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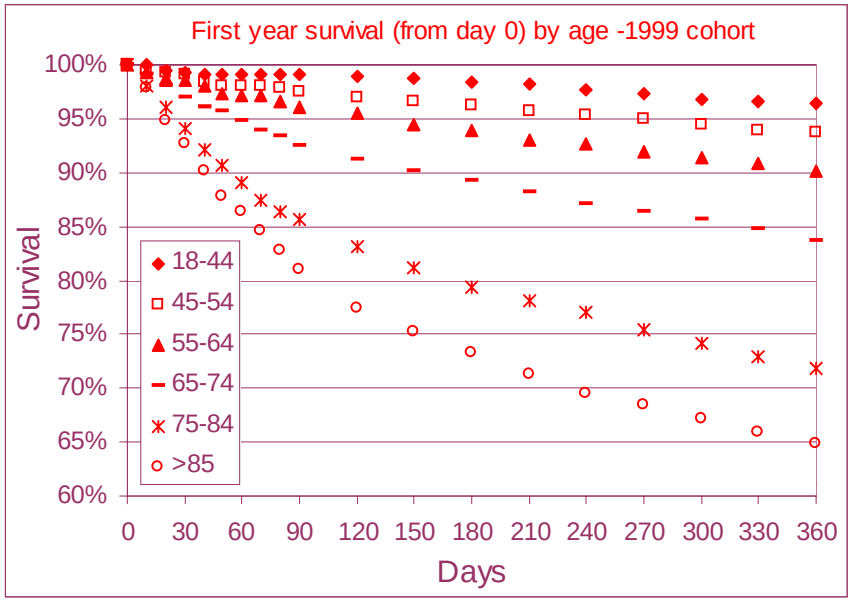
The Fourth Annual Report

The UK Renal Registry

December 2001



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Registry Staffing and the next report

In the last year the Registry has experienced several unexpected changes of staff. The Registry has now increased its staffing and has been fortunate to recruit two data managers, with excellent renal experience, and a senior medical statistician Professor Dirk van Schalkwyk from Cape Town University. The Registry is in the process of recruiting a junior statistician. In conjunction with the Richard Bright Renal Unit in Bristol, a Clinical Research Fellow has been recruited to help with analysis and preparation of reports and papers.

The increase in staff has facilitated retrieval and loading of data from the year 2001, and it is hoped to close the database at the end of March 2002. This will enable sufficient time for timely production of a detailed report on the significantly increased number of units participating in the Registry during 2002.

Contents

Index of Figures

Index of Tables

Chapter 1: Summary of the year 2001 report on data from 2000

After consultation with the participating renal units, a phased programme towards removal of anonymity has been agreed. This year the incidence and prevalence data in chapters 4 and 5 are identified by named renal unit.

All the renal units in the UK are now negotiating participation in the Renal Registry.

The data presented in this report relate to England and Wales. Due to technical difficulties, data held in the Scottish Renal Registry could not be transferred.

For the first time, data are presented on acceptance rates for treatment by Health Authority.

The estimated annual rate of adult patients starting renal replacement therapy (RRT) in England and Wales is 89 per million population (pmp) indicating that approximately 5350 patients started RRT in 2000. This is identical to the 1999 report. Incidence rates calculated from health authorities with complete Registry coverage varied from 157 down to 52.

Haemodialysis was the modality of RRT at a day 90 for 60% of dialysis patients in England & Wales (58.8% in 1999). By the end of the first year, 16% of patients starting on PD had changed to HD, similar to last year's data.

In England & Wales there was a 4.8% increase in the total number of patients on RRT between the 1st January and 31st December 2000. This comprised a 5.1% increase in the number of patients on dialysis and a 4.6% increase in those with a transplant. For individual Health Authorities, the estimated dialysis prevalence varied from 329 to 693 pmp.

The median age for all patients on treatment on 31/12/2000 was 54 years.

Reporting of ethnic origin has improved. The proportion of white patients in individual units varied from 39% to 100%, Asian from 0% to 56%, and Black from 0% to 15%.

Diabetes accounted for 16% of current incident patients, but 10% of all prevalent patients. Of prevalent dialysis patients 66% were on haemodialysis; HD is the predominant form of dialysis at all ages, but especially in the elderly. Connect PD has almost ceased. Cycling PD made little impact overall, but in a few units is the predominant form of PD

The 90-day survival is 95% (95%CI 94-96%) for those aged less than 65 and 83% (95%CI 81-85%) for patients aged 65 and over. The one-year survival is 86% (95%CI 84-88%) for those aged less than 65 and 66% (95%CI 63-69%) for patients aged 65 and over.

The first year survival from day 0 of renal replacement therapy was 96%, 94%, 90%, 84%, 72%, 65% for patients aged 18-34, 35- 44, 45-54, 55-64, 65- 74, and 85+ respectively.

The one-year survival of all prevalent patients established on renal replacement therapy for at least 90 days was 83.7%, and the two-year survival 68.4%.

There are marked differences between centres in survival rates, but these are not consistent. Serial studies on one year survival rates for individual centres from 1997 – 1999, after adjustment to a standard age, showed wide variation. There was no relationship between a centre's 90-day or 1- year-after-90 day survival, and the mortality rate of the local population for all cause mortality, or cardiac mortality.

There were 82 satellite units in England & Wales on 31st March 1999 (73 in 1998), with 67% of main renal units possessing a satellite. There was a diverse range of models of service provision. 43% were not on an acute hospital site; there was a median of 8 HD stations, (range 3-31), and 19 units (26%) were commercially run. Only 9 units (12%) had regular daytime onsite medical supervision. Of the 2599 patients being treated in the renal satellite units, 42% were aged 65 or over, similar to the UK as a whole.

In England & Wales, 74 % of patients achieved a URR > 65% compared with 65% in 1999 and 57% in 1998.

There was a continuing rise in URRs over the 2 years from starting dialysis from 57% achieving a URR > 65% in the first 6 months (48% in 1999) to 83% at 2 years (73% in 1999).

There is continuing improvement in the management of renal anaemia. In haemodialysis, 79% of patients had a haemoglobin > 10g/dl compared to 72% in 1999 and 69% in 1998. In PD 86% of patients had a haemoglobin >10g/dl in 2000, 80% in 1999, 78% in 1998

A joint analysis of data held by UK Transplant and the Renal Registry showed that the factors significantly affecting whether a patient is listed for transplant are: age ($p<0.0001$), primary renal disease ($p<0.0001$), and the size of the renal unit ($p<0.0001$), with large units listing patients more quickly. Gender and ethnicity of the patient and whether the dialysis hospital also has a transplant unit were not found to have a significant effect.

Pre-emptive listing (listing before dialysis) occurred in 21% of adults under 35 years old, only 4% of adults aged 55-64, and vary rarely in those over 65.

The Renal Registry has a unique data collection system with huge potential for the future. This offers an opportunity for automated data collection for multi-centre studies and trials. There is also considerable interest in collection of data on cohorts of pre-end stage renal failure. Once the work of connecting the rest of the UK sites has been completed, the members of the Renal Association will be consulted on these future projects.

With almost complete coverage of the UK, the UK Renal Registry is ideally situated to aid the implementation and monitoring of the National Service Framework.

Chapter 2: Introduction to the 2001 Report

Although this 2001 Renal Registry report is somewhat smaller than its immediate predecessor, it does contain the same basic data, from an increased number of renal units. The data are presented in a form to make it comparable with earlier reports. There is less commentary related to much of the core data, as the comments from last year remain valid for these data. There are also fewer chapters concerning activity somewhat peripheral to core Registry activity.

For the first time in this report, data are presented on acceptance rates for treatment by health authority. There are two other important additions. Chapter 3 contains details of the recently completed survey of satellite dialysis units in the UK, which was supported by the Renal Registry. Chapter 9 contains detailed statistical analysis not available before, on the survival of both incident and prevalent patients. Since 1999, there has been an improvement in reporting of data concerning ethnic origin and morbidity, although these areas still remain major concerns for the Registry.

This report on data from the year 2000 contains data from six renal units not previously included in the Renal Registry. During the year 2001 there has been a marked increase in the rate of new units joining the Renal Registry and there are now only 8 of the 75 renal units in the United Kingdom who are not linked to the Registry or in the process of being linked. These remaining 8 units are all in discussion with the Registry, and hope to join when once they have adequate electronic patient information systems.

Area covered by the Renal Registry.

The 2001 UK Renal Registry report refers to activity in 2000 and covers 54% of the UK adult population. In total 28 of the 63 adult units (45 %) in England and Wales (Table 2.1) have contributed to the report The English and Welsh units cover 51% of the population of 52.2 million. One centre in England, included in the previous year's report, did not manage to submit all its data in time to be included in this report

Although the 11 adult renal units in Scotland had submitted all their 2000 data to the Scottish Registry, due to a technical problem it was not possible to transfer the 2000 incident patient data, to the UK Registry in time for this report. It has though been possible to analyse the survival of the 1999 incident cohort from Scotland and also the prevalent cohort alive on 1st January 2000.

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

Centres in the 2001 Registry report

			Estimated Population (millions)
England & Wales			
Birmingham	Heartlands Hospital		.60
Bristol	Southmead Hospital		1.50
Cardiff	University of Wales Hospital		1.30
Carlisle	Cumberland Infirmary		.36
Carshalton	St Helier Hospital		1.80
Coventry	Walsgrave Hospital		.85
*Derby	Derby City Hospital		.48
Exeter	Royal Devon and Exeter Hospital		.75
Gloucester	Gloucester Royal Hospital		.55
Hull	Hull Royal Infirmary		1.02
*Leeds	Leeds General Infirmary		.90
Leeds	St James's Hospital		1.30
Leicester	Leicester General Hospital		1.80
*London	Guys and St Thomas Hospital		1.70
Middlesborough	South Cleveland Hospital		1.00
Nottingham	Nottingham City Hospital		1.16
Oxford	Churchill Hospital		1.80
Plymouth	Derriford Hospital		.55
Preston	Royal Preston Hospital		1.56
*Reading	Royal Berkshire Hospital		.60
Sheffield	Northern General Hospital		1.75
Southend	Southend Hospital		.35
Sunderland	Sunderland Royal Hospital		.34
*Swansea	Morriston hospital		.70
Wolverhampton	Newcross Hospital		.49
Wordsley	Stourbridge Hospital		.42
Wrexham	Maelor General Hospital		.42
*York	York District Hospital		.39
		Total	**26.44**

* - these units are reported by the Registry for the first time
All the above renal units in England & Wales run the CCL proton software.

Scotland		Estimated Population (millions)
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	
	Total	**5.10**

Centres recently joined the Registry

The following renal units have joined the Registry since the database was closed for this report. At least one file has been successfully loaded onto the Registry database from each site.

	(indicates IT system used by hospital)	Estimated Population (millions)
Basildon	(Mediqal)	
Bradford	Bradford Royal Infirmary –(proton)	.60
Cambridge	Addenbrookes Hospital –(proton)	1.42
Liverpool	Royal Infirmary –(proton)	1.75
London	Kings College Hospital (Filemaker Pro own system)	1.01
London	St Mary's Hospital –(proton)	.81
Newcastle	(New CCL Windows system)	1.31
Portsmouth	St Mary's Hospital –(proton)	2.00
Rhyl	Ysbyty Clwyd (via Liverpool)	
Stevenage	Lister (was on previously but developed new system)	1.25
Truro	Royal Cornwall Hospital (proton)	.36
Wirral	Arrowe Park Hospital (proton)	

Centres in the process of joining the Registry

Work is in progress to connect the following centres to the Registry.

	(indicates IT system used by hospital)	Estimated Population (millions)
Bangor	Ysbyty Gwynedd –(Baxter system)	
Birmingham	Queen Elizabeth Hospital – (own system)	1.82
Dorset	Dorchester Hospital - (Mediqal)	.60
Ipswich	Ipswich Hospital –(Baxter system)	.33
Canterbury	Kent & Canterbury – (Velos system)	.91
London	Hammersmith + Charring Cross - (Own system)	1.3
London	Royal Free –(King's system)	.67
London	Royal London – (King's system)	
Manchester -Hope	Hope Hospital - (EDS hospital system)	
Norwich	Norfolk & Norwich Hospital –(Mediqal)	.84

Centres in discussion with the Registry

All the remaining renal units have made contact with the Registry and are considering how to facilitate joining. These are:

		Estimated Population (millions)
Northern Ireland	Belfast + 3 renal units – (Mediqal system)	
Brighton	(Buying new system)	.98
Chelmsford	Broomfield Hospital (Buying new system)	
London	St George's – (Own system)	
Manchester –Royal	(Buying new system)	
Middlesex /UCLH	(Infoflex system – not adequate for Registry)	1.40
Shrewsbury	(Joining Bristol's proton system)	
Stoke	(Buying Cybernius - new Canadian system)	.70

Software and links to the Registry

The factor preventing these remaining units from joining the Registry is that they do not yet have satisfactory active electronic patient information systems. For some of these units there has been a lack of finance available to purchase suitable systems.

From the above lists it is evident that there are now 13 systems available for purchase and use in renal units. The Registry is working with the relevant companies to help them provide appropriate software links to the Registry.

In addition, the Lister renal unit in Stevenage has developed an in-house system, which has a working Registry interface. The software has been offered free by the Trust to the NHS Information Agency (NHSIA), and there has been an agreement with the NHSIA to support the system. There is an annual support charge levied by the NHSIA for this system.

Paediatric Registry Links

In the UK there are an estimated 750 patients aged under 18 on renal replacement therapy. As most of the 11 UK paediatric renal units are small, the British Association of Paediatric Nephrology (BAPN) was able to set up its own database to collect data. The last 2 UK Registry Reports have included a chapter of analyses from these data.

The paediatric registry has had difficulties with analysis of the paediatric data, and more recently with collection of data. There is a lack of direct funding of manpower resources to run the Paediatric Registry. Another problem has been the variable transfer of patients aged 15- 18 to adult units. In order to integrate these data with the adult Registry, and also provide funded resources for data management, the BAPN has asked the adult Registry to assess ways to collect this paediatric data. The Registry has obtained a grant from the English Department of Health to help automate data collection from the paediatric renal units, and will progress with this in 2002.

Anonymity and confidentiality

There is considerable pressure for the Renal Registry to cease reporting centres anonymously. Removal of anonymity would not only aid the development of comparative audit and assist learning from best practice, but also would also assure public accountability. This has been discussed in the Renal Registry Committee and at the Renal Association Executive Committee, with both in agreement of the importance of structuring a timescale for removal of anonymity. After consultation with the participating renal units, a phased programme towards removal of anonymity was agreed. This year the incidence and prevalence data in chapters 4 and 5 are identified by named renal unit. This move has been aided by the introduction of software enabling allocation of patient postcodes to health authorities, which have known population demographics. This provides more accurate incidence and prevalence rates than the estimated renal unit catchment populations provided by the units themselves. In subsequent reports there will be phased removal of anonymity from data related to the indicators of quality of care, such as KT/V, haemoglobin, serum phosphate.

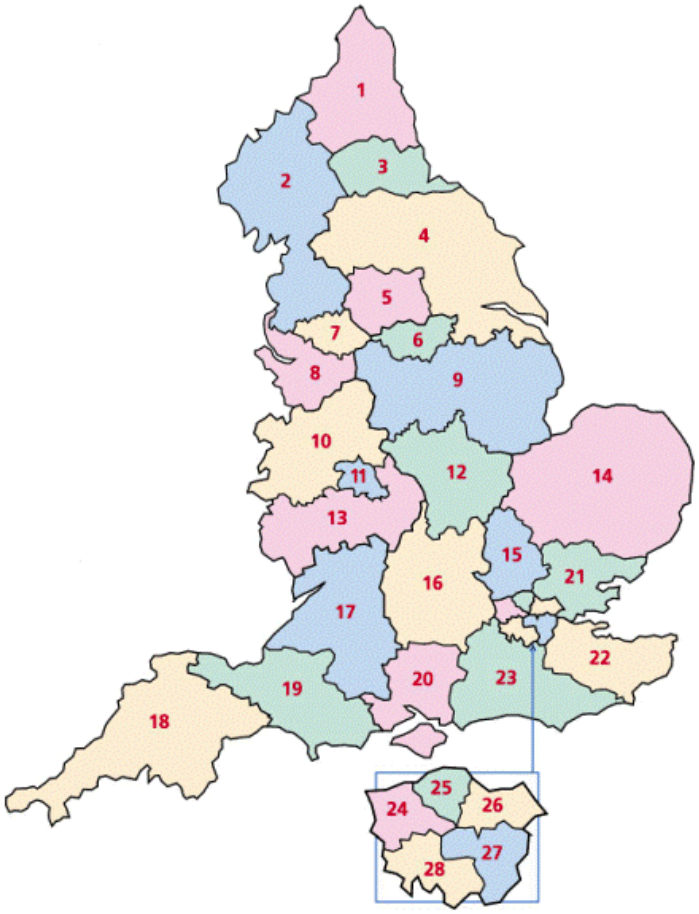
Meaningful comparison of outcomes between renal units requires the ability to correct for case-mix. The co-morbidity data available to the Registry is not yet adequate for this. There also needs to be better standardisation of the definitions and coding of acute renal failure and endstage renal failure. Investigation by the Registry has shown that apparently high 90-day death rates in some units are due to inclusion of patients with acute renal failure. Until robust data are available that will permit correction for case-mix, the Registry wishes to maintain anonymity for outcome statistics.

Where anonymity has been retained in the Report, 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.

As it may be possible to identify a centre by the number of patients treated there, throughout this report the anonymous analyses which compare centres do not show actual numbers of patients in each centre.

New methods of Commissioning Renal Services

In April 2002 the existing 95 Health Authorities in England will be reformed as 28 Strategic Health Authorities (StHAs). The proposed new boundaries and a list of the StHAs are shown below.



1. Tyne, Wear and Northumberland
2. Cumbria & Lancashire
3. County Durham & Tees Valley
4. North Yorkshire and York, East Riding & Hull, North & North East Lincolnshire
5. West Yorkshire
6. South Yorkshire
7. Greater Manchester
8. Cheshire & Merseyside
9. Trent
10. West Midlands North
11. West Midlands Central
12. Leicestershire & Northamptonshire & Rutland
13. West Midlands South
14. Norfolk, Suffolk and Cambridgeshire
15. Bedfordshire & Hertfordshire
16. Thames Valley
17. Avon, Gloucestershire & Wiltshire
18. South West Peninsula
19. Somerset & Dorset
20. Hampshire & Isle of Wight
21. Essex
22. Kent
23. Surrey & Sussex
24. London North West
25. London Central
26. London North East
27. London South East
28. London South West

Figure 2.1 Map of new Strategic Health Authorities

Within this rearrangement is the devolvement of power to primary care trusts (PCTs). It was initially stated that these "will take responsibility for securing the full range of services for their local populations".

Since the consultation process, which started in mid 2001, there has been a considerable change in the wording of these proposals. The tertiary services that must be contracted for through a PCT consortium have now been defined in a 'National Specialised Services Definitions Set', and include renal services.

The following paragraph has been copied from the DOH document:- 'HARevenueResourceLimits2002-2003Annex8.doc' 28 November 2001

PCTs will work in consortia to ensure that specialised services (as defined in the National Specialised Services Definitions Set) continue to be effectively commissioned at StHA and supra StHA levels. The NHS must ensure that local arrangements maintain service continuity and allow co-ordinated service development, where appropriate, on a national scale. PCTs will be financially bound and organisationally committed to the decisions made through these

consortia. PCTs must honour existing agreements (financial and otherwise) negotiated by Regional Specialised Commissioning Groups and current specialised service commissioners.

In 2002-03, Regional Specialised Commissioning Groups (RSCGs) will have a specific role in developing PCT capacity to commission specialised services as part of a planned transition to successor arrangements. Ensuring that enough people with the right skills continue in their roles is particularly important in the context of specialised services

It is envisaged that StHAs will have a role in monitoring the performance of the specialised commissioning consortia.

The services included in the National Specialised Services Definitions Set can be found on the DOH website at: *http://www.doh.gov.uk/specialisedservicesdefinitions*

Renal Services definition

This definition of renal services has been copied from the above website.

Renal Services have been a national priority since 1993 when the National Renal Review was set up. In February 2000 the Department of Health announced that a Renal National Service Framework (NSF) would be developed. When the renal NSF is published, it will be the key reference document for commissioning renal services. This definition will therefore be updated at that stage to ensure consistency with the renal NSF. It is not anticipated that there will be any change in the identification of renal services as specialised services that require collective commissioning arrangements.

All nephrology should be considered as specialised, including:

Treatment for End Stage Renal Failure (ESRF)
Treatment for acute renal failure
General nephrology (provided in a main nephrology unit)
Renal related surgery

Interpretation of the data within the report

***We again state that caution must be used in interpretation of any apparent differences between centres*.**

As in last year's report, the 95% confidence interval is shown for compliance with a Standard. Calculation of this confidence interval (based on the Poisson distribution), and the width of the confidence interval, depends on the number of patients within the Standard and the number of patients with data.

To assess whether there is overall significant difference of 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 intervals between centres in these 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 40 centres and then centre Y with the other

39 centres. Thus 79 comparisons have been made and in any comparison at least 4 are likely to be "statistically significant" by chance at the commonly accepted 1 in 20 level. If 41 centres were compared with one another, then 860 individual comparisons would be made, and one would expect to find 42 "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.

The Registry has not tested for "significant difference" between the highest achiever of the standard and the lowest achiever, as these centres were not identifiable in advance of looking at the data, which renders the comparison invalid in statistical terms.

Integration with the audit cycle.

The UK Renal Registry is part of a national renal audit cycle as shown. With the presentation of this Registry data to the renal community, the challenge to nephrologists and the developing National Service Framework is to find effective and creative ways to use the data in the implementation part of the cycle, in order to improve clinical practice. The Renal Registry is at the forefront of speciality-based national developments in quality assurance/improvement, and not all the necessary formal structures are yet in place to allow full value to be derived from this opportunity.

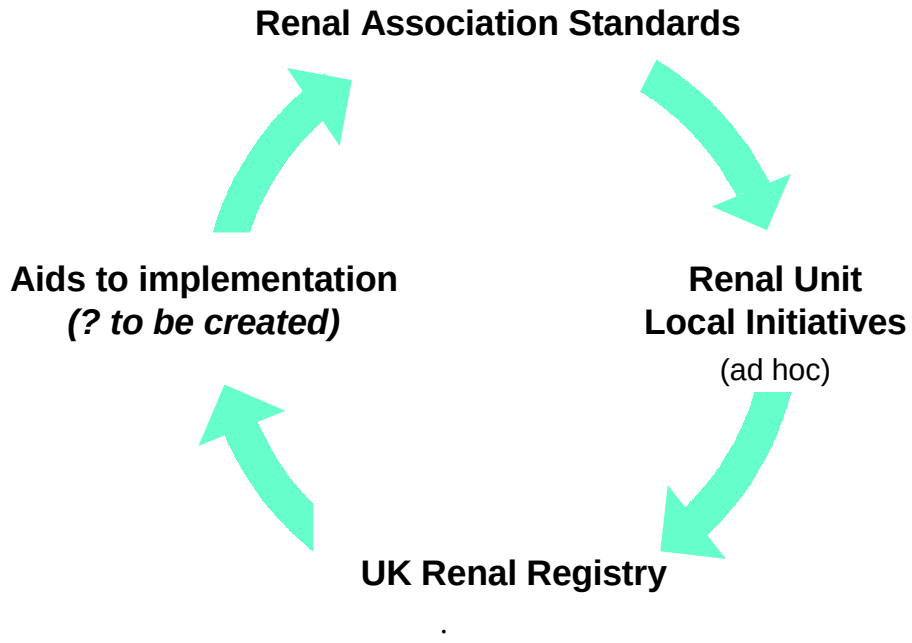


Figure 2.2 Renal Registry audit cycle

The Registry and Clinical Governance

There has been considerable debate within the Renal Association Trustee and Executive committees, and the Registry committee, about the Registry's responsibilities under clinical governance, particularly if an individual renal unit appears to be under-performing in some areas of activity. . For apparently serious errors of under-performance, the Registry will

discuss this further with the renal unit and help check the validity of these data. The Registry Report is also sent to the Chief Executive of each Trust in which a renal unit is situated, since the responsibility for clinical governance within the Trust lies with the Chief Executive. The Chief Executive is informed of the code of the Trust's renal unit within the report. If, after such investigation, the problems persist, the Registry will recommend the renal unit seek an external peer review, and may need to inform the local commissioners.

Distribution of Report

The Renal Association has made a grant towards part of the report costs, 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: 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

Future potential of the Registry

The Renal Registry has a unique data collection system with huge potential for the future. With almost complete coverage of the UK, the Registry is ideally situated to aid the implementation and monitoring of the National Service Framework.

The Registry software resources in place at renal units offer an opportunity for automated data collection for multi-centre studies and trials. From the outset the database was designed to facilitate this, with provision for patients to be specifically flagged, and allowing easy addition of new data items, without requiring alterations to the existing basic software. The extension to research applications will require attention to compliance with Data Protection Act, an issue that is further discussed in Appendix D.

There is also considerable interest in collection of data on cohorts of pre-end stage renal failure patients: many renal units already hold these data in their renal systems. Once the work of connecting the rest of the UK sites been completed, the members of the Renal Association will be consulted on these future projects.

Chapter 3: A national survey of renal satellite units in England and Wales

Summary

In order to meet the increasing demand for haemodialysis in the UK and to improve access to these services, renal satellite units have developed. These are largely nurse run chronic haemodialysis centres linked to main renal units.

There were 82 satellite units in England & Wales on 31st March 1999 (73 in 1998), with 67% of main renal units possessing a satellite.

A renal satellite unit is defined as a haemodialysis facility which is linked to a main renal unit and not autonomous for medical decisions, and which provides chronic out patient maintenance haemodialysis, but without in-patient nephrology beds on-site.

Satellite units varied in their location and size with 43% not on an acute hospital site, a median of 8 HD stations, (range 3-31), and 19 units (26%) were commercially run. Only 9 units (12%) had regular daytime onsite medical supervision. Of the 2599 patients being treated in the renal satellite units, 42% were aged 65 or over, compared with 45% of haemodialysed aged 65 or over in the UK as a whole. 12% of patients dialysing in satellite units were diabetic and 28% of satellite units also accepted patients dialysing for their first time. Commercially run renal satellite units were more likely to be based on sites that were not within hospital grounds and were significantly larger than NHS renal satellite units (median number of HD stations 12 vs 8 $p<.001$). They were also less likely to accept patients who were hepatitis B positive.

There was a diverse range of models of service provision for renal satellite units in England and Wales. They are heterogeneous in size, location, funding and staffing and despite relatively low levels of medical input are treating elderly patients with considerable comorbidity. It is important that their effectiveness, quality of care, acceptability to patients and carers and costs are evaluated.

Introduction

During the 1960s and 1970s renal replacement therapy programmes in the UK were provided by a small number of renal units based in teaching hospitals covering large catchment populations. Until CAPD was introduced in the late 1970's treatment was restricted to younger patients without significant comorbidity, the majority of whom were trained to undergo Home Haemodialysis. Facilities for unit haemodialysis in the UK were very limited by contrast with the situation elsewhere in Europe.

In the 1980's renal services expanded in the UK. This expansion was partly due to investment prompted by a national target set in 1984[1] and also by the widespread use of CAPD, which allowed the treatment of an increased number of patients without the need for additional haemodialysis facilities. However, despite this, as the prevalence of patients requiring treatment for end-stage renal failure has continued to rise the majority of main renal units

have experienced progressive congestion of their haemodialysis facilities. This is contributed to by the increasing population of elderly patients with other co-morbid illnesses who are unable to manage CAPD, a decrease in the use of home haemodialysis programmes and the limited life-span of CAPD as a treatment.

In 1992 the Department of Health in England commissioned a survey of all renal units. The results of this survey showed that the acceptance rate of new patients starting renal replacement therapy in 1991/2 was 67 per million population (pmp), which was well below the minimum estimated need of 80 pmp for the population under the age of 80[2-4]. Moreover, there was considerable geographic variation between areas in both the supply of services and in acceptance rates. Whilst this was in part due to different population age and ethnic minority profiles, distance from renal units was inversely related to the acceptance rate, particularly in non-metropolitan areas, suggesting that access to services was a barrier to referral[5].

In the early 1980's a few satellite renal units had been established in different parts of the country and then in 1994 National Renal Purchasing Guidelines, which were distributed to health authorities as a guide to commissioning effective renal care, recommended that the development of renal satellite units be expanded to improve geographical accessibility.[6] These units would be attached to main renal units (MRU) and provide a chronic maintenance haemodialysis service, run by nurses, and mainly for the benefit of patients living at some distance from the main unit.

These Guidelines hastened the development of renal satellite units and the decentralisation of renal services. Over the past decade the annual acceptance rates for renal replacement therapy in England has increased from 67 pmp in 1991/1992[6] to 82pmp in 1995[7] and 92 pmp in 1998[8.] As shown in figure 3.1 the greatest growth has been in satellite haemodialysis.

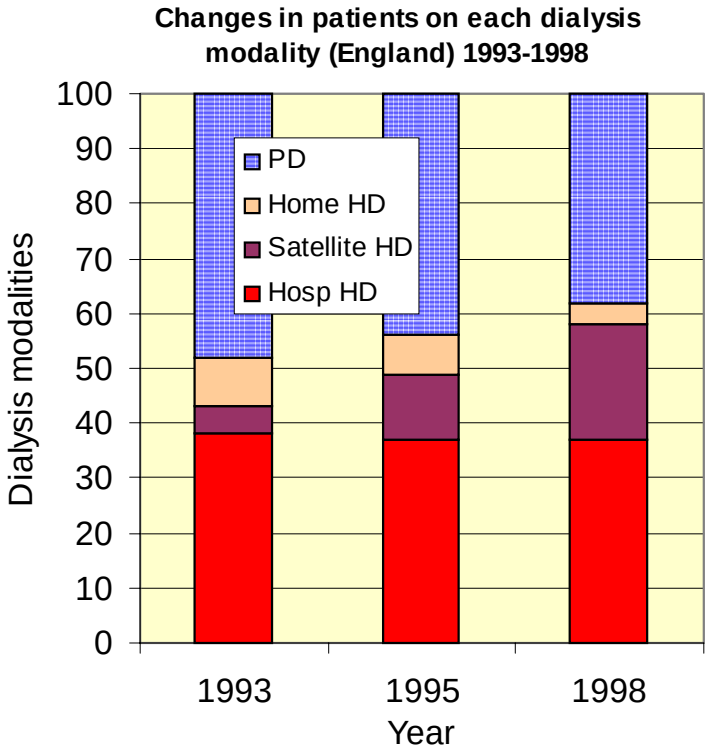


Figure 3.1: Changes in Dialysis Modality in England 1993-1998

Table 3.1 shows that whilst the number of haemodialysis stations within main units increased by 37% over this period, there was a 300% increase in the number of haemodialysis stations within renal satellite units[8,9] .

	1993	1995	1998	% increase
Main Renal Units	52	51	52	0%
Main unit HD stations	743	832	1021	37%
Satellite Units	36	60	73	103%
Satellite unit HD stations	189	472	761	303%

- source- National Renal Surveys

Table 3.1: Changes in Renal Units in England 1993-1998

This is a survey of renal satellite units in England and Wales, focusing on their service delivery and organisational structure.

Methods

The directors of all renal units in England and Wales with a satellite unit attached, were contacted to confirm the number and name of each satellite units linked with their main unit.

A renal satellite unit is defined as a haemodialysis facility which is linked to a main renal unit and not autonomous for medical decisions, and which provides chronic out patient maintenance haemodialysis, but without in-patient nephrology beds on-site.

A questionnaire was sent seeking information on the structure, organisation and processes of care. Information was requested on policies for accepting patients categorised as high-risk, with temporary vascular access and for first dialysis. Details were sought about the arrangements for elective and emergency medical input. Demographic data were collected on the proportions of patients who were over 65 years of age and of those with diabetes. The questionnaire was piloted in two renal satellite units. Questionnaires were sent out at the beginning of 1999 requesting data relating to the 31st of March of that year.

Data were entered directly into SPSS using "automated forms scanning". Standard summary statistics were used to describe the baseline data. Comparisons between different categories of renal satellite units were made by using either the Pearson's Chi-squared test, the Mann-Whitney-U test or the two-sample t-test where appropriate.

Results

Of the 57 main renal units identified, 38 (67%) had a total of 82 renal satellite units. Questionnaires were returned from 74 (90%) of these units. Two main renal units didn't respond (with six renal satellite units).

Figure 3.2 demonstrates that while 5 main renal units had 4 or more satellite units; 19 (33%) did not have a satellite unit. In several cases a single satellite unit served more than one main renal unit.

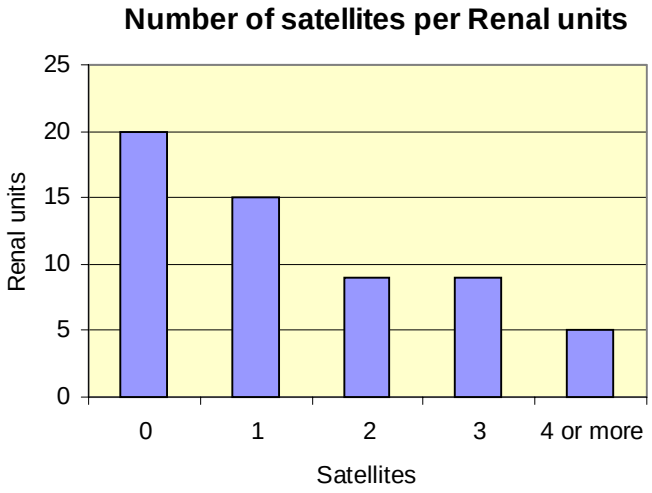


Figure 3.2: Numbers of Renal Satellite Units linked to Main Renal Units

Of the 2599 patients treated in the satellite units that responded to the survey, 1518 (58%) were male, 1101 (42%) were over 65 years (unit median 50%, IQR 35-58%, range 0-88%), and 311 (12%) were diabetic (unit median 14%, IQR 10-18%, range 0-42%).

Location	**Numbers**
Acute hospital	42/74 (57%)
Other hospital	23/74 (31%)
Non hospital	9/74 (12%)
Unit management	NHS 55 (74%), Private 19 (26%)
Median number of HD stations (range)	8 (3-31)
Median number of patients (range)	34 (8-120)
Support services	
CAPD support	6/69 (9%)
Home HD support	6/69 (9%)
APD support	4/69 (6%)
Integral out-patient clinic	18/66 (27%)
Permanent medical cover	9/74 (12%)
Consultant	*5/9 (56%)*
Associate specialist	*1/9 (11%)*
Staff grade	*3/9 (33%)*
SPR	*3/9 (33%)*
Non-permanent medical cover	*65/74 (88%)*
Methods of receiving medical care	
Phone call to MRU	*57/65 (88%)*
GP Visits	*4/65 (6%)*
Ambulance 999 call	*25/65 (38%)*
Onsite emergency cover from local hospital	*29/65 (45%)* *(81% for those on acute hospital site)*
Call out of MRU staff	7/65 (11%)
Other	16/65 (25%)
Patient : Nurse Ratio	5.6
Patient : All Staff Ratio**	4.0

*denominator varies due to missing data ** includes healthcare assistants

Table 3.2: Organisational characteristics of renal satellite units in England and Wales

Satellite units were sited mainly in acute hospitals (57%), with 31% on other hospital sites and 12% on non-hospital sites. Ownership was predominantly by the National Health Service (NHS), although a significant proportion 19 (26%) were commercially run, mainly by two companies. The size of the satellite units varied considerably, with a median of 8 haemodialysis stations (range 3-31) and 34 patients (range 8-120) per unit. Six satellite units (9%) also provided support for patients on other forms of renal replacement therapy. However, 27% did offer an integral out-patient clinic, thereby avoiding the need for the satellite patients to travel to the main renal unit for regular follow-up.

Only 9 (12%) satellite units had permanent daytime medical cover (defined as a doctor regularly on site during the daytime most days of the week). This was mainly at consultant level (5/9), with other grades of doctor providing cover in the other hospitals. In the 65 (88%) satellite units which did not have on-site daytime medical cover, medical care was sought by a variety of means, principally by telephone advice from the main renal unit. A few satellite units (6%) also relied on cover from a local primary care physician. For more serious situations, 45% reported that they relied on support from the local acute hospital (rising to 81% for those units on an acute hospital site), 38% relied on emergency ambulance calls, and 11% would call out a doctor from the main renal unit.

The average number of patients to whole time equivalent (WTE) staff ratio was 5.6 for nursing staff and 4.0 when healthcare assistants (HCAs) were included.

Policy	Number of units (Percentage)
Accept for first dialysis	18/65* (28%)
Temporary neckline	63/74 (86%)
Hep B +ve patent	36/74 (49%)
Hep C +ve patent	54/74 (73%)
HIV +ve patent	45/74 (61%)

* missing data

Table 3.3: Treatment Acceptance Policies of Renal Satellite Units

Eighteen (28%) renal satellite units accepted patients for their first dialysis without stabilising them first in the main renal unit, and 63 (85%) accepted patients with a temporary neckline: Seventy three of the 74 renal satellite unit would accept patients with a permanent tunnelled neckline. Only 36 (49%) renal satellite units would accept patients who were Hepatitis B positive, 54 (73%) accepted Hepatitis C positive patients, and 45 (61%) accepted HIV positive patients.

Forty one (55%) renal satellite units dialysed some patients for less than 3 times per week (median 3% of patients per renal satellite unit). The most common factors influencing this decision were residual renal function in 28 units and patient choice in 20 units. Only 4 (10%) renal satellite units reported lack of staff or haemodialysis station time as a reason for dialysing patients less than thrice weekly. Only 4 (5%) renal satellite units reported re-use of dialysers.

The majority of patients travelled for dialysis by hospital car (median 70% of patients per unit), 20% drove themselves and 5% relied upon ambulance transport

Table 3.4 compares NHS and commercially run renal satellite units. NHS renal satellite units were more likely to be on an acute (60% vs 47%) or other hospital (36% vs 16%) site. There was also a significant difference in unit size; commercialy run renal satellite units had a greater number of haemodialysis stations and patients, but did not differ in the patient: staff ratio or in the proportions of patients over 65 or diabetic.

Renal satellite unit characteristics	**NHS (55)**	**Private (19)**	**P value**
Location			
Acute hospital	33 (60%)	9 (47%)	.001
Other hospital	20 (36%)	3 (16%)	.001
Non hospital	2 (4%)	7 (37%)	.001
Median number of HD stations (range)	8 (3-16%)	12 (6-31)	<.001
Median number of patients (range)	28 (8-96)	44 (22-120)	.014
Patient:Staffing Ratios			
Patient : Nurse	5.5	5.8	NS
Patient : All Staff	3.7	5.5	NS
Unit treatment acceptance policies			
Accept for first dialysis	10/47 (21%)	8/18 (44%)	NS
Temporary neckline	50/55 (91%)	13/18 (72%)	0.045
Hep B +ve patent	34/55 (62%)	4/19 (21%)	0.002
Hep C +ve patent	17/55 (31%)	3/19 (16%)	NS
HIV +ve patent	25/55 (45%)	4/19 (21%)	NS

Table 3.4: Comparison of NHS and Private Renal Satellite Units

Treatment acceptance policies did not generally differ significantly, except that private renal satellite units were less likely to accept patients with temporary necklines or hepatitis B infection.

The location of a renal satellite unit, (acute hospital site, non-hospital site or non-acute hospital site) appeared to have little impact on the organisation or processes of care. There was a non significant trend for renal satellite units on acute hospital sites to have slightly more nurses but fewer overall staff per patient than those on a non-acute site (Patient: Nurse Ratio Acute 5.4, non-Acute 5.9; Patient: All Staff Ratio Acute 4.1 non-Acute 3.8). Integral outpatient clinics were more common in renal satellite units based on acute hospital sites than in other locations.

The satellite units with permanent medical staffing, they were more likely to accept patients for their first dialysis (62% vs 23% in non-medically staffed units, p=.019), and to provide an integrated out-patient clinic (86% vs 20% in non-medically staffed units, p=<.001).

Discussion

During the 1990s there was a significant increase in both the number of renal satellite units in England and Wales and the number of patients dialysing within them[7,8]. This development allowed expansion of patient numbers on haemodialysis and a reduction in patient travelling times to and from dialysis sessions. Renal satellite units have been opened in smaller towns in both rural areas and on the periphery of large conurbations, as well as in urban areas. This survey shows that renal satellite units are heterogeneous in size, location, finance, and the services they provide.

A key feature is that most are nurse run with no onsite medical cover. Despite this many are not based on acute hospital sites, some being sited on business parks or shopping centres that are some distance from the acute hospital services. Whilst there is some selection used when referring patients for satellite care, the proportions of patients on haemodialysis aged over 65 (42%) and with comorbidity such as diabetes (12%) are similar to those found by the UK Renal Registry for all HD patients at participating renal units in 1999 (45% over 65 years old and 14% diabetic respectively[9]). Moreover some of the satellite units also provide a haemodialysis service for patients who have not been previously stabilised on haemodialysis in the main renal unit. Senior nursing staff in these satellite renal units therefore carry a significant clinical and managerial responsibility.

The link between the private sector and provision of renal services is well established and the choice to utilise a private company to provide a renal satellite unit is becoming increasingly common. The 1996 Renal Review[7] found that 19% of renal satellite units in England and Wales had private sector involvement, rising to 26% by 1999. This study has shown many similarities in the services provided by private and NHS units. This is not surprising, as whilst the ownership of the units differs, the medical management remains the responsibility of an NHS consultant nephrologist. However there are differences, with private renal satellite units being significantly larger and also less likely to accept Hepatitis B+ve patients who would require an isolation cubicle with a dedicated machine[10].

In response to the increasing demand for renal replacement therapy, the growth in satellite haemodialysis care is a trend that is likely to continue. Key factors contributing to this increase are the current unmet need for renal replacement therapy, which is compounded by demographic change in ethnic minority groups with higher rates of renal failure such as Indo-Asians and African Caribbeans[11]. Modelling shows that a steady state of the prevalent pool will not be reached for several decades [12]. Given the shortage of kidneys for transplantation, there will be an increasing need for haemodialysis. Satellite care seems a suitable option to providing an accessible haemodialysis service for an increasing elderly population on renal replacement therapy.

In response to the increasing demand for renal replacement therapy, the growth in satellite haemodialysis care is a trend that is likely to continue. Key factors contributing to this increase are the current unmet need for renal replacement therapy, which is compounded by demographic change in ethnic minority groups with higher rates of renal failure such as Indo-Asians and African Caribbeans[11]. Modelling shows that a steady state of the prevalent pool will not be reached for several decades [12]. Given the shortage of kidneys for transplantation, there will be an increasing need for haemodialysis. Satellite care seems a suitable option to providing an accessible haemodialysis service for an increasing elderly population on renal replacement therapy.

The increase in demand for renal replacement therapy and resultant expansion in haemodialysis services is occurring in all other developed countries[13,14]. However most of these countries have a higher proportion and absolute number of patients on hospital haemodialysis than in the UK. They also have more renal centres and doctors per million population. Renal satellite care is described in the international literature although there is no universal definition for a renal satellite unit. In some countries, minimal care facilities (whereby the patients carry out their own dialysis in a centre with no medical supervision and often without a trained nurse on site), are included in the number of patients on satellite

dialysis. This makes comparison across countries problematic. Nevertheless data from national registries suggests there has been a major growth in renal satellite units in other countries[14,15].

Several questions are raised by the findings of this survey. :-

1. The optimal size for a renal satellite unit is unclear. Currently there is a large variation in size which in part reflects the geographical distribution of the catchment population of the main renal unit.
2. As a significant proportion of patients dialysing in these units are elderly and or diabetic, with co-existing co-morbidity, the safety of renal satellite units sited far from an acute medical facility needs to be investigated as most renal satellite units do not have permanent medical cover.
3. It is also important to evaluate patients' views of dialysis away from the main unit, and the impact of care in a renal satellite unit on the patients' quality of life.
4. As renal satellite units are becoming a significant part of the provision of renal replacement therapy in the UK, their cost effectiveness and how this varies by type of renal satellite unit needs to be evaluated.
5. As demand for renal replacement therapy continues to grow, more satellite renal units are likely to open, which might enable main renal units to concentrate on the treatment of the more complex and unstable haemodialysis patients. However it is possible that some renal satellite units, particularly those on an acute hospital site with a large local catchment population, will evolve into medically staffed autonomous renal units. These would then provide not only a chronic haemodialysis service for all haemodialysis patients in their catchment area, but also a full nephrology service. This would be closer to the model of services in other developed countries.

Further Work

This study has shown a diverse range of models of service provision for the renal satellite units in England and Wales. There is an ongoing second phase of this study, funded by the Health Technology Assessment Programme at the Department of Health, with the aims of :-

1. Comparing the effectiveness, safety and acceptability of care for renal satellite units patients with a similar group of dialysis patients dialysing in the main renal unit.

2. Identifying and contrasting the resource use of both sets of patients and the resulting cost differences between the satellite and parent main units.

3. Determining the improvement in geographical accessibility from dialysing in an renal satellite unit.

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Chapter 4: New Adult Patients Starting Renal Replacement Therapy

Summary

The estimated rate of adult patients starting renal replacement therapy (RRT) in the England & Wales is 89 pmp indicating that approximately 5350 patients started RRT in 2000. This figure is identical to the 1999 report.

Incidence rates calculated from health authorities with complete Registry coverage varied from 157 down to 52 per million population.

Haemodialysis was the modality of RRT at a day 90 for 60% of dialysis patients in England & Wales (58.8% in 1999)

By the end of the first year 16% of patients starting on PD had changed to HD, similar to last year's data.

The 90-day survival is 95% (95%CI 94-96%) for those aged less than 65 and 83% (95%CI 81-85%) for patients aged 65 and over.

The one-year survival is 86% (95%CI 84-88%) for those aged less than 65 and 66% (95%CI 63-69%) for patients aged 65 and over.

The consistency of many of these results from year to year, as more units join the Registry, gives grounds for confidence that the population of patients followed by the Registry is representative of the UK as a whole.

Introduction

This year the Registry has taken the first step towards relating details of new patients accepted for renal replacement treatment to local populations. A further change is that with the agreement of contributing centres, anonymity has been dropped for acceptance rates, demographic data and primary renal diagnosis.

The number of units participating in the registry has increased by 5, (6 new, one unable to return the data for this period) to 28 of the 57 units (48%) in England and Wales.

	England & Wales
No. of Units	28
No. of new patients on Registry	2357
Catchment population million	26.44
New patients pmp	89
(95% C.I.)	(85 – 93)
New patients per Unit	90

Table 4.1: Summary of new adult patients accepted during 2000

Acceptance Rates

Last year's report showed a wide variation in estimated acceptance rates between centres These calculations were based on estimates of catchment population given by each centre. However in many areas there are no clearly defined catchment areas. This is probably a major cause for the wide variation because of unknown extent of cross-boundary flows of patients. Now that the Registry covers larger contiguous areas of the UK it has been possible to make a start on calculating rates according to the known population of Health Authorities. Eventually this approach will make it possible to relate new patient acceptances to the needs of local populations, taking into account differences in age and ethnicity. Rates could be age standardised to control for differences in age structure and likewise by ethnicity once 2001 Census data are available. It will also help to identify variations due to differing referral practices, and differing policies for acceptance for therapy, which in some cases are determined by resource limitations.

Acceptance rates calculated by Health Authority (table 4.2)

These data have been calculated by mapping patient post codes (after using a post code correction package) to Health Authorities, using the NHS Organisational postcode mapping supplied by the Department of Health. England and Wales population figures for each health authority have been obtained from the Office for National.

This table includes only those Health Authorities with complete / near complete coverage by the Registry.

In England

HA Code	Region	HA name	Population	1998 pmp	1999 pmp	2000 pmp	Patient Number
QDT	Y01	Calderdale and Kirklees	583800			**81**	47
QDE	Y01	County Durham and Darlington	607800	100	74	**72**	44
QDF	Y01	East Riding and Hull	574500	71	71	**89**	51
QDH	Y01	Leeds	727400			**77**	56
QDK	Y01	North Cumbria	319300	125	72	**69**	22
QDR	Y01	North Yorkshire	742400			**93**	69
QDN	Y01	Sunderland	292300	51	86	**82**	24
QDP	Y01	Tees	556300	108	92	**83**	46
QDQ	Y01	Wakefield	318800			**100**	32
QCG	Y02	Barnsley	228100	70	83	**61**	14
QCK	Y02	Doncaster	290500	76	83	**79**	23
QCL	Y02	Leicestershire	928700	108	89	**92**	85
QCM	Y02	Lincolnshire	623100	82	91	**88**	55
QCH	Y02	North Derbyshire	370200	51	62	**59**	22
QCN	Y02	North Nottinghamshire	388900	116	95	**108**	42
QCP	Y02	Nottingham	642700	120	110	**96**	62
QCQ	Y02	Rotherham	254400	51	63	**102**	26
QCR	Y02	Sheffield	531100	88	90	**81**	43
QDL	Y02	South Humber	308600	104	65	**75**	23
QCJ	Y02	Southern Derbyshire	567500			**56**	32

HA Code	Region	HA name	Population	1998 pmp	1999 pmp	2000 pmp	Patient Number
QEA	Y07	Coventry	304300	112	115	**118**	36
QEC	Y07	Dudley	311500	80	64	**71**	22
QEG	Y07	Solihull	205600	83	73	**88**	18
QEK	Y07	Walsall	261200		115	**77**	20
QEL	Y07	Warwickshire	506700	97	116	**101**	51
QEM	Y07	Wolverhampton	241600		99	**157**	38
QCX	Y08	East Lancashire	511200	39	68	**74**	38
QC4	Y08	Morecambe Bay	310300	45	71	**100**	31
QCY	Y08	North-West Lancashire	466300	75	69	**79**	37
QAD	Y10	Croydon	338200	50	56	**89**	30
QAH	Y10	Lambeth, Southwark and Lewisham	745200			**78**	58
QA7	Y11	Berkshire	556600			**108**	60
QA8	Y11	Buckinghamshire	618900	63	76	**71**	44
QCC	Y11	Northamptonshire	615800	71	73	**89**	55
QCE	Y11	Oxfordshire	616700	76	65	**62**	38
QD8	Y12	Avon	999300	82	84	**109**	109
QDY	Y12	Gloucestershire	557300	90	95	**88**	49
QDX	Y12	North and East Devon	479300	81	88	**92**	44
QD5	Y12	Somerset	489300	67	84	**69**	34
QD6	Y12	South and West Devon	589100	119	107	**97**	57

Table 4.2: Acceptance rate by Health Authority England.

Health Authorities in Wales

HA Code	Region	HA name	Population	1998 pmp	1999 pmp	2000 pmp	Patient Number
QW1	W00	Gwent	557200	102	75	**93**	52
QW2	W00	Bro Taf	739600	88	111	**97**	72
QW5	W00	Morgannwg	499700	26	14	**82**	41

Table 4.3: Acceptance rate by Health Authority Wales

Other health authorities in England& Wales do not have complete coverage from Registry units to enable the take-on rate to be calculated. With the rapidly increasing coverage by the Registry it is anticipated that a much more complete picture will be available in the next report.

These data continue to show a wide variation in take-on rate around the country from 52 per million per annum to 157 per million per annum. Whilst the unit with the highest acceptance has a relatively high ethnic minority population, and the very lowest areas have relatively small ethnic minority populations, there is no clear relationship between acceptance rates and the proportion of population from ethnic minorities.

With the formation of large strategic health authorities as described in Chapter 2, this geographic variation in acceptance rates may be partially obscured if reporting is done by such large areas. From table 4.2 it can be seen that contiguous areas with widely differing take-on rates will be merged into one authority, giving an average rate hiding the variation. To monitor the variation, it will therefore be necessary to continue to monitor acceptance rates for geographic areas smaller than those covered by the new strategic authorities.

Using data from those areas with good Registry coverage, the annual acceptance rate in England is 86 per million population and 92 per million population in Wales.

Acceptance of new patients by renal unit (table 4.4)

The number of patients accepted by each renal unit is shown in table 4.4

		Number of new patients		
Centre	**Estimated catchment pop**	**1998**	**1999**	**2000**
Bristol	1.50	122	119	151
Carlisle	0.36	40	26	27
Carshalton	1.67	141	108	117
Coventry	0.85	87	92	89
Cardiff	1.30	137	138	137
Derby	0.48			26
Exeter	0.75	74	82	71
Gloucester	0.55	49	59	46
Guys	1.73			122
Heartlands	0.60	71	71	77
Hull	0.84	73	65	81
Leicester	1.73	181	161	177
Leeds GI	0.90			68
Nottingham	1.16	129	128	113
Oxford	1.80	146	139	144
Plymouth	0.55	71	67	63
Preston	1.56	79	105	118
Reading	0.60			54
S Cleveland	1.00	109	92	90
Sheffield	1.75	129	134	136
Southend	0.35		43	39
StJames, Leeds	1.30	71	79	89
Sunderland	0.34	41	45	46
Swansea	0.70			61
Wolverhampton	0.49		75	77
Wordsley	0.42	46	43	40
Wrexham	0.42		51	58
York	0.34			40
Total E&W	**26.44**	**N/A**	**N/A**	**2357**

Table 4.4: Number of new patients accepted by renal units

Acceptance rate by Renal Unit

As discussed at the start of this chapter, the renal unit catchment populations are estimates based on information either from the local renal unit or the 1992 national renal survey, which analysed patient distributions in England by postcode and calculated a catchment population for each English renal unit. Many Health Authority boundaries have changed slightly over the last 10 years causing some redistribution, and cross boundary flow patterns between units will also have altered. The Welsh renal unit at Wrexham is uncertain of its cross boundary flow from England. For this reason incidence rates have not been calculated for each renal unit, as the estimates of catchment are not considered sufficiently accurate to render such a calculation meaningful. The difficulties are illustrated in the following paragraphs.

1. An example of differences in unit acceptance rates which are almost certainly due to difficulties in establishing the catchment population is provided by Leeds where the incidence rates calculated from the Health Authority population was 77 pmp compared with the figures calculated from the catchment populations estimated by the hospitals which serve Leeds - St. James' (estimated unit acceptance rate 61 pmp) and Leeds General Infirmary (estimated acceptance rate 90.7 pmp). Mapping individual patients from each unit it is clear that are large areas from which patients may go to either unit, rendering catchment populations difficult to assess. This probably explains much of the apparent variation between the units. It would be necessary to have more details of the demography of the city to assess possible variation due to differences in age and ethnic distribution.

2. A further instance where the figures are difficult to interpret is provided by the Plymouth unit in south and west Devon (unit rate 140 pmp, Health Authority 97pmp) and the Exeter unit in north and east Devon (unit rate 84 pmp, Health Authority 92pmp). Again, although the acceptance rate may be genuinely higher in south and west Devon, mapping shows that much of the difference in unit acceptance rates is likely to be explained by difficulties in establishing the size of the catchment populations, and influx of patients to Plymouth from Cornwall.

3. A further example is North Cumbria. The Carlisle renal unit quotes the same catchment population as the North Cumbria Health Authority, of 0.32 million. The Health Authority annual acceptance rate is 69 pmp, yet it is almost exclusively served by Carlisle whose calculated acceptance rate would be 84pmp. Inspection of the patients' addresses indicates that the difference is due to several patients referred from outside the HA boundary into Carlisle, again an example of cross-boundary flow and an underestimate of the effective catchment population of the unit concerned.

4. In the case of smaller units and Health Authorities, small changes year on year in the number of new patients will be reflected in relatively large changes in acceptance rates.

The catchment populations shown in table 4.4 now take into account some of these considerations and as a result are slightly different from that shown in last years report.

Ethnicity

The number of units providing details of ethnicity has increased considerably; in the 1999 report only 6 units provided data on at least 85% of patients, in the 2000 report this had

increased to 12 and the figure for the current report is 17. In England, ethnicity data was missing in 24% of all the patients reported to the Registry in 2000 compared with 34% in the previous year. In 17 units the returns were high (>87%) rendering data from these units useful. Eight units provided little or no ethnicity data. In Wales and Scotland it is not health authority policy to collect ethnicity data. There was a notable increase in the percentage of Asian patients quoted by the Leicester unit – from 10% last year to 41.5% in this report.

Centre	% sent	White	Black	Asian	Chinese	Other
Gloucester	100	100.0				
Heartlands	100	85.7	2.6	7.8		2.6
Nottingham	100	87.6	4.4	6.2		1.8
Sheffield	100	94.9		4.4		0.7
Wolverhampton	100	80.5	5.2	13.0		1.3
Wordsley	100	92.5		7.5		
Exeter	99	98.6	1.4			
Preston	98	87.9		12.1		
Bristol	97	93.8	1.4	4.8		
Reading	96	78.8	3.8	13.5		1.9
Guys	95	73.3	22.9	1.9		
Plymouth	94	94.9	3.4	1.7		
Sunderland	93	100.0				
Southend	92	97.2	2.8			
Coventry	90	82.5	1.2	16.3		
Leicester	90	56.0	1.9	41.5		
St James, Leeds	87	89.6	1.3	7.8		1.3
Hull	78	98.4				1.6
Derby	*46*	*100.0*				
S Cleveland	*41*	*94.6*		*5.4*		
Carshalton	*26*					
Carlisle	*7*					
Oxford	*6*					
Leeds GI	*4*					
York	0					
England	**76**	**86.0**	**3.3**	**9.7**		**0.7**

Table 4.5: Ethnicity by centre

	Median age of incident patients	
Centre	**Ethnic minority**	**All**
Hull	41	65
Preston	47	60
Plymouth	47	67
Sheffield	49	58
Reading	51	60
Carshalton	55	60
Southend	56	68
Leicester	56	61
Heartlands	56	66
Guys	57	59
Wolverhampton	62	69
Coventry	63	62
Nottingham	63	65
Exeter	63	64
Wordsley	63	64

StJames, Leeds	64	63
SCleveland	64	67
Bristol	64	67
England	**57**	**64**

Table 4.6: Median age of ethnic groups accepted for renal replacement therapy

Higher acceptance rates are to be expected from the ethnic minority groups. The ethnic minority communities are also younger than the indigenous white populations. This is clearly reflected by the lower median age of those from ethnic minorities starting renal replacement therapy (table 4.5). As the ethnic communities age, even larger numbers of patients from them will be expected to start RRT.

Age and Gender

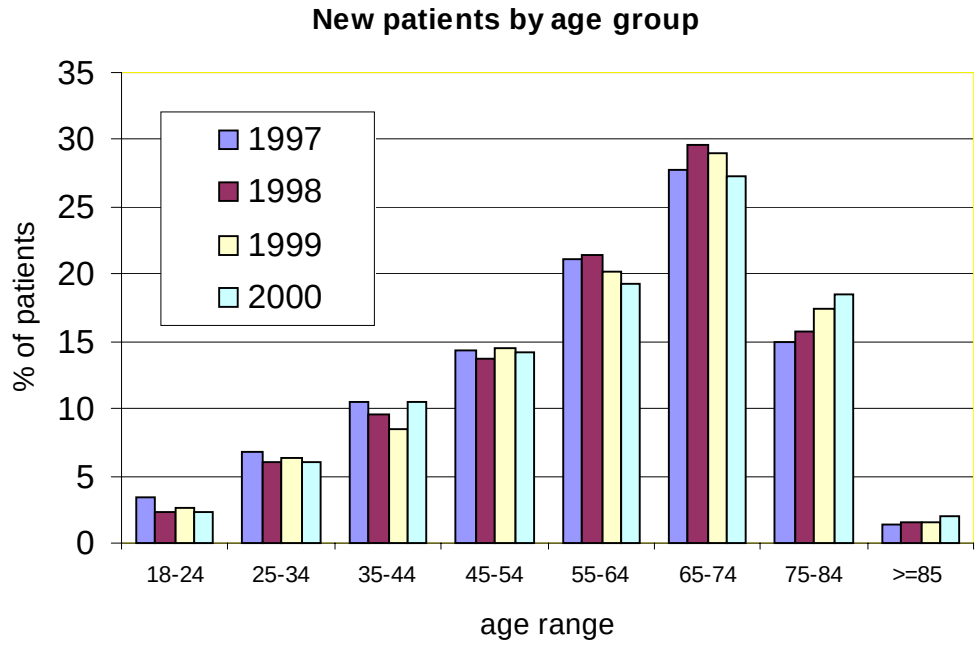


Figure 4.1: New patients by age group1997 - 2000

Figure 4.1 shows a four year increase in the proportion of over 75s taken onto the renal replacement programme. The incidence rate of 320 per million population in this age group is low when compared to other European populations, and probably still reflects an unmet need. Figure 4.2 shows the median age in each renal unit.

Percentage of males accepted for RRT				
Year	1997	1998	1999	2000
England & Wales	63.1	62.8	62.2	59.3

Table 4.7: Percentage of males by age 1999-2000

Although these data are not from the same centres there appears to be a trend over the 4 years to an increasing percentage of females being started on renal replacement therapy. This may be due to an increase in the incidence in patients aged 75-84 year age group, which is predominantly female in the general population.

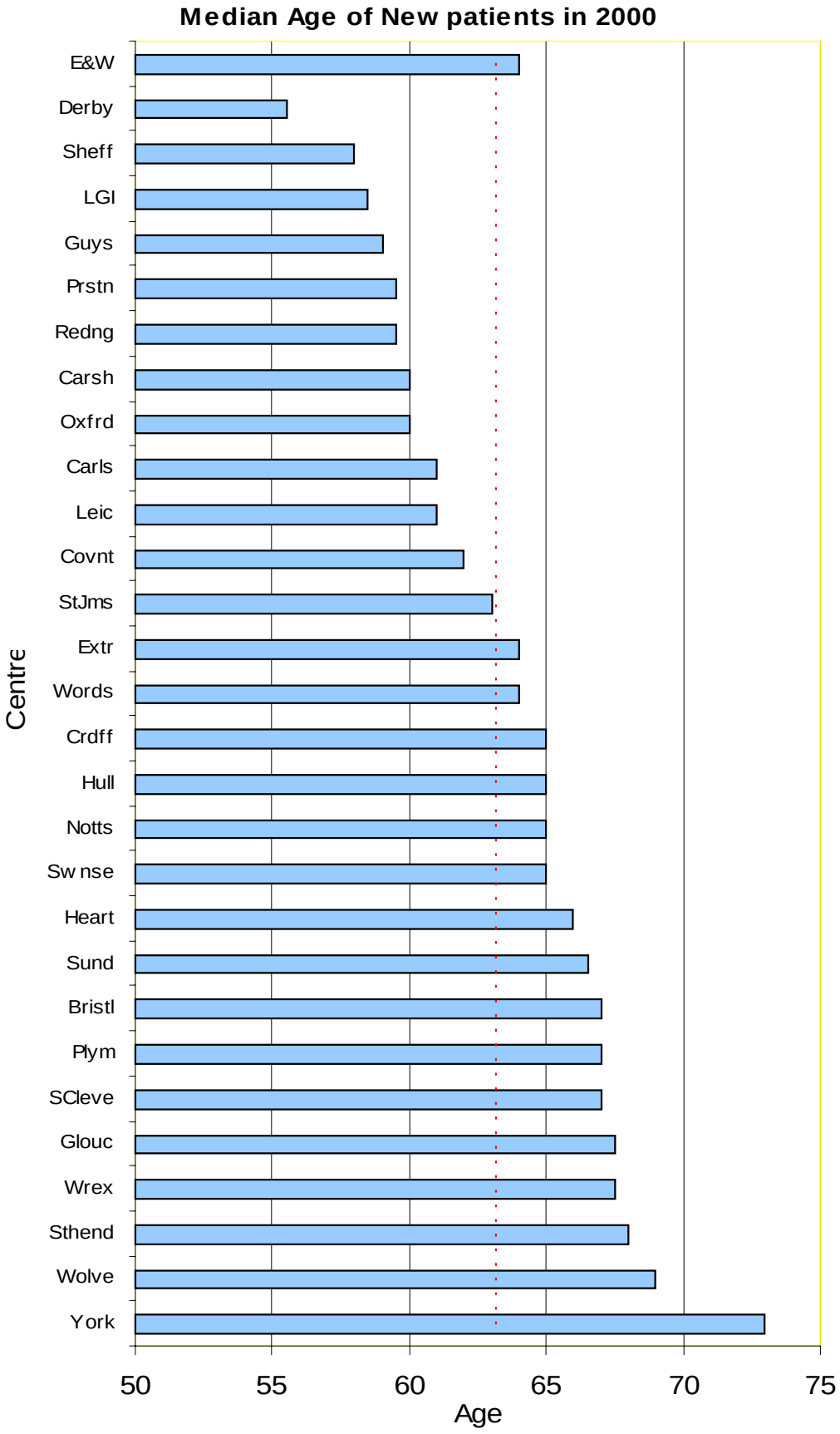


Figure 4.2: Median Age of New Patients in 2000

Primary Renal Diagnosis

The primary renal diagnoses for England and Wales, and by renal unit, are shown in tables 4.8 and 4.9. The high proportion of diabetic nephropathy seen in the USA and much of Europe, particularly the north, is still not seen in England and Wales. Diabetic nephropathy does not appear to be increasing as a proportion of the total patients starting RRT.

Diagnosis	E&W < 65	E&W ≥ 65	M:F
Aetiology uncertain and GN not proven	16	24	1.7
Glomerulonephritis	14	6	2.3
Diabetes	19	13	1.5
Polycystic Kidney	10	2	1.1
Pyelonephritis	8	7	1.0
Renal Vascular disease	2	10	2.1
Hypertension	4	5	2.4
Other	13	12	1.3
No diagnosis sent	15	20	1.8
Total patients	**1217**	**1160**	**1.5**

Table 4.8: Percentage Primary renal diagnosis by age, and gender ratios

Unit	Not sent	Aetiology unk. *	Diabetes	GN	Pyelo-nephritis	Polycystic Kidney	Reno-Vasc	Hypertens	Other
Gloucester	0	32.6	8.7	15.2	6.5	8.7	13.0	0.0	15.2
Heartlands	0	23.4	18.2	11.7	7.8	7.8	9.1	2.6	19.5
Reading	0	24.1	22.2	14.8	9.3	9.3	5.6	1.9	13.0
Sheffield	0	23.5	19.9	8.8	8.1	5.1	5.9	7.4	21.3
Wolverhampton	0	28.6	26.0	7.8	11.7	7.8	2.6	9.1	6.5
Wordsley	0	35.0	22.5	2.5	5.0	7.5	5.0	12.5	10.0
Nottingham	1	26.8	23.2	12.5	7.1	7.1	10.7	3.6	8.9
S Cleveland	1	36.0	14.6	13.5	6.7	6.7	6.7	6.7	9.0
Bristol	1	24.8	14.1	11.4	8.7	8.7	9.4	3.4	19.5
StJames, Leeds	2	19.5	13.8	9.2	16.1	10.3	8.0	0.0	23.0
Guys	3	17.8	28.0	11.0	8.5	7.6	10.2	5.9	11.0
York	8	32.4	5.4	8.1	16.2	2.7	10.8	8.1	16.2
Swansea	8	5.4	23.2	21.4	14.3	1.8	8.9	8.9	16.1
Carlisle	11	20.8	20.8	16.7	8.3	8.3	8.3	0.0	16.7
Coventry	13	20.8	20.8	9.1	11.7	1.3	9.1	13.0	14.3
Leeds GI	15	19.0	22.4	19.0	8.6	5.2	6.9	5.2	13.8
Hull	15	24.6	27.5	14.5	5.8	7.2	4.3	4.3	11.6
Preston	17	23.5	22.4	13.3	10.2	6.1	5.1	1.0	18.4
Sunderland	17	15.8	31.6	7.9	5.3	5.3	2.6	21.1	10.5
Leicester	18	34.2	15.1	10.3	10.3	2.7	8.2	6.2	13.0
Southend	18	34.4	15.6	6.3	6.3	6.3	6.3	6.3	18.8
Oxford	20	19.1	15.7	14.8	7.8	16.5	5.2	2.6	18.3
Cardiff	34	-	-	-	-	-	-	-	-
Plymouth	35	-	-	-	-	-	-	-	-
Exeter	46	-	-	-	-	-	-	-	-
Wrexham	90	-	-	-	-	-	-	-	-
E&W	**17**	**24.1**	**19.6**	**12.2**	**8.9**	**7.2**	**7.3**	**5.5**	**15.2**

* - Aetiology uncertain and Glomerulonephritis not proven

Diagnostic distributions were not calculated for units with less than 80% returns for diagnosis.

Table 4.9: Percentage diagnostic distribution of new RRT patients by unit

Treatment modality

The proportion of patients in each unit established on haemodialysis by day 90, and the variations with age are shown in figures 4.3 and 4.4.

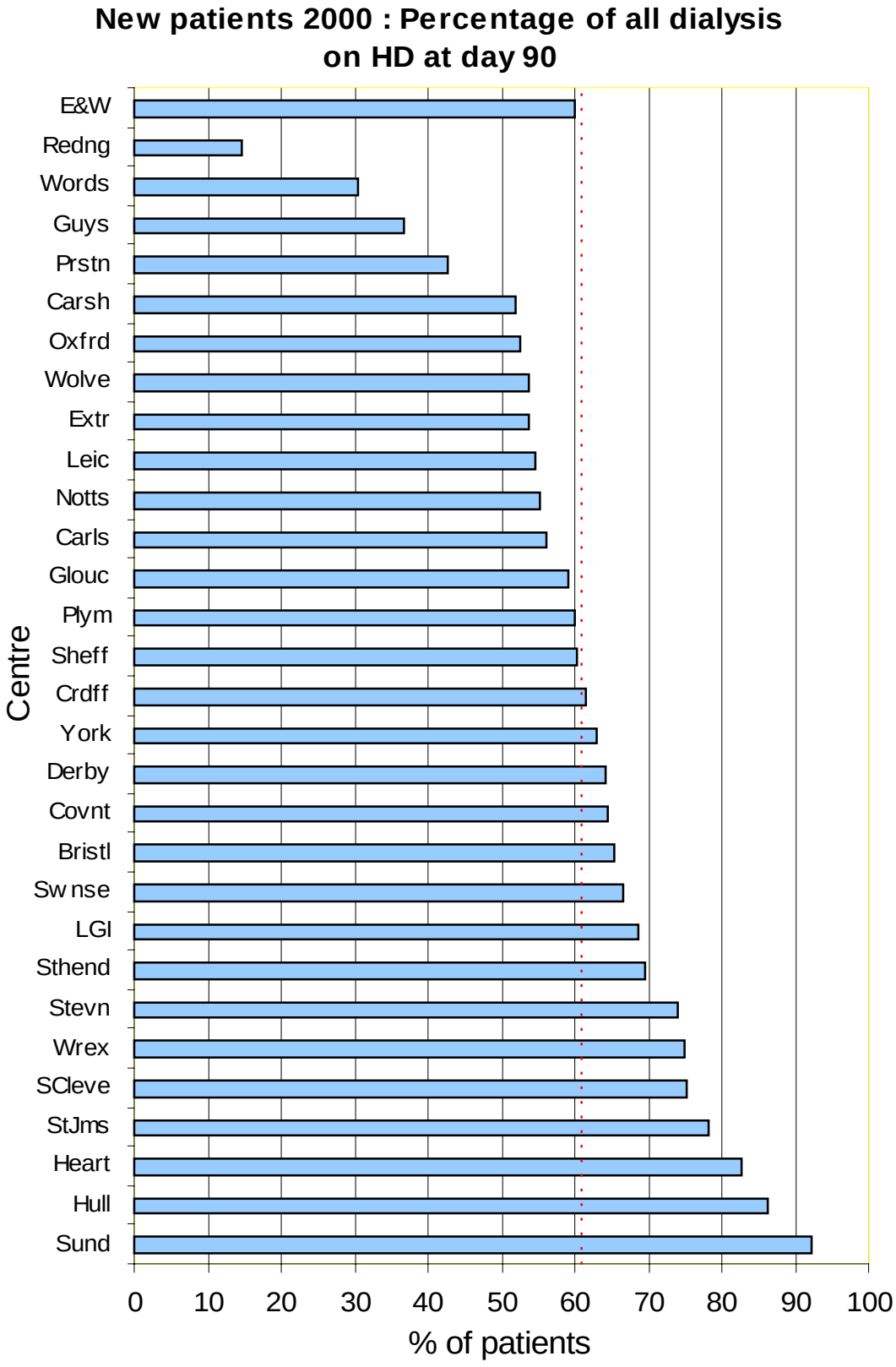


Figure 4.3: New patients 2000 - percentage of all dialysis on HD at day 90

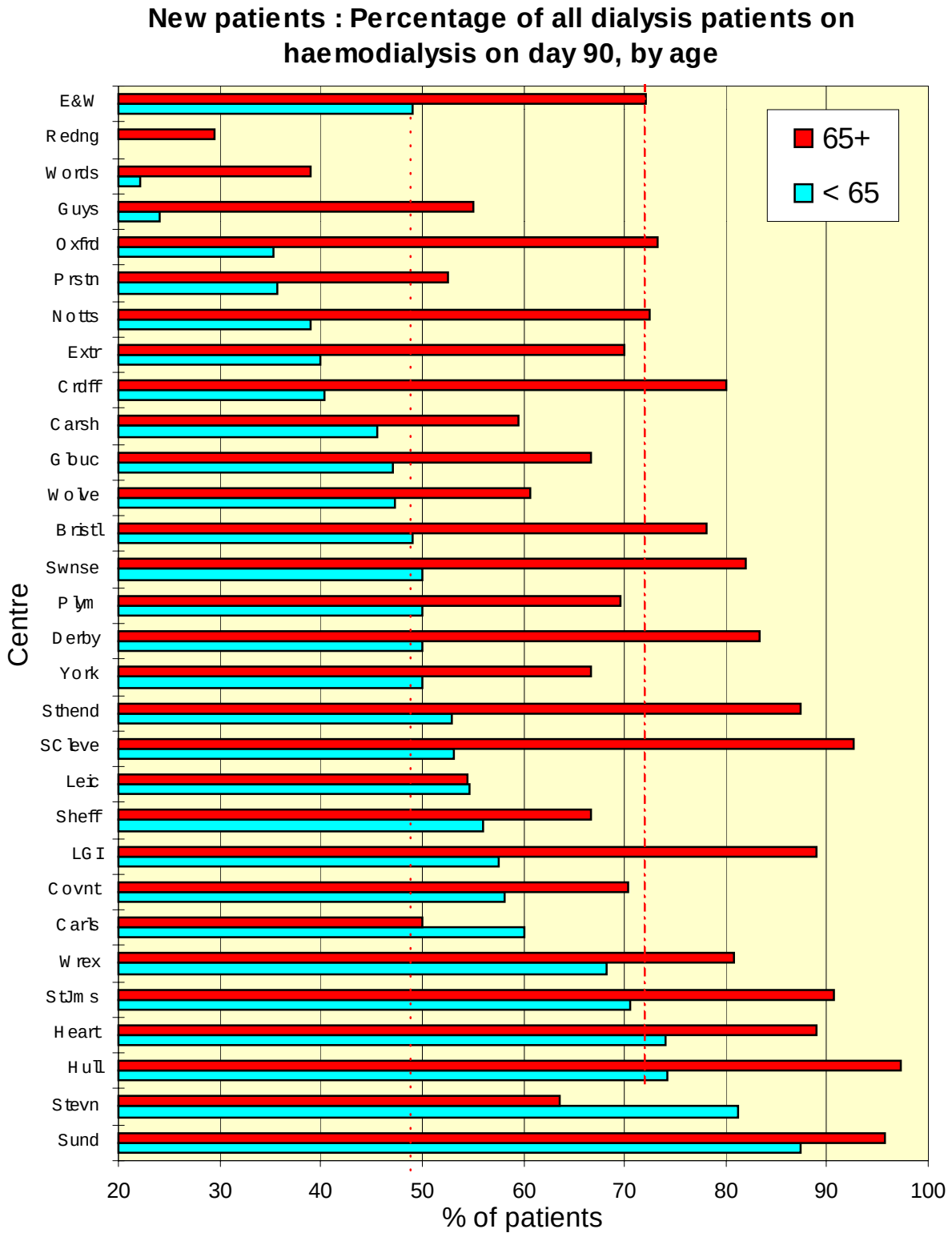


Figure 4.4: New patients - % of all dialysis patients on haemodialysis on day 90, by age

By day 90, 53 % of patients were established on haemodialysis, 35% on peritoneal dialysis, 1.6% transplanted, 0.3% stopped treatment without recovery, 8.8% died and 1.3% transferred out to a non-Registry centre.

The first change of treatment modality

This analysis includes the 2191 patients from the 23 E&W centres and 11 Scottish centres who started RRT on dialysis in 1999 and analyses the first change in modality in the 12 months from the established modality at day 90.

Change of treatment modality within the first year

Established on Haemodialysis		
Modality	*No of patients*	*Percentage*
Remains on HD	899	68
Changed to PD	46	4
Transplanted	70	5
Transferred out elsewhere	8	0.6
Recovered	16	1.2
Stopped Treatment (died)	15	1.1
Died (no change in modality)	262	20

Table 4.10: HD patients at 90 days: changes in modality in subsequent year

The results in Table 4.10 are almost identical to those in the 2000 Report although only 4% changed to PD in the first year rather than the 6% reported previously

Established on Peritoneal Dialysis		
Modality	*No of patients*	*Percentage*
Remains on PD	558	65
Change to HD	117	14
Transplanted	84	10
Transferred out elsewhere	7	0.8
Recovered	7	0.8
Stopped Treatment (died)	3	0.4
Died (no change in modality)	87	10

Table 4.11: PD patients at 90 days: changes in modality in one year

The results in Table 4.11 are identical to those in the 2000 Report.

The consistency of this data with the change from 912 patients to 2478 covering more varied regions of the country strongly suggests that this practice is reflective of the UK as a whole.

First modality change over 2 years

Only centres on the Registry in 1998 had a full annual cohort of patients available for a 2-year follow up period. The analysis includes 2123 patients.

Patients who were on haemodialysis after the first 90 days

These figures are similar to those in last year's Report except for a marked fall in the percentage of patients transplanted - from 9% at one year and 18% at 2 years down to 3% and 7% respectively (table 4.12). This fall is probably explained by the increased waiting lists for transplantation without a corresponding increase in the transplant rate.

Established on Haemodialysis	**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 HD	868	70	623	50
Changed to PD	55	4	63	5
Transplanted	61	5	130	10
Transferred out elsewhere	6	0.5	8	0.6
Recovered	14	1	20	1.6
Stopped Treatment (died)	27	2	35	3
Died (with no change in modality)	212	17	364	29
Total	1243		1243	

Table 4.12: Changes in modality over the first 2 years for patients on HD

Patients who were on peritoneal dialysis after the first 90 days

Established on PD	**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	557	63	351	40
Changed to HD	142	16	211	24
Transplanted	85	10	152	17
Transferred out	5	0.6	6	0.7
Recovered	6	0.7	10	1
Stopped Treatment (died)	2	0.2	3	0.3
Died (with no change in modality)	83	9	147	17
Total	880		880	

Table 4.13: Changes in modality over the first 2 years for patients on PD

These data confirm the findings in the Report 2000, even though this previous report was on a smaller data set. Compared with last year there is a fall in the percentage of patients transplanted at one year from 11% to 7% and at 2 years from 20% down to 13% (table 4.13). This has been reflected in a greatly increased shift from PD to HD. The PD technique survival has effectively remained the same at 66% at one year and 41% at 2 years, but this was maintained at the expense of an increased shift to HD from 11% to 17% at one year and 20% to 24% at 2 years. The continual future rise in transplant waiting lists will have HD resource implications. As patients stay longer on PD, more of the inadequately dialysed patients will have to be transferred to HD.
Few centres appear to be recoding withdrawal of treatment prior to death.

Survival of new patients starting renal replacement therapy

The revised renal standards document concluded that *"it is hard to set survival standards at present because these should be age sex and co-morbidity adjusted and this is not yet possible from Registry data. The last Standards document recommended at least 90% survival of patients 18-55 with standard primary renal disease. This may have been too low as the rate in participating centres in the Registry was 97%, though numbers were small. "*

Standard Primary Renal Disease is a definition from EDTA which excludes patients with renal disease due to diabetes and other systemic diseases. It is more widespread practice to simply exclude diabetics, so we have also quoted these figures to allow comparison with reports from other registries.

All the one and two year survival figures quoted in this chapter are from the first day of dialysis, not day 90 as quoted from the USA.

Comparison with the Standard recommendation

Patients 18-55 - One Year Survival (95% CI)		
First Treatment	*Standard Primary Renal Disease* **1999**	**All Diseases Except Diabetes 1999**
All	92.8 (90.5-95.2)	91.7 (89.5-93.9)
Haemodialysis	89.2 (95.9-93.5)	87.4 (83.6-91.2)
Peritoneal dialysis	97.5 (95.0-100)	98.0 (96.0-100)

Table 4.14: One Year Patients Survival – patients age 18-55, 1999 cohort

These survival figures are not as high as the revised standards document quotes from the Registry.

Survival of all new patients

As shown before, a high proportion (46%) of deaths within the first year occur within the first 90 days (tables 4.15, 4.16), a period excluded from the USA registry report.

Age	**Deaths/No of new patients**	**KM Survival Analysis (%)**	**KM 95% Confidence Interval**
< 65	66/1337	95	94-96
≥ 65	208/1232	83	81-85
All	274/2569	89	88-90

Table 4.15: 90-day survival of new patients, 1999 cohort

Age	Deaths/No of new patients	KM Survival Analysis (%)	KM 95% Confidence Interval	Death Rate Per 100 Patient Years
< 65	180/1337	86	84-88	14.7
≥ 65	418/1232	66	63-69	41.8
All	598/2569	76	75-78	27.0

Table 4.16: One Year Survival of new patients, 1999 cohort

Age	Numbers of patients			KM survival		KM 95% CI
	3/12	1 year	2 years	1 year	2 year	2 year survival
<65	67/1282	163/1282	263/1282	87%	79%	77-81
≥ 65	217/1129	399/1129	583/1129	64%	47%	44-50
All	284/2411	562/2411	846/2411	76%	64%	62-66

Table 4.17: Two-year survival of new patients, 1998 cohort

The high proportion of first year deaths which occurs in the first 90 days also differs between age groups. This renders correction for age, gender, and diagnosis, using the Cox proportional hazards method, difficult. Further detailed analysis of patterns of death and the implications for standardisation of data and comparison between registries is presented in chapter 9.

Age distributions and relative risk of death

Age band	Increased risk of death
45-54	18.5
55-64	14.6
65-74	9.1
>75	4.5

Table 4.18: Increased risk of death within one year of starting dialysis – non-diabetics

Table 4.18 shows the increased risk of death for non-diabetic dialysis patients compared with people of the same age in the general population. These data are similar to those published by Mignon et al in 1993

References

Mignon, F., Michel, C., Mentre, F., and Viron, B. (1993). Worldwide demographics and future trends of the management of renal failure in the elderly. Kidney International, 43(Supplement 41), S18–26.

Chapter 5: All Patients Receiving Renal Replacement Therapy In 2000

Summary

In England & Wales there was a 4.8% increase in the total number of patients on RRT between the 1st January 2000 and 31st December 2000. This comprised a 5.1% increase in the number of patients on dialysis and 4.6% increase in those with a functioning transplant. This compares with 4.3% increase for the centres on the Registry during 1999. These data are consistent with the annual rises shown in the 1992, 1995 and 1998 Renal Reviews.

On December 31st 2000, 1414656 patients receiving Renal Replacement Therapy from 28 renal units were enrolled in the Renal Registry in England and Wales. The number of patients in units with data for both 1998 and 1999 increased by 4.3% during 1999. For individual English and Welsh Health Authorities, the estimated dialysis prevalence varied from 329 to 693 pmp. In England and Wales, the average number of patients on RRT in each unit was 523.

The median age for all patients on treatment on 31/12/00 was 54 years, unchanged from the 2 previous years. The median age of patients on peritoneal dialysis remains lower than that of those on haemodialysis. .

61% of all patients on treatment were male: this preponderance occurs at all ages.

Reporting of ethnic origin has improved. The proportion of white patients in individual units varied from 39% to 100%, Asian from 0% to 56%, and Black from 0% to 15%.

The most common primary renal disease recorded for prevalent patients under 65 years old was glomerulonephritis. In 28% of those over 65 it was not possible to give a diagnosis.

Diabetes accounted for 16% of current incident patients, but 10% of all prevalent patients. Of those classified as Type I diabetics, 27% under 65 years old were on PD compared with 31% of Type 2 diabetics and 14% of the under 65 non-diabetics. In the over 65-year-old patients, use of PD was markedly) less common (20% type I, 28% type II, 20% non-diabetic).

In England & Wales 66% of dialysis patients were on haemodialysis. The trend to an increased proportion of total patients on haemodialysis continues, but the proportion of dialysis patients on haemodialysis is now growing very slowly. Up to the age of 54 more patients are treated by transplantation than by dialysis. Haemodialysis is the predominant form of dialysis at all ages but especially in the older age groups. Connect PD has almost completely ceased. Cycling PD has not made much impact overall, but in a few units is the predominant form of PD

The one-year survival of all patients established on renal replacement therapy for at least 90 days was 83.7%, and the two-year survival 68.4%.

Introduction

On December 31st 2000, 14656 patients receiving Renal Replacement Therapy from 28 renal units in England and Wales were enrolled in the Renal Registry. This chapter describes their demographic details, diagnosis and treatment, and gives an analysis of the 1-year survival of patients who had been established for at least 3 months on RRT on 31/12/99. Anonymity has been removed. Prevalence rates are presented by Health Authority.

Overall Prevalence Rate

An overall summary of the prevalence of patients on renal replacement therapy in England and Wales is shown in table 5.1. The overall prevalence has a wide potential margin of error as it is calculated from the estimated catchment populations of the renal units. As discussed in chapter 4 there are significant errors in these estimates.

	England & Wales
No. of units	28
No. of patients	14656
Population (m)*	26.44
Patients (pmp)*	554
Mean Pats/unit	523

*=estimated figures

Table 5.1: Summary of adult patients registered and total population covered 31/12/2000

Renal unit activity

From table 5.2 it can be seen that there is a continuing increase in the number of prevalent patients on RRT in England and Wales, and in almost every participating unit. This increase is larger for the dialysis population than the transplant population.

Renal units	**No of patients**	**% increase in dialysis in 2000**	**% increase all patients**
Bristol	913	6.1	4.3
Cardiff	973	11.3	5.0
Carlisle	161	11.9	1.9
Carshalton	679	2.6	2.0
Coventry	525	6.7	5.0
Derby	119	9.4	14.4
Exeter	450	11.8	5.9
Gloucester	243	9.3	11.0
Guys	1222	1.0	6.0
Heart lands	460	3.8	2.7
Hull	446	-2.2	2.5
Leeds GI	344	10.3	
Leeds St James	817	9.9	
Leeds total	*1161*	*10.1*	*4.6*
Leicester	983	3.8	4.8

Renal units	No of patients	% increase in dialysis in 2000	% increase all patients
Nottingham	801	4.6	3.1
Oxford	1247	-0.6	2.5
Plymouth	421	7.1	7.1
Preston	532	9.3	8.6
Reading	182	1.8	3.4
S. Cleveland	485	6.4	6.8
Sheffield	867	7.4	6.5
Southend	158	-3.1	5.3
Sunderland	251	6.7	4.6
Swansea	314	1.3	6.8
Wolverhampton	328	8.6	8.3
Wordsley	254	0.6	0.4
Wrexham	248	3.3	3.8
York	129	1.7	6.6
E&W	14646	5.1	4.8

Table 5.2: Increase in prevalent patients, by unit,

In England & Wales there was a 4.8% increase in the total number of patients on RRT between the 1st January 2000 and 31st December 2000. This comprised a 5.1% increase in the number of patients on dialysis and a 4.6% increase in those with a functioning transplant. This compares with 4.3% increase for the centres on the Registry during 1999. These data are consistent with the annual rises shown in the 1992, 1995, and 1998 Renal Reviews.

Prevalence by Health Authority

The estimated catchment populations for each renal unit are not reliable, as discussed in chapter 4, so the prevalence related to individual renal units has not been calculated. Prevalence in health authorities with complete or near complete registry coverage has been calculated and is shown in table 5.3.

HA				Prevalence				
						Total		
Code	**Region**	**HA name**	**Population**	HD	PD	Dial.	Trans.	RRT
QDT	Y01	Calderdale and Kirklees	583,800	180	65	245	272	518
QDE	Y01	County Durham and Darlington	607,800	168	31	199	194	393
QDF	Y01	East Riding and Hull	574,500	207	89	296	216	512
QDH	Y01	Leeds	727,400	232	70	302	268	571
QDK	Y01	North Cumbria	319,300	160	91	251	254	504
QDR	Y01	North Yorkshire	742,400	182	73	255	214	469
QDN	Y01	Sunderland	292,300	202	27	229	222	452
QDP	Y01	Tees	556,300	165	47	212	306	518
QDQ	Y01	Wakefield	318,800	201	97	298	257	555
QCG	Y02	Barnsley	228,100	197	79	276	298	574
QCK	Y02	Doncaster	290,500	231	76	307	207	513
QCL	Y02	Leicestershire	928,700	202	146	348	300	649
QCM	Y02	Lincolnshire	623,100	159	143	302	212	514
QCH	Y02	North Derbyshire	370,200	159	73	232	213	446
QCN	Y02	North Nottinghamshire	388,900	221	113	334	216	550

HA				Prevalence				
						Total		
Code	**Region**	**HA name**	**Population**	HD	PD	Dial.	Trans.	RRT
QCP	Y02	Nottingham	642,700	272	143	415	238	653
QCQ	Y02	Rotherham	254,400	236	79	315	248	562
QCR	Y02	Sheffield	531,100	265	51	316	196	512
QDL	Y02	South Humber	308,600	279	81	360	230	590
QCJ	Y02	Southern Derbyshire	567,500	199	132	331	277	608
QEA	Y07	Coventry	304,300	289	131	420	256	677
QEC	Y07	Dudley	311,500	167	164	331	196	526
QEG	Y07	Solihull	205,600	190	68	258	156	413
QEK	Y07	Walsall	261,200	226	96	322	57	379
QEL	Y07	Warwickshire	506,700	189	132	321	288	610
QEM	Y07	Wolverhampton	241,600	373	145	518	161	679
QCX	Y08	East Lancashire	511,200	147	80	227	131	358
QC4	Y08	Morecambe Bay	310,300	122	81	203	126	329
QCY	Y08	North-West Lancashire	466,300	139	107	246	165	412
QAD	Y10	Croydon	338,200	157	98	255	186	441
QAH	Y10	Lambeth, Southwark and Lewisham	745,200	191	121	312	204	515
QA7	Y11	Berkshire	556,600	138	192	330	363	693
QA8	Y11	Buckinghamshire	618,900	163	87	250	273	524
QAK	Y11	East Surrey	419,900	93	74	167	236	402
QCC	Y11	Northamptonshire	615,800	172	96	268	245	513
QCE	Y11	Oxfordshire	616,700	133	84	217	274	491
QD8	Y12	Avon	999,300	223	72	295	297	592
QDY	Y12	Gloucestershire	557,300	217	90	307	336	642
QDX	Y12	North and East Devon	479,300	169	100	269	273	542
QD5	Y12	Somerset	489,300	200	80	280	221	501
QD6	Y12	South and West Devon	589,100	205	109	314	273	587

HA				HD		Dial	Tx	RRT
Code	**Region**	**HA name**	**Population**	prev	PD prev	prev	prev	prev
QW1	W00	Gwent	557,200	174	102	276	343	619
QW2	W00	Bro Taf	739,600	204	95	299	333	632
QW5	W00	Morgannwg	499,700	174	110	284	274	558

Table 5.3: Prevalence of renal replacement therapy by Health authority.

Change in prevalence 1998 –2000 by Health Authority

Even where the Registry does not have complete coverage of a health authority, the proportion of population covered by the same renal unit is probably constant on a year-to-year basis.

HA code	Region	HA text	Prev 2000pmp	Prev 1999pmp	Prev 1998pmp	% change 99-00	% change 98-99
QDE	Y01	County Durham and Darlington	393	344	336	14.4	2.5
QDF	Y01	East Riding and Hull	512	463	447	10.5	3.5
QDK	Y01	North Cumbria	504	501	485	0.6	3.2
QDN	Y01	Sunderland	452	438	431	3.1	1.6

HA code	Region	HA text	Prev 2000pmp	Prev 1999pmp	Prev 1998pmp	% change 99-00	% change 98-99
QDP	Y01	Tees	518	482	466	7.5	3.5
QCG	Y02	Barnsley	574	509	460	12.9	10.5
QCK	Y02	Doncaster	513	465	423	10.4	9.8
QCL	Y02	Leicestershire	649	602	600	7.9	0.4
QCM	Y02	Lincolnshire	512	456	425	12.3	7.2
QCH	Y02	North Derbyshire	446	405	397	10.0	2.0
QCN	Y02	North Nottinghamshire	550	496	465	10.9	6.6
QCP	Y02	Nottingham	653	624	577	4.7	8.1
QCQ	Y02	Rotherham	562	460	448	22.2	2.6
QCR	Y02	Sheffield	512	442	409	15.7	8.3
QDL	Y02	South Humber	590	544	531	8.3	2.4
QD9	Y07	Birmingham	259	237	226	9.2	4.8
QEA	Y07	Coventry	677	664	670	2.0	-1.0
QEC	Y07	Dudley	526	494	472	6.5	4.8
QEE	Y07	Sandwell	182	169	145	8.2	16.7
QEG	Y07	Solihull	413	355	365	16.4	-2.7
QEK	Y07	Walsall	379	333		13.8	
QEL	Y07	Warwickshire	610	555	519	10.0	6.8
QEM	Y07	Wolverhampton	679	592		14.7	
QEN	Y07	Worcestershire	162	145	145	11.5	0.0
QCX	Y08	East Lancashire	360	276	270	30.5	2.2
QC4	Y08	Morecambe Bay	329	235	226	39.7	4.3
QCY	Y08	North-West Lancashire	412	315	300	30.6	5.0
QC1	Y08	South Lancashire	182	134		35.7	
QER	Y09	Cambridgeshire	143	122	111	17.5	9.6
QED	Y09	Herefordshire	149	137	137	8.7	0.0
QAY	Y09	South Essex	237	213		11.3	
QAD	Y10	Croydon	361	355	322	1.7	10.1
QAJ	Y10	Merton, Sutton and Wandsworth	241	220	214	9.4	3.0
QA8	Y11	Buckinghamshire	466	431	422	8.2	2.1
QAK	Y11	East Surrey	360	348	324	3.4	7.4
QCC	Y11	Northamptonshire	512	463	445	10.5	4.0
QCE	Y11	Oxfordshire	491	454	431	8.2	5.3
QD8	Y12	Avon	592	550	534	7.6	3.0
QDY	Y12	Gloucestershire	641	511	458	25.3	11.8
QDX	Y12	North and East Devon	547	503	463	8.7	8.6
QD5	Y12	Somerset	501	472	431	6.1	9.5
QD6	Y12	South and West Devon	584	535	502	9.2	6.4
QD7	Y12	Wiltshire	347	337	342	2.9	-1.4
QW1	W00	Gwent	617	560	549	10.3	2.0
QW2	W00	Bro Taf	631	581	533	8.6	9.1

Table 5.4: Change of prevalence of RRT by Health authority, 1998-2000.

In England & Wales there was a 4.8% increase in the total number of patients on RRT between the 1st January 2000 and 31st December 2000. This comprised a 5.1% increase in the number of patients on dialysis and a 4.6% increase in those with a functioning transplant. This compares with 4.3% increase for the centres on the Registry during 1999. The figures for individual health authorities are shown in table 5.4.

Age

The median age for all patients on treatment on 31/12/200 was 54 years (table 5.5), which is unchanged from the previous year. The median age of patients on peritoneal dialysis remains lower than that of those on haemodialysis.

	Transplants	Peritoneal dialysis	Haemodialysis	All
Median age E&W	**48**	**58**	**63**	**54**
Range between units	**44 - 52**	**46 - 62**	**56 - 70**	**50 - 66**

Table 5.5: Median age and treatment modality

The age distribution of prevalent patients is shown in figure 5.1

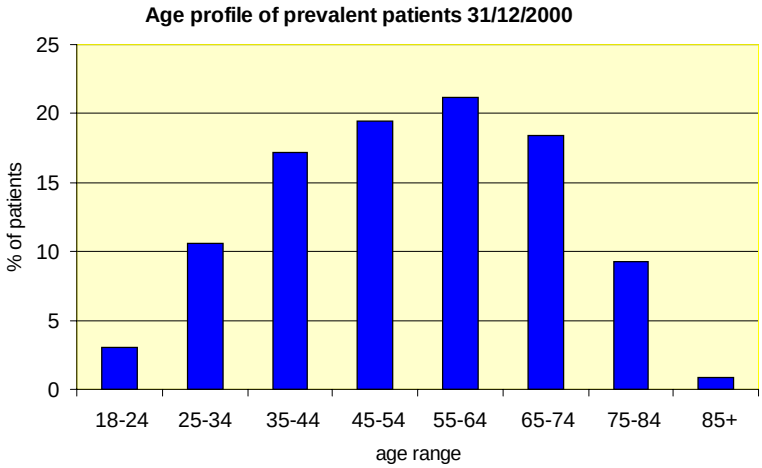


Figure 5.1: Age profile of prevalent patients

In England and Wales, 28% of patients were aged 65 or over and 10% were over the age of 75. This is unchanged from last year.

The younger age distribution of transplant patients is shown in figure 5.2

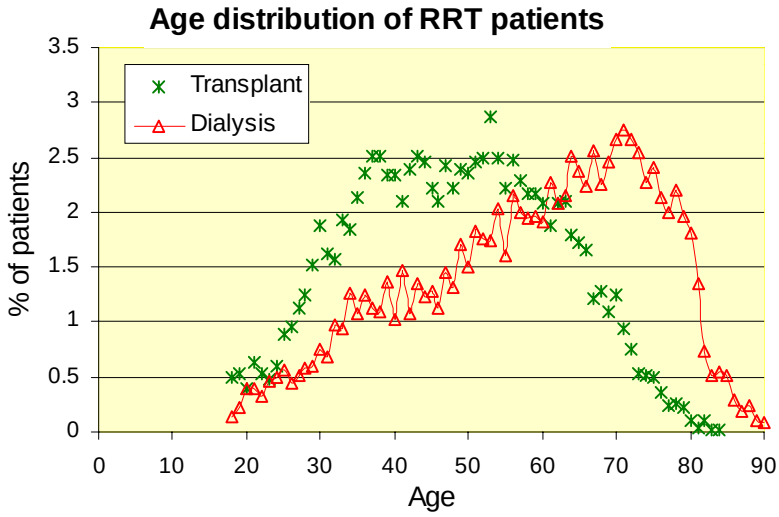


Figure 5.2: Age distributions of transplanted and dialysis patients

Figure 5.3 demonstrates the wide variation in median age (56 to 69) of dialysis patients in individual units. Whilst differences in local populations may account for some of this variation, referral and acceptance policies, survival rates and available resources are also likely to have a major impact.

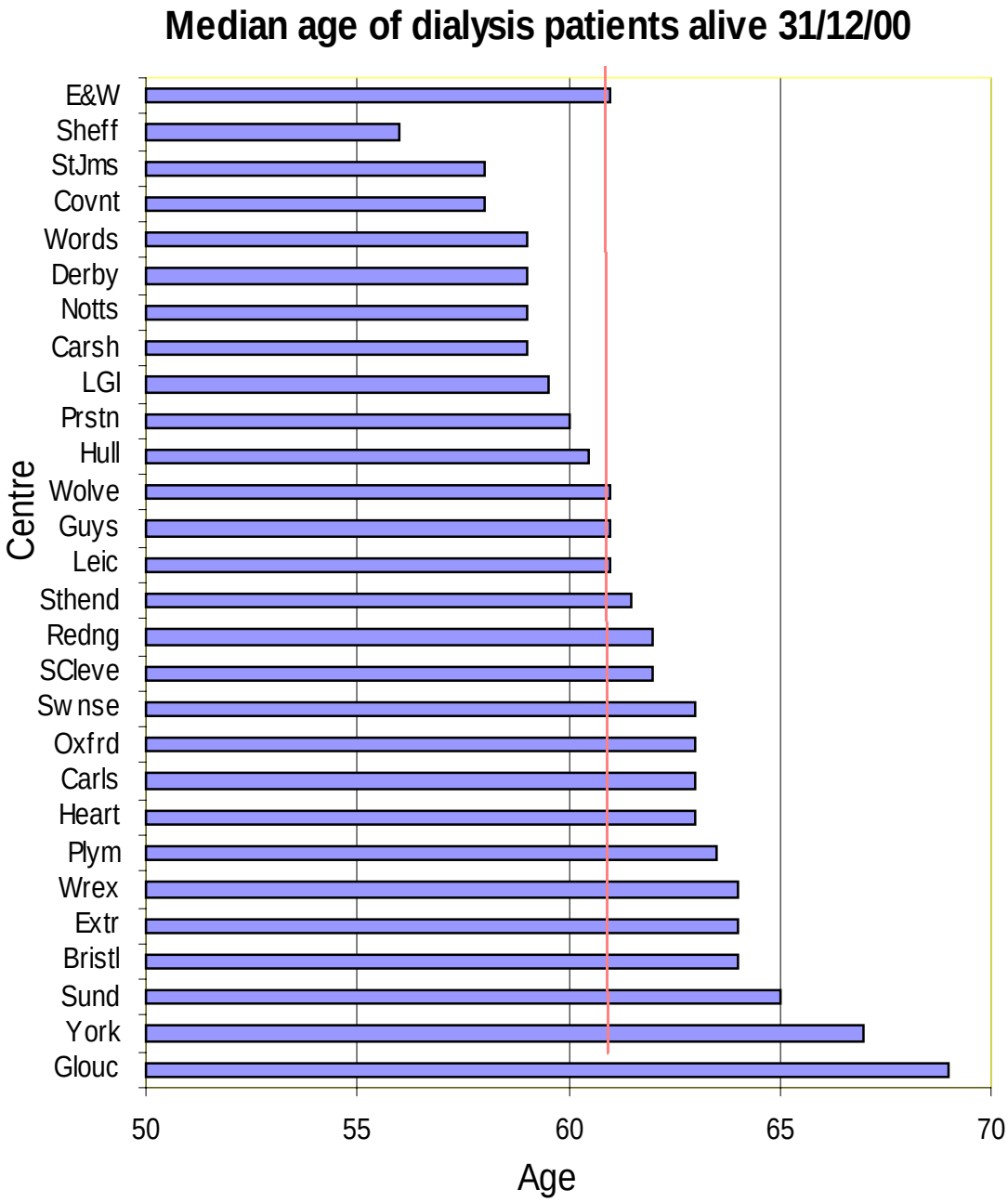


Figure 5.3: Median age of dialysis patients alive 31.12.00

Gender

Overall 61% of all patients on treatment were male: the male preponderance occurs at all ages. The ration was similar in all age groups (figure 5.4). While the numbers are small the high proportion of males in the older age groups occurs in spite of the greater proportion of women in the general population at that age.

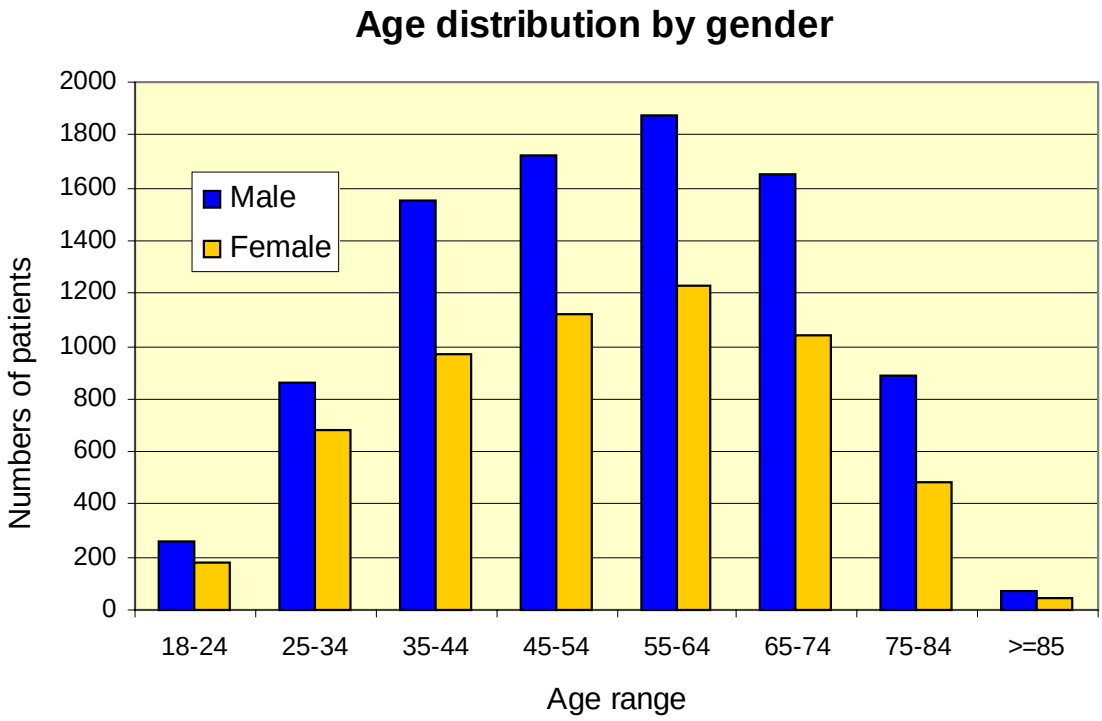


Figure 5.4: Age distribution by gender.

Ethnicity

Reporting of ethnic origin has improved. It is not currently a health service policy to collect ethnicity data in Scotland or Wales, so ethnicity data were not available from the Scottish or Welsh units. Of the English units, 4 provided little or no data at all while information was complete on at least 84% of patients in 21 units (table 5.6). The proportion of white patients in individual units varied from 39% to 100%, Asian from 0% to 56%, and Black from 0% to 15%.

	% with data complete	% White	% Black	% Asian	% Chinese	% Other
Exeter	100	100	0	0.	0	0
Gloucester	100	100	0	0	0	0
Sheffield	100	94	1	3	1	0
Preston	100	88	1	10	0	1
Wordsley	100	89	2	9	0	0
Heart lands	100	76	5	18	1	0
Wolverhampton	99	78	6	14	1	0

	% with data complete	% White	% Black	% Asian	% Chinese	% Other
Southend	99	95	3	2	0	0
Bristol	98	93	3	2	1	1
Plymouth	98	97	1	0	0	0
Reading	98	73	7	17	2	2
Hull	97	99	0	0	0	0
St James	96	88	3	9	0	0
Sunderland	96	99	1	0	0	0
Coventry	94	81	2	16	0	0
Leicester	92	39	2	56	1	2
Nottingham	92	88	5	7	0	1
Guys	92	80	15	4	1	0
Carshalton	86	71	5	5	1	18
S. Cleveland	85	96	0	4	0	1
Derby	84	86	2	9	1	1
Cardiff	27					
York	13					
Carlisle	13					
Swansea	9					
Oxford	3					
Leeds GI	3					
Wrexham	0					
E&W	**75**	**84.2**	**3.7**	**10.1**	**0.5**	**1.5**

Table 5.6: Ethnicity

The percentages of patients with a functioning transplant belonging to each ethnic minority group are listed in table 5.7. There is a slightly lower percentage of the Asian and Black population with a transplant. This may be considered surprising in view of the relatively low age distribution of the ethnic minority patients, but difficulties in tissue matching and the higher incidence of diabetics with increased co-morbidity in this population may reduce the opportunities for transplantation.

% White	% Black	% Asian	% Chinese	% Other
86.8	2.2	8.8	0.5	1.6

Table 5.7: Percentage of transplanted patients in each ethnic group.

Primary Renal Disease

Details of primary renal disease, based on the original EDTA coding classification are shown in table 5.8. In as many as 27.9% of those over 65 it was not possible to give a diagnosis. Missing data were much more common in patients over 65 with 10% missing compared with 3% in patients aged under 65. Diabetes accounted for just over 10% of patients in both age groups, a much lower proportion than the 16% in current incident patients.

Diagnosis	% All patients	Inter unit range	% Age < 65	%Age ≥ 65	M : F Ratio
Aetiology uncertain *	22.	3 - 31	21	28	1.7
Glomerulonephritis**	16	3 - 25	18	9	2.3
Pyelonephritis	14	1 - 21	15	11	1.1
Diabetes	11	6 - 20	10	11	1.5
Renal Vascular disease	3	3 - 14	2	10	2.4
Hypertension	6	1 - 15	6	6	2.4
Polycystic kidney	9	1 - 10	10	4	1.0
Not sent	5	0 - 79	4	11	1.8
Other	13	3 - 21	14	10	1.3
Total Number of Patients	**14033**		**11140**	**2893**	**1.55**

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

Table 5.8: Primary renal disease in all patients, and according to age and gender

Diabetes

Diabetes was recorded as the primary diagnosis in 10% of all prevalent patients. The median age of type I diabetics was 51, and type II diabetics 65. Further details are given in table 5.9.

	Type I	Type II	Non-Diabetics
M : F ratio	1.40	1.62	1.54
Median Age on 31/12/00	51	65	54
Median Age started ESRF	47	63	45
Median years on treatment	2.6	2.2	
% on HD	39	61	
% on PD	27	26	
% transplanted	34	13	

Table 5.9: Type of diabetes, median age, gender ratio, modality

From table 5.10 it is clear that at any age diabetics are less likely to have received a transplant than other patients. Although more younger dialysing diabetics are on haemodialysis than peritoneal dialysis, the ratio of HD to PD is lower than in other patients. For older diabetics, the proportion on haemodialysis is very high.

Modality	Type I < 65	Type II < 65	Non-diabetics < 65	Type I ≥ 65	Type II ≥ 65	Non-diabetics ≥ 65
% HD	31	50	25	70	75	55
% PD	27	31	14	20	28	20
% transplant	42	19	61	7	5	25

Table 5.10: Treatment modality by age and diabetic status.

Modalities of Treatment

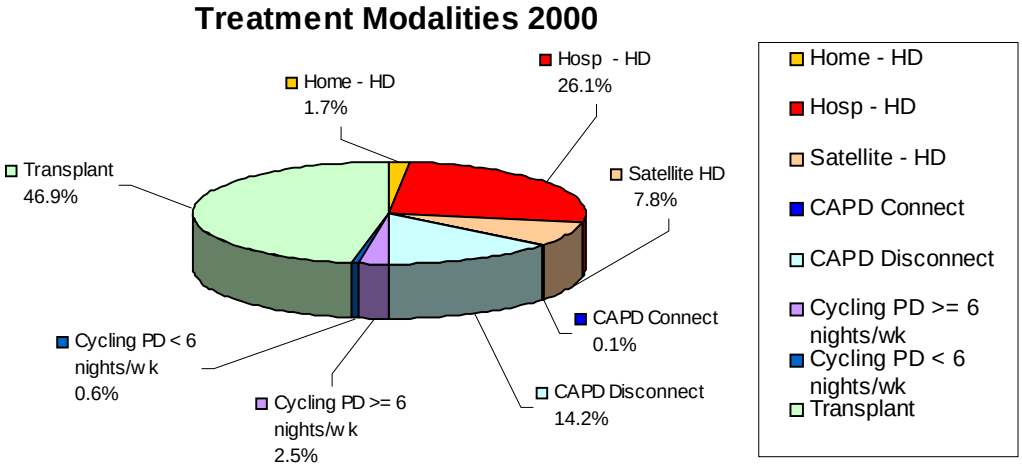


Figure 5.5: Treatment modalities 31/12/200.

The number of patients on renal replacement therapy continues to rise, but the percentage of patients with a functioning transplant has continued to fall for the last 4 years. There are even fewer patients left on connect PD (0.1% 2000 and 0.7% 1999). Cycling PD has increased from 1.6% to 3.1% of all renal replacement therapy (figure 5.5).

	18-24	25-34	34-44	45-54	55-64	65-74	75-84	85+
Haemodialysis	2	7	11	14	19	26	19	*
Peritoneal Dialysis	3	8	13	19	23	22	11	*
Transplant	4	14	23	24	22	11	2	*

*- number very small

Table 5.11: Percentage on each modality according to age

In England & Wales 66% of dialysis patients were on haemodialysis. The variations in patterns of treatment with age are shown in figure 5.6 and table 5.11. Up to the age of 54 more patients are treated by transplantation than by dialysis. Haemodialysis is the predominant form of dialysis at all ages but more so in the older age groups.

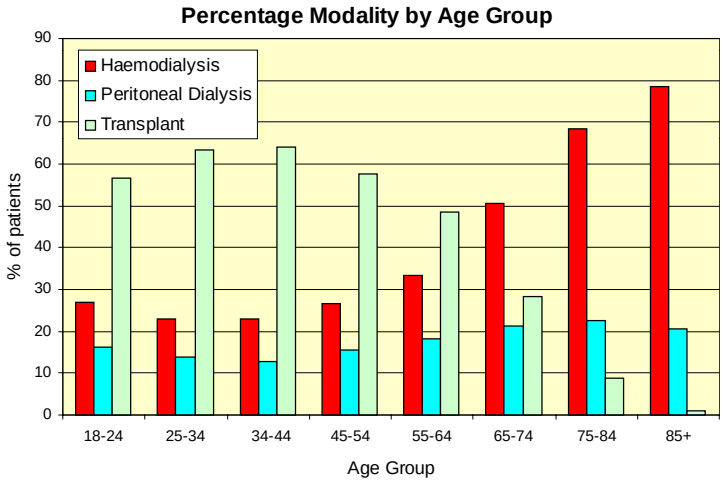


Figure 5.6: In each age group, percentage of patients on each modality.

Haemodialysis

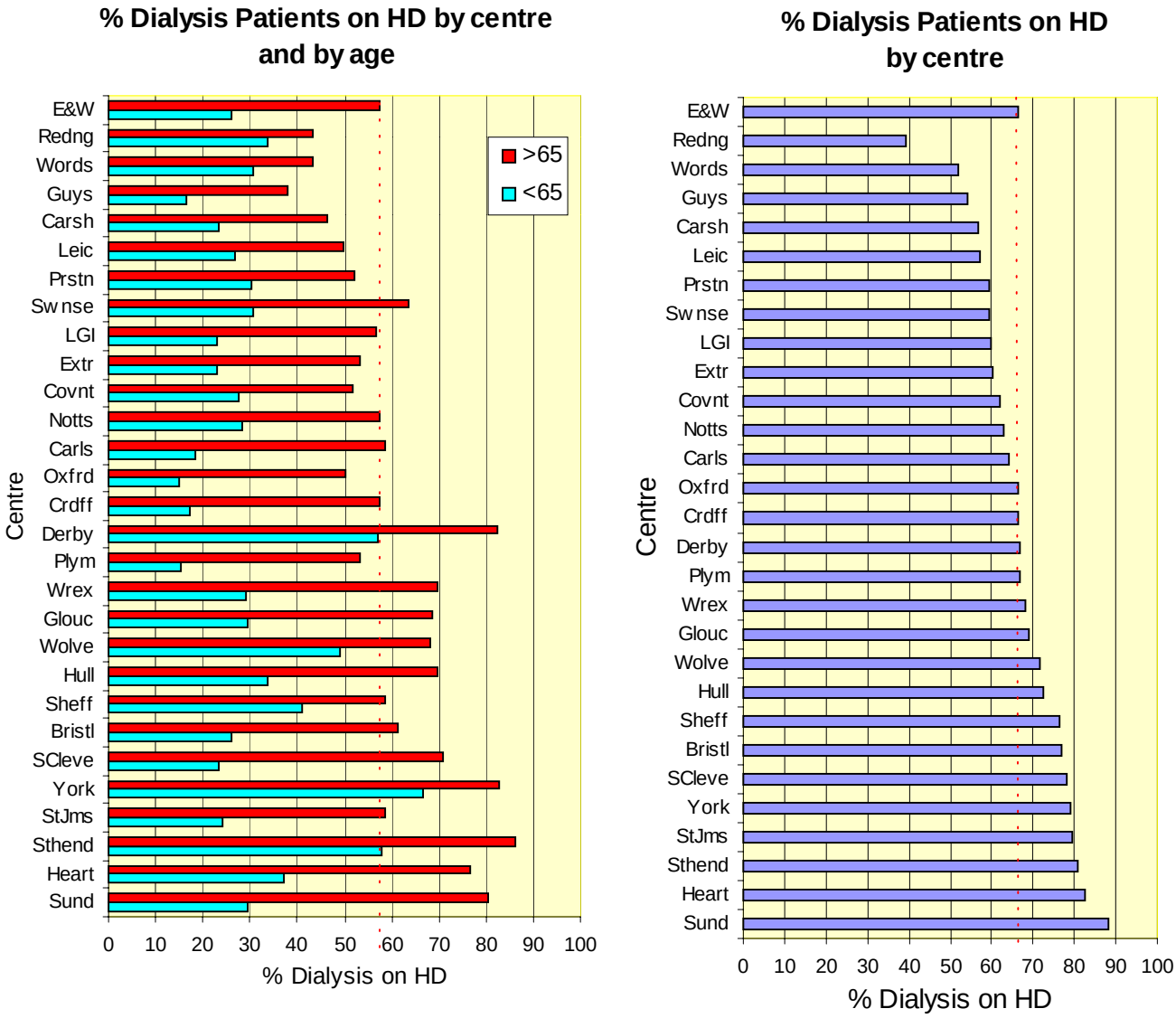


Figure 5.7: Percentage dialysis patients on haemodialysis by centre and age.

The proportion of dialysis patients treated by haemodialysis as opposed to peritoneal dialysis varied widely from unit to unit and cannot be explained by age alone (Figure 5.7)

The percentage of patients on haemodialysis treated in satellite units in England & Wales was 22%: home haemodialysis was only 5% of haemodialysis (figure 5.8).

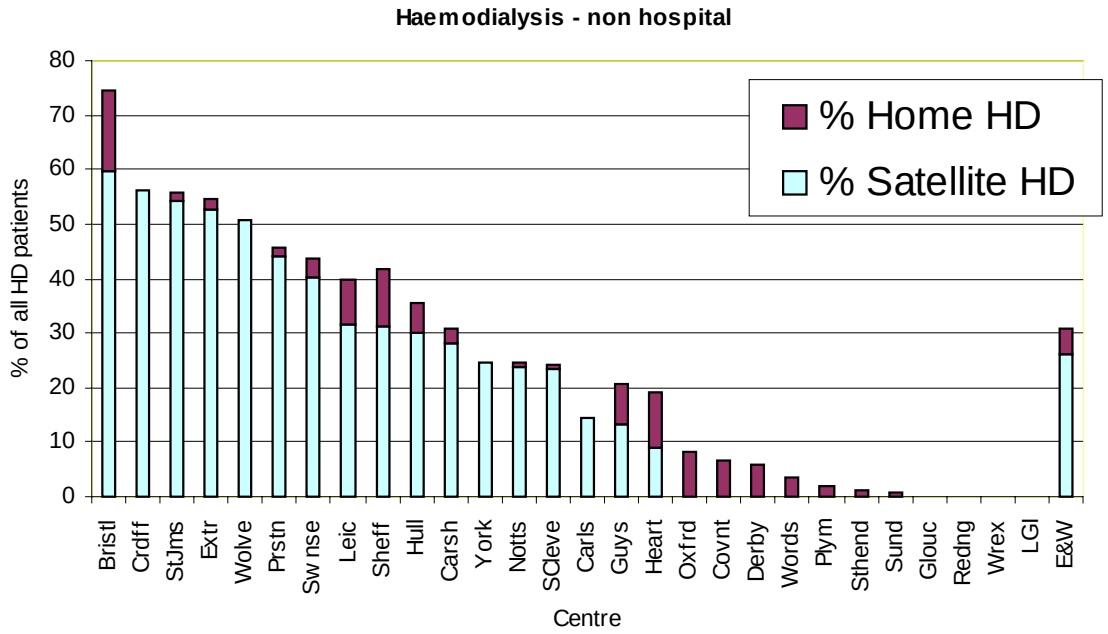


Figure 5.8: Proportion of HD patients treated by home and satellite dialysis, by centre.

Peritoneal Dialysis

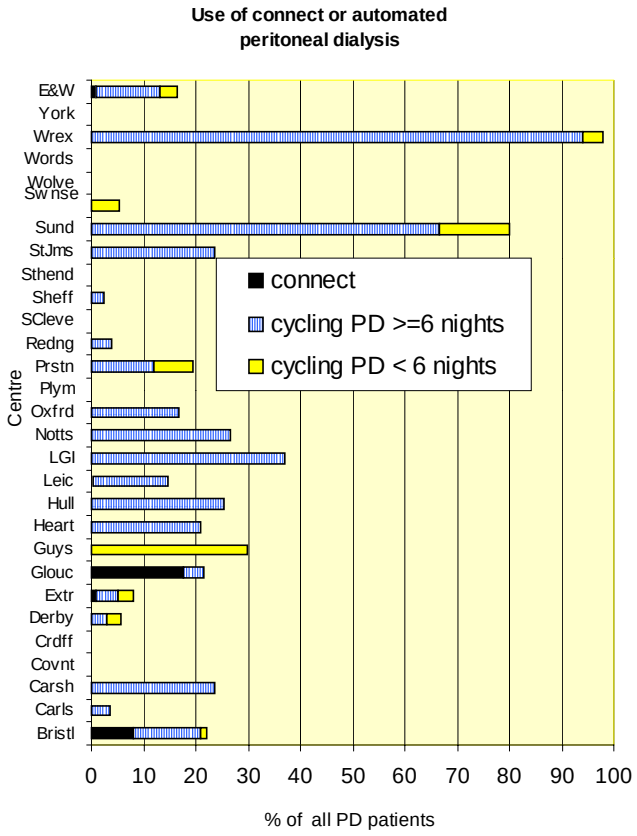


Figure 5.9: Use of connect and automated PD as percentage of total PD.

The percentages of patients on each of the main types of peritoneal dialysis in individual units are shown in Figure 5.9. Only one centre used significant amounts of Connect PD, 2 other centres used it in less than 10% of PD patients. It was not used at all in the remaining centres. Cycling PD/APD is used in 18% of PD patients. There was a wide variation between units from 98% to 0% in the percentage of patients treated with one or other form of cycling PD.

Modality and primary diagnosis

There was wide variation in the probability of transplantation according to primary diagnosis (table 5.12), but there were no differences in the percentage of dialysis patients on either PD or HD by primary renal diagnosis. Diabetic patients, with a poorer overall survival make up a lower percentage of transplanted patients and as shown in last years report. Diabetics aged under 65 were less likely to be transplanted than others of a similar age.

Diagnosis	% on HD	% on PD	% Transplanted
Aetiology uncertain*	23	21	22
Glomerulonephritis	12	15	19
Pyelonephritis	12	12	18
Diabetes	14	16	6
Reno-vascular disease	5	4	1
Hypertension	6	5	5
Polycystic Kidney	7	6	12
Not sent	8	9	2
Other	13	12	15

* = Includes patients listed as “glomerulonephritis not biopsy proven

Table 5.12: Proportion of patients on each modality by diagnostic category.

Modality and gender

	%Home HD	% Hosp HD	% Satellite HD	% connect PD	% disconnect PD	% cycling PD >=6 nights	% cycling PD < 6 nights
Male	3.8	45.9	17.4	0.2	28.0	3.7	1.0
Female	2.2	45.8	16.9	0.3	28.5	4.8	1.4

Table 5.13: Treatment modality and gender

Home haemodialysis was more common in males than females (table 5.13); this is consistent with last year’s data. Cycling PD was slightly more common in females.

	Age < 65 HD	Age < 65 PD	Age < 65 Transp	Age ≥ 65 HD	Age ≥ 65 PD	Age ≥ 65 Transp
Male	26.6	15.0	58.4	56.8	23.1	20.1
Female	25.7	18.9	55.4	58.6	18.1	23.2

Table 5.14: Treatment modality, age, and gender

In patients aged 65 and over, PD was more common in males, in comparison to being less common in those aged less than 65 years (table 5.14).

Change in treatment modalities 1997 –2000

The pool of renal units participating in the Registry has changed over the last 4 years so changes in treatment modality are difficult to interpret. There seems to be a trend towards more haemodialysis, relatively stable numbers on peritoneal dialysis, with the proportion with a transplant falling (table 5.15).

At year end	Home - HD	Hosp – HD	Satellite - HD	**Total HD**	CAPD Conn.	CAPD Disconnect	Cycling PD >= 6 nights/wk	Cycling PD < 6 nights/wk	**Total PD**	**Transplant**
1997	3.7	19.67	9.03	**32.4**	2.68	12.91	1.02	0.04	**16.65**	**50.95**
1998	2.4	23.6	5.6	**31.6**	0.9	16.6	0.9	0.1	**18.5**	**49.9**
1999	2.0	21.9	10.9	**34.8**	0.7	15.0	1.6	0.5	**17.8**	**47.3**
2000	1.7	26.1	7.8	**35.6**	0.1	14.2	2.5	0.6	**17.4**	**46.9**

Table 5.15: Proportion of patients with different modalities of RRT 1997-2000

Long term trends

Both England & Wales and Scotland have shown an increasing percentage of patients being treated with haemodialysis (figure 5.10), with the steepest rise being since 1995. The 2000 data show this trend may be levelling in England & Wales. This may be due to capacity problems, with the Registry noting an increased use of twice weekly dialysis (chapter 6). The England data for 1992 and 1995 were from the national review.

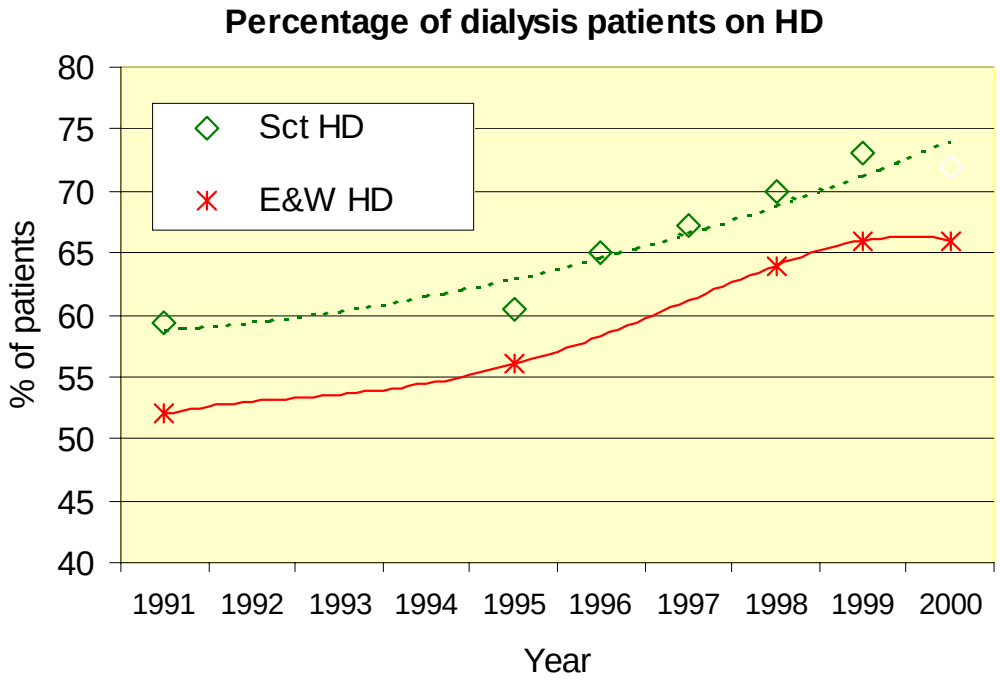


Figure 5.10: Percentage of dialysis patients on haemodialysis by year

Survival on renal replacement therapy

The one-year survival of all patients established on renal replacement therapy for at least 90 days on 1/1/200 was analysed, and the two-year survival of similar patients alive on 1/1/1999. The median age of the prevalent patients in both 1999 and 2000 was 61 years.

	Dialysis patients		Transplant patients	
	1999	**2000**	**1999**	**2000**
K-M 1 yr survival	84.8	83.7	97.5%	97.3%
(95% CI)	83.8 – 85.8	82.7 – 84.7	97.0 – 97.9	96.8- 97.7
K-M 2 yr survival	68.4			
(95% CI)	66.9 – 69.9			

Table 5.16: Survival of all dialysis patients

There was a slightly different group of centres on the Registry in 2000 from that in 1999, thus the apparent slightly lower survival in 2000 is difficult to interpret.

As expected the transplanted patients have a lower mortality than dialysis patients, but these patients are a selected younger fit population with a lower median age. Comparing transplant patients with non-diabetic dialysis patients aged less than 55 (tables 5.16, 5.17) there is still better survival of 97.3% v 92.1% survival during 2000. The relatively poor prognosis of diabetic patients is demonstrated.

	Diabetic	**Non-diabetic**	**All**
KM 1 yr survival < 65	78.7%	92.1%	**89.9**
(95% CI) 2000	75.1 – 82.4	91.1 – 93.2	**88.8 – 90.9**
-M 1 yr survival ≥ 65	71.7%	76.0%	**75.4**
(95% CI) 2000	66.4 – 77.1	74.1 – 77.9	**73.7 – 77.2**

Table 5.17: Survival of dialysis patients alive on 1/1/2000, by age <65 and >65 years.

The marked deterioration in prognosis with advancing age is shown in table 5.18. The trend is similar in diabetics (table5.19).

	KM survival	Stand Error	95% CI
18-34	96.4%	0.84%	94.7% - 98.0%
35-44	92.4%	1.09%	90.3% - 94.6%
45-54	89.0%	1.08%	86.8% - 91.1%
55-64	86.0%	1.03%	84.0% - 88.0%
65-74	78.2%	1.12%	76.0% - 80.4%
75-84	71.5%	1.52%	68.5% - 74.5%
85+	68.0%	5.38%	57.5% - 78.6%

Table 5.18: Survival of all prevalent dialysis patients by age band

	Non diabetic			Diabetic		
	KM survival	Stand Error	95% CI	**KM survival**	Stand Error	95% CI
<55	**93.9%**	0.60%	92.7% - 95.1%	**81.5%**	2.32%	77.0% - 86.1%
55-64	**88.7%**	1.07%	86.6% - 90.8%	**78.4%**	2.85%	72.8% - 84.0%
65-74	**79.0%**	1.25%	76.5% - 81.4%	**74.2%**	3.00%	68.3% - 80.1%
>=75	71.9%	1.57%	68.8% - 75.0%	**62.9%**	6.28%	50.6% - 75.2%

Table 5.19: Survival during 2000 of dialysis patients by age and diabetes

Prevalent survival by centre

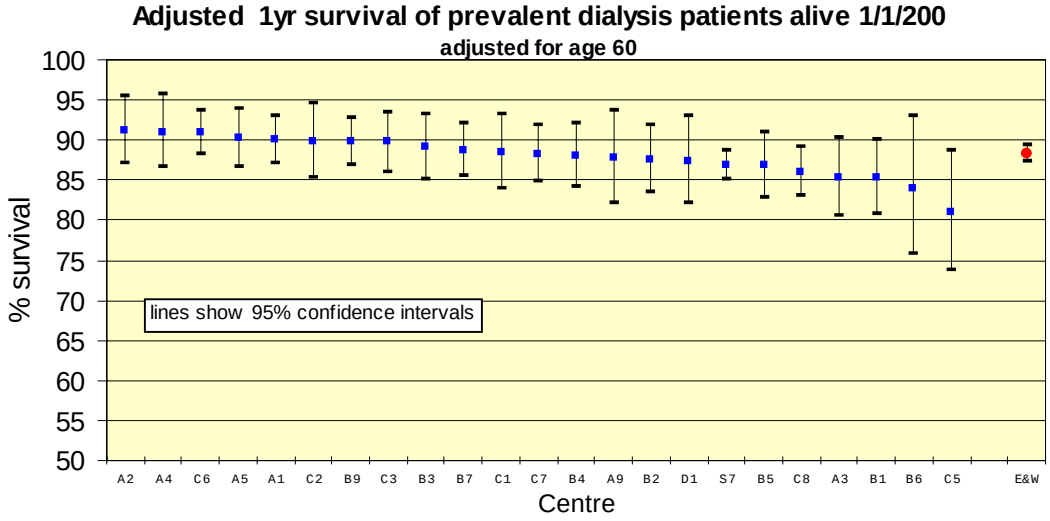


Figure 5.11: Survival of prevalent patients alive 1/1/2000
There was no significant difference in the year 2000 prevalent survival by centre.

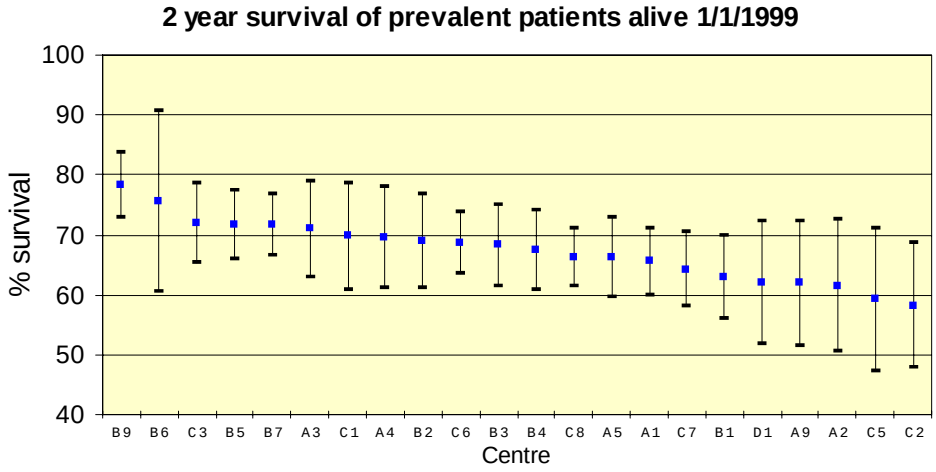


Figure 5.12: 2year survival of prevalent patients alive 1/1/1999
Figure 5.12 it should be noted is unadjusted data

Chapter 6: Adequacy of haemodialysis (Urea reduction ratio)

Summary

In England & Wales a uniform method of measuring the post dialysis urea sample (as suggested in the 1997 Renal Association standards document) has still not been implemented. This standardisation is essential to permit meaningful comparative audit among participating renal units.

In England & Wales, 74 % of patients achieved a URR > 65% compared with 65% in 1999 and 57% in 1998.

Due to 'population distribution curves', centres will need to reach a median URR of 75% for almost all patients to have a URR >65%. No centres achieved the RA standard

A cross sectional analysis of patients in 2000 showed there was a continuing rise in URRs over the 2 years from starting dialysis. This rose from 57% achieving a URR > 65% in the first 6 months (48% in 1999) to 83% achieving this at 2 years (73% in 1999).

Within England and Wales, there has been a year on year increase in dialysis adequacy over the four years of the Registry. The Renal Registry data demonstrate that 'adequate' URR results can be achieved. It is hoped that the wide variation in URR achieved in these early cycles of audit of hospital haemodialysis will continue to decrease.

Attention is drawn to the limitation in the use of URR to measure dialysis adequacy. It is used at present as it permits verifiable comparison between centres from the data collected by the Registry.

Haemodialysis frequency

The Standards document states "*The frequency of dialysis should be three times per week in the majority of patients. Reduction of dialysis frequency to twice per week because of insufficient dialysis facilities is unacceptable***".**

Twice weekly haemodialysis is not recommended except where there is good preservation of residual renal function. One would expect this to be well under 10% of total patients

The Registry has found it difficult to obtain complete, or near complete, returns of frequency of dialysis from many renal units and is therefore not sufficiently confident of its figures to publish them. However the clinical directors forum of the Renal Association has recently conducted a survey of this issue (Scoble). In those renal units with good Registry returns there was good concordance of the data between the survey and the Registry. From this survey 53 units have returned data so far,

Whilst overall only 6.2% of patients in the UK dialyse less than three times a week, there is a range between renal units of 0% to 39%. At least 10% of patients dialyse twice weekly in 23% of units, and 6 units had more than 20% dialysing twice weekly. Twice weekly dialysis

is particularly common in Northern Ireland but rare in Scotland. Both the survey and the Registry have ascertained that in Northern Ireland the main reason given was financial constraints. Limitation of resources was a major cause in England, either through physical lack of space (3 units), financial constraints (3), patient preference (3) and nursing staff constraints (1).

Solute clearance Standards

The Renal Standards document considers both Kt/V and Urea Reduction Ratio (URR) as indicators of adequacy of haemodialysis, and recommends that all patients stable on three times a week haemodialysis should have:

A urea reduction ratio > 65%

or ***Kt/V > 1.2 (dialysis and residual renal function)***

Interpretation of results

Formulae for calculation of dialysis clearance

Several different methods are in use for calculating Kt/V, and they give results which vary significantly. Some calculations include the contribution from residual renal function, and need collection of post dialysis urea blood urea samples from the previous dialysis. Other formulae ignore residual renal function, and require, as a minimum, knowledge of pre and post dialysis weights, and duration of treatment. For meaningful comparisons, the Registry would need to calculate Kt/V by a single method from the raw data. This raw data is not available from many units. The simpler calculation of URR, the percentage fall in blood urea during a dialysis session, only requires knowledge of pre and post dialysis blood urea, and thus remains the method used by the Registry. This ignores any contribution to clearance by residual renal function. URR has been shown to correlate with patient survival (Owen, Held).

Post dialysis urea samples

At present, post dialysis sampling methodology is not uniform across units. This has a major effect on post dialysis urea measurements. This is discussed more fully in the 1999 Registry report.

In 2000, the renal standards document recommended the “slow flow” method of collecting post dialysis urea samples, but three methods of collecting samples are described in the new renal standards document. There has been no major move by centres to a single “post urea” measurement technique. In 1999 some of the centres in England moved to the Mactier “stop-dialysate-flow” method (see appendix E), which is the sole recommended method in Scotland. It has been observed that there are often major discrepancies between recommended methods and actual practice. Use of the Mactier method has been shown to give higher post dialysis urea readings and thus a lower URR than the two other main methods in use. Thus centres using this technique will appear to have lower dialysis clearance and lower achievement of the standard compared with centres the other methods.

Centres achievement of the Standard

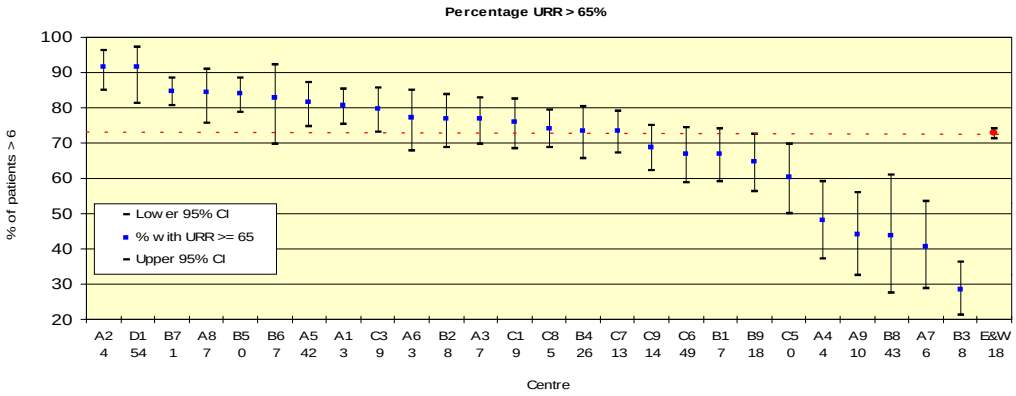


Figure 6.1: Achievement of the RA Standard for haemodialysis clearance

The overall, the achievement of the Renal Association standard improved again in 2000. In England & Wales, 74 % of patients achieved a URR > 65% compared with 65% in 1999 and 57% in 1998.

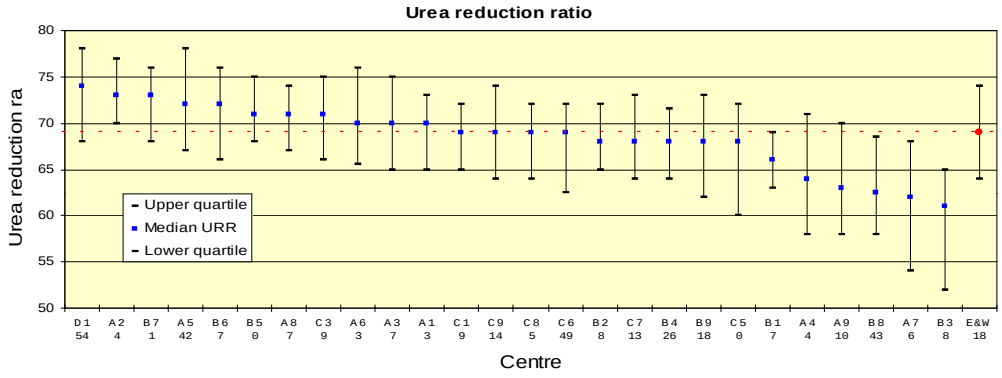


Figure 6.2: Percentage patients with URR ≥ 65% in the last quarter of 2000

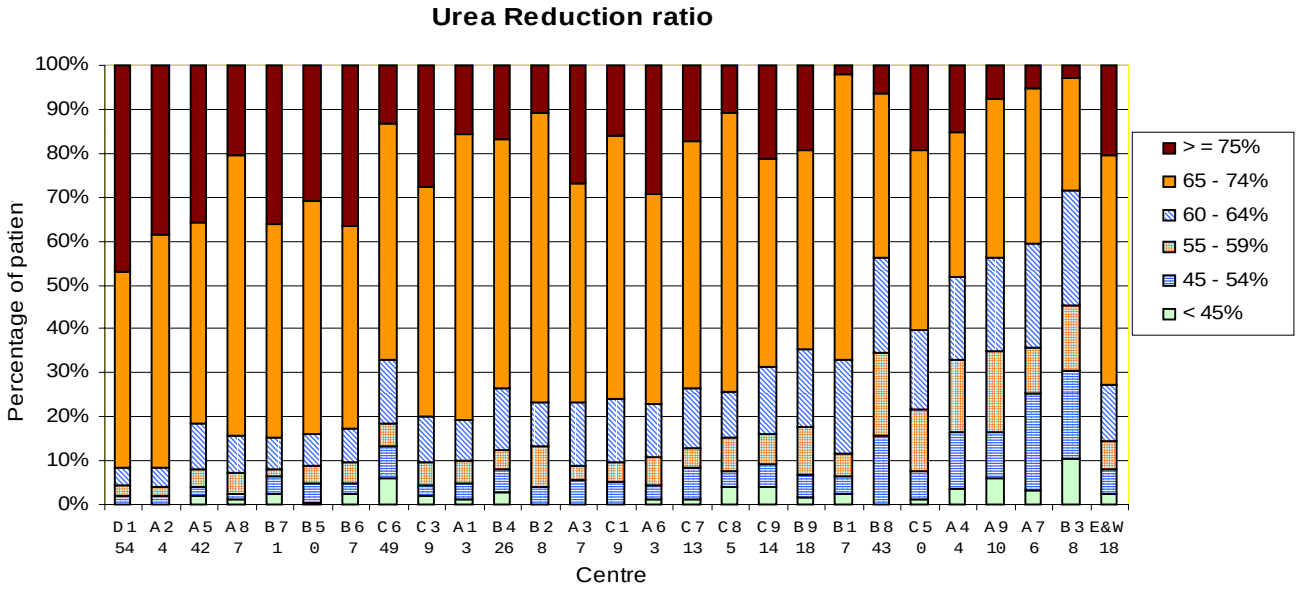


Figure 6.3 Urea reduction ration distribution

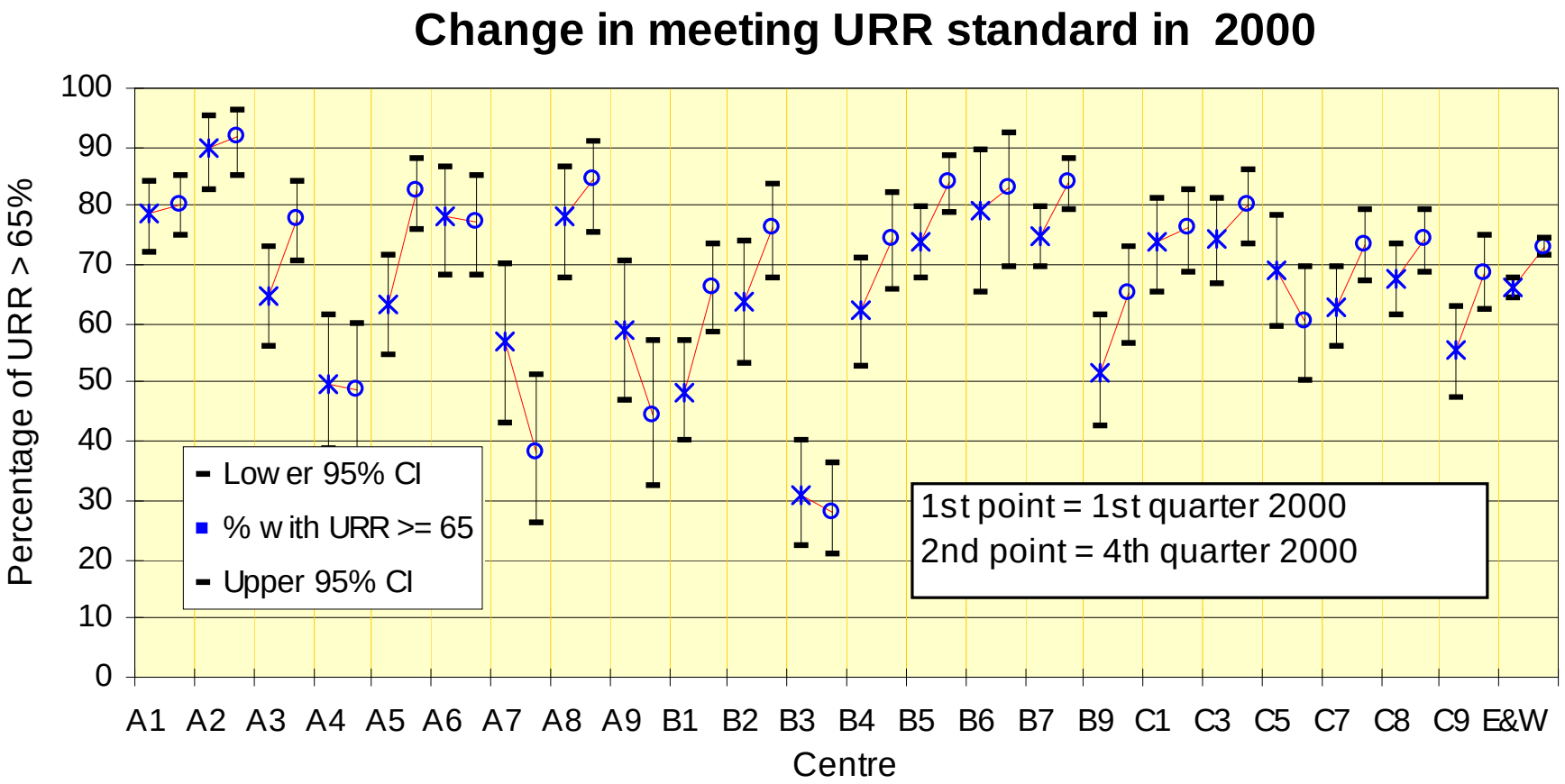


Figure 6.4: Change in meeting URR standard in 2000

Changes achievement of URR standard during 1998-2000

Centre	Percentage patients with URR>65%			
	Quarter 1 1998	Quarter 4 1998	Quarter 4 1999	Quarter 4 2000
A1	59	67	80	80
A2	96	84	89	92
A4	56	55	51	49
A5	46	57	51	83
A6				77
B1	67	40	52	66
B3	18	29	34	28
B4	53	60	62	75
B5	51	51	70	84
B6	70	92	87	83
B7	71	64	70	84
B9	61	55	50	65
C1	50	64	82	76
C3	68	64	70	80
C5	73	57	65	60
C7	49	61	62	73
C8	62	45	70	74
E&W	**57**	**57**	**65**	**74**

Table 6.1: Change in achievement of URR standard during 1998-2000

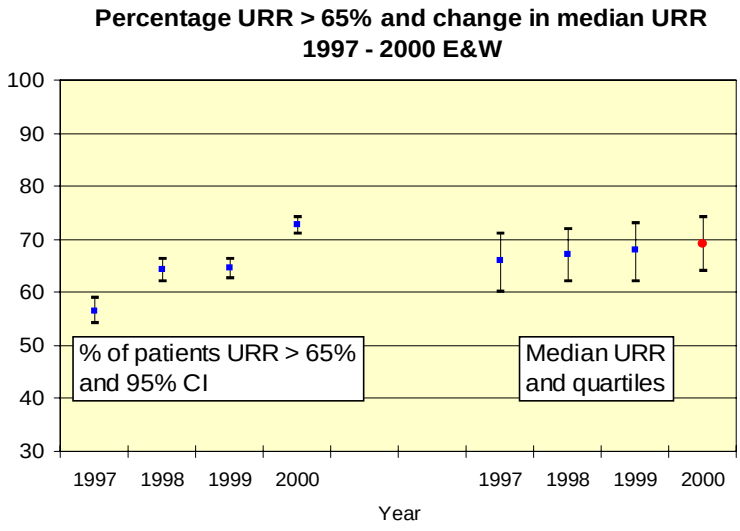


Figure 6.4: Percentage URR . 65% and change in median URR 1997- 2000

In the last 4 years, England & Wales have shown a substantial rise in the percentage of patients achieving a URR > 65% but still lag behind the US, where 82% of patients achieve a URR >65% with a median URR of 71.4%. The median URR in E&W is 69%. Because of the steepness of the distribution curve around this point, there need only be a small change in median URR to achieve a large change in achievement of the standard, as is illustrated in figure 6.4. It would only need a small improvement in median URR to obtain the same results as in the US. The US data sits on the UK predictive line of identity between median URR and % achieving URR>65%. This indicates that distributions of data and working practice in the two countries may have close similarities.

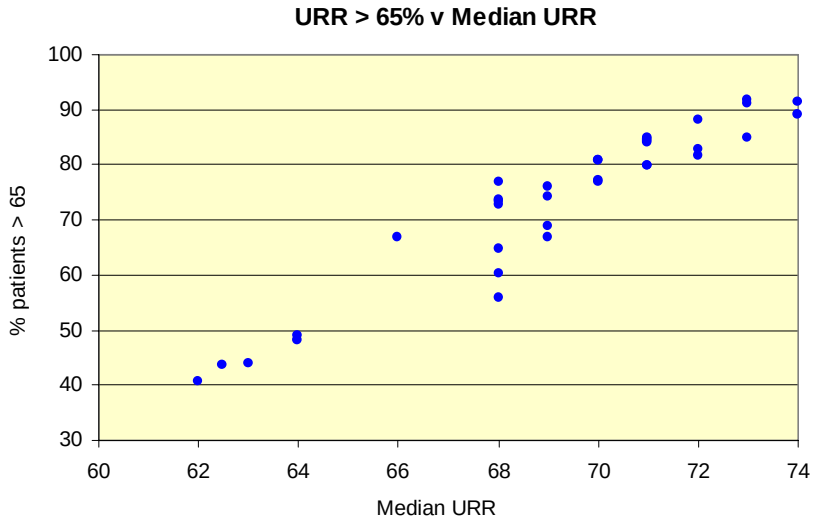


Figure 6.5: URR achievement and median URR

The improvement in attainment of the URR standard in England and Wales from 1997 to 2000 looks impressive (fig 6.4), but some caution must be used in interpretation, as there are increasing numbers of renal units each year, and thus different renal units included. That the improvement is real is suggested by the significant improvement in performance of participating units during 2000.

Achievement of standards in new renal replacement therapy patients starting haemodialysis

As reported last year, URRs were lower in new patients on haemodialysis than in patients from the same unit established on treatment for more than 3 months (fig 6.6). This may in part be due to early patients retaining a degree of residual renal function and needing less dialysis. However the 2000 data shows a considerable improvement URR in this early period indicating that there are additional factors involved.

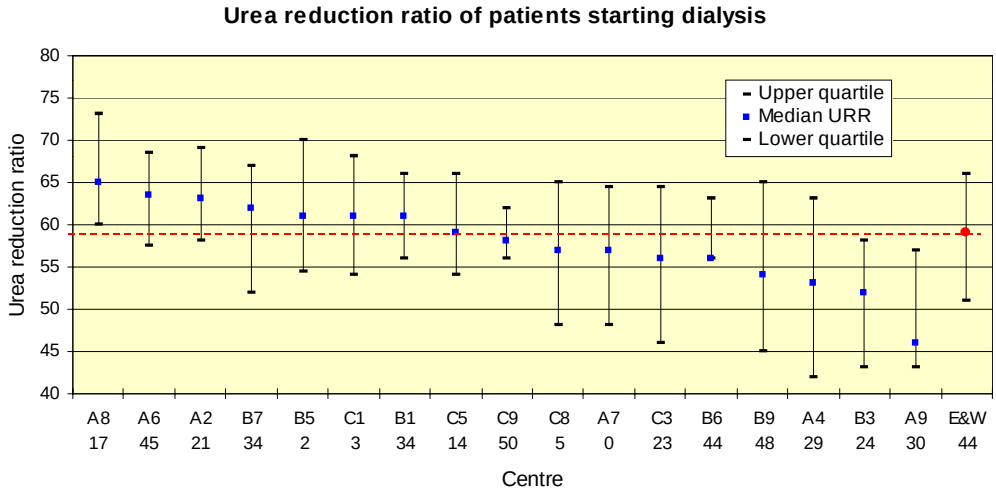
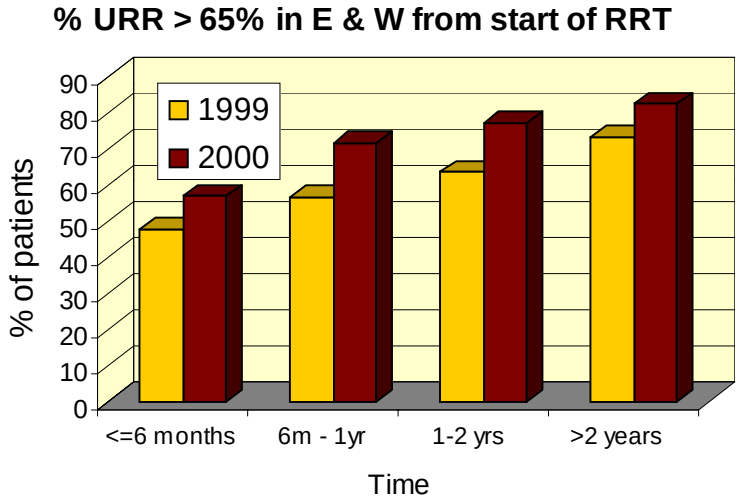


Figure 6.6: Median URR within first three months of HD

As shown in last years report, URRs were lower in patients starting dialysis than those of all HD patients at the same unit (which excludes patients within the first 3 months). This in part was probably partly due to a degree of residual renal function, although the 2000 data shows a considerable improvement in this target (Fig 6.7) indicating that there are additional factors involved In the UK, URRs slowly increased with time on RRT with the median URR changing from 66% (64% in 1999) in the first 6 months to 71% (69% in 1999) at 2 years. Although the change in median URR is small, due to the steep slope of the distribution curve, there is a substantial increase in the percentage of patients with a URR > 65% throughout these time periods (fig 6.7). This does not necessarily indicate that the URR of individuals increases with time. It may be that those patients who died in the earlier periods had a lower URR than the survivors. The Registry is collecting sequential individual patient data and will analyse this at a later date. The year on year improvement in dialysis clearance is also reflected in these figures.



This figure shows "cross-sectional" results for all patients at the year-end on dialysis for the specified time

Figure 6.7 Change in URR by length of time on RRT in 1999 –2000

Chapter 7: Haemoglobin and related variables

This chapter describes the position at the end of 2000 for all units from England and Wales on the Registry.

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

Summary

There is continuing evidence of improvement in the management of renal anaemia in centres submitting data to the Registry. In haemodialysis, 79% of patients had a haemoglobin > 10g/dl compared to 72% in 1999 and 69% in 1998. In peritoneal dialysis 86% of patients had a haemoglobin >10g/dl in 2000 compared to 80% in 1999 and 78% in 1998. An increasing proportion of centres achieved the Renal Association standard for both haemodialysis and peritoneal dialysis patients.

There is evidence of significantly different approaches to iron replacement in different centres.

There is evidence of different approaches to management of renal anaemia pre-dialysis, which will in part reflect availability of erythropoiesis stimulating treatments. In different centres, between 19% and 61% of patients started dialysis with a haemoglobin greater than 10g/dl.

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 2000 was used in the analysis. Centres with less than 50% completeness of data were not shown on the figures. In the figures, data completeness is indicated by the percentage missing figure below the code letter for the renal unit. No laboratory harmonisation is used for haemoglobin.

Haemoglobin achievement by dialysis units

The data for haemoglobin concentrations have been presented in a variety of ways. This has enabled comparison with the Renal Association Standard for haemoglobin achievement but also provides centres with their median haemoglobin. The spread of haemoglobin concentrations may indicate differences in the way that units manage renal anaemia and a number of different measures of spread have been included.

In both modalities a higher proportion of patients included in the 2000 data achieved the RA Standard haemoglobin of 10g/dl than in previous years, but it should be noted that in each year new centres have been added to the Registry. In haemodialysis 79% of patients had a haemoglobin >10g/dl compared to 72% in 1999 and 69% in 1998. In peritoneal dialysis 86% of patients had a haemoglobin >10g/dl in 2000 compared to 80% in 1999 and 78% in 1998.

5 of the 27 centres with sufficient data achieved the Standard of 85% of haemodialysis patients with haemoglobin >10g/dl (2 of 22 centres in 1999). 14 of the 27 centres had 95% confidence intervals that included 85% (5 of 22 in 1999).

19 of 27 centres achieved the Standard for peritoneal dialysis (9 of 22 in 1999) and all but 2 centres data had 95% confidence intervals that included the 85% standard.

These data provide increasing evidence that the RA Standard for haemoglobin is achievable. For the first time the percentage of patients with haemoglobin greater than 11.0g/dl is shown in this years report. 85% of patients with a haemoglobin greater than 11.0g/dl has been recommended as the standard in European centres. No centre achieved this standard for haemodialysis patients (range 40% to 75% ≥ 11g/dl) but 3 centres achieved the European standard for peritoneal dialysis (range 46% to 93% ≥ 11g/dl).

There were some differences between centres, e.g. in haemodialysis centres B5 and B6 both achieved the standard but in centre B5 there was a considerably higher proportion of patients with haemoglobin greater than 12g/dl and a median haemoglobin of 11.9g/dl compared to 11.3g/dl in B6. Whether this is a statistical quirk influenced by centre size or the result of a successful targeting strategy in B6 is uncertain. In peritoneal dialysis B6 had a broad spread.

Centre	% data return	Median Hb g/dl	90% range	Quartile range	% Hb ≥ 10 g/dl	Mean Hb g/dl	Standard deviation
A1	97	11.4	8.5 - 13.4	10.2 - 12.3	79	11.2	1.5
A2	99	10.9	7.6 - 13.5	9.6 - 12.0	68	10.7	1.8
A3	99	11.5	8.4 - 14.0	10.4 - 12.6	83	11.4	1.7
A4	98	10.7	7.7 - 13.4	9.9 - 11.7	72	10.8	1.5
A5	94	11.8	8.3 - 13.9	10.5 - 12.7	82	11.5	1.7
A6	98	11.8	9.4 - 14.2	10.7 - 12.8	85	11.8	1.6
A7	98	11.2	8.6 - 13.9	10.4 - 11.9	84	11.2	1.5
A8	93	11.8	8.5 - 14.0	10.9 - 12.7	90	11.7	1.5
A9	99	11.3	8.3 - 13.6	10.5 - 12.4	82	11.3	1.6
B1	95	10.6	8.1 - 12.8	9.9 - 11.4	74	10.6	1.4
B2	97	11.3	8.7 - 14.1	10.4 - 12.6	82	11.3	1.7
B3	97	11.1	8.8 - 13.9	10.3 - 12.0	80	11.1	1.4
B4	89	10.8	7.9 - 13.7	9.9 - 12.0	73	10.8	1.8
B5	100	11.9	9.3 - 14.7	11.0 - 12.8	91	11.9	1.6
B6	93	11.4	9.3 - 12.9	10.6 - 12.0	90	11.3	1.1
B7	87	11.0	8.7 - 13.2	10.0 - 11.8	77	10.9	1.4
B8	76	10.6	8.1 - 14.3	9.3 - 11.9	67	10.8	1.9
B9	95	11.1	8.1 - 14.0	10.0 - 12.1	76	11.2	1.8
C1	92	11.5	7.8 - 13.8	10.2 - 12.2	78	11.2	1.7
C3	78	11.0	8.1 - 13.2	9.9 - 12.0	74	10.9	1.6
C4	69	11.4	8.5 - 14.0	10.4 - 12.5	84	11.4	1.6
C5	91	11.0	8.0 - 15.0	10.0 - 12.0	88	11.4	1.8
C6	100	11.5	8.7 - 13.5	10.2 - 12.4	80	11.3	1.5
C7	89	10.8	8.0 - 13.2	9.9 - 11.8	73	10.8	1.6
C8	83	11.1	8.6 - 14.1	10.3 - 12.1	81	11.2	1.5
C9	94	10.4	8.2 - 13.5	9.5 - 11.7	64	10.6	1.7
D1	82	11.3	7.9 - 13.5	10.5 - 12.3	82	11.2	1.7
E&W	90	11.2	8.3 - 13.8	10.1 - 12.2	79	11.2	1.6

Table 7.1: Haemoglobin data for patients on haemodialysis

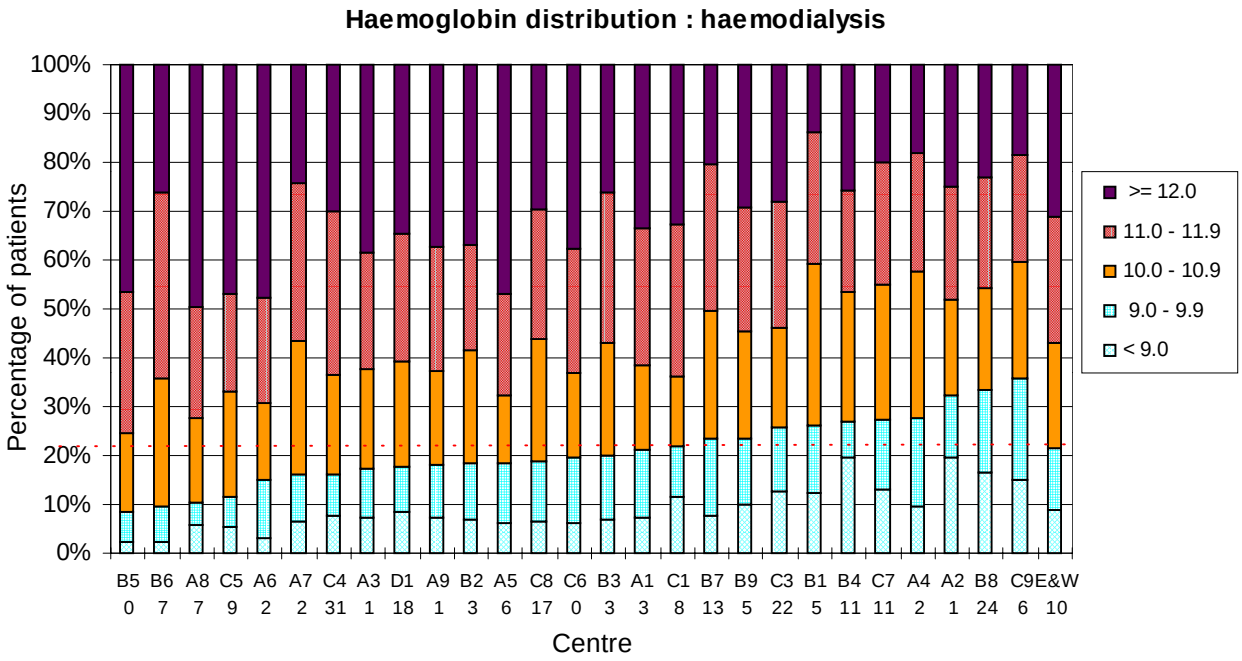


Figure 7.1: Haemoglobin in patients on HD by 1g/dl bands

Figure 7.1 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

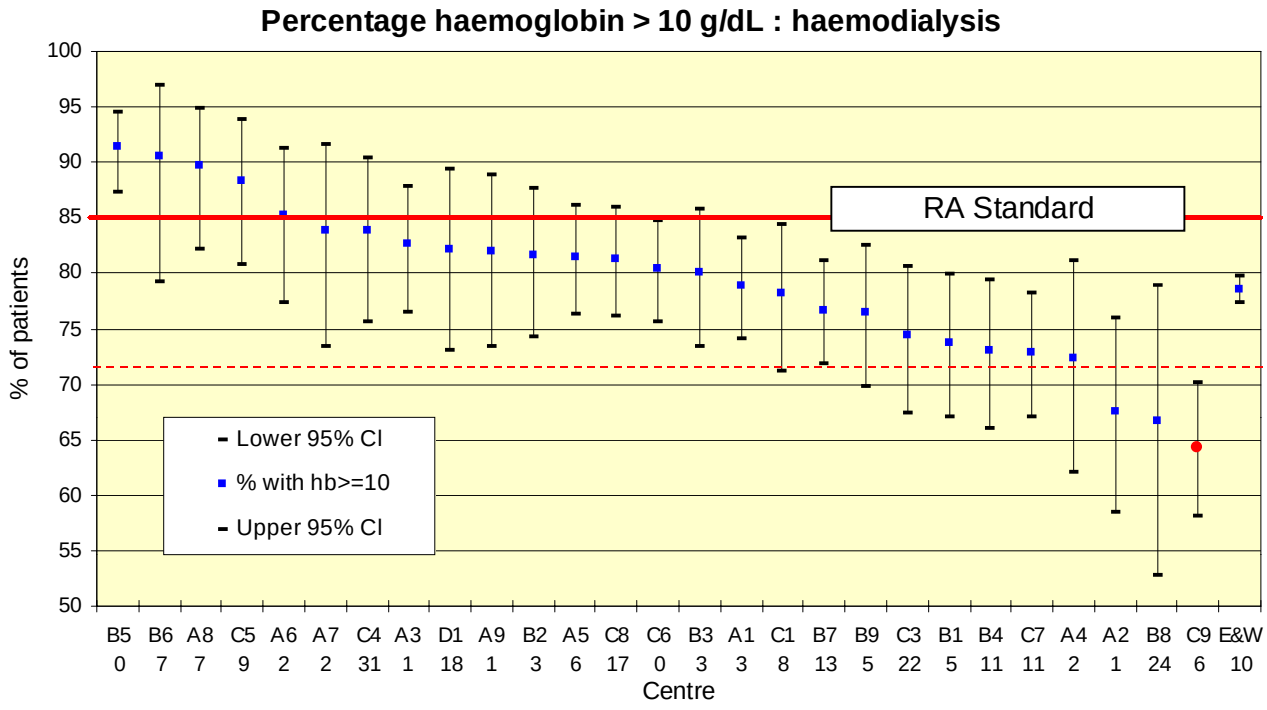


Figure 7.2: Percentage of HD patients by centre achieving the RA Standard

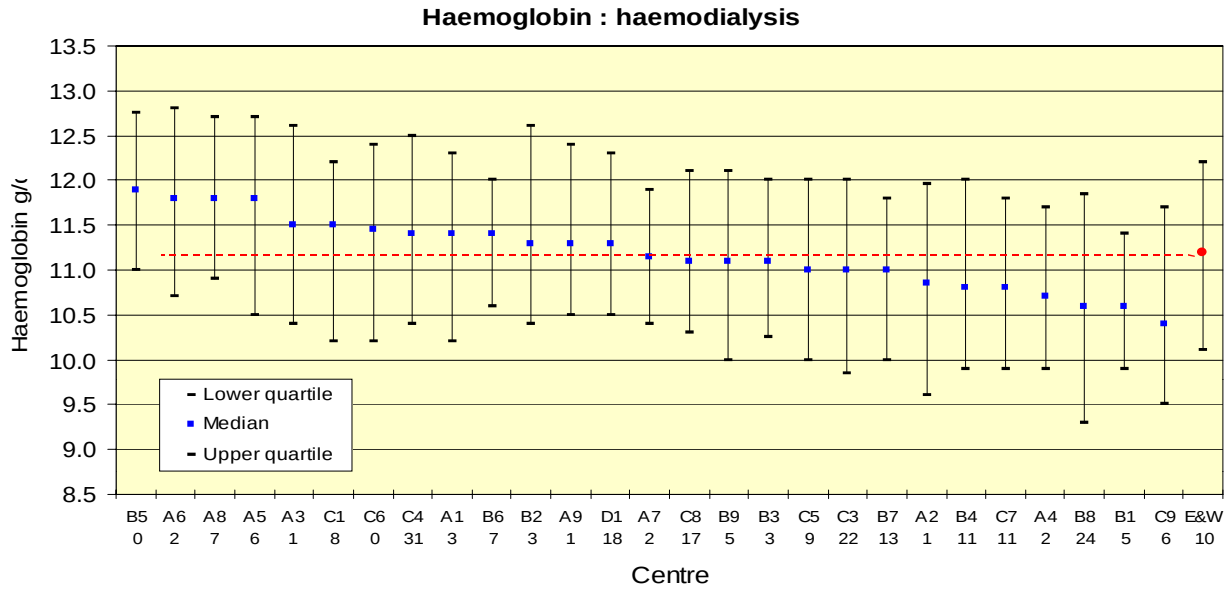


Figure 7.3: Haemoglobin median and quartile ranges for haemodialysis patients

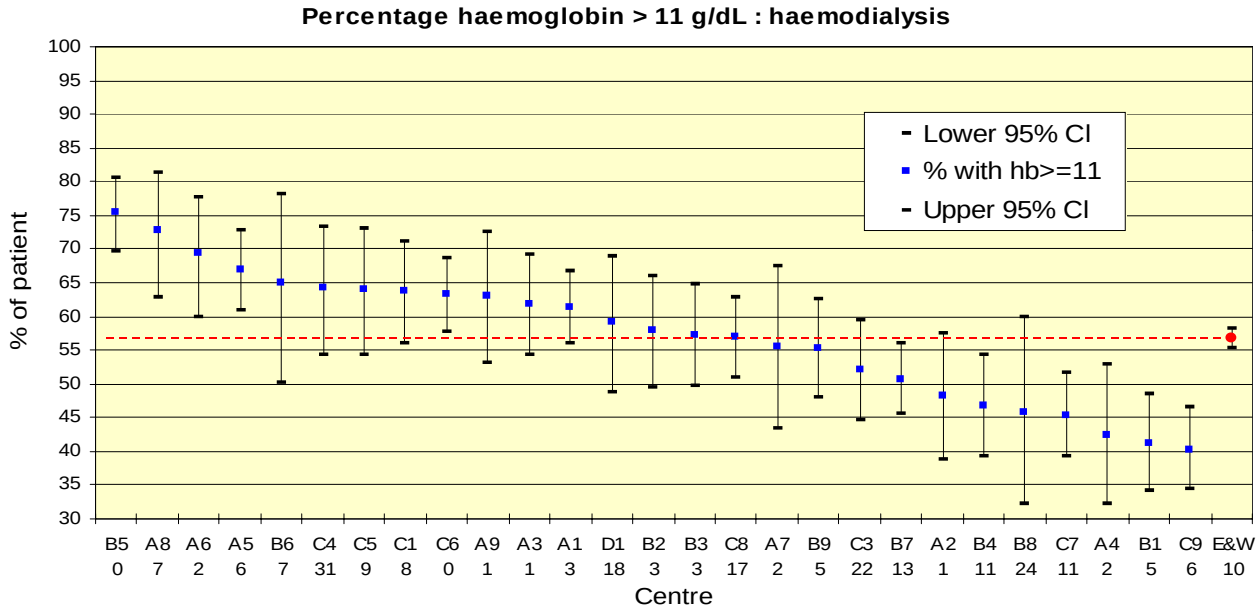


Figure 7.4: Percentage of HD patients by centre achieving the European Standard

Centre	% data return	Median Hb g/dl	90% range	Quartile range	% Hb ≥ 10 g/dl	Mean Hb g/dl	Standard deviation
A1	100	11.9	10.3 - 13.9	11.2 - 12.9	96	11.9	1.3
A2	100	11.3	9.0 - 14.0	10.6 - 12.6	83	11.4	1.5
A3	98	12.4	9.2 - 15.8	11.5 - 13.6	91	12.5	1.7
A4	100	11.6	9.2 - 13.9	10.8 - 12.6	88	11.6	1.4
A5	98	11.7	8.9 - 15.0	10.5 - 12.6	83	11.7	1.8
A6	96	11.9	9.4 - 15.9	11.2 - 13.1	94	12.2	1.8
A7	97	11.6	8.7 - 13.7	10.5 - 12.6	85	11.5	1.6
A8	100	11.4	9.5 - 14.4	10.5 - 12.9	92	11.6	1.6
A9	100	11.7	9.9 - 13.7	10.4 - 13.2	91	11.9	1.5
B1	98	11.0	8.6 - 14.1	9.7 - 12.1	69	11.0	1.8
B2	99	11.9	9.7 - 14.2	11.2 - 12.6	92	11.9	1.3
B3	94	11.3	8.9 - 13.7	10.4 - 12.6	87	11.4	1.5
B4	99	11.6	8.8 - 14.7	10.7 - 12.7	88	11.7	1.6
B5	100	12.0	8.5 - 15.0	11.6 - 13.3	90	12.1	1.7
B6	100	12.3	9.4 - 15.1	10.9 - 13.1	79	12.0	1.9
B7	100	10.9	7.9 - 14.1	9.9 - 12.3	73	11.0	1.8
B8	94	11.6	8.6 - 14.2	10.6 - 12.3	84	11.4	1.6
B9	99	12.0	9.3 - 14.6	10.8 - 12.8	86	11.9	1.7
C1	95	12.0	8.6 - 14.3	10.9 - 12.9	87	11.8	1.5
C3	96	11.8	9.7 - 13.3	10.6 - 12.8	91	11.6	1.3
C4	98	11.3	8.8 - 13.8	10.3 - 12.3	81	11.2	1.6
C5	100	12.0	10.0 - 14.0	11.0 - 13.0	100	12.1	1.3
C6	99	11.6	9.2 - 14.6	10.5 - 13.0	87	11.8	1.8
C7	90	11.5	9.1 - 14.1	10.6 - 12.3	85	11.4	1.5
C8	97	11.3	9.0 - 14.3	10.5 - 12.6	85	11.5	1.6
C9	96	11.4	8.8 - 13.9	10.4 - 12.6	82	11.4	1.6
D1	90	12.3	10.5 - 14.4	11.3 - 13.4	100	12.4	1.3
E&W	95	11.6	9.0 - 14.3	10.6 - 12.7	86	11.6	1.6

Table 7.2: Haemoglobin data for patients on peritoneal dialysis

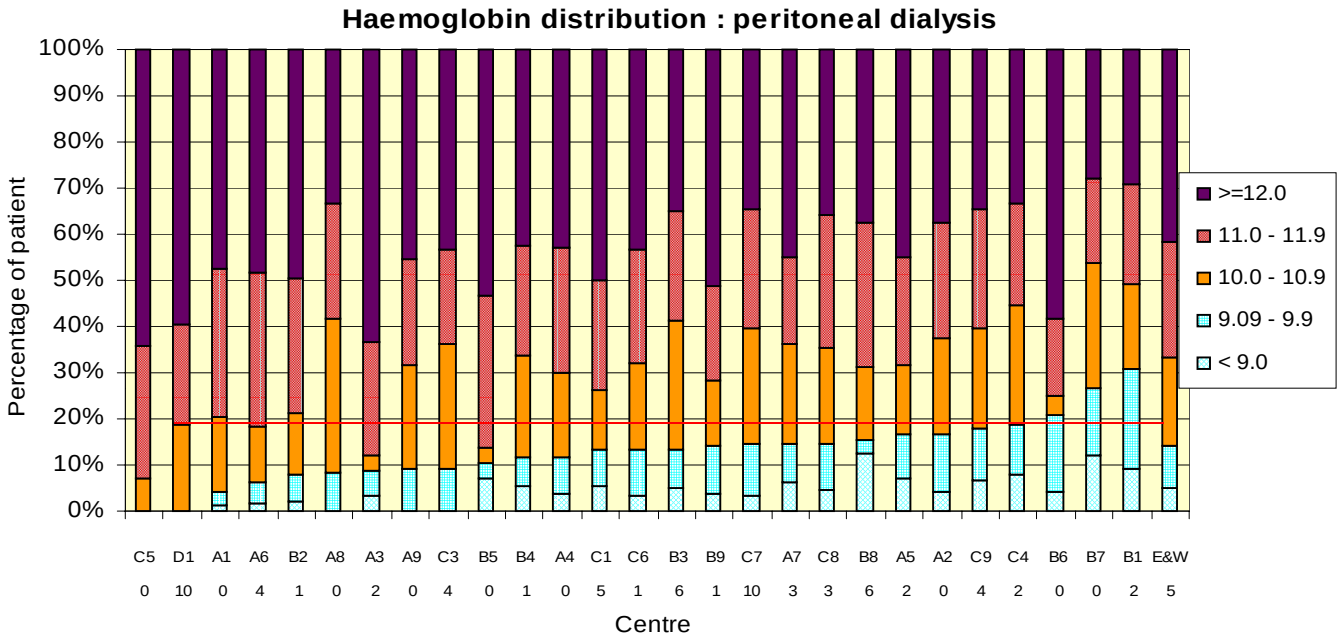


Figure 7.5: Distribution of haemoglobin for patients on PD by 1g/dl bands

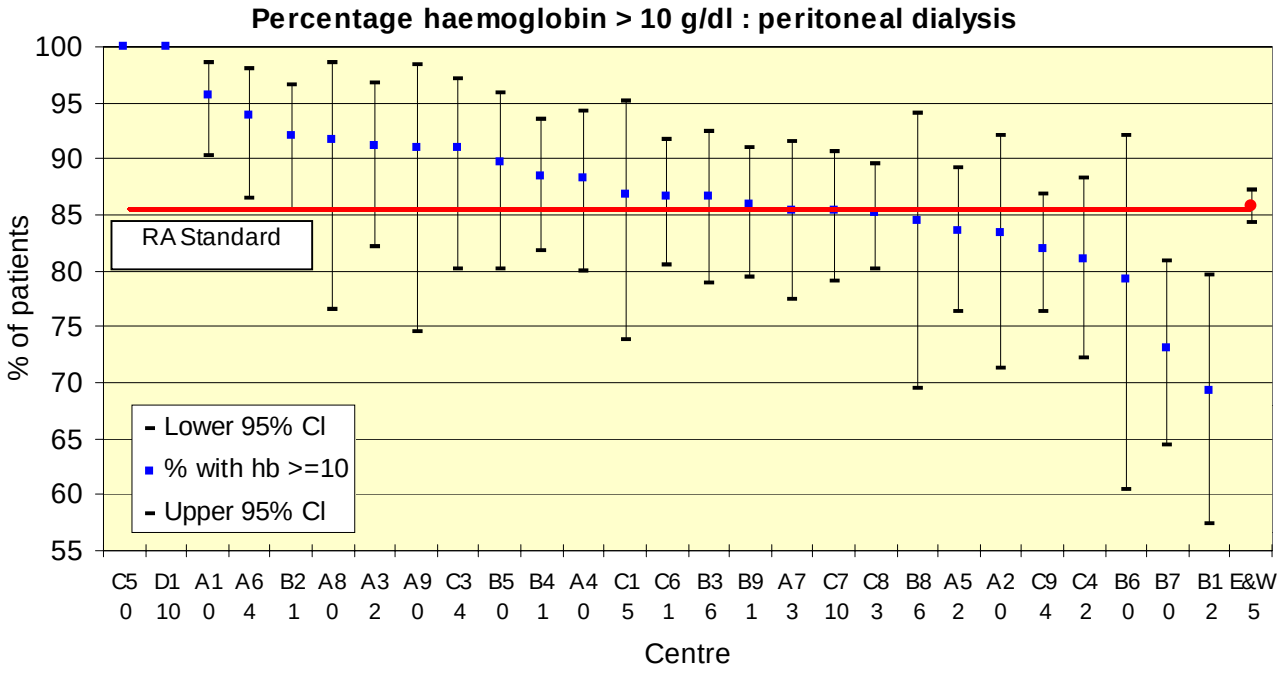


Figure 7.6: Percentage of PD patients by centre achieving the RA Standard

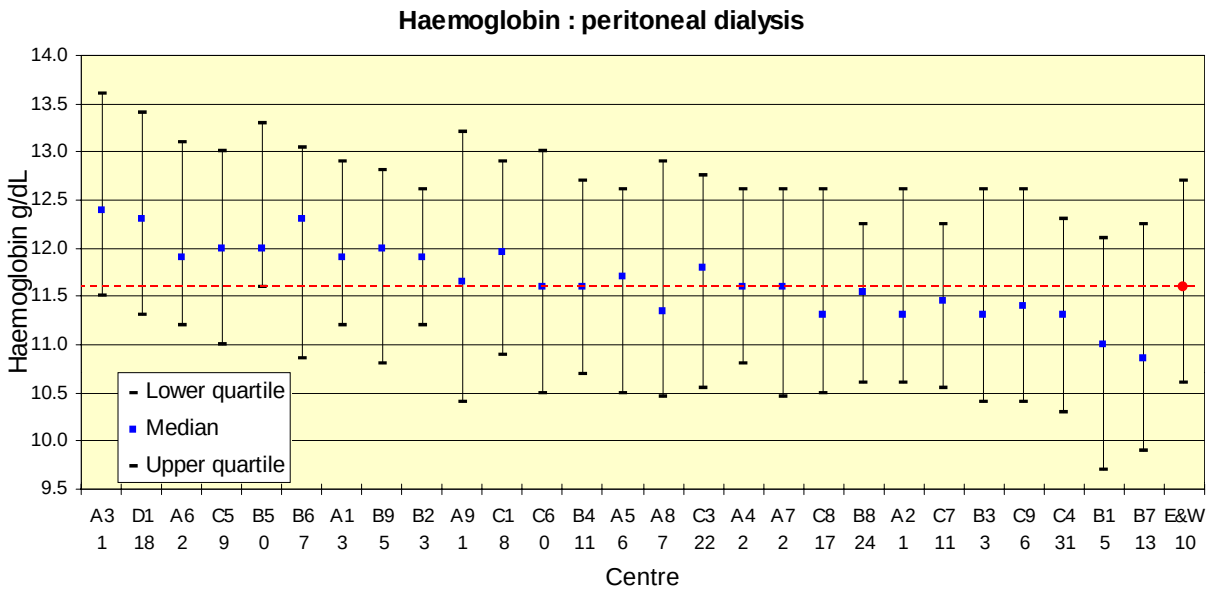


Figure 7.7: Percentage of PD patients by centre achieving a haemoglobin of at least 11.0 g/dl

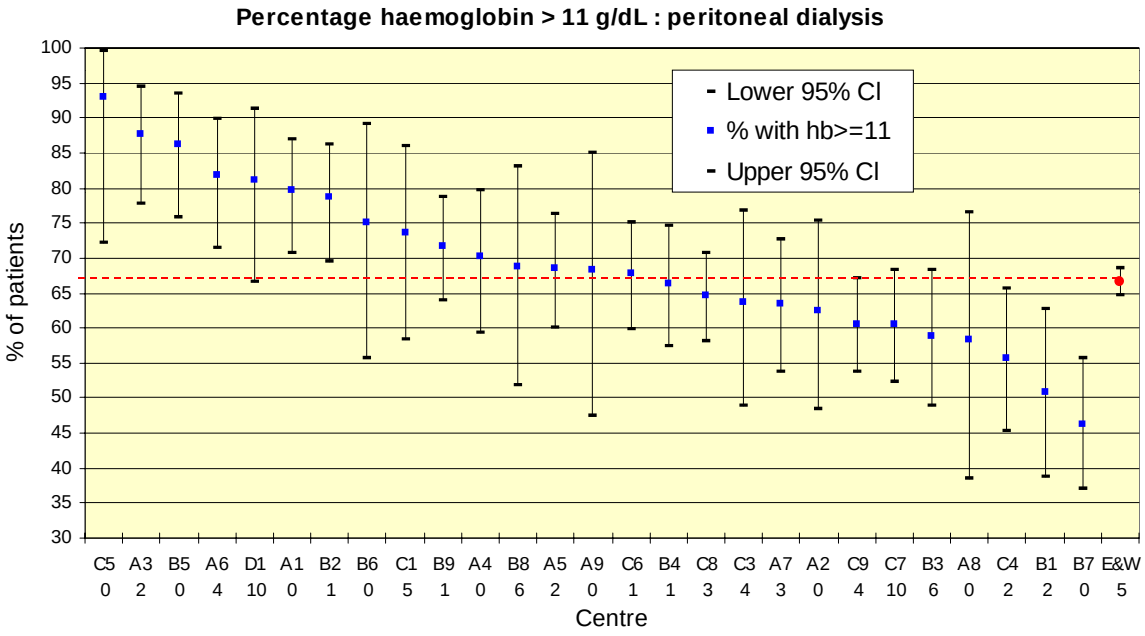


Figure 7.8: Haemoglobin median and quartile ranges for peritoneal dialysis patients

Factors influencing haemoglobin

Erythropoietin prescription and iron stores influence haemoglobin concentration. Other influences are less certain. Erythropoietin data are not available in this years report.

Haemoglobin and serum ferritin

Centres use different variables as measures of iron stores: serum ferritin is most commonly used. For this report, serum ferritin levels have been analysed and are shown in tables 7.3 and 7.4. 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 and 200mcg/l can be compared between units using the 95% confidence intervals shown in figures 9-12.

Centre	% data return	Median ferritin	90% range	Quartile range	**% ferritin ≥ 100µg/l**
A1	100	287	45 - 947	159 - 447	84
A2	100	247	43 - 833	138 - 404	85
A3	99	433	124 - 980	310 - 642	97
A4	100	268	70 - 877	147 - 435	91
A5	94	461	66 - 1069	264 - 698	93
A6	98	400	105 - 740	294 - 532	96
A7	100	622	118 - 1096	372 - 929	97
A8	93	468	252 - 887	405 - 565	99
A9	100	341	164 - 597	253 - 404	99
B1	95	380	161 - 748	267 - 486	97
B2	99	242	97 - 1327	164 - 350	95
B3	98	312	95 - 922	195 - 461	94
B4	80	344	64 - 964	182 - 568	91
B5	100	496	179 - 826	413 - 621	98
B6	96	447	120 - 763	304 - 571	98
B7	100	566	91 - 1287	308 - 764	95
B8	76	301	77 - 1675	159 - 460	85
B9	88	349	112 - 906	222 - 530	97
C1	89	330	88 - 1213	169 - 508	93
C2	2	*	*	*	*
C3	84	153	30 - 566	83 - 242	68
C4	60	809	142 - 1219	559 - 994	98
C5	95	358	63 - 1190	224 - 541	93
C6	99	334	52 - 867	198 - 532	90
C7	89	525	116 - 1308	302 - 719	96
C8	97	288	51 - 858	161 - 469	88
C9	89	500	90 - 1306	271 - 778	93
D1	84	282	115 - 804	210 - 426	97
E&W	92	377	72 - 1038	215 - 586	92

* insufficient data

Table 7.3: Serum Ferritin concentration in haemodialysis patients

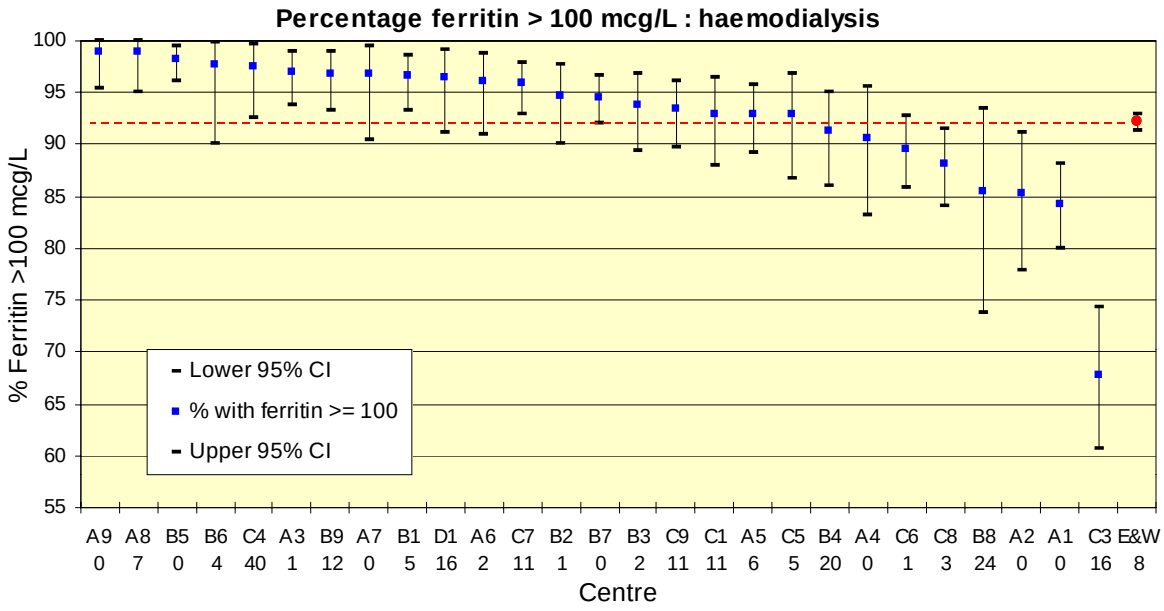


Figure 7.9: Percentage of HD patients with serum ferritin > 100 mcg/dl

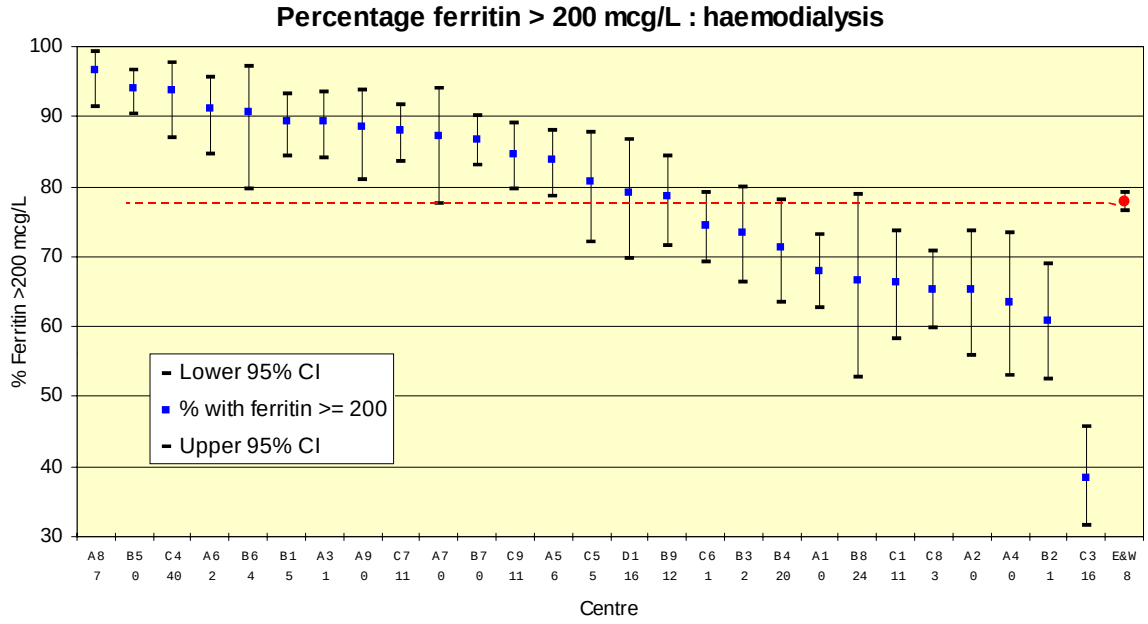
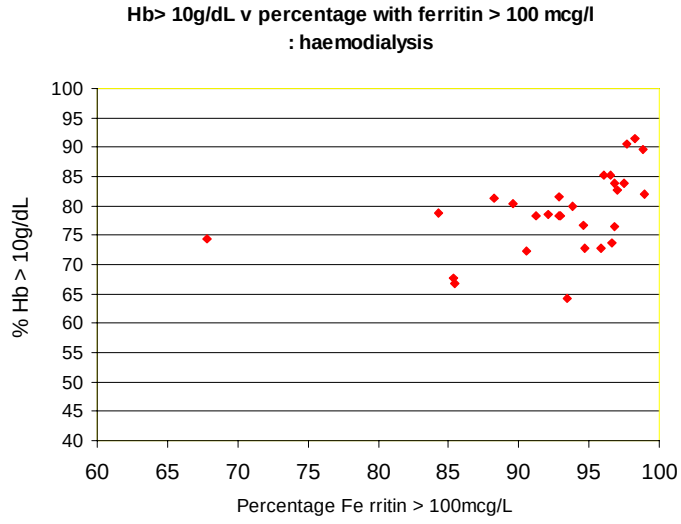


Figure 7.10: Percentage of HD patients with serum ferritin > 200 mcg/dl

Centre	% data return	Median ferritin µg/l	90% range	Quartile range	% ferritin > 100µg/l
A1	100	213	46 - 720	128 - 325	84
A2	94	184	28 - 896	105 - 268	76
A3	100	97	17 - 660	64 - 232	47
A4	90	220	43 - 747	128 - 356	83
A5	94	202	27 - 791	107 - 374	77
A6	96	340	46 - 830	205 - 453	91
A7	99	272	65 - 857	189 - 427	92
A8	100	271	67 - 687	168 -481	88
A9	100	214	28 - 620	122 - 436	77
B1	98	309	91 - 850	170 - 521	92
B2	100	277	30 - 878	164 - 408	83
B3	93	153	27 - 599	78.5 - 271	68
B4	98	230	49 - 788	137 - 383	84
B5	100	281	121 - 783	192 - 439	98
B6	100	420	247 - 951	372 -511	100
B7	100	342	62 - 1292	197 - 383	90
B8	85	195	19 - 522	111 - 344	79
B9	94	290	77 - 1205	181 - 458	92
C1	95	281	32 - 1248	153 - 614	87
C3	98	192	60 - 546	116 - 285	87
C4	97	216	49 - 1089	135 - 442	84
C5	93	283	51 - 722	137 - 450	77
C6	96	194	23 - 790	94 - 317	74
C7	90	233	49 - 675	130 - 368	84
C8	96	334	97 - 1068	197 - 489	95
C9	85	147	35 - 885	92 - 391	71
D1	98	276	33 - 737	141 - 369	83
E&W	**93**	**237**	**43 - 850**	**134 - 410**	**83**

* insufficient data

Table 7.4: Serum Ferritin concentration in peritoneal dialysis patients



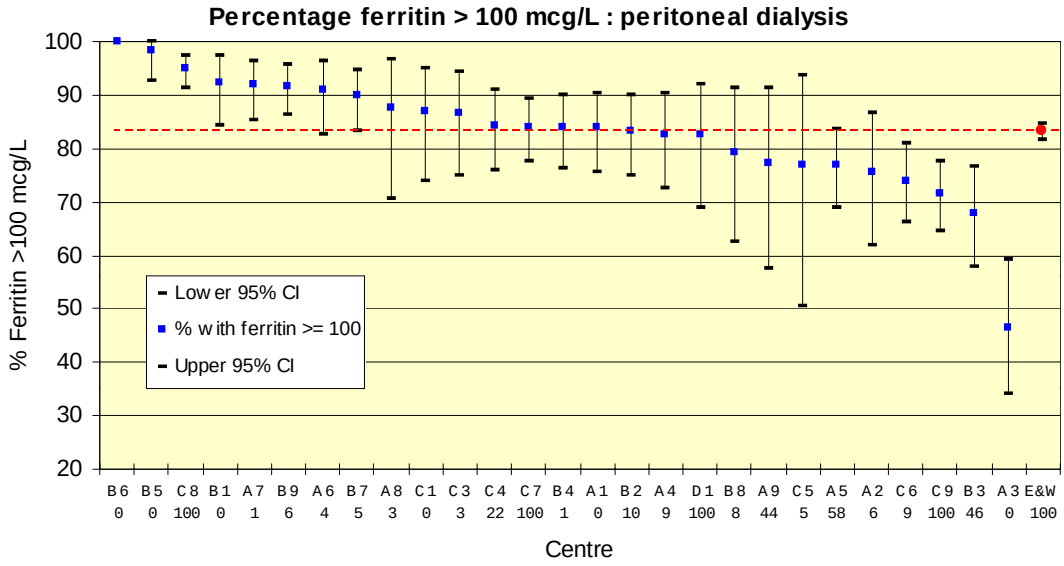


Figure 7.11: Percentage of PD patients with serum ferritin > 100 mcg/dl

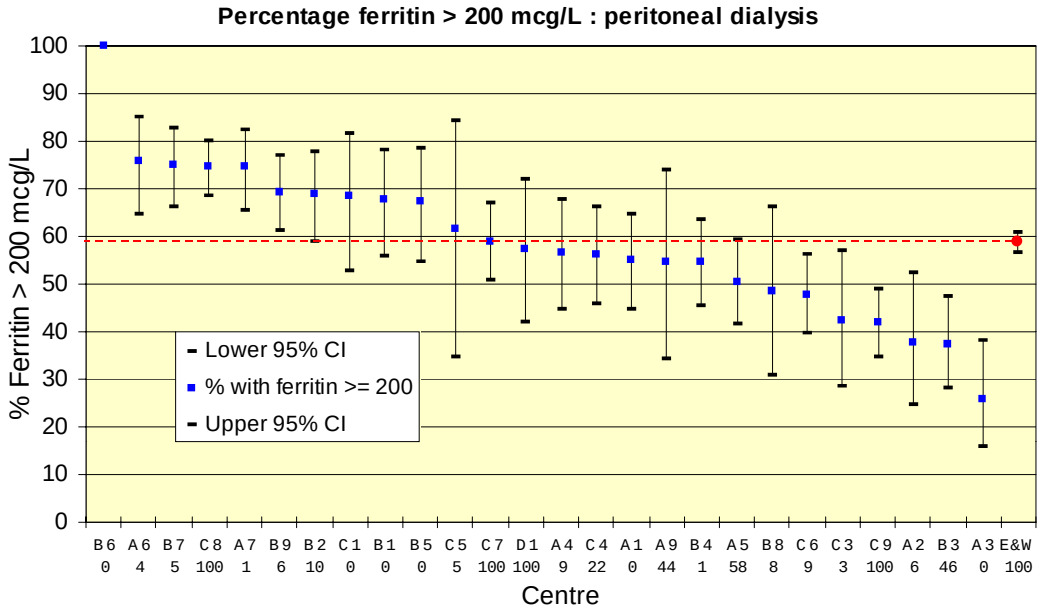


Figure 7.12: Percentage of PD patients with serum ferritin > 200 mcg/dl

Most centres had ferritin levels greater than 100 mcg/L in a high proportion of patients. The proportion with this ferritin level was higher in haemodialysis than peritoneal dialysis patients. This could reflect a greater difficulty in giving intravenous iron to peritoneal dialysis patients or could indicate that peritoneal dialysis patients achieve acceptable levels of haemoglobin with a lesser iron requirement.

Policies on iron treatment differ between centres and in individual centres may differ between haemodialysis and peritoneal dialysis. Centre C3 is a low outlier for ferritin in haemodialysis but has above average proportion with ferritin ≥ 100 mcg/dl in peritoneal dialysis. Centre A3 is a low outlier in peritoneal dialysis patients but has 97% of haemodialysis patients with ferritin ≥ 100 mcg/dl.

Centre C4 has 98% of haemodialysis patients with ferritin ≥ 100 mcg/dl but a median ferritin of 809 mcg/dl compared to Centre A9 which has 99% with ferritin ≥ 100 mcg/dl but a median of 341 mcg/dl.

As in previous years there is no direct relationship demonstrated between serum ferritin levels and the achievement of the Renal Association Standard for haemoglobin.

Haemoglobin at start of dialysis

The haemoglobin concentration in the first quarter in which a patient starts dialysis will reflect the pre-dialysis management in those patients already under medical review within a centre but will also be affected by the proportion of patients presenting late for renal replacement therapy.

Centre	% data return	Median Hb g/dl	90% range	Quartile range	%Hb > 10g/dL
A1	99	9.9	7.3-12.5	8.6-10.9	49
A2	98	9.6	7.5-12.3	8.6-10.4	38
A3	96	10.2	7.8-12.9	9.3-11.7	61
A4	100	10.4	8.6-12.1	9.6-11.1	55
A5	99	10.4	8.2-13.2	9.3-11.3	59
A6	78	9.8	7.0-13.6	8.8-11.0	49
A7	98	10.1	8.2-12.8	9.2-11.2	53
A8	80	10.4	7.9-12.5	8.9-10.9	66
A9	92	9.7	7.1-11.9	8.6-10.8	39
B1	98	9.4	7.1-11.6	8.7-10.4	37
B2	94	10.1	8.3-12.0	9.3-10.8	55
B3	83	9.8	7.8-12.9	8.9-11.1	49
B4	91	9.8	6.9-12.7	8.6-11.2	48
B5	98	10.5	8.0-13.0	9.1-11.7	59
B6	100	9.9	8.6-13.4	9.2-11.1	48
B7	90	9.5	7.5-12.1	8.6-10.5	38
B8	42	9.3	5.1-10.7	8.2-10.2	36
B9	90	10.1	7.3-13.1	8.9-11.1	55
C1	98	8.8	6.7-11.9	7.7-9.6	19
C3	82	9.5	7.2-12.2	8.3-10.7	38
C4	82	9.5	7.4-11.7	8.9-10.4	38
C5	85	9.0	7.0-12.1	9.0-11.0	41
C6	95	10.4	7.7-13.6	9.2-11.6	59
C7	96	9.4	7.4-11.7	8.5-10.4	32
C8	90	10.4	8.0-13.2	9.3-11.5	60
C9	39	*	*	*	*
D1	76	10.1	7.9-13.0	9.5-11.4	52
E&W	86	9.9	7.4-12.7	8.9-11.0	48

Table 7.5: Haemoglobin at start of dialysis

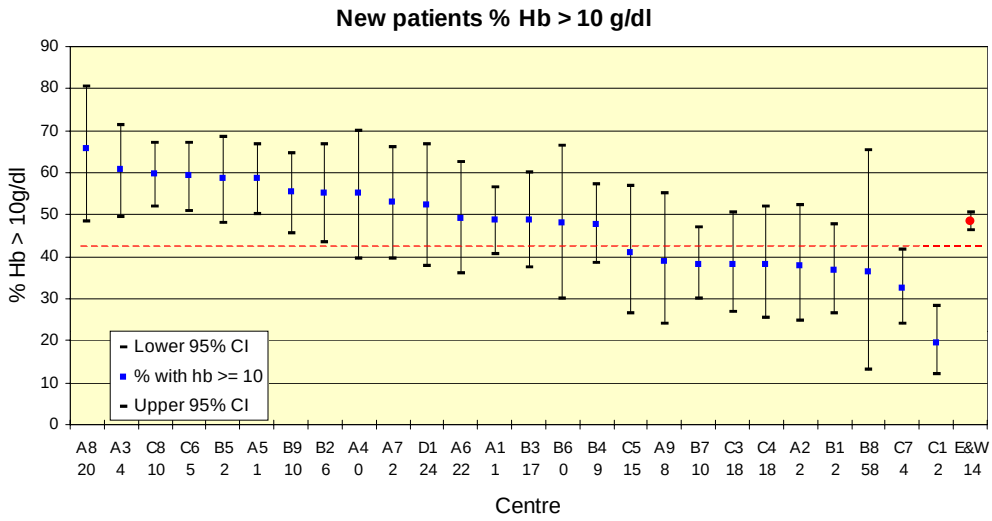


Figure 7.13: Percentage haemoglobin ≥10g/dl for new patients

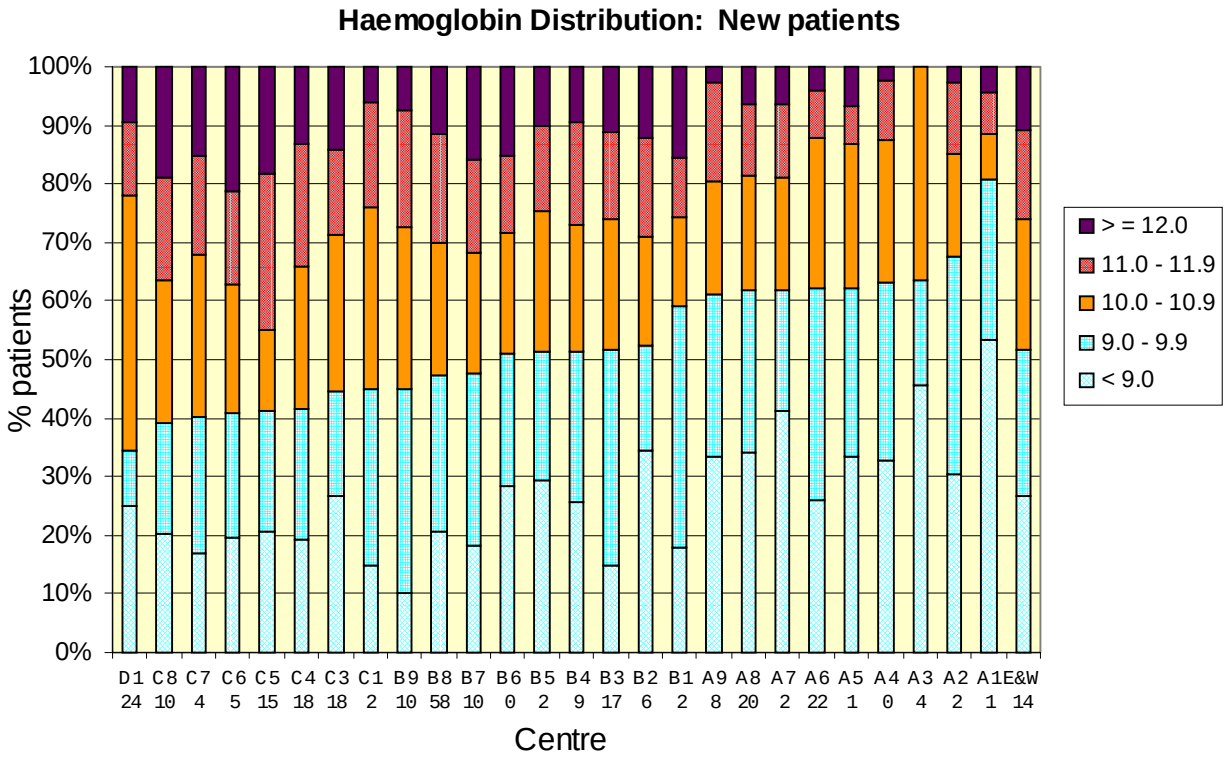


Figure 7.14: Haemoglobin distribution at start of dialysis

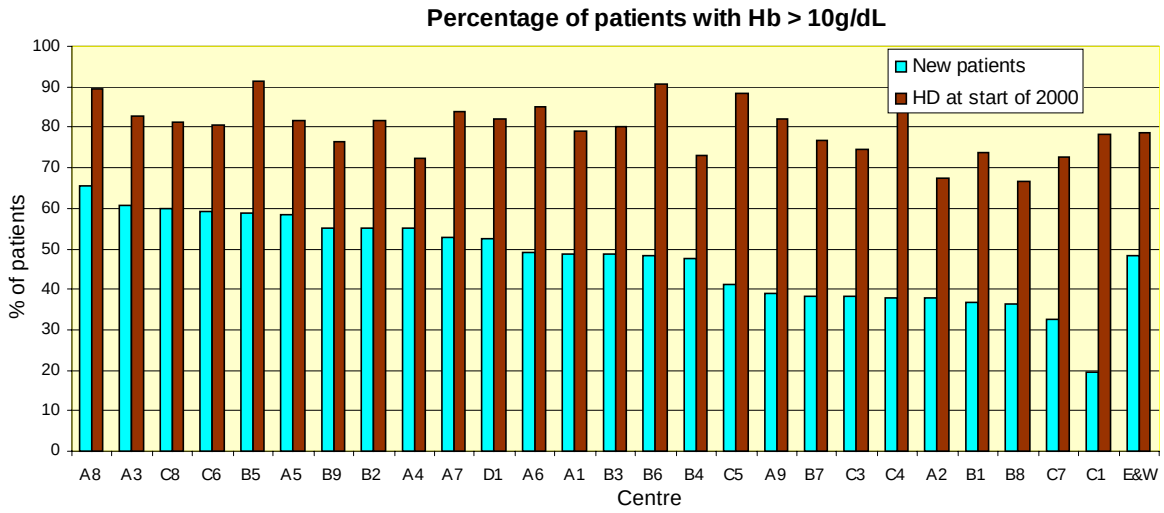


Figure 7.15: Percentage with haemoglobin > 10g/dl: new and prevalent patients

A significant proportion of new patients are very anaemic with haemoglobin < 9g/dl which may reflect patients presenting late with uraemia. The large variation in new patients haemoglobin between centres and the lack of relationship between haemoglobin of new patients and haemoglobin of established patients probably reflects differing policies on use of erythropoiesis stimulating treatments in pre-dialysis patients. Current standards for anaemia management in renal failure do not apply pre-dialysis.

Change in Haemoglobin Achievement 1999 -2000

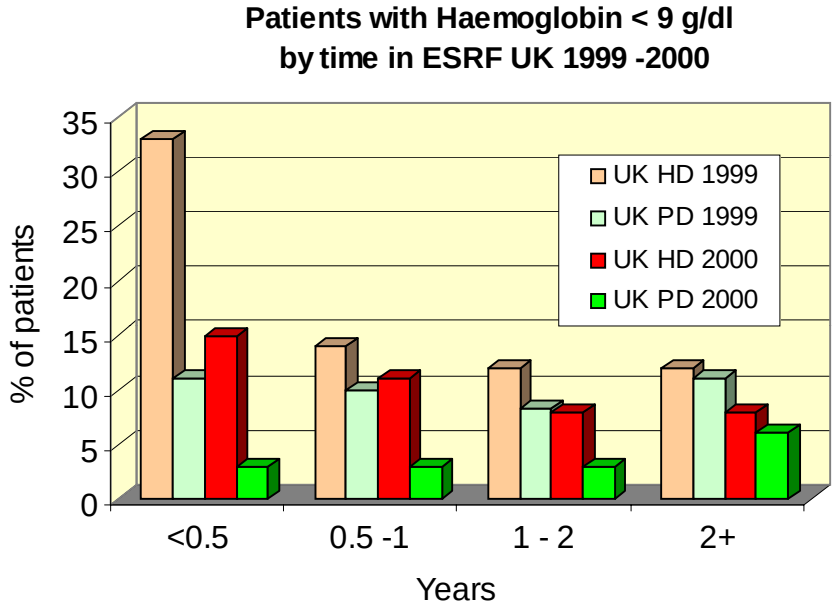


Figure 7.16: Haemoglobin < 9 g/dl in 1st 2 years since of RRT

Figure 7.16 shows that since 1999 fewer patients are starting renal replacement therapy severely anaemic with a haemoglobin of less than 9 g/dl. For patients both on haemodialysis and peritoneal dialysis this proportion has more than halved. These results for 2000 are now similar to those achieved in the 1999 US data.

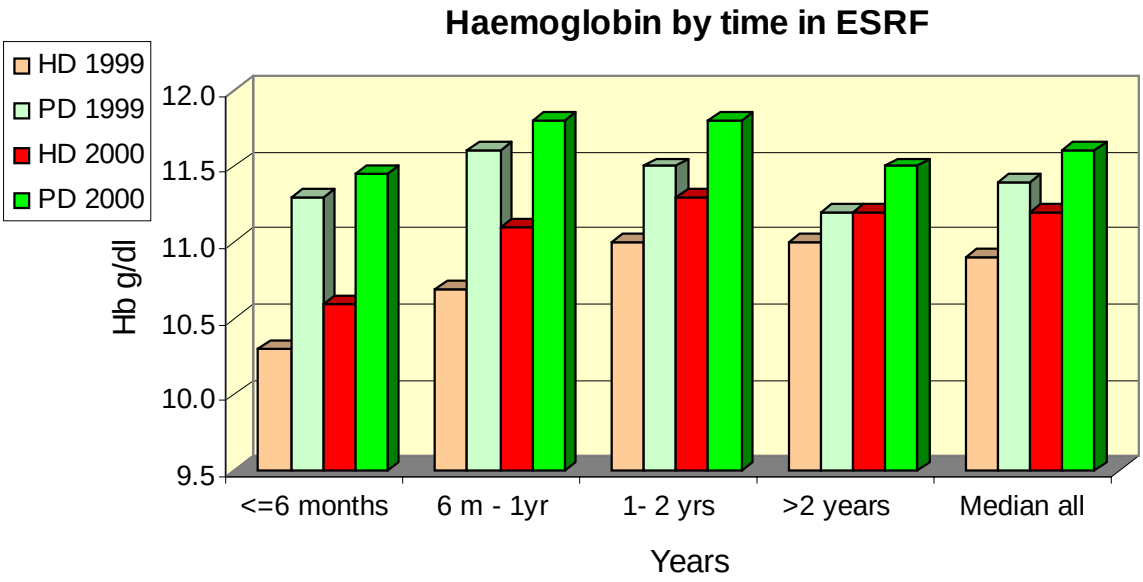


Figure 7.17: Median haemoglobin by time on RRT

In 2000 there has been a marked rise in median haemoglobins for patients on both dialysis modalities, across all time points. There is now no fall in haemoglobin for patients on PD after 1- 2 years, although the fall in haemoglobin still occurs for those on PD > 2years, although to a lesser extent. As shown last year, a median haemoglobin of 11.5g dl should indicate that > 85% of patients have a haemoglobin above 10 g/dl and achieve the Renal Associations standard.

Figures 7.18 show the improvement for patients on haemodialysis across all centres with 2 years of data. Two of the newer centres A6 and C9 with no data for 1999 show no improvement in the year 2000.

Figure 7.19 is a similar graph for patients on peritoneal dialysis. Centre B6 is the only centre to show a drop in achieving the standard over this time period.

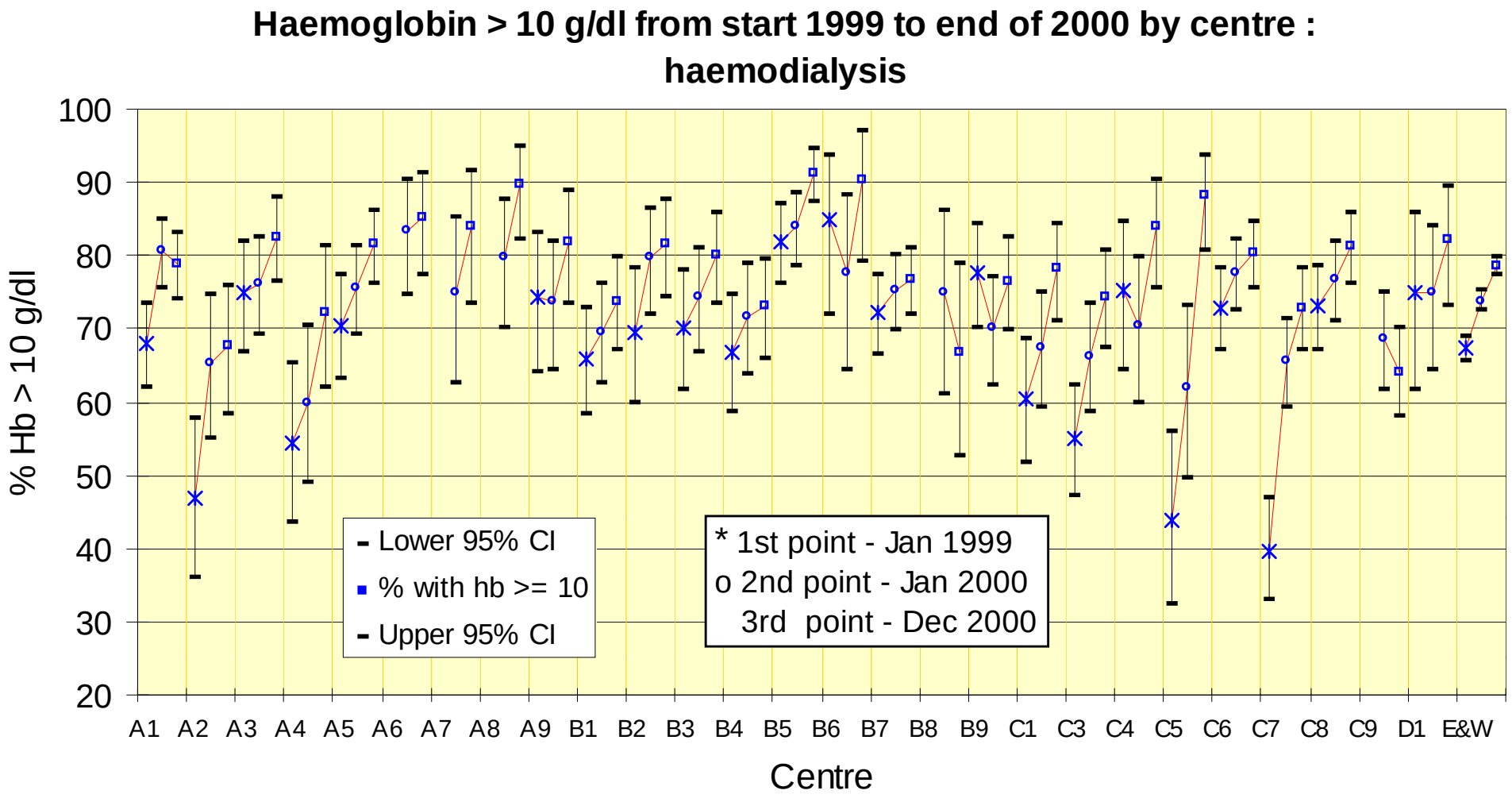


Figure 7.18: Change in haemoglobin 1999 –2000 haemodialysis

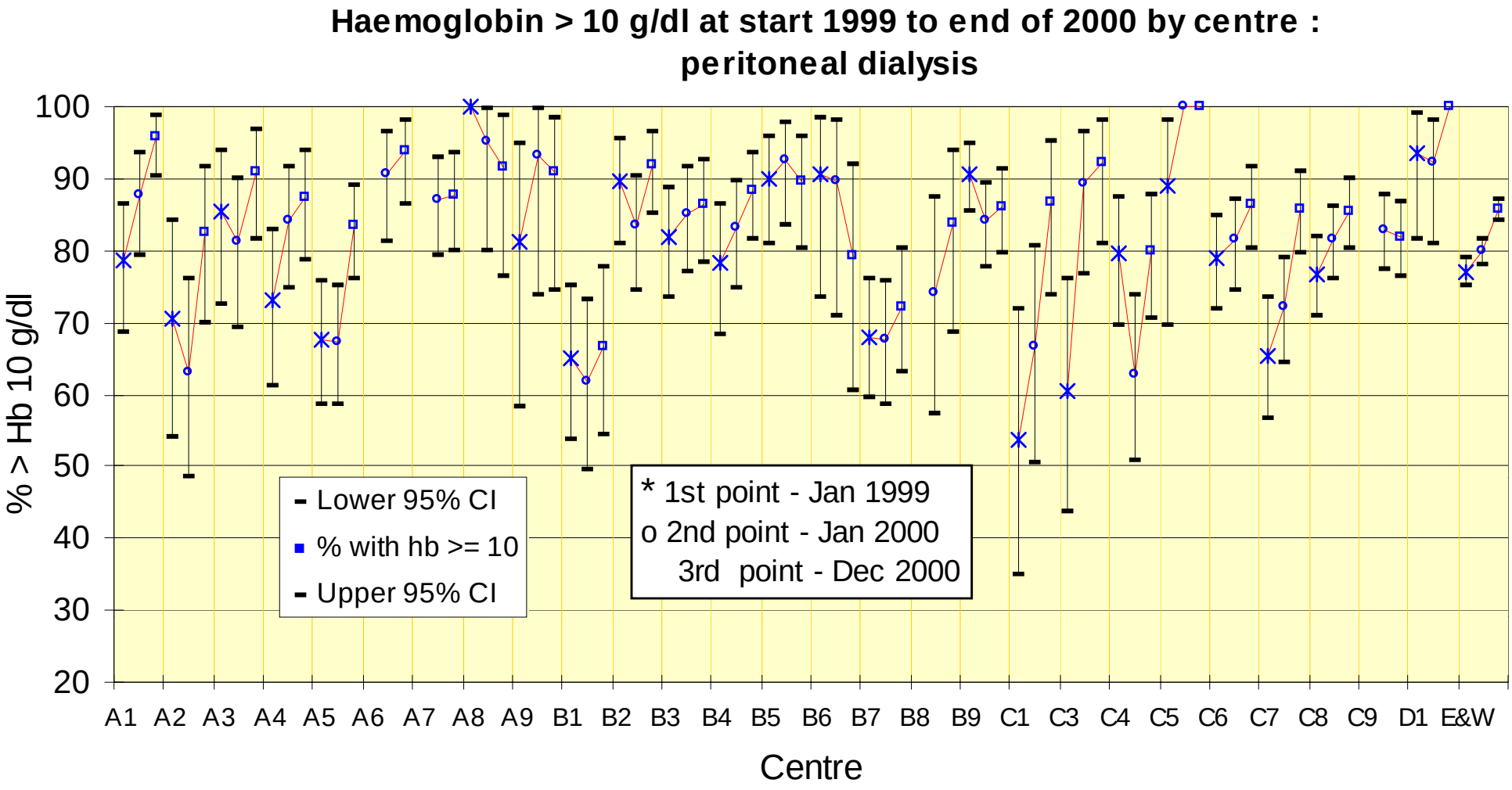


Figure 7.19: Change in haemoglobin 1999 –2000 peritoneal dialysis

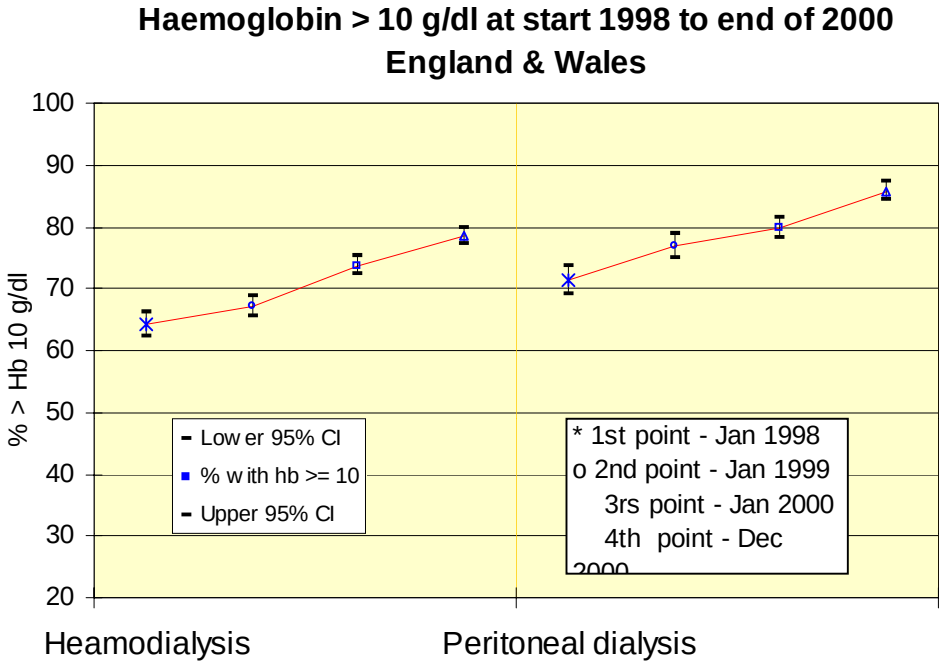


Figure 7.20: Improvement in E&W of achieving the Hb standard 1998-2000

The US data for October 2000, from the ESRD Clinical Performance Measures project showed that 91% of patients had a haemoglobin ≥10 g/dl and 74% achieved a haemoglobin ≥11 g/dl. Median haemoglobin in the US was 11.7 g/dl, which is consistent with the Registry prediction a median haemoglobin of 11.5g/dl is required to achieve 85% of patients above 10g/dl.

Conclusion

There is continuing evidence of improvement in the management of renal anaemia in centres submitting data to the Renal Registry. For peritoneal dialysis 86% of all patients whose data had been submitted to the Registry had a haemoglobin ≥10 g/dl. An increasing proportion of centres achieved the Renal Association standard for both haemodialysis and peritoneal dialysis patients.

There is evidence of significantly different approaches to iron replacement in different centres.

There is evidence of different approaches to management of renal anaemia pre-dialysis which will in part reflect availability of erythropoiesis stimulating treatments.

Chapter 8: 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 8.1.

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
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 8.1 Renal Association Standards

This year due to previously mentioned problems with albumin measurement and correction of calcium, these graphs have not been included here although will be released in the 'web' publication. Also the parathyroid hormone level achievements have been standardised at < 23 pmol/l rather than the local laboratory range as these locally provided ranges have shown not to be population, method or equipment based.

Data are included for the last quarter of 2000. 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 previous reports 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 again this year in detail in the appendix.

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 and the significance of the ranking order has not been tested. 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

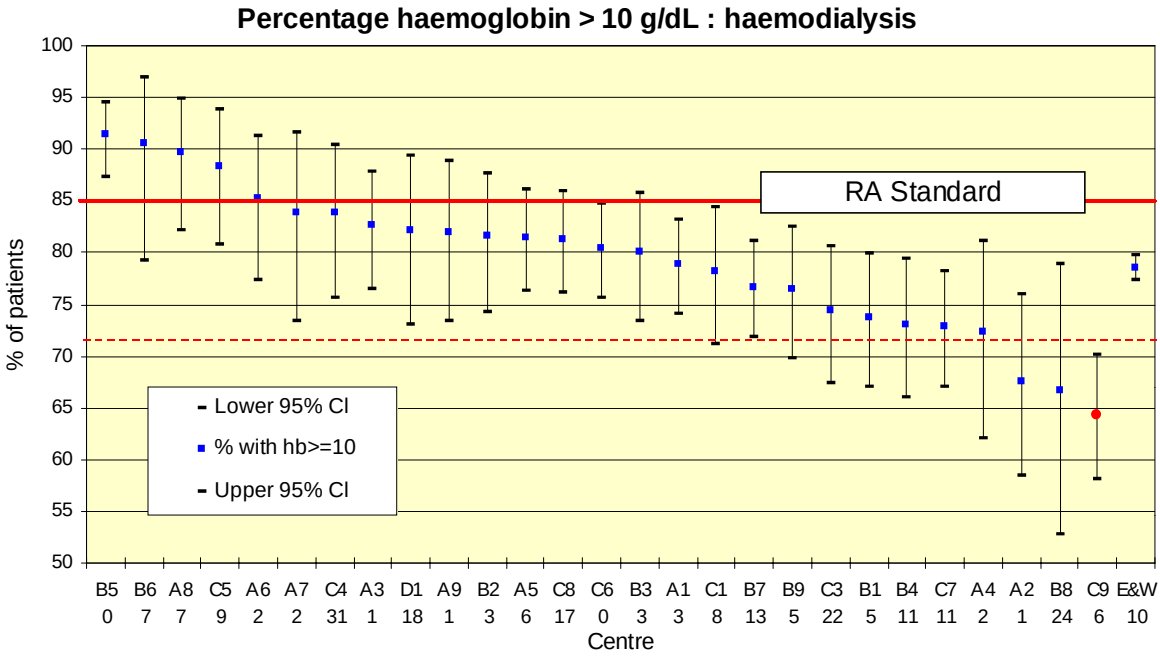


Figure 8.1 Haemoglobin Percentage of HD patients achieving the RA Standard

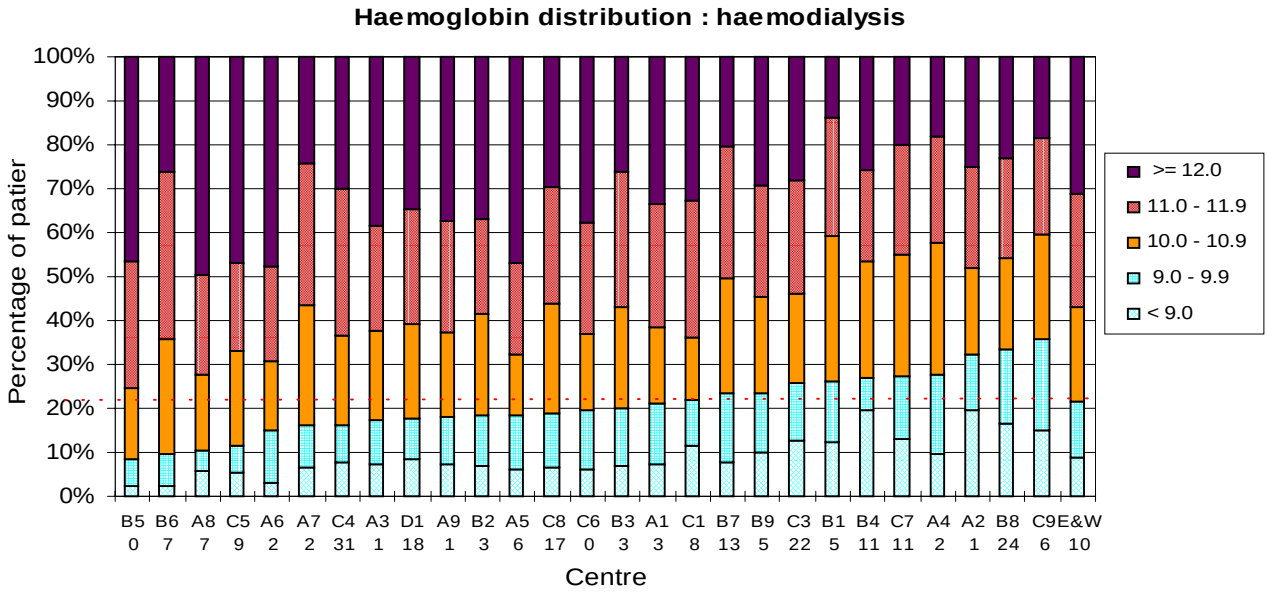


Figure 8.2 Haemoglobin for patients on HD by 1g/dl bands

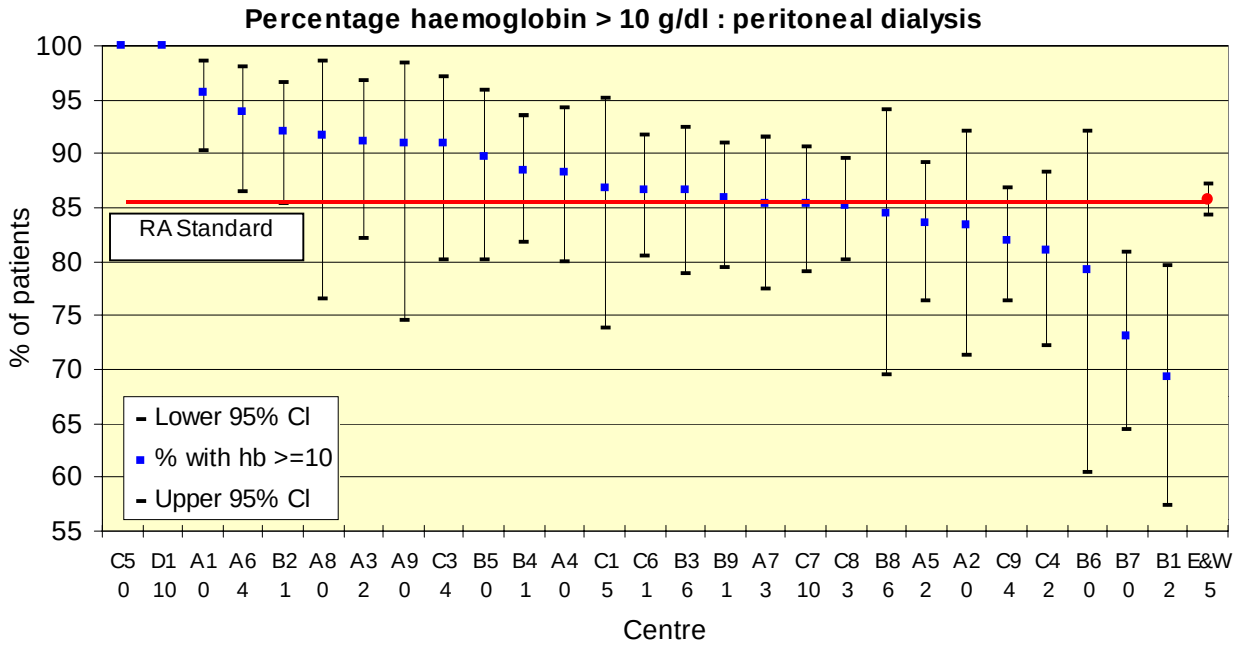


Figure 8.3 Percentage of PD patients by centre achieving the RA Standard

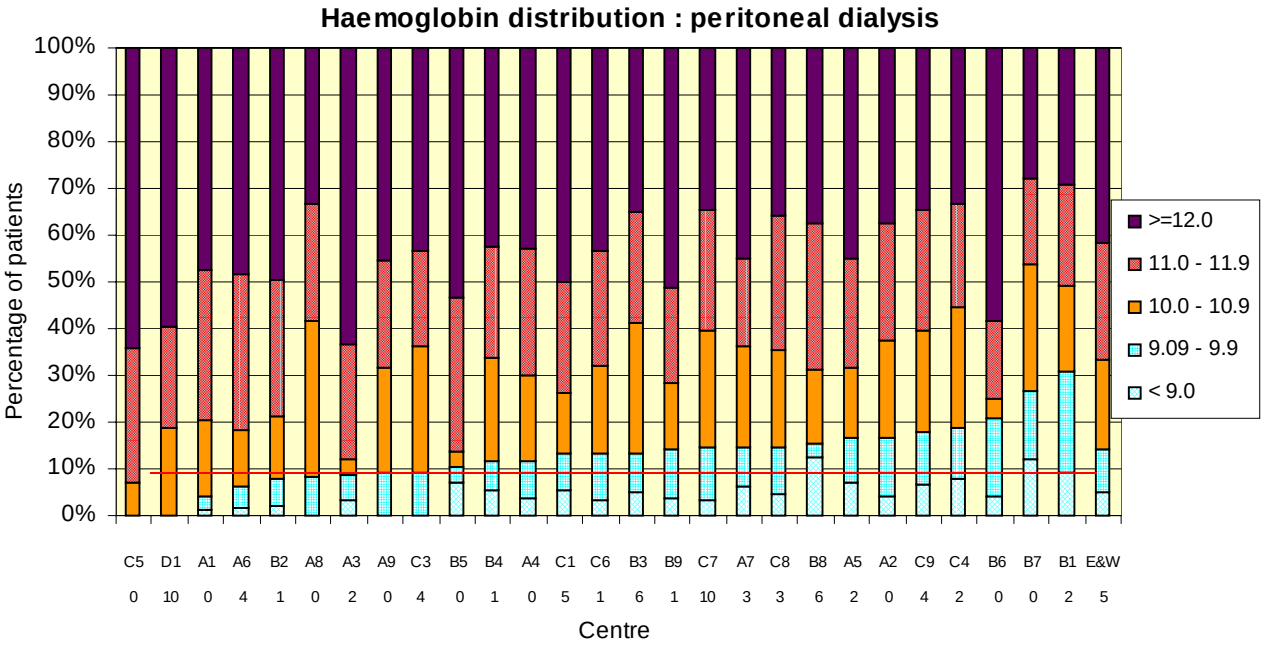


Figure 8.4 Distribution of haemoglobin for patients on PD by 1g/dl bands

Serum Bicarbonate

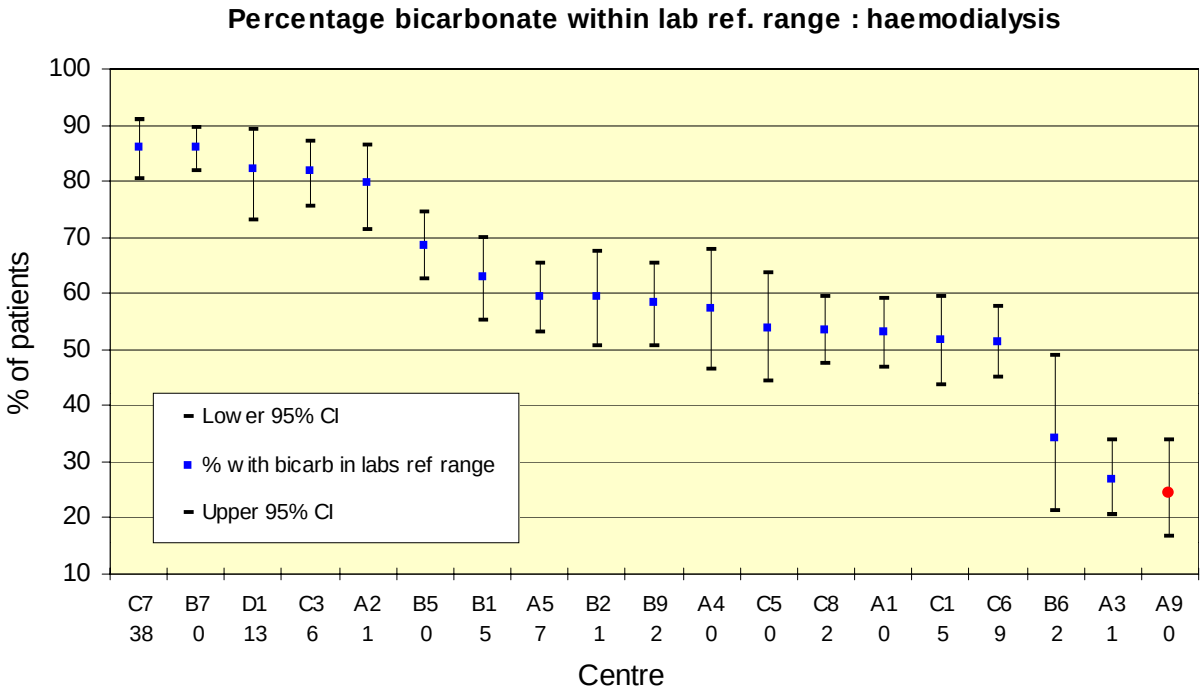


Figure 8.5 Percentage bicarbonate in lab reference range for haemodialysis

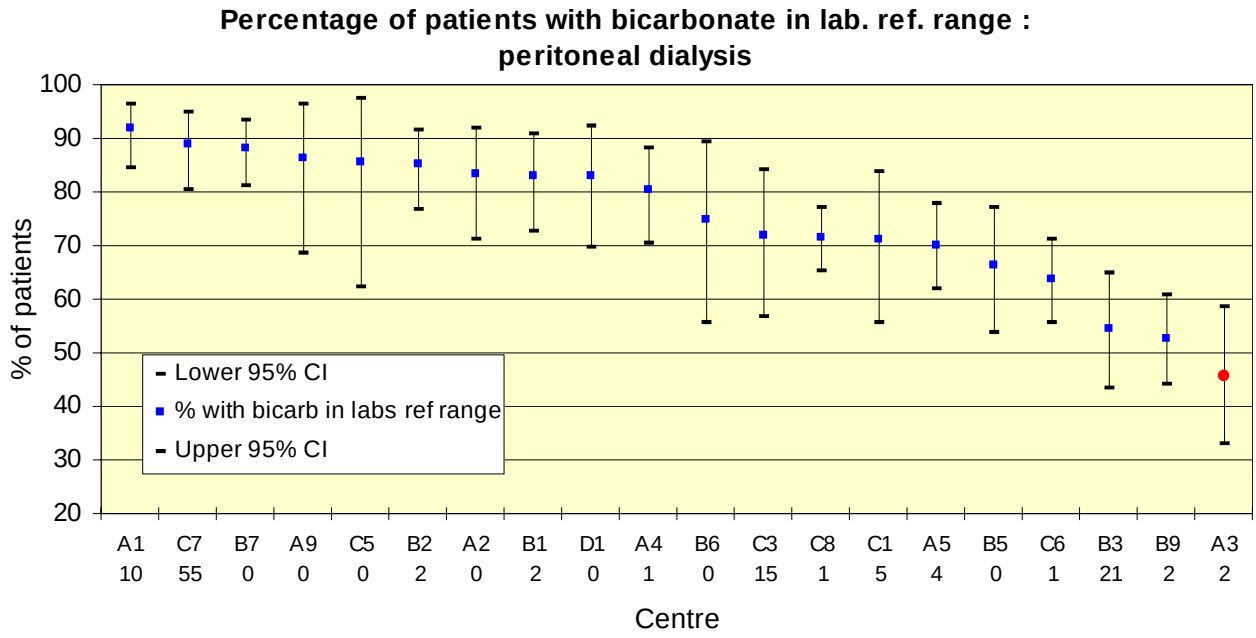


Figure 8.6 Percentage bicarbonate in lab reference range for peritoneal dialysis

Serum Phosphate

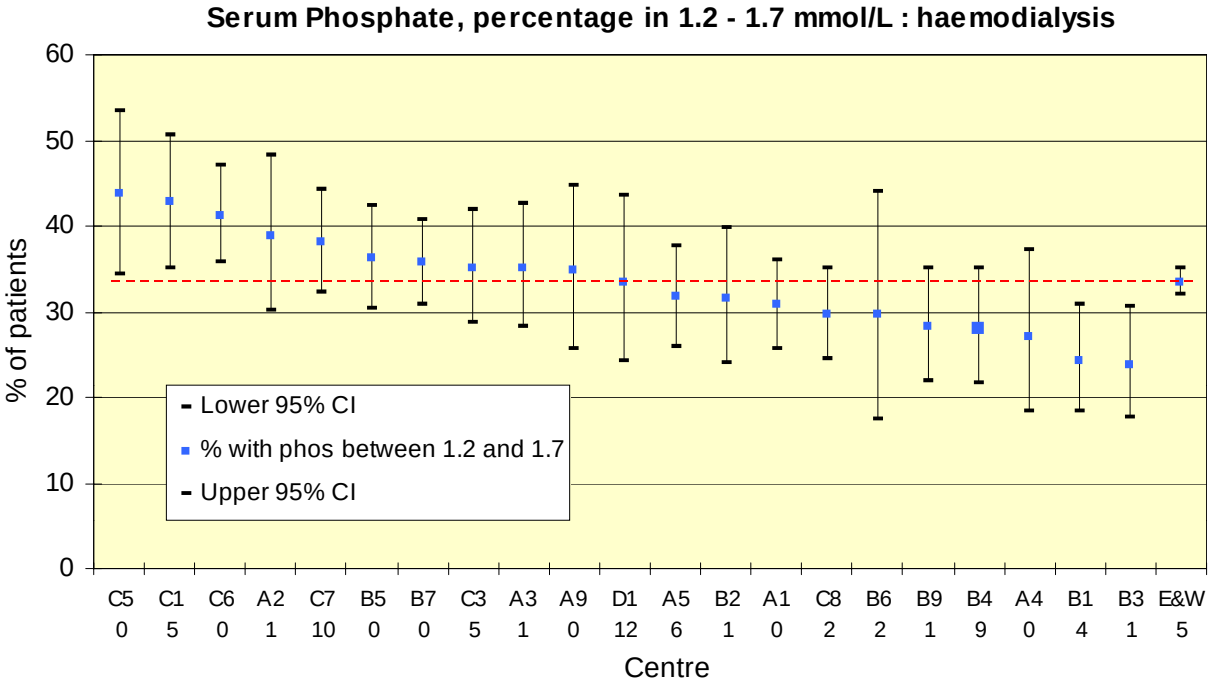


Figure 8.7 Percentage serum phosphate in range 1.2-1.7 for haemodialysis

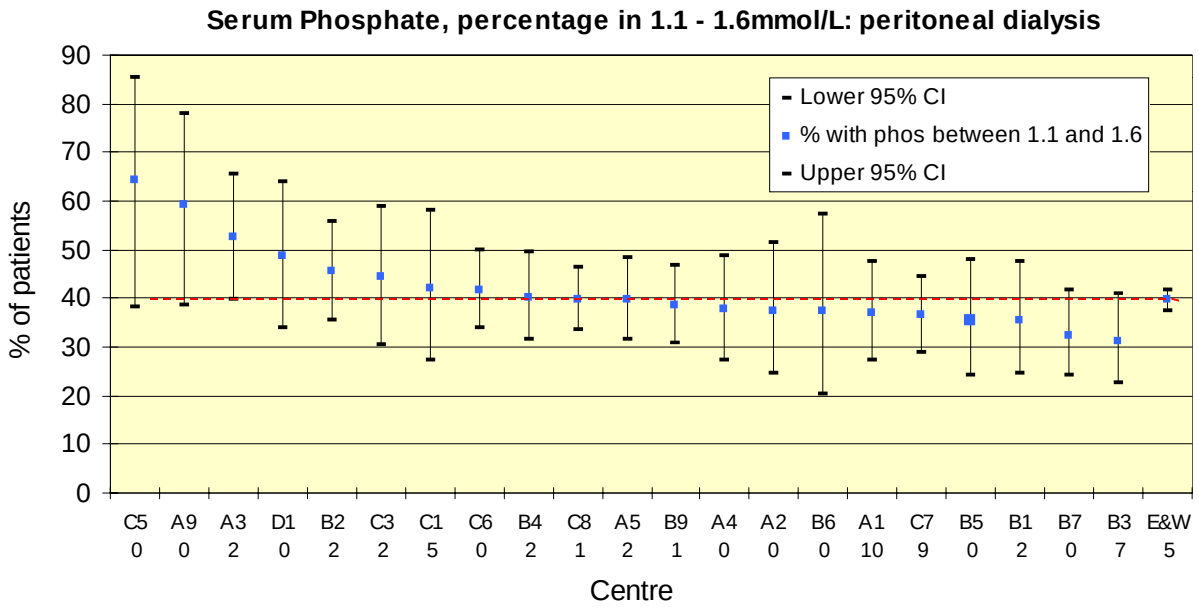


Figure 8.8 Percentage serum phosphate in range 1.1-1.6 for peritoneal dialysis

Intact parathyroid hormone

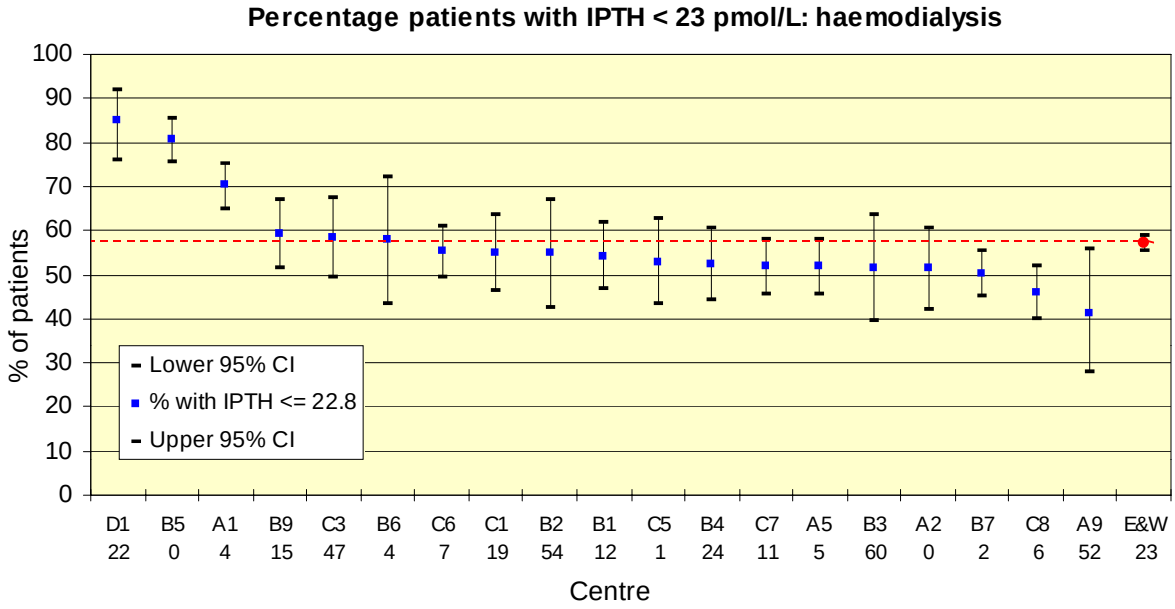


Figure 8.9 Percentage patients with iPTH in 3x lab range on haemodialysis

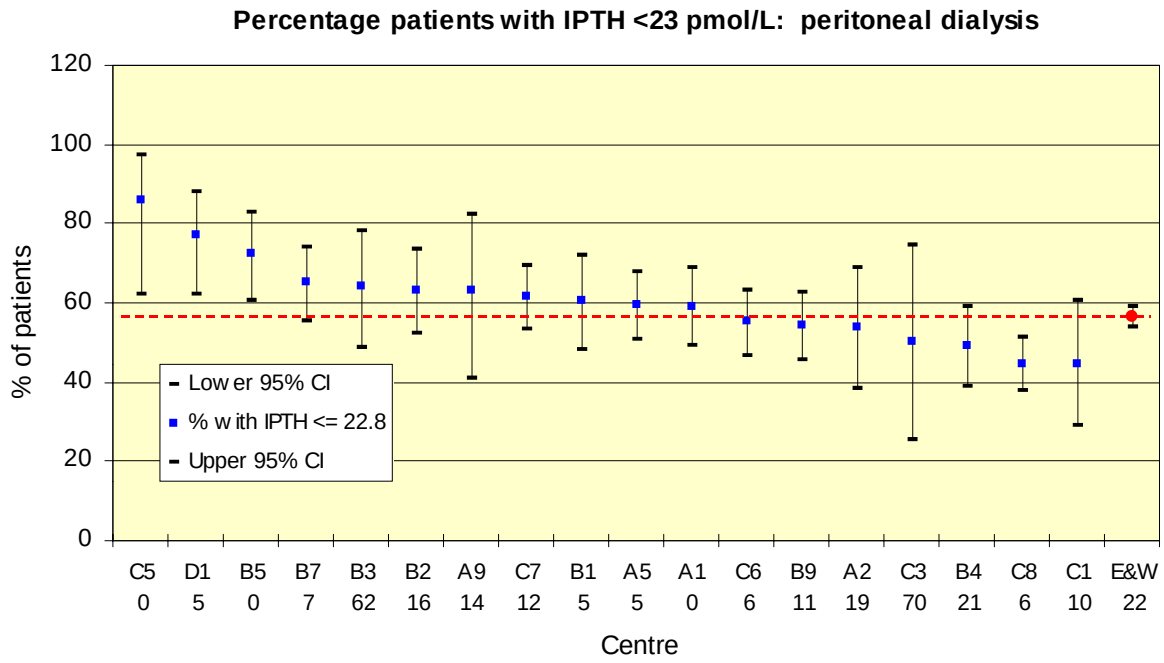


Figure 8.10 Percentage patients with iPTH in 3x lab range on peritoneal dialysis

Dialysis Adequacy

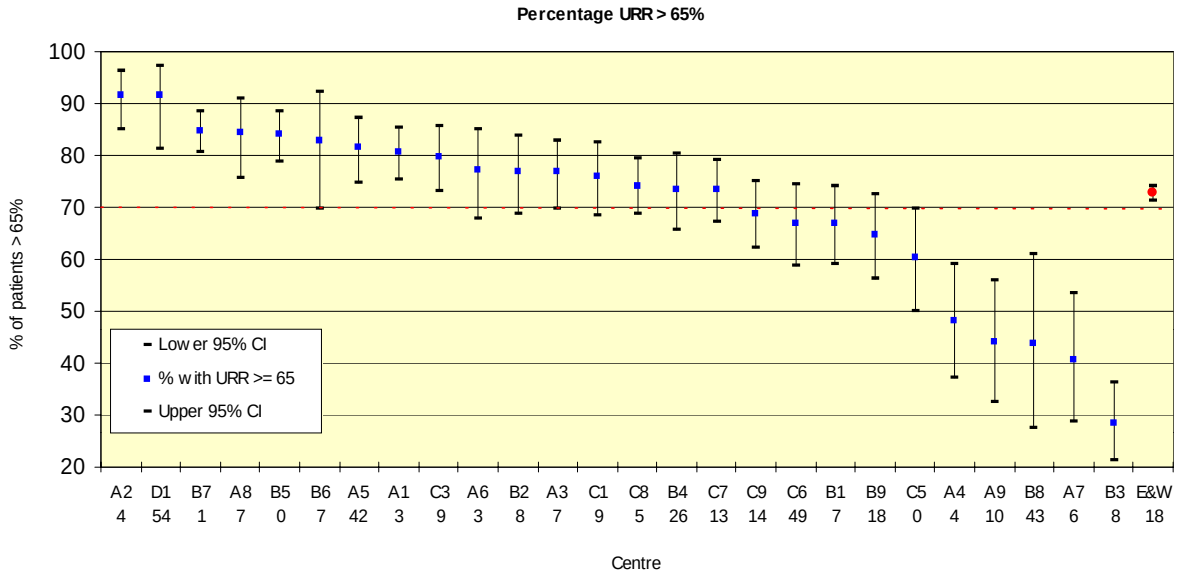


Figure 8.11 Percentage URR > 65%

Blood Pressure

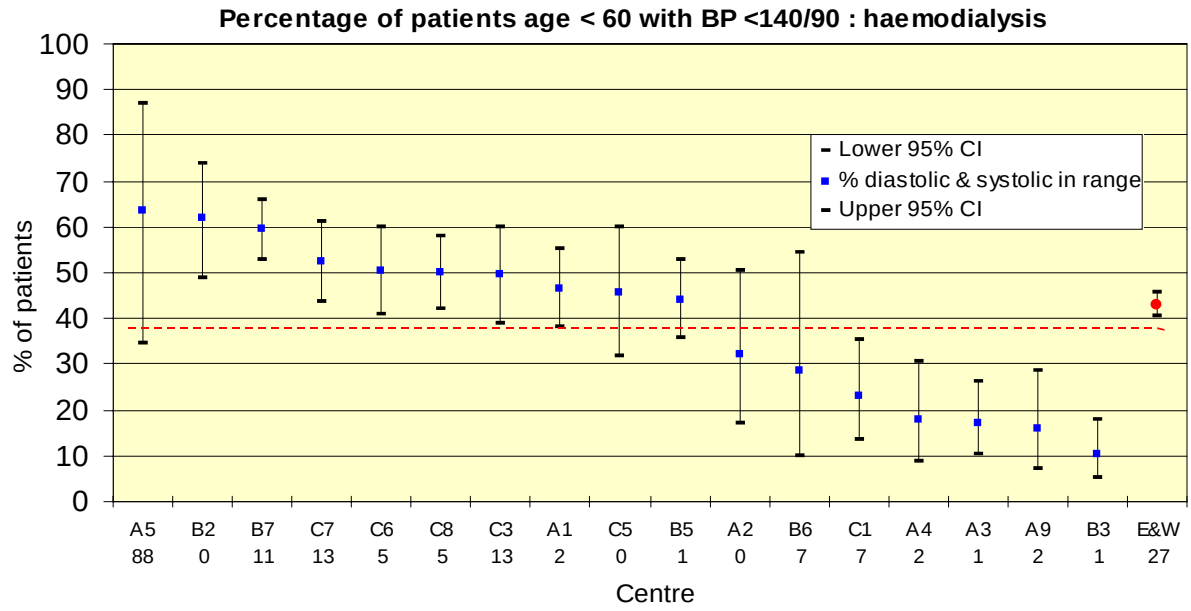


Figure 8.12 Percentage haemodialysis patients <60 with BP in RA Standard range

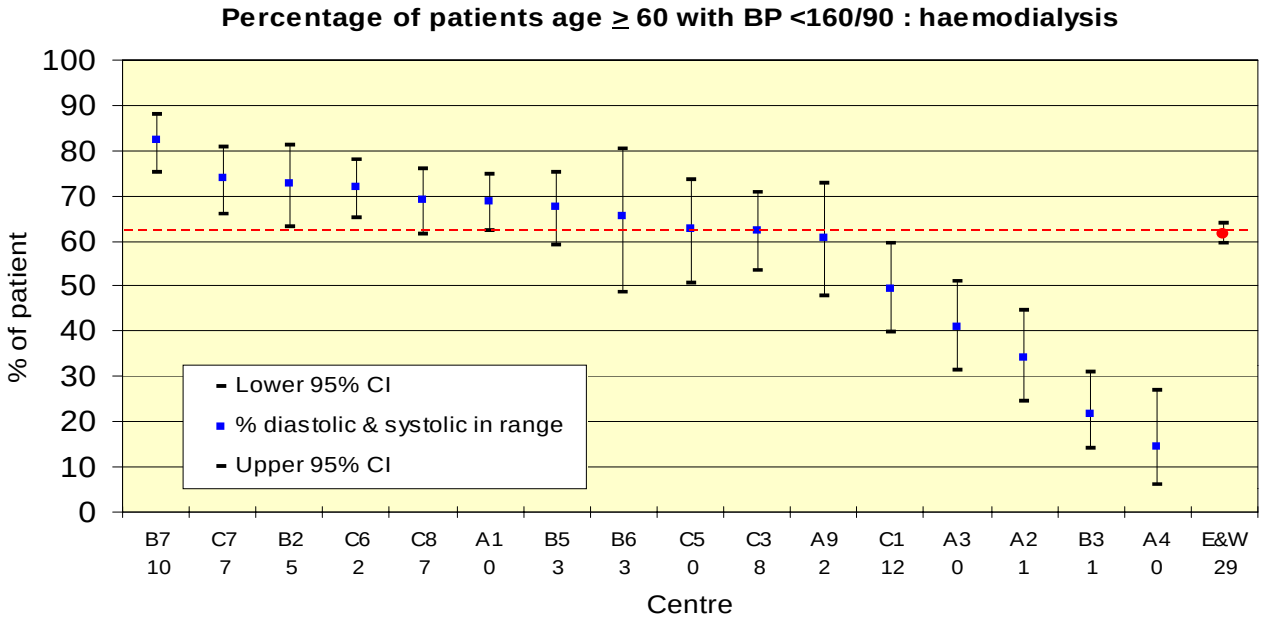


Figure 8.13 Percentage patients >60 with BP in RA Standard on haemodialysis

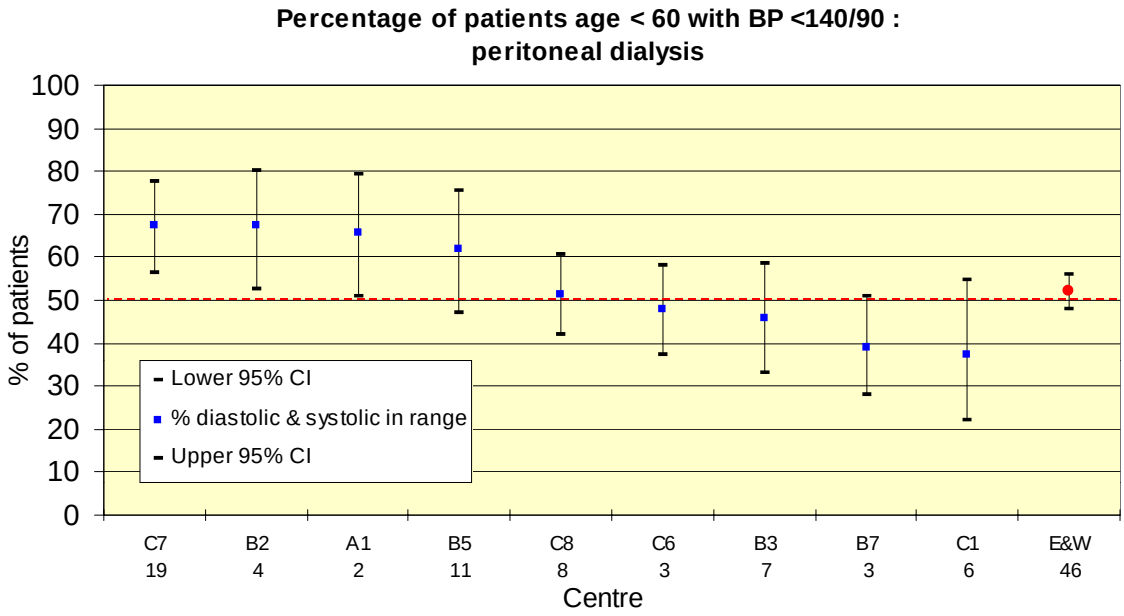


Figure 8.14 Percentage pts age <60 with BP in RA Standard range on peritoneal dialysis

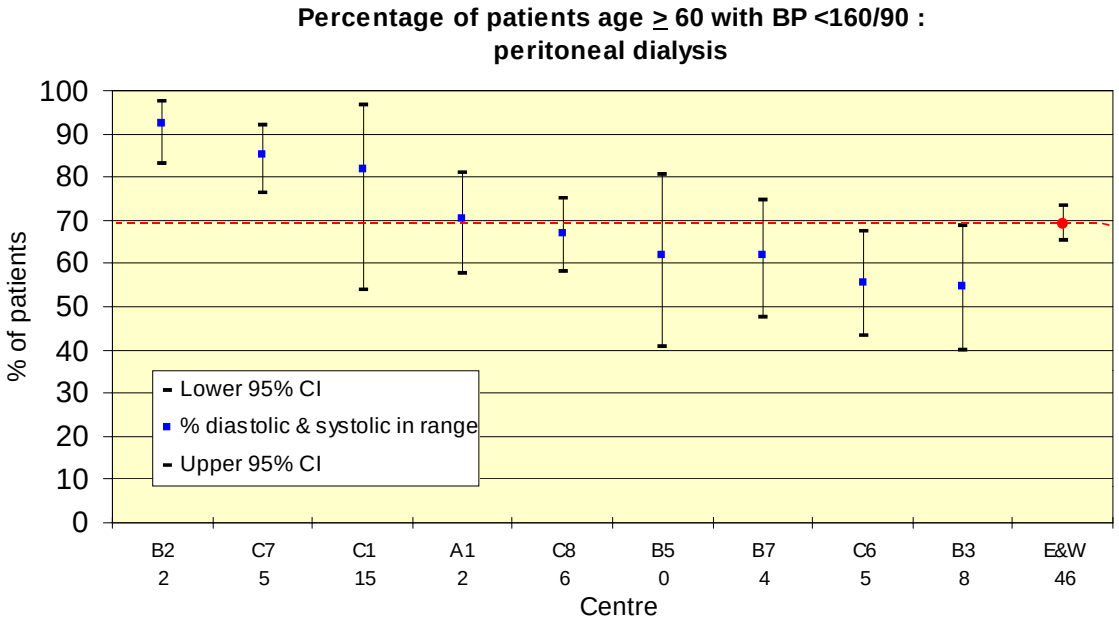


Figure 8.15 Percentage pts age >60 with BP in RA Standard range on peritoneal dialysis

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. Degrees of freedom are equal to the number of centres with over 50% completeness minus 1.

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 = 105.7, d.f. = 27, p<0.001).

For patients on PD, the percentage of patients with haemoglobin ≥10g/dl was found to differ significantly between centres (X^2 = 62.7, d.f. = 27, 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 = 252.9, d.f. = 27, p<0.001).

For patients on PD, the percentage of patients with ferritin ≥100 was found to differ significantly between centres (X^2 =164.1, d.f. = 27, 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 = 378.7, d.f. = 19, p<0.001).

For patients on PD, the percentage of patients with bicarbonate within the Standard differed significantly between centres (X^2 = 129.6, d.f. = 19, 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 = 144.8, d.f. = 20, 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 = 36.0, d.f. = 20 p<0.015). [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 = 138.3, d.f. = 18, p<0.001).

For patients on PD, the percentage of patients with PTH ≤ 22.8 pmol/L differed significantly between centres (X^2 = 76.3, d.f. = 18, p<0.001).

Chapter 9: Survival of incident adult patients

Summary

The first year survival from day 0 of renal replacement therapy was 96%, 94%, 90%, 84%, 72%, 65% for patients aged 18-34, 35- 44, 45-54, 55-64, 65- 74, 85+ respectively.

There was no relationship between a centre's 90 day or 1 year after 90 day survival and the mortality rate of the local population for all cause mortality or only cardiac mortality

There are marked differences between centres in survival rates, but these are not consistent. Serial studies on one year survival rates for individual centres from 1997 – 1999, after adjustment to a standard age, showed wide variation

Introduction

The 'Renal Registry' database enables analysis of the influence of different factors on patient survival. These factors are related to patient case mix [e.g. age, gender, ethnicity, underlying diagnosis & other co-morbidity] or are dependent on treatment [e.g. haemoglobin, mode of dialysis, serum phosphate]. For individual renal units such analysis allows comparison with performance in previous years, and with other centres.

Survival rates can either be looked at in relation to:

(a) An *'incident cohort'* in which patients who started renal replacement therapy in a particular year are included

or

(b) A 'prevalent cohort' in which all (or a defined group) of patients undergoing renal replacement therapy at a particular time are included

The analyses presented in this chapter examine survival whilst on renal replacement therapy, including transplantation, of incident patients. Patients are censored when moving to a centre which does not report to the Registry.

Death rates in different centres contributing to the UK Renal Registry are reported here. These are very crude data. Adjustment can be made between centres on the basis of age, but there is need for more detailed information relating to co-morbidity and ethnic origin. With this lack of information about case-mix, no significance can currently be attributed to any apparent differences in survival between centres.

Statistical Methods

The 'number of days at risk ' was calculated for each patient and the sum of these values for all patients divided by 365 represents the 'number of patient years at risk'. The mortality rate was defined as :

$$\frac{\text{Number of deaths on dialysis}}{\text{Number of patient years at risk}}$$

The unadjusted survival probabilities (with 95% confidence intervals) were calculated using the Kaplan Meier Method in which the probability of surviving more than a given time can be estimated for members of a 'cohort of patients' without accounting for the characteristics of the members of that cohort. Where centres are small or the survival probabilities greater than 90% the confidence intervals are only approximate.

In order to estimate the differences in survival of different subgroups of patients within the cohort a 'Stratified Proportional Hazards Model (Cox) ' was used where appropriate. The results from the Cox Model are interpreted using a hazard ratio. For example, for diabetics when compared with non-diabetics, the hazard ratio is the ratio of the estimated hazards for diabetics relative to non-diabetics, where the hazard is the risk of dying at time t given that the individual has survived until this time. The underlying assumption of a proportional hazards model is that this ratio remains constant throughout the time period under consideration. The proportional hazards model was tested for validity in all cases.

Survival patterns

This analysis relates primarily to the 1999 cohort of patients, with earlier patients studied for the longer-term survival analysis. Analysis of the survival of incident patients reveals a complex picture. As shown in chapter 4, the death rate in the first 90 days is much higher than in the rest of the first year (table 9.1). The high early risk of death my also vary by age and diagnosis.

Age	90 day KM Survival	1 yr KM Survival
< 65	95	86
≥ 65	83	66
All	89	76

Table 9.1 90 day & 1 yr survival

The number of deaths per 100 live patients in each 30-day time interval was plotted. Figure 9.1 shows that the death rate levels not at day 90, but at day 150. Thereafter the death rate appears fairly constant.

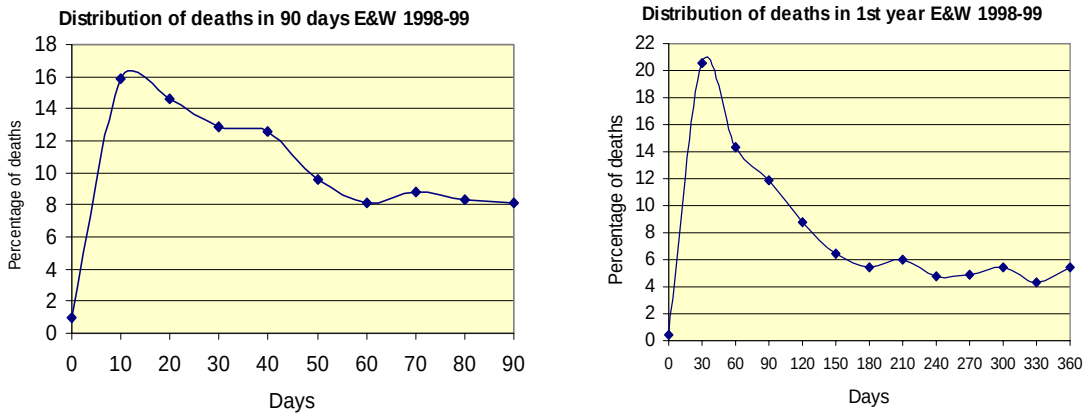


Figure 9.1 Distribution of deaths in the 1st year

Fig. 9.1 shows the distribution of deaths as a percentage of all deaths within the 90-day and 360 day time period. When analysed as a percentage of total deaths in the 1st year, 20% occur within the first 30 days and 47% within 90 days for England & Wales.

Figure 9.2 shows the difference between Scotland (with a generally higher mortality) and England & Wales. There is an apparent greater variation in the Scottish data due to smaller numbers of patients in this group.

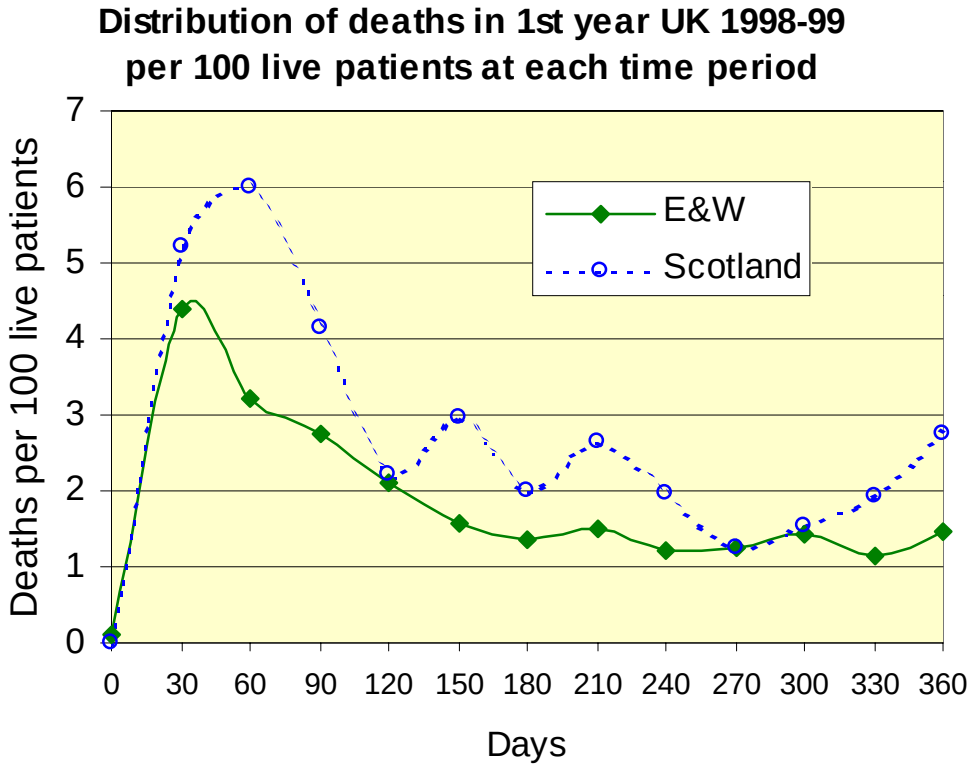


Figure 9.2 Distribution of deaths in 1st year UK 98 – 99 per 100 live patients at each time period

The distribution of deaths in the first few months may also show differences between units, even where overall survival is similar. Different distribution patterns may give an indication of differences in practice.

The "hazard function"

The hazard function is the probability of dying in a short time interval. The hazards expressed below are the probability of dying on any single day

Survival within the first 90 days

Analysis of the hazard of death within the first 90 days shows that for patients aged over 65 there is a large hazard of death at the start of renal replacement therapy, which then falls rapidly. This compares with the risk for those aged less than 65 years, which decreases to day 60 and then rises. By day 90 the 95% confidence intervals for these two groups overlap.

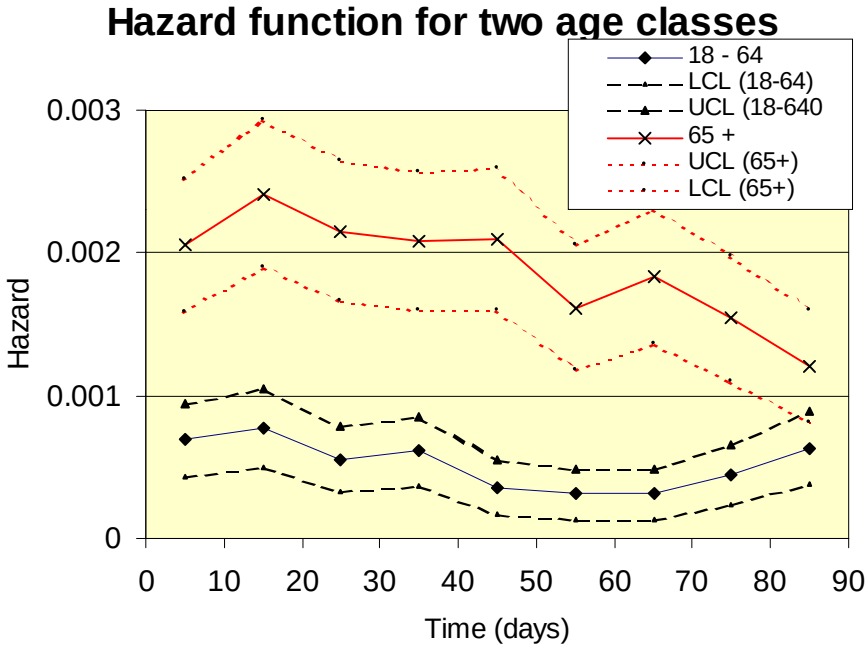


Figure 9.3 The hazard function for incident adults aged above and below 65 years

Calculation of the ratio of the hazard of death for those aged over 65: aged less than 65, confirms that the ratio between these two groups is not constant throughout the first 90 days (figure 9.4).

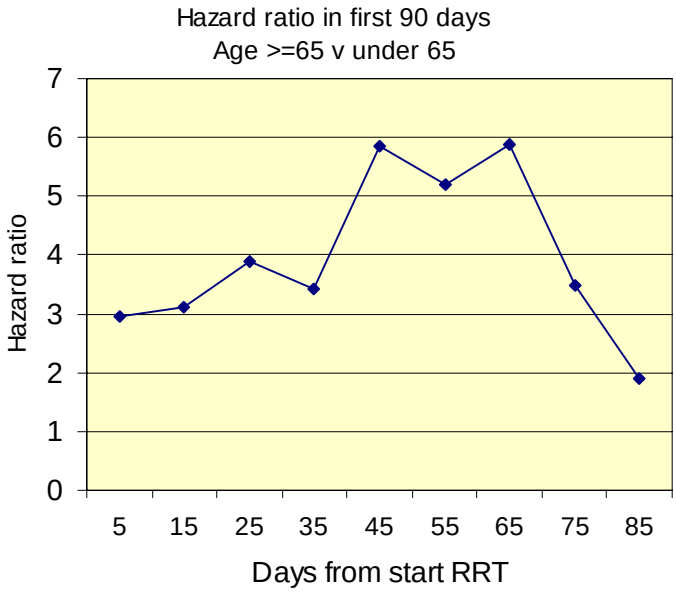


Figure 9.4 The ratio of the hazard of death for aged>65 : aged <65, in the first 90 days.

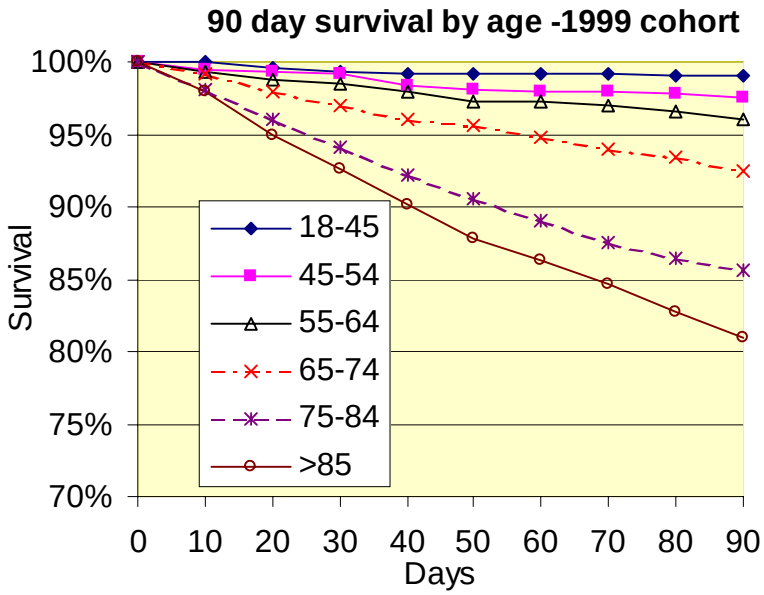


Figure 9.5 Kaplan-Meier survival curves by age band for 90 days

The figure above shows the Kaplan-Meier survival curves and indicates the different mortality rates between the different age bands in the first 90 days for those patients starting Renal Replacement Therapy in 1999.

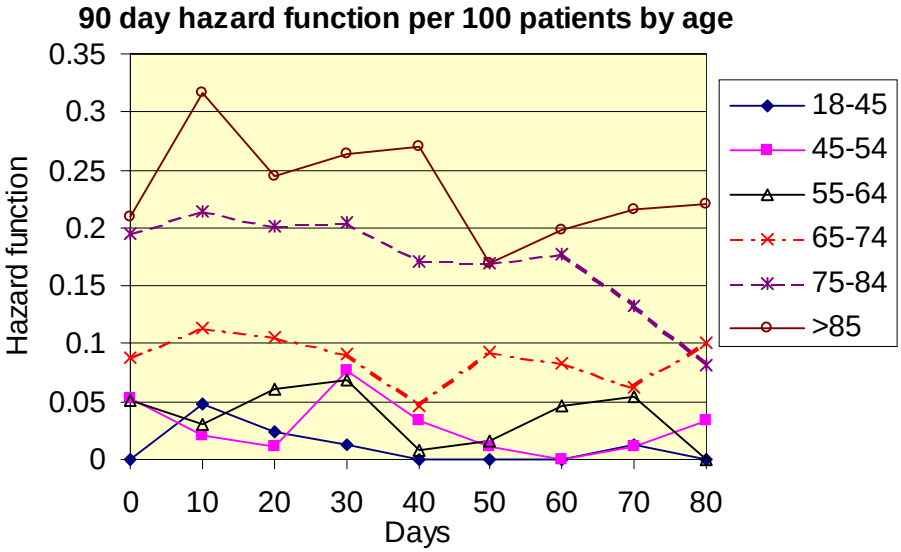


Figure 9.6 Hazard function by age band for the 1st 90 days

The hazard functions shown in figure 9.6 indicate that the hazard of death is not of a constant proportionality between the different age bands during the first 90 days. Thus the Cox proportional hazard model cannot be used on this untransformed data to adjust survival by centre to the same age for all centres. Through the use of a standard statistical method of log, log transformation, it is possible to obtain proportionality between the age bands, for use in

the application of a proportional hazards model (Figure 9.7). These methods were used in making age adjustments in the individual centre data shown later.

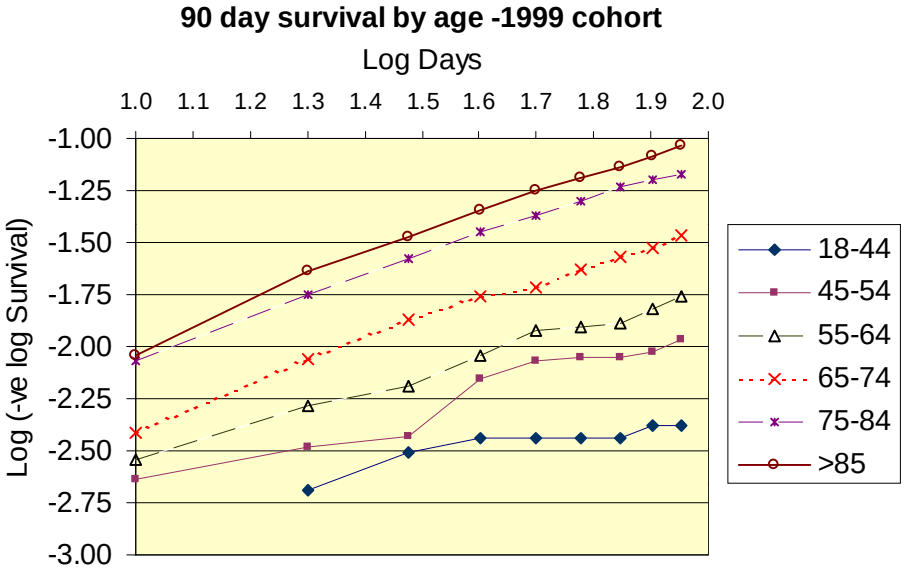


Figure 9.7 Log log transformation of Survival function over 90 days by age

Survival over 360 days from start of Renal Replacement therapy

Kaplan-Meier survival curves over 360 days from the first renal replacement therapy for the same age bands are shown in figure 9.8. There is a marked variation from 96% survival in the 18-44 age group to 65% in those over 85.

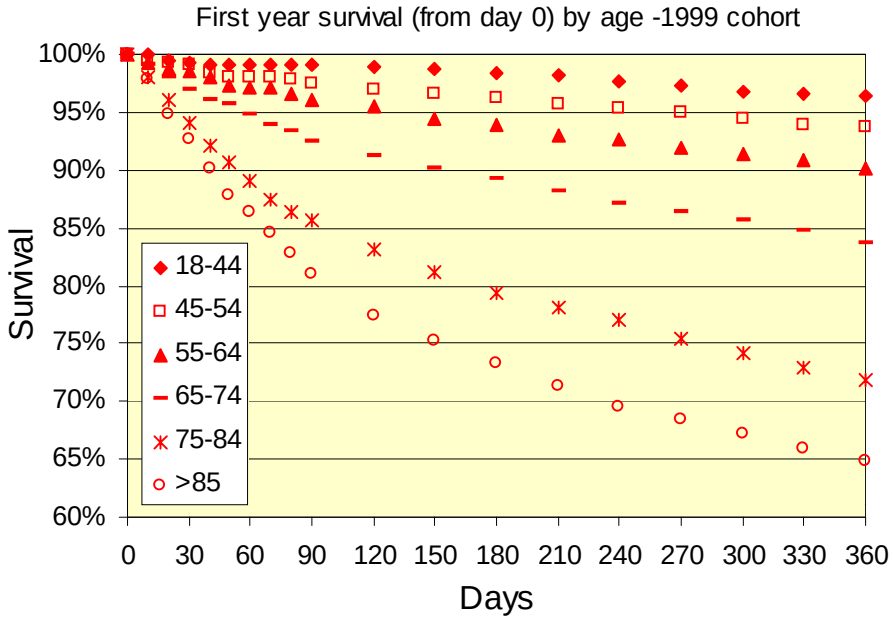


Figure 9.8 Survival in the first year of renal replacement therapy

Death within three years from start of Renal Replacement therapy

Figure 9.9 shows that the hazard of death falls dramatically in the early months, and by 4 months is half that at the start of renal replacement therapy.

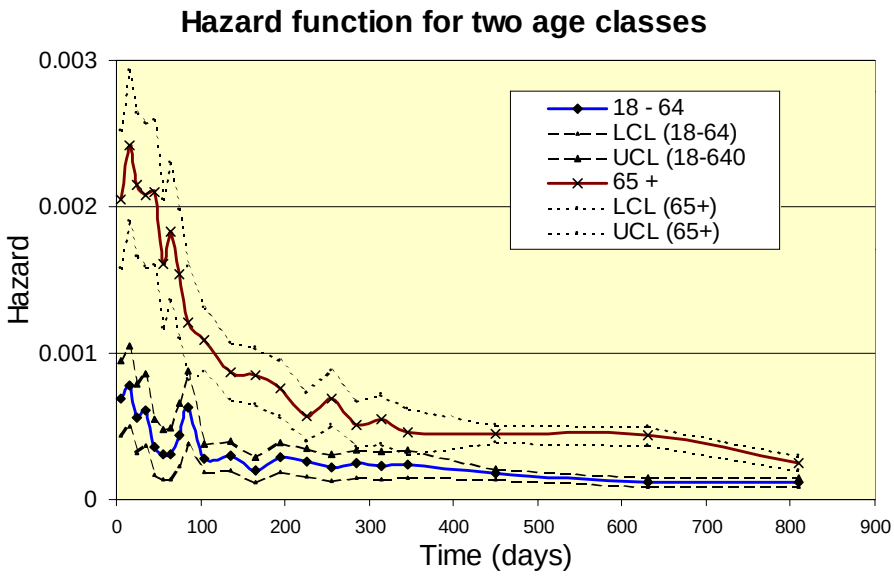


Figure 9.9 Hazard of death over three years from starting renal replacement therapy

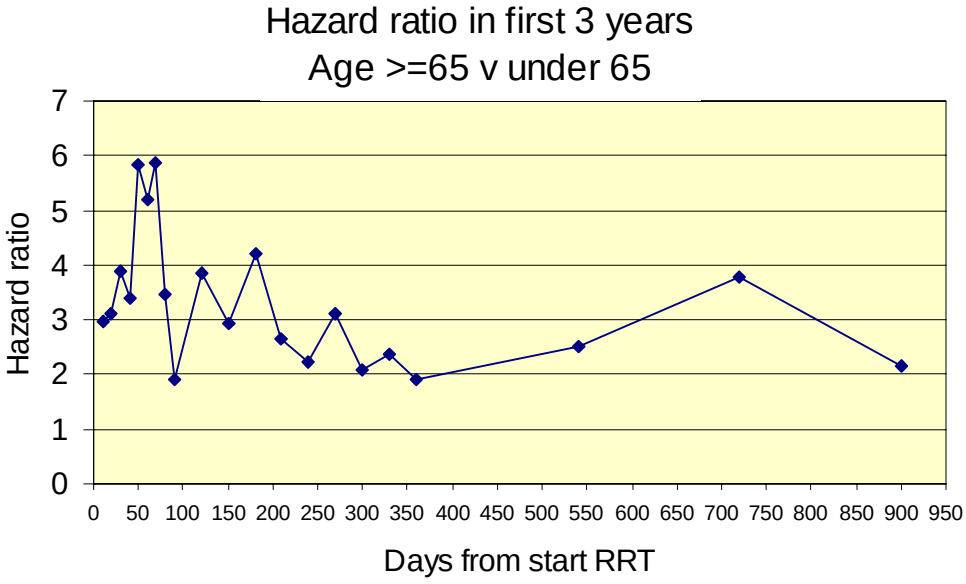


Figure 9.10 Ratio of hazard of death over 3 years, above and below age 65

The ratio of hazard of death shown between those above and below age 65 is shown in figure 9.10. The number of patients in the later periods is small and the confidence intervals wide. Beyond 150 – 200 days the hazard ratio does not change significantly.

Survival in individual centres

The survival of incident patients in individual centres is shown in figures 9.11 and 9.12. The results are age adjusted. As already discussed, the different hazard ratio between different age groups in the first 90 days and subsequent time renders it invalid to use the Cox proportional hazard method to make adjustments throughout the first year. Thus periods of 90 days and one year after 90 days have been used. In the absence of good co-morbidity date no adjustment can be made for co-morbidity. It thus not possible to attach significance to any apparent differences between centres.

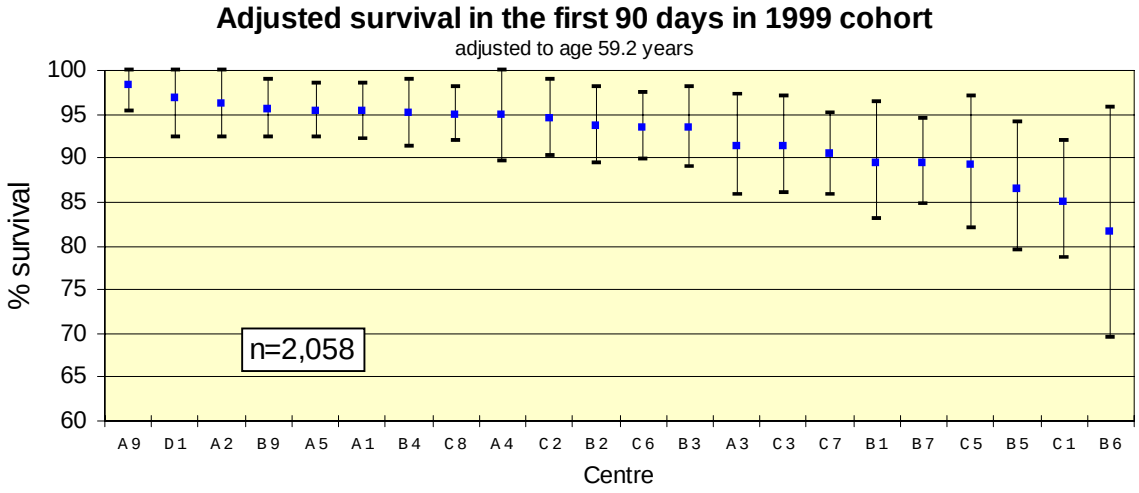


Figure 9.11: Adjusted survival in the first 90 days in 1999 cohort

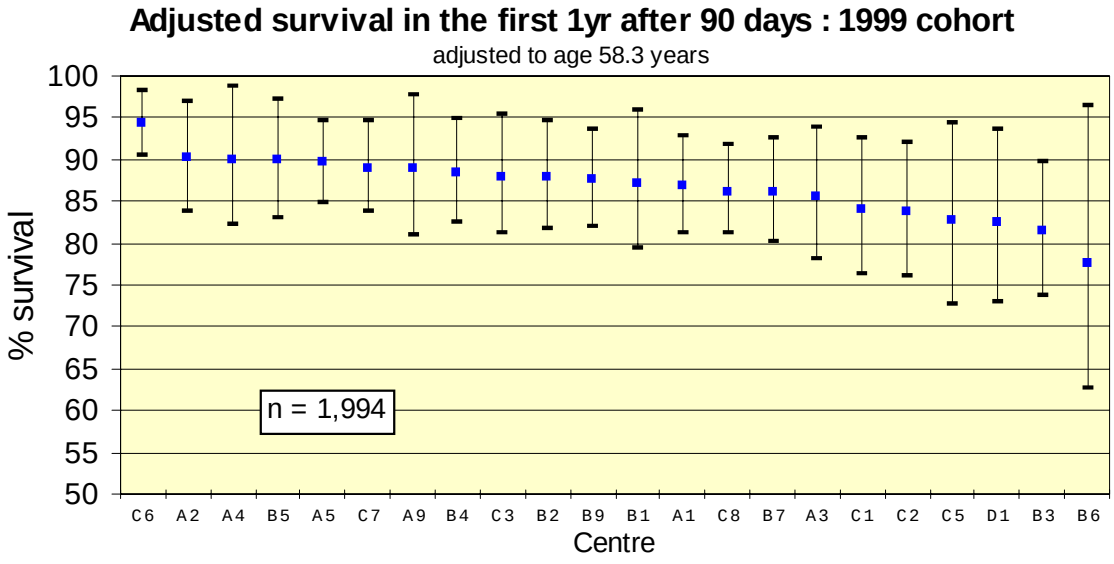


Figure 9.12: Adjusted survival in the first 1yr after 90 days in the 1999 cohort

First year survival by centre aged <65 and >65 years

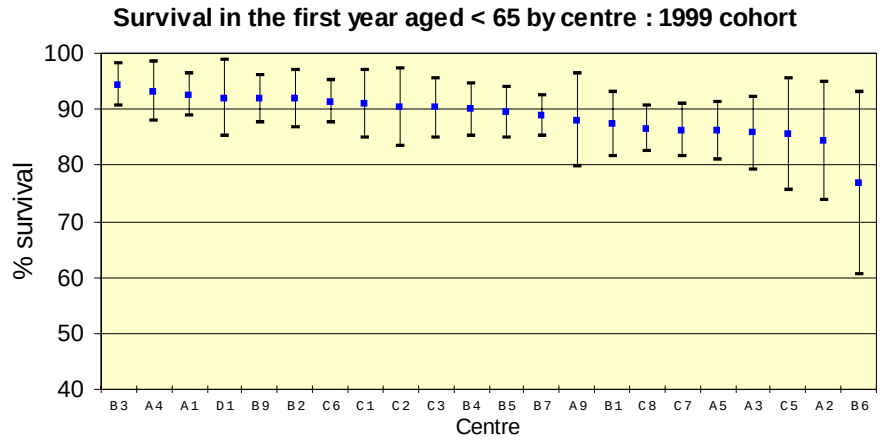


Figure 9.13 First year survival patients aged <65 by centre

The first year survival by centre from day 0 of starting renal replacement therapy is shown below. By showing survival separately for those aged under 65 and over 65 years it has not required an adjustment for age.

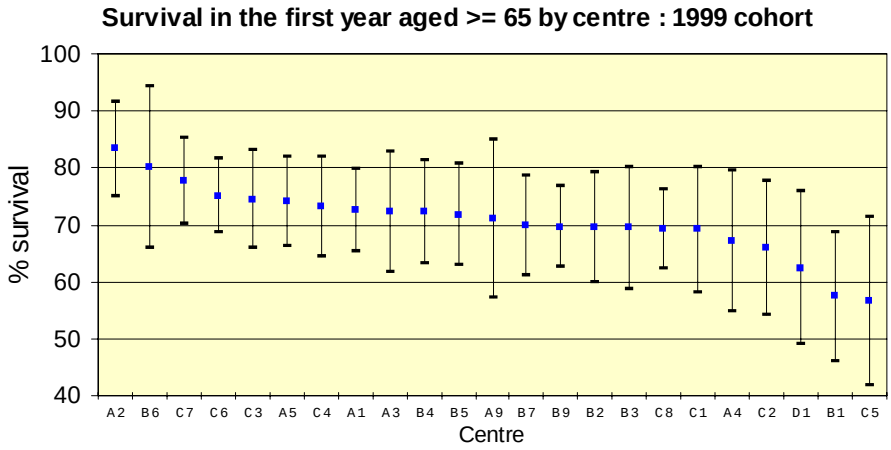


Figure 9.14 First year survival patients aged ≥65 by centre

Changes in survival 1997 – 1999 by centre

The 90-day survival for each individual centre was originally adjusted using the Cox proportional hazards model, to a standard age of 59.2 years. This was chosen as it was the median age of the patients starting RRT in England and Wales during 1997. This median age varies on a year-by-year basis. In addition the median age in 1997 of those surviving 1year after 90 days is slightly younger at 58.3 years, as more of the older patients die within the first 90 days. This produced a separate age to adjust survival to for the 1 year after 90 days. This year in the 1999 data we have kept to this method, although for the serial data we have adjusted both the 90 day and 1 year after 90 days data to the same age of 60 years. The age of 60 has been reached in agreement with several other international registries to standardise survival adjustment for comparative purposes. In future reports all comparative survival will be adjusted to this figure. Direct international comparison is still limited, as countries vary in the percentage of diabetic patients with poorer survival and ethnic minorities with better survival.

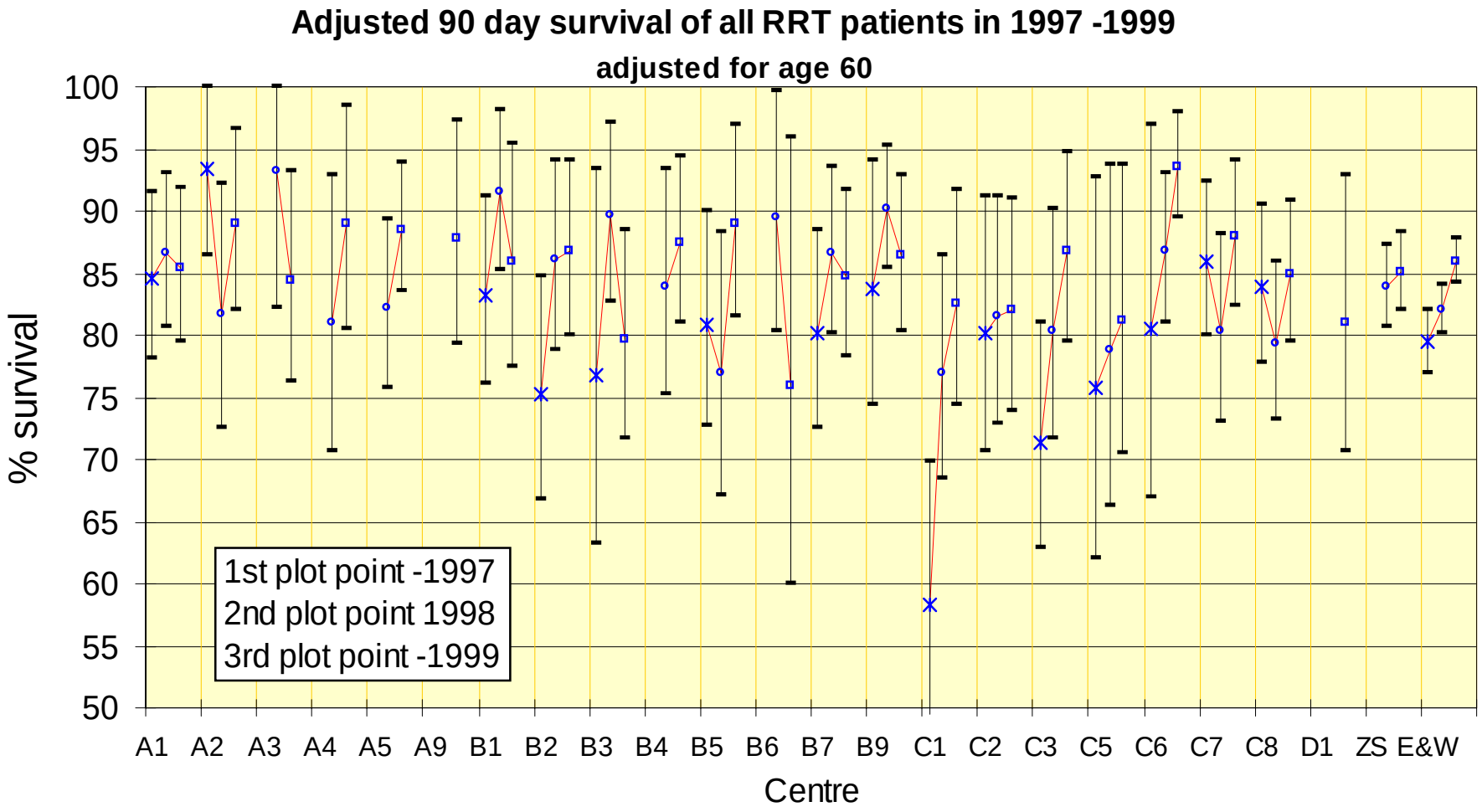


Figure 9.15 Survival 90 day 1997 -1999

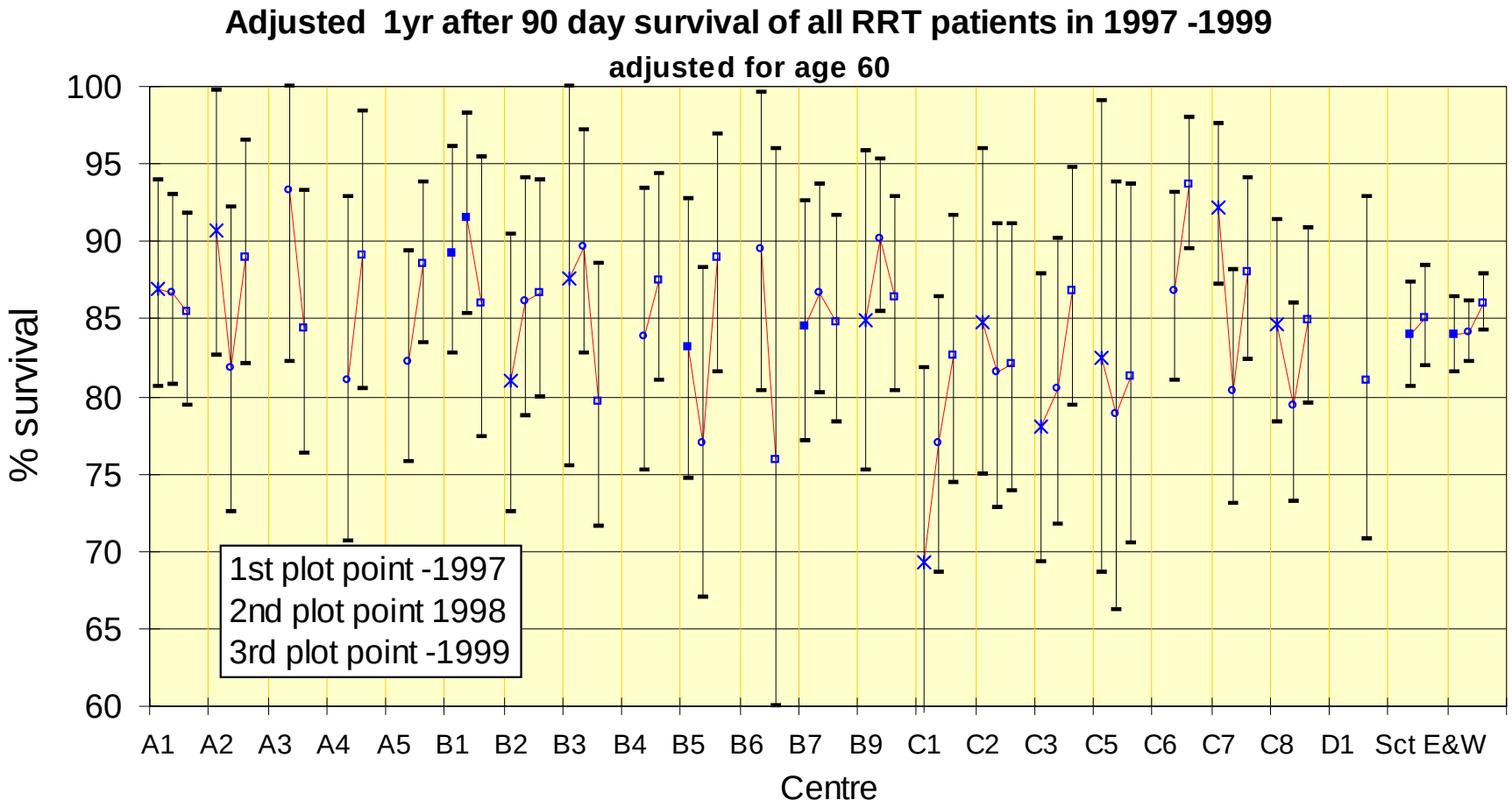


Figure 9.16 Survival 1 year after 90 days 1997-99

Relationship of centre survival to population mortality

To investigate whether the low 90 day survival rate was related to increased 'local' co-morbidity factors, data on 'all cause mortality' was obtained from the Office for National Statistics (ONS). The death rate for the local population by health authority was plotted against the 90-day and one year after 90 days survival of patients starting renal replacement therapy.

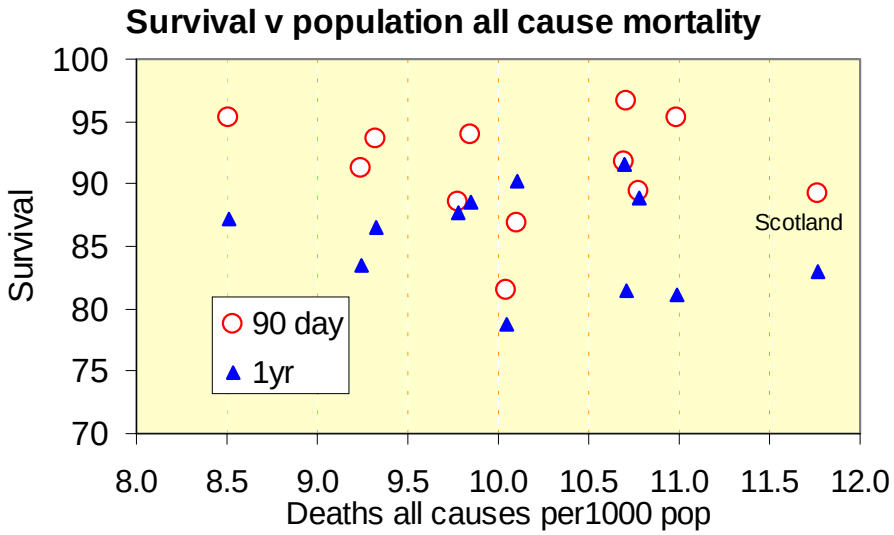


Figure 9.17 All cause population mortality v RRT survival

There appeared to be no correlation between local population mortality rates and mortality rate on renal replacement therapy either at 90 days or 1 year after 90 days (figure 9.17).

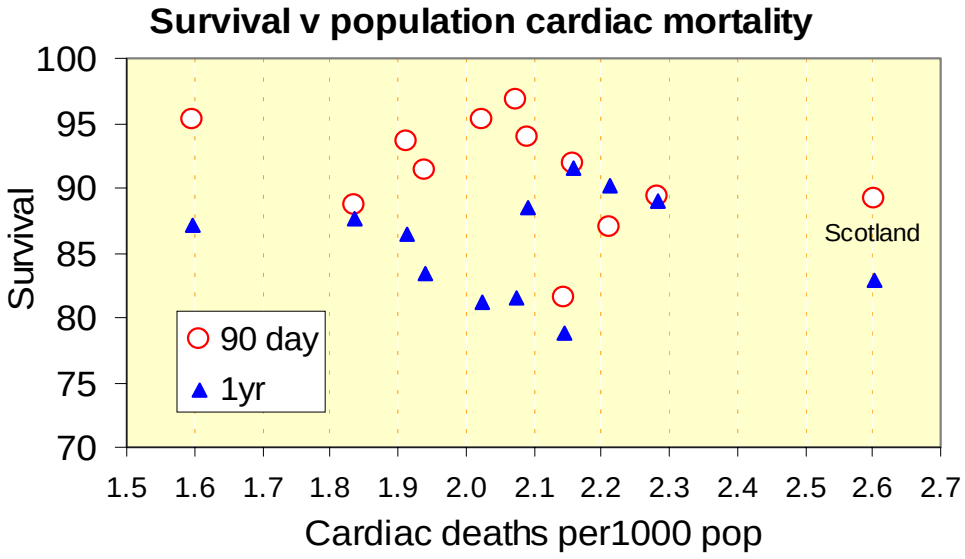


Figure 9.18 Population cardiac mortality v RRT survival

Figure 9.18 demonstrates no relation between the population cardiac mortality and survival at 90 days or 1 year after 90 days.

Chapter 10: Listing for Renal Transplantation

This chapter was written in collaboration with UK Transplant and the British Transplantation Society.

Summary

This is a joint analysis of data held by UK Transplant and the Renal Registry.

The time to listing for transplantation, and factors relating to this, were analysed in 4944 patients (2602 <65 years), from 34 renal units throughout the UK, who started renal replacement therapy during 1998 or 1999.

Factors that significantly affected whether a patient was listed for transplant were: age ($p<0.0001$), primary renal disease ($p<0.0001$), and the size of the renal unit ($p=0.0001$), with large units listing patients more quickly.

Gender and ethnicity of the patient and whether the dialysis hospital also has a transplant unit were not found to have a significant effect.

Of the 2602 patients aged 18-64 years, 1110 (43%) were listed for transplantation within one year, 1347 (52%) within two years and 1406 (54%) by 2½ years. This compares with 3%, 4% and 5%, respectively, of those aged >64 years.

Pre-emptive listing (listing before dialysis) occurred in 21% of adults under 35 years old, only 4% of adults aged 55-64, and vary rarely in those over 65.

The chance of a patient less than 65 years old on dialysis being listed for transplant varied significantly between primary renal disease groups. It was as low for diabetes as renal vascular disease, and best for those with polycystic kidney disease and glomerulonephritis.

Larger renal units were more likely to list patients than smaller ones ($p<0.0001$), and had higher rates of pre-emptive listing for transplantation.

Introduction

This work was carried out as a joint project with UK Transplant. Data have been analysed only for those centres on both the Renal Registry and the UK Transplant databases. UK Transplant holds the waiting list, recipient tissue typing data and donor information for patients waiting for, or having received, a renal transplant in the UK. Linking this data with the pre-transplant history, post-transplant failure data, and quarterly biochemistry and blood pressure data, collected by the Renal Registry provides a unique database.

It is possible to analyse the whole Renal Replacement Therapy history of patients from participating centres in a longitudinal manner, and relate this to the events around renal transplantation. The first such analyses were presented in the 2000 report. With more centres joining the Registry it is anticipated that it will shortly be possible to develop substantially more detailed and comprehensive analyses for joint publication.

This chapter examines factors related to access to the national waiting list for renal transplantation.

Listing for transplantation

Figure 10.1, originally produced in the 2000 Registry Report, indicates that at any one time the majority of dialysis patients are not on the national transplant waiting list. Even in the 18-24 age group, 35% of dialysis patients are not registered on the national transplant waiting list. The time taken for new patients to be registered on the waiting list from first starting dialysis may significantly influence these data.

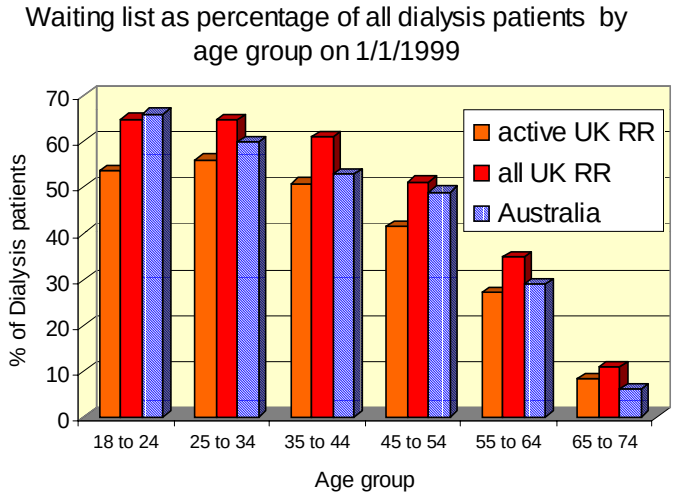


Figure 10.1: Waiting lists as a percentage of all dialysis patients

Figure 10.1 only includes data from centres on the UK Renal Registry and is therefore an approximation for the UK. Patients listed for transplantation before needing dialysis but not yet dialysing were not included. The "all UK RR" numbers include those patients temporarily suspended from the waiting list. The Australian data, taken from the ANZDATA report, excludes suspended patients (personal communication).

Patients studied and statistical methods

The Renal Registry, covering approximately 50% of the UK, reported 4944 patients (2602 <65 years) starting their first renal replacement therapy during 1998 or 1999. The databases of UK Transplant and the UK Renal Registry have been linked to obtain a unique dataset comprising data for 4944 adult renal dialysis patients and their associated listing dates where applicable. Using these data, the aim of this study was to investigate factors that influence whether a patient is listed for renal transplant on the national waiting list.

Patients were from 34 dialysis units throughout the UK, 17 of which were also transplant centres. Factors included in the analysis were age at start of renal replacement therapy, primary disease, gender, ethnicity, and for the renal units renal replacement therapy

prevalence rate and whether the renal unit has its own attached transplant service. Separate multifactorial logistic models were developed for patients aged less than 65 years and patients aged 65 years or older for the binary outcome listed/not listed. Cox's proportional hazards regression models were fitted to analyse the combined effect of these factors.

Factors influencing listing for transplantation

Factors that significantly affected whether a patient was listed for transplant were: age ($p<0.0001$), primary renal disease ($p<0.0001$), and the size of the renal unit ($p=0.0001$). Gender and ethnicity of the patient and whether the dialysis hospital also has a transplant unit were not found to have a significant effect.

Age

To analyse the effect of age on the time from starting renal replacement therapy to listing on the active transplant waiting list, Kaplan-Meier survival curves were constructed for patients grouped by age (see figure 10.2). Patients who died were censored at time of death. Those who were listed before starting dialysis were included with a time to listing of 0 days.

Age was a major factor in determining the speed of listing for transplantation (figure 10.2). As expected, the percentage of patients listed decreased with increasing age over 34 years ($p<0.0001$), and listing took longer. Of the 2602 patients aged 18-64 years, 1110 (43%) were listed for transplantation within one year, 1347 (52%) within two years and 1406 (54%) by 2½ years. This compares with 3%, 4% and 5%, respectively, of those aged >64 years. Multifactorial analysis of the 2342 patients aged 65 or older showed primary disease and age to be significant.

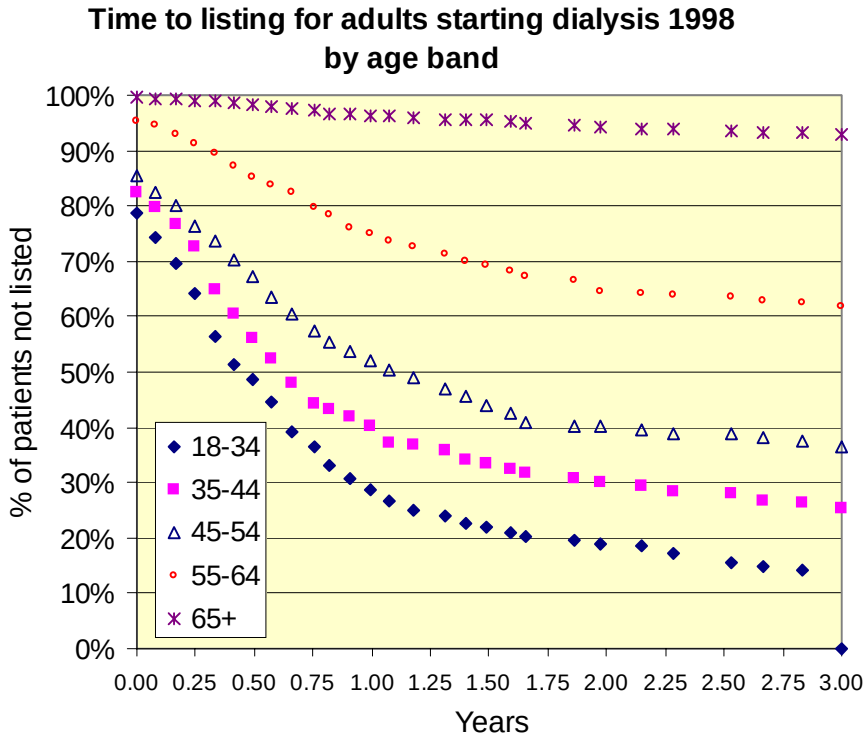


Figure 10.2: Time to listing for adult patients.

Of patients aged 18-34, 21% were pre-emptively listed for transplantation, by age 55-64 this had fallen to 4%, and was very rare in those over 65.

There appeared to be long delays in listing patients. The proportions in each age group finally listed by the time of this analysis were (in ascending age order) 86%, 75%, 77%, 42%, and 9%. In the 55-64 year old age group delays in listing for transplantation may be due to the need to investigate co-morbidity, particularly cardio-vascular disease and fitness for operation. This is unlikely to explain the delays in listing the younger patients.

Primary renal disease

Age-adjusted results for the primary disease groups are shown in table 10.1:

Primary disease	No. of patients starting dialysis	Relative chance of listing	95% confidence interval	P value
Aetiology uncertain/GN not proven (baseline)	470	1.0		
Glomerulonephritis (GN)	349	1.7	1.2 – 2.3	0.002
Pyelonephritis	242	1.3	0.9 – 1.9	0.1
Diabetes	540	0.3	0.2 - 0.4	<0.0001
Renal Vascular Disease	78	0.3	0.2 – 0.6	0.0001
Hypertension	122	1.4	0.9 – 2.1	0.2
Polycystic kidneys	237	3.0	2.0 – 4.3	<0.0001
Other	360	0.3	0.2 - 0.4	<0.0001
Not reported	204	0.4	0.2 - 0.6	0.0001

Table 10.1: Primary renal disease and listing for transplantation – age adjusted.

The chance of a patient less than 65 years old on dialysis being listed for transplant varied significantly between primary renal disease groups. It was low for diabetes and renal vascular disease, and highest for those with polycystic kidney disease and glomerulonephritis.

Characteristics of the renal unit

It initially appeared that patients were more likely to be listed pre-emptively, and more quickly in renal units which were also transplant units. However, further analysis showed this to be related to the size of the renal unit, especially with regard to the number of patients under 65, and not to the presence of a transplant centre. Larger renal units were more likely to list patients than smaller ones ($p<0.0001$), and had higher rates of pre-emptive listing for transplantation (without preceding dialysis). The reason why larger renal units list more patients and list them more quickly are unclear. Whether this is due to pressure on dialysis facilities, more active clinical management, or other factors requires investigation.

Future audit

The reasons for the variations in time to listing need further understanding. Centre by centre analysis of the pre-dialysis work up for transplantation, and time to listing, show wide variation between centres and could form the basis of useful comparative audit of the performance and effectiveness of different renal units.

Chapter 11: Quality Assurance, Improvement and the NSF

This year the national coverage is again increased. With recent developments there is the real prospect of complete national enrolment. The UK Renal Registry is now on a sound financial and organisational footing, and leads nationally in the area of audit and speciality-based data collection. The Registry has started the process of removing anonymity where the data are reliable.

Each Annual Report has shown a different emphasis, while maintaining the core demographic and quality assurance data necessary for planning and comparative audit. The UKRR Reports have been a vehicle for the early publication of several pieces of work, on Renal Manpower, the Renal Review and now the HTA Satellite Dialysis Survey. These are important to prevent misconceptions both at individual units and the Department of Health, and is especially relevant in this first National Service Framework year.

There is evidence about the validity of the Registry data. Comparison with the Renal Review data in the 2000 Report showed the demographic and clinical outcome data from the Registry to be representative of the UK as a whole. Successive Reports show consistent findings in the clinical variable distributions. Further progress at renal unit level has been made in recording patient ethnicity and co-morbidity, as demonstrated in this year's document. A yet greater improvement is required, particularly if reliable comparative mortality data are to be presented in future. The agreement to progressively release the anonymity restrictions at renal unit level should act as a spur in this effort, since under-reporting of co-morbidity will always tend to portray unit outcomes in a worse light than necessary.

Experience from undertaking Registry activities suggests that a more explicit and structured approach to quality assurance and improvement is required, in order to support the development of the Speciality in the light of audit data and the Standards Document. The Registry itself is not mandated or resourced to translate its findings into action at Unit clinical level. This problem is clearly illustrated by the persisting weakness of the data on dialysis dose (URR), because of indeterminate post-dialysis sampling methods. It is not currently the task of any particular renal group to consider Registry findings and then influence the clinical community to improve methodology and outcomes. While it may be more comfortable to leave such a default, given the many day to day pressures with which clinicians grapple, it will be hard to maintain the initial impetus of the Registry, and its support, if the findings are not fully employed to improve and develop management of renal patients. The UK, through the Registry, has a unique potential in Europe to translate this national effort into continuing quality improvement at the level of patient outcomes. Further consideration of the structures of the audit cycle will be required to capitalise on this lead position.

A National Service Framework for renal services is in process of production. This is therefore a very important year for the UK renal community. This report, should contribute significantly to the NSF and the further development of the Speciality. If appropriately resourced, the database should in future be pivotal in the monitoring and development of the NSF.

Appendix A: The Renal Registry Rationale

1. Executive summary
2. Introduction
3. Statement of intent
4. Relationships of the renal registry
5. The role of the Renal Registry for nephrologists
6. The role of the Renal Registry for trust managers
7. The role of the Renal Registry for commissioning agencies
8. The role of the Renal Registry National Quality Assurance schemes
9. The role of the Renal Registry for patients.
10. Abbreviations
11. References

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 three ad hoc national data collections from England and Wales were solicited from renal centres in 1992, 1996 and 1999. 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 ED

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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 RRT 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 RRT 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

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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 renal satellite unit is defined as a haemodialysis facility which is linked to a main renal unit and not autonomous for medical decisions, and which provides chronic out patient maintenance haemodialysis, but with no acute or in-patient nephrology beds on-site

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.

Start of end stage renal failure

This is defined as the date of the first dialysis (or of pre-emptive transplant).

If a patient is started as ‘Acute’ renal failure and does not recover the date of start of renal replacement should be backdated to the start of acute dialysis.

If a patient is started on dialysis and dialysis is temporarily stopped for under 90 days for any reason (including access failure and awaiting formation of further access) except recovery of

renal function the date of start of RRT remains the date of first dialysis. If they stopped for longer than 90 days they are classed as recovered.

Analysis criteria

Definition of the Take-On population (Incidence)

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 on renal replacement therapy (RRT) are **excluded** in the take on population for that centre. Patients restarting dialysis after a failed transplant are also excluded (unless they started RRT in that current year).

Since patients who restarted RRT after recovering from ESRF, are included in the take-on population the following scenarios can occur:- A patient may start RRT in 1999, recover and then restart RRT in 1999. These patients are counted twice in the analysis providing they have been receiving RRT 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.

Definition of the Prevalent population

This is calculated as all patients that are alive on 31st December and includes the incident cohort for that year alive on that date.

Death rate calculation

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.

Odd Ratio

Odds of dying :-

$$\frac{\text{Probability of dying for someone with a phosphate of 1.71-2.10 mmol/L}}{\text{probability of surviving for someone with a phosphate of 1.71 –2.10 mmol/L}}$$

Odds ratio is the $\frac{\text{odds of dying with a phosphate of 1.71-2.10}}{\text{odds of dying in the reference group}}$

Hazard Function

The hazard function is the probability of dying in a short time interval considering survival to that interval.

Hazard ratio

$$\frac{\text{Probability of dying in the next interval for a phosphate of 1.71-2.10 mmol/L}}{\text{probability of dying in the next interval for a phosphate in the ref range}}$$

Survival analyses of prevalent cohort

These analyses exclude the current years incident cohort

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 RRT 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 RRT for longer than 90 days, since the patient must have started RRT 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 1999, would be included for quarter 1/99, even though the number of days on RRT 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 RRT was calculated from the day the patient restarted RRT. For example, for a patient with an initial treatment start date of the 1st March 1999, who recovered on the 1st June 1999 and then resumed RRT again on the 1st November 1999, the number of days on RRT would be calculated from the 1st November 1999. The patient would be excluded from the analysis for quarter 4/99, since on the 31st December 1999, they only would have been on RRT for 60 days. The patient would be included in the analysis from quarter 1/2000 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 99, 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 RRT

This is obtained from the treatment modality of the take-on population after 90 days of being on RRT. For this reason patients who started treatment between 1/10/98 and 31/9/99 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.

Patient's 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 prevalent patients

The death rate within year was calculated separately for the patients established on dialysis and with a functioning transplant on 1st January 1999. 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 1999 and 31st December 1999. 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 1/1/99.
2. Patients who had a transplant between 1/7/98 and 31/12/98 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 1/7/98 and 31/12/98.
4. The few patients who recovered renal function in 1999 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 1/1/99 were included and were counted as being at risk for one day.
8. Patients who died on the day of the transplant were censored on this day, rather than counted as a dialysis death.

Appendix C: Data Protection and the UK Renal Registry in 2002

Introduction

The political and social context of data management has changed since the UK Renal Registry was established. In particular, there has been growing concern that the NHS should become more 'patient-centred'. In addition, the benefits of data collection for science and research are no longer assumed to be self-evident and need to be demonstrated outside the medical arena. Whenever patient identification is a necessary component of the research or data collection it has become important to obtain informed consent.

This has ethical and legal considerations. Although the formal position has evolved with the Data Protection and Human Rights Acts of 1998 certain circumstances have suggested the need for further legislation. For example, very large research exercises make consent impractical to obtain, the condition of some patients makes consent impossible, and the bias introduced by selective refusal/omissions might make data un-interpretable.

European Law -Directive 95/46/EC

This law relates to the protection of individuals with regard to the processing of personal data and on the free movement of such data.

1) Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.

Paragraph 1 shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

The EU law therefore excludes collection of medical information from the data protection laws.

The Health and Social Care Act 2001 (England & Wales)

In England & Wales, Section 60 of the Health and Social Care Act 2001 provides discretionary powers to the secretary of state ensuring that the patient identifiable information needed to support essential NHS activity can be used without the individual consent of patients. The powers can only be used to support medical purposes that are in the interests of patients or the wider public, where consent is not a practicable alternative and where anonymised information will not suffice. The decisions are to be reviewed annually. An effort towards obtaining consent or the development of patient anonymity is expected of any group seeking to use Section 60.

The Patient Information Advisory Group (PIAG). has been established as the advisory mechanism to the secretary of state. Because of the numerous activities that might require consideration, it has been anticipated that broad classes of exceptions will be formulated, with only a limited number of applications requiring detailed PIAG consultation. The Registry hopes that one such class might encompass generic, registry-type, data collection. The UK Renal Registry has submitted its application to PIAG for consideration of exemption from the need to seek individual patient consent.

The Registry Case

The Registry is the cornerstone of monitoring renal replacement therapy in Britain. Involvement of all UK renal units is confidently expected within the next few years. This has been mandated by advice from the Department of Health to Health Authorities. The Registry is funded by a capitation fee from health authorities, endorsed by the Department. The annual Reports are the basis of assessment for health provision, management and outcomes in renal disease nationally. The accurate demographic and quality performance data will be one foundation of the renal National Service Framework which is currently under development. The evidence of treatment distribution is critical to ensure the developing NHS agenda on equity of patient access. These clinical data are the basis of national comparative audit and quality improvement initiatives that are equal to, or in advance of, any developments in other medical specialities. It is hoped that these benefits of the Registry will be recognised as being sufficiently important to invoke the term 'essential NHS activity' thus enabling the secretary of state to use his discretionary powers (Section 60, Health & Social Care Act).

There are over 37,000 patients on the Registry database. Some will have been identified retrospectively after an acute presentation, others may have been unable to give consent through incapacity of one kind or another. The need for patient identification hinges on the need to track the course of treatment between renal dialysis and transplant units. If any compelling example of this need were required, the demise of the previous European Renal Registry was in part because of the intractable difficulties of following patients during transitions of treatment, with a huge 'lost to follow up' cohort.

The Renal Registry will be at the heart of the Renal NSF and supplies crucial information to government about an expanding and resource-intensive service. Patient identification is required for data validation.

The way forward

The principles of data protection are scrupulously observed at the Registry and only those directly involved in data validation and analysis have access to patent-identifiable material.

Nevertheless, it is necessary to explore how individual patient consent can best be obtained. This might involve a single Registry-solicited enrolment at the start of renal treatment. It is also important to establish, perhaps from data already available, what bias would be introduced were selective refusal to consent a factor. The suggestion that receiving NHS treatment for renal disease should carry an obligation to individuals to provide consent is not widely supported. A formula for satisfying all the ethical and legal issues may yet develop

from other experience of the practicalities of NHS data collection. It should be noted that other applications of the Registry database would have to be examined on their merits and the availability of the data for all purposes, such as identification of patients for research, cannot be assumed.

The current Renal Registry data collection has continued in the confidence that existing data protection procedures, apart from consent, are well established and that the case for exception under the Clause 60 provisions will have a prima facie validity. The Registry anticipates detailed examination of its submission to PIAG, while the possibility of obtaining consent is examined further within the discipline.

Appendix D: 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 response to rejection of the foreign graft, which

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.

Appendix E: Measurement of dialysis adequacy

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).

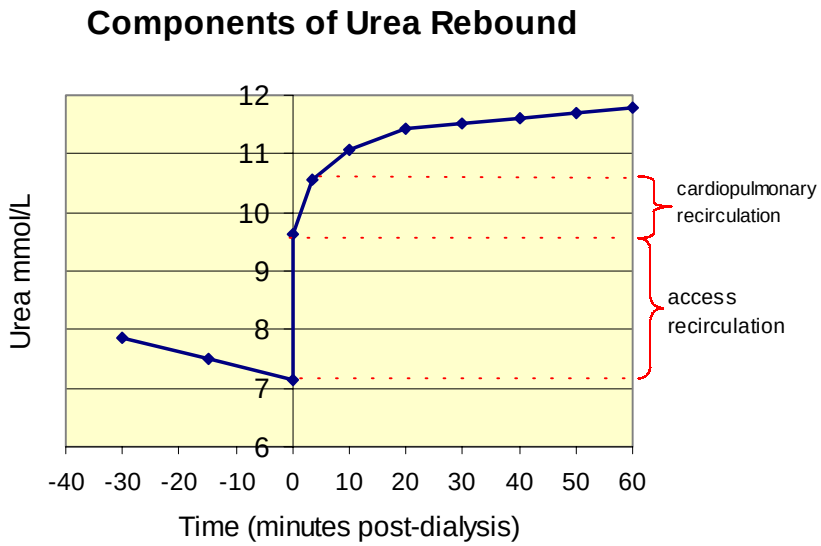

Figure D.1 Components of urea rebound (from the DOQI report)

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 1999 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 Figures 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.

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Appendix F: Laboratory conversion factors & Centre Names

	Conversion factors from SI units
Albumin	g/dl = g/L x 0.1
Calcium	mg/dl = mmol/L x 4
Phosphate	mg/dl = mmol/L x 3.1
Cholesterol	Mg/dl = mmol/L x 38.5
PTH	ng/L = pmol/L x 9.5
Urea	

Centre abbreviations used in chapter 4 & 5

City	**Abbrev**	**Renal Unit**
Birmingham Heartlands	Heart	Heartlands Hospital
Bristol	Bristl	Southmead Hospital
Cardiff	Crdff	University of Wales Hospital
Carlisle	Carls	Cumberland Infirmary
Carshalton	Carsh	St Helier Hospital
Coventry	Covnt	Walsgrave Hospital
Derby	Derby	Derby City Hospital
Exeter	Extr	Royal Devon and Exeter Hospital
Gloucester	Glouc	Gloucester Royal Hospital
Hull	Hull	Hull Royal Infirmary
Leeds LGI	LGI	Leeds General Infirmary
Leeds, St James'	StJms	St James's Hospital
Leicester	Leic	Leicester General Hospital
London - Guys	Guys	Guys and St Thomas Hospital
Middlesbrough	SCleve	South Cleveland Hospital
Nottingham	Notts	Nottingham City Hospital
Oxford	Oxfrd	Churchill Hospital
Plymouth	Plym	Derriford Hospital
Preston	Prstn	Royal Preston Hospital
Reading	Redng	Royal Berkshire Hospital
Sheffield	Sheff	Northern General Hospital
Southend	Sthend	Southend Hospital
Stourbridge	Words	Sunderland Royal Hospital
Sunderland	Sund	Morriston hospital
Swansea	Swnse	Newcross Hospital
Wolverhampton	Wolve	Stourbridge Hospital
Wrexham	Wrex	Maelor General Hospital
York	York	York District Hospital