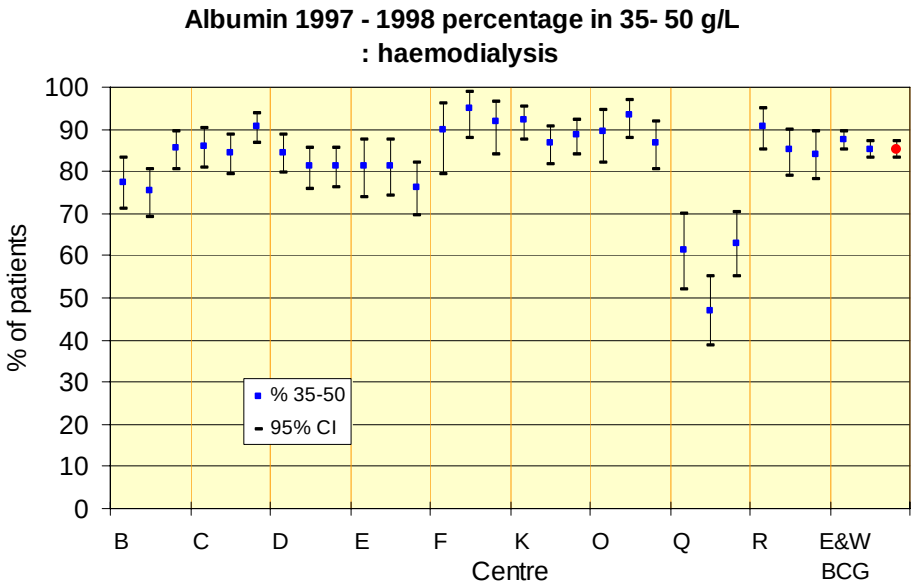


Figure 9.9 Percentage albumin in range 35-50 g/L on haemodialysis, 1997-1998

Peritoneal dialysis

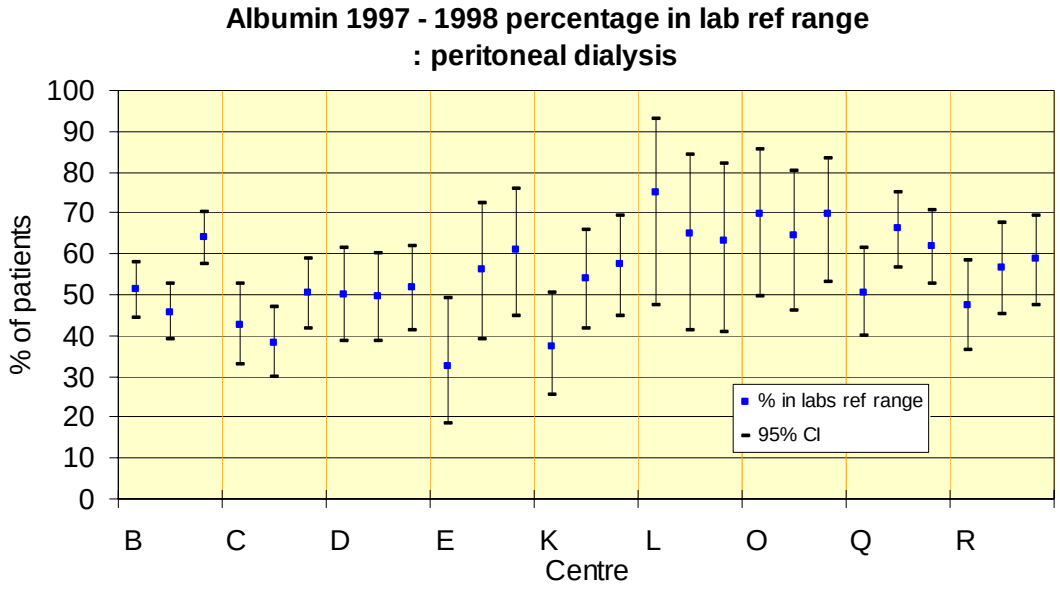


Figure 9.10 Percentage albumin in laboratory reference range on peritoneal dialysis, 1997-1998

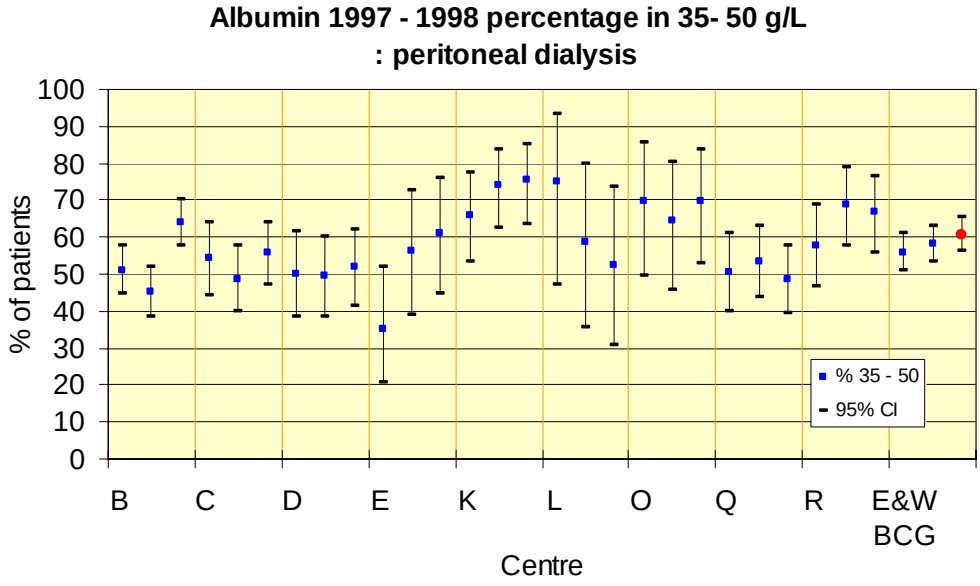


Figure 9.11 Percentage albumin in range 35-50 g/L on peritoneal dialysis, 1997-1998

There appears to be a trend to an increase in albumin of peritoneal dialysis patients over 2 years. There are marked increases for centres E and K although the 95% CI still overlap. Centre B with the smallest CI may be showing a significant improvement. Centre E has increased dialysis adequacy in peritoneal dialysis patients and reduced peritonitis rates during this period (personal communication). Centre K is unable to account for this rise by any change in practice.

Change in albumin for 1998

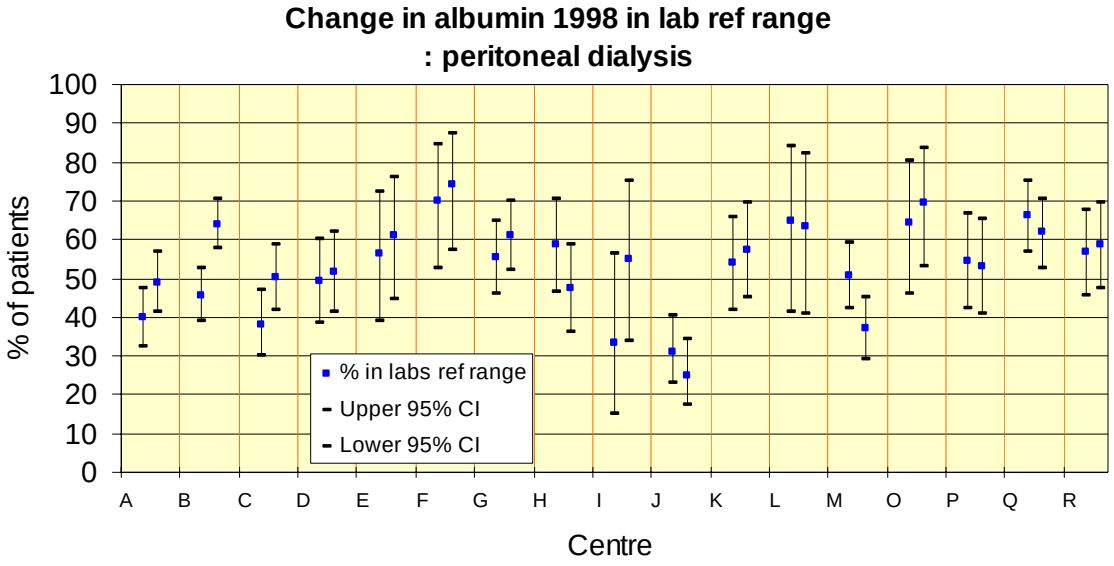


Figure 9.12 Change in albumin in laboratory reference range on peritoneal dialysis, 1998

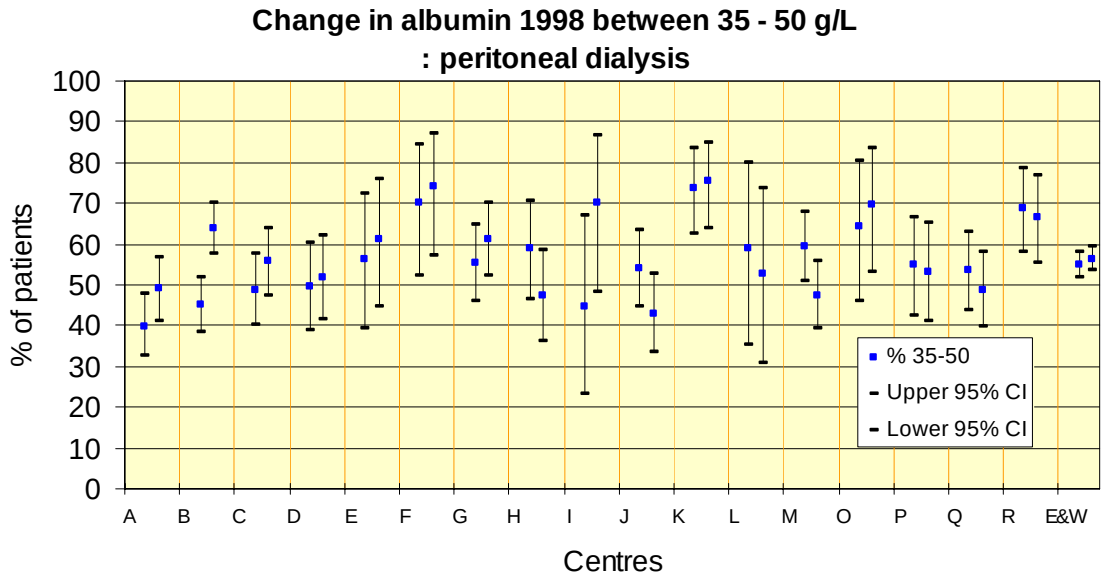


Figure 9.13 Change in albumin between 35-50 g/L on peritoneal dialysis, 1998

Bicarbonate

Bicarbonate measurement

There is no laboratory harmonisation factor available for bicarbonate as it is technically difficult to distribute stable samples for comparative quality assurance. Laboratory methodologies and reference ranges are listed in table 9.2.

Centre	Methodology	Ref range mmol/L	Derivation of ref Range
A	PEPC	24-30	Manufacturer
B	Enzymatic	22-30	Local
C	PEPC	22-31	Not available
D	PEPC	20-29	Text book
E	Actual	22-30	Text book
F	Electrode	24-32	Text book
G	Enzymatic	22-30	Local
H	PEPC	20-30	Manufacturer
I	PEPC	23-30	Local
J	PEPC	24-30	Text book
K	PEPC	20-28	Local
L	PEPC	23-30	Not available
M	PEPC	24-30	Local
N	PEPC	23-31	Manufacturer
O	PEPC	22-29	Text book
P	PEPC	22-29	Local
Q	PEPC	18-28	Local
R	Beckman	22-31	Local
T	PEPC	23-30	Local

Table 9.2 Bicarbonate methodology and reference ranges

Haemodialysis

The Renal Association Standard is that all patients ***should be within the local normal range***.

Home dialysis patients are excluded from this analysis as sera may have been sent through the post with decay of samples and misleading results.

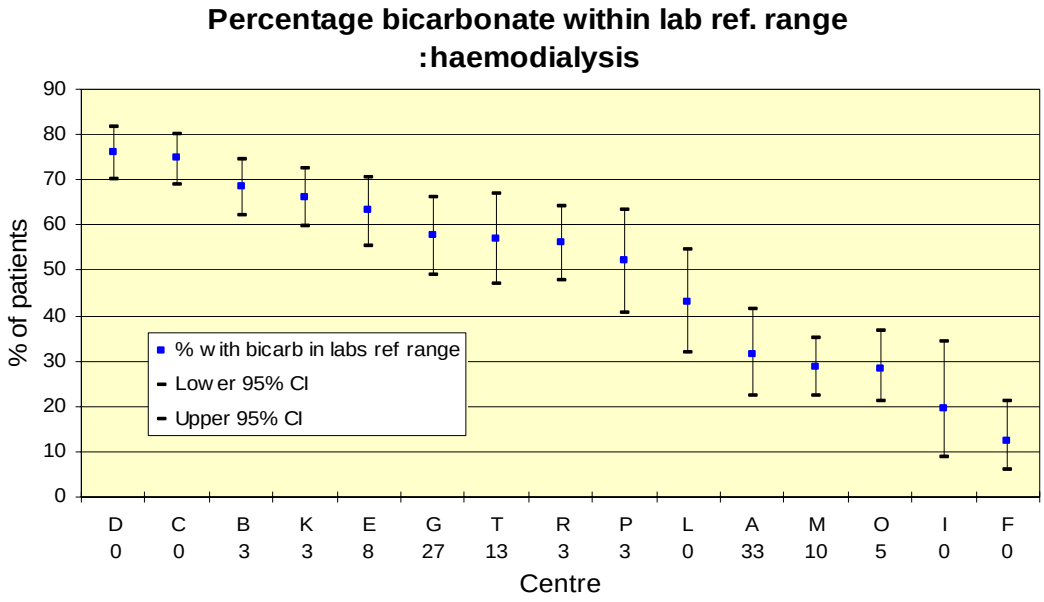


Figure 9.14 Percentage bicarbonate in laboratory reference range on haemodialysis

A chi-squared test was used to determine whether the percentage of patients with bicarbonate within the Standard varied between centres. For patients on haemodialysis, the percentage of patients with bicarbonate within the Standard differed significantly between centres ($X^2 = 292.4$, d.f. = 14, $p<0.001$).

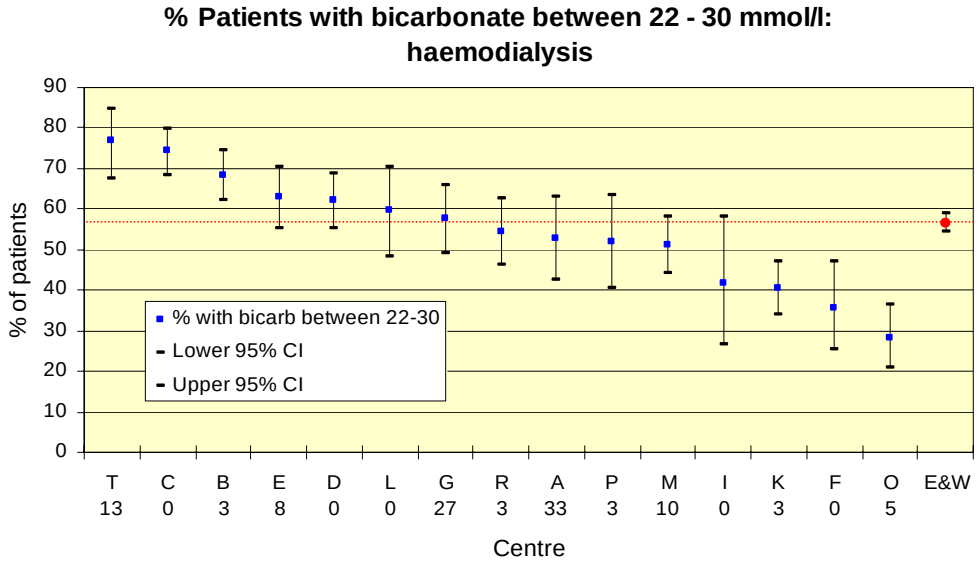


Figure 9.15 Percentage patients with bicarbonate in range 22-30 mmol/L on haemodialysis

The median serum bicarbonate on haemodialysis varied from 20 – 24 mmol/L. Centres F and I had the some of the lowest bicarbonates and also had the highest urea reduction ratios.

Whether analysed as percentage within the laboratory reference range or the range 22-30 mmol/L there were significant variations between centres.

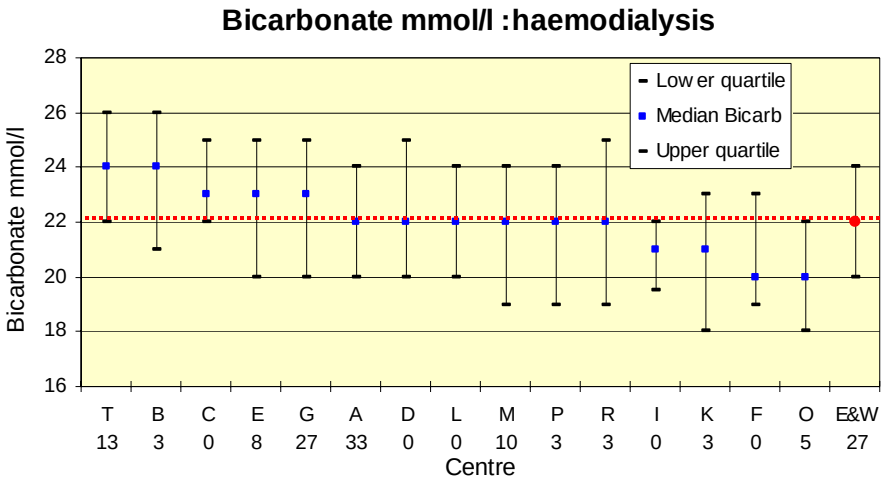


Figure 9.16 Median bicarbonate (mmol/L) on haemodialysis

Peritoneal dialysis

The Renal Association Standard is that patients should have a bicarbonate between ***the lower local normal to upper local normal +3mmol/L.***

For patients on peritoneal dialysis, the percentage of patients with bicarbonate within the Standard differed significantly between centres ($X^2 = 63.7$, d.f. = 14, $p<0.001$).

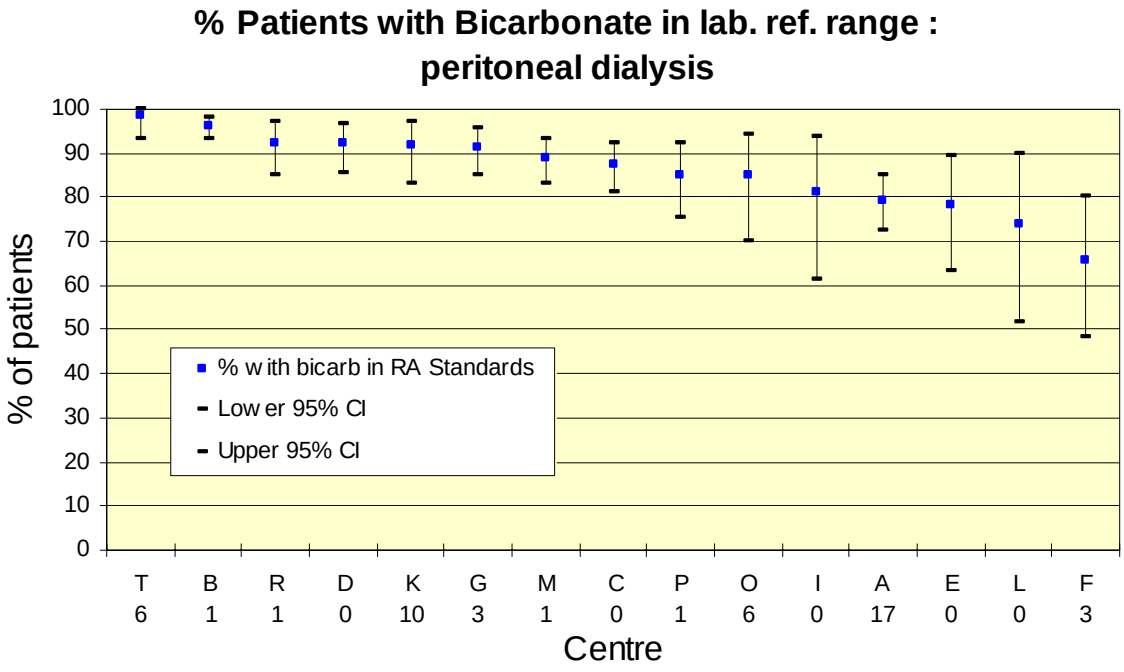


Figure 9.17 Percentage patients with bicarbonate in laboratory reference range on peritoneal dialysis

Serum bicarbonate for patients on peritoneal dialysis also varied widely from a median of 24 to 29 mmol/L. Centres B& T have high bicarbonate values for both peritoneal dialysis and haemodialysis and this might be related to laboratory measurement. This

contrasts with centre M with the highest values on peritoneal dialysis and 'middle' values on haemodialysis.

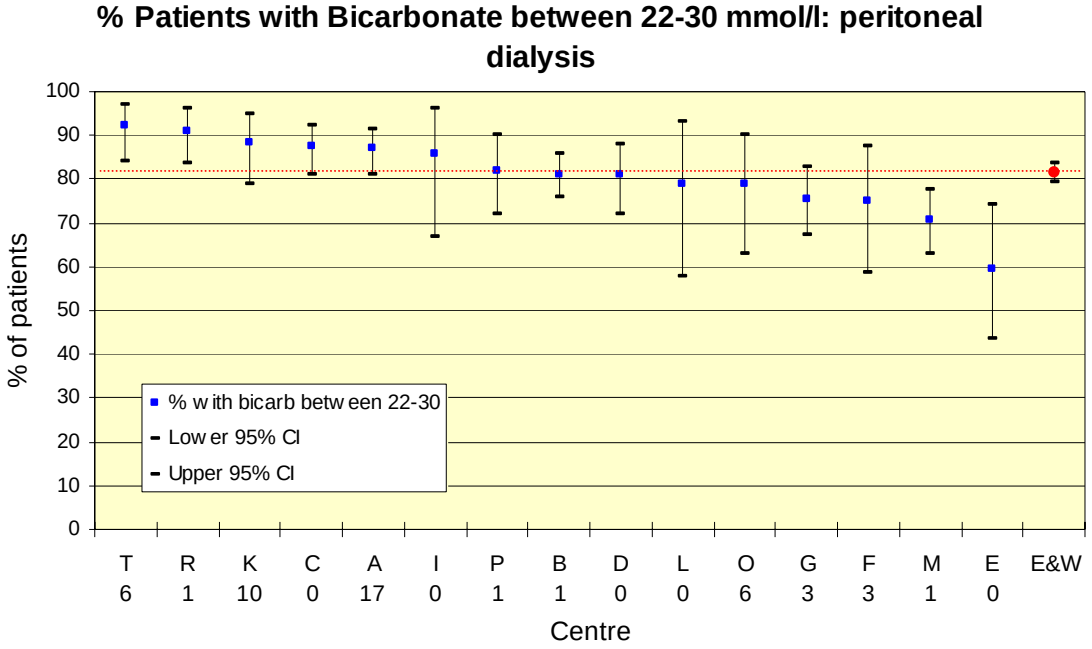


Figure 9.18 Percentage patients with bicarbonate in range 22-30 mmol/L on peritoneal dialysis

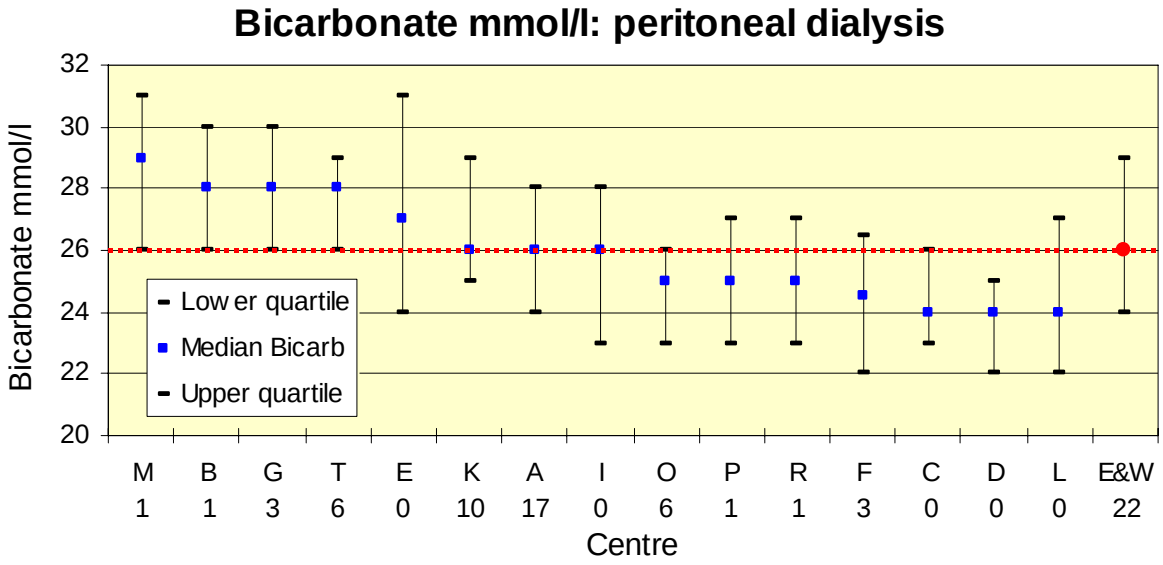


Figure 9.19 Bicarbonate (mmol/L) on peritoneal dialysis

Cholesterol

Conversion factor: mg/dl = mmol/L x 38.5

The Renal Standards document has no recommended reference range for serum cholesterol

Introduction

The Renal Registry is able to harmonise cholesterol data to facilitate direct comparisons of measurements between centres.

Most nephrologists are probably looking towards serum cholesterol levels of <5.2 mmol/L for men and women, especially in patients with vascular disease or diabetes, in accordance with the Chief Medical Officer's guidelines. The Renal Registry has analysed the most recent cholesterol data over one year as many centres only measure this annually. It may even be the case, where this has been measured previously and the result was normal without use of a lipid-lowering agent, that the centre may not measure it again. The treatment modality was defined on 31/12/98. Some patients may have changed modality over the course of the preceding year, but they were included in their category of modality on 31/12/98.

Haemodialysis

A chi-squared test was used to determine whether the percentage of patients with cholesterol ≤ 5.2 differed between centres. Note that the analysis considered laboratory harmonised cholesterol.
For patients on haemodialysis, the percentage of patients with cholesterol ≤ 5.2 differed significantly between centres (X^2 = 13.8, d.f. = 5, p=0.017).

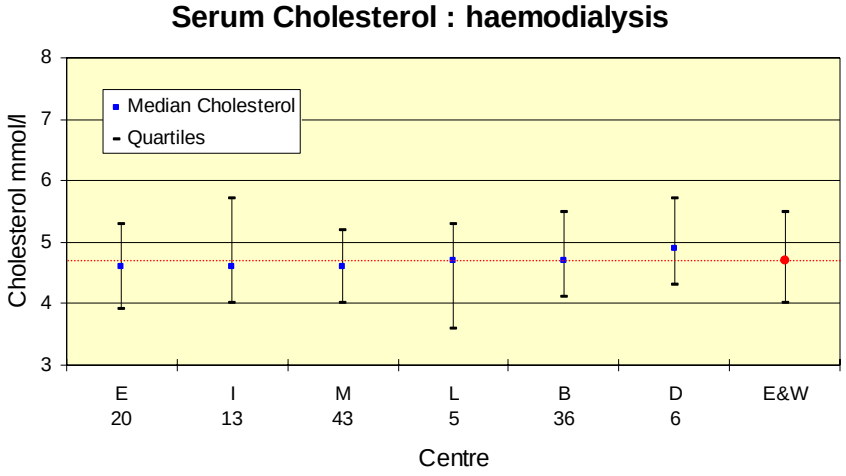


Figure 9.20 Median serum cholesterol (mmol/L) on haemodialysis

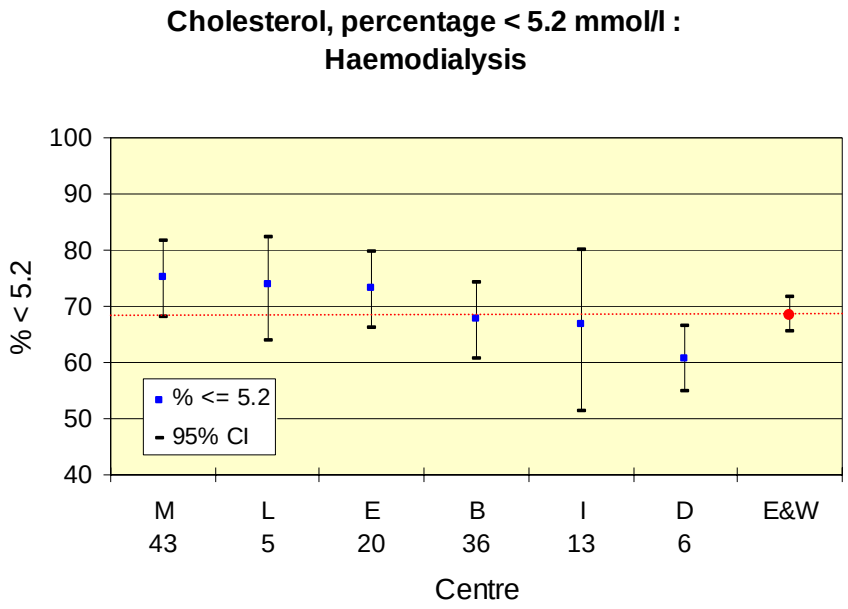


Figure 9.21 Percentage cholesterol < 5.2 mmol/L on haemodialysis

Peritoneal dialysis

For patients on peritoneal dialysis, the percentage of patients with cholesterol ≤ 5.2 was **not** found to differ significantly between centres (X^2 = 18.2, d.f. = 11, p=0.077).

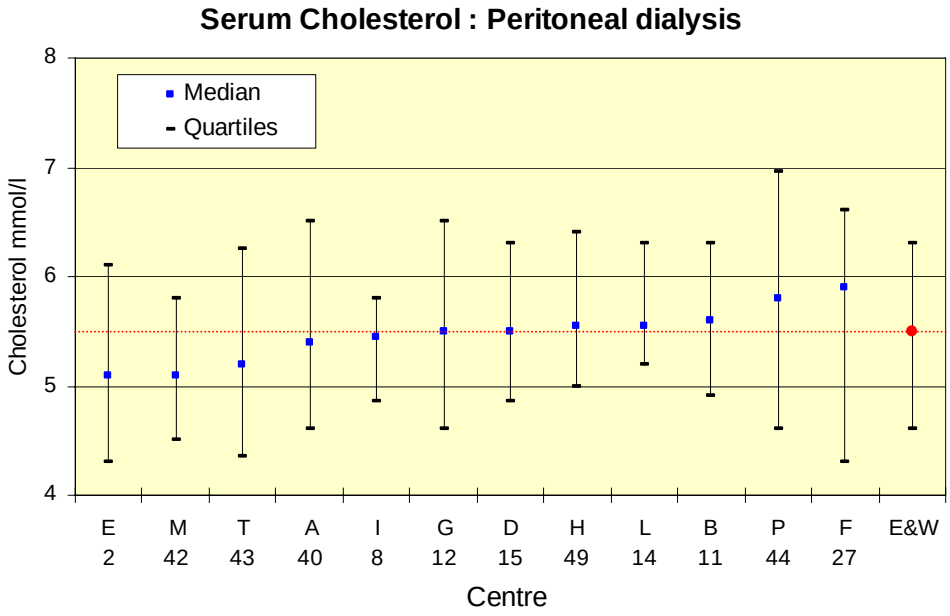


Figure 9.22 Serum cholesterol (mmol/L) on peritoneal dialysis

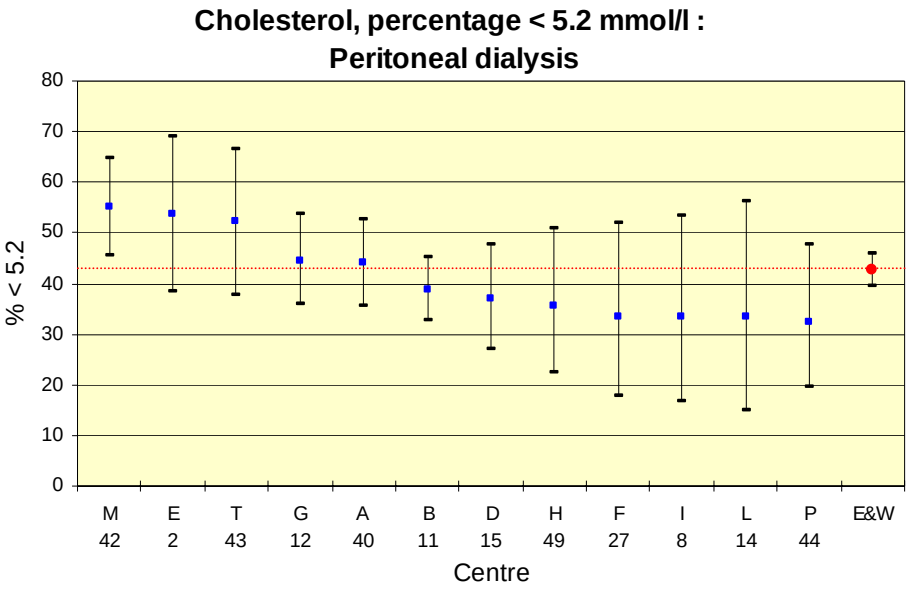


Figure 9.23 Percentage cholesterol < 5.2 mmol/L on peritoneal dialysis

Change in cholesterol 1997 – 1998

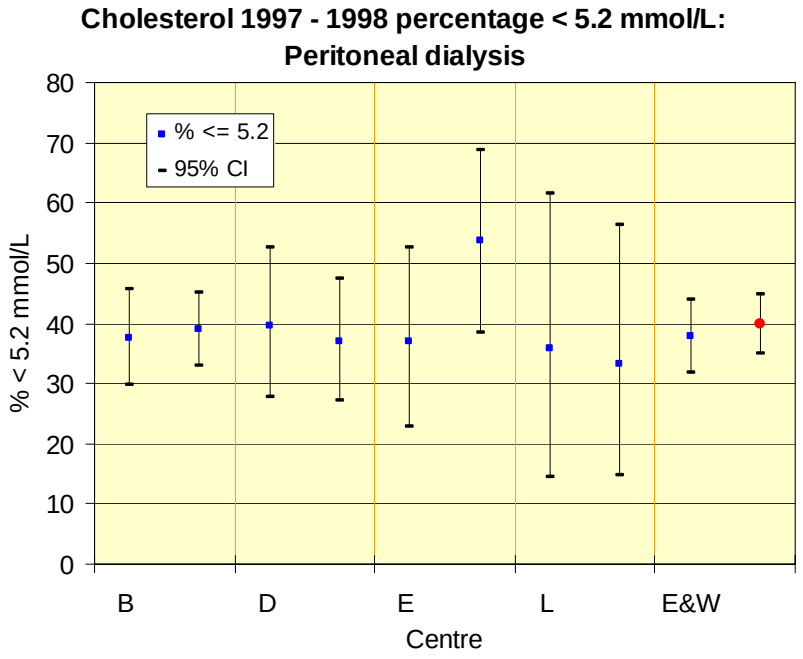


Figure 9.24 Percentage cholesterol < 5.2 mmol/L on peritoneal dialysis, 1997-1998

There was insufficient data on haemodialysis patients to look at changes. For patients on peritoneal dialysis there was no significant change towards lower cholesterols over the two year period

Conclusions

1. Albumin remains a complex methodological issue and also creates interpretive difficulties with calcium measurement.

2. There are problems with stability of bicarbonate

3. The Association of Clinical Biochemists has instigated a national audit of laboratory reference ranges to address problems with the use of reference ranges to drive Standards

Chapter 10: Blood Pressure

Introduction

The Renal Association Standards Document recommends similar blood pressure control for haemodialysis and peritoneal dialysis patients, although no standard is recommended for transplant patients. The standards for systolic and diastolic blood pressure vary in relation to age, although available evidence does not support this. Hypertension is of greater prognostic significance in the elderly because of their markedly higher background risk (Lever and Ramsay). Studies such as the HOT study (Hansson et al) show benefits from treating the elderly similarly to younger patients. The WHO/ISH (Guidelines subcommittee) and the British Hypertension Society guidelines (Ramsay et al) adopt the same treatment thresholds and targets for the elderly as for younger patients. Hypertension, especially systolic hypertension, is generally considered to be more frequent and more difficult to control in older people. The standards are:

Age <60:	***BP < 140/90 mmHg.***	***(predialysis for haemodialysis patients)***
Age >60:	***BP < 160/90 mmHg.***	***(predialysis for haemodialysis patients)***
		(Korotkoff V if auscultation is used)

These standards are equivalent to a mean arterial pressure of 106.7 and 113.3 respectively.

Whilst it is generally accepted that very low blood pressures are a poor prognostic sign in dialysis patients, the significance of high pressures is less certain. In many studies of dialysis patients raised blood pressure is not necessarily associated with poor outcome (Duranti et al, Foley et al, Iseki et al, Port et al, Salem) possibly because of the cardio-protective effects of many of the hypotensive agents prescribed for such patients. Post dialysis blood pressure may also be of importance (Port et al), but the Registry, although collecting this, is not currently analysing this. It is not clear which of systolic, diastolic, or mean arterial pressure is the best indicator of prognosis. The Registry data are presented by achievement of the standard for combined systolic and diastolic pressure, and then in terms of systolic and diastolic pressures separately, and finally mean arterial pressure.

Results

The data are displayed in figures 10.1 – 10.24.

These are clearly difficult standards to attain. As expected the blood pressures of haemodialysis patients are higher than those of peritoneal dialysis patients. In many units the median blood pressure of older and younger patients is similar, but as the standard is more liberal for older patients there is better attainment of the standard in this age group. Thus for haemodialysis patients only about 40% of those aged under 60

have a blood pressure within the recommended standard, and 60% of those over 60. For peritoneal dialysis patients the respective figures are 49% and 68%.

Achievement of combined systolic and diastolic standard

Haemodialysis

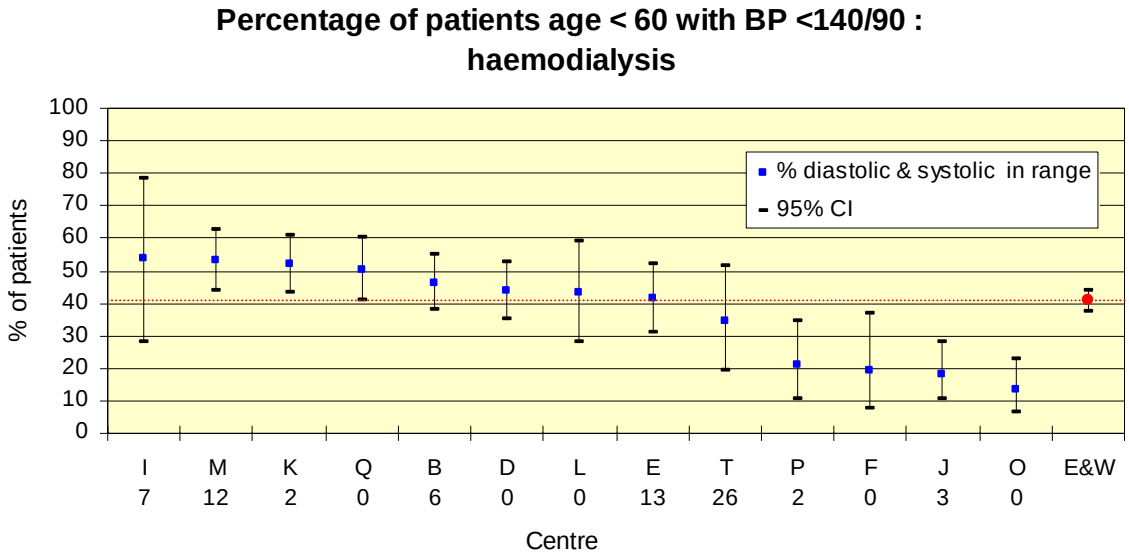


Figure 10.1 Percentage of patients age < 60 with BP < 140/90 on haemodialysis

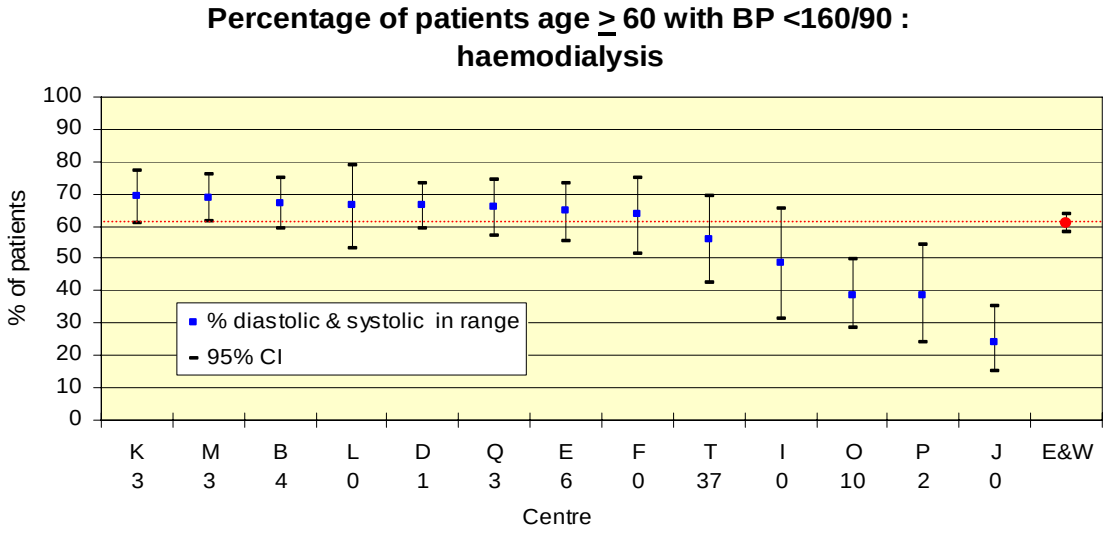


Figure 10.2 Percentage of patients age ≥ 60 with BP < 160/90 on haemodialysis

Peritoneal dialysis

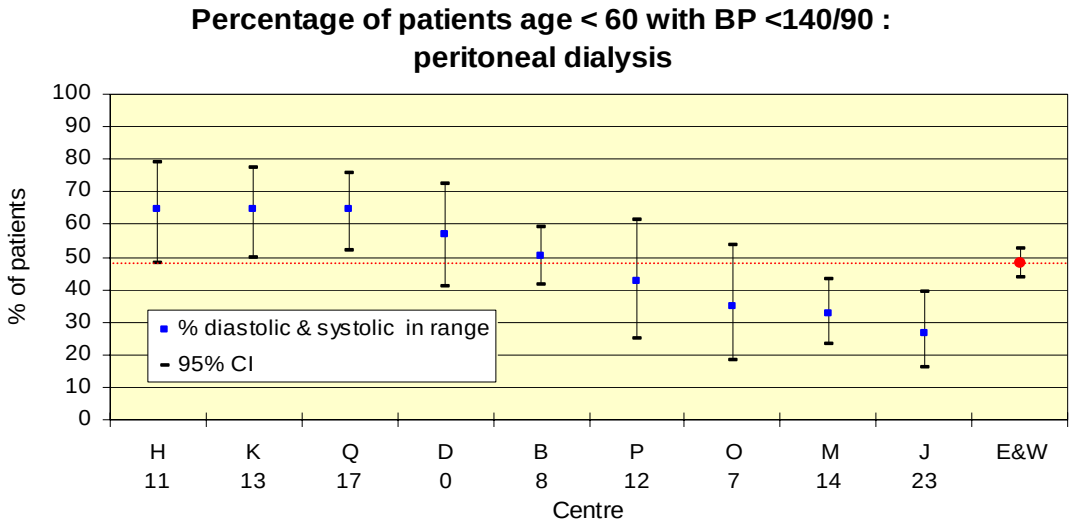


Figure 10.3 Percentage of patients age < 60 with BP < 140/90 on peritoneal dialysis

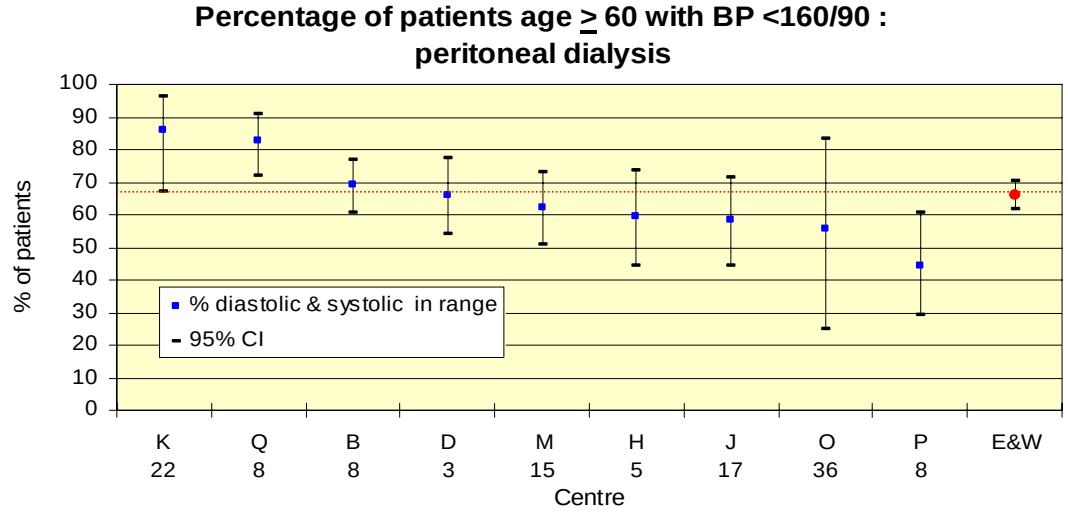


Figure 10.4 Percentage of patients age ≥ 60 with BP < 160/90 on peritoneal dialysis

Systolic pressure alone

Haemodialysis

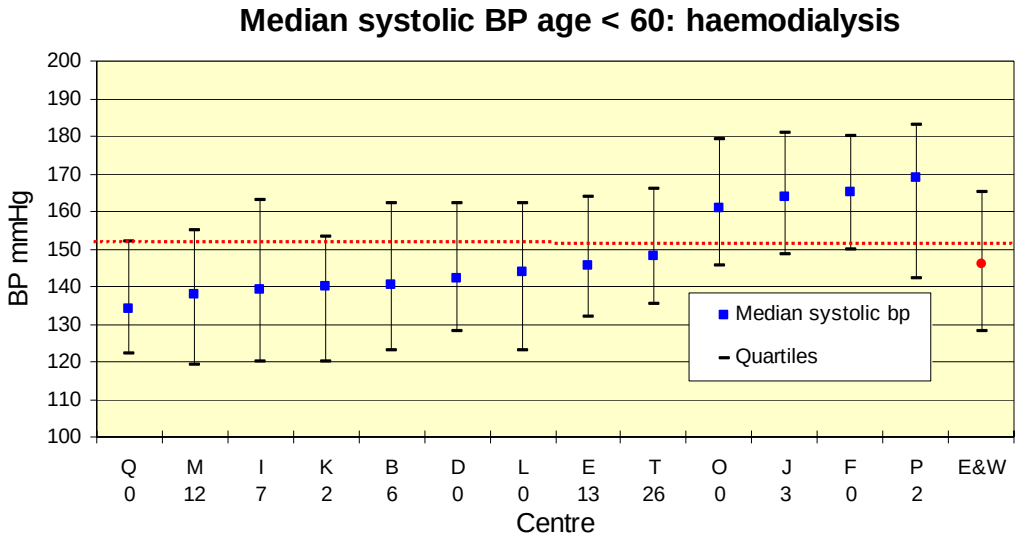


Figure 10.5 Median systolic blood pressure age < 60 on haemodialysis

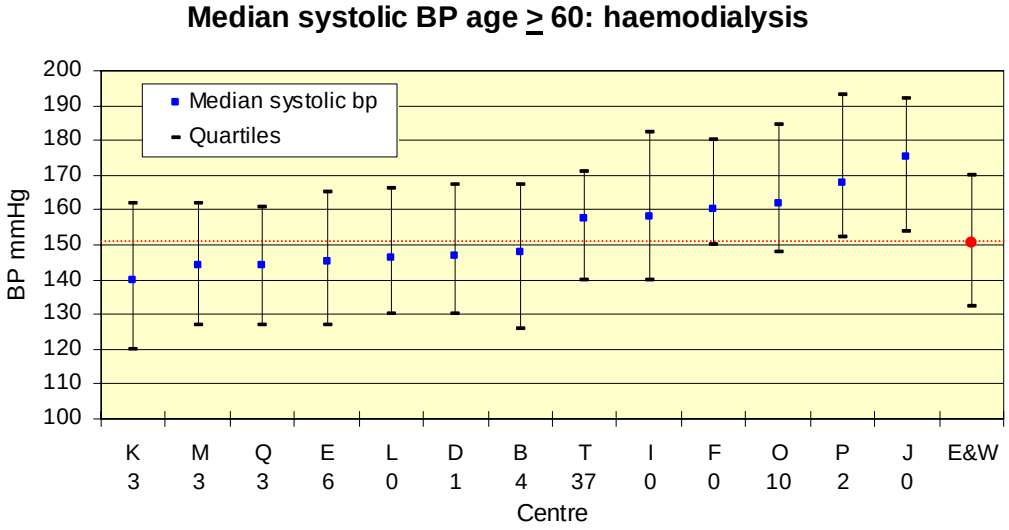


Figure 10.6 Median systolic blood pressure age ≥ 60 on haemodialysis

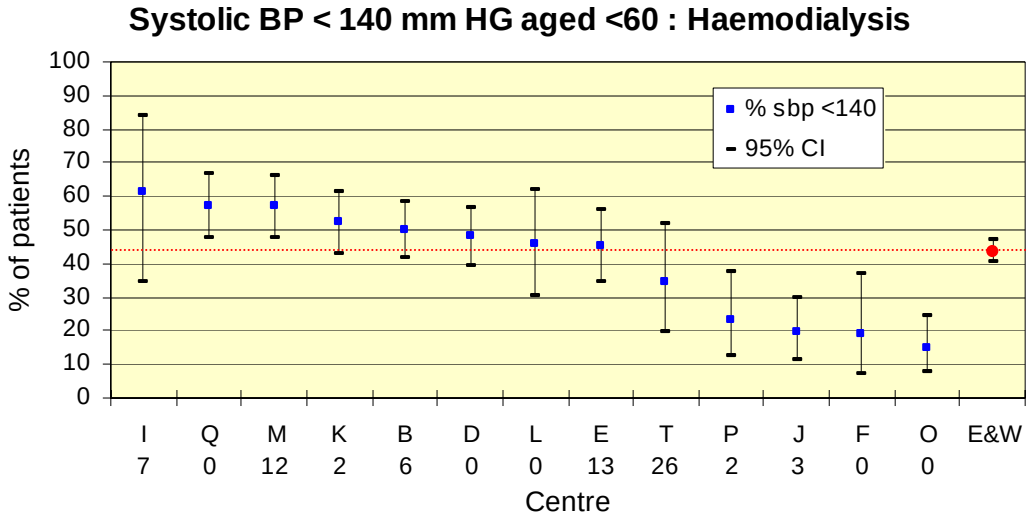


Figure 10.7 Percentage of patients with systolic BP < 140 mm Hg aged < 60 on haemodialysis

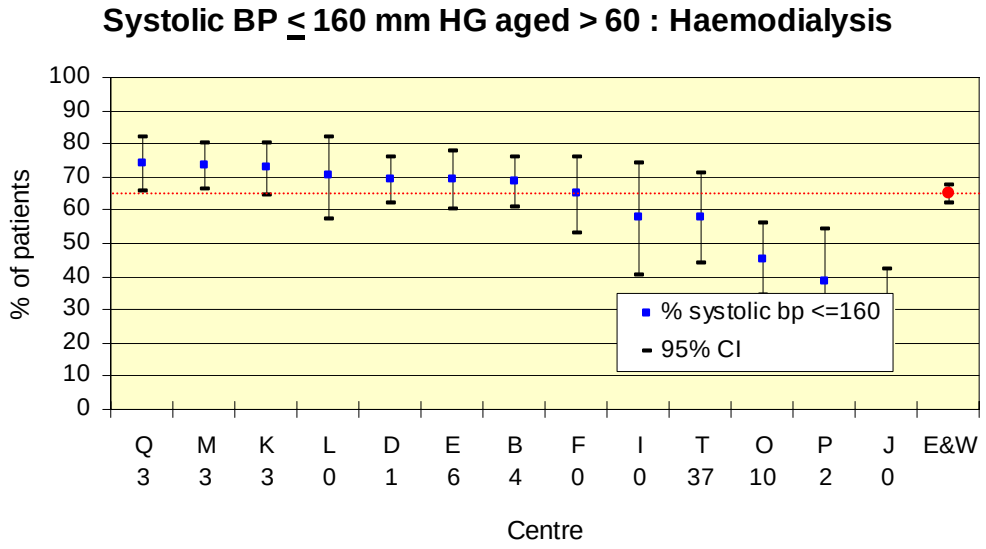


Figure 10.8 Percentage of patients with systolic BP ≤ 160 mm Hg aged > 60 on haemodialysis

There is little difference in systolic blood pressure control achieved in haemodialysis patients in the two age groups, with only 3mmHg. difference between the Registry median systolic pressure for those above and below age the age of 60.

Peritoneal dialysis

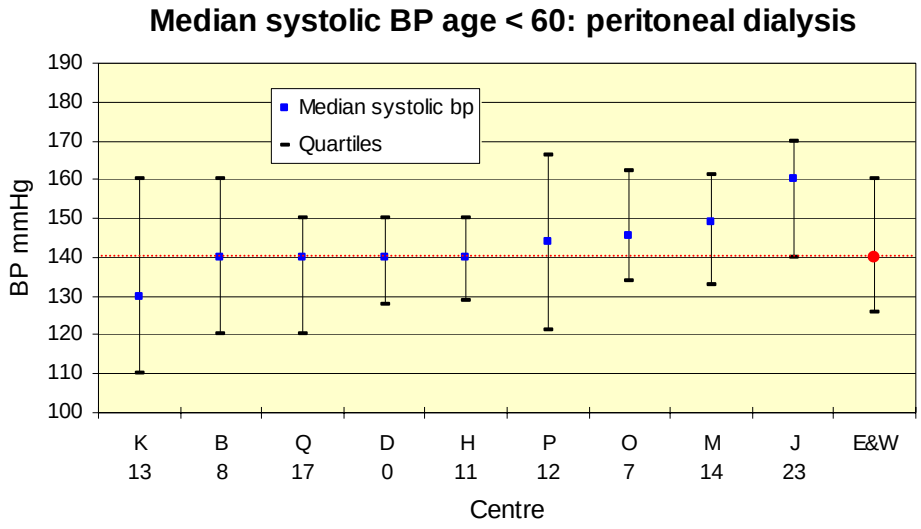


Figure 10.9 Median systolic blood pressure age < 60 on peritoneal dialysis

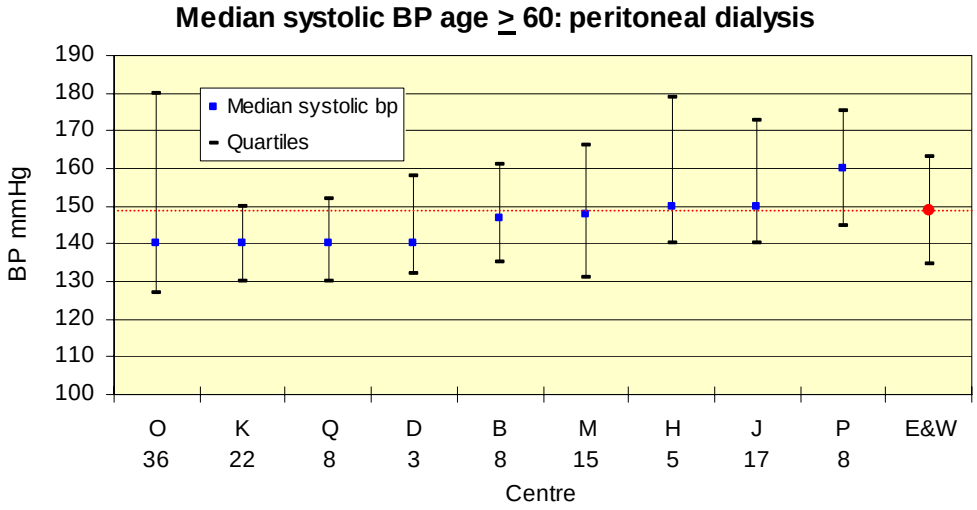


Figure 10.10 Median systolic blood pressure age ≥ 60 on peritoneal dialysis

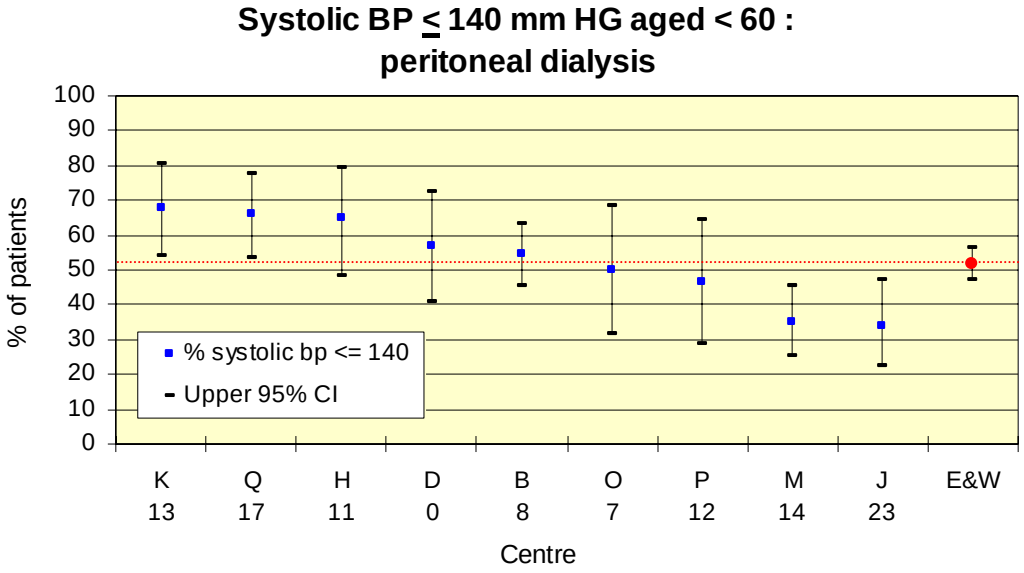


Figure 10.11 Percentage of patients with systolic BP ≤ 140 mm Hg age < 60 : peritoneal dialysis

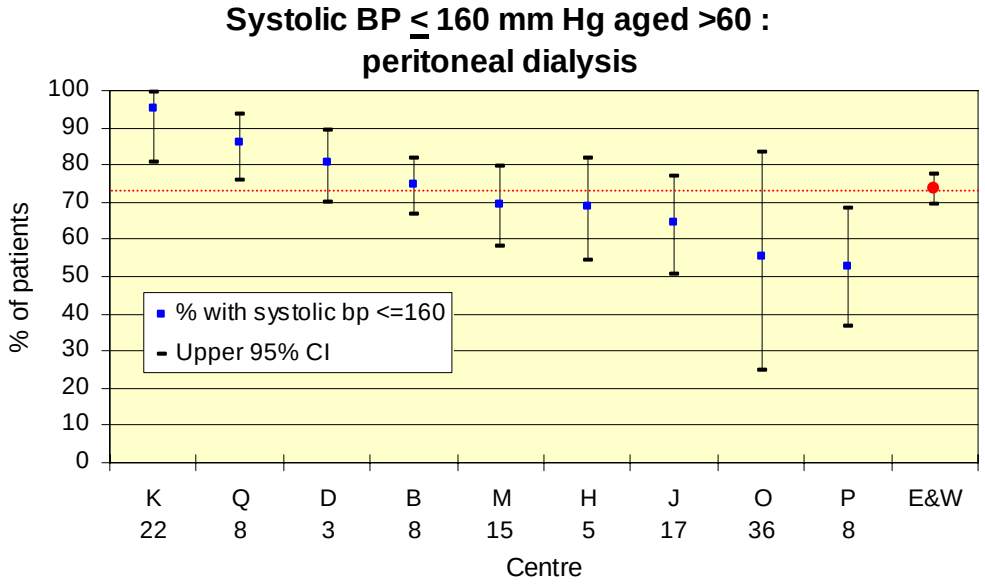


Figure 10.12 Percentage of patients with systolic BP ≤ 160 mm HG age < 60 : peritoneal dialysis

The systolic pressure of peritoneal dialysis patients is lower than that of haemodialysis patients. There are lower pressures in those under 60 than in those over 60.

Diastolic pressure alone

Haemodialysis

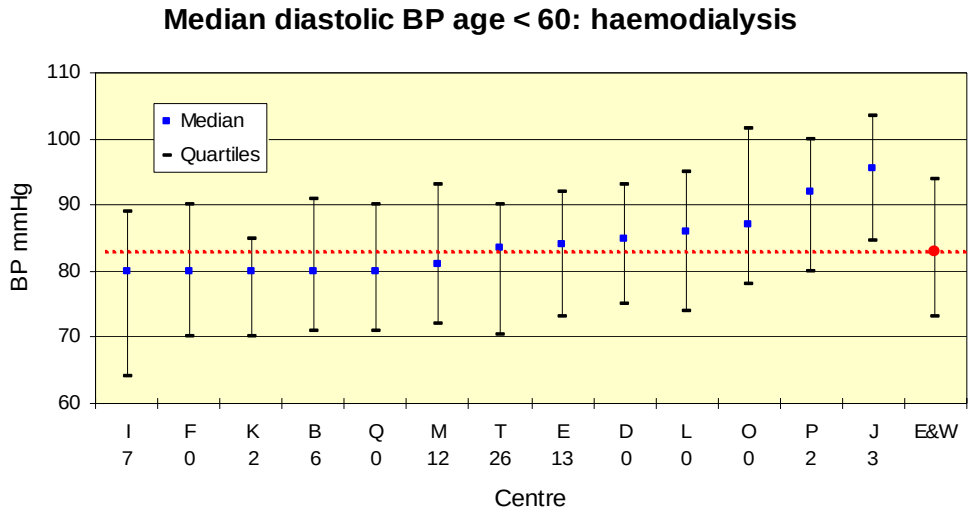


Figure 10.13 Median diastolic blood pressure age < 60 on haemodialysis

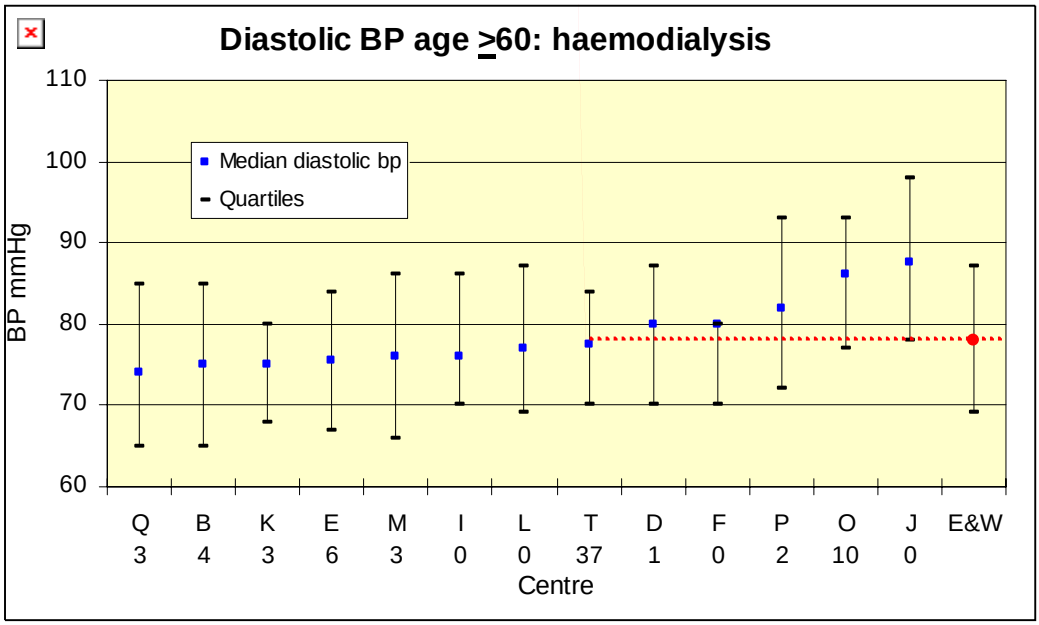


Figure 10.14 Median diastolic blood pressure age > 60 on haemodialysis

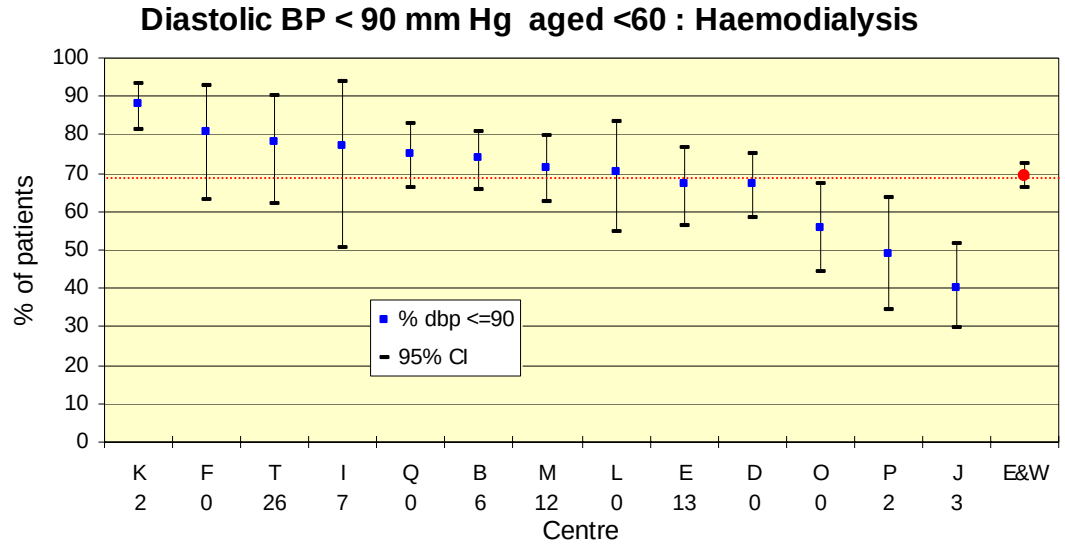


Figure 10.15 Percentage of patients age < 60 with diastolic BP < 90 mmHg on haemodialysis

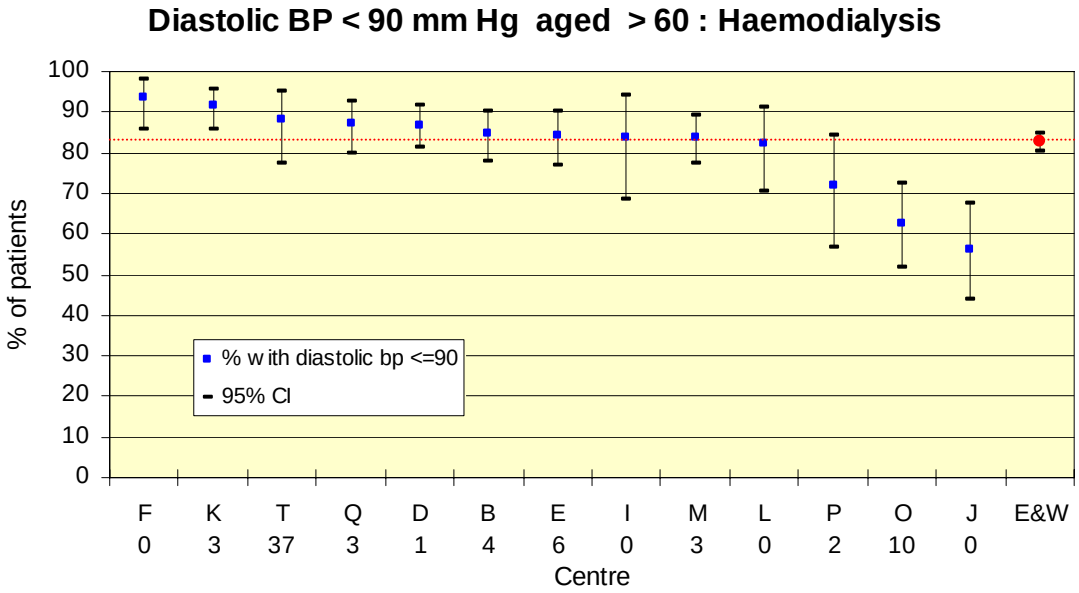


Figure 10.16 Percentage of patients age ≥ 60 with diastolic BP < 90 mmHg on haemodialysis

The median diastolic pressure in older haemodialysis patients is lower than for younger patients. Many more patients achieve the diastolic pressure target than the systolic pressure target.

Peritoneal dialysis

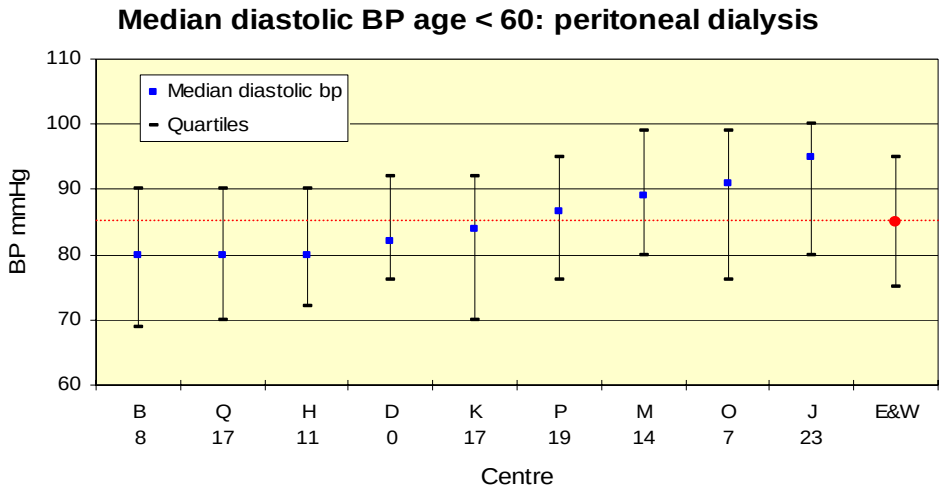


Figure 10.17 Median diastolic blood pressure age < 60 on peritoneal dialysis

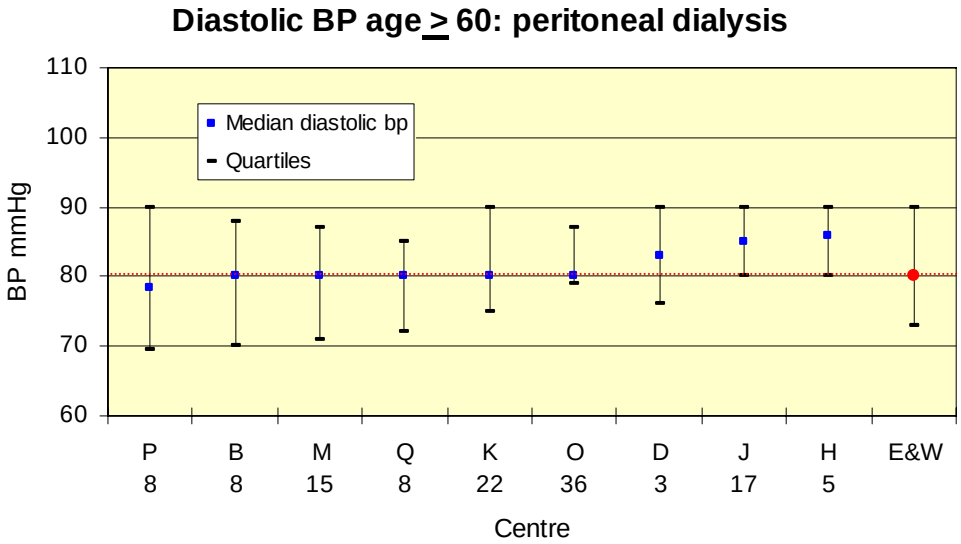


Figure 10.18 Median diastolic blood pressure age > 60 on peritoneal dialysis

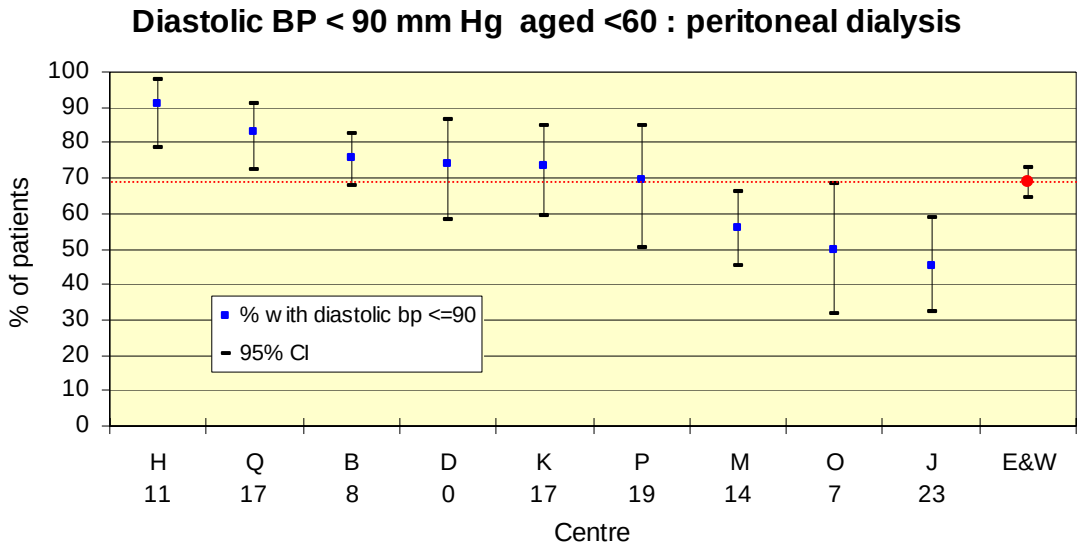


Figure 10.19 Percentage patients age < 60 with diastolic BP < 90 mmHg on peritoneal dialysis

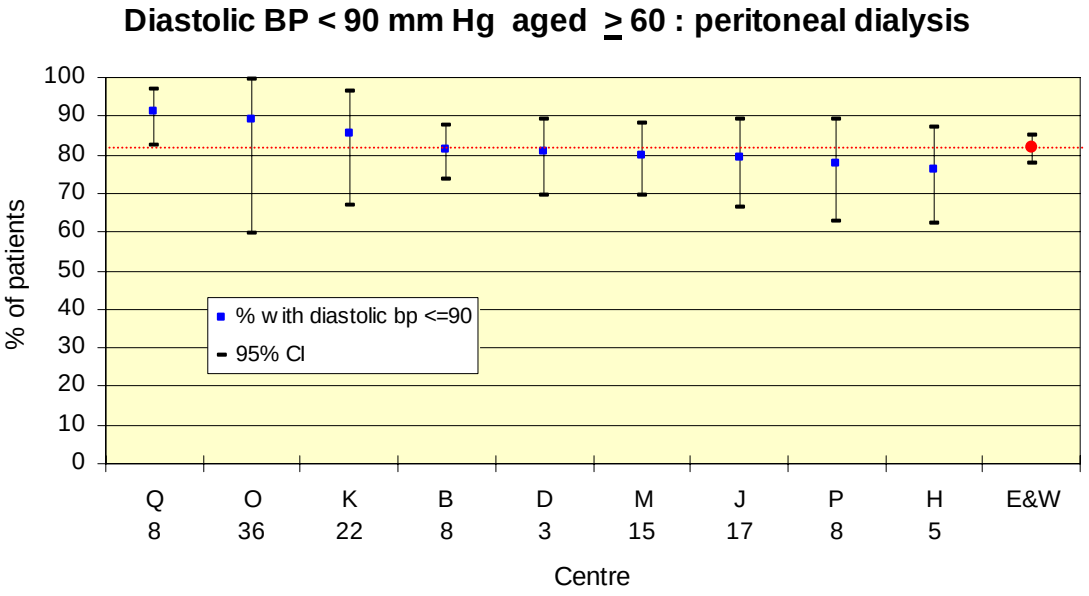


Figure 10.20 Percentage patients age ≥ 60 with diastolic BP < 90 mmHg on peritoneal dialysis

The median diastolic pressure in older peritoneal dialysis patients is lower than for younger patients. Many more patients achieve the diastolic pressure target than the systolic pressure target.

Mean arterial pressure

Haemodialysis

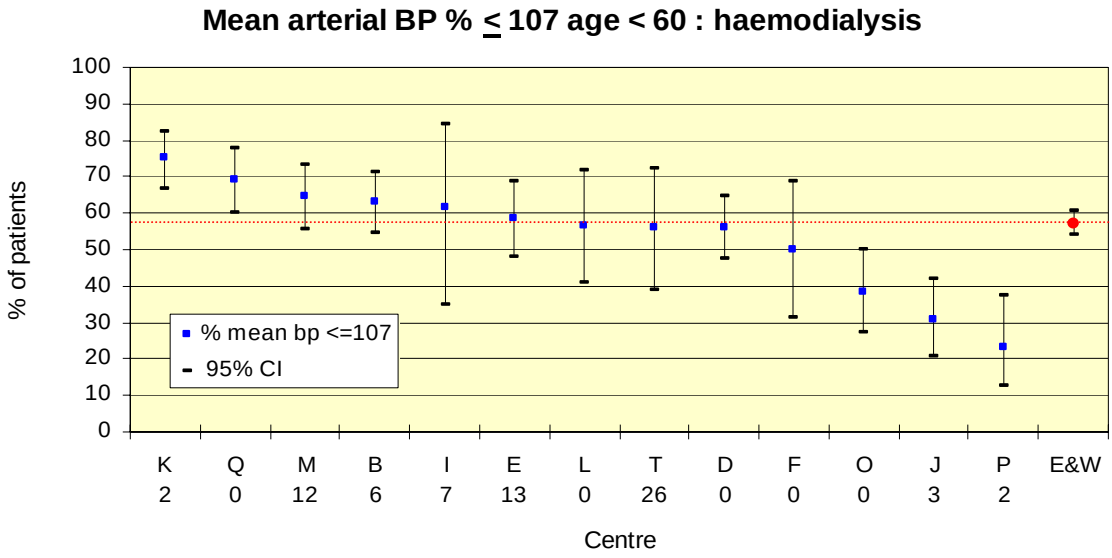


Figure 10.21 Percentage patients age <60 with mean arterial BP ≤ 107 on haemodialysis

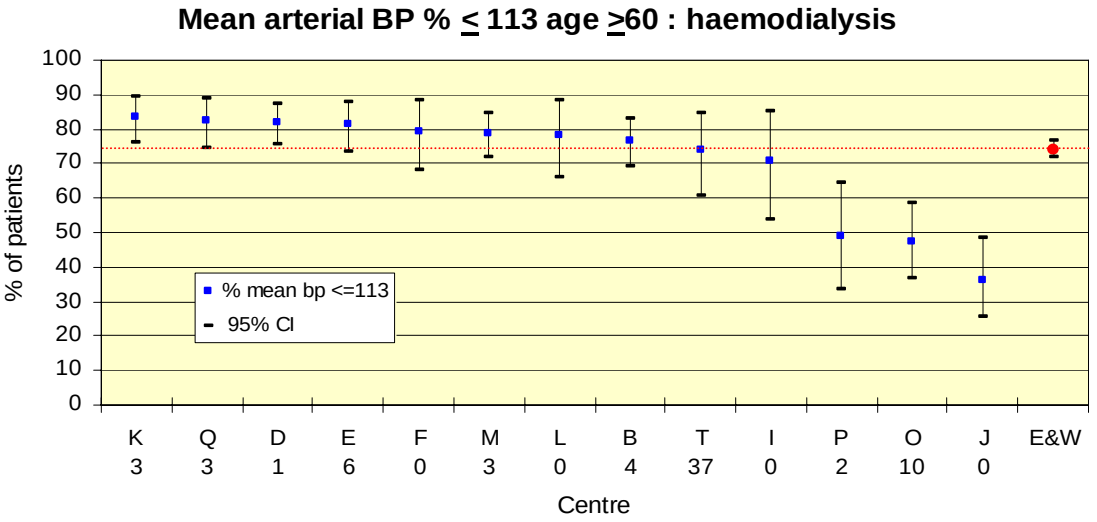


Figure 10.22 Percentage patients age ≥ 60 with mean arterial BP ≤ 113 on haemodialysis

Peritoneal dialysis

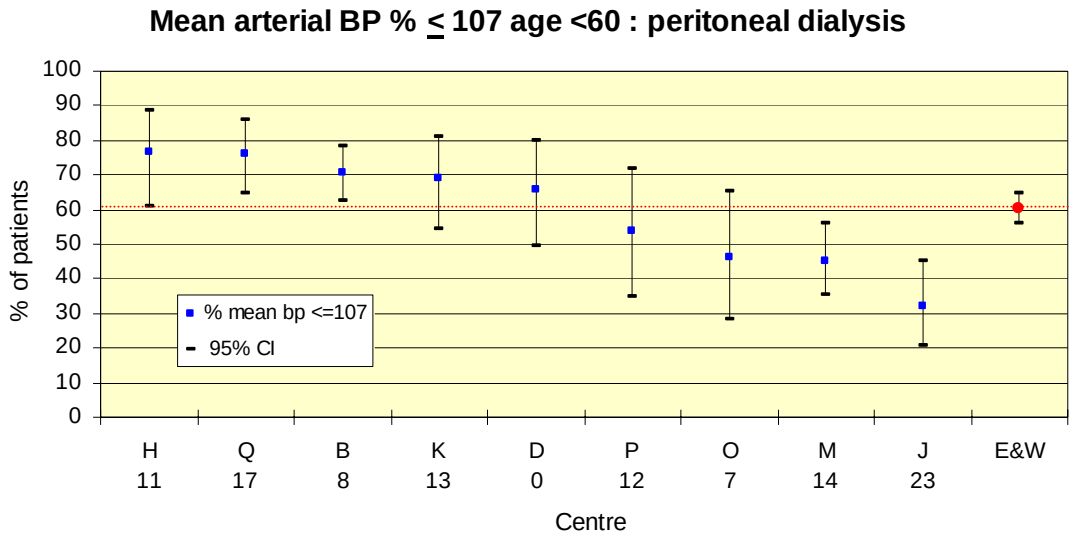


Figure 10.23 Percentage patients age < 60 with mean arterial BP ≤ 107 on peritoneal dialysis

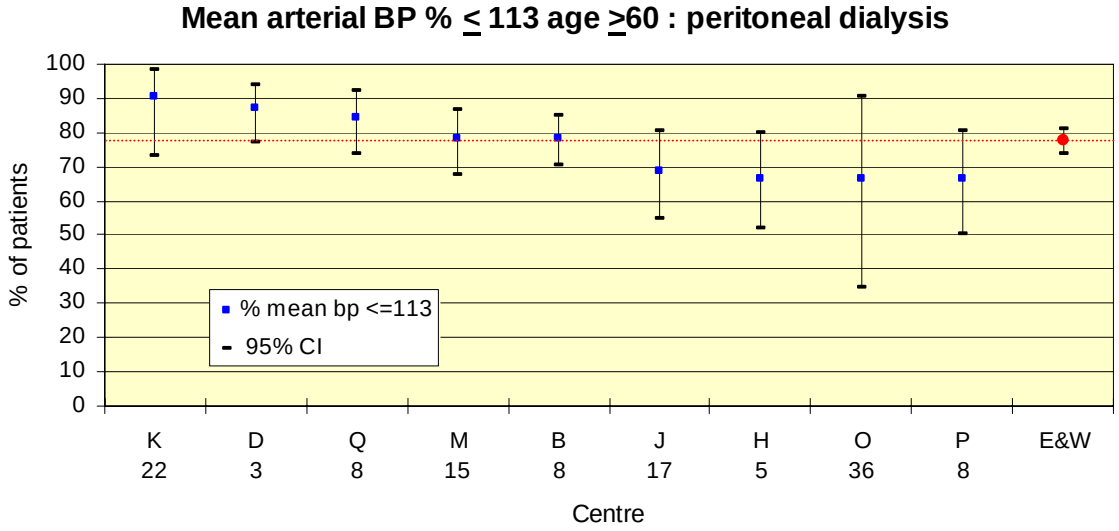


Figure 10.24 Percentage patients age ≥ 60 with mean arterial BP ≤ 113 on peritoneal dialysis

Comment on mean arterial pressure data

More patients achieve a mean arterial pressure equivalent to the recommended standards than achieve the combined arterial and diastolic standards, with little difference between the modalities. As already discussed the elderly have a higher achievement of the standard than the young because of the more liberal standard. The high achievement in the elderly is partly due to their lower diastolic pressures. The prognostic significance of the mean arterial pressure as compared with the combined systolic and diastolic standard is not certain.

Comment on blood pressure data

The proposed blood pressure Standards are difficult to attain. There are significant differences between units, but even in those achieving the lowest blood pressures nearly 50% of haemodialysis patients have a pre-dialysis pressure above the recommended standard. In four units 20% or less of younger haemodialysis patients achieve the standard. There is also a wide variation in peritoneal dialysis patients. For many units there is consistency of performance across the age range in both modalities, some consistently coming nearer to attaining the standards in all patient groups than others.

To achieve better overall standards will need considerable investment to provide more effective dialysis, better sodium balance, more outpatient staff time, and drugs. This could lead to significant patient morbidity from drug side effects and dialysis hypotension. Nevertheless most dialysis and transplant patients die of cardiovascular disease, and hypertension is one of the major factors determining cardiovascular outcome in other patient groups. Before embarking on the investment necessary to achieve better blood pressure control research is needed on the relationship of blood pressure control to outcome in end stage renal failure. This will help to determine the appropriateness of the current recommended standards for blood pressure control in end stage renal failure. Continued Registry activity in serially monitoring blood pressure and other variables in individual patients and relating these factors to eventual outcome will help to inform this debate.

References

1. Duranti E, Imperiali P, Sasdelli M.
   Is hypertension a mortality risk factor in dialysis?
   Kidney International Supple 1996 June; 55: S173-4.

2. Foley RN, Parfrey, PS, Harnett JD, Kent GM, Murray DC, Barre PE.
   Impact of hypertension on cardiomyopathy, morbidity and mortality in end-stage renal disease.
   Kidney International 1996 May; 49 (5): 1379-85.

3. Guidelines Subcommittee
   1999 World Health Organization – International Society of Hypertension Guidelines for the Management of Hypertension.
   Journal of Hypertension 1999 17: 151-183.

4. Hansson L, Zanchetti A, Carruthers SG, Dahlof B, Elmfeldt D, Julius S, Menard J, Rahn KH, Wedel H, Westerling S
   Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomised trial
   Lancet 1998; 352:11755-1762

5. Iseki K, Miyasato F, Tokuyama K, Nishime K, Uehara H, Shiohira Y, Sunagawa H, Yoshira K, Yoshi S, Toma S, Kowatari T, Wake T, Oura T, Fukiyama K.
Low diastolic blood pressure, hypoalbuminemia and risk of death in a cohort of chronic hemodialysis patients.
Kidney International 1997, Apr; 51 (4): 1212-7.

6. Lever AF, Ramsay LE
Treatment of hypertension in the elderly.
J. Hypertension 1995, June; 13 (6): 571-9.

7. Port FK, Hulbert-Shearon TE, Wolfe RA, Bloembergen WE, Golper TA, Agodoa LY, Young EW.
Predialysis blood pressure and mortality risk in a national sample of maintenance haemodialysis patients.
American Journal of Kidney Disease 1999; 33:507-17

8. Ramsay LE, Williams B, Johnston GD, MacGregor GA, Poston L, Potter JF, Poulter NR, Russell G.
Guidelines for management of hypertension: report of the third working party of the British Hypertension Society.
J Human Hypertension 1999 13: 569-592.

9. Salem MM, Bower J.
Hypertension in the hemodialysis population: any relation to one-year survival?
American J Kidney Disease 1996 Nov; 28 (5): 737-40.

10. Salem MM.
Hypertension in the haemodialysis population: any relationship to 2-yaers survival?
Nephrology Dialysis Transplantation 1999 Jan; 14 (1): 125-8.

11. The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure.
Arch Intern Med 1997 157: 2413-2445.

12. Zager PG, Nikolic J, Brown RH, Campbell MA, Hunt WC, Peterson D, Van Stone J, Levey A, Meyer KB, Klag MJ, Johnson HK, Clark E, Sadler JH, Teredesai P.
"U" curve association of blood pressure and mortality in hemodialysis patients.
Medical Directors of Dialysis Clinic, Inc.
Kidney International 1998 Aug; 54 (2): 561-9.

Chapter 11: Renal Transplantation

Introduction

A chapter on renal transplantation is provided for the first time.

Information regarding national transplant activity in the UK, together with patient and graft survival data, are provided annually by the United Kingdom Transplant Support Service Authority (UKTSSA) and will not be duplicated here.

The Renal Association Standards document contained standards and recommendations for renal transplantation which were developed in conjunction with the British Transplantation Society. The British Transplantation Society subsequently produced a more detailed standards document in 1998 entitled "Towards standards for organ and tissue transplantation in the United Kingdom". These documents largely address organisational issues of renal transplantation, and histocompatibility matching and allocation of donor kidneys. The standards for outcome in renal transplantation address the proportion of recipients with immediate graft function together with patient and graft survival. Whilst it is recommended that blood pressure, serum creatinine and cholesterol are monitored, no standards are recommended for these variables.

This first report on renal transplantation from the Renal Registry has attempted to provide data not available from other sources. These include data relating transplant patients to the pool of dialysis patients from which they are drawn. Data on graft renal function and indices of quality of care are reported. Data related to pre-transplant and post-transplant history are also being collected, but data collection on these variables, which may have significant influence on graft outcome, is not sufficiently advanced to enable meaningful analyses to be performed at present.

It is too early to present graft or patient outcome data on the 1998 cohort of patients who received a renal transplant: these will be presented in the next Registry report.

Transplants performed 1998

In 1998, 656 patients under follow up in participating units were transplanted. Details are given in tables 11.1 and 11.2. The intent is to provide data on transplant activity related to the patients on Renal Replacement Therapy in units participating in the Registry. Thus data on patients transferring in from non-registry units specifically for transplantation are excluded, but data on patients from registry units transferring to non-registry units for transplantation are included.

	Median age	Number
E&W (19 renal units)	43.0	524
Scotland (all units)	39.0	132
Total Registry	**42.0**	**656**

Table 11.1 New transplants from the Registry 1998

The sex distribution is slightly different for Scotland but England and Wales are fairly similar. The newly transplanted patients did not differ in gender from the established transplanted patients although there were some possible differences in primary diagnosis (Table 11.2). In the established transplant patients diabetes was less common. This may reflect a relative reluctance to treat diabetic patients in the past, and the shorter prognosis of diabetic patients.

	New transplants in 1998		Established transplants 1/1/98	
	%	No	%	No
Aetiology uncertain/GN not proven	18.6	122	24.0	1508
Glomerulonephritis	23.5	154	18.7	1175
Pyelonephritis	14.5	95	18.6	1171
Diabetes	10.5	69	6.0	380
Renal Vascular disease	1.2	8	1.1	70
Hypertension	3.7	24	5.1	320
Polycystic Kidney	11.3	74	11.4	713
Not sent	4.7	31	1.4	85
Other	12.0	79	13.7	859

Table 11.2 Primary diagnosis of transplant patients.

Patients with established renal transplants

The age distribution of the prevalent transplanted patients is shown in figure 11.1. The median age was 48 compared with 60 for the dialysis population from which they were drawn.

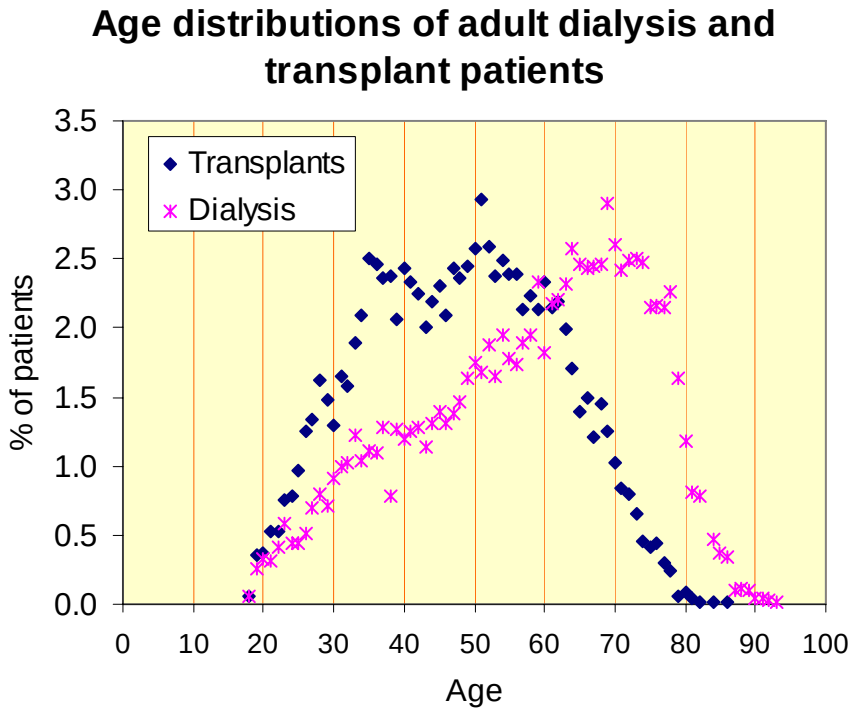


Figure 11.1 Age histogram of dialysis and transplant patients

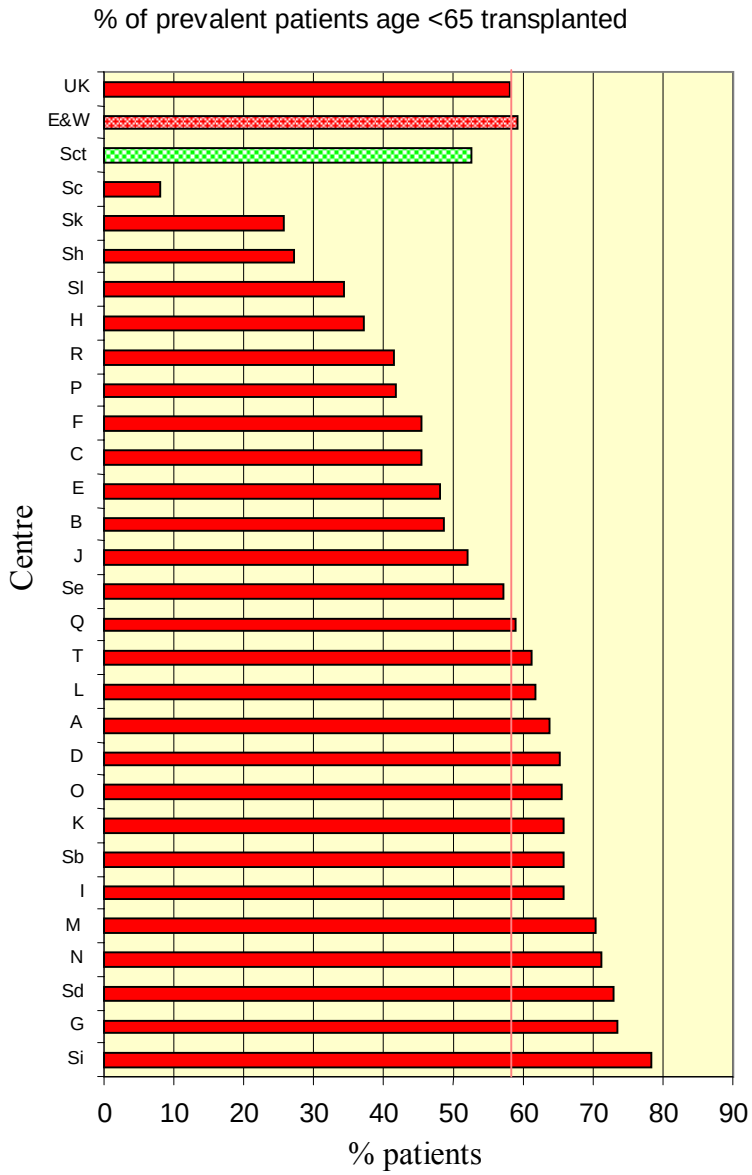


Figure 11.2 Percentage of prevalent RRT patients age >65 with a functioning transplant on 31/12/98

The percentage of all renal replacement therapy patients age less than 65 years with a functioning renal transplant at the end of 1998 is shown for each participating centre in figure 11.2.

For individual registry units, the proportion of the prevalent dialysis patients under 65 years old that had ever had a renal transplant is illustrated in figure 11.3. These figures are an underestimate, as some patients had no information regarding previous transplantation when transferring in on dialysis from a non-registry unit and are treated as unknown.

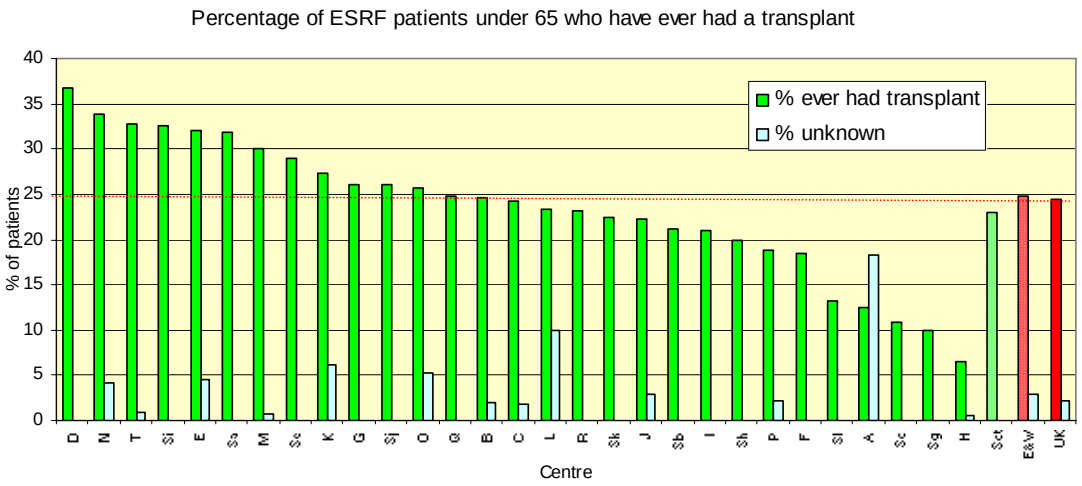


Figure 11.3 Percentage of current renal replacement therapy patients age < 65 who have ever received a renal transplant – currently functioning or not

The Registry cannot explain the different proportions observed between units. Plausible explanations include differences in age of units (patients in older units likely to have had a longer exposure to possible transplantation than in newer units) and differences in the proportion of prevalent dialysis patients made up by ethnic minorities which are harder to HLA match and thus transplant. The Registry does not currently have sufficient data to test these hypotheses.

Transplantation in patients with diabetes mellitus

Diabetics are a group of patients with End Stage Renal Failure whose prognosis has been shown to improve with renal transplantation. Some physicians therefore would give priority to diabetics awaiting transplantation. However the prognosis of diabetics transplanted is less than that of non-diabetics, largely due to death with a functioning graft. As there is shortage of organs some transplant practitioners feel it is more appropriate to give the organs to recipients who will survive longer. Figure 11.4 shows the proportion of patients in each registry centre with a functioning renal transplant on 31/12/98 with a primary diagnosis of diabetes mellitus.

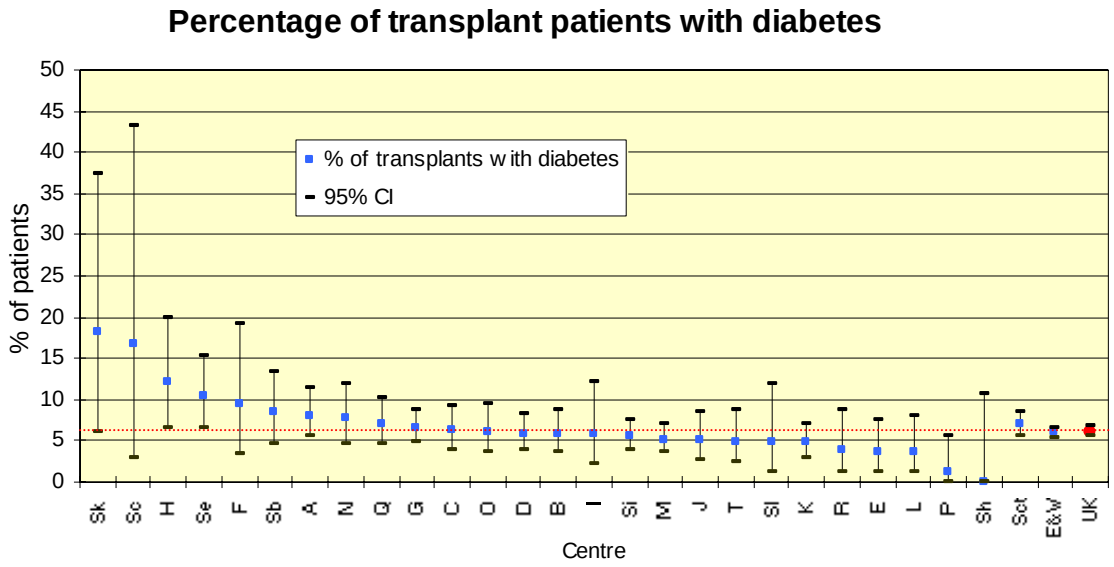


Figure 11.4 Percentage of current transplant patients with diabetes mellitus, by centre

The percentage of prevalent endstage renal failure patients in each centre with a primary diagnosis of diabetes mellitus with a functioning renal transplant on 31/12/98 is illustrated in figure 11.5.

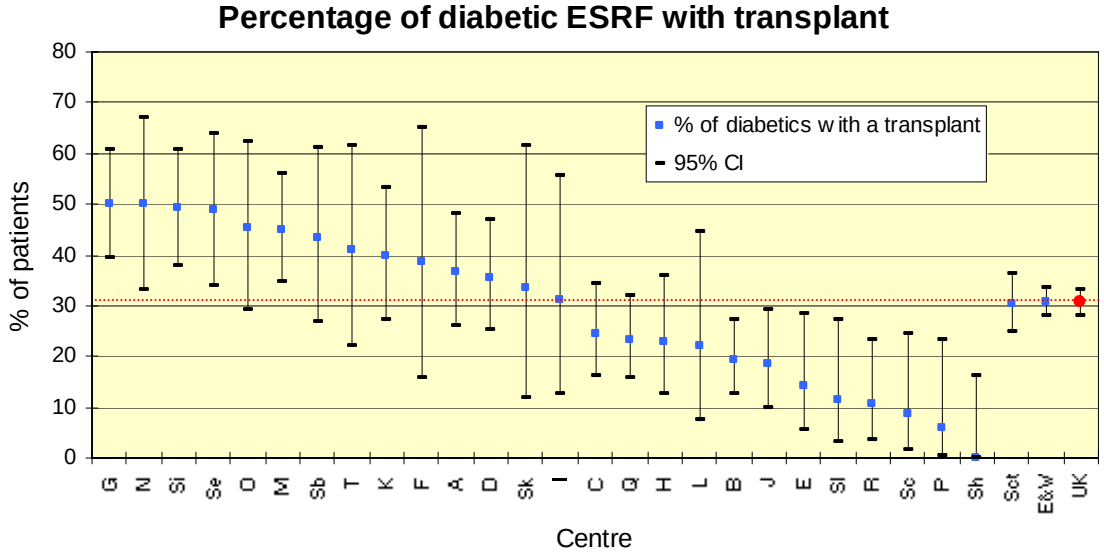


Figure 11.5 Percentage of diabetic ESRF patients with a transplant

To compare the differences within each unit between diabetic and non-diabetic patients, the ratio of % diabetics under 65 with a transplant to non-diabetics under 65 was calculated. The age limit was used in an effort to make the populations comparable, as most patients receiving a transplant are under 65, and diabetics have a lower median age than non-diabetics on RRT. These figures are demonstrated in figure 11.6. Centres with fewer than 20 diabetic patients aged under 65 have been excluded from the graph.

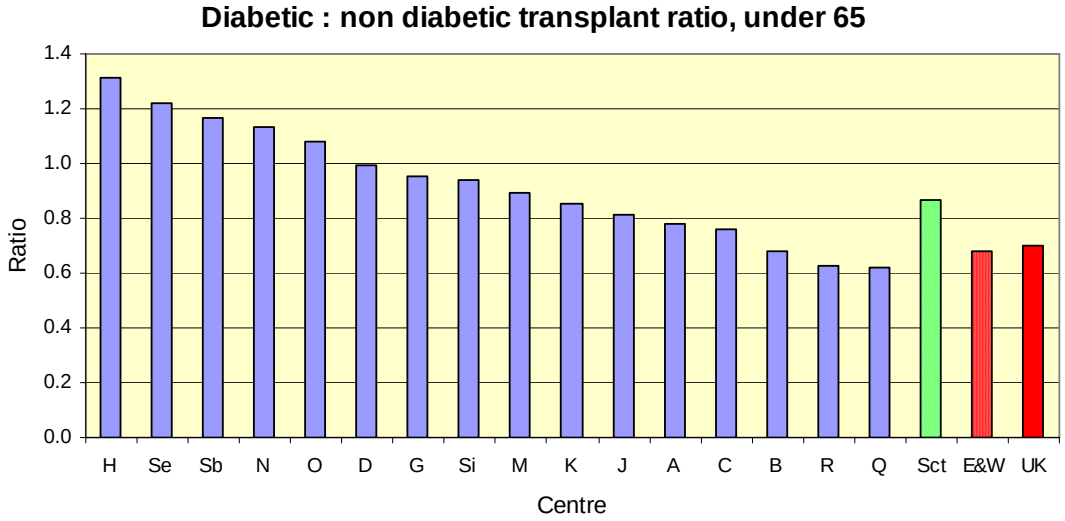


Figure 11.6 Ratio of % patients with a transplant under 65, diabetics: non-diabetics

In order to identify reasons for these observed differences between centres, a number of variables need to be examined, including the overall percentage of live ESRF patients with diabetes, the median age of this diabetic cohort, and the percentage of the cohort originating from ethnic minorities (and thus likely to experience difficulty in HLA matching). Some of the difference in the proportion of transplant patients with a primary diagnosis of diabetes mellitus observed between centres could be accounted for by differences in these variables. There will be sufficient patients on the Registry for this analysis to be presented in next year's report.

Overall diabetics seem less likely to receive a transplant than non-diabetics, but there appear to be differences of approach between units with regard to attitudes towards transplantation of diabetics.

Failed transplants

Within the participating centres, approximately 9% of all patients commencing dialysis in 1998 were patients whose renal transplants had failed during the year as opposed to new patients on Renal Replacement Therapy.

Dialysis modality 90 days after a transplant had failed was related to the dialysis modality before transplantation. Of those restarting dialysis, 77% of patients on haemodialysis before transplantation returned to haemodialysis after transplant failure, while 66% of CAPD patients returned to peritoneal dialysis. This analysis considered patients whose transplants failed between 1/10/1997 and the 30/9/1998, who resumed dialysis at a Renal Registry centre, regardless of where the patient had been transplanted. Patients whose transplant failed on the day of transplant have not been considered.

Survival of patients with established renal transplants

The UKTSSA annual report provides information on graft survival within the UK although follow-up information is not collected on patients once they return to dialysis.

The one-year survival figures presented are for those patients alive on 1/1/98. Patients who had been transplanted within six months prior to this date were excluded from these figures as they were still considered to be in the post-operative transplant risk group. Survival was calculated both censoring at return to dialysis and with continuing follow-up of patients after return to dialysis (Table 11.3).

	No. of patients	No patients died	Death rate (95% CI)	K-M 1 yr survival (95% CI)
Transplant	4853	121	2.6	97.4%
Censored at dialysis			(2.1- 3.1)	(97.0% - 97.9%)
Transplant	4853	141	3.0	97.1%
Incl dialysis return			(2.5 –3.5)	(96.6% - 97.5%)

Table 11.3 Survival during 1998 of established transplant patients alive 1.1.98

Quality of transplant function

Future reports will compare the quality of graft function between units by prospectively comparing creatinine and calculated creatinine clearance at set time points after transplantation. Correlation of graft function with pre- and post-transplant variables such as blood pressure, CMV status, serum cholesterol etc. will be possible as the Registry accumulates data over a longer time period. At present there are insufficient data to perform such analyses.

This analysis considered transplant patients on the 31/12/1998 who had had their transplant for more than a year. The most recent serum creatinine within 6 months was used in the analysis.

There was no relationship between primary diagnosis and graft function (Table 11.4).

Diagnosis	% with creatinine < 200
Aetiology uncertain*	80.5
Glomerulonephritis	76.6
Pyelonephritis	78.0
Diabetes	72.0
Renal Vascular disease	88.0
Hypertension	77.2
Polycystic Kidney	82.7
Not sent	83.1
Other	78.4

* Includes “glomerulonephritis– not histologically proven”

Table 11.4 Relationship between transplant function and primary renal diagnosis

A crude examination of graft function is demonstrated in figure 11.7 where the percentage of established transplant patients with a serum creatinine greater than 250 micromols/l is shown for each unit. There differences between units are significant but as yet unexplained.

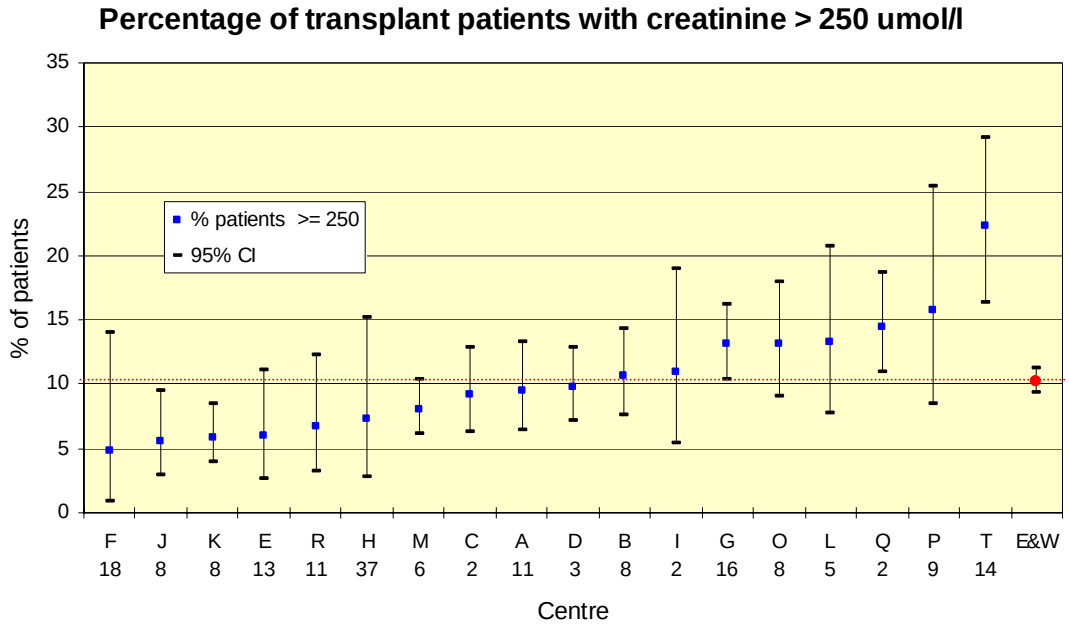


Figure 11.7 Percentage of established transplant patients with serum creatinine greater than 250 micromols/l

Haemoglobin in transplanted patients

There are no recommended haemoglobin standards for renal transplant patients. Figure 11.8 shows the percentage of transplant patients in each participating Registry unit with haemoglobin less than 10g/dL and 9g/dL respectively, at least 6 months after transplantation. The variation is unexplained (1-10% of transplant patients with Hb <10g/dL depending on unit) but possible reasons include quality of graft function, type of immunosuppression (use of azathioprine and mycophenolate mofetil) and use of erythropoietin in where there are failing grafts.

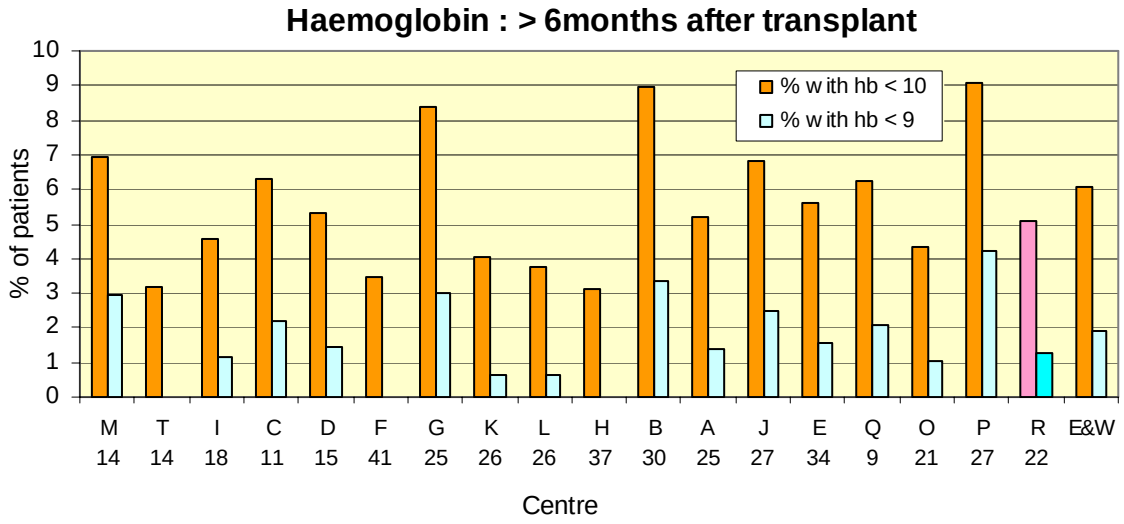


Figure 11.8 Haemoglobin of established transplant patients – by centre

As expected haemoglobin is lower in women and those with higher serum creatinine (Table 11.5).

		Haemoglobin							
Gender	Creatinine	Mean Hb	Std dev	5th centile	Lower quartile	Median Hb	Upper quartile	95th centile	No. with data
Male	<250	13.5	1.6	10.8	12.3	13.5	14.6	16.1	1913
Male	250+	11.4	1.9	8.7	10.0	11.2	12.6	14.8	284
Female	<250	12.4	1.6	9.9	11.2	12.4	13.4	15.1	1235
Female	250+	10.6	1.7	7.5	9.4	10.8	11.7	13.3	142

Table 11.5 Renal transplant patients: relationship of haemoglobin and creatinine

Serum cholesterol

The distribution of serum cholesterol in transplantees according to centre is shown in figure 11.9.

This analysis considered transplant patients on the 31/12/1998 who had had their transplant for more than a year. The most recent serum cholesterol over a 12 month period was used and the cholesterol was harmonised for inter-laboratory variation.

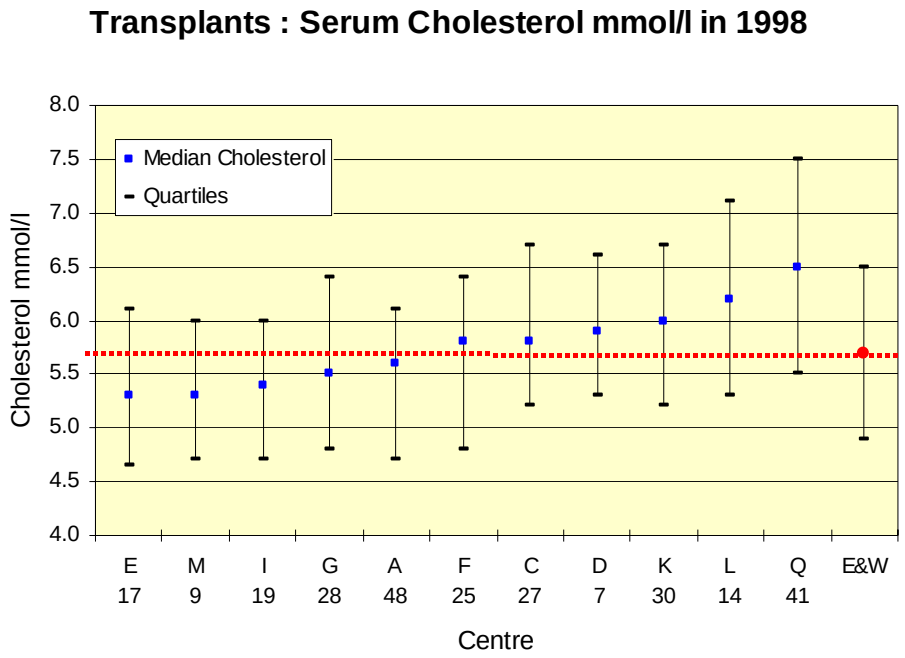


Figure 11.9 Serum cholesterol levels for transplant patients – by centre

The total death rate in the population with established renal transplants whilst the graft is functioning is surprisingly low at around 2-3% per annum. The overall death from cardiovascular disease in the UK transplant population is at least 8-10 fold more common than in the gender and aged-matched general population. However the relationship between serum cholesterol and prognosis in transplant patients has not been studied. Nevertheless, in the general population, total cholesterol is an important risk factor for cardiovascular disease. Current recommendations for primary prevention in the *high-risk* general population advise a total cholesterol above 5.5 mmol/l as a trigger for prescribing cholesterol-lowering agents. Transplantees have usually experienced a period of dialysis, frequently with concomitant hypertension, and have a high incidence of hypertension post transplantation. Considering this together with the known high death rate from cardiovascular disease they could be considered high risk and suitable for primary prevention of cardiovascular disease.

In most units the median serum cholesterol of transplantees is above the recommended level for primary prevention in high-risk patients. Serum cholesterol in these patients is not related to serum creatinine (Table 11.6)

	Serum cholesterol					
Serum Creatinine	**5th centile**	**Lower quartile**	**Median cholesterol**	**Upper quartile**	**95th centile**	**No. with data**
<150	4.0	4.9	5.7	6.4	7.8	1388.0
150-250	3.8	4.9	5.7	6.5	8.0	953.0
250+	3.9	5.1	5.8	6.6	8.5	274.0

Table 11.6 Renal transplant patients: relationship of serum cholesterol and creatinine

Blood pressure

Neither the Renal Association nor the British Transplantation Society has recommended standards for blood pressure control in transplanted patients. In the following analysis the standards recommended for dialysis patients have been adopted, although many would argue that the acceptance of higher blood pressure in the elderly is not appropriate (British hypertensive society guidelines).

There may be errors due to incomplete data. Table 11.7 shows the percentage of renal transplant recipients with blood pressure data. Blood pressure recordings are also likely to be subject to a variety of biases. Fit patients with infrequent clinic attendance will have infrequent BP assessment. High BP readings may be selectively included or excluded from computer records depending on operator bias. The following data must be interpreted with this in mind.

	% with BP return from last 6 months	
Centre	**Age < 60**	**Age > 60**
A	0	0
B	86	94
C	2	1
D	65	57
E	3	0
F	0	0
G	83	83
H	3	0
I	3	0
J	87	91
K	89	95
L	6	0
M	34	27
N	0	0
O	65	60
P	83	68
Q	95	96
R	0	0
T	26	24
E&W	50	47

Table 11.7 Completeness of BP returns for transplant patients

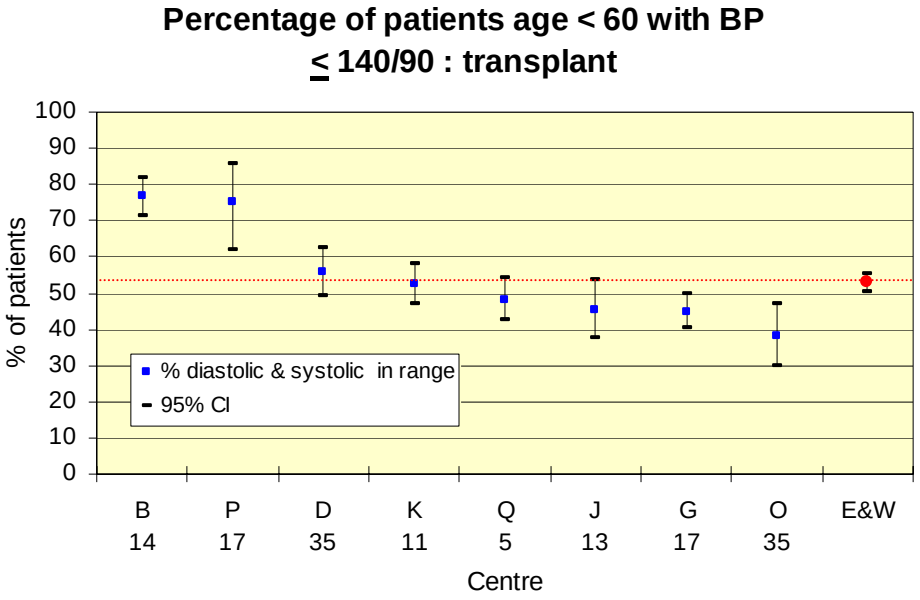


Figure 11.10 % patients under 60 with systolic and diastolic BP below 140/90 mmHg

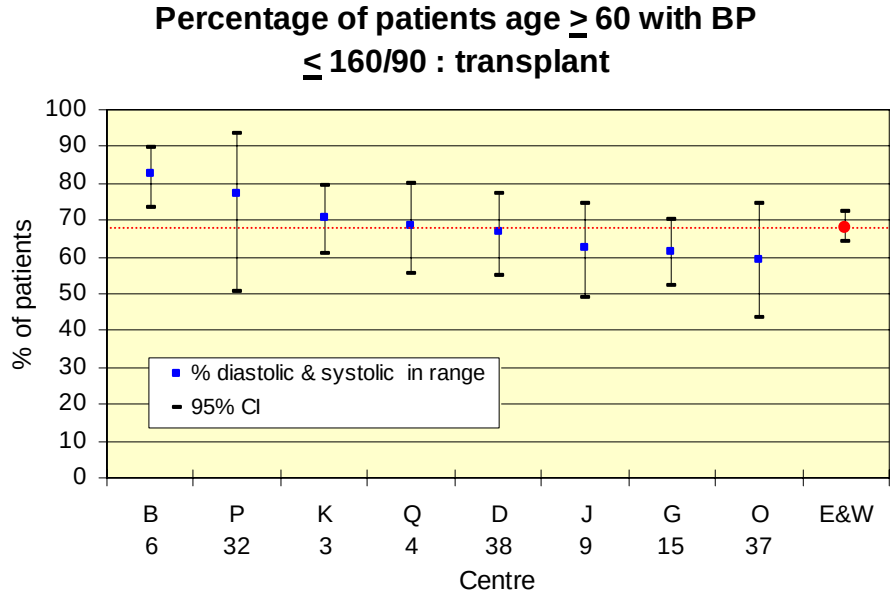


Figure 11.11 % patients over 60 with systolic and diastolic BP below 160/90 mmHg

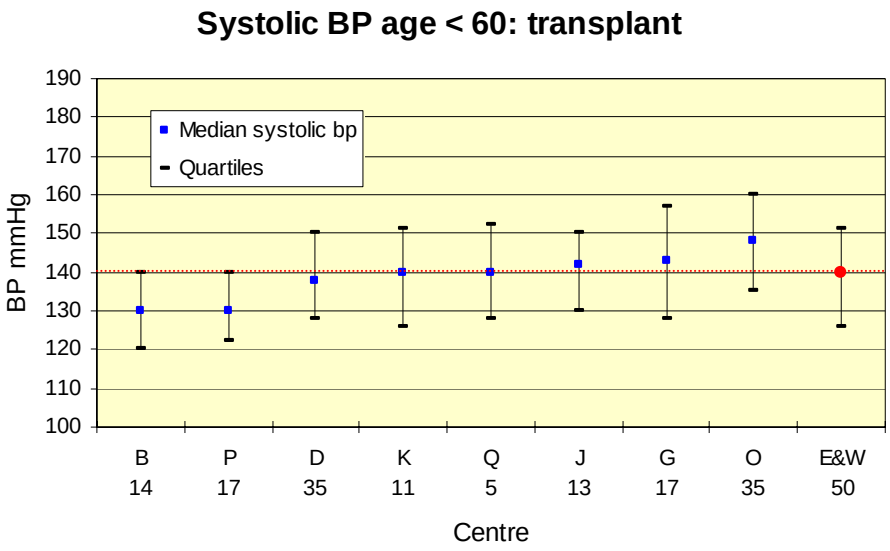


Figure 11.12 Transplant patients under 60: median systolic pressure

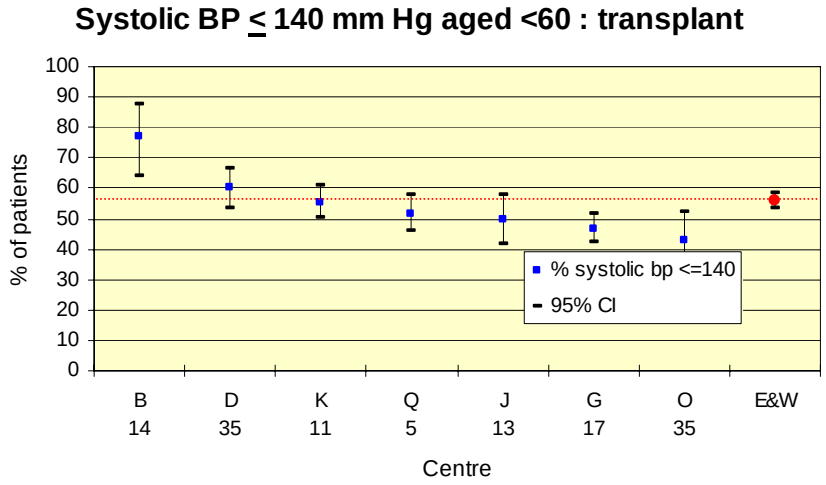


Figure 11.13 Percentage transplant patients under 60 with systolic BP ≤140 mmHg

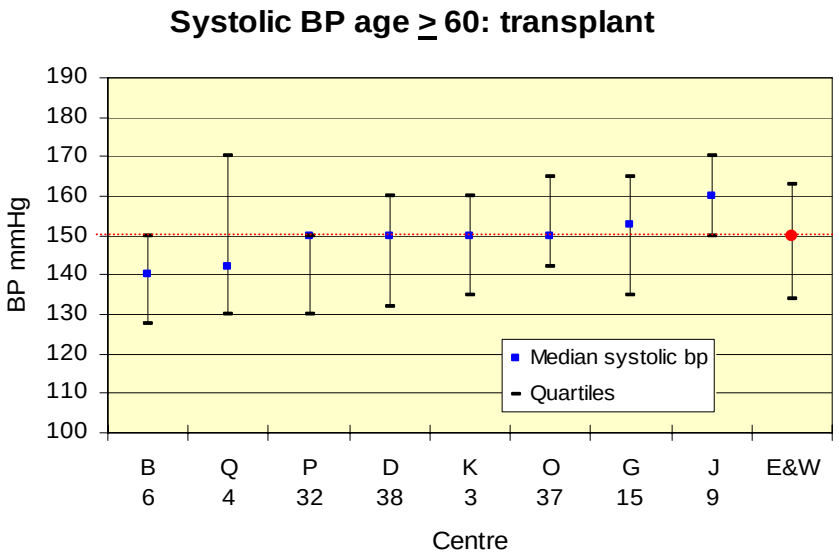


Figure 11.14 Transplant patients over 60: median systolic pressure

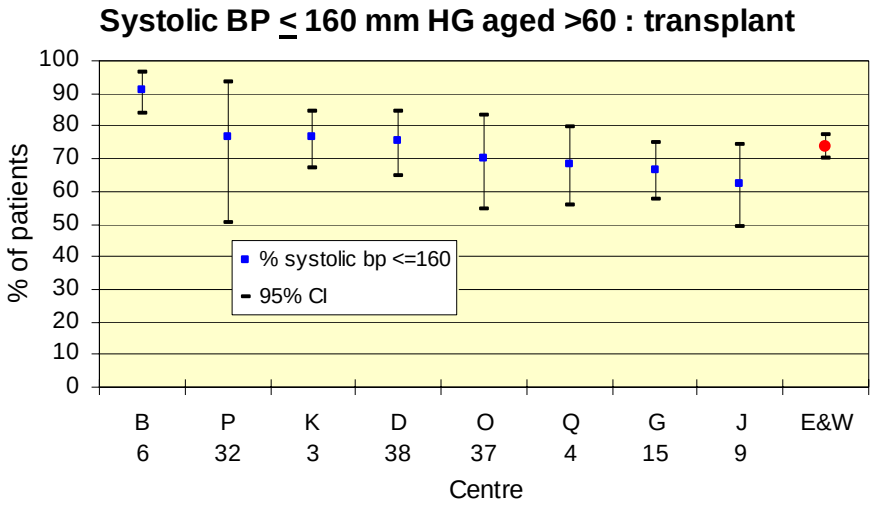


Figure 11.15 % patients over 60 with systolic BP ≤160 mmHg

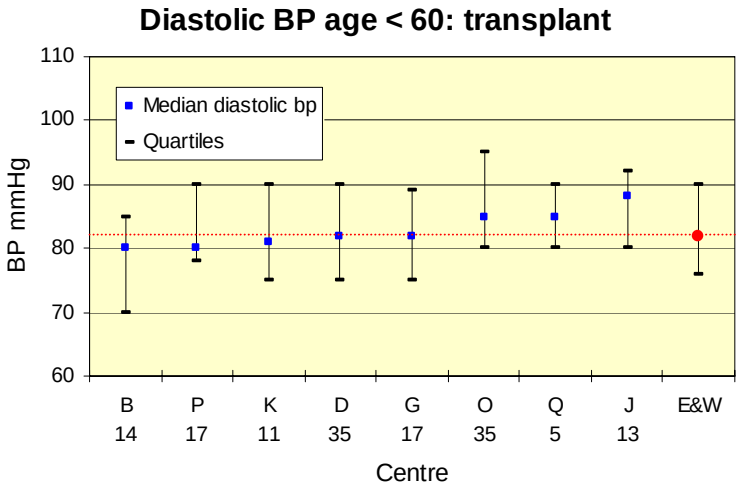


Figure 11.16 Transplant patients under 60; median diastolic pressure

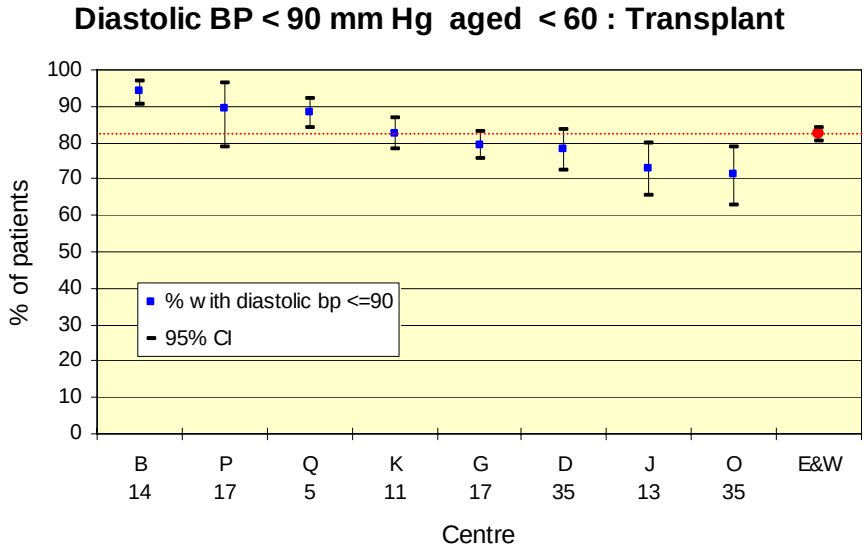


Figure 11.17 % patients under 60 with diastolic pressure ≤90mmHg

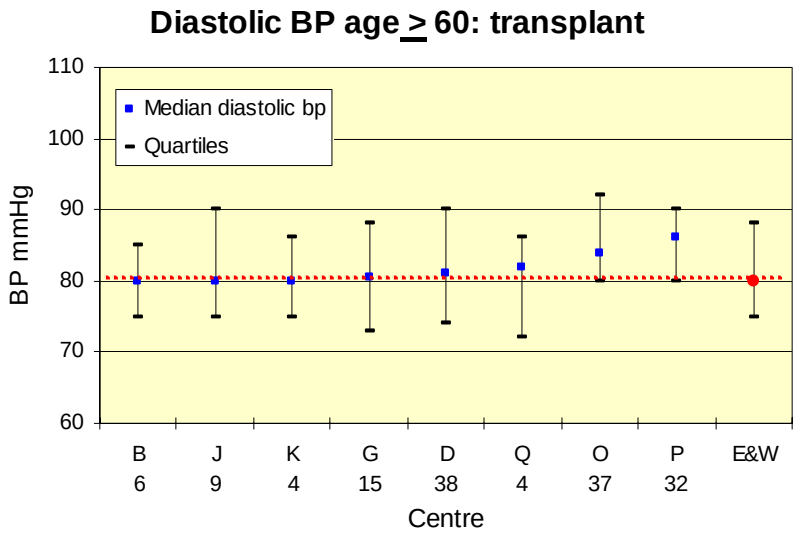


Figure 11.18 Transplant patients over 60: median diastolic pressure

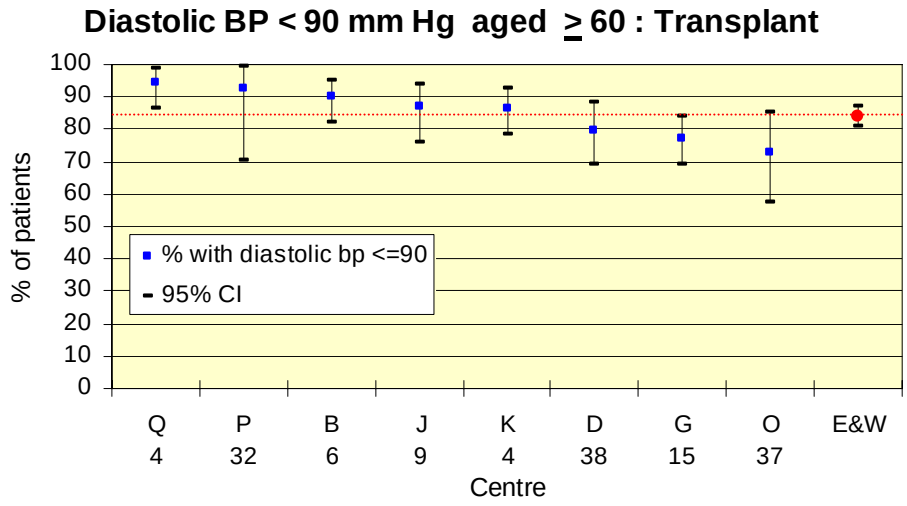


Figure 11.19 % patients over 60 with diastolic pressure ≤90mHg

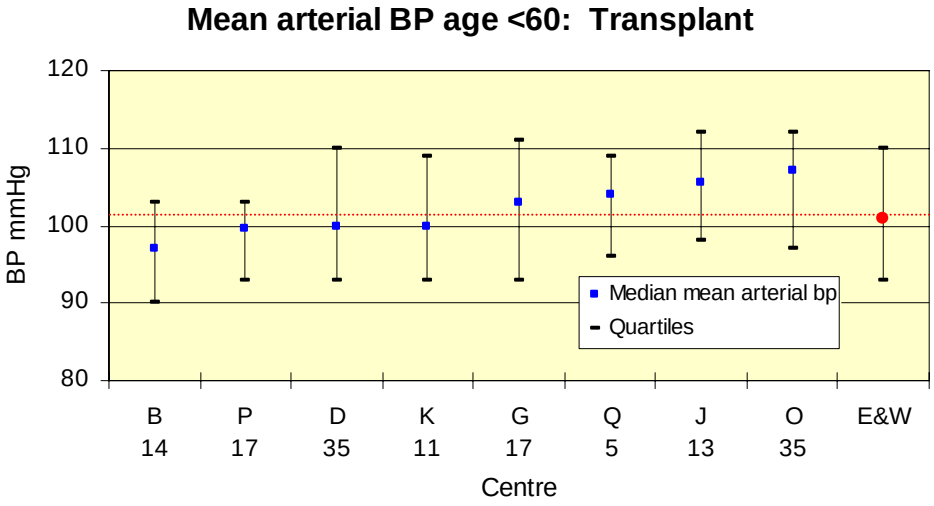


Figure 11.20 Transplant patients under 60: median mean arterial pressure

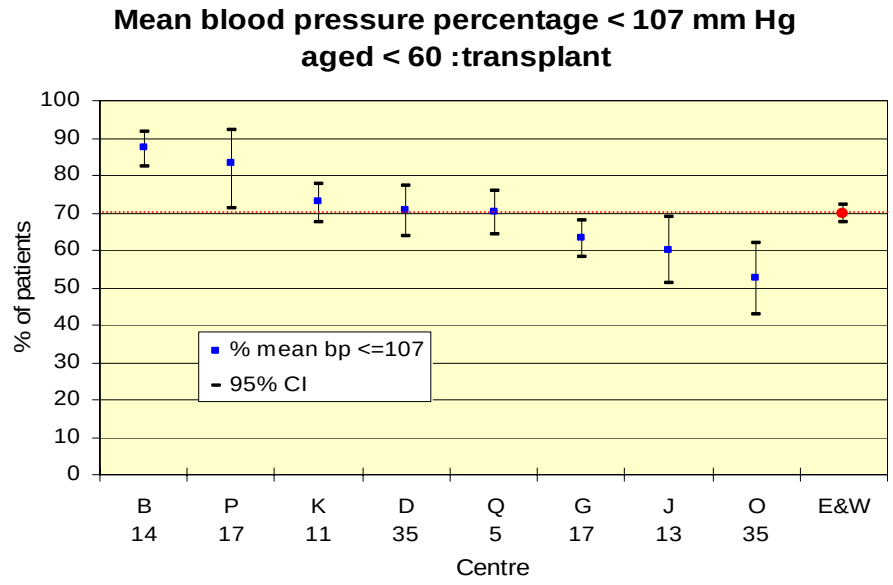


Figure 11.21 % patients under 60 with mean arterial pressure ≤107 mmHg

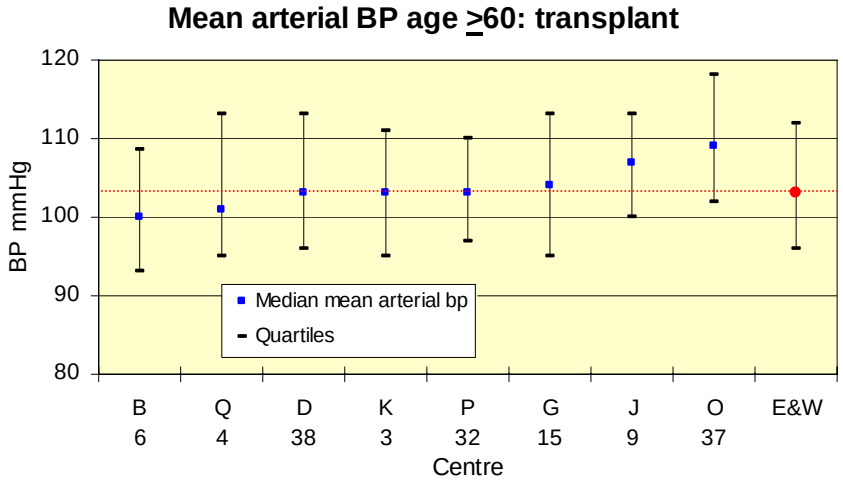


Figure 11.22 Transplant patients over 60: median mean arterial pressure

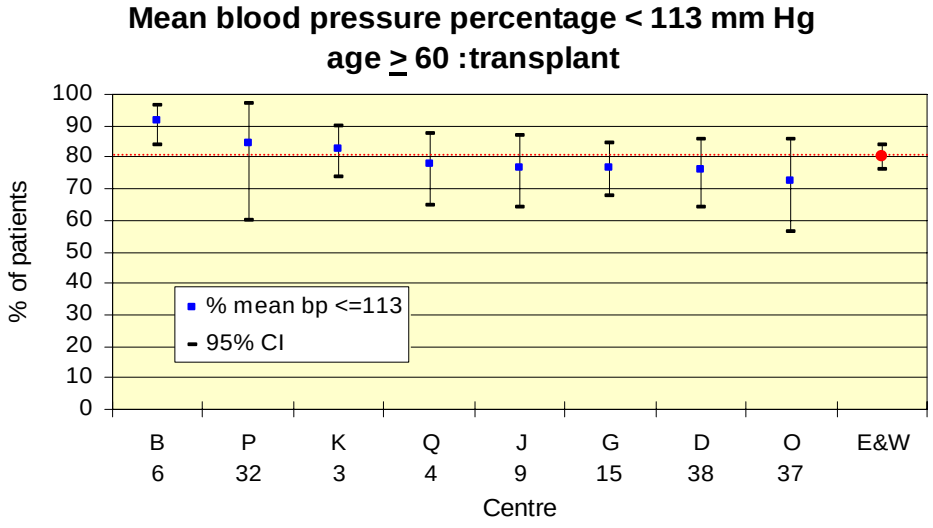


Figure 11.23 % patients over 60 with mean arterial pressure ≤113 mmHg`

There is more variation between centres in blood pressure achieved in the younger patients than the older ones, and more variation in the systolic pressure achieved than diastolic. Control of systolic hypertension seems more difficult to achieve than control of diastolic hypertension.

The overall median diastolic pressure in those above and below age 60 is similar at 83 mmHg. and 84 mmHg. Overall achievement of the standard in younger and older patients is 82.9% and 84% respectively. There is variation between units in the proportion of patients with blood pressure within the desired range which is significant for younger patients.

Considering all the transplant patients in the Registry, systolic pressures achieved are different in the two age ranges. For younger patients the median systolic pressure is 140 mmHg., for older patients 150 mmHg. The percentage achieving the "standard" is 56% for younger patients and 73% for older patients. This reflects the more liberal standard for older patients. If more rigorous criteria were used for older patients, i.e. upper limit 140 mmHg, then the proportion achieving the standard would be less than for younger patients. The variation between units is again significant for younger patients.

The Registry median for mean arterial pressure is 101 mmHg. for younger patients and 103 mmHg. for older patients. 70% of younger patients are within the desired range, with a significant variation between units. 80% of older patients are within the more liberal range for this age group, but the variations between units may not be significant in these older patients.

From these figures some units seem to control both systolic and diastolic pressure to significantly lower levels than others. This may have important implications for subsequent cardiovascular disease and long-term patient survival. As the Registry collects further sequential data on these patients, the relationship of blood pressure to graft and patient survival will be investigated

Chapter 12: Co-morbidity of new patients

Collection of co-morbidity data is essential for the Registry to assess national outcomes, to compare outcomes between centres, and to assess the effect of quality indicators and measured variables (e.g. blood pressure, haemoglobin, serum phosphate) on prognosis. Co-morbidity data is sought from all new patients starting renal replacement therapy. It has not been requested from existing patients when renal units first join the registry. Co-morbidity is only currently collected as at the time of starting renal replacement therapy.

The Renal Registry sub-committee reviewed the USRDS co-morbidity data and thought the 45 minutes per patient to complete that complex data set was not feasible in a busy UK unit. Therefore a "Yes/No" data set was specified to keep this time down less than 5 minutes and to only include items that can be precisely defined. After widespread consultation the following items were selected as those which, in the light of current knowledge, are those most likely to yield most information and to be amenable to precise and easy definition.

The most pressing need for the Registry is to improve the returns of co-morbidity data from patients starting renal replacement therapy. The Registry is collecting a unique database of sequential measures of quality of treatment on individual patients. This will act as a source for investigating the importance in determining prognosis of factors such as control of blood pressure, serum phosphate, haemoglobin, and serum cholesterol. The Registry is also a powerful tool for comparative audit. Without good co-morbidity data to enable comparisons of groups of similar patients the value of this data will be greatly reduced.

Co-morbidity Screen

The Registry installs a screen onto renal unit data systems to facilitate entry and collection of co-morbidity data. The CCL Proton is the data system most widely used: the co-morbidity screen for this is shown below. All these are "yes/no" fields:-

```
_ Angina                                  _ Claudication
_ Previous MI within last 3 months        _ Ischaemic / Neuropathic ulcers
_ Previous MI > 3 months ago              _ Angioplasty (non coronary)
_ Previous CABG or coronary angioplasty   _ Amputation for Periph Vasc Dis

_ Cerebrovascular disease                 _ Smoking
_ Diabetes (not causing ESRF)
_ Chronic Obstructive Pulmonary Disease
_ Liver Disease
_ Malignancy
```

Co-morbidity Data

Only four sites managed to return some co-morbidity on patients in 1998. It is hoped this will increase in 1999. Centres B, D, K, Q returned complete co-morbidity data set for 81%, 45%, 72% and 11% of patients respectively. The incomplete co-morbidity was partly due to some centres starting collection of data part way through the year.

The table below shows in the first column for the centre, the percentage of all new patients in 1998 with the co-morbidity data returned. The second column shows the percentage of patients with the specified co-morbidity as a percentage of those patients from whom co-morbidity data was received.

Centre	B		D		K	
Co-morbidity	**% of new**	**% of returns**	**% of new**	**% of returns**	**% of new**	**% of returns**
Angina	15	**18**	12	**25**	19	**25**
Previous MI < 3 months	1	**1**	2	**4**	2	**3**
Previous MI > 3 months	9	**11**	4	**8**	14	**19**
Previous CABG	4	**5**	2	**4**	7	**10**
Claudication	12	**14**	6	**13**	2	**6**
Ischaemic /neuropathic ulcers	8	**9**	4	**8**	0	**0**
Angioplasty non-coronary	4	**5**	4	**9**	0	**0**
Amputation for PVD	4	**5**	6	**12**	2	**3**
Cerebrovascular disease	6	**7**	12	**25**	14	**19**
Diabetes (not as a cause of ESRF)	10	**12**	6	**13**	7	**10**
COPD	3	**4**	4	**8**	2	**3**
Liver disease	1	**1**	2	**4**	0	**0**
Malignancy	8	**9**	6	**13**	12	**16**
Smoker	12	**15**	10	**22**	5	*****

Table 12.1 Co-morbidity in 1998 for selected centres

The percentage of patients who smoked was not calculated for centre K as they returned a large proportion of patients as unknown. The co-morbidity for centre Q is not shown, as the numbers were small.

Diabetes, not as a cause of end stage renal failure, was consistent between centres at 10-13 % of all patients with returns. Centre K starts fewer new patients with peripheral vascular co-morbidity and a higher proportion with cardiac co-morbidity.

It is not yet possible to weight the co-morbidity scores for risk, but for each individual patient the co-morbidity has been summed with the overall results shown in figure 12.1. Any patient with '*unknown*' for any of the co-morbidity items was excluded. Overall 47% of patients had some co-morbidity.

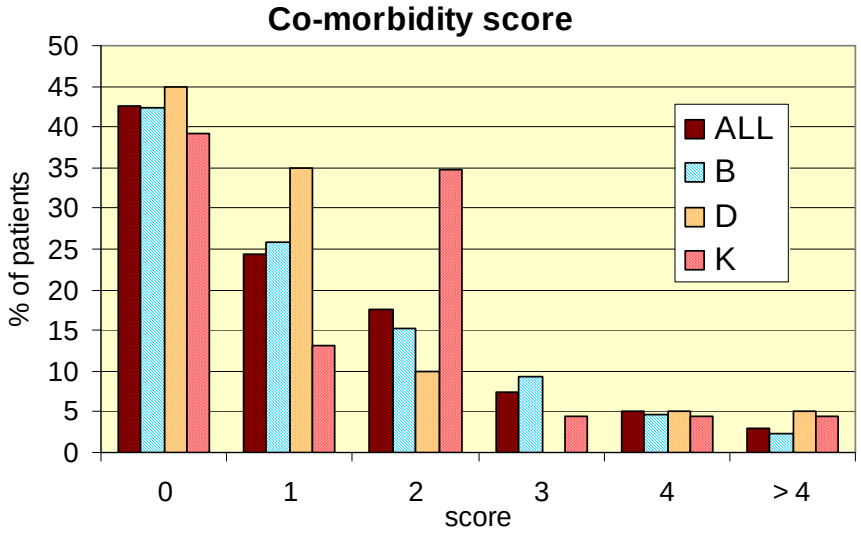


Figure 12.1 Co-morbidity score

The mean co-morbidity for centres B,D,K is 1.2, 1.0, 1.3 respectively.

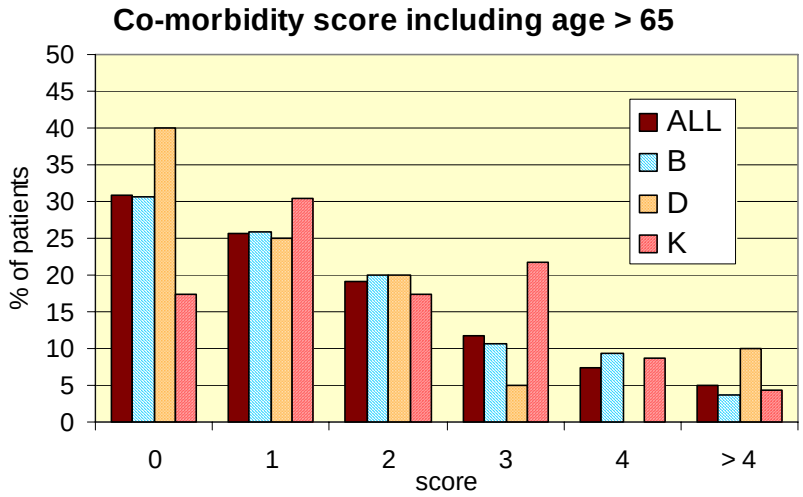


Figure 12.2 Co-morbidity score including patients age > 65

Patients over 65 in renal replacement therapy are at increased risk of death. In figure 12.2 a score of +1 has been added to the co-morbidity if the patient was over 65. This produced a mean patient co-morbidity score of 1.6, 1.4 and 1.9 for centres B, D, K respectively.

Co-morbidity definitions

Angina

History of chest pain on exercise with or without ECG changes, ETT, radionucleotide imaging or angiography.

Previous MI within last 3 months

MI diagnosed by ST segment elevation, Q waves in relevant leads, enzyme rise > x2 upper limit of normal (or rise in CKMB above local reference range).

Previous MI > 3 months ago

From time of start of renal replacement therapy.

Previous CABG or coronary angioplasty

Cerebrovascular disease

Any history of strokes (whatever cause) and including TIA caused by carotid disease.

Diabetes (not causing ESRF)

This includes diet controlled diabetics.

Chronic Obstructive Pulmonary Disease

This is defined as a slowly progressive airways disorder characterised by obstruction of the expiratory airflow which does not change markedly over several months, may be accompanied by airways hyper-reactivity and may be partially reversible.

N.B. chronic bronchitis and emphysema may occur in the absence of airflow obstruction. Asthma patients may rarely develop airflow obstruction that does not improve with steroids.

Liver Disease

This is defined as any abnormal LFTs at the time of registration.

Malignancy

Defined as any history of malignancy (even if curative) e.g. removal of basal cell carcinoma, melanoma.

Claudication

Current claudication based on a history, with or without Doppler or angiographic evidence.

Ischaemic / Neuropathic ulcers

Current presence of these ulcers.

Angioplasty (non coronary)

Amputation for Peripheral Vascular Disease

Smoking

Current smoker or history within the last year.

Chapter 13: Performance Against Renal Association Standards

Introduction

The Standards Committee of the Renal Association have identified a number of laboratory and clinical variables which may relate to quality of care or outcomes and have recommended minimum standards or target ranges which should be achieved in established dialysis patients These are shown in table 13.1.

Standard	*Haemodialysis*	*Peritoneal dialysis*
Haemoglobin	≥10g/dl in >85% of patients	≥10g/dl in >85% of patients
Calcium	Local normal range	Local normal range
Phosphate	1.2-1.7 mmol/l	1.1-1.6 mmol/l
Albumin	Local normal range	70% of patients in the local normal range
Potassium	3.5-6.5 mmol/l	3.3-5.5 mmol/l
Bicarbonate	Local normal range	Lower local normal to upper local normal +3mmol/l
Parathyroid Hormone	2–3x local normal range	2–3x local normal range
Systolic BP	≤160 mmHg aged over 60 ≤140 mmHg aged under 60	≤160 mmHg aged over 60 ≤140 mmHg aged under 60
Diastolic BP	≤90 mmHg	≤90 mmHg
Adequacy	URR ≥65% or KT/V ≥1.2	CC>50l/week or KT/V.1.7 for CAPD (65l/week and 2.0 for APD

Table 13.1 Renal Association Standards

Renal Registry data can be used to:
1) Compare performance of individual units against the Standard
2) Compare performance of units with each other
3) Examine year on year performance to identify improvement.

Data are included for the last quarter of 1998. Patients were excluded if they had not been on renal replacement therapy for at least three months or if they had transferred unit or changed dialysis modality in the three month period prior to data sampling. This ensures that the results for a unit reflect stable treatment patterns and are not adversely affected by new patients which the unit has not had chance to treat effectively.

The problems of comparing biochemical variables such as albumin, calcium and bicarbonate identified in the 1998 report still apply; and comparative data must be interpreted with caution. Achievement of Standards defined around the local laboratory reference range is dependent on the source of derivation for the reference range. Biochemical data have been harmonised as described previously. The harmonisation constants for an individual laboratory change year on year and are monitored. The urea

reduction ratios may be influenced by post-dialysis sampling techniques; this is discussed in detail in chapter 5.

Results have been ranked in order of performance purely for clarity of presentation, otherwise the figures would be difficult to read. The ranking does not necessarily imply significant differences in the performance of different units. The figures which show a percentage of patients reaching a 'target' also include the 95% confidence interval for that percentage. This provides an estimate in the potential variation around this figure in repeated measurement and provides an indication of the overlap between centres. Some of the results are also shown as bar charts divided into bands. The numbers immediately under each centre on the figures are the percentage of missing data from that centre for patients on that treatment modality. These methods are the best way the Registry has found to convey the underlying data for the larger number of centres.

Overview of presentation

In the following section the figures use a common modified box-plot format with data presented separately for haemodialysis and peritoneal dialysis. The figures showing the percentage of patients reaching the Renal Association Standard include the 95% confidence interval calculated for this figure. Where medians are displayed, the 25th and 75th centiles for the unit are included. Figures showing the percentage within a range (as defined by the Renal Association Standard or a Renal Registry defined range) also include the 95% confidence interval calculated for this figure. Data completeness is indicated by the "percentage missing" figure below the unit code letter.

Haemoglobin

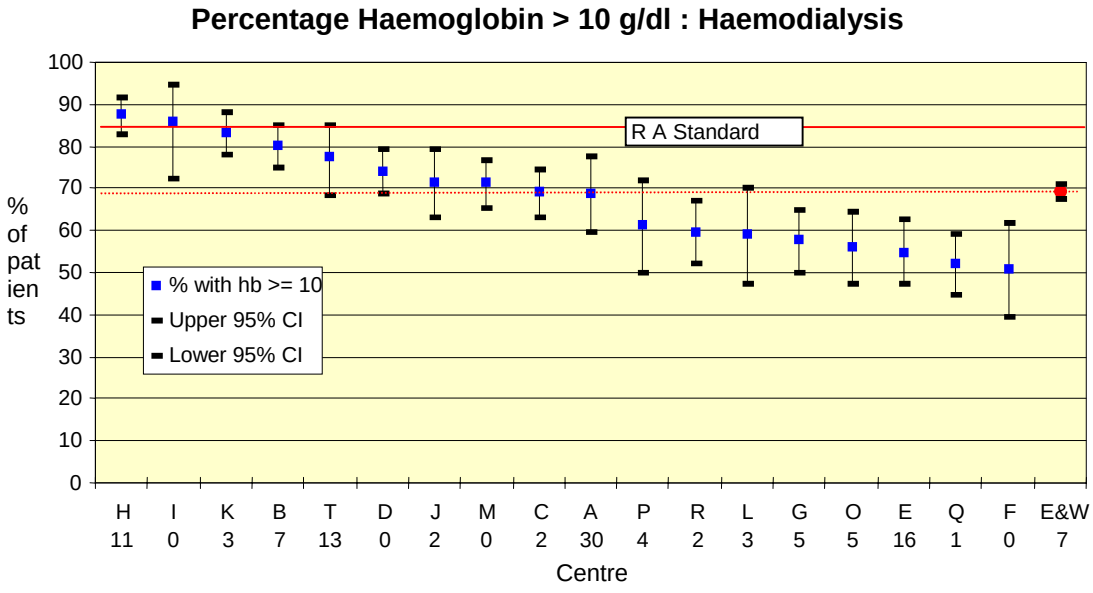


Figure 13.1 Haemoglobin Percentage of HD patients achieving the RA Standard

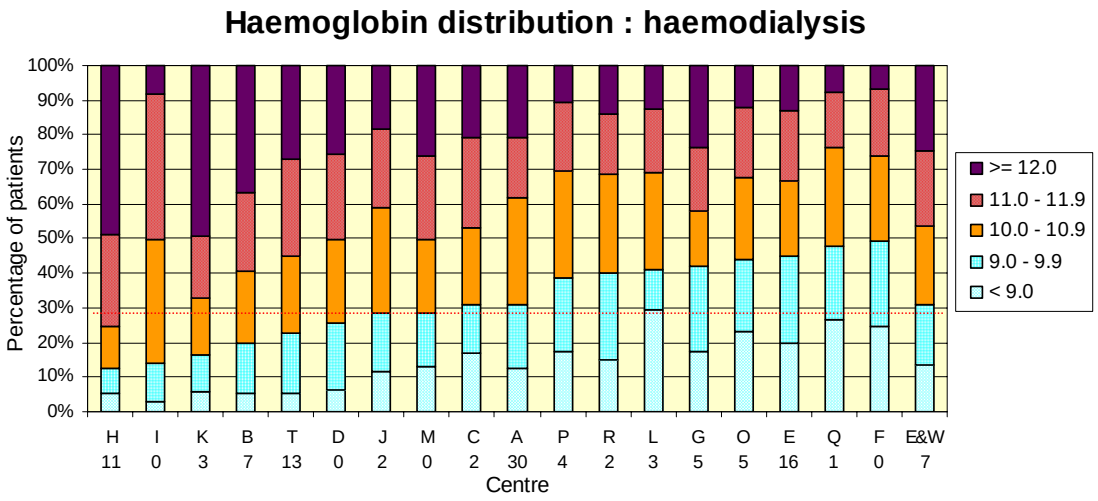


Figure 13.2 Haemoglobin for patients on HD by 1g/dl bands

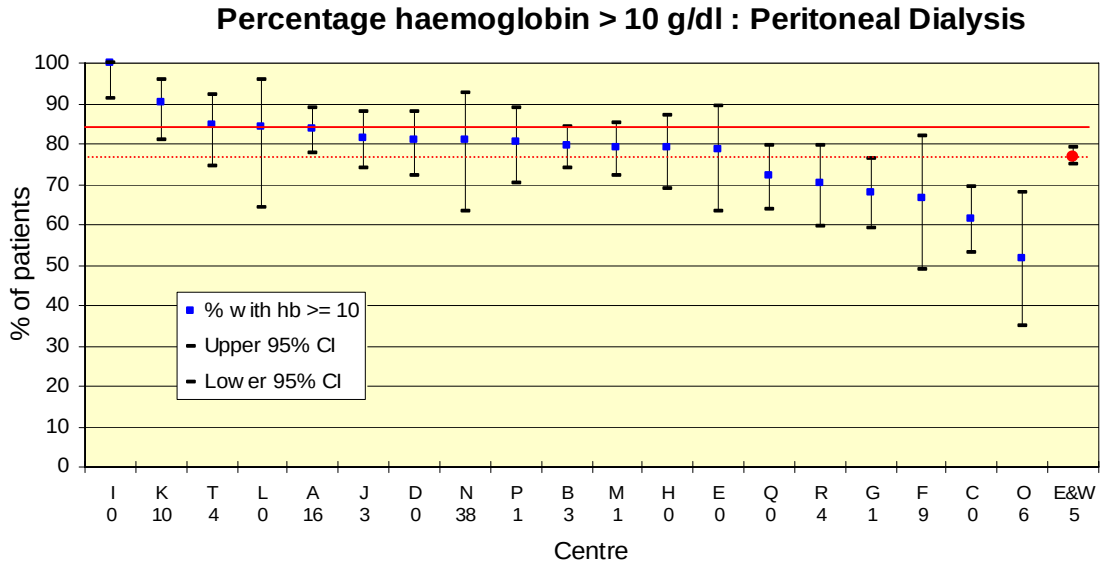


Figure 13.3 Percentage patients with haemoglobin > 10g/dl on peritoneal dialysis

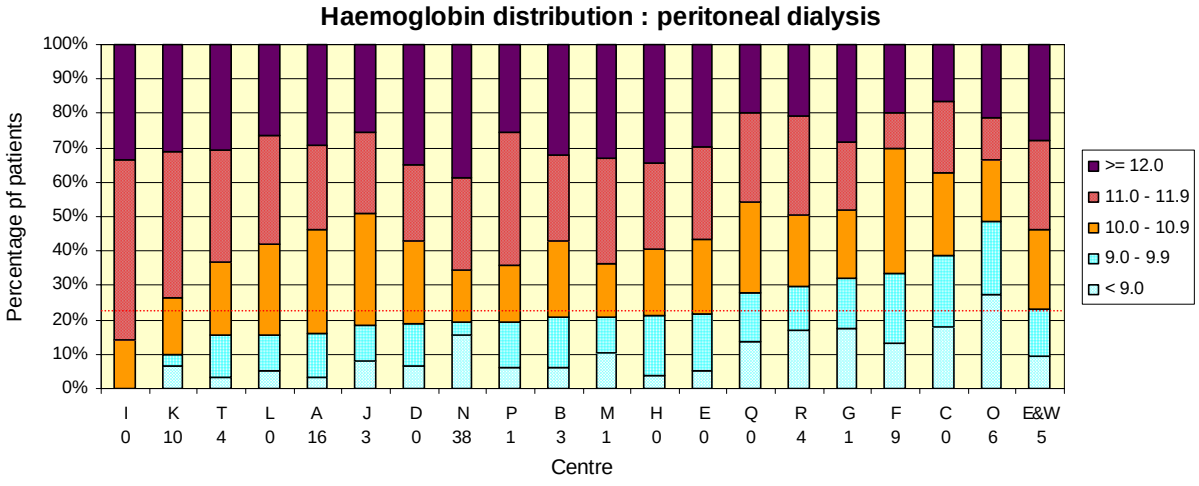


Figure 13.4 Haemoglobin distribution on peritoneal dialysis

Albumin

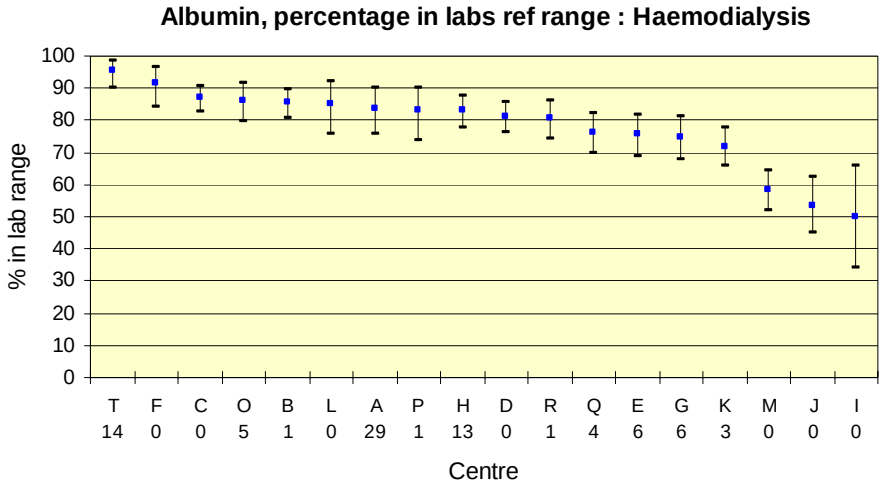


Figure 13.5 Percentage albumin in lab reference range for haemodialysis

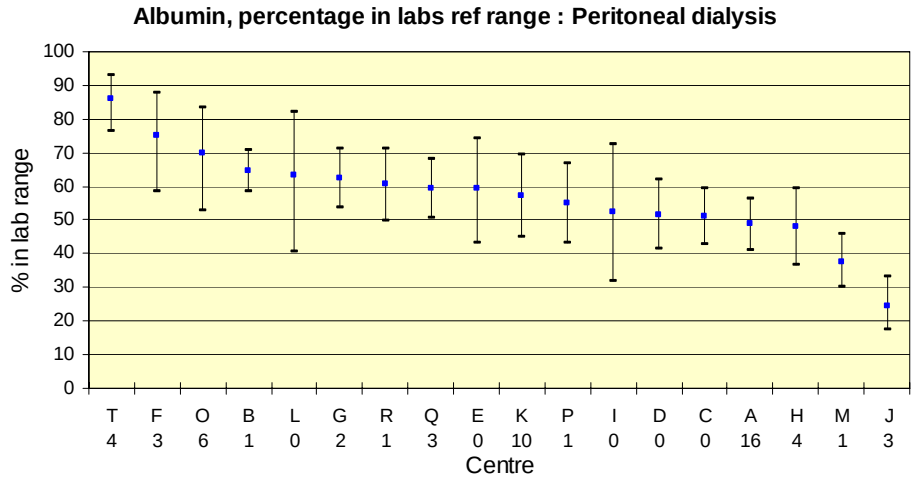


Figure 13.6 Percentage albumin in lab reference range for peritoneal dialysis

Bicarbonate

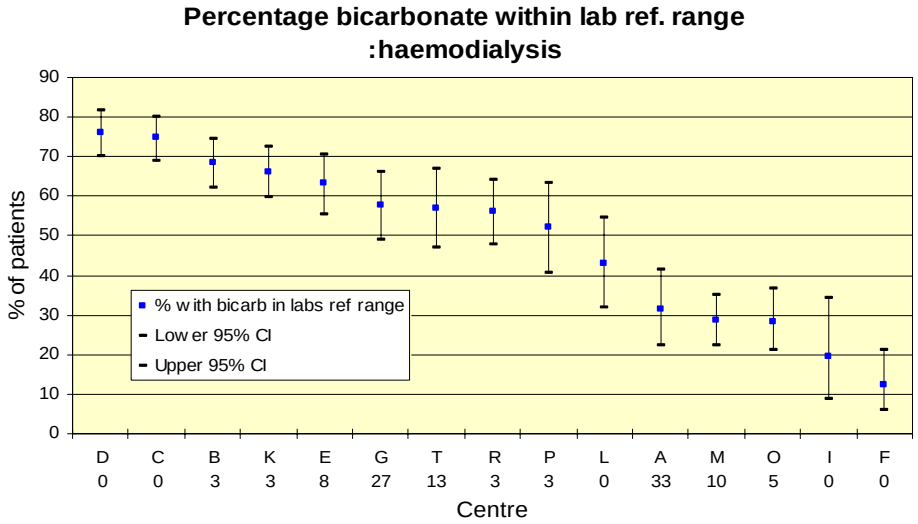


Figure 13.7 Percentage bicarbonate in lab reference range for haemodialysis

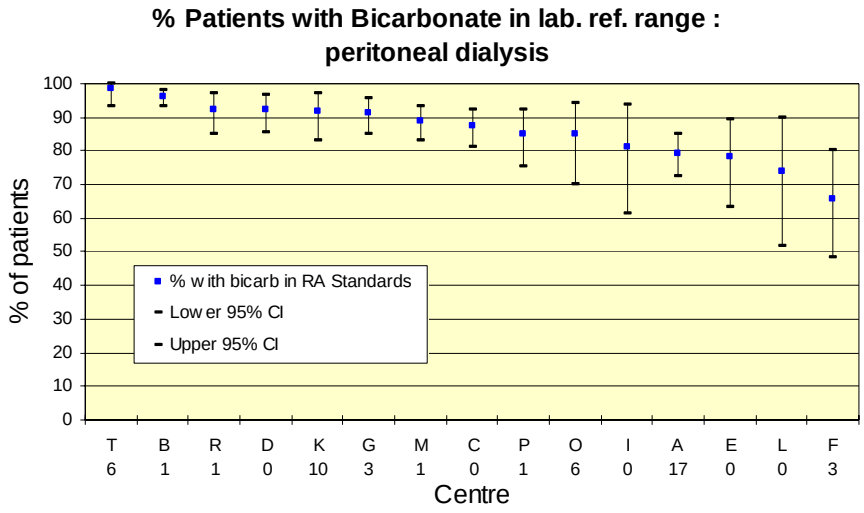


Figure 13.8 Percentage bicarbonate in lab reference range for peritoneal dialysis

Calcium

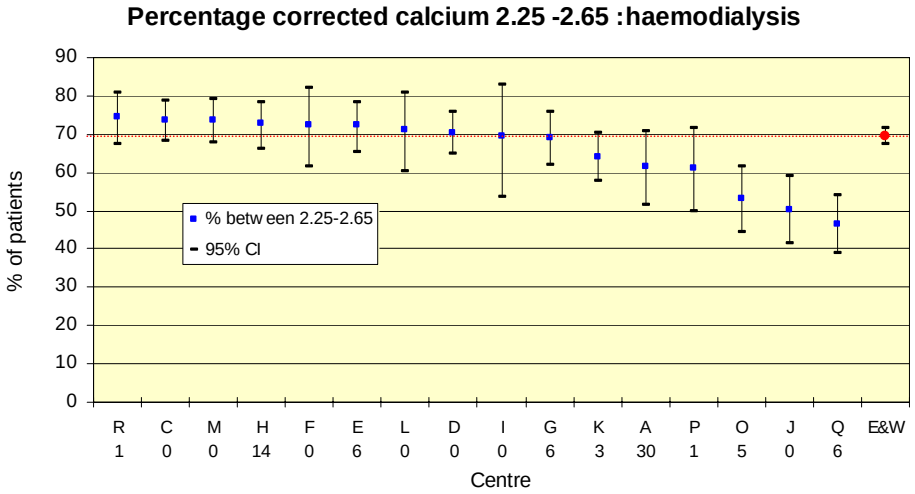


Figure 13.9 Percentage corrected calcium in 2.25-2.65 for haemodialysis

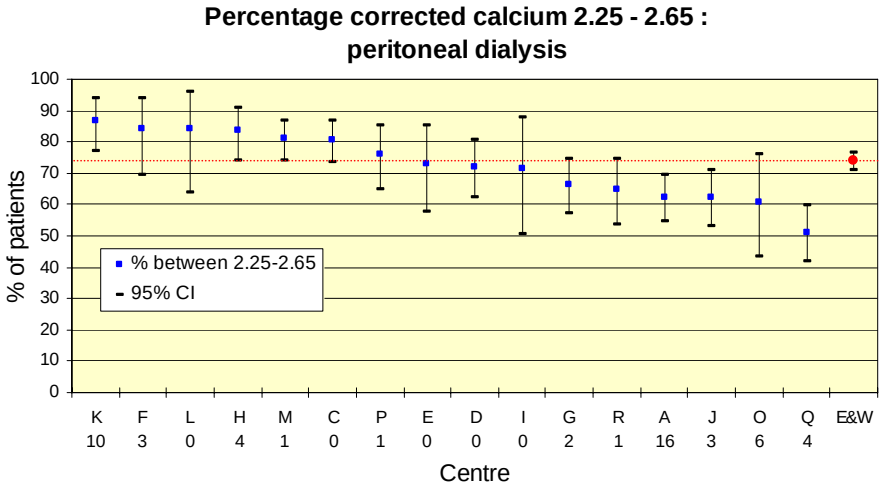


Figure 13.10 Percentage corrected calcium in 2.25-2.65 for peritoneal dialysis

Phosphate

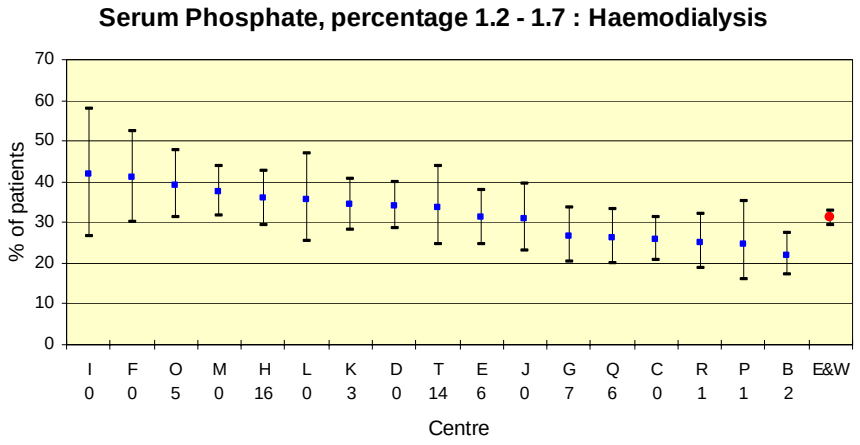


Figure 13.11 Percentage serum phosphate in range 1.2-1.7 for haemodialysis

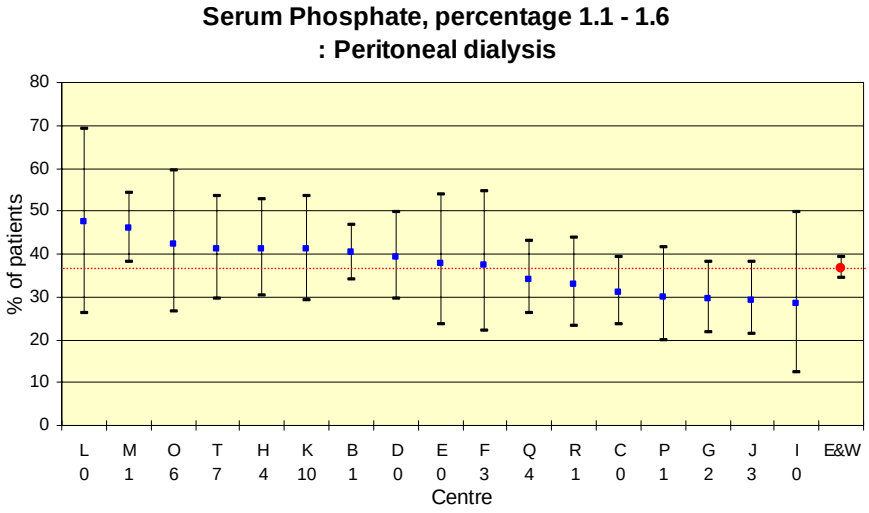


Figure 13.12 Percentage serum phosphate in range 1.1-1.6 for peritoneal dialysis

Intact parathyroid hormone

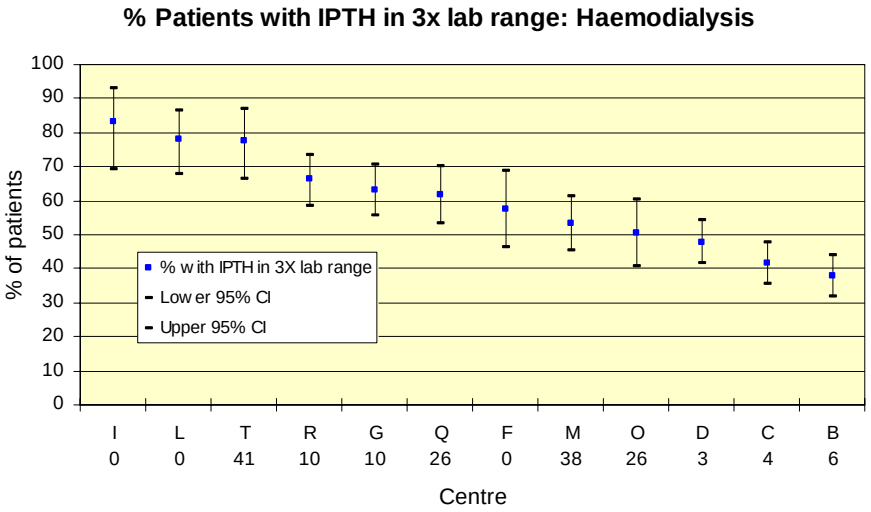


Figure 13.13 Percentage iPTH in 3x lab range for haemodialysis

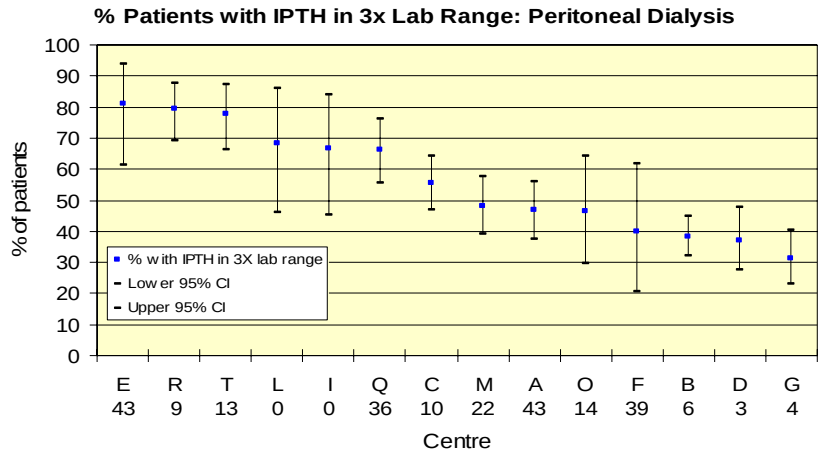


Figure 13.14 Percentage iPTH in 3x lab range for peritoneal dialysis

Blood Pressure

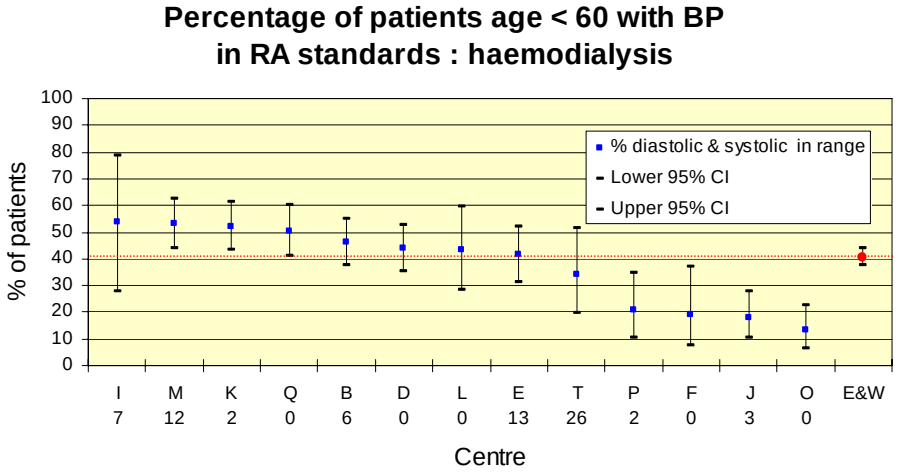


Figure 13.15 Percentage haemodialysis patients age < 60 with BP in RA Standard range

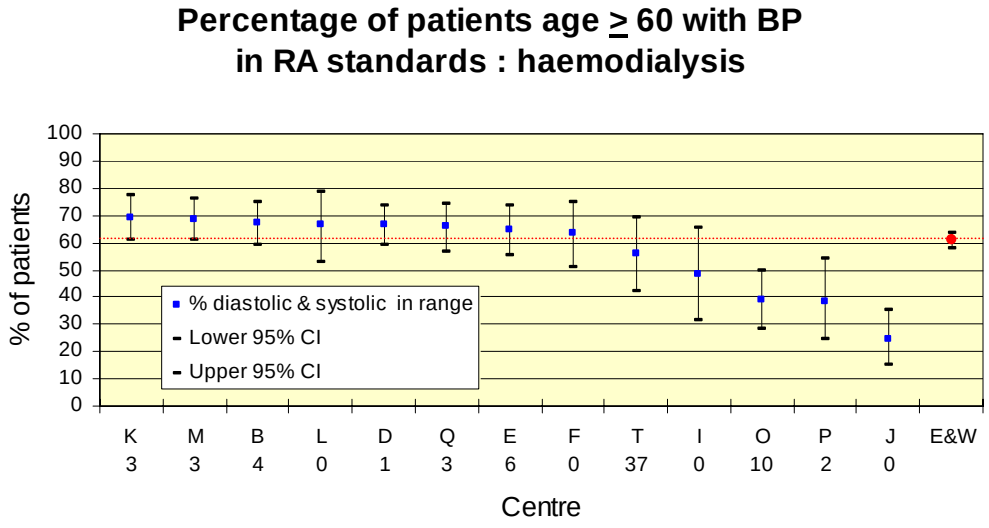


Figure 13.16 Percentage patients age ≥ 60 with BP in RA Standard on haemodialysis

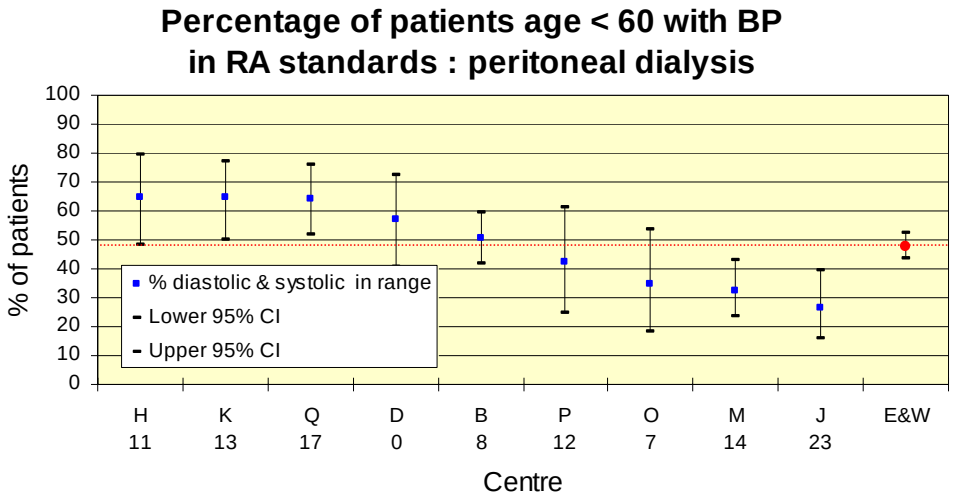


Figure 13.17 Percentage pts age < 60 with BP in RA Standard on peritoneal dialysis

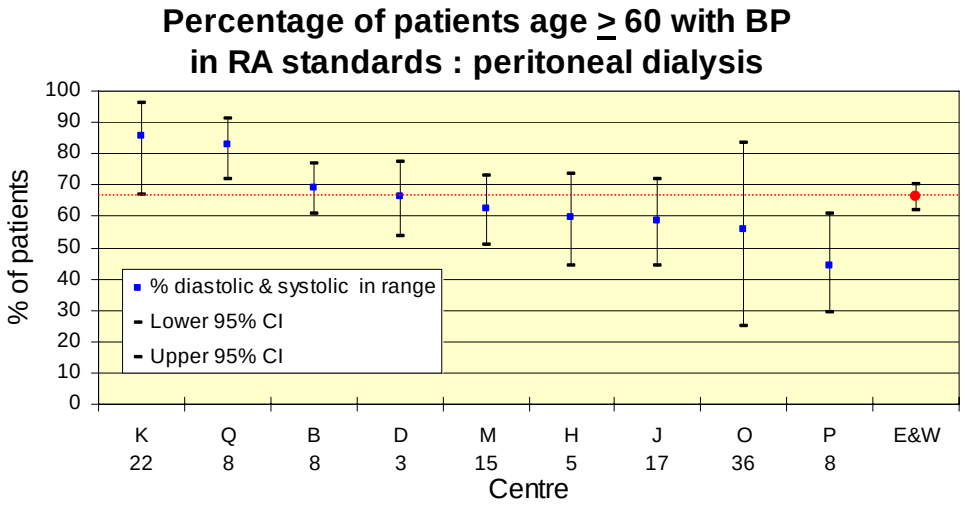


Figure 13.18 Percentage pts age ≥ 60 with BP in RA Standard on peritoneal dialysis

Dialysis Adequacy

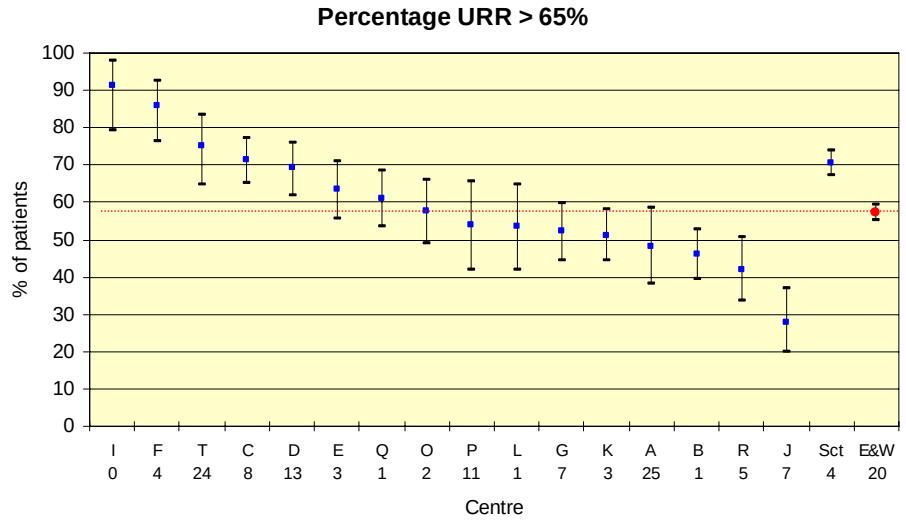


Figure 13.19 Percentage URR > 65%

Statistical analysis

Methodology

Chi-squared tests were used to see whether the percentage of patients with data in a given range varied significantly between centres.

Haemoglobin

A chi-squared test was used to determine whether the percentage of patients with haemoglobin ≥10g/dl differed between centres.

For patients on HD, the percentage of patients with haemoglobin ≥10g/dl was found to differ significantly between centres ($X^2 = 164.0$, d.f. = 17, $p<0.001$).

For patients on PD, the percentage of patients with haemoglobin ≥10g/dl was found to differ significantly between centres ($X^2 = 64.5$, d.f. = 18, $p<0.001$).

Ferritin

A chi-squared test was used to determine whether the percentage of patients with ferritin ≥100 mcg/L differed between centres.

For patients on HD, the percentage of patients with ferritin ≥100 was found to differ significantly between centres ($X^2 = 352.1$, d.f. = 17, $p<0.001$).

For patients on PD, the percentage of patients with ferritin ≥100 was found to differ significantly between centres ($X^2 = 93.7$, d.f. = 18, $p<0.001$).

Albumin

A chi-squared test was used to determine whether the percentage of patients with albumin below and greater than or equal to the labs lower reference range limit differed between centres. Note that centres using the BCP method to measure albumin have been included in the analysis since the labs reference range has been used in the analysis.

For patients on HD, the percentage of patients with albumin greater than or equal to the labs lower reference range limit differed significantly between centres ($X^2 = 184.2$, d.f. = 17, $p<0.001$).

For patients on PD, the percentage of patients with albumin greater than or equal to the labs lower reference range limit differed significantly between centres ($X^2 = 113.2$, d.f. = 17, $p<0.001$).

Bicarbonate

A chi-squared test was used to determine whether the percentage of patients with bicarbonate within the Standard varied between centres. For this analysis, note that the patients were categorised as having bicarbonate within the Standard or not having a bicarbonate within the Standard (regardless of whether the patient's bicarbonate was below or above the Standard). Note that the Standards are different for HD and PD.

For patients on HD, the percentage of patients with bicarbonate within the Standard differed significantly between centres ($X^2 = 292.4$, d.f. = 14, $p<0.001$).

For patients on PD, the percentage of patients with bicarbonate within the Standard differed significantly between centres ($X^2 = 63.7$, d.f. = 14, $p<0.001$).

Phosphate

For patients on HD, a chi-squared test was used to determine whether the percentage of patients with phosphate ≤ 1.70 mmol/L differed between centres. For patients on PD, a chi-squared test was used to determine whether the percentage of patients with phosphate ≤ 1.60 mmol/L differed between centres. Note that the analysis considered lab-harmonised phosphate.

For patients on HD, the percentage of patients with phosphate ≤ 1.70 mmol/L differed significantly between centres ($X^2 = 100.7$, d.f. = 16, $p<0.001$). [Note this does not fit in with text in the Report for phosphate.]

For patients on PD, the percentage of patients with phosphate ≤ 1.60 mmol/L differed significantly between centres ($X^2 = 34.4$, d.f. = 16, $p=0.005$). [Note this does not fit in with text in the Report for phosphate.]

PTH

A chi-squared test was used to determine whether the percentage of patients with PTH ≤ 22.8 pmol/L differed between centres. Note that the analysis considered lab harmonised PTH.

For patients on HD, the percentage of patients with PTH ≤ 22.8 pmol/L differed significantly between centres ($X^2 = 96.7$, d.f. = 11, $p<0.001$).

For patients on PD, the percentage of patients with PTH ≤ 22.8 pmol/L differed significantly between centres ($X^2 = 55.9$, d.f. = 13, $p<0.001$).

URR

A chi-squared test was used to determine whether the percentage of patients with URR ≥ 65% differed between centres. This analysis only included the English and Welsh Units.

The percentage of patients with URR ≥ 65% was found to vary significantly between centres ($X^2 = 148.2$, d.f. = 15, $p<0.001$).

Blood Pressure

A chi-squared test was used to determine whether the percentage of patients with both systolic and diastolic blood pressure within range differed between centres. Note that the analysis for transplant patients excluded patients who had a transplant in 1998.

For patients on HD, aged 60 or more, the percentage of patients reaching the Standard for both systolic and diastolic blood pressure differed significantly between centres ($X^2 = 79.4$, d.f. = 12, $p<0.001$).

For patients on HD, aged under 60, the percentage of patients reaching the Standard for both systolic and diastolic blood pressure differed significantly between centres ($X^2 = 69.5$, d.f. = 12, $p<0.001$).

For patients on PD, aged 60 or more, the percentage of patients reaching the Standard for both systolic and diastolic blood pressure differed significantly between centres ($X^2 = 21.8$, d.f. = 8, $p=0.005$).

For patients on PD, aged under 60, the percentage of patients reaching the Standard for both systolic and diastolic blood pressure differed significantly between centres ($X^2 = 36.8$, d.f. = 8, $p<0.001$).

Chapter 14 International Comparisons with UK Renal Registry Data

Introduction

There are very few contemporary sources dealing with clinical variables on a large scale. The data derived from National Medical Care by Lowrie et al is now less current. The most comparable data are collected annually by the Healthcare Finance Administration (HCFA) in the USA as part of the now superseded ESRD Clinical Indicators Project (CIP) and material is available from the 1998 Report, which encompasses the past five years. The Registry presents here some selected comparative data that will form the basis of a more extended treatment in future.

Scope of the international comparison

The ESRD CIP was a large-scale data collection from a random sample of 400 prevalent dialysis patients from each of 18 Regional 'Networks' (approximately 4-9 patients from each chosen centre) serving the End Stage Renal Disease programme in the US. This gave a study population of over 9000 patients to compare with the UK Renal Registry dialysis patient group (which includes all patients at participating centres) of nearly 5300. The HCFA return was on paper and the sample included haemodialysis and peritoneal dialysis patients, in the ratio of 5:1. The data were focused on dialysis solute clearance, renal anaemia (haematocrit / haemoglobin, serum ferritin, EPO administration), serum albumin and blood pressure. Dialysis dose was calculated as URR, and as Kt/V from dialyser characteristics, treatment time and blood flow data. The method for serum albumin measurement is indicated to allow for the variation between bromocresol green and bromocresol purple.

It is important to note that the HCFA results are the means of three, monthly records (allowing for incompleteness of return), whereas the UK data are single point values. The figures show comparative data for the UK and the HCFA random sample in several categories. The range of renal unit size and funding regulations for reimbursement may be relevant factors in determining standards of care, but comparative data on these are not presented here.

The HCFA data are a series of cross-sectional studies. Sequential data on individual patients are not collected. Thus data relating to time on dialysis are from patients all alive at the date of data collection who have been on renal replacement therapy for variable periods of time. There are no data from the same patient at different time points.

Urea reduction ratio in haemodialysis

The URR ranges for the USA bear comparison with the distributions of England and Wales, and Scotland. There is a shift of the curve to the right in the US data, with a more pronounced truncation of high values in the 'snail' shaped distributions. The US

data is more comparable to the data from Scotland and this may reflect the cycles of comparative audit of dialysis adequacy carried out in over the last 5 years in Scotland. More than a quarter of the mean URRs in the HCFA data are below 65%, but this percentage is reduced when calculated for Kt/V > 1.2, since URR 65% and Kt/V 1.2 are not exactly equivalent. Since 1993 the annual US data collection has shown a steady increase in URR values, with the use of longer dialysis times and dialysers of greater clearance.

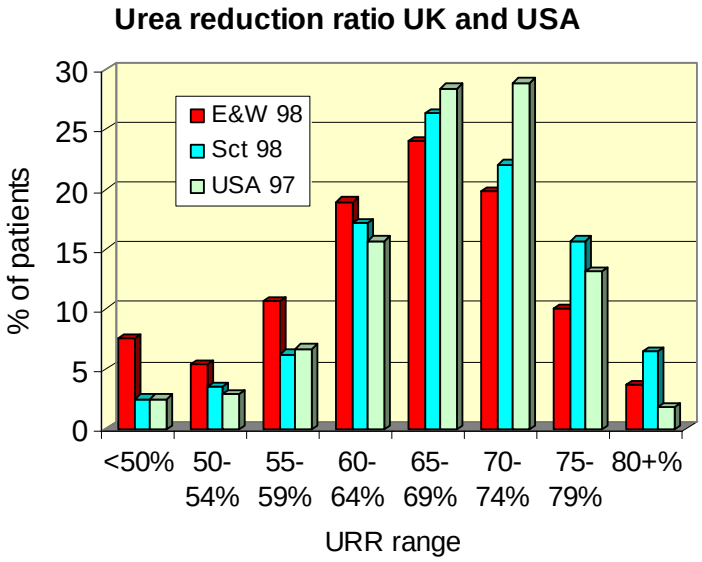


Figure 14.1 URR in the UK and USA

Renal Anaemia

Haemoglobin / haematocrit

Haemoglobin data from the USA are often presented in terms of haematocrit, and 30% has been used as a criterion of adequate treatment there, just as 10g/dl was used in the Renal Association Standards Document. These two values are not identical. The 30% haematocrit is comparable with haemoglobin of 9.7g/dl and figure 14.2 shows the UK data compared with the HCFA data at that level.

The duration of renal replacement therapy is also relevant, since figures 14.2 and 14.3 show anaemia is more severe in patients in the first few months of renal replacement therapy than in those who have received renal replacement therapy for over one year.

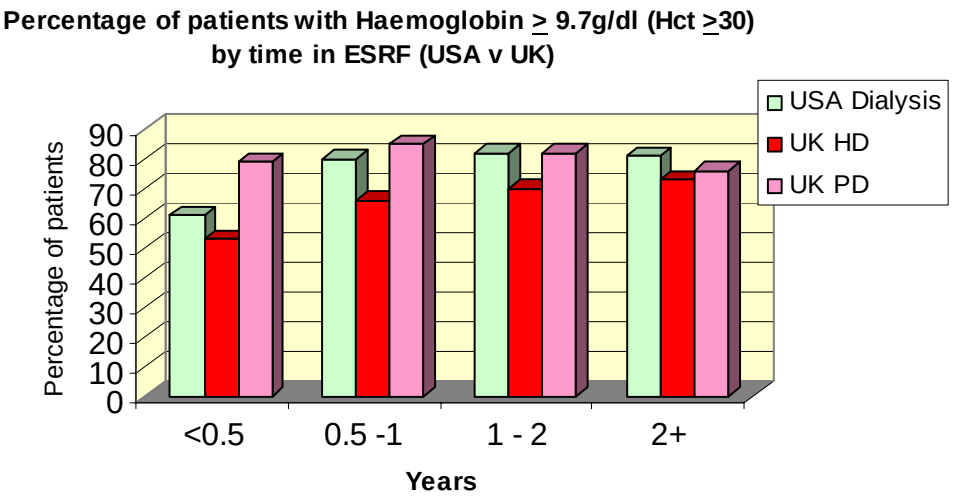


Figure 14.2 Haemoglobin > 9.7 g/dl comparison of UK vs. USA by time in ESRF

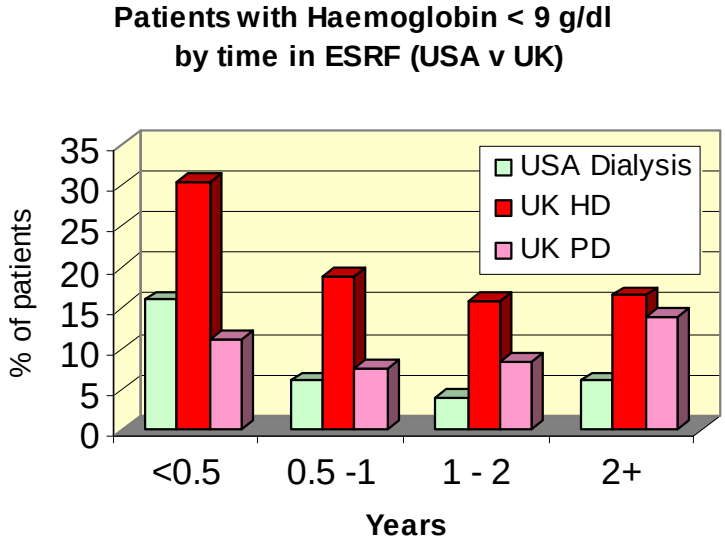


Figure 14.3 Haemoglobin < 9 g/dl comparison of UK vs. USA by time in ESRF

Serum ferritin

HCFA reports 81% of haemodialysis patients having a serum ferritin > 100 mcg/L, and this is comparable to 84% of UK Registry haemodialysis patients with a serum ferritin > 100 mcg/L. The distribution of serum ferritin for these patients is not available from HCFA

For patients on peritoneal dialysis, the distribution of serum ferritin of patients in the UK and US were very similar (figure 14.4).

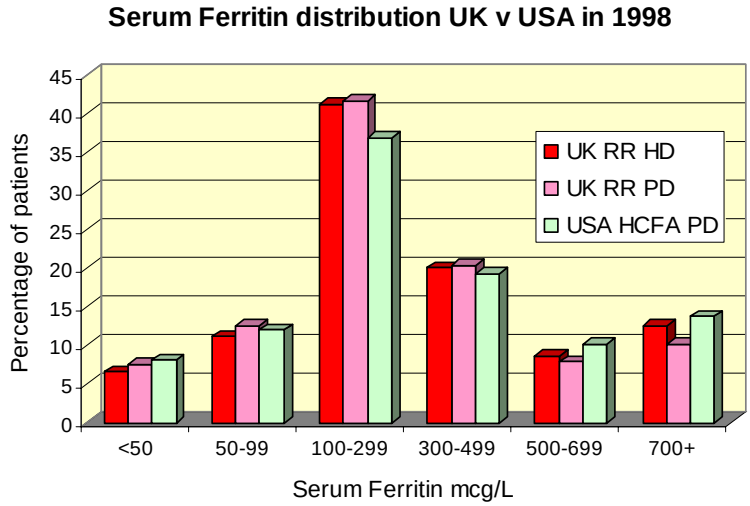


Figure 14.4 Serum Ferritin distribution UK vs. USA in 1998

Erythropoietin prescription data for the UK are not widely available from clinical databases as yet. In any event, the use of intravenous dosing in the US would make comparison with the subcutaneous administration typical of the UK less interpretable. There is a restriction on reimbursement for EPO for patients with higher haematocrits in the USA, which has a strong influence on prescribing protocols. This operates at haemoglobin levels which are not even reached in many UK renal units that are cash-limited.

Serum Albumin Concentration

The HCFA data show that US patients have relatively low serum albumin levels over the first year on renal replacement therapy. Haemodialysis patients in the UK do not show such a low serum albumin in this period (figure 14.5).

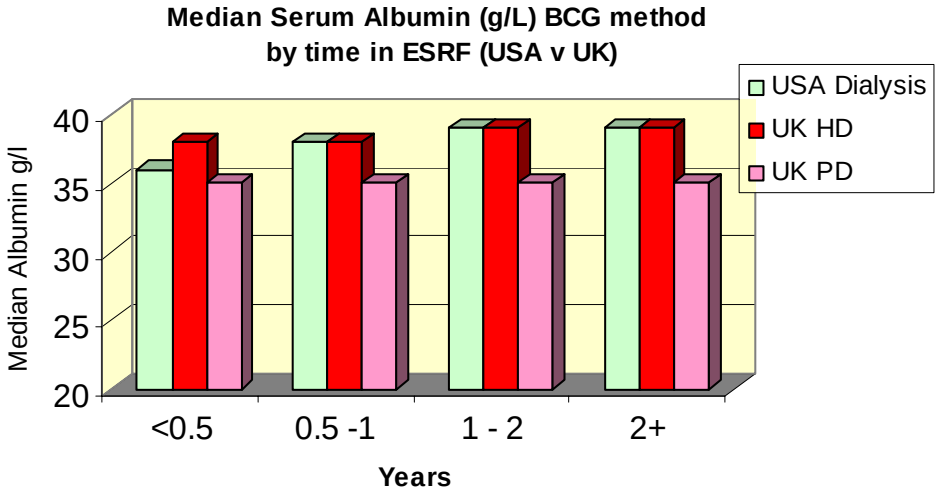


Figure 14.5 Median Serum Albumin BCG method by time in ESRF (USA vs. UK)

Transplantation

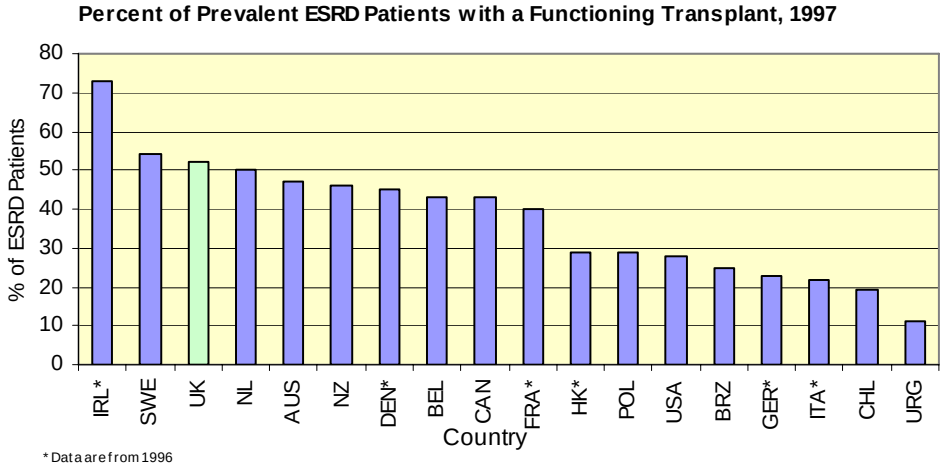


Figure 14.6 % prevalent CSRD patients with a functioning transplant in 1997

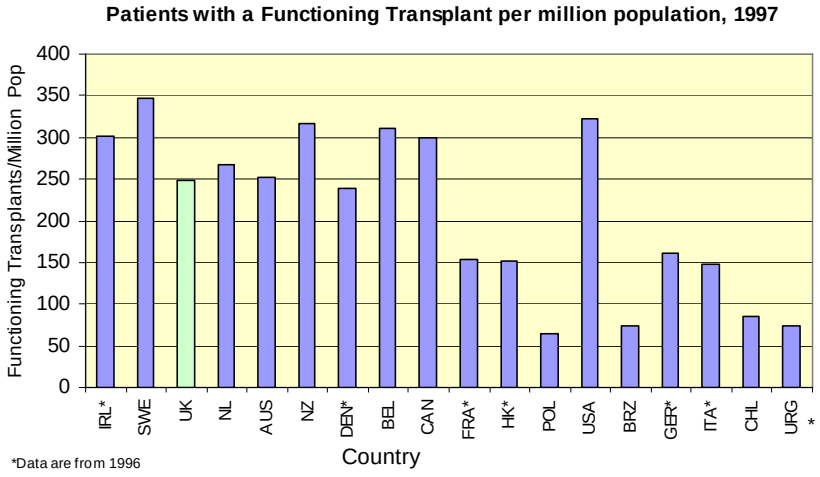


Figure 14.7 Patients with a functioning transplant per million population, 1997

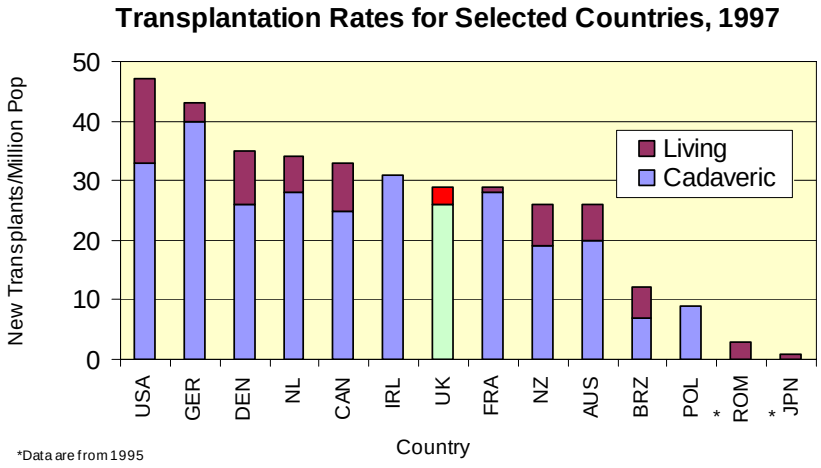


Figure 14.8 Transplantation rates for selected countries, 1997

The above figures rely heavily on the data presented in the 1999 USRDS Report. The USA has the highest transplant rate per million population (figure 14.8), but in spite of this, has one of the lowest percentages of renal replacement therapy patients with a functioning transplant (figure 14.6). This is the result of the large end stage renal failure

programme in the US. When analysed on the basis of function transplant per million population (figure 14.7) the US has one of the highest rates. In contrast, the UK has a high percentage of renal replacement therapy patients with a functioning transplant and this is mainly a legacy of the previously low percentage of patients starting renal replacement therapy compared with other countries. With the increase in these numbers and the acceptance of both older and less fit patients who are unsuitable for transplantation, the percentage of patients transplanted in the UK will decline. In addition there has also been a reduction in the number of cadaver donors in the UK with only a small compensatory increase in living related donors.

Conclusions

The clinical variables presented here show a picture that is very comparable between the random US sample of mean data and UK Registry single point values. This is despite major differences in the health care systems, if not in fundamental principles of treatment.

There is achievement of higher URR and haemoglobin in the US but the degree of difference between the UK and US is perhaps less than might have been expected. There is a significant non-compliance with Standards in each country. The HCFA data show a progressive improvement in URR from 1993 to 1997. How far this is the consequence of comparative audit or other factors that may have changed the aspirations of clinical staff is unknown.

The importance of adequate iron replacement appears to have been learned.

A more detailed analysis will be of interest in regard to gender, age and race. The availability of data from the new HCFA Clinical Performance Measures Project in 2000 will be of interest and the Renal Registry will work to broaden the scope of the variables that will be available for comparison with them.

References

1. Health Care Financing Administration. *1998 Annual Report, End Stage Renal Disease Core Indicators Project. D*epartment of Health and Human Services, Health Care Financing Administration, Office of Clinical Standards and Quality, Baltimore, Maryland.
2. Healthcare Systems: An International Review. Nephrol Dial Transplant 1999;14 (Suppl 6). Ed. Gokal R, Horl W, Lamiere N
3. Owen WF, Lew NL, Liu Y. Lowrie KG, Lazarus JM. The urea reduction ratio and serum albumin as predictors of mortality in patients undergoing haemodialysis. N Engl J Med 1993; 329: 1001-1006.
4. US Renal Data System, USRDS 1999 Annual Data Report

Chapter 15: Report of the Paediatric Renal Registry 1999

Prepared by Dr M Lewis

Introduction

In parallel with the creation of the National Renal Registry, the British Association for Paediatric Nephrology (BAPN) has established a Paediatric Registry. The pattern of diseases and requirements of paediatric patients are very different to those of adult patients and care is much more centralised in regional units. Although patient numbers are relatively small, gathering data is problematic as, unlike adult units, there was no one predominant information management system in use from which data can be downloaded. Therefore a separate Paediatric Registry was created to facilitate data collection, and knowing that overall numbers were small, a separate database was written. This database was created so that it would specifically deal with all paediatric requirements and automatically calculates important parameters, such as predicted glomerular filtration rate (pGFR), height, weight and body mass index standard deviation scores. The field format of the database is compatible with the National Registry, so that it will be possible to download paediatric data as a block into the National Registry. This will become important as more children with renal failure reach adulthood and hopefully it will allow a complete data set to be available within the National Renal Registry for these patients.

Over the past 3 years, the database has been written and installed in all 13 centres in the United Kingdom dealing with children with end stage renal failure (ESRF). It has also been installed in Dublin and the data set to be presented includes data from Dublin which deals with all paediatric ESRF for Eire.

This report includes a complete data set of demographic data, details of diagnoses and details of initial ESRF management from all centre involved. The data refer to patients under the age of 18 years and currently under treatment up to August 1999.

The BAPN recently commenced the collection of time-line data on all current patients and this will be available for analysis in the next 12 months.

The paediatric ESRF population

Assessment of the size of the paediatric ESRF population is hampered by varying patterns of referral for teenagers and varying attitudes to ESRF in neonates. There is probably complete referral of patients between the ages of 1 and 15 years to paediatric nephrology centres. Between the ages of 15 and 18 years, referral is incomplete and many patients will be referred directly to an adult nephrology centre. In some cases, this of course, will be entirely appropriate, in others it could lead to a failure to look in detail at specific paediatric problems, such as, growth and puberty. It will only be possible to ascertain the extent of this problem when the paediatric data sets and adult data sets are both complete and are amalgamated. With regard to infants with ESRF, not all neonatal units would routinely refer such patients to paediatric nephrology

centres as attitudes to ESRF management from birth vary. In addition, there will be a number of patients who either commence management but die before 90 days of age or in whom, because of associated abnormalities or specific complications, a positive decision is made not to pursue ESRF management. At present, there is no estimate of the size of this group. To try and ascertain this for the future, a specific field has been added to the paediatric database to allow entry of these patients so that this subgroup can be subsequently analysed. Initially this will provide data on those infants who are referred to paediatric nephrology centres but either die early or are not offered ESRF treatment for positive reasons. To define the group of patients not referred will need specific liaison with all neonatal and paediatric units.

The ESRF population, under 18 years of age on the 1st August 1999 is shown in Table 15.1 with the population broken down according to age and sex. It can be seen that the total under 18 year old population stood at 755. Of these, 532 were under the age of 15. This is an increase of 24% since 1992 when an audit placed the number at 429. As with all other studies of paediatric ESRF, males far outweigh females; the male to female ratio being 1.76:1, which is similar to the adult ratio. There is still a great male predominance when specific diagnoses, such as, posterior urethral valves and prune belly syndrome are excluded from the data analysis. This appears to be explained by a higher incidence of renal dysplasia in males (see Diagnosis section). Figure 15.1 shows the age distribution of the patients graphically. There is a steady increase of population size with age reflecting both the continued presentation of ESRF throughout childhood and the prolonged survival of patients with renal failure in the first few years of life. The fall in numbers after the age of 15 years, reflects both the variable referral of older patients to Adult Units and the variable age at which patients who commence ESRF management in childhood are referred on to Adult Units.

Age Group	Males	Females	Total
<2 years	11	7	**18**
2 – 5 years	37	11	**48**
5 – 10 years	103	52	**155**
10 – 15 years	188	123	**311**
15 – 18 years	142	81	**223**
All Ages	**481**	**274**	**755**

Table 15.1 Age and sex distribution of the paediatric ESRF population

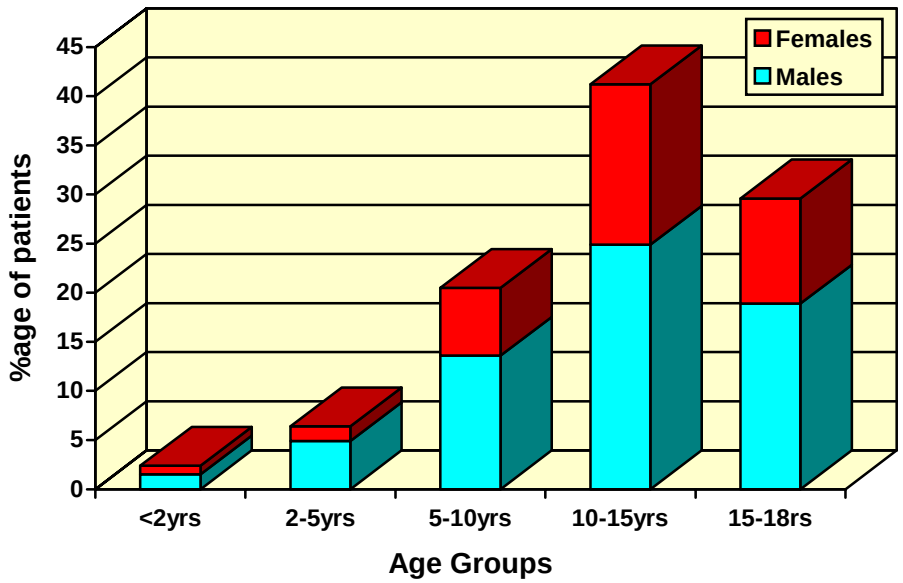


Figure 15.1 Age distribution of the current paediatric ESRF population

Table 15.2 shows the prevalence of ESRF in the paediatric population and the annual take-on rate as judged by an average of the last 3 years. For this analysis, patients from Eire were excluded. It can be seen that within the UK the prevalence is 12.2 per million of the population with a take-on rate of 1.7 per million total population. When looked at in terms of the paediatric population, the take-on rate across all ages is between 5.2 and 7.5 per million children. The prevalence varies from 13.6 per million in the under 4 year old population to 53.4 per million in the under 18 year old population. This latter figure will almost certainly be an under-estimate due to the direct referral of young people between the ages of 15 and 18 years to adult services.

	Population	Patients	New Patients	Prevalence (per million)	Take On Rate (per million)
Whole UK Population	59,236,522	725	101	12.2	1.7
Population <18yrs old	13,582,356	725	101	53.4	7.4
Population <14yrs old	11,379,835	434	82	38.1	7.2
Population <9yrs old	7,584,382	169	41	22.3	5.5
Population <4yrs old	3,670,665	50	21	13.6	5.7

Table 15.2 Prevalence of ESRF and take on rate to the paediatric ESRF programme

Reporting of ethnicity was incomplete and data was only available for 690 patients (91.4% of the population). Table 15.3 shows this broken down into a crude sub-grouping of patients from the Asian sub-continent, Black patients, White patients and Others. The percentages in each group have been compared to data obtained from the Office for National Statistics for 1995-7. It can be seen that patients from the Asian sub-continent are very much over-represented. This is presumably secondary to an increase in inherited disorders related to a high frequency of consanguineous marriage.

Also attitudes to termination of pregnancy after antenatal diagnosis vary widely. Finding a 10% prevalence of Asian patients with ESRF in the paediatric population has significant implications for health care and provision.

	Males	Females	Total	% age Patients	Population Distribution
Asian Subcontinent	40	31	71	10.3%	4.7%
Black	7	6	13	1.9%	3.0%
White	380	210	590	85.5%	90.6%
Other	11	5	16	2.3%	1.7%

Table 15.3 Ethnic mix of the paediatric ESRF population

Primary ESRF diagnoses in prevalent patients

Primary ESRF diagnoses were available in 683 (90.5%) of cases. To avoid erroneous coding a specific diagnostic list was created by the BAPN Registry Sub-Committee and these word terms were then mapped to ICD 10 Read 2 and EDTA codes. Diagnoses were selected from sub-categorised pick-lists to avoid the entry of misleading or variable terminology. In all, 73 diagnoses were available; these being divided amongst 7 diagnostic groups.

For the patients coded 52 diagnoses were used. Table 15.4 lists the diagnoses in alphabetical order together with the frequency of their usage and sex distribution. Table 15.5 shows the same data in a sub-categorised format**.** The most common cause of renal failure in the paediatric population is renal dysplasia; this accounting for almost 28% of cases. In 20% this was isolated renal dysplasia and in the rest it was renal dysplasia associated with other conditions. Overall, there was a 2:1 ratio of males to females with renal dysplasia and even discounting syndromic diagnoses, such as, prune belly syndrome which only occur in boys, the ratio remained 1.8:1.

Obstructive uropathy was the next most common cause accounting for 20.2% of cases. Of these, 15.7% were secondary to posterior urethral valves. Once this latter condition had been excluded, there was no difference in the incidence of renal failure secondary to obstructive uropathy between the sexes. The finding that 48% of paediatric ESRF is secondary to either renal dysplasia or obstructive uropathy is not new and emphasises the need for research in these specific areas to allow the potential of antenatal diagnosis and treatment.

Glomerulopathies, the most common cause of renal failure in adult practice, accounted for 17% of the paediatric population. As can be seen the spectrum of disease is quite wide and the only frequently seen condition is primary focal segmental glomerulo-sclerosis at 6.4% of the total population.

Reflux nephropathy, previously one of the most common causes of ESRF, now accounts for only 7.2% of cases and even if including those patients presented with unexplained ESRF, the total only amounts to 9.2%. This may be due to increased awareness of the problems of urinary tract infection in childhood and earlier intervention. Alternatively it may be due to altered classification. Nephronophthisis, a condition often associated

with renal failure of uncertain aetiology and a frequent differential diagnosis in a patient presenting with small kidneys and renal failure in later childhood, was stated to be the primary cause of ESRF in 5.3% of cases. Thus the total frequency of reflux nephropathy, nephronophthisis and renal failure of uncertain aetiology is 14.5%.

Congenital nephrotic syndrome is a condition which was always associated with early death and is most frequently seen in Finland. With the advent of aggressive therapy, including daily intravenous albumin infusions followed by early bilateral nephrectomy and dialysis and transplantation, the numbers of children surviving with this condition are increasing. In this survey, congenital nephrotic syndrome accounted for 6.9% of patients. It was noticeable that there was marked geographic variability in the frequency of this condition, the maximum being in Ireland, where it accounted for 18.6% of all the cases of ESRF.

Cystinosis and recessive polycystic kidney disease are the other two common inherited disorders seen but these each only account for 2% of cases.

Diagnosis	Males	Females	Total
Acquired obstructive uropathy	2	0	**2**
Alport's syndrome	6	2	**8**
Anti-GBM disease	0	2	**2**
Autosomal recessive PKD	7	5	**12**
Barrter's syndrome	1	1	**2**
Branchio-oto-renal syndrome	1	1	**2**
Chronic renal failure - uncertain aetiology	6	8	**14**
Cis-platinum toxicity	1	0	**1**
Congenital nephrotic syndrome (DMS)	5	1	**6**
Congenital nephrotic syndrome (Finnish)	10	8	**18**
Congenital nephrotic syndrome (FSGS)	1	4	**5**
Congenital nephrotic syndrome (unspecified)	4	14	**18**
Congenital obstructive uropathy - Bladder outlet obstruction (not PUV)	4	3	**7**
Congenital obstructive uropathy (not bladder outlet obstruction)	5	3	**8**
Congenital obstructive uropathy - Posterior urethral valves	107	0	**107**
Cortical necrosis	9	4	**13**
Crescentic glomerulonephritis	1	5	**6**
Cyclosporin Nephrotoxicity	2	0	**2**
Cystinosis	8	6	**14**
D+ Haemolytic uraemic syndrome	10	10	**20**
D neg Haemolytic uraemic syndrome	2	0	**2**
Glomerulonephritis (unspecified)	3	1	**4**
Henoch Schoenlein nephritis	7	4	**11**
IgA nephropathy	1	2	**3**
Lawrence Moon Biedl syndrome	2	2	**4**
Megacystis megaureter	1	0	**1**
Mesangio-capillary glomerulonephritis Type 1	2	1	**3**
Mesangio-capillary glomerulonephritis Type 2	2	4	**6**
Mesoblastic nephroma	1	0	**1**
Multicystic dysplastic kidneys	8	7	**15**
Nephronophthisis	24	12	**36**
Neuropathic bladder	6	8	**14**
Other cytotoxic drug nephrotoxicity	0	1	**1**
Polycystic kidney disease (other)	3	0	**3**
Primary focal segmental glomerulo-sclerosis	23	21	**44**
Primary hyperoxaluria type 1	2	1	**3**
Primary interstitial nephritis	5	3	**8**
Proliferative glomerulonephritis	2	3	**5**
Prune belly syndrome	15	0	**15**
Reflux nephropathy	21	28	**49**
Renal artery stenosis	2	2	**4**
Renal artery thrombosis	1	1	**2**
Renal dysplasia	92	47	**139**
Renal hypoplasia	7	6	**13**
Renal trauma	1	1	**2**
Renal tubular acidosis	3	0	**3**
Renal vein thrombosis	6	4	**10**

Diagnosis	Males	Females	Total
Tubular disorders (other)	1	0	**1**
Vasculitis (unspecified)	0	3	**3**
Wegner's granulomatosis	0	1	**1**
Wilms' nephropathy	1	1	**2**
Wilms' tumour	4	4	**8**
Totals	**438**	**245**	**683**

Table 15.4 Diagnoses causing ESRF in the paediatric population

Diagnostic Group	Males	Females	Total	% of Total
Renal Dysplasia and related conditions				
Renal dysplasia	92	47	**139**	**20.4%**
Multicystic dysplastic kidneys	8	7	**15**	**2.2%**
Prune belly syndrome	15	0	**15**	**2.2%**
Renal hypoplasia	7	6	**13**	**1.9%**
Lawrence Moon Biedl syndrome	2	2	**4**	**0.6%**
Branchio-oto-renal syndrome	1	1	**2**	**0.3%**
Megacystis megaureter	1	0	**1**	**0.1%**
Total with Primary Renal Dysplasia	**126**	**63**	**189**	**27.7%**
Obstructive Uropathy				
Posterior urethral valves	107	0	**107**	**15.7%**
Neuropathic bladder	6	8	**14**	**2.0%**
Congenital obstructive uropathy (not BOO)	5	3	**8**	**1.2%**
Congenital bladder outlet obstruction (not PUV)	4	3	**7**	**1.0%**
Acquired obstructive uropathy	2	0	**2**	**0.3%**
Total with Obstructive Uropathy	**124**	**14**	**138**	**20.2%**
Glomerulonephritis, Vasculitis and Glomerulopathy				
Primary focal segmental glomerulo-sclerosis	23	21	**44**	**6.4%**
D+ Haemolytic uraemic syndrome	10	10	**20**	**2.9%**
Henoch Schoenlein nephritis	7	4	**11**	**1.6%**
Alport's syndrome	6	2	**8**	**1.2%**
Crescentic glomerulonephritis	1	5	**6**	**0.9%**
Mesangio-capillary glomerulonephritis Type 2	2	4	**6**	**0.9%**
Proliferative glomerulonephritis	2	3	**5**	**0.7%**
Glomerulonephritis (unspecified)	3	1	**4**	**0.6%**
IgA nephropathy	1	2	**3**	**0.4%**
Mesangio-capillary glomerulonephritis Type 1	2	1	**3**	**0.4%**
Vasculitis (unspecified)	0	3	**3**	**0.4%**
Anti-GBM disease	0	2	**2**	**0.3%**
D neg Haemolytic uraemic syndrome	2	0	**2**	**0.3%**
Wegner's granulomatosis	0	1	**1**	**0.1%**
Total with Glomerular Disease	**59**	**59**	**118**	**17.3%**
Reflux Nephropathy and CRF of Uncertain Aetiology				
Reflux nephropathy	21	28	**49**	**7.2%**
Chronic renal failure - uncertain aetiology	6	8	**14**	**2.0%**
Total with Reflux Nephropathy and CRF of Uncertain Aetiology	**27**	**36**	**63**	**9.2%**
Primary Tubular and Interstitial Disorders				
Nephronophthisis	24	12	**36**	**5.3%**
Primary interstitial nephritis	5	3	**8**	**1.2%**
Renal tubular acidosis	3	0	**3**	**0.4%**
Barrter's syndrome	1	1	**2**	**0.3%**
Tubular disorders (other)	1	0	**1**	**0.1%**
Total with Primary Tubular and Interstitial Disorders	**34**	**16**	**50**	**7.3%**
Congenital Nephrotic Syndrome				
Congenital nephrotic syndrome (Finnish)	10	8	**18**	**2.6%**
Congenital nephrotic syndrome (unspecified)	4	14	**18**	**2.6%**
Congenital nephrotic syndrome (DMS)	5	1	**6**	**0.9%**
Congenital nephrotic syndrome (FSGS)	1	4	**5**	**0.7%**
Total with Congenital Nephrotic Syndrome	**20**	**27**	**47**	**6.9%**
Renal Vascular Disorders				
Cortical necrosis	9	4	**13**	**1.9%**
Renal vein thrombosis	6	4	**10**	**1.5%**
Renal artery stenosis	2	2	**4**	**0.6%**
Renal artery thrombosis	1	1	**2**	**0.3%**
Renal trauma	1	1	**2**	**0.3%**
Total with Renal Vascular Disorders	**19**	**12**	**31**	**4.5%**
Metabolic Diseases and Drug Nephrotoxicity				
Cystinosis	8	6	**14**	**2.0%**
Primary hyperoxaluria type 1	2	1	**3**	**0.4%**
Cyclosporin Nephrotoxicity	2	0	**2**	**0.3%**
Cis-platinum toxicity	1	0	**1**	**0.1%**

Diagnostic Group	Males	Females	Total	% of Total
Other cytotoxic drug nephrotoxicity	0	1	**1**	**0.1%**
Total with Metabolic Diseases and Drug Nephrotoxicity	**13**	**8**	**21**	**3.1%**
Polycystic Kidney Disease				
Autosomal recessive PKD	7	5	**12**	**1.8%**
Polycystic kidney disease (other)	3	0	**3**	**0.4%**
Total with Polycystic Kidney Disease	**10**	**5**	**15**	**2.2%**
Malignant and Related Diseases				
Wilms' tumour	4	4	**8**	**1.2%**
Wilms' nephropathy	1	1	**2**	**0.3%**
Mesoblastic nephroma	1	0	**1**	**0.1%**
Total with Malignant and Related Diseases	**6**	**5**	**11**	**1.6%**

Table 15.5 Grouped ESRF diagnoses for the paediatric population

Commencement of ESRF treatment

Data on the age of commencement of ESRF management was available in only 79.2% of cases. In part, this is an expected problem due to an attempt now to document patients who may have been in renal failure for 10 years or more and whose early history is missing. It is to be hoped that with prospective data collection this figure will increase significantly. There is, however, a significant difference in the completeness of records between individual units and this is being addressed. Table 15.6 and Figure 15.2 show the age at commencement of ESRF treatment broken down according to age group and sex. It can be seen that the picture is very different to that shown in Figure 15.1. Although only 8.7% of the current ESRF population are currently under 5 years of age 38.8% of patients commenced ESRF treatment below the age of 5 years. The difference between these two distributions clearly shows the high incidence of ESRF in early childhood as one might expect from the diagnoses causing renal failure. The larger percentage of older patients in the age distribution of the population is a testament to the success of ESRF treatment in young patients and an explanation for the increase in the total population over the past decade. Figure 15.2 also clearly shows the preponderance of males which is most marked in those starting ESRF management early due to the timing of ESRF in the male predominated diagnoses of renal dysplasia and posterior urethral valves.

ESRF start age	Males	Females	Total	% of patients
<1yr	57	16	73	12.2%
1-2yrs	38	18	56	9.4%
2-5yrs	75	28	103	17.2%
5-10yrs	113	73	186	31.1%
10-15yrs	87	78	165	27.6%
15-18yrs	11	4	15	2.5%

Table 15.6 Age distribution of patients at the start of ESRF treatment

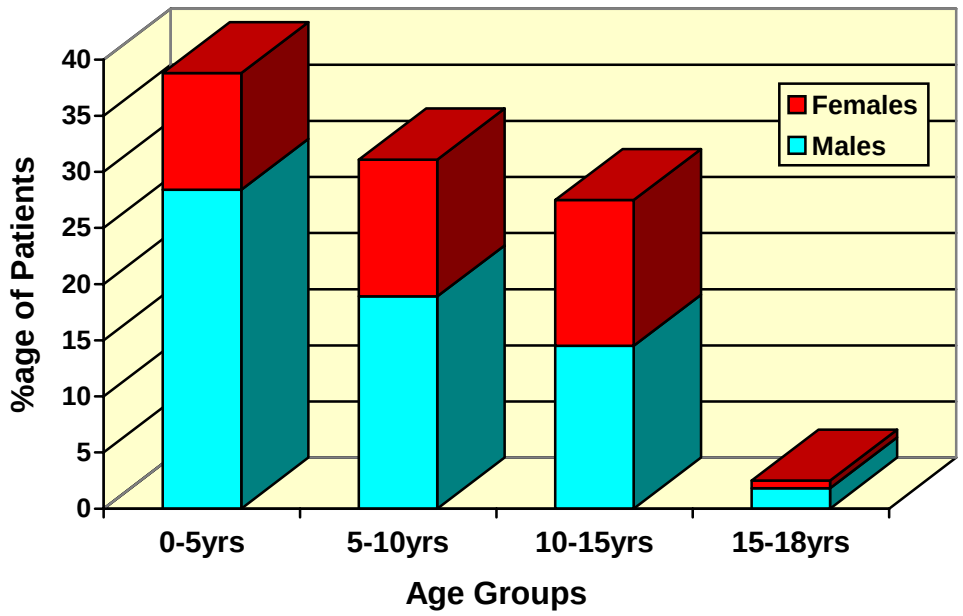


Figure 15.2 Age and sex distribution at the start of ESRF treatment

Details of treatment modality 90 days after entering an ESRF programme were available for 564 (74.7%) of patients. Again, it is to be hoped that the incompleteness of data in this field is secondary to the difficulty in extracting historic details and with prospective data collection, a more complete data return should be possible. Figure 15.3 shows the frequency of the different treatment modalities broken down according to age. Automated peritoneal dialysis is the most popular intervention in the infant and young child. After the age of 5, CAPD and haemodialysis become more common, though haemodialysis is the least common treatment over all age ranges. The proportion which have received a renal transplant by day 90, rises rapidly through childhood, reaching almost 30% in the 10-15 year old group. This represents the popularity of pre-emptive transplantation in paediatric practice though the number receiving renal transplants prior to any form of dialysis cannot be ascertained from this data set. Throughout the age ranges, between 3 - 7% of patients are receiving no dialysis and do not have a transplant on day 90. This group demonstrate the difficulty in maintaining dialysis in paediatric patients and the frequency with which patients are between interventions at any one point.

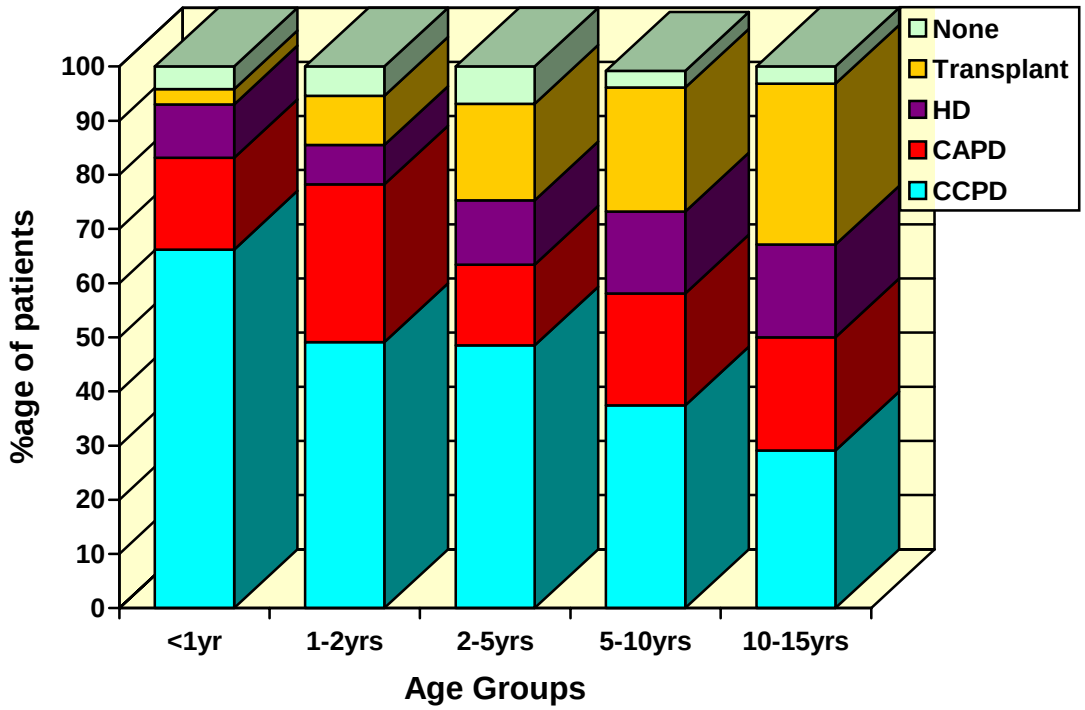


Figure 15.3 Treatment modality at day 90 according to age

Estimation of renal function has been made using the predicted GFR as calculated by the Schwartz formula to try to take account of varying size and body mass. The pGFR at the start of ESRF treatment was quite variable. Some of this is secondary to decisions based on rate of change of GFR, some to the need to perform bilateral nephrectomies (e.g. in congenital nephrotic syndrome) and some due to variability in symptomatology and growth. Figure 15.4 shows the median, interquartile range and range of pGFR at the start of ESRF management for patients broken down according to age group and whether the initial treatment was dialysis or a transplant. It can be seen that on the whole pGFR in those who had been transplanted by day 90 was higher than that in those on dialysis. This reached statistical significance in the 5 to 10 year old group (p=0.0157 Mann-Whitney U test) and in the 10 to 15 year old group (p=0.0008 Mann Whitney U test) and presumably reflects pre-emptive transplantation in these groups where patients are placed on the list in anticipation of needing dialysis and are transplanted before dialysis has become necessary.

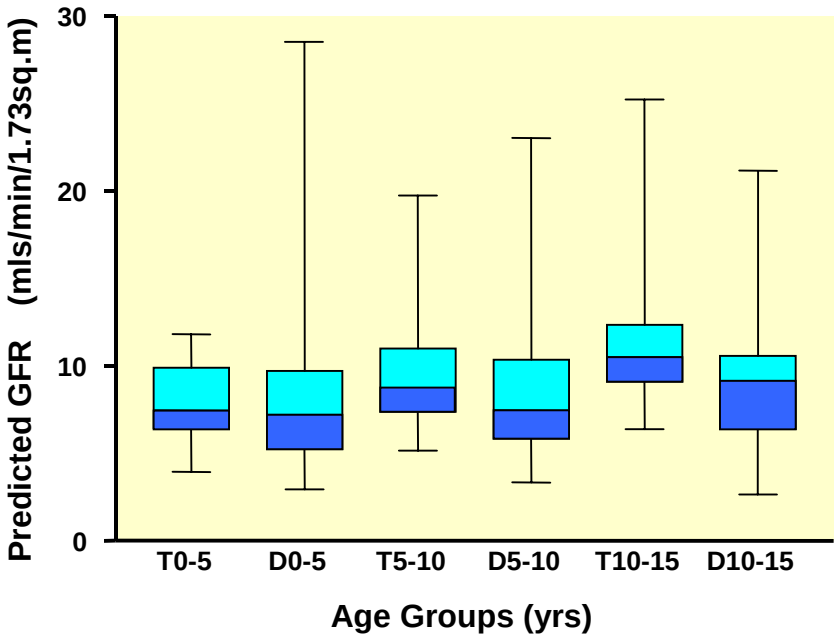


Figure 15.4 Predicted GFR start of ESRF treatment (Tx-y = transplant, Dx-y = dialysis)

Growth

Growth is a major problem in paediatric patients with renal failure. This was studied by heights with standard deviations (s.d.) from the mean for age and the change in standard deviation score from the mean with time. Many factors contribute to stature at the time of commencement of ESRF treatment including the duration of chronic renal failure, the presence of confounding biochemical problems such as acidosis, the severity of renal osteodystrophy and the presence of underlying conditions associated with growth failure (such as cystinosis). Figure 15.5 shows the percentage of children greater than 3s.d., 2-3 s.d., 1-2 s.d. and 0-1 s.d. below the mean for height at the start of ESRF treatment. Overall 45% of this cohort were more then 2 s.d. from the mean for height and 21% were more than 3 s.d. below the mean for height at the start of ESRF treatment. The proportion which was very small decreased steadily as the age of ESRF treatment commencement increased. This is because of the greater contribution of patients with acquired rather than congenital diseases in the older paediatric population. Limited data is presented below on the time between presentation to a paediatric nephrologist and the commencement of ESRF treatment but the true effect of paediatric nephrological care and appropriate use of agents such as growth hormone will only become apparent when full time-line data becomes available in the future.

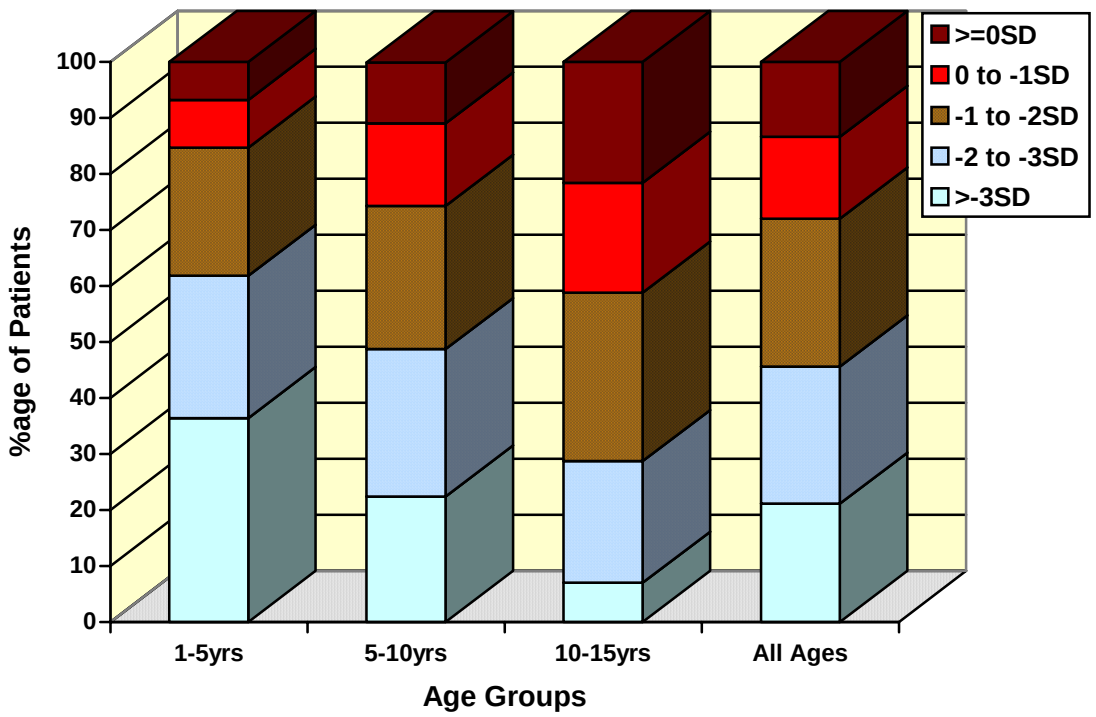


Figure 15.5 Percentage of children below the mean for height at start of ESRF treatment

Presentation to paediatric nephrology services

The database collects data on age, height, weight and creatinine at presentation to the paediatric nephrology service. These data will turn out to be important to see whether intervention by paediatric nephrologists prevents co-morbid complications, loss of height and delays the decline into ESRF. For the current cohort, collection of this data has been inevitably retrospective and with many patients having long histories and voluminous notes, the data is incomplete. Prospective collection of the data in the future ought to allow for more reliable analysis.

Currently, data were available on only 432 patients (57.2% of the population). Figure 15.6 shows the predicted glomerular filtration rate at the time of presentation split into groups of those with a predicted GFR >50, 20-50, 10-20 and <10mls/min/1.73m². It can be seen that over one third of patients were at ESRF at the time of presentation and a further 25% were almost at end stage with a GFR of between 10-20. Only 13% of patients had a GFR above 50 at the time they were first seen. As many of the diagnoses are congenital lesions which can be identified early and lead to a steady progressive decline in renal function, there is clearly scope for establishing a pattern of earlier tertiary referral.

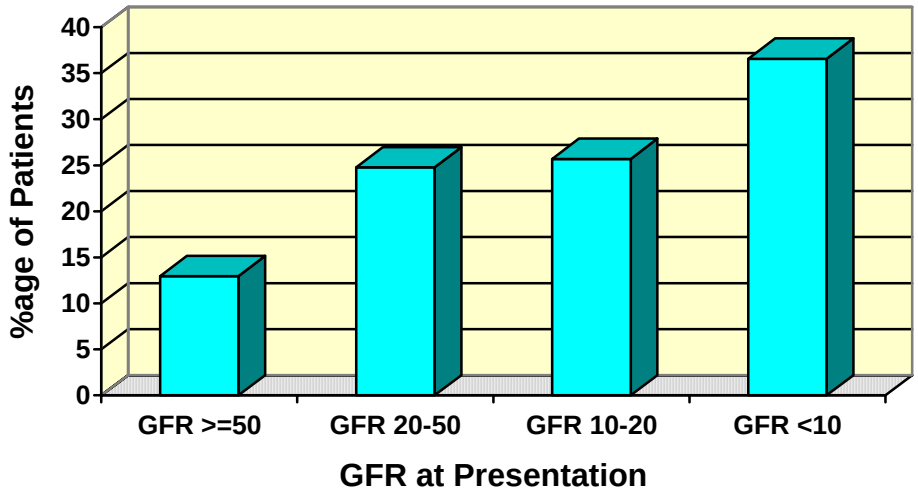


Figure 15.6 GFR at presentation to a paediatric nephrologist

Data on height at presentation and then subsequently when entering ESRF was even more sparse. To judge change in height, only patients where complete data was available and where there was a gap of at least one year between presentation and commencing end stage treatment were studied. This limited the analysis to 210 patients which at just 27.8% of the population means that the results of this analysis need to be interpreted with caution. The data is shown in Table 15.7. It is pleasing to see that 36% of patients either maintained their height percentile or crossed percentiles in a positive direction. 50% of patients lost height and fell up to two standard deviations from their starting point. Almost 14% of patients suffered major growth problems falling over two standard deviations from the point at which they started. Unfortunately, the numbers of patients with complete data available were too small to allow sub-analysis according to age at presentation, diagnosis and time from presentation to end stage.

Height change	>3 s.d. loss	2-3 s.d. loss	1-2 s.d. loss	0-1 s.d. loss	Stable or gain
Patients	11	18	40	65	76
% Patients	5.24	8.57	19.05	30.95	36.19

Table 15.7 Height change between presentation and end stage renal failure

Co-morbidity & death

Data on co-morbidity and death were very sparse and collection of this data to date has been too incomplete to allow meaningful analysis. As these are important factors in the planning and prevention of health care services, extra effort is going to be required in these areas in the future. Prospective rather than retrospective data collection, as ought to be the case from now on, will hopefully aid this.

Within co-morbidity, one area of particular note will be exact ascertainment of the prevalence of significant developmental delay at commencement of renal failure therapy as this varies significantly in the reporting to date from zero to 20% of patients. Consanguinity has clearly been under-reported when judging the diagnoses within

certain families and this highlights the major defects that exist in all our hospital case notes.

Whilst building this data set the emphasis has been on collecting data on current patients. This will have inevitably meant the omission of some patients who have died during the past 2 years of data collection. Despite this, there has been a minimum of 20 deaths over the past 2 years, giving an annual death rate of in excess of 0.7%. The most frequent cause of death appears to be elective treatment withdrawal after loss of dialysis access sites.

Conclusion

Collection of data in paediatric patients with end stage renal failure has previously been limited to that collected by the EDTA and the specific data collected by UKTSSA. This project is the start of the first comprehensive data collection exercise for the whole of the United Kingdom and Ireland. The creation of a specific database and the personal installation of this in all centres has led to an excellent reporting rate, but despite this obtaining a complete data set in all areas has been difficult. The limited numbers of patients with ESRF in childhood make the collection and maintenance of such a database essential if we are going to accurately study management trends and interventions and not be misled by the false promises of trends in small local populations.

The collection of this static data set has led to clear definition of the patient numbers and disease spectrum leading to end stage renal failure in childhood. It has also clearly shown trends in the age at which end stage renal failure management is instigated and which therapies are used initially. Over the next 12 months the paediatric Registry will be prospectively collecting static data and will add to this time-lines of treatments including dialysis modality, the use and results of growth hormone and erythropoietin therapy and transplantation statistics. Use of these data over next 5 years, will allow examination of trends and success rates, both within individual patient groups and between centres.

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Appendix A: The Renal Registry Rationale

1. Executive summary
2. Introduction
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4. Relationships of the renal registry
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A:1 Executive summary

1.1 The Renal Registry has been established by the Renal Association to act as a resource in the development of patient care in renal disease.

1.2 The Registry will act as a source of comparative data for Audit/Benchmarking, Planning, Policy and Research. The collection and analysis of sequential biochemical and haematological data will be a unique feature of the Registry.

1.3 Agreements will be made with participating renal centres which ensure a formal relationship with the Registry and safeguard confidentiality

1.4 The essence of the Agreement will be the acceptance of the Renal Registry Data Set Specification as the basis of data transfer and retention.

1.5 Data will be collected quarterly to maintain Unit-level quality assurance, with an annual report and six monthly Unit Reports.

1.6 Ultimately activity will have to be self-funded by capitation of renal patients from commissioning agencies.

1.7 The Registry is likely, with the express agreement of participants, to become responsible for providing data to Trusts, Commissioning Authorities and Regional Offices, and the new ERA-EDTA Registry.

1.8 The development of the Registry will be open to influence from all interested parties, including Clinicians, Trusts, Commissioning Authorities and Patient Groups.

1.9 The Registry has charitable status through the Renal Association.

A:2 Introduction

2.1 Registry-based National Specialty Comparative Audit is likely to be one of the cornerstones of NHS development. "The National Renal Review" published in 1995 recommended participation of renal units in comparative audit (1). Chief Executives are now responsible for Clinical Governance and comparative audit at national level will be an essential part of this agenda, (2). The UK Renal Registry will facilitate such audit. This audit demands regular transmission of large volumes of data, which has become possible with developments in electronic data handling. The Scottish Renal Registry, established with financial support from the Scottish Office, demonstrated the practicalities of electronic data collection in a UK renal environment.

2.2 The need for careful comparative audit is likely to be confirmed through the development of Government Agencies, such as the National Institute for Clinical Excellence (NICE) and the Centre for Health Improvement (CHIMP). The final relationship of the Registry to these organisations as they develop is yet to be defined.

2.3 Demographic information on patients receiving Renal Replacement Therapy (RRT) throughout Europe was collected from 1965 in the Registry of the European Dialysis and Transplant Association (EDTA). This voluntary exercise was conducted on paper and by post, demanded considerable effort and time from participating units, and eventually proved impossible for many UK renal units. In recent years the incompleteness of UK data returns to EDTA has meant that it was not possible to build a picture of activity RRT in the UK for planning and policy purposes, although two ad hoc national data collections from England and Wales were solicited from renal centres in 1992 and 1996. The Registry will meet this need for demographic and economic data necessary for effective planning.

2.4 Together with the need to know the demographic and economic elements of the Health Service has developed a need to underpin clinical activity more rigorously through the scientific evidence base (for example the Cochrane Initiative) and by quality assurance activity through audit. These initiatives require comprehensive information about the Structures Processes and Outcomes' of RRT, which go well beyond the detail previously compiled by EDTA.

2.5 The Registry is recognised as one of the few High Quality Clinical Databases available for general use (3).

2.6 The aspiration for renal services to be provided within a National Service Framework (NSF) is underpinned by the development of the Renal Registry (A First Class Service: Quality in the new NHS) (4). Although the Department of Health has no immediate plans for a NSF for renal services, the Renal Alliance, a group comprising patients, nephrologists and representatives of other groups involved with renal care, is in the process of developing a shadow NSF. Input from the Renal Registry will be an important feature of the Framework.

2.7 Similar cultural pressures have more recently affected all clinical disciplines, so that Registries are implemented or planned in cardiac surgery, intensive care, diabetes etc.

2.8 The Renal Association has made a start in the area of Audit by publishing guidelines in 'Renal Standards' documents. It was apparent during the development of the guidelines that many criteria of clinical performance were uncertain or unknown, and that only the accumulated data of practising renal units could provide the evidence for advice on best practice and what might realistically be achieved. A common data registration provides the simplest device for such comparative audit.

2.9 The recent emphasis on Evidence Based Practice is being supported by the changes in research funding (Culyer Report), which lean towards collaborative projects and include both basic science and 'Health Services Research' components. It is apparent that a RRT database could be invaluable to a wide range of research studies

2.10 It can be seen that the need for a Registry of RRT has developed for a variety of reasons; international comparisons, national planning, local Trust and Health Authority management, standard setting, audit, and research. The opportunity for data gathering partly arises from improvements in information technology. While it was possible to see the need for a national renal database a decade and a half ago, the circumstances are now ideal for the maintenance of a data repository for all the purposes described above,

supported by the clinical users and resourced for national benchmarking as a routine part of RRT management.

A:3 Statement of intent

The Renal Registry provides a focus for the collection and analysis of standardised data relating to the incidence, clinical management and outcome of renal disease. Data will be accepted quarterly according to the Renal Registry Data Set Specification (RRDSS) by automatic downloading from renal centre databases. There will be a core data set, with optional elements of special interest which may be entered by agreement for defined periods. A Report will be published annually to allow comparative audit of facilities, patient demographics, quality of care and outcome measures. Participation is voluntary but the expectation is that all UK renal and transplant units will take advantage of the database by their involvement ultimately. There will be an early concentration on RRT, including transplantation, with an extension to other nephrological activity at a later date. The Registry will provide an independent source of data and analysis on national activity in renal disease.

A:4 Relationships of the Renal Registry

4.1 The Registry is a registered Charity through the Renal Association (No. 800733). It was established by a sub-committee of the Renal Association, with additional representation from the British Transplantation Society (BTS) the British Association for Paediatric Nephrology (BAPN), and the Scottish Renal Registry. There is cross representation with the Renal Association Standards and Clinical Trials Committees. The Registry has a Chairman and Secretary nominated by the Renal Association. The Registry has an observer from the Department of Health, and participants from the National Federation of Kidney Patients Associations and Health Care Commissioners.

4.2 It is anticipated that there will be a need for the development of a number of sub-committees as the database and participation enlarges, particularly for data analysis and interpretation.

4.3 The Scottish Renal Registry sends data to the Renal Registry for joint reporting and comparison.

4.4 It is anticipated that the return of English, Welsh and Northern Irish data to the EDTA Registry will be through the Renal Registry. The Scottish Renal Registry already sends data to EDTA.

4.5 A paediatric database has been developed in collaboration with the Renal Registry, and the two databases are compatible. Data from paediatric renal units will be entered on the database, which will allow long-term studies of renal cohorts over a wide range of age.

4.6 The basis of participation for Renal Units nationally will be an Agreement to accept the Renal Registry Data Set Specification for the transmission and retention of data. This will consist of a core data set of some 200 items and further optional elements, which will be returned on a special understanding with the unit for a defined period of reporting. The Agreement will specify the conditions of participation and guarantee Unit anonymity until there is general agreement to disclosure of Unit identity. The responsibilities of the Unit and Registry are clarified in the clauses of the Agreement, as well as the conditions of publication of data. The recent Data Protection Act may have implications for the Registry (5), but the Department of Health has indicated that Registry activity may continue in its present form pending further discussion and clarification of the act.

A:5 The role of the Registry for nephrologists

5.1 The clinical community have become increasingly aware of the need to define and understand their activities, particularly in relation to national standards and other renal units.

5.2 The Registry is run by a sub-committee of the Renal Association and therefore by colleagues with similar concerns and experience.

5.3 The Renal Standards documents are designed to give a basis for unit structure and performance, as well as patient-based elements such as case-mix and outcomes. It is anticipated that Standards will become

increasingly based on research evidence and the Cochrane Collaboration has resourced reviews of renal topics recently, which will support the conversion from clinical anecdote.

5.4 The registry data will be available to allow comparative review of many elements of renal unit practice. Data will be anonymised and presented to allow a contrast of individual unit activity and results against national aggregated data.

5.5 Reports of demographic and treatment variables will be available to the participating centres for distribution to Trust, Health Authorities and Regional Offices as required and agreed with the Unit. Reports should facilitate discussion between clinicians, Trust officers and Commissioners.

5.6 Customised data reports can be made available by agreement with the Registry sub-committee. A donation to cover any costs incurred will be requested.

5.7 The Registry committee will welcome suggestions for topics of national audit or research which colleagues feel are of sufficient widespread interest for the Registry to undertake.

5.8 The database has been designed to provide research database facilities for future participation in national and international trials. Members of the Renal Association and other interested parties are welcome to apply to the Registry sub-committee to conduct local or national audit and research using the database. All such projects will need the agreement of the Registry sub-committee, and any costs involved must be met by the applicants.

5.9 These facilities will only be sustainable through co-operation between nephrologists and the Registry. There is a need for high quality and comprehensive data entry at source. Attention will be necessary to the conditions listed in formal Agreements with the Registry.

A:6 The role of the Registry for Trust Managers

6.1 As the basis of the Clinical Governance initiative, the gathering and registration of data relating to patient management is regarded as an essential part of routine patient management in the health service.

6.2 One of the principles of health service informatics is that the best data are acquired from clinical information recorded at the point of health care delivery.

6.3 Renal Services data entered on local systems by staff directly engaged with patients is likely to be of the highest quality, and it is this that the Registry intends to capture.

6.4 The Registry will provide a cost-effective source of detailed information on renal services.

6.5 The regular reports of the Registry will supply the details of patient demographics, treatment numbers and changes, treatment quality and outcomes. Data will be compared with national standards and national performance for benchmarking and quality assurance. The assessment of contract activity and service delivery will be possible through the data returns without the need for further, costly Trust or commissioner administrative activity. These data should be particularly valuable to Contracts Managers and those responsible for Clinical Governance.

6.6 Data will be available on Unit case mix, infrastructure and facilities.

6.7 It is anticipated that data on patients with renal disease other than those requiring RRT will become available in time.

6.8 It is anticipated that Trust interests will ultimately be served by the participation of a national trust representative in the management body of the Registry as Registry activity expands.

A:7 The role of the Registry for Commissioners of health care

7.1 The Commissioners of health care are taken to include Regional Specialty Commissioning Groups and those supporting them, Primary Care Groups (PCGs) and Health Authorities.

7.2 The use of information sources such as the Registry is advised in the National Renal Review so as to promote benchmarking and quality assurance on renal programmes. The comprehensive tracking of relatively small but costly renal cohorts should be regarded as a routine part of case management.

7.3 The Registry will be able to provide validated, comparative reports of renal unit activity on a regular basis to participating centres. These will allow assessment of unit performance in a wide range of variables relating to 'Structure, Process and Outcome' measures.

7.4 There are economies of scale in the performance of audit through the Registry, since multiple local audits will no longer be required.

7.5 The incidence of ESRF treated locally will be apparent from new patient registrations. Mortality and renal transplant rates should also be of interest. The geographical origin of ESRF cases will be indicated by postcode data, which allows the assessment of referral and treatment patterns. This information will allow the expression of geographical and ethnic variations. These data will indicate unmet need in the population and permit judgements of the equity of service provision. The future Registry database should give information on nephrology and pre-dialysis patients, which will allow prediction of the need for ESRF facilities.

7.6 Registry data will be used to track patient acceptance and prevalence rates over time, which will allow the modelling of future demand and validation of predictions.

7.7 Information on the clinical diagnosis of new and existing RRT patients will point to areas where possible preventive measures will have maximal impact.

7.8 The results of higher acceptance rates in the elderly and the consequences of increasing demand from ethnic groups bearing a high prevalence of renal, circulatory and diabetic disease will be measurable.

7.9 Comparative data will be available in all categories for national and regional benchmarking.

7.10 The Registry offers independent expertise in the analysis of Renal Services data and their interpretation, a resource that is widely required but difficult to obtain.

7.11 The cost of supporting the Registry is estimated at between £10 and £15 per registered patient per annum, which is less than 0.05% of the typical cost of a dialysis patient per annum. It is expected that the costs will need to be explicit in renal services contracts so as to ensure the continuation of the Registry on a sound basis.

7.12 The Registry sub-committee now includes a representative of health care commissioners, which allows an influence on the development of the Registry and the topics of interest in data collection and analysis.

A:8 The role of the Registry for national quality assurance agencies

8.1 The role of the Registry in national QA as developed through NICE and CHImp will depend on decisions as to the roles of those agencies (6).

8.2 The demographic, diagnostic and outcomes data could support the investigation of clinical effectiveness in a variety of ways, depending on the focus of interest.

8.3 There may be pressure from some quarters to publish reports in which renal units are clearly identified. The maintenance of Unit anonymity is likely to be important to some, and it may compromise cooperation significantly if abrogated without agreement. Ultimately it is possible that a decision could be forced on the

Registry from outside, although it is hoped this situation will not arise. Consideration of this issue in particular would be welcome in nephrological circles, with correspondence to the Registry Sub-Committee.

A:9 The role of the Registry for patients

The ultimate aim of the Registry is to improve care for patients with renal disease. Appropriate use of the registry information should improve equity of access to care, adequacy of facilities, availability of important but high cost therapies such as erythropoietin, and appropriate and efficient use of resources. The continuing comparative audit of the quality of care should facilitate improvement of care and outcomes of care. It is intended to identify and publish examples of good practice. In these ways patients will be the ultimate beneficiaries of the exercise.

A:10 Abbreviations

ARF	Acute Renal Failure
BAPN	British Association of Paediatric Nephrology
BTS	British Transplantation Society
CCL	Clinical Computing Limited
CHImp	Commission for Health Improvement
EDTA	European Dialysis and Transplant Association
ERA	European Renal Association
ESRF	End Stage Renal Failure
HCFA	USA Health Care Finance Administration
NFKPA	National Federation of Kidney Patients' Associations
NHS	National Health Service
NICE	National Institute of Clinical Excellence
PCG	Primary Care Group
RRDSS	Renal Registry Data Set Specification
RRT	Renal Replacement Therapy
UKTSSA	United Kingdom Transplant Support Service Authority
USRDS	United States Renal Data System

A:11 References

1. NHS Executive. Review of Renal Services in England 1993-4. London: Department of Health 1996.Black N. High-quality clinical databases: breaking down barriers. Editorial. Lancet 1999; 353:1205-1206.

2. Black N. Clinical Governance: fine words or action? Br Med J 1998;316:297-298.

3. Black N. High-quality clinical databases: breaking down barriers. Editorial. Lancet 1999; 353:1205-1206.

4. NHS Executive. A First Class Service: Quality in the New NHS. London: Department of Health 1998.

5. Office of the Data Protection Registrar. The Data Protection Act 1998: an introduction. Wilmslow: Office of the Data Protection Registrar, 1998.

6. Rawlins M. In pursuit of excellence: the National Institute of Clinical Excellence. Lancet 1999;353:1079-1082.

Appendix B: Definition, statistical methodology, analysis criteria

Definitions of analysis quarters

Quarter	Dates
Quarter 1	1 January – 31 March
Quarter 2	1 April – 30 June
Quarter 3	1 July – 30 September
Quarter 4	1 October – 31 December

The quarterly biochemistry data are extracted from renal unit systems as the last data item stored for that quarter. If the patient treatment modality is haemodialysis, the software will try to select a pre-dialysis value.

Renal Registry modality definitions

Home haemodialysis

A home haemodialysis patient ceases to be classed as such, if they need greater than 2 weeks of hospital dialysis when not an inpatient.

Satellite dialysis unit

A satellite unit is a centre which is distinct from the parent hospital where the consultant nephrologist is based.

Treatment modality at 90 days

This is used by the USRDS and is the modality that the patient is on at day 90 regardless of any changes from the start. It is a general indicator of initial dialysis, but could miss failed CAPD. This would also miss patients intended for home haemodialysis, who will not be home yet. This is modality is calculated by the Registry, which allows the definition to be changed.

Analysis criteria

Take-On population

The take-on population in a year included patients who later recovered from ESRF after 90 days from the start of treatment. Patients newly transferred into a centre who are already in ESRF are not included in the take on population for that centre.

Since patients who restarted ESRF treatment after recovering from ESRF, are included in the take-on population the following scenarios can occur:- a patient may start ESRF treatment in 1996, recover and then restart ESRF treatment in 1996. These patients are counted twice in the analysis providing they have been receiving ESRF treatment for greater than 90 days on each occasion.

Patients who started treatment at a centre and then transferred out soon after receiving treatment are counted at the original centre for all analyses of treatment on the 90th day.

Criteria for analysis by treatment modality in a quarter

The following quarterly entries were included and excluded: -

Patients on haemodialysis with a treatment centre of 'elsewhere' were **removed**. It should be noted that there were some patients on transplant with a treatment centre of 'Elsewhere'. These patients were **included.**

Entries for which the hospital centre was not the primary treatment centre were removed from the analysis of data for that centre.

Patients who had been on ESRF treatment for less than 90 days were removed. (by definition of ESRF) There were a few exceptions to these rules:-

1. If a patient's initial entry on the treatment time line contained a **'transferred in'** code, then the patient was assumed to have been on ESRF for longer than 90 days, since the patient must have started ESRF treatment earlier than this elsewhere. Therefore, patients with an initial entry on the treatment timeline with a **'transferred in'** code were included for all quarters. For example, a patient with an initial treatment modality of **'transferred in'** on the 1st March 1996, would be included for quarter 1/97, even though the number of days on ESRF treatment would be calculated as 30 days.

2. For patients who **recovered** renal function, for a period of time, then went into ESRF, the length of time on ESRF treatment was calculated from the day the patient restarted ESRF treatment. For example, for a patient with an initial treatment start date of the 1st March 1996, who recovered on the 1st June 1996 and then resumed ESRF treatment again on the 1st November 1996, the number of days on ESRF treatment would be calculated from the 1st November 1996. The patient would be excluded from the analysis for quarter 4/96, since on the 31st December 1996, they only would have been on ESRF treatment for 60 days. The patient would be included in the analysis from quarter 1/97 onwards.

Patients who had **transferred out** or **stopped treatment without recovery of function** before the end of the quarter, were excluded.

Criteria for analysis of biochemistry in a quarter

The analysis used information from the quarterly treatment table. In addition to the treatment modality criteria listed above, patients with the following quarterly entries were also excluded: -

1. Patients who had **'transferred in'** to the centre in that particular quarter were excluded. For example, if a patient transferred in on the 1st March 96, then the patient was excluded from that biochemistry analysis of the centre they transferred to in that quarter.

2. Patients who had changed treatment modality in that particular quarter were excluded.

Treatment modality on day 90 of starting ESRF treatment

This is obtained from the treatment modality of the take-on population after 90 days of being on ESRF. For this reason patients who started treatment between 1/10/96 and 31/9/97 were used in this analysis.

The sample used was that defined by the take-on population.

Patients are counted at their take-on hospital centre rather than at their hospital centre on day 90. This is important since some patients had transferred out of their initial hospital centre by day 90.

Patients who died before they reached 90 days are excluded.

One year survival of the take-on population

The sample used was the same as that defined for the take-on population except for recovered renal function patients, who were excluded.

Patients who transferred out of their initial treatment centre, were censored on the day they transferred out if there was no further information in the timeline.

Analysis of one year survival of stock

The death rate within year was calculated separately for the patients established on dialysis and with a functioning transplant on 1st January 1997. As there is an increased death rate in the first six months following transplantation, patients were only included in the analysis if they had not received a transplant between 1st July 1996 and 31st December 1996. For the same reason patients who received a transplant within the year were censored at the time of transplantation.

The sample criteria thus became:

1. Patients who had been receiving renal replacement therapy for more than 90 days on 1/1/97.
2. Patients who had a transplant between 1/7/96 and 31/12/96 were excluded
3. Patients who transferred into a Registry centre were excluded if information was not available to confirm that they had not received a transplant between 1/7/96 and 31/12/96.
4. The few patients who recovered renal function in 1997 were excluded.
5. Patients who transferred out of a Registry centre to a non-Registry centre were censored at that date
6. A transplant patient whose transplant failed was censored at the time of restarting dialysis, and dialysis patients who received a transplant were censored at the time of transplant.
7. Patients who died, received a transplant, or transferred out on 1/1/97 were included and were counted as being at risk for one day.

Patients who died on the day of the transplant were censored on this day, rather than counted as a dialysis death.

Appendix C: Renal services described for non-physicians

(reproduced from the Renal Association Standards document)

This appendix is taken from the Renal Association Standards document and provides background information on renal failure and discusses the services available for its treatment.

Chronic renal failure

1. In chronic irreversible renal failure, the kidneys are slowly destroyed over months or years. To begin with there is little to see or find, and this means that many patients present for medical help very late in their disease, or even in the terminal stages. Tiredness, anaemia, a feeling of being 'run down' are often the only symptoms. However, if high blood pressure develops, as often happens when the kidneys fail, or is the prime cause of the kidney disease, it may cause headache, breathlessness and perhaps angina. Ankle swelling may occur if there is a considerable loss of protein in the urine.

2. Progressive loss of kidney function is often described as chronic renal insufficiency when in its early stages, chronic renal failure when it becomes obvious, and end stage renal failure when it reaches its terminal stage. At this point, if nothing is done, the patient will die. Two complementary forms of treatment, dialysis and renal transplantation are available and both are needed if end stage renal disease is to be treated.

3. The incidence of end stage renal failure rises steeply with advancing age. Consequently an increasing proportion of patients treated for end stage renal failure in this country are elderly and the proportion is even higher in some other developed countries. Evidence from the United States suggests that the relative risk of end stage renal failure in the black population (predominantly of African origin) is two to four times higher than for whites [US Renal Data System 1993]. Data collected during the review of renal specialist services in London suggest that there is in the Thames regions a similar greater risk of renal failure in certain ethnic populations (Asian and Afro-Caribbean) than in whites [Roderick et al 1994]; this is supported by national mortality statistics [Raleigh et al 1996]. people from the Indian subcontinent have a higher prevalence of non-insulin dependent diabetes, and those with diabetes are more likely than whites to develop renal failure. This partly explains the higher acceptance rate of Asians on to renal replacement programmes.

Causes of renal failure

4. Most renal diseases that cause renal failure fall into a few categories:-

   I. Auto-immune disease. 'Glomerulonephritis' or 'nephritis' describes a group of diseases in which the glomeruli (the filters that start the process of urine formation) are damaged by the body's immunological response to tissue changes or infections elsewhere. Together, all forms of nephritis account for about 30% of renal failure in Britain. The most severe forms are therefore treated with medications that suppress the immune response, but treatment makes only a small impact on the progress of this group of patients to end stage renal failure

   II. Systemic disease. Although many generalised diseases such as systemic lupus, vasculitis, amyloidosis and myelomatosis can cause kidney failure, by far the most important cause is diabetes mellitus (about 20% of all renal disease in many countries). Progressive kidney damage may begin after some years of diabetes, particularly if the blood sugar and high blood pressure have been poorly controlled. Careful lifelong supervision of diabetes has a major impact in preventing kidney damage.

   III. High' brood pressure. Severe ('accelerated') hypertension damages the kidneys, but the damage can be halted — and to some extent reversed — by early detection and early treatment of high blood pressure. This is a common cause of renal failure in patients of African origin.

   IV. Obstruction. Anything that obstructs the free flow of urine can cause back-pressure on the kidneys. Much the commonest cause is enlargement of the prostate in elderly men; although only a small proportion of them develop kidney failure,

prostatism is so common that it becomes a major cause of renal failure over the age of 70 [Feest et al 1990, 1993].

V. Infection of urine. Cystitis is a very common condition, affecting about half of all women at some time in their lives, but it rarely has serious consequences. However, infection of the urine in young children or patients with obstruction, kidney stones or other abnormalities of the urinary tract may result in scarring of the kidney and eventual kidney failure.

VI. Genetic disease. One common disease, polycystic kidneys, and many rare inherited diseases affecting the kidneys account for about 8% of all kidney failure in Britain. Although present at birth, polycystic kidney disease often causes no symptoms until middle age or later. Understanding of its genetic basis is rapidly advancing and may lead to the development of effective treatment.

VII. Disease of renal blood vessels. This is being more and more frequently recognised as a cause of renal failure, both acute and chronic. It is especially common in patients aged more than 65 years.

Co-morbidity

5. Renal failure is often accompanied by other disease processes. Some are due to the primary disease, e.g. diabetes may cause blindness and diseases of the nerves and blood vessels. Others, such as anaemia, bone disease and heart failure, are con sequences of the renal failure. Coincidental diseases such as chronic bronchitis and arthritis are particularly common in older patients with renal failure. All these conditions, collectively called co-morbidity, can influence the choice of treatment for renal failure and may reduce its benefits. Expert assessment of the patient before end stage renal failure can reduce co-morbidity and increase the benefit and cost effectiveness of treatment. Thus early detection and referral of patients at risk of renal failure is important. Studies in France and in the United States showed that the mortality rate among patients aged over 55 years at the start of regular dialysis increased dramatically if dialysis was started late in the illness [Jungers et al 1993; Byrne et al 1994]

Renal replacement therapy

6. The term renal replacement therapy is used to describe treatments for end stage renal failure in which, in the absence of kidney function, the removal of waste products from the body is achieved by dialysis and other kidney functions are supplemented by drugs. The term also covers the complete replacement of all kidney functions by transplantation.

Renal dialysis

7. Dialysis involves the removal of waste products from the blood by allowing these products to diffuse across a thin membrane into dialysis fluid, which is then discarded along with the toxic waste products. The fluid is chemically composed to draw or "attract' excess salts and water from the blood to cross the membrane, without the blood itself being in contact with the fluid.

Haemodialysis

8. The method first used to achieve dialysis was the artificial kidney, or haemodialysis. This involves the attachment of the patient's circulation to a machine through which fluid is passed, and exchange can take place. A disadvantage of this method is that some form of permanent access to the circulation must be produced to be used at every treatment. Each session lasts 4-5 hours and is needed three times a week.

Peritoneal dialysis

9. The alternative is peritoneal dialysis, often carried out in the form of continuous ambulatory peritoneal dialysis (CAPD). In this technique, fluid is introduced into the peritoneal cavity (which lies around the bowel) for approximately 6 hours before withdrawal. The washing fluid must be sterile in order to avoid peritonitis (infection and inflammation of the peritoneum), which is the main complication of the treatment. A silastic tube must be implanted into the peritoneum and this may give problems such as kinking and malposition. Each fluid exchange lasts 30-60 minutes and is repeated three or four times daily. Neither form of dialysis corrects the loss of the hormones secreted by the normal kidney so replacement with synthetic erythropoietin and vitamin D is often necessary.

Renal transplantation

10. Renal transplantation replaces all the kidney's functions, so erythropoietin and vitamin D supplementation are unnecessary. A single kidney is placed, usually in the pelvis close to the bladder, to which the ureter is connected. The kidney is attached to a nearby artery

and vein. The immediate problem is the body's acute rejection of the foreign graft, which has largely been overcome during the first months using drugs such as steroids and cyclosporin. These drugs, and others that can be used for that purpose, have many undesirable side effects, including the acceleration of vascular disease, so myocardial infarcts and strokes are commoner in transplant patients than in age-matched controls. During subsequent years there is a steady loss of transplanted kidneys owing to a process of chronic rejection; treatment of this is quite unsatisfactory at the moment, so many patients require a second or even a third graft over several decades, with further periods of dialysis in between.

11. The main problem with expanding transplantation is the shortage of suitable kidneys to transplant. Although the situation can be improved it is now clear that, whatever social and medical structures are present and whatever legislation is adopted, there will inevitably be a shortage of kidneys from humans. This remains the case even if kidneys from the newly dead (cadaver kidneys) are retrieved with maximum efficiency, and living donors (usually but not always from close blood relatives of the recipient) are used wherever appropriate. Hope for the future rests with solving the problems of xenotransplantation (that is using animal kidneys), probably from pigs, although baboons have also been suggested and are closer to humans. Many problems remain unsolved and it is thought highly unlikely that xenotransplantation will become a reliable treatment for end stage renal failure within the next 10 years.

Appendix D: Data Tables

1. Patients starting renal replacement in 1998

Take-on figures for new patients on dialysis				
	aged < 65		aged >65	
Centre	% on HD	% on PD	% on HD	% on PD
A	45	55	37	63
B	38	62	55	45
C	39	61	52	48
D	53	47	62	38
E	72	28	89	11
F	47	53	60	40
G	72	28	80	20
H	67	33	76	24
I	29	71	63	38
J	39	61	65	35
K	49	51	89	11
L	62	38	64	36
M	32	68	54	46
N	52	48	92	8
O	63	37	82	18
P	46	54	67	33
Q	57	43	80	20
R	47	53	71	29
Sa	76	24	67	33
Sb	55	45	72	28
Sc	71	29	85	15
Se	75	25	87	13
Sf	73	27	90	10
Sg	64	36	86	14
Sh	38	62	25	75
Si	56	44	66	34
Sj	50	50	87	13
Sk	38	62	77	23
Sl	44	56	70	30
T	39	61	66	34
E&W	49	51	67	33
Scotland	60	40	76	24
UK	52	48	69	31

Table D.1.1 Take-on of new dialysis patients

Take-on figures for new patients on dialysis				
	aged <65		aged >65	
	No. on HD	No. on PD	No. on HD	No. on PD
E&W	424	434	454	219
Scotland	156	102	156	50
UK	580	536	610	269

Table D.1.2 Take-on totals of new dialysis patients

Treatment modalities at 90 days						
Centre	**% on HD**	**% on PD**	**% on transplant**	**% transferred out**	**% stopped treatment**	**% died**
A	38	53	3	1		6
B	39	49	4			8
C	39	53				8
D	46	34	7	2	3	9
E	71	17	1			12
F	50	41		5		5
G	64	20	9			7
H	57	24	6	7		7
I	41	49	3			8
J	39	38	4	2	1	16
K	54	29	4	4		9
L	56	33	8			3
M	34	48	10	1		7
N	59	23	2		2	15
O	52	21	1			26
P	51	43		2		4
Q	56	29	5			11
R	50	36		1	1	11
Sa	65	26				9
Sb	46	28			2	24
Sc	67	19			1	12
Se	67	17	5			12
Sf	63	15				22
Sg	65	29				6
Sh	33	61				6
Si	50	32	1		1	16
Sj	67	26				7
Sk	45	40				15
Sl	52	37				11
T	48	38		5		9
E&W	49	36	4	1	0	10
Scotland	57	28	1		1	14
UK	51	34	3	1	0	10

Table D.1.3 Treatment modalities at 90 days

Treatment modalities at 90 days						
	No. on HD	**No. on PD**	**No. on transplant**	**No. transferred out**	**No. stopped treatment**	**No. died**
E&W	878	653	70	26	7	173
Scotland	312	152	5		3	74
UK	1190	805	75	26	10	247

Table D.1.4 Number of patients per treatment modality at 90 days

First treatment modality			
Centre	**% on HD**	**% on PD**	**% on transplant**
A	42	58	1
B	45	52	3
C	44	56	
D	56	40	5
E	82	18	
F	55	45	
G	70	24	6
H	71	29	
I	51	49	
J	54	41	4
K	62	34	4
L	58	42	
M	38	54	9
N	70	30	
O	78	22	
P	53	47	
Q	66	30	4
R	62	38	
Sa	72	28	
Sb	67	33	
Sc	78	22	
Se	79	21	
Sf	81	19	
Sg	68	32	
Sh	39	61	
Si	57	42	1
Sj	74	26	
Sk	53	48	
Sl	59	41	
T	56	44	
E&W	58	40	2
Scotland	67	33	0
UK	60	38	2

Table D.1.5 First treatment modality

First treatment modality – patient numbers			
	No. on HD	No. on PD	No. on transplant
E&W	1043	720	44
Scotland	366	179	1
UK	1409	899	45

Table D.1.6 First treatment modality - patient numbers

Treatment by gender						
	Haemodialysis			Peritoneal Dialysis		
Centre	% Male	% Female	M:F ratio	% Male	% Female	M:F ratio
A	73	24	3.0	64	33	1.9
B	60	40	1.5	50	50	1.0
C	73	27	2.7	70	30	2.3
D	66	34	1.9	52	48	1.1
E	65	35	1.9	54	46	1.2
F	73	27	2.7	67	33	2.0
G	56	44	1.3	59	41	1.4
H	66	32	2.1	64	36	1.8
I	60	40	1.5	83	17	4.9
J	63	37	1.7	65	35	1.9
K	58	42	1.4	48	52	0.9
L	55	45	1.2	75	25	3.0
M	78	22	3.5	65	35	1.9
N	69	31	2.2	86	14	6.1
O	57	43	1.3	68	32	2.1
P	54	46	1.2	65	35	1.9
Q	49	51	1.0	53	47	1.1
R	78	22	3.5	93	4	23.3
Sa	64	36	1.8	45	55	0.8
Sb	72	28	2.6	67	33	2.0
Sc	53	47	1.1	62	38	1.6
Se	63	38	1.7	79	21	3.8
Sf	59	41	1.4	50	50	1.0
Sg	65	35	1.9	56	44	1.3
Sh	33	67	0.5	45	55	0.8
Si	59	41	1.4	57	43	1.3
Sj	78	22	3.5	86	14	6.1
Sk	56	44	1.3	31	69	0.4
Sl	54	46	1.2	59	41	1.4
T	79	21	3.8	76	21	3.6
E&W	64	36	1.8	64	36	1.8
Scotland	61	39	1.6	57	43	1.3
UK	63	37	1.7	62	37	1.7

Table D.1.7 Treatment modalities by gender

Treatment by gender						
	Haemodialysis			Peritoneal Dialysis		
	No. males	No. females	No. unknown	No. males	No. females	No. unknown
Scotland	189	123		87	65	
E&W	564	312	2	416	233	4
UK	753	435	2	503	298	4

Table D.1.8 Treatment modality numbers by gender

2. Current patients 1998

	Treatment Modalities by centre							
	for patients aged < 65				for patients aged > 65			
Centre	% on HD	% on PD	% on Transplant	HD:PD	% on HD	% on PD	% on Transplant	HD:PD
A	35	54	11	0.7	16	20	64	0.8
B	44	39	17	1.1	26	26	48	1.0
C	48	26	26	1.9	36	18	46	2.0
D	55	22	23	2.5	27	8	65	3.3
E	75	12	13	6.2	43	9	48	4.6
F	74	16	10	4.5	30	24	45	1.3
G	47	16	37	2.9	13	13	73	1.0
H	77	17	7	4.6	43	20	37	2.1
I	52	20	28	2.7	19	15	66	1.2
J	42	31	27	1.3	24	24	52	1.0
K	58	11	31	5.1	24	10	66	2.4
L	67	8	26	8.8	28	10	62	2.7
M	43	21	36	2.1	16	13	70	1.2
N	51	20	29	2.6	17	12	71	1.4
O	63	10	26	6.2	25	9	65	2.8
P	46	42	12	1.1	32	26	42	1.2
Q	59	25	16	2.3	23	18	59	1.3
R	67	17	16	3.9	35	24	41	1.4
Sa	80	20		4.0	84	16		5.3
Sb	60	12	28	5.1	25	9	66	2.7
Sc	81	15	4	5.4	62	30	8	2.1
Se	64	20	16	3.2	32	10	57	3.1
Sf	78	22		3.5	83	17		4.7
Sg	56	44		1.3	55	45		1.2
Sh	48	43	10	1.1	33	40	27	0.8
Si	40	21	39	1.9	12	10	78	1.2
Sj	75	25		3.0	80	20		4.0
Sk	66	28	7	2.4	42	32	26	1.3
Sl	65	19	16	3.5	46	20	34	2.3
T	54	23	23	2.4	20	18	61	1.1
E&W	53	24	23	2.2	25	16	59	1.5
Scotland	61	21	19	2.9	32	15	53	2.1
UK	55	23	22	2.3	26	16	58	1.6

Table D.2.1 Treatment modalities for patients aged under 65 and over 65

	Treatment Modality numbers					
	for patients aged < 65			for patients aged > 65		
	No. on HD	No. on PD	No. on transplant	No. on HD	No. on PD	No. on transplant
E&W	1875	1236	4523	1538	688	650
Scotland	602	287	990	387	132	768
UK	2477	1523	5513	1925	820	118

Table D.2.2 Numbers of patients under and over 65 per treatment modality

Haemodialysis Modalities with gender ratios									
Centre		Haemodialysis		Home Haemodialysis		Hospital Haemodialysis		Satellite Haemodialysis	
Code	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio
A	1.7	22	1.0	2	3.0	41	1.0	0	n/a
B	1.6	31	1.0	5	3.8	32	1.0	14	1.0
C	1.6	38	1.2	9	1.0	37	1.2	19	1.0
D	1.6	35	1.1	14	2.3	25	0.7	35	1.0
E	1.6	54	1.1	11	1.5	65	0.9	8	2.6
F	1.6	50	1.1	0	n/a	71	1.0	0	n/a
G	1.4	21	1.0	0	n/a	30	1.2	30	0.8
H	1.8	56	1.1	0	n/a	75	1.2	0	0.0
I	1.7	29	1.0	0	n/a	45	1.0	18	1.0
J	1.8	29	1.2	4	1.5	48	1.2	0	n/a
K	1.6	31	1.0	2	1.9	36	1.2	37	0.9
L	1.7	39	1.1	1	n/a	80	0.9	0	n/a
M	1.5	24	1.2	8	1.3	53	1.1	0	n/a
N	1.8	28	0.9	1	0.5	65	0.9	0	n/a
O	1.4	35	0.8	2	0.0	58	0.9	20	1.4
P	1.8	36	1.0	3	2.2	51	1.0	0	n/a
Q	1.5	31	1.0	1	0.8	47	1.2	14	0.8
R	2.1	44	0.7	6	0.6	49	0.8	11	1.5
Sa	1.4	83	1.2	23	1.5	60	1.0	0	n/a
Sb	1.4	34	1.1	7	2.2	71	1.1	0	n/a
Sc	1.1	69	1.1	0	n/a	74	1.1	0	n/a
Se	1.9	40	0.9	4	4.7	72	1.0	0	n/a
Sf	1.1	81	0.8	0	n/a	81	0.8	0	n/a
Sg	1.6	55	1.6	0	n/a	55	1.6	0	n/a
Sh	1.3	37	0.5	2	0.0	46	0.6	0	n/a
Si	1.3	17	0.9	1	0.8	58	1.0	0	n/a
Sj	1.6	78	1.4	1	n/a	77	1.4	0	n/a
Sk	1.3	49	1.7	4	1.3	58	1.4	0	n/a
Sl	1.3	52	1.1	2	1.4	71	1.0	0	n/a
T	1.9	32	1.6	1	n/a	33	1.5	28	0.9
E&W	1.6	32	1.1	5	1.5	46	1.0	14	1.0
Scotland	1.4	39	1.1	5	1.8	66	1.0	0	n/a
UK	1.6	34	1.1	5	1.5	50	1.0	11	1.0

Table D.2.3 Haemodialysis modalities and gender ratios

Peritoneal Dialysis Modalities with gender ratios													
Centre		Peritoneal Dialysis		Standard PD		Disconnect PD		Cycling PD >= 6 nights		Cycling PD < 6 nights		Unknown type PD	
Centre	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio
A	1.7	30	1.0	0	n/a	58	1.0	0	n/a	0	n/a	0	n/a
B	1.6	29	0.8	0	0.0	44	0.9	5	1.0	0	n/a	0	n/a
C	1.6	20	1.0	0	n/a	33	0.9	1	0.3	0	n/a	0	n/a
D	1.6	12	0.9	14	1.1	9	1.1	2	0.0	1	0.6	0	n/a
E	1.6	10	0.8	0	n/a	14	0.6	2	3.1	0	n/a	0	n/a
F	1.6	21	1.0	5	1.1	24	1.0	1	0.0	0	n/a	0	n/a
G	1.4	14	1.0	0	n/a	40	1.0	0	n/a	0	n/a	0	n/a
H	1.8	19	0.6	0	n/a	25	0.6	0	n/a	0	n/a	0	n/a
I	1.7	17	0.9	0	n/a	30	0.8	7	2.5	0	n/a	0	n/a
J	1.8	26	0.9	0	n/a	47	0.8	0	n/a	0	0.0	0	n/a
K	1.6	10	0.8	1	0.3	22	0.9	2	0.5	0	n/a	0	n/a
L	1.7	9	2.5	0	n/a	12	1.6	6	n/a	1	0.0	0	n/a
M	1.5	15	0.9	0	n/a	34	0.8	5	1.0	0	0.0	0	n/a
N	1.8	14	1.2	0	n/a	34	1.2	0	n/a	0	n/a	0	n/a
O	1.4	9	1.0	0	n/a	21	1.2	0	n/a	0	n/a	0	n/a
P	1.8	31	0.9	0	n/a	46	1.0	0	n/a	0	n/a	0	n/a
Q	1.5	20	0.8	0	n/a	37	0.9	1	0.8	0	n/a	0	n/a
R	2.1	22	1.3	0	n/a	25	1.8	9	0.9	0	n/a	0	n/a
Sa	1.4	17	0.5	0	n/a	17	0.5	1	n/a	0	n/a	0	n/a
Sb	1.4	10	0.7	0	n/a	21	0.7	2	0.7	0	n/a	0	n/a
Sc	1.1	24	0.9	0	n/a	23	0.9	3	0.6	0	n/a	0	n/a
Se	1.9	13	0.8	0	n/a	20	1.1	4	0.3	0	n/a	0	n/a
Sf	1.1	19	4.4	0	n/a	6	n/a	9	1.8	3	n/a	0	n/a
Sg	1.6	45	0.6	0	n/a	40	0.5	5	n/a	0	n/a	0	n/a
Sh	1.3	41	1.6	0	n/a	42	1.3	10	n/a	0	n/a	0	n/a
Si	1.3	12	0.9	0	n/a	37	0.9	3	1.4	1	1.7	0	n/a
Sj	1.6	22	0.3	0	n/a	6	0.2	16	0.4	0	n/a	0	n/a
Sk	1.3	31	0.7	0	n/a	32	0.6	7	0.6	0	n/a	0	n/a
Sl	1.3	20	1.1	0	n/a	16	0.7	11	1.8	0	n/a	0	n/a
T	1.9	20	1.1	4	0.9	34	0.8	0	n/a	1	n/a	1	0.0
E&W	1.6	18	0.9	1	1.0	32	0.9	2	0.9	0	0.5	0	0.0
Scotland	1.4	17	0.8	0	n/a	24	0.8	5	1.1	0	2.9	0	n/a
UK	1.6	18	0.9	1	1.0	31	0.9	3	0.9	0	0.9	0	0.0

Table D.2.4 Haemodialysis modalities and gender ratios

Median ages and dialysis modalities by centre					
Centre	**Median age on Dialysis**	**Median age on HD**	**Median age on PD**	**Median age on transplant**	**Median age for all**
A	66	64	53	47	51
B	60	60	59	47	61
C	54	54	59	46	48
D	63	62	57	51	55
E	62	63	59	49	54
F	68	70	67	48	55
G	60	64	61	47	61
H	64	66	65	49	55
I	63	66	62	51	57
J	59	58	57	50	54
K	58	61	62	49	56
L	63	65	60	49	61
M	61	64	51	51	55
N	66	69	60	48	55
O	61	63	52	47	50
P	60	59	52		59
Q	60	61	58	46	52
R	59	61	54	46	54
Sa	56	52	52	52	56
Sb	60	62	55	51	54
Sc	61	62	62	52	56
Se	59	59	60	45	53
Sf	59	59	59		59
Sg	59	60	23	22	22
Sh	56	53	50	44	51
Si	60	62	49	51	54
Sj	61	61	59	46	51
Sk	54	54	58		61
Sl	60	61	57		56
T	64	67	54	48	52
E&W	61	62	59	49	54
Scotland	59	59	58	48	54
UK	60	62	57	46	52

Table D.2.5 Treatment modality median ages by centre

Dialysis Modalities for patients aged under 65								
Centre	**% on Home HD**	**% on Hosp HD**	**% on Satellite HD**	**% on standard PD**	**% on disconnect PD**	**% on cycling PD >=6 nights**	**% on cycling PD < 6 nights**	**% on unknown type PD**
A	3	43			54			
B	7	30	12	0	43	7		
C	12	37	17		34	0		
D	25	29	23	8	12	3	0	
E	18	58	6		16	1		
F		56		7	35	2		
G		25	25		50			
H		68			32			
I		34	21		34	11		
J	6	43			50		1	
K	4	33	33	1	26	2		
L	2	72			15	10	2	
M	12	43			37	8		
N	3	56			41			
O	3	58	13		27			
P	5	50			45			
Q	0	43	13		42	2		
R	9	41	9		27	14		
Sa	32	52			16			
Sb	11	62			24	3		
Sc		68			27	5		
Se	7	69			20	5		
Sf		83			9	4	4	
Sg		55			38	8		
Sh	3	43			45	10		
Si	1	53			41	4	1	
Sj	2	78			4	16		
Sk	5	52			34	9		
Sl	3	66			15	15		
T	2	30	21	7	39		1	1
E&W	7	41	12	1	36	3	0	0
Scotland	7	61			26	6	0	
UK	7	46	9	1	33	4	0	0

Table D.2.6 Dialysis modalities for patients aged under 65

Dialysis Modalities for patients aged 65 and over								
Centre	**% on Home HD**	**% on Hosp HD**	**% on Satellite HD**	**% on standard PD**	**% on disconnect PD**	**% on cycling PD >=6 nights**	**% on cycling PD < 6 nights**	**% on unknown type PD**
A	1	39	0	0	60	0	0	0
B	1	35	17	0	45	2	0	0
C	1	37	27	0	33	2	0	0
D	3	20	49	22	6	0	1	0
E	3	72	11	0	10	3	0	0
F	0	82	0	3	15	0	0	0
G	0	37	37	0	25	0	0	0
H	0	82	1	0	18	0	0	0
I	0	58	15	0	24	3	0	0
J	0	57	0	0	43	0	0	0
K	0	41	42	1	14	2	0	0
L	0	90	0	0	8	2	0	0
M	2	66	0	0	31	2	1	0
N	0	72	0	0	28	0	0	0
O	0	58	28	0	14	0	0	0
P	0	53	0	0	47	0	0	0
Q	1	53	16	0	30	0	0	0
R	1	63	15	0	20	0	0	0
Sa	4	76	0	0	18	2	0	0
Sb	0	84	0	0	16	0	0	0
Sc	0	84	0	0	16	0	0	0
Se	0	76	0	0	19	4	1	0
Sf	0	78	0	0	0	22	0	0
Sg	0	56	0	0	44	0	0	0
Sh	0	53	0	0	37	11	0	0
Si	0	66	0	0	32	1	1	0
Sj	0	75	0	0	9	16	0	0
Sk	0	70	0	0	26	4	0	0
Sl	0	78	0	0	17	5	0	0
T	0	36	35	0	29	0	1	0
E&W	1	52	16	2	28	1	0	0
Scotland	0	74	0	0	22	3	0	0
UK	1	56	13	2	27	1	0	0

Table D.2.7 Dialysis modalities for patients aged over 65

Patients Age Ranges by Centre								
Centre	**% 18-24**	**% 25-34**	**% 35-44**	**% 45-54**	**% 55-64**	**% 65-74**	**% 75-84**	**% 85+**
A	2	13	13	19	21	18	12	2
B	2	11	17	18	23	19	8	1
C	2	12	19	23	22	16	4	0
D	3	10	15	21	23	19	9	1
E	4	12	12	19	20	25	8	0
F	4	6	13	14	19	24	17	4
G	4	13	20	23	19	15	6	0
H	2	11	11	14	24	24	13	2
I	1	10	15	23	22	24	6	
J	3	14	17	17	22	18	8	1
K	4	15	19	20	21	15	7	
L	3	11	15	19	23	26	4	
M	2	9	17	24	21	18	8	0
N	4	8	17	19	19	16	14	2
O	3	12	18	18	23	17	9	0
P	2	9	14	22	25	22	6	
Q	3	11	20	22	21	15	7	
R	3	12	16	22	19	20	9	
Sa	2	15	12	20	18	21	10	1
Sb	5	13	18	20	19	17	7	1
Sc	1	8	11	20	22	26	11	1
Se	3	11	19	19	23	16	9	
Sf	3	13	9	22	25	19	9	
Sg	2	14	14	16	24	22	7	2
Sh	5	11	16	21	20	26		1
Si	3	15	24	20	20	14	4	0
Sj	1	6	18	13	22	20	20	
Sk	6	15	19	20	14	21	7	
Sl	3	12	13	19	20	22	10	1
T	2	12	17	17	20	20	12	1
E&W	3	11	17	20	21	18	8	1
Scotland	3	13	19	20	20	18	7	1
UK	3	12	17	20	21	18	8	1

Table D.2.8 Age ranges by centre

Treatment Modalities with gender ratios										
	No. of males	**No. of females**	**No. unknown**	**M:F ratio**	**No. on HD**	**M:F ratio**	**No. on PD**	**M:F ratio**	**No. on transplant**	**M:F ratio**
E&W	6484	4014	12	1.6	3413	1.7	1924	1.5	5173	1.6
Scotland	1466	1050		1.4	989	1.5	419	1.1	1108	1.4
UK	7950	5064	12	1.6	4402	1.7	2343	1.4	6281	1.6

Table D.2.9 Numbers of patients by treatment modality with gender ratios

Non-diabetic dialysis modalities (all patients)											
Centre	**% on HD**	**% on Home HD**	**% on Hospital HD**	**% on Satellite HD**	**% on PD**	**% on CAPD Standard**	**% on CAPD Disconnect**	**% on Cycling PD>=6 nights/wk**	**% on Cycling PD<6 nights/wk**	**% on PD Type Unknown**	**% on Transplant**
A	18	2	37	0	28	0	60	0	0	0	54
B	29	6	32	12	27	0	44	5	0	0	44
C	38	11	37	20	18	0	31	1	0	0	44
D	33	16	22	35	12	15	10	1	1	0	55
E	52	12	63	9	10	0	14	2	0	0	38
F	49	0	69	0	22	5	25	1	0	0	29
G	18	0	27	29	14	0	44	0	0	0	68
H	59	0	78	0	16	0	22	0	0	0	25
I	26	0	42	18	17	0	33	7	0	0	57
J	28	5	49	0	24	0	46	0	0	0	49
K	31	3	35	40	9	1	19	2	0	0	60
L	38	1	81	0	8	0	11	6	1	0	53
M	23	8	56	0	13	0	31	5	0	0	63
N	27	2	66	0	13	0	33	0	0	0	60
O	32	2	56	21	9	0	21	0	0	0	59
P	37	4	53	0	28	0	43	0	0	0	35
Q	28	1	45	15	18	0	38	2	0	0	54
R	45	7	47	12	23	0	24	10	0	0	32
Sa	84	25	59	0	16	0	15	1	0	0	
Sb	33	8	72	0	9	0	19	1	0	0	58
Sc	71	0	76	0	22	0	22	2	0	0	6
Se	40	5	73	0	12	0	19	3	1	0	48
Sf	83	0	83	0	17	0	4	8	4	0	
Sg	59	0	59	0	41	0	36	5	0	0	
Sh	36	2	47	0	38	0	40	11	0	0	27
Si	16	1	60	0	10	0	36	3	0	0	74
Sj	79	1	77	0	21	0	4	17	0	0	
Sk	51	4	58	0	31	0	30	8	0	0	19
Sl	52	2	72	0	18	0	14	11	0	0	30
T	28	2	37	28	14	5	28	0	0	1	59
E&W	31	5	45	14	17	2	31	2	0	0	53
Scotland	39	5	67	0	15	0	22	5	0	0	46
UK	32	5	50	11	16	1	29	3	0	0	51

Table D.2.10 Treatment modalities for non-diabetic patients

Non-diabetic dialysis modalities (all patients)			
	No. on HD	**No. on PD**	**No. on Transplant**
E&W	2812	1513	4786
Scotland	866	331	1030
UK	3678	1844	5816

Table D.2.11 Numbers of non-diabetic patients by treatment modality

Non-diabetic treatment modalities for patients aged under 65											
Centre	**% on HD**	**% on Home HD**	**% on Hospital HD**	**% on Satellite HD**	**% on PD**	**% on CAPD Standard**	**% on CAPD Disconnect**	**% on Cycling PD>=6 nights/wk**	**% on Cycling PD<6 nights/wk**	**% on PD Type Unknown**	**% on Transplant**
A	13	5	41	0	15	0	54	0	0	0	72
B	24	9	31	11	23	0	42	6	0	0	53
C	35	14	36	17	17	0	32	0	0	0	48
D	26	27	26	24	8	8	13	2	1	0	66
E	42	19	57	7	8	0	16	1	0	0	50
F	28	0	52	0	26	8	38	2	0	0	45
G	11	0	22	25	13	0	54	0	0	0	76
H	44	0	71	0	18	0	29	0	0	0	38
I	17	0	34	19	15	0	38	9	0	0	68
J	24	8	45	0	21	0	47	0	1	0	55
K	24	4	33	37	8	1	23	2	0	0	68
L	28	2	74	0	9	0	13	9	2	0	63
M	16	13	47	0	11	0	32	8	0	0	73
N	16	3	57	0	11	0	40	0	0	0	73
O	23	3	53	16	9	0	27	0	0	0	68
P	33	6	54	0	22	0	40	0	0	0	44
Q	20	1	40	14	16	0	42	2	0	0	64
R	36	11	37	11	25	0	25	16	0	0	39
Sa	85	36	48	0	15	0	15	0	0	0	
Sb	25	13	63	0	8	0	23	2	0	0	66
Sc	65	0	71	0	27	0	26	3	0	0	8
Se	33	8	71	0	9	0	18	3	0	0	58
Sf	88	0	88	0	13	0	6	0	6	0	
Sg	62	0	62	0	38	0	31	7	0	0	
Sh	35	3	47	0	35	0	41	9	0	0	31
Si	11	1	55	0	9	0	38	5	0	0	80
Sj	81	2	79	0	19	0	2	16	0	0	
Sk	45	6	53	0	31	0	31	10	0	0	24
Sl	46	3	69	0	18	0	13	15	0	0	36
T	20	3	34	23	14	8	31	0	0	1	66
E&W	23	9	41	12	14	1	34	3	0	0	62
Scotland	32	8	62	0	13	0	23	6	0	0	55
UK	25	9	46	10	14	1	31	4	0	0	61

Table D.2.12 Treatment modalities for non-diabetic patients aged under 65

Non-diabetic dialysis modalities for patients aged < 65			
	No. on HD	**No. on PD**	**No. on Transplant**
E&W	1561	952	4165
Scotland	535	222	914
UK	2096	1174	5079

Table D.2.13 Numbers of non-diabetic patients aged under 65 by treatment modality

Non-diabetic treatment modalities for patients aged 65 and over											
Centre	**% on HD**	**% on Home HD**	**% on Hospital HD**	**% on Satellite HD**	**% on PD**	**% on CAPD Standard**	**% on CAPD Disconnect**	**% on Cycling PD>=6 nights/wk**	**% on Cycling PD<6 nights/wk**	**% on PD Type Unknown**	**% on Transplant**
A	30	1	35	0	56	0	65	0	0	0	14
B	40	1	35	15	39	0	47	2	0	0	21
C	50	1	39	29	23	0	30	2	0	0	27
D	51	3	17	49	23	24	6	0	1	0	26
E	73	3	70	12	13	0	11	4	0	0	15
F	73	0	81	0	17	3	16	0	0	0	10
G	42	0	35	35	17	0	29	0	0	0	41
H	81	0	84	1	14	0	15	0	0	0	5
I	46	0	50	18	22	0	29	4	0	0	32
J	38	0	56	0	30	0	44	0	0	0	32
K	58	0	40	45	10	1	12	2	0	0	32
L	64	0	90	0	7	0	7	2	0	0	29
M	42	2	66	0	20	0	30	2	0	0	38
N	49	0	74	0	18	0	26	0	0	0	33
O	60	0	60	26	9	0	13	0	0	0	31
P	45	0	52	0	42	0	48	0	0	0	13
Q	57	1	51	17	25	0	30	0	0	0	18
R	67	1	62	14	19	0	22	0	0	0	14
Sa	82	4	78	0	18	0	16	2	0	0	
Sb	58	0	85	0	10	0	15	0	0	0	32
Sc	82	0	85	0	14	0	15	0	0	0	4
Se	61	0	74	0	21	0	20	4	1	0	18
Sf	75	0	75	0	25	0	0	25	0	0	
Sg	53	0	53	0	47	0	47	0	0	0	
Sh	40	0	46	0	47	0	38	15	0	0	13
Si	37	0	68	0	18	0	32	0	0	0	45
Sj	75	0	75	0	25	0	7	18	0	0	
Sk	64	0	69	0	29	0	27	4	0	0	7
Sl	65	0	79	0	17	0	17	4	0	0	17
T	49	0	41	37	14	0	22	0	0	0	37
E&W	51	1	52	16	23	2	28	1	0	0	26
Scotland	60	0	75	0	20	0	21	4	0	0	21
UK	53	1	56	13	22	2	26	1	0	0	25

Table D.2.14 Treatment modalities for non-diabetic patients aged over 65

Non-diabetic dialysis modalities for patients aged 65 and over			
	No. on HD	**No. on PD**	**No. on Transplant**
E&W	1251	561	621
Scotland	331	109	116
UK	1582	670	737

Table D.2.15 Numbers of non-diabetic patients aged over 65 by treatment modality

Diabetic Patient Dialysis Modalities											
Centre	**% on HD**	**% on Home HD**	**% on Hospital HD**	**% on Satellite HD**	**% on PD**	**% on CAPD Standard**	**% on CAPD Disconnect**	**% on Cycling PD>=6 nights/wk**	**% on Cycling PD<6 nights/wk**	**% on PD Type Unknown**	**% on Transplant**
A	13	0	20	0	51	0	80	0	0	0	37
B	40	0	33	17	40	0	43	7	0	0	19
C	39	0	39	13	37	0	47	2	0	0	24
D	53	2	47	34	11	9	4	4	0	0	36
E	71	3	77	3	14	0	13	3	0	0	14
F	54	0	88	0	8	0	13	0	0	0	38
G	39	0	40	38	11	0	21	0	0	0	50
H	46	0	59	0	31	0	41	0	0	0	23
I	56	0	64	18	13	0	9	9	0	0	31
J	38	0	47	0	43	0	53	0	0	0	18
K	36	0	41	19	25	3	38	0	0	0	40
L	56	0	71	0	22	0	21	7	0	0	22
M	23	4	38	0	32	0	53	4	0	0	45
N	31	0	63	0	19	0	38	0	0	0	50
O	39	0	56	17	15	0	28	0	0	0	45
P	29	0	31	0	65	0	69	0	0	0	6
Q	48	0	53	9	29	0	38	0	0	0	23
R	59	0	55	12	30	0	27	6	0	0	11
Sa	72	0	72	0	28	0	28	0	0	0	
Sb	37	0	65	0	20	0	29	6	0	0	43
Sc	52	0	57	0	39	0	33	10	0	0	9
Se	29	0	57	0	22	0	29	14	0	0	49
Sf	80	0	80	0	20	0	0	20	0	0	
Sg	20	0	20	0	80	0	60	20	0	0	
Sh	45	0	45	0	55	0	45	9	0	0	
Si	23	0	44	0	28	0	47	3	6	0	49
Sj	73	0	73	0	27	0	18	9	0	0	
Sk	33	0	50	0	33	0	50	0	0	0	33
Sl	54	0	61	0	35	0	26	13	0	0	12
T	32	0	8	46	27	8	38	0	0	0	41
E&W	40	1	45	12	29	1	39	2	0	0	31
Scotland	40	0	57	0	30	0	34	8	1	0	30
UK	40	0	48	10	29	1	38	3	0	0	31

Table D.2.16 Treatment modalities for diabetic patients

Diabetic Patient Dialysis Modalities			
	No. on HD	**No. on PD**	**No. on Transplant**
E&W	397	288	303
Scotland	100	76	77
UK	497	364	380

Table D.2.17 Numbers of diabetic patients by treatment modality

Diabetics						
Centre	Median age on 31.12.98	Median age at start of treat	% with age known at start of treat	M:F ratio	Median time on ESRF treatment	
					in days	in years
A	51	47	86	1.5	750	2.1
B	57	54	97	1.8	885	2.4
C	55	50	99	3.1	853	2.3
D	57	53	99	1.0	1055	2.9
E	61	60	91	1.5	437	1.2
F	54	45	99	1.6	1029	2.8
G	55	53	94	1.9	1051	2.9
H	59	56	94	1.2	913	2.5
I	61	61	85	2.2	390	1.1
J	59	56	96	2.8	885	2.4
K	58	53	95	2.3	1198	3.3
L	56	51	88	3.5	589	1.6
M	51	45	97	1.2	1376	3.8
N	53	47	90	0.9	1965	5.4
O	58	54	94	1.4	802	2.2
P	58	57	98	1.4	311	0.9
Q	54	51	99	1.6	524	1.4
R	58	54	97	2.4	647	1.8
Sa	58	56	100	1.0	454	1.2
Sb	52	48	100	1.1	1147	3.1
Sc	61	58	100	1.3	514	1.4
Se	48	44	100	1.4	1445	4.0
Sf	54	52	100	4.0	304	0.8
Sg	44	42	100	4.0	430	1.2
Sh	66	66	99	0.8	469	1.3
Si	49	45	100	1.3	1067	2.9
Sj	58	58	100	0.6	798	2.2
Sk	41	35	100	0.5	1111	3.0
Sl	62	60	99	1.4	689	1.9
T	52	46	97	1.8	1864	5.1
E&W	55	52	95	1.7	869	2.4
Scotland	52	50	100	1.2	799	2.2
UK	54	51	96	1.6	847	2.3

Table D.2.18 Diabetics

Transplant rates with gender ratios			
Centre	Overall M:F	% on transplant	M:F
A	1.7	47	1.0
B	1.6	40	1.1
C	1.6	42	0.9
D	1.6	53	1.0
E	1.6	36	1.0
F	1.6	30	0.9
G	1.4	66	1.0
H	1.8	25	1.1
I	1.7	55	1.0
J	1.8	45	0.9
K	1.6	58	1.0
L	1.7	51	0.8
M	1.5	61	1.0
N	1.8	58	1.0
O	1.4	55	1.2
P	1.8	33	1.0
Q	1.5	49	1.1
R	2.1	34	1.4
Sa	1.4		unknown
Sb	1.4	56	1.0
Sc	1.1	7	0.5
Se	1.9	47	1.2
Sf	1.1		unknown
Sg	1.6		unknown
Sh	1.3	22	1.4
Si	1.3	71	1.0
Sj	1.6		unknown
Sk	1.3	21	0.5
Sl	1.3	28	0.8
T	1.9	49	0.7
E&W	1.6	49	1.0
Scotland	1.4	44	1.0
UK	1.6	48	1.0

Table D.2.19 Transplant gender ratios

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