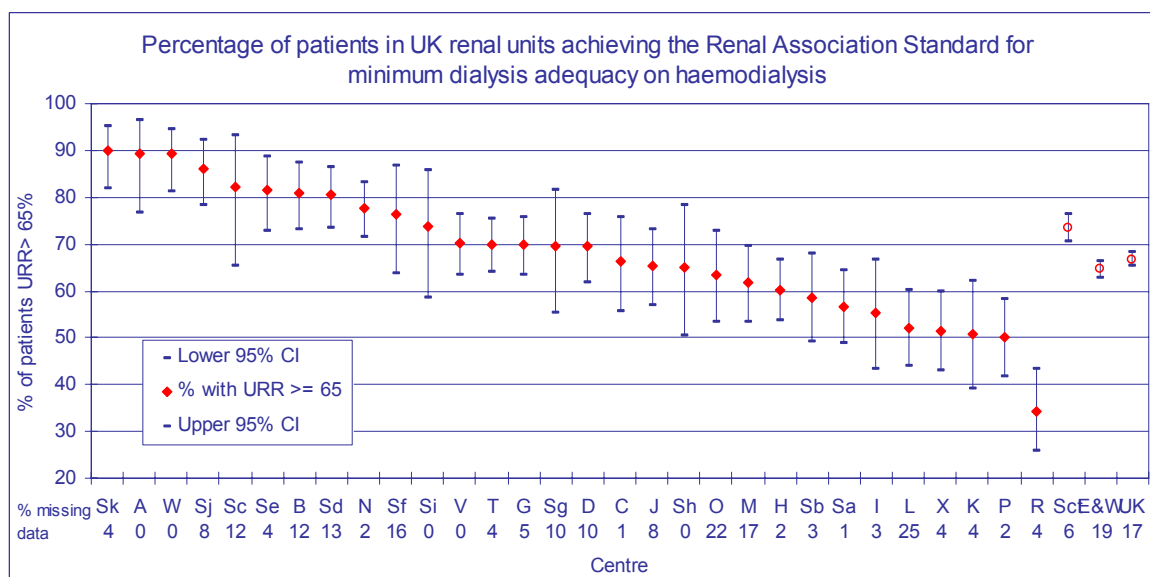


## The Third Annual Report

# The UK Renal Registry

December 2000



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in association with

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# Contents

EDITORS .....	II
EDITORIAL CONSULTATION .....	II
CONTRIBUTORS .....	II
UK RENAL REGISTRY .....	III
THE UK RENAL REGISTRY SUBCOMMITTEE .....	III
<b>CHAPTER 1: SUMMARY OF THE YEAR 2000 REPORT ON DATA FROM 1999.....</b>	<b>1</b>
<b>CHAPTER 2: INTRODUCTION TO THE 2000 REPORT .....</b>	<b>3</b>
INTRODUCTION .....	3
Difficulties.....	4
Integration with the audit cycle .....	4
AREA COVERED BY THE RENAL REGISTRY.....	5
THE INDEPENDENCE OF THE UK RENAL REGISTRY .....	8
ANONYMITY AND CONFIDENTIALITY .....	8
STATISTICAL INTERPRETATION OF THE REPORT .....	8
DISTRIBUTION OF REPORT .....	9
<b>CHAPTER 3: THE 1999 UK RENAL SURVEY - ADULT PATIENT NUMBERS, RENAL UNIT FACILITIES AND PROCESSES OF CARE.....</b>	<b>11</b>
METHODS.....	11
NEW PATIENTS STARTING RENAL REPLACEMENT THERAPY .....	12
Changes in acceptance rates in England and Wales 1993-1998 .....	13
PREVALENT PATIENTS RECEIVING RENAL REPLACEMENT THERAPY 31/12/98 .....	14
Changes in prevalence 1993-1998 .....	14
RENAL UNIT FACILITIES .....	15
Changes in renal facilities in England and Wales 1993-1998 .....	16
STAFFING IN RENAL UNITS .....	17
Changes in staffing in England and Wales 1993-1998 .....	19
PROCESSES OF CARE.....	20
Changes in processes of care in England and Wales 1993-1998 .....	20
FACTORS RESTRICTING DEVELOPMENT OF RENAL SERVICES .....	22
REGIONAL COMPARISONS .....	22
PREVALENCE OF HEPATITIS IN PATIENTS ON RENAL REPLACEMENT THERAPY .....	24
Hepatitis C.....	24
Hepatitis B.....	24
DISCUSSION .....	25
REFERENCES .....	26
<b>CHAPTER 4: NEW ADULT PATIENTS STARTING RENAL REPLACEMENT THERAPY IN 1999 .....</b>	<b>27</b>
SUMMARY .....	27
INTRODUCTION .....	27
ACCEPTANCE RATES .....	28
INCIDENCE RATE OF RRT PER MILLION POPULATION BY AGE.....	29
GENDER .....	32
ETHNICITY .....	33
PRIMARY RENAL DIAGNOSIS .....	34
TREATMENT MODALITY .....	35
THE FIRST CHANGE OF TREATMENT MODALITY .....	38
Change of treatment modality within the first year .....	38
FIRST MODALITY CHANGE OVER 2 YEARS .....	38
Patients who were on haemodialysis after the first 90 days .....	38
Patients who were on peritoneal dialysis after the first 90 days .....	39
NEW PATIENT SURVIVAL .....	39
Analysis criteria.....	40
Comparison with the Standard recommendation .....	40
Survival of all new patients – further analysis.....	41
One year survival.....	41

Two year survival .....	42
COMMENT .....	42
<b>CHAPTER 5: ALL PATIENTS RECEIVING RENAL REPLACEMENT THERAPY IN 1999 ....</b>	<b>43</b>
SUMMARY .....	43
INTRODUCTION .....	44
PREVALENCE RATES .....	44
AGE .....	46
GENDER .....	48
ETHNICITY .....	49
PRIMARY RENAL DISEASE .....	50
DIABETES .....	50
MODALITIES OF TREATMENT .....	51
Haemodialysis .....	52
Peritoneal Dialysis .....	54
Modality and gender .....	55
CHANGE IN TREATMENT MODALITIES 1998 –1999 .....	55
LONG TERM TRENDS .....	56
SURVIVAL ON RENAL REPLACEMENT THERAPY .....	56
REFERENCES .....	59
<b>CHAPTER 6: ADEQUACY OF HAEMODIALYSIS (UREA REDUCTION RATIO) .....</b>	<b>61</b>
SUMMARY .....	61
HAEMODIALYSIS FREQUENCY .....	61
SOLUTE CLEARANCE STANDARDS .....	61
INTERPRETATION OF RESULTS .....	62
CENTRE ACHIEVEMENT OF THE STANDARD .....	62
CHANGE IN URR DURING 1998-99 .....	64
ACHIEVEMENT OF STANDARDS IN PATIENTS STARTING HAEMODIALYSIS IN1999 .....	67
INTERNATIONAL COMPARISON .....	68
INTERPRETATION OF RESULTS (REPRODUCED FROM 1999 REPORT) .....	68
Urea rebound and timing of blood samples .....	68
Practical problems of timing of blood samples .....	69
Current UK practice in blood sampling .....	69
Implications for URR results calculated by the Renal Registry .....	70
REFERENCES .....	70
<b>CHAPTER 7: HAEMOGLOBIN AND RELATED VARIABLES .....</b>	<b>73</b>
SUMMARY .....	73
INCLUSION CRITERIA .....	74
HAEMOGLOBIN ACHIEVEMENT BY DIALYSIS UNITS .....	74
FACTORS INFLUENCING HAEMOGLOBIN .....	78
Haemoglobin and serum ferritin .....	78
Haemoglobin and erythropoietin .....	82
ERYTHROPOIETIN AND TIME ON RENAL REPLACEMENT THERAPY .....	83
AGE AND ANAEMIA MANAGEMENT .....	84
Haemodialysis .....	84
Peritoneal dialysis .....	84
ERYTHROPOIETIN PRESCRIPTION AND GENDER .....	84
Haemodialysis .....	84
Peritoneal dialysis .....	85
COMPLIANCE WITH RENAL ASSOCIATION STANDARDS AND MEDIAN HAEMOGLOBIN .....	86
CHANGES IN HAEMOGLOBIN OVER TIME .....	87
Data selection .....	87
HAEMOGLOBIN AT START OF DIALYSIS .....	87
CHANGES IN HAEMOGLOBIN OF PREVALENT PATIENTS 1998-1999 .....	89
Haemodialysis .....	90
Peritoneal dialysis .....	91
CHANGE IN HAEMOGLOBIN ACHIEVED THROUGH 1999 .....	93
Haemodialysis .....	93



Peritoneal dialysis.....	95
ANALYSIS OF CHANGES IN HAEMOGLOBIN OF INDIVIDUALS DURING 1999 .....	96
CONCLUSION.....	96
<b>CHAPTER 8: SERUM CALCIUM, PHOSPHATE AND PARATHYROID HORMONE.....</b>	<b>99</b>
SUMMARY.....	99
INTRODUCTION .....	99
HARMONISATION OF LABORATORY DATA BETWEEN HOSPITALS .....	99
SERUM CALCIUM.....	100
Measurement of serum calcium.....	100
Corrected serum calcium.....	100
Uncorrected serum calcium.....	102
SERUM PHOSPHATE.....	103
Measurement of phosphate.....	104
Haemodialysis .....	104
Peritoneal dialysis.....	105
Significance of differences in serum phosphate between centres.....	106
Changes in serum phosphate 1998 – 1999.....	106
SERUM PARATHYROID HORMONE.....	108
Haemodialysis .....	108
Peritoneal dialysis .....	109
Significance of differences in serum iPTH between centres.....	110
CONCLUSIONS.....	110
<b>CHAPTER 9: SERUM ALBUMIN AND SERUM BICARBONATE.....</b>	<b>113</b>
SERUM ALBUMIN .....	113
Albumin measurement.....	113
Haemodialysis .....	115
Peritoneal dialysis.....	117
Discussion .....	118
CHANGES IN ALBUMIN 1998-1999 .....	118
Haemodialysis .....	118
Peritoneal dialysis.....	119
CHANGE IN ALBUMIN FOR 1999 .....	120
Discussion .....	120
Conclusions .....	121
SERUM BICARBONATE .....	121
Bicarbonate measurement.....	121
Haemodialysis .....	123
Discussion .....	124
Peritoneal dialysis.....	124
Discussion .....	125
<b>CHAPTER 10: FACTORS WHICH MAY INFLUENCE CARDIOVASCULAR DISEASE – BLOOD PRESSURE AND SERUM CHOLESTEROL .....</b>	<b>127</b>
BLOOD PRESSURE.....	127
Introduction .....	127
Achievement of combined systolic and diastolic standard .....	128
Systolic pressure alone .....	130
Diastolic pressure alone.....	134
Mean arterial pressure .....	137
Further problems .....	139
Relationship of measured blood pressure to outcomes.....	140
SERUM CHOLESTEROL .....	140
Introduction .....	140
Methods.....	141
Results .....	141
Haemodialysis .....	141
Peritoneal dialysis.....	142
CHANGE IN CHOLESTEROL 1998–1999.....	143

Clinical trial of cholesterol lowering in CRF.....	144
REFERENCES .....	144
<b>CHAPTER 11: RENAL TRANSPLANTATION.....</b>	<b>147</b>
SUMMARY .....	147
INTRODUCTION .....	147
TRANSPLANTS PERFORMED 1999 .....	147
PATIENTS WITH ESTABLISHED RENAL TRANSPLANTS .....	148
TRANSPLANTATION IN PATIENTS WITH DIABETES MELLITUS .....	150
ETHNICITY .....	152
FAILED TRANSPLANTS.....	153
SURVIVAL OF PATIENTS WITH ESTABLISHED RENAL TRANSPLANTS.....	153
QUALITY OF TRANSPLANT FUNCTION.....	154
HAEMOGLOBIN IN TRANSPLANTED PATIENTS.....	155
SERUM CHOLESTEROL.....	157
CHANGES IN SERUM CHOLESTEROL 1998-99.....	159
BLOOD PRESSURE.....	160
CONCLUSION.....	165
REFERENCES .....	165
<b>CHAPTER 12: CO-MORBIDITY OF NEW PATIENTS.....</b>	<b>167</b>
SUMMARY.....	167
CO-MORBIDITY RETURNS .....	167
CO-MORBIDITY DEFINITIONS.....	167
Angina .....	167
Previous MI within last 3 months.....	167
Previous MI > 3 months ago.....	168
Previous CABG or coronary angioplasty .....	168
Cerebrovascular disease .....	168
Diabetes (not causing ESRF).....	168
Chronic Obstructive Pulmonary Disease.....	168
Liver Disease.....	168
Malignancy.....	168
Claudication.....	168
Ischaemic / Neuropathic ulcers.....	168
Angioplasty (non coronary).....	168
Amputation for Peripheral Vascular Disease.....	168
Smoking.....	168
Co-morbidity Screen .....	169
COMMENT .....	169
<b>CHAPTER 13: PERFORMANCE AGAINST RENAL ASSOCIATION STANDARDS .....</b>	<b>171</b>
INTRODUCTION .....	171
OVERVIEW OF PRESENTATION .....	172
HAEMOGLOBIN .....	172
SERUM ALBUMIN .....	174
SERUM BICARBONATE .....	175
SERUM CALCIUM .....	176
SERUM PHOSPHATE.....	177
INTACT PARATHYROID HORMONE .....	178
BLOOD PRESSURE .....	179
DIALYSIS ADEQUACY .....	181
STATISTICAL ANALYSIS.....	182
Methodology .....	182
<b>CHAPTER 14: INTERNATIONAL COMPARISONS WITH UK RENAL REGISTRY DATA..</b>	<b>185</b>
INCIDENCE & PREVALENCE .....	185

<b>PREVALENT DIALYSIS P.M.P.....</b>	<b>185</b>
<b>% INCIDENT ESRD WITH DIABETES.....</b>	<b>185</b>
TREATMENT MODALITIES.....	186
<b>TRANSPLANTED.....</b>	<b>186</b>
TRANSPLANTATION.....	187
UREA REDUCTION RATIO IN HAEMODIALYSIS.....	187
RENAL ANAEMIA.....	188
<b>CHAPTER 15: REPORT OF THE PAEDIATRIC RENAL REGISTRY.....</b>	<b>189</b>
SUMMARY.....	189
INTRODUCTION.....	190
POPULATION STUDIED.....	190
TREATMENT MODALITY.....	192
TRANSPLANT ORIGINS AND IMMUNOSUPPRESSIVE REGIMES.....	193
RENAL FUNCTION IN PATIENTS WITH TRANSPLANTS.....	195
GROWTH AND NUTRITION IN PATIENTS WITH TRANSPLANTS.....	196
DIALYSIS MODALITY AND ACCESS.....	198
DIALYSIS EFFICIENCY.....	200
GROWTH AND NUTRITION IN DIALYSIS PATIENTS.....	201
BONE DISEASE, PTH AND PHOSPHATE.....	204
HAEMOGLOBIN AND ERYTHROPOIETIN USAGE IN DIALYSIS PATIENTS.....	205
CONCLUSION.....	206
<b>CHAPTER 16: SURVIVAL OF PATIENTS ON DIALYSIS.....</b>	<b>207</b>
INTRODUCTION.....	207
STATISTICAL METHODS.....	207
SURVIVAL WHILST ON DIALYSIS OF THE INCIDENT 1997 AND 1998 COHORTS.....	208
Introduction.....	208
Patient Cohort.....	208
Statistical methods.....	208
Results.....	209
Discussion.....	215
SURVIVAL OF PATIENTS ESTABLISHED ON DIALYSIS – THE PREVALENT COHORT.....	216
The effects of age, gender and diabetes.....	216
The effect of Age, on the survival of Established Dialysis Patients.....	216
The effect of 'Length of Time on RRT' on Survival of Established Dialysis Patients.....	217
The effect of Gender and Diabetes on the Survival of Established Dialysis Patients.....	219
Variation between centres of 1 year survival (1998) of established dialysis patients.....	221
Variation between centres in 2-year survival (1997-98) of established dialysis patients.....	222
Discussion.....	224
REFERENCES.....	225
<b>CHAPTER 17: SURVIVAL ON RENAL REPLACEMENT THERAPY: ASSOCIATIONS WITH ALBUMIN, UREA REDUCTION RATIO AND PHOSPHATE.....</b>	<b>227</b>
BACKGROUND.....	227
PATIENT SELECTION AND STATISTICAL METHODS.....	227
SERUM ALBUMIN.....	228
Sample size.....	228
Methods.....	228
Results.....	229
UREA REDUCTION RATIO.....	231
Sample size.....	231
Statistical Methods.....	231
Results.....	232
SERUM PHOSPHATE.....	232
Sample size.....	232
Method.....	232

Results .....	233
DISCUSSION .....	234
REFERENCES .....	235
<b>CHAPTER 18: SURVIVAL IN DIALYSIS PATIENTS: ASSOCIATIONS WITH HAEMOGLOBIN ACHIEVED AND BLOOD PRESSURE CONTROL .....</b>	<b>237</b>
HAEMOGLOBIN ACHIEVED .....	237
Subjects .....	237
Methods .....	237
Results .....	238
Discussion .....	239
Conclusion .....	239
THE ASSOCIATION BETWEEN BLOOD PRESSURE AND RISK OF DEATH .....	239
Sample .....	239
Methods .....	240
Systolic Blood Pressure .....	240
Diastolic Blood Pressure .....	241
Mean Arterial Blood Pressure .....	241
Pulse Pressure .....	242
Comment .....	242
<b>CHAPTER 19: THE INFLUENCE OF SOCIO-ECONOMIC DEPRIVATION ON SURVIVAL OF PREVALENT DIALYSIS PATIENTS .....</b>	<b>243</b>
SUMMARY .....	243
AIM .....	243
BACKGROUND .....	243
METHODS .....	243
Inclusion .....	243
Exclusion criteria .....	243
Deprivation measure .....	244
Censoring .....	244
RESULTS .....	244
DISCUSSION .....	246
CONCLUSION .....	246
Comparison of UK Deprivation Scores .....	247
REFERENCES .....	247
<b>CHAPTER 20: TRANSPLANTATION AND WAITING LISTS .....</b>	<b>249</b>
SUMMARY .....	249
INTRODUCTION .....	250
10 YEAR CHANGES IN AGE AT TRANSPLANTATION .....	250
10 YEAR CHANGES IN USE OF LOCAL AND EXCHANGED KIDNEYS .....	251
FIVE YEAR CHANGES IN THE TRANSPLANT ACTIVE WAITING LIST BY AGE .....	251
LISTING FOR TRANSPLANTATION .....	252
ACCESS TO TRANSPLANTATION .....	253
DIABETES, TRANSPLANTATION AND WAITING LISTS .....	255
<b>CHAPTER 21: NHS PURCHASING &amp; SUPPLY AGENCY - EQUIPMENT SUPPLIED FOR RRT IN ENGLAND .....</b>	<b>257</b>
AN OVERVIEW OF THE AGENCY .....	257
THE RENAL EXPERTISE OF THE AGENCY .....	257
CURRENT MARKET SITUATION .....	258
CURRENT MARKET SHARES .....	258
HELP AVAILABLE FOR TRUSTS .....	259
FURTHER INFORMATION .....	260
<b>CHAPTER 22: DIABETES, MEASUREMENT OF GLYCATED HAEMOGLOBIN AND DATA FROM THE DIABETIC REGISTRY .....</b>	<b>261</b>
SUMMARY .....	261
Summary on HBA1c standardisation .....	261

Summary of UKDIABS data .....	262
HBA1C STANDARDISATION .....	262
Detailed description of the background to the current situation .....	262
UK DIABETIC REGISTRY .....	264
Overview of the UK Diabetic Registry .....	264
Diabetic dataset .....	264
Results .....	265
Creatinine clearance .....	266
<b>CHAPTER 23: THE NEXT STEPS .....</b>	<b>271</b>
INTRODUCTION .....	271
INCREASED PARTICIPATION .....	271
IMPROVE DATA QUALITY .....	271
EXPAND THE DATABASE .....	272
COMPLETE THE AUDIT CYCLE .....	272
INSIGHTS FROM REGISTRY ACTIVITY, AND ITS LIMITATIONS .....	273
CONCLUSION .....	275
REFERENCES .....	275
<b>APPENDIX A: THE RENAL REGISTRY RATIONALE .....</b>	<b>277</b>
A:1 EXECUTIVE SUMMARY .....	277
A:2 INTRODUCTION .....	278
A:3 STATEMENT OF INTENT .....	279
A:4 RELATIONSHIPS OF THE RENAL REGISTRY .....	279
A:5 THE ROLE OF THE REGISTRY FOR NEPHROLOGISTS .....	279
A:6 THE ROLE OF THE REGISTRY FOR TRUST MANAGERS .....	280
A:7 THE ROLE OF THE REGISTRY FOR COMMISSIONERS OF HEALTH CARE .....	280
A:8 THE ROLE OF THE REGISTRY FOR NATIONAL QUALITY ASSURANCE AGENCIES .....	281
A:9 THE ROLE OF THE REGISTRY FOR PATIENTS .....	282
A:10 ABBREVIATIONS .....	282
A:11 REFERENCES .....	282
<b>APPENDIX B: DEFINITION, STATISTICAL METHODOLOGY, ANALYSIS CRITERIA .....</b>	<b>283</b>
DEFINITIONS OF ANALYSIS QUARTERS .....	283
RENAL REGISTRY MODALITY DEFINITIONS .....	283
Home haemodialysis .....	283
Satellite dialysis unit .....	283
Treatment modality at 90 days .....	283
Start of end stage renal failure .....	283
ANALYSIS CRITERIA .....	284
Take-On population .....	284
Criteria for analysis by treatment modality in a quarter .....	284
Criteria for analysis of biochemistry in a quarter .....	285
Treatment modality on day 90 of starting RRT .....	285
One year survival of the take-on population .....	285
Analysis of one year survival of prevalent patients .....	285
<b>APPENDIX C: RENAL SERVICES DESCRIBED FOR NON-PHYSICIANS .....</b>	<b>287</b>



## Figures

Figure 2.1 Renal Registry audit cycle.....	4
Figure 2.2 Coverage of the Renal Registry .....	7
Figure 3.1 Number of patients on each modality - England 1993-98.....	15
Figure 3.2 Change in patients on dialysis modality 93-98 .....	15
Figure 3.3 Incidence and prevalence rates (p.m.p.) of RRT patients by region .....	23
Figure 4.1 Estimated new patients starting RRT by centre per million of population .....	28
Figure 4.2 Estimated incidence per million population by age .....	29
Figure 4.3 New RRT patients by age group for the UK.....	30
Figure 4.4 Changes in new RRT patients by age group – Scotland with England & Wales .....	30
Figure 4.5 Median age of new patients in each unit .....	31
Figure 4.6 Estimated acceptance rate p.m.p. and age .....	32
Figure 4.7 New patients 1999 – proportion male by age.....	32
Figure 4.8 Percentage of patients established on HD at day 90 by centre.....	36
Figure 4.9 Percentage of patients established on HD at day 90 by centre and by age .....	37
Figure 5.1 Estimated dialysis prevalence per million population by centre .....	45
Figure 5.2a Prevalence rates p.m.p. for RRT by age .....	46
Figure 5.2b Age profile of prevalent patients .....	47
Figure 5.3 Median age of dialysis patients alive 31.12.99 .....	47
Figure 5.4 Median age at each centre and length of time on RRT in the UK .....	48
Figure 5.5 Percentage of male patients according to age.....	48
Figure 5.6 Patients in each modality according to age.....	51
Figure 5.7 Percentage of patients on each dialysis modality .....	52
Figure 5.8 Proportion of patients treated by HD according to centre and age.....	53
Figure 5.9 Percentage of haemodialysis patients treated at home and in satellite units .....	53
Figure 5.10 Use of connect and automated PD as percentage of total PD.....	54
Figure 5.11 Percentage of dialysis patients on haemodialysis by year .....	56
Figure 6.1 Percentage patients with URR > 65% in the last quarter of 1999 .....	62
Figure 6.1b Achievement of the RA Standard for haemodialysis .....	64
Figure 6.3 URR achievement and median URR.....	64
Figure 6.4 Change in meeting URR standard in 1999.....	65
Figure 6.5 Change in meeting URR standard over 2 years. ....	66
Figure 6.6 Achievement of URR within the 1st three months of HD.....	67
Figure 6.7 Change in URR by length of time on RRT in 1999 .....	67
Figure 6.8 Urea reduction ratios in UK and USA .....	68
Figure 6.9 Components of urea rebound (from the DOQI report).....	69
Figure 7.1 Haemoglobin patients on HD by 1g/dl bands .....	75
Figure 7.3 Haemoglobin median and quartile range for haemodialysis patients .....	76
Figure 7.4 Distribution of haemoglobin for patients on PD by 1g/dl bands.....	77
Figure 7.5 Percentage of PD patients by centre achieving the RA Standard.....	77
Figure 7.6 Median haemoglobin on peritoneal dialysis .....	78
Figure 7.7 Percentage of HD patients with serum ferritin > 100 mcg/l.....	79
Figure 7.8 Percentage serum ferritin > 200 mcg/l on HD.....	79
Figure 7.9 Haemoglobin > 10 g/dl vs. serum ferritin > 100 mcg/l on haemodialysis.....	80
Figure 7.10 Percentage serum ferritin > 100 mcg/l on peritoneal dialysis .....	81
Figure 7.11 Percentage serum ferritin > 200 mcg/l on peritoneal dialysis .....	81
Figure 7.12 Haemoglobin > 10 g/dl vs. ferritin > 100 mcg/l on peritoneal dialysis.....	82
Figure 7.13 Percentage of haemodialysis patients on epo by age and gender .....	85
Figure 7.14 Percentage of peritoneal dialysis patients on epo by age.....	86
Figure 7.15 Percent Hb above 10g/dl and median Hb in individual centres (HD) .....	86
Figure 7.16 Percent Hb above 10g/dl and median Hb in individual centres (PD).....	87
Figure 7.17 Median haemoglobin and 90% range at start of dialysis treatment .....	88
Figure 7.18 Percentage haemoglobin > 10g/dl for new patients.....	88

Figure 7.19 Haemoglobin distribution at start of dialysis .....	89
Figure 7.20 Percentage with haemoglobin > 10g/dL: new and prevalent patients.....	89
Figure 7.21 Hb ≥ 10 g/dl from 1997 to end 1998, on haemodialysis.....	90
Figure 7.22 Median haemoglobin 1997-1998 on haemodialysis .....	91
Figure 7.23 Percentage with Hb > 10g/dl 1998 to end 1999, on Peritoneal dialysis .....	91
Figure 7.24 Median haemoglobin 1998- 1999 on peritoneal dialysis .....	92
Figure 7.25 15 to 85% quantiles for median Hb on HD at each quarter from 1st 1998 to 4th 1999.....	92
Figure 7.26 15 to 85% quantiles for median Hb on PD at each quarter from 1st 1998 to 4th 1999.....	93
Figure 7.27 Hb > 10g/dl at start and end of 1999, on Haemodialysis .....	94
Figure 7.28 Median Haemoglobin, Haemodialysis, start and end of 1999 .....	94
Figure 7.29 Hb > 10g/dl at start and end of 1999, on Peritoneal Dialysis .....	95
Figure 7.30 Peritoneal Dialysis results at start and end of 1999 .....	95
Figure 7.31 Change of haemoglobin in individuals from 1st to 4th quarters of 1999 .....	96
Figure 8.1 Percentage corrected serum calcium within 2.25-2.65 mmol/L on HD .....	101
Figure 8.2 Median corrected serum calcium on haemodialysis .....	101
Figure 8.3 Percentage corrected serum calcium in range 2.25-2.65 mmol/L: on PD .....	102
Figure 8.4 Median corrected serum calcium on peritoneal dialysis .....	102
Figure 8.5 Median uncorrected serum calcium on haemodialysis.....	103
Figure 8.6 Median uncorrected serum calcium on peritoneal dialysis.....	103
Figure 8.7 Percentage patients with phosphate between 1.2 and 1.7 mmol/L: - HD.....	104
Figure 8.8 Median serum phosphate on haemodialysis .....	105
Figure 8.9 Percentage patients with serum phosphate between 1.1 and 1.6 mmol/L: PD .....	105
Figure 8.10 Median serum phosphate on peritoneal dialysis .....	106
Figure 8.11 Serum phosphate distribution by year .....	106
Figure 8.12 Change in % phosphate 1998 – 1999 in range 1.2-1.7 mmol/L: haemodialysis.....	107
Figure 8.13 Change in phosphate 1998-1999 between 1.1 and 1.6 mmol/L: peritoneal dialysis	107
Figure 8.14 Percentage patients with serum iPTH in 3x lab range on HD .....	109
Figure 8.15 Median intact serum parathyroid hormone on HD .....	109
Figure 8.16 Percentage patients with serum iPTH in 3x lab range on PD .....	109
Figure 8.17 Median serum intact parathyroid hormone on peritoneal dialysis .....	110
Figure 9.1 Comparison of methods of measuring albumin .....	113
Figure 9.2 Percentage albumin in laboratory reference range on haemodialysis .....	115
Figure 9.3 Percentage albumin in range 35-50 g/L on haemodialysis .....	115
Figure 9.4 Serum albumin on haemodialysis .....	116
Figure 9.5 Median urea reduction ratio and albumin.....	116
Figure 9.6 Percentage albumin in laboratory reference range on peritoneal dialysis .....	117
Figure 9.7 Percentage albumin in range 35-50 g/L on peritoneal dialysis .....	117
Figure 9.8 Serum albumin on peritoneal dialysis.....	117
Figure 9.9 Percentage albumin in lab reference range on haemodialysis, 1998-1999.....	118
Figure 9.10 Percentage albumin in range 35-50 g/L on haemodialysis, 1998-1999 .....	118
Figure 9.11 Percentage albumin in laboratory reference range on peritoneal dialysis, 1998-1999 .....	119
Figure 9.12 Percentage albumin in range 35-50 g/L on peritoneal dialysis, 1998-1999 .....	119
Figure 9.13 Change in albumin in laboratory reference range on peritoneal dialysis, 1999.....	120
Figure 9.14 Change in albumin between 35-50 g/L on peritoneal dialysis, 1999.....	120
Figure 9.15 Percentage bicarbonate in laboratory reference range on haemodialysis .....	123
Figure 9.17 Median bicarbonate (mmol/L) on haemodialysis.....	124
Figure 9.18 Percentage patients with bicarbonate in laboratory reference range on PD .....	124
Figure 9.19 Percentage patients with bicarbonate in range 22-30 mmol/L on PD .....	125
Figure 9.20 Bicarbonate (mmol/L) on peritoneal dialysis .....	125
Figure 10.1 Percentage of patients age < 60 with BP < 140/90 on haemodialysis.....	128
Figure 10.2 Percentage of patients age > 60 with BP < 160/90 on haemodialysis.....	129
Figure 10.3 Percentage of patients age < 60 with BP < 140/90 on PD .....	129



Figure 10.4	Percentage of patients age > 60 with BP < 160/90 on PD .....	130
Figure 10.5	Median systolic blood pressure age < 60 on haemodialysis.....	131
Figure 10.6	Median systolic blood pressure age > 60 on haemodialysis.....	131
Figure 10.7	Percentage of patients with systolic BP < 140 mm Hg aged < 60 on HD.....	132
Figure 10.8	Percentage of patients with systolic BP < 160 mm Hg aged > 60 on HD.....	132
Figure 10.9	Median systolic blood pressure age < 60 on peritoneal dialysis.....	133
Figure 10.10	Median systolic blood pressure age > 60 on peritoneal dialysis.....	133
Figure 10.11	Percentage of patients with systolic BP < 140 mm Hg age < 60: PD .....	134
Figure 10.12	Percentage of patients with systolic BP < 160 mm HG age > 60: PD .....	134
Figure 10.13	Median diastolic blood pressure age < 60 on haemodialysis .....	134
Figure 10.14	Percentage of patients age < 60 with diastolic BP < 90 mmHg on HD .....	135
Figure 10.15	Percentage of patients age > 60 with diastolic BP < 90 mmHg on HD .....	135
Figure 10.16	Median diastolic blood pressure age < 60 on PD.....	136
Figure 10.17	Median diastolic blood pressure age > 60 on peritoneal dialysis .....	136
Figure 10.18	Percentage patients age < 60 with diastolic BP < 90 mmHg on PD .....	136
Figure 10.19	Percentage patients age > 60 with diastolic BP < 90 mmHg on PD .....	137
Figure 10.20	Percentage patients age < 60 with mean arterial BP < 107 on HD .....	137
Figure 10.21	Percentage patients age > 60 with mean arterial BP < 113 on HD .....	138
Figure 10.22	Percentage patients age < 60 with mean arterial BP < 107 PD .....	138
Figure 10.23	Percentage patients age > 60 with mean arterial BP < 113 on PD.....	138
Figure 10.24	Median serum cholesterol (mmol/L) on haemodialysis .....	141
Figure 10.25	Percentage cholesterol < 5.0 mmol/L on haemodialysis.....	142
Figure 10.26	Serum cholesterol (mmol/L) on peritoneal dialysis.....	142
Figure 10.27	Percentage cholesterol < 5.0 mmol/L on peritoneal dialysis.....	143
Figure 10.28	Percentage cholesterol < 5.0 mmol/L on haemodialysis, 1998-1999 .....	143
Figure 10.29	Percentage cholesterol < 5.0 mmol/L on peritoneal dialysis, 1998-1999 .....	144
Figure 11.1	Age histogram of dialysis and transplant patients .....	148
Figure 11.2	Treatment modality of all prevalent patients < 65.....	149
Figure 11.3	Percentage of prevalent dialysis patients age <65 years who have ever received a renal transplant .....	150
Figure 11.4	Percentage of current transplant patients with diabetes mellitus, by centre.....	150
Figure 11.5	Percentage of diabetic ESRF patients with a transplant, by centre .....	151
Figure 11.6	Ratio of % patients with a transplant under 65, diabetics : non-diabetics.....	151
Figure 11.7	Ethnic minority distribution of transplant patients < 65 by centre.....	152
Figure 11.9	Median serum creatinine of prevalent transplant patients, by centre .....	154
Figure 11.10	Percentage of established transplant patients with serum creatinine >250 umols/l .....	155
Figure 11.11	Median haemoglobin of transplant patients by centre .....	155
Figure 11.12	Haemoglobin achieved in established transplant patients – by centre.....	156
Figure 11.13	Median Hb of patients with serum creatinine greater and less than 250 umol/l...	156
Figure 11.14	Median Serum cholesterol for transplant patients – by centre.....	157
Figure 11.15	Percentage of transplant patients with cholesterol <5.0 mmol/L.....	158
Figure 11.17	Percentage transplant patients with a serum cholesterol < 5.0 mmol/l in 1998-9	159
Figure 11.18	% patients under 60 with systolic and diastolic BP below 140/90 mmHg.....	161
Figure 11.19	% patients over 60 with systolic and diastolic BP below 160/90 mmHg .....	161
Figure 11.20	Transplant patients under 60: median systolic pressure.....	162
Figure 11.21	Percentage transplant patients under 60 with systolic BP <140 mmHg .....	162
Figure 11.22	Transplant patients over 60: median systolic pressure.....	162
Figure 11.23	% patients over 60 with systolic BP <160 mmHg.....	163
Figure 11.24	Transplant patients under 60; median diastolic pressure .....	163
Figure 11.25	% patients under 60 with diastolic BP <90mmHg .....	163
Figure 11.26	Transplant patients over 60: median diastolic pressure.....	164
Figure 11.27	% patients over 60 with diastolic BP <90mHg .....	164
Figure 12.1	A typical co-morbidity entry screen .....	169
Figure 13.1	Haemoglobin Percentage of HD patients achieving the RA Standard.....	172

Figure 13.2	Haemoglobin for patients on HD by 1g/dl bands .....	173
Figure 13.3	Percentage of PD patients by centre achieving the RA Standard.....	173
Figure 13.4	Distribution of haemoglobin for patients on PD by 1g/dl bands.....	174
Figure 13.5	Percentage albumin in lab reference range for haemodialysis .....	174
Figure 13.6	Percentage albumin in lab reference range for peritoneal dialysis .....	175
Figure 13.7	Percentage bicarbonate in lab reference range for haemodialysis .....	175
Figure 13.8	Percentage bicarbonate in lab reference range for peritoneal dialysis .....	176
Figure 13.9	Percentage corrected calcium in 2.25-2.65 for haemodialysis.....	176
Figure 13.10	Percentage corrected calcium in 2.25-2.65 for peritoneal dialysis.....	177
Figure 13.11	Percentage serum phosphate in range 1.1-1.6 for haemodialysis .....	177
Figure 13.12	Percentage serum phosphate in range 1.1-1.6 for peritoneal dialysis .....	178
Figure 13.13	Percentage patients with iPTH in 3x lab range on haemodialysis .....	178
Figure 13.14	Percentage patients with iPTH in 3x lab range on peritoneal dialysis .....	179
Figure 13.15	Percentage haemodialysis patients age < 60 with BP in RA Standard range .....	179
Figure 13.16	Percentage patients age > 60 with BP in RA Standard on haemodialysis.....	180
Figure 13.17	Percentage pts age < 60 with BP in RA Standard on peritoneal dialysis .....	180
Figure 13.18	Percentage pts age > 60 with BP in RA Standard on peritoneal dialysis .....	181
Figure 13.19	Percentage URR > 65% .....	181
Figure 14.1	Incidence of renal replacement therapy by age group.....	185
Figure 14.2	Prevalence of renal replacement therapy by age group .....	186
Figure 14.3	Transplant waiting list by age group.....	187
Figure 14.4	URR in the UK and USA.....	187
Figure 14.5	Haemoglobin > 9.7 g/dl comparison of UK vs. USA by time in ESRF .....	188
Figure 14.6	Haemoglobin < 9 g/dl comparison of UK vs. USA by time in ESRF .....	188
Figure 14.7	Serum Ferritin distribution UK vs. USA in 1999.....	188
Figure 15.1	Age distribution of population. ....	190
Figure 15.2	Age distribution of the patients at presentation with ESRF. ....	191
Figure 15.3	Age distribution of patients presenting with ESRF in the previous year.....	191
Figure 15.4	Age distribution of the patients according to treatment.....	192
Figure 15.5	Types of graft used.....	193
Figure 15.6	Types of graft used over the past year .....	194
Figure 15.7	Basic immunosuppression regimens.....	194
Figure 15.8	Breakdown of immunosuppressive regimes split according to the calcineurin inhibitor (CI) used.....	195
Figure 15.9	Predicted GFR in patients with functioning allografts.....	196
Figure 15.10	Growth in patients with a functioning allograft.....	197
Figure 15.11	Body mass index in patients with functioning renal allografts. ....	198
Figure 15.12	Distribution of patients between PD and HD currently. ....	198
Figure 15.13	Distribution of patients between PD and HD at Day 90 of ESRF.....	199
Figure 15.14	Vascular access for dialysis in different age-groups. ....	199
Figure 15.15	Division of PD patients between automated PD (APD) and CAPD.....	200
Figure 15.16	Dialysis efficiency as measured by pGFR in HD and PD patients.....	201
Figure 15.17	Height achievement in dialysis patients. ....	202
Figure 15.18	A comparison of height achieved in dialysis (Dx) vs transplant (Tx) patients. ....	202
Figure 15.19	Body mass index in patients on dialysis. ....	203
Figure 15.20	A comparison of BMI in dialysis (Dx) vs transplant (Tx) patients.....	203
Figure 15.21	Serum phosphate in dialysis patients split according to dialysis modality. ....	204
Figure 15.22	Serum PTH in dialysis patients split according to dialysis modality.....	205
Figure 15.23	Haemoglobin in dialysis patients split according to dialysis modality. ....	205
Figure 16.1a	Adjusted survival during the first 90 days, 1997 cohort.....	210
Figure 16.1b	Adjusted survival during the first 90 days, 1998 cohort .....	211
Figure 16.2a	Survival during the year after the first 90 days, 1997.....	213
Figure 16.2b	Survival during the year after the first 90 days, 1998 cohort .....	214
Figure 16.4	Relationship between acceptance rate and survival on dialysis.....	215
Figure 16.5	1 year survival of prevalent dialysis patients by age band .....	217

<b>Figure 16.6 The 1 year survival of diabetic and non-diabetic dialysis patients of different ages on RRT for &gt;1 year.</b>	<b>220</b>
<b>Figure 16.7 Adjusted 1-year survival of all dialysis patients in 1998.</b>	<b>222</b>
<b>Figure 16.8 Adjusted 2-year survival of all dialysis patients in 1997-1998</b>	<b>224</b>
<b>Figure 20.1a&amp;b Transplantation by age groups 1988 -98</b>	<b>250</b>
<b>Figure 20.2 Transplanted local kidneys 1988 - 98</b>	<b>251</b>
<b>Figure 20.3 Transplant waiting lists 1993-98.</b>	<b>251</b>
<b>Figure 20.4 Transplants by age 1993-98.</b>	<b>252</b>
<b>Figure 20.5 Waiting lists as a percentage of all dialysis patients</b>	<b>252</b>
<b>Figure 20.6 Suspended patients as a proportion of the waiting list</b>	<b>253</b>
<b>Figure 20.7 Percentage of all dialysis patients on waiting list by centre</b>	<b>253</b>
<b>Figure 20.8 Percentage of dialysis patients aged &lt;65 on waiting list by centre</b>	<b>254</b>
<b>Figure 20.9 Percentage of dialysis patients aged &lt;60 on waiting list by centre</b>	<b>254</b>
<b>Figure 20.10 Number of diabetics transplanted</b>	<b>255</b>
<b>Figure 20.11 Diabetics on the waiting list by centre</b>	<b>255</b>
<b>Figure 21.1 UK dialyser market share</b>	<b>258</b>
<b>Figure 21.2 Market shares of haemodialysis equipment, inclusive of machines, but excluding dialysers.</b>	<b>259</b>
<b>Figure 21.3 Market shares of PD supplies, inclusive of all CAPD, APD and IPD.</b>	<b>259</b>
<b>Figure 22.1 The proportion of patients with a creatinine measured at annual review</b>	<b>265</b>
<b>Figure 22.2 The percentage serum creatinine measurements &gt; 200µmol/l.</b>	<b>265</b>
<b>Figure 22.3 Calculated creatinine clearance and duration of diabetes – type I diabetics.</b>	<b>266</b>
<b>Figure 22.4 Calculated creatinine clearance and age – type I diabetics.</b>	<b>266</b>
<b>Fig 22.5 Decline in creatinine clearance in diabetics v non-diabetic males.</b>	<b>267</b>
<b>Fig 22.6 Decline in creatinine clearance in diabetics v non-diabetic females.</b>	<b>267</b>
<b>Figure 22.7 Calculated creatinine clearance and duration of diabetes – type II diabetics.</b>	<b>267</b>
<b>Figure 22.8 Calculated creatinine clearance and age – type II diabetics.</b>	<b>268</b>
<b>Figure 22.9 Systolic blood pressure and renal impairment in Type1 diabetics</b>	<b>268</b>
<b>Figure 22.10 Association between diastolic BP and renal impairment in type I diabetics.</b>	<b>269</b>
<b>Figure 22.11 The relationship between renal impairment and systolic blood pressure in type II diabetics.</b>	<b>269</b>
<b>Figure 23.1 The audit cycle.</b>	<b>272</b>
<b>Figure 23.2 Haemoglobin distributions for UK centres</b>	<b>273</b>
<b>Figure 23.3 Median Hb against the Percentage &gt; 10g/dl</b>	<b>274</b>
<b>Figure 23.4 Average population haematocrit plotted against %haematocrit &gt;30 in 2 US studies</b>	<b>274</b>



## Tables

Tables 2.2 New units joined the Registry since the Report.....	6
Tables 2.3 Renal units joining the Registry.....	6
Table 3.1 Acceptance data for new patients accepted onto RRT in 1998.....	12
Table 3.2 Acceptance rate for new patients on RRT 1993-1998 in the UK.....	13
Table 3.3 Changing profile of patients accepted onto RRT in the UK.....	13
Table 3.4 UK Patients receiving Renal Replacement Therapy – Dec 31 1998.....	14
Table 3.5 Patients receiving RRT in England (1993-1998) & Wales (1995-98).....	14
Table 3.6 Renal unit facilities in the UK – 31/12/1998.....	16
Table 3.7 Satellite dialysis units in the UK – 31/12/1998.....	16
Table 3.8 Changes in renal unit facilities in England 1993-98 and Wales 1995-98.....	17
Table 3.9 Changes in satellite haemodialysis provision in England & Wales.....	17
Table 3.10 Medical staffing in renal units in the UK 1998.....	18
Table 3.11 Professions allied to medicine staffing in the UK 31/12/1998.....	19
Table 3.12 Changes in staffing in renal units in England & Wales 1993-8.....	19
Table 3.13 Process measures of dialysis care for renal units in the UK 1998.....	20
Table 3.14 Changes in process measures of dialysis care in England 1993-1998.....	21
Table 3.15 Changes in process measures of dialysis in Wales 1995-98.....	22
Table 3.16 Constraining factors (of the responding units).....	22
Table 3.17 Regional treatment rates 1998 pmp.....	23
Table 3.18: Changes in regional treatment rates p.m.p. 1995-8.....	23
Table 3.19 Regional rates of supply of RRT facilities and staff 31/12/1998.....	24
Table 3.20 Changes in patient number and medical staff in England 1993-98.....	26
Table 4.1 Summary of new adult patients accepted during 1999.....	27
Table 4.2 UK population distribution by age group (% of total population).....	29
Table 4.3 Percentage of males accepted for RRT.....	32
Table 4.4 Ethnicity by centre.....	33
Table 4.5 % Primary renal diagnosis by age, and gender ratios.....	34
Table 4.6 Percentage diagnostic distribution of new RRT patients by unit.....	35
Table 4.7 HD patients at 90 days: changes in modality in subsequent year.....	38
Table 4.8 PD patients at 90 days: changes in modality in one year.....	38
Table 4.9 Changes in modality over the first 2 years for patients on HD.....	39
Table 4.10 Changes in modality over the first 2 years for patients on PD.....	39
Table 4.11 One Year Patients Survival – patients age 18-55.....	40
Table 4.12 Ninety day survival of 1998 and combined 1997-8 cohort patients.....	41
Table 4.13 One year survival of new patients, by age at start of therapy in 1998.....	41
Table 4.14 One year survival of new patients from 1997.....	41
Table 4.15 Two year survival of 1997 cohort patients.....	42
Table 5.1 Summary of adult patients registered and total population covered.....	45
Table 5.2 Median age and treatment modality.....	46
Table 5.3 Ethnicity.....	49
Table 5.4 Primary renal disease in all patients, and according to age and gender.....	50
Table 5.5 Median age of prevalent diabetics.....	50
Table 5.6 Treatment according to type of diabetes and country.....	51
Tables 5.7a and 5.7b Type of diabetes – age, sex ratio, treatment.....	51
Table 5.8 Percentage modality according to age.....	52
Table 5.9 Proportion of patients on PD by diagnostic category.....	55
Table 5.10 Treatment modality and gender.....	55
Table 5.11 Proportion of patients with different modalities of RRT 1999 and 1998.....	55
Table 5.12 Number of patients with different modalities of RRT 1998 and 1999 in same centres.....	55
Table 5.13a Survival during 1999 of dialysis patients alive on 1/1/1999.....	57
Table 5.13b Survival during 1999 of transplant patients alive on 1/1/1999.....	57
Table 5.14 Survival during 1999 of dialysis patients alive on 1/1/1999 by age.....	57

Table 5.15a Survival of dialysis patients aged < 65 .....	58
Table 5.15b Survival during 1999 of dialysis patients aged >65 .....	58
Table 5.16 Survival during 1999 of non-diabetic dialysis patients by age.....	58
Table 5.17 Mortality in the general UK population .....	59
Table 7.1 Haemoglobin data for patients on haemodialysis .....	75
Table 7.2 Haemoglobin data for patients on peritoneal dialysis .....	77
Table 7.3 Serum Ferritin concentration in haemodialysis patients .....	79
Table 7.4 Ferritin concentrations in peritoneal dialysis patients .....	80
Table 7.5 Erythropoietin prescribing in haemodialysis patients .....	83
Table 7.6 Erythropoietin prescribing in peritoneal dialysis patients and weekly dose.....	83
Table 7.7 Percentage of patients prescribed erythropoietin against time on RRT .....	83
Table 7.8 Erythropoietin prescription by age in haemodialysis patients .....	84
Table 7.9 Erythropoietin prescription by age in peritoneal dialysis patients .....	84
Table 7.10 Haemoglobin and gender in HD patients .....	85
Table 7.11 Haemoglobin and gender in peritoneal dialysis patients .....	85
Table 7.12 Haemoglobin at start of dialysis .....	88
Table 7.13 Change in Hb for all centres in 1st qtr. of 1998, 1999 and 4th qtr. of 1999.....	90
Table 7.14 Change in Hb for all centres returning data in 1 <sup>st</sup> and 4 <sup>th</sup> quarter of 1998.....	93
Table 8.1 Laboratory methodologies for serum calcium .....	100
Table 8.2 Methodologies for measurement of serum phosphate.....	104
Table 8.3 Laboratory methodology for serum iPTH .....	108
Table 9.1 Methods and ranges of albumin measurement .....	114
Table 9.2 Bicarbonate methodology and reference ranges.....	122
Table 11.1 New transplants from the Registry 1999 .....	148
Table 11.2 Primary diagnosis of transplant patients in the UK.....	148
Table 11.3 Survival during 1999 of established transplant patients alive 1.1.99.....	153
Table 11.4 Relationship between transplant function and primary renal diagnosis.....	154
Table 11.5 Transplant patients: relationship between haemoglobin, creatinine and gender...	157
Table 11.6 Renal transplant patients: relationship of serum cholesterol and creatinine .....	158
Figure 11.16 Median serum cholesterol, mmol/l, in transplant patients by centre 1998-9.....	159
Table 11.7 Completeness of BP returns for transplant patients .....	160
Table 11.8 Relationship between BP and graft function in transplant patients in E&W.....	164
Table 12.1 Data returns from centres of co-morbidity at start of renal replacement therapy..	167
Table 13.1 Renal Association Standards .....	171
Table 14.1 Prevalence and incidence of RRT in several countries .....	185
Table 14.2 Modality pattern in several countries .....	186
Table 15.1 Comparison of patient stock and treatments between 1992 and 2000.....	192
Table 15.2 Comparison of standardised GFR with clearance in litres/week. ....	200
Table 16.1 Relationship of age and hazard of death in 1997 cohort .....	209
Table 16.2 Survival during the first 90 days on dialysis 1998 cohort .....	210
Table 16.3 survival of patients over 1 year after first 90 days in 1998 and 1997 cohort.....	212
Table 16.4 Survival probabilities during the year after the first 90 days, adjusted by quartiles. .....	212
Figure 16.3 Comparison of the 90 day and 1 year survival on dialysis .....	214
Table 16.5 UK and USA new patient characteristics .....	215
Table 16.6 Age and 1 year survival of dialysis patients on RRT for at least a year. ....	217
Table 16.7 Time on RRT and risk of death (Hazard ratio) for dialysis patients on RRT for at least a year. ....	218
Table 16.8 One Year Survival Rates for all patients in 1998.....	222
Table 16.9 Two-year survival rates 1997-1998 .....	223
Table 18.1. Relationship between haemoglobin and one year hazard of death .....	238
Table 18.2. Systolic pressure and hazard of death .....	240
Table 18.3. Diastolic pressure and hazard of death .....	241
Table 18.4. Mean arterial pressure and hazard of death.....	241
Table 18.5. The association between pulse pressure and hazard of death .....	242

<b>Table 19.1 Unadjusted analysis.....</b>	<b>245</b>
<b>Table 19.2 Unadjusted analysis excluding H .....</b>	<b>245</b>
<b>Table 19.3 Adjusted deprivation analysis .....</b>	<b>245</b>
<b>Table 19.4 Comparative UK deprivation scores.....</b>	<b>247</b>





## **Chapter 1: Summary of the year 2000 report on data from 1999**

For new patients in 1999, haemodialysis was the modality of RRT at a day 90 in 58.8% of dialysis patients in England & Wales compared with 66.8% in Scotland.

By the end of the first year 16% of patients starting RRT on peritoneal dialysis (PD) had changed to haemodialysis (HD).

3.1% of all patients starting dialysis in the UK in 1999 were patients with failed transplants.

For new patients, the 90 day survival is 95% (95%CI 94-97%) for those aged less than 65 and 81% (95%CI 78-83%) for patients aged 65 and over. The one year survival is 88% (95%CI 86-89%) for those aged less than 65 and 65% (95%CI 62-68%) for patients aged 65 and over.

Diabetic nephropathy was the cause of renal failure in 16% of new patients, and just over 10% of all prevalent patients.

From a 1998 survey of all the renal units in the UK, 96 adults per million population per year started renal replacement therapy (RRT), (92 England, 128 Wales, 105 Scotland).

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On 31/12/99, the Renal Registry was following 14772 adult patients receiving RRT in 35 renal units across the UK. The units participating in the Registry experienced an annual growth in patient numbers of 4.3% during 1999.

Haemodialysis is the predominant form of dialysis at all ages but especially in the older age groups. In England & Wales 66% of dialysis patients were on HD compared with 73% in Scotland. An increasing percentage of patients are being treated with HD, with the steepest rise being since 1995.

So few patients are now on “standard” CAPD that it should no longer be called “standard”. “Connect PD” may be a better term.

The one-year survival of all patients established on RRT for at least 90 days on 1/1/1999 was 83.7 % for the UK (84.8 for England & Wales and 78.8 for Scotland). The lower survival in Scotland may reflect the generally lower survival of the Scottish population itself, rather than any factor related to RRT.

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In England & Wales a uniform method of measuring the post dialysis urea sample has not yet been implemented.

A cross sectional analysis of haemodialysis patients in 1999 showed there was a continuing rise in urea reduction ratios (URR) over the 2 years from starting dialysis. This rose from 40% achieving a URR > 65% in the first 6 months to 70% achieving this at 2 years.

Within England and Wales, there has been a year on year increase in dialysis adequacy over the three years of the Registry. It is hoped that the wide variation in URR achieved in these early cycles of audit of hospital haemodialysis will continue to decrease.

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Of the 22 renal units in England and Wales with adequate data returns, the Renal Association standard for haemoglobin in dialysis patients of 85% with haemoglobin of at least 10 g/dl was achieved by 2 units for haemodialysis patients, and 9 for peritoneal dialysis patients.

Haemoglobin levels improved: 72% of HD patients and 80% of PD patients in England & Wales achieved a haemoglobin of 10g/dl or more. Erythropoietin is given to 86% (range between renal units of 79% - 97%) of HD patients and 63% (36% - 88%) of PD patients.

Serum ferritin concentrations were above 100mcg/l in 88% of HD patients in England and Wales (unit range 67%-100%) and in 80% of PD patients (unit range 62%-96%).

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There are continuing problems with comparative audit of corrected serum calcium due to difficulties with albumin measurements. Reliance on the BCG method to measure serum albumin (which over-estimates serum albumin) to correct calcium may be concealing hypercalcaemia. Due to interference with the BCG method from non-albumin proteins in uraemic sera, the BCP assay should be recommended.

Centres have difficulty achieving the target phosphate concentrations. These targets may not be achievable with current phosphate binders and dialysis regimes.

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Only three centres returned any significant co-morbidity data. The most pressing need for the Registry is to improve the returns of co-morbidity data from patients starting renal replacement therapy. Without good co-morbidity data to enable comparisons of groups of similar patients the value of this data will be greatly reduced

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Of paediatric patients, 76% had a functioning graft: 405 (86.7%) cadaveric and 62 (13.3%) living related. There was a significant increase in live related grafts, to 30%. 103 (22%) patients had pre-emptive grafts. Graft outcome was excellent in over 85% of cases.

Normalisation of growth and nutritional status are important goals of treatment in children. 37.5% of patients on PD and 43.8% of those on HD were less than 2 s.d. below the mean for height. 20.6% of dialysis patients were receiving growth hormone. After transplantation linear growth improved, with 29% of patients less than 2 s.d. below the mean for height.

---

28% of the 6838 dialysis patients on the Renal Registry in 1998 were on the active transplant waiting list. There is a large variation (16-38%) in the percentage of dialysis patients on the transplant active waiting list from centre to centre in the Registry.

In 1993, 16% of the total number of UK patients on the waiting list were suspended and this had risen to 19% on the 1<sup>st</sup> January 1999.

For Renal Registry centres only 22% of dialysing diabetics aged under 65 were on the active waiting list compared with 44% of non-diabetics

The annual death rate of patients with established renal transplants is low at 2.9% for the whole UK (including patients with failed grafts returning to dialysis). There are marked differences in control of modifiable risk factors for cardiovascular disease such as serum cholesterol and blood pressure. Control of these factors is often poor.

## Chapter 2: Introduction to the 2000 report

### *Introduction*

The role of a clinical Registry may seem self-evident. The aggregation, analysis and presentation of information about any discipline have obvious benefits in enlarging scientific and technical understanding, demonstrating trends in management, and supporting planning and development. Historically, it also acts as a powerful mirror, to reflect the development of a Speciality. However, demographic trends develop only slowly, data change little from year to year, and lose interest to clinicians. In addition, improved IT now allows data analysis at Unit level. The interests of clinicians have broadened, to include the delivery of health care and quality assurance of clinical outcomes, and they want more from data collection and analysis. There is thus a need to re-assess the role of a Renal Registry. It is important to look for some 'added-value' for reported data, so as to reward and sustain the effort of data collection and transmission. It is appropriate to restate the potential value from the Renal Registry activity.

**Demographic data collection.** This data is still of vital importance for informed planning, prediction, purchasing decisions and contracting. In addition to standard estimates of acceptance rates, death rates transplant rates, etc., the large volumes of data in the Renal Registry allow more detailed analysis. Important examples for planning include the study of initial modalities of treatment and transfers of modality as discussed in chapter 4. Another example is the analysis of transplant failures, the subsequent modality of such patients, and the influence of this on haemodialysis demand as described in chapter 5 and 11.

**Survival analysis.** The large numbers of patients on the Registry allow stratification by age, gender, and diagnosis. Survival of populations can then be adjusted to a standard age and diagnosis mix. This permits some comparison of survival between renal units, presented here for the first time.

**Clinical practice and survival.** Standard adjustment of risk factors, together with the quarterly serial collection of intermediate markers of clinical outcome from all individuals on the Renal Registry, facilitate analysis of factors which may influence survival, such as haemoglobin concentration, serum phosphate control, blood pressure control. This will inform units where to focus their clinical activity to best advantage. Several such analyses are presented in this report

**Audit and Quality Assurance.** A major current issue is the quality assurance (QA) of clinical outcomes and the performance of Renal Units in clinical and cost effectiveness. With the collection of serial clinical data the Registry is in a unique position to contribute to such clinical and comparative audit.

The UKRR relies on large numbers (fifteen thousand patients) to achieve a rapid publication of 'good enough' material, sufficient at least to generate hypotheses, raise questions and display current trends. Experience has confirmed the practicality of near complete data capture on large patient numbers, with presentation as distributions that vary widely in absolute terms but, as is demonstrated in this report, that also show an impressive uniformity of range/dispersion. Distributions are generally stable unless a major effort has been made to influence clinical outcomes. The data are able to confirm improvement or deterioration

against a backdrop of random variation. They indicate the necessary scope of changes required to meet official standards and demonstrate de facto compliance or the possibility of compliance. They illustrate the gaps between desirable and achieved outcomes and indicate the likely cost and effort of bridging them.

**UK Renal Registry focus on individuals.** The need for the clinician to maintain a focus on the individual as well as the cohort is important to recognise in Registry work as well as in clinical practice. Serial data analysis of individuals may show marked oscillation of results, as demonstrated in the haemoglobin data, when the cohort may be apparently stable. The individual’s position in the cohort a diagnostic tool able to reveal otherwise covert needs for clinical attention.

**Difficulties**

There are difficulties. The UKRR data are of uncertain quality for Unit comparison because laboratory harmonisation is incomplete. Correction of values like serum calcium is controversial. Further exercises to validate the data collected are needed. More work is necessary to improve these issues, but at least the problems have been rendered apparent. The ‘maturity’ of Renal Unit patient cohorts must also vary, so that in most cases current data are indicative rather than definitive for comparative purposes. Data protection rules may yet threaten the exercise. Having said all of that, the comparison of different Units opens up the area of QA and prepares the ground for improvement.

**Integration with the audit cycle.**

The UK Renal Registry is part of the renal audit cycle as shown. With the presentation of this registry data to the renal community, the challenge to nephrologists is to find effective and creative ways to use the data in the implementation part of the cycle, in order to improve clinical practice

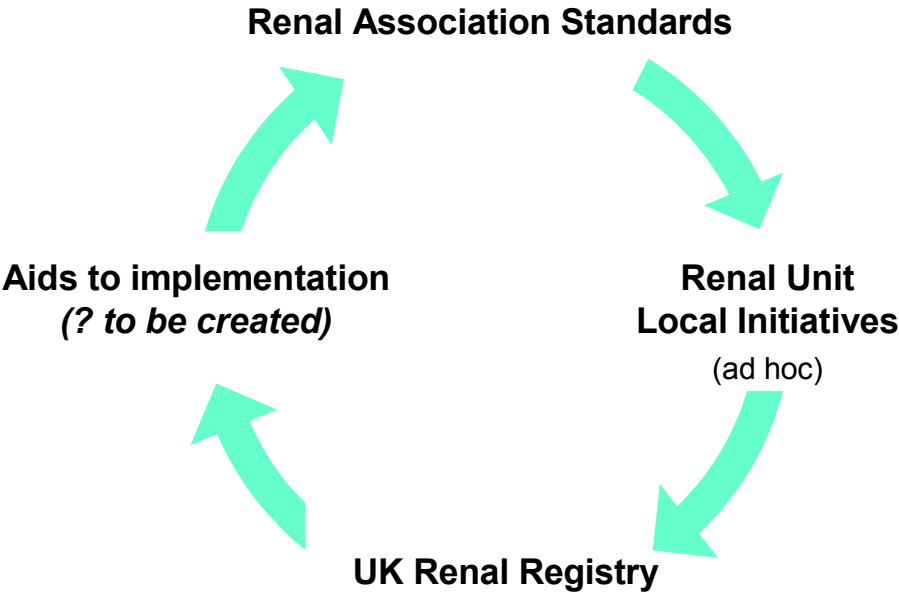


Figure 2.1 Renal Registry audit cycle

## **Area covered by the Renal Registry.**

The 2000 UK Renal Registry report refers to activity in 1999 and covers 47% of the UK adult population, and all paediatric renal replacement activity. In total 35 renal units have contributed to the report, including all 11 adult renal units in Scotland and 23 of the 63 Units (37 %) in England and Wales (Table 2.1). The English and Welsh units cover 43% of the population of 52.2 million.

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

<b>England &amp; Wales</b>		<b>Population (millions)</b>
	<b>Total</b>	<b>22.5</b>
Birmingham	Heartlands Hospital	.60
Bristol	Southmead Hospital	1.50
Carlisle	Cumberland Infirmary	.32
Carshalton	St Helier Hospital	1.80
Cardiff	University of Wales Hospital	1.30
Coventry	Walsgrave Hospital	.85
Exeter	Royal Devon and Exeter Hospital	.85
Gloucester	Gloucester Royal Hospital	.55
Hull	Hull Royal Infirmary	1.02
Leeds	St James's Hospital	1.45
Leicester	Leicester General Hospital	1.80
Middlesbrough	South Cleveland Hospital	1.00
Nottingham	Nottingham City Hospital	.86
Oxford	Churchill Hospital	1.80
Plymouth	Derriford Hospital	.45
Preston	Royal Preston Hospital	1.6
Sheffield	Northern General Hospital	1.75
Stevenage	Lister Hospital	1.25
Stourbridge	Wordsley Hospital	.42
Southend	Southend Hospital	.35
Sunderland	Sunderland Royal Hospital	.34
Wolverhampton	Newcross Hospital	.35
Wrexham	Maelor General Hospital	.32
<b>Scotland</b>	<b>Total</b>	<b>5.10</b>
Aberdeen	Aberdeen Royal Infirmary	
Airdrie	Monklands District General Hospital	
Dunfermline	Queen Margaret Hospital	
Dumfries	Dumfries & Galloway Royal Infirmary	
Dundee	Ninewells Hospital	
Edinburgh	Royal Infirmary	
Glasgow	Glasgow Royal Infirmary	
	Stobhill General Hospital	
	Western Infirmary	
Kilmarnock	Crosshouse Hospital	
Inverness	Raigmore Hospital	

Table 2.1 Participating adult centres

The 12 renal units in Table 2.2 have already joined the Registry (software completed) and a further 7 indicated in Table 2.3 are in the process of joining

Bradford	Bradford Royal Infirmary	.60
Canterbury	Kent and Canterbury -Velos system	
Liverpool	Royal Infirmary	1.75
Leeds	Leeds General Infirmary	.75
London	Guys and St Thomas Hospital	
London	St Mary's Hospital	.64
Portsmouth	St Mary's Hospital	2.00
Reading	Royal Berkshire Hospital	
Rhyl	Ysbyty Clwyd (via Liverpool)	
Swansea	Morrison hospital	.70
Truro	Royal Cornwall Hospital	
York	York District Hospital	.25

**Tables 2.2 New units joined the Registry since the Report**

The following centres are in the process of being connected

Bangor	Ysbyty Gwynedd -Baxter system	
Ipswich	Ipswich Hospital -Baxter system	
Derby	Derby City Hospital	
London	Kings College Hospital (own system)	.81
London	Royal Free (own system)	
London	St Georges (own system)	
Newcastle	New CCL system	

**Tables 2.3 Renal units joining the Registry**

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

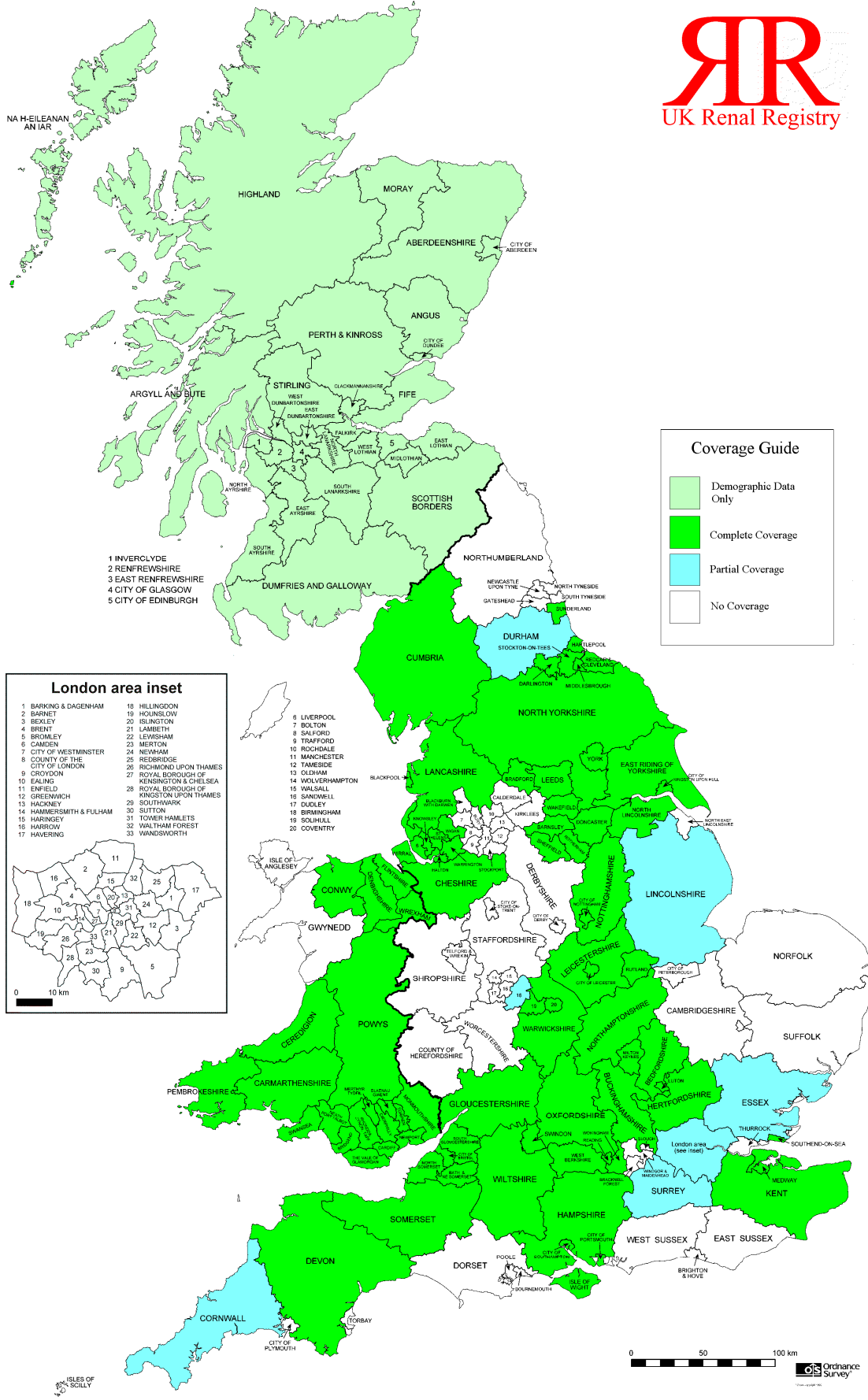


Figure 2.2 Coverage of the Renal Registry

## ***The independence of the UK Renal Registry***

The UK Renal Registry is managed by a sub-committee of the Renal Association. The Renal Association established the UK Renal Registry, with support from the Department of Health, the British Association for Paediatric Nephrology, and the British Transplantation Society. Each of these organisations has representatives on the Registry sub-committee. The Registry has close links with the Scottish Renal Registry. The initial development of the Registry was financed by grants from the Department of Health and from industry. Continuing activity is largely funded through payment by participating renal units of an annual fee per patient registered. In this way the Registry will be able to remain an independent source of data and analysis on national activity in renal disease. The Department of Health and Industry continue to give additional generous support.

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

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

## ***Anonymity and confidentiality***

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

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

## ***Statistical Interpretation of the Report***

In this years report the 95% confidence interval is shown for compliance within a Standard. Calculation of this confidence interval takes into account the number of patients within the Standard and the number of patients with data.

To assess whether there is overall significant variation among the percentage reaching the Standard between centres, a chi-squared test has been used. Caution should be used when interpreting "no overlap" of 95% confidence interval between centres in 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 interval do not overlap. In this process the eye compares centre X with the other 18 centres and then centre Y with the other 17 centres. Thus 35 comparisons have been made and in any comparison at least 2 are likely to be "statistically significant" by chance, at the commonly accepted 1 in 20 level. If 19 centres were compared with one another, then 171 individual comparisons would be made, and one would expect to find 9 "statistically significant" differences. To test for significance



between individual centres to see where the differences lie would require multiple testing in this way and therefore was not performed by the Registry.

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

### ***Distribution of Report***

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

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

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



## **Chapter 3: The 1999 UK Renal Survey - adult patient numbers, renal unit facilities and processes of care**

A survey to document the provision of renal care in the United Kingdom to the end of 1998 was commissioned and funded by the Department of Health and was conducted in collaboration with the UK Renal Registry.

This is the first survey of the provision of Renal Replacement Therapy (RRT) throughout the whole UK. Data were obtained from all the renal units functioning on 31/12/98. The survey complements the data from the Renal Registry. The Registry provides indicative information on treatment rates in the UK, albeit from only a sample of the population, but it does not provide detailed information on the facilities available to provide renal replacement therapy.

In the UK, the cost of RRT consumes 2% of the NHS budget and this is predicted to reach 3% within five years. In the USA, the annual cost is estimated to be in excess of \$15 billion<sup>1</sup>. For health care planning purposes it is clearly important to have a clear understanding of changes in this high cost therapy, and to ensure that there is equity of access to care throughout the UK. Hence this further review of RRT in the UK was commissioned.

During the last ten years there has been a continuing substantial increase in the number of patients receiving Renal Replacement Therapy (RRT) in the UK. The 1993 National Renal Review returned a figure for England of 396 people per million population (p.m.p.)<sup>2</sup>; the report of 1995 returned 476 p.m.p.<sup>3</sup>, and the number is currently estimated to be over 520 p.m.p.<sup>4</sup> Similar trends have been observed in Wales<sup>4</sup> and Scotland<sup>5</sup>. Prevalence in the USA is 909 p.m.p.<sup>1</sup> The acceptance rate of new patients requiring RRT is rising throughout the world: in the UK there has been more than a four-fold increase since 1980<sup>3</sup>.

As patient numbers increase, facilities for renal care will have to change in both volume and pattern of provision. Earlier surveys<sup>2,3</sup> showed the proportion of patients on haemodialysis to be increasing, and that the number of main renal units remained stable between 1993 and 1995. There was an increase in the haemodialysis treatment shifts, number of permanent dialysis stations, and temporary haemodialysis stations, and a major increase of satellite units.

The demographic data from the UK Renal Registry was compared with the data from this survey of 100% of renal units to assess how representative the Registry is of the UK as a whole.

### **Methods**

A questionnaire was sent to all adult renal units in the United Kingdom. Scotland and Northern Ireland were included in the survey for the first time. Information was sought on numbers and grades of medical and nursing staff, structure of care, some key processes of treatment including bicarbonate dialysis and disconnect catheter for peritoneal dialysis), numbers of prevalent patients (stock) at the end of 1998, new patients accepted on to RRT 1996-98, and the number of transplants performed 1996-98. Information was also sought on the number of patients on erythropoietin treatment and the number of patients on RRT who were Hepatitis B and Hepatitis C positive.

The questionnaires were first distributed in January 1999. Initial responses were slow and patchy and it was necessary to resend the questionnaire to many units. In over half the units, missing items of data, especially on details of staffing, were obtained by subsequent telephone contacts which were often multiple. Two units needed a site visit in order to obtain the data. The final validated data were not complete until August 2000. Eventually data were obtained from all the 71 identified renal units in the U.K.

The data were entered onto an Excel spreadsheet and analysed using this and SAS software. The office for National Statistics (ONS) mid-year population estimates for England and Wales and the mid-year population estimates published by the Registrar General for Scotland were used to calculate the population denominators for the acceptance and prevalence per million population rates. 95% confidence intervals are shown for the acceptance rates, prevalence rates and some of the process measures. To determine whether the variations in acceptance and prevalence rates were statistically significant between England, Wales, Scotland and Northern Ireland, Poisson regression analysis was used.

Consultant staff Whole Time Equivalent (WTE) were based on the total number of sessions divided by a weighted average of total sessions reported. Renal unit directors were telephoned and asked the number of sessions of each consultant dedicated to nephrology. WTE estimations were not made for junior medical staff.

Data were compared with those collected for the 1993 National Renal Review, and 1995 national survey and with data obtained by the UK Renal Registry and the Scottish Renal Registry. Any discrepancies with data held by the registries were carefully investigated in what proved to be a useful validation process.

Individual unit's responses are shown by region in the appendix.

### ***New patients starting renal replacement therapy***

The acceptance rate for new adult patients in the UK is 96 per million population and the data are shown in Table 3.1. There was a significant variation between the acceptance rates pmp in England, Wales, Scotland and N. Ireland ( $p < 0.0001$ , Poisson regression) with the rate lowest in England at 92 p.m.p. Given the larger ethnic minority population in England a higher rate would have been expected, suggesting there may be unmet need there. The acceptance rate is progressively rising (table 2), as is the proportion of new patients who are over 65 years of age (47%) or diabetic (19%)

	England	Wales	Scotland	N. Ireland	Total UK
No of renal units	52	5	11	3	71
Patient numbers	4,566	374	536	181	5,657
Unit median (range)	79 (28-228)	49 (35-147)	53 (19-86)	N/A	70 (19-228)
Acceptance rate pmp (95% CI)	92 (90-95)	128 (115-141)	105 (96-114)	107 (92-124)	96 (93-98)

**Table 3.1 Acceptance data for new patients accepted onto RRT in 1998**

## Changes in acceptance rates in England and Wales 1993-1998

The acceptance rates in the UK have steadily risen as is shown in Tables 3.2 and 3.3.

Acceptance data:	England	Wales	Scotland*
1991/2 patient numbers	3,247	-	317
1991/2 rate pmp	67	-	62
Unit median (range)	60 (15-138)	-	-
No. of units with complete data	52	-	11
1993 patient numbers	3,197	275	404
1993 rate pmp	73	95	79
Unit median (range)	64 (7-158)	25 (21-134)	-
No. of units with complete data	46	5	11
1994 patient numbers	3,371	308	388
1994 rate pmp	77	106	76
Unit median (range)	63 (4-169)	29 (20-142)	-
No. of units with complete data	47	5	11
1995 patient numbers	3,726	318	445
1995 rate pmp	82	109	87
Unit median (range)	72 (11-163)	27 (20-152)	-
No. of units with complete data	49	5	11
<b>1998 patient numbers</b>	<b>4,566</b>	<b>374</b>	<b>536</b>
<b>1998 rate pmp</b>	<b>92</b>	<b>128</b>	<b>105</b>
Unit median (range)	79 (28-228)	49 (35-147)	53 (19-86)
No of renal units	52	5	11

\* Pre 1998 data from Scottish renal registry

**Table 3.2 Acceptance rate for new patients on RRT 1993-1998 in the UK**

In the 1993 National Renal Review the annual acceptance rate for 1991/2 was quoted originally as 65 p.m.p rather than the rate quoted above at 67 p.m.p. In the 1993 review, individual patient data were used to produce the acceptance rates; all patients not resident in England (including Welsh & Scottish patients), under 16s, and duplicate records were excluded.

	% over 65	% diabetic
1976-78 (UK)	1	2
1982-84 (UK)	11	8
1986-88 (UK)	23	12
1991-92 (England)	37	14
1995 (England and Wales)	39	15
1998 (UK)	47	19

Sources: EDTA 1976-1988, National Renal Surveys 1991-1998

**Table 3.3 Changing profile of patients accepted onto RRT in the UK**

## **Prevalent patients receiving renal replacement therapy 31/12/98**

The UK is now treating over 30,000 patients with end stage renal failure, at a rate of 526 per million population (table 3.4). There was significant variation between the prevalence rates p.m.p. in England, Scotland, Wales and Northern Ireland ( $p < 0.0001$ , Poisson regression). England has a significantly lower rate than either Wales or Scotland. The quoted prevalence for Scotland is marginally lower than that quoted in the Scottish Renal Registry report. The Scottish Registry figures included paediatric patients.

	<b>England</b> 1998	<b>Wales</b> 1998	<b>Scotland</b> 1998	<b>N. Ireland</b> 1998	<b>Total UK</b> <b>1998</b>
No. of units	52	5	11	3	<b>71</b>
Patient numbers	25,892	1,716	2,798	741	<b>31,147</b>
Rate pmp (95% CI)	523 (517-530)	585 (558-613)	546 (526-567)	439 (408-472)	<b>526 (520-532)</b>
Haemodialysis	7,788 (30%)	451 (26%)	976 (35%)	356 (48%)	<b>9,571 (31%)</b>
Home haemodialysis	516 (2%)	17 (1%)	69 (2%)	0	<b>602 (2%)</b>
Peritoneal dialysis	5,101 (20%)	301 (18%)	441 (16%)	84 (11%)	<b>5,927 (19%)</b>
Transplants	12,487 (48%)	947 (55%)	1,312 (47%)	301 (41%)	<b>15,047 (48%)</b>
Total patients	25,892	1,716	2,798	741	<b>31,147</b>

**Table 3.4 UK Patients receiving Renal Replacement Therapy – Dec 31 1998**

The predominant modality of dialysis is hospital-based haemodialysis. The proportions of haemodialysis to peritoneal dialysis patients are similar in England and Wales, but in Scotland and Northern Ireland there is a considerably greater use of haemodialysis therapy.

## **Changes in prevalence 1993-1998**

The changes in the numbers and distribution of prevalent patients in England from 1993 to 1998 and in Wales from 1995 to 1998 are shown in Table 3.5. The trend in England is also illustrated in Figure 3.1. The general pattern is for the greatest absolute and proportional increase to be in unit based haemodialysis (including satellite unit dialysis). Whilst the numbers transplanted and on PD continue to rise, the growth is much less than in haemodialysis, producing proportional falls in these modalities. The proportion of transplant patients in Wales appears to be rising, even in the face of the high acceptance rate for renal replacement therapy.

	<b>England</b> 1993	<b>England</b> corrected 1995	<b>England</b> <b>1998</b>	<b>Wales</b> 1995	<b>Wales</b> <b>1998</b>
No. of units	52	51	<b>52</b>	5	<b>5</b>
Patient numbers	19,212	22,322*	<b>25,892</b>	1,560	<b>1,716</b>
Rate pmp	396	458	<b>523</b>	535	<b>585</b>
Haemodialysis	3,899 (20%)	5,383(24%)	<b>7,788 (30%)</b>	388 (27%)	<b>451 (26%)</b>
Home haemodialysis	806 (4%)	725 (3%)	<b>516 (2%)</b>	33 (2%)	<b>17 (1%)</b>
Peritoneal dialysis	4,340 (23%)	4,880(22%)	<b>5101 (20%)</b>	314 (22%)	<b>301 (18%)</b>
Transplants	10,167 (53%)	11,334 (51%)**	<b>12,487 (48%)</b>	685 (48%)	<b>947 (55%)</b>
Total patients	19,212	22,322	<b>25,892</b>	1,420	<b>1,716</b>

\* Includes estimated data from the two missing units in England.

\*\* Error in transplant data 1995 corrected from 1995 national review.

**Table 3.5 Patients receiving RRT in England (1993-1998) & Wales (1995-98)**

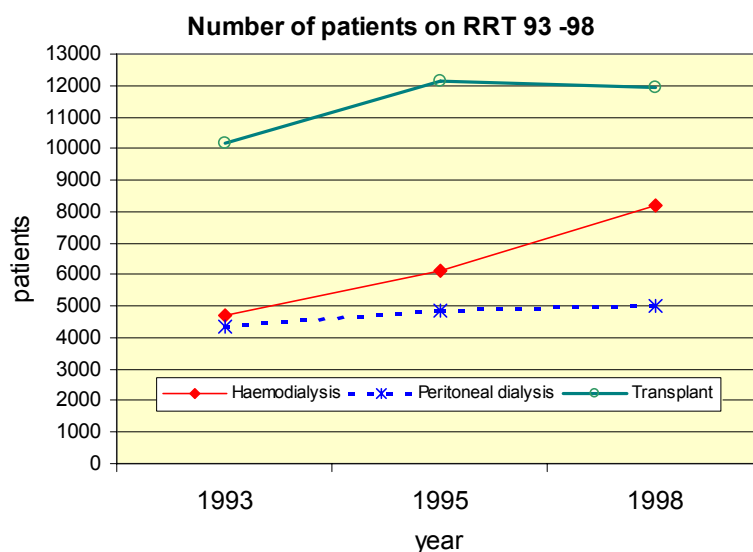


Figure 3.1 Number of patients on each modality - England 1993-98

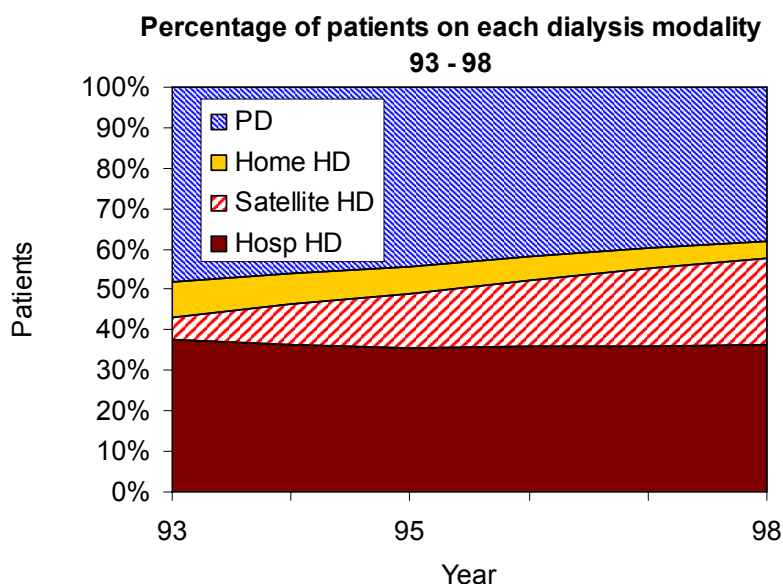


Figure 3.2 Change in patients on dialysis modality 93-98

The area of greatest proportional growth is satellite-based haemodialysis (Figure 3.2). 36% of haemodialysis stations and 31% of haemodialysis patients are now in satellite units.

### Renal unit facilities

Renal unit facilities at the end of 1998 are summarised in Table 3.6. "Temporary" haemodialysis stations were defined as stations which were not part of an agreed establishment with the commissioners, but had been temporarily created to deal with excessive patient loads. These were usually in in-patient areas. 5% of haemodialysis was carried out in such facilities although there were no temporary stations in Wales. Of permanent haemodialysis stations, 38% were in satellite units. The large variation in patterns

of care is illustrated by wide variation in the number of haemodialysis stations per renal unit (6-55) or satellite unit (2-41) (Tables 3.6 and 3.7).

	<b>England</b>	<b>Wales</b>	<b>Scotland</b>	<b>N. Ireland</b>	<b>Total UK</b>
Main renal units	52	5	11	3	71
Units per million population	1.1	1.7	2.1	1.8	1.2
<b>Total beds</b>	1,210	93	195	44	<b>1,542</b>
Unit no of beds median (range)	22 (0-64)	15 (0-38)	17 (0-35)	16 (4-24)	<b>22 (0-64)</b>
Beds per million population	24	32	38	26	<b>26</b>
<b>Haemodialysis</b>					
Unit no of fixed stations median (range)	19 (7-55)	16 (10-23)	18 (9-39)	16 (6-40)	<b>18 (6-55)</b>
Fixed stations	1021	83	210	62	<b>1376</b>
Satellite stations (proportion of satellite to total number of stations)	761 (40%)	47 (36%)	24 (9%)	10 (14%)	<b>842 (36%)</b>
Temporary stations	108	0	13	2	<b>123</b>
Total HD stations	1,890	130	247	74	<b>2,341</b>
Stations per million population	38	44	48	44	<b>40</b>
Ratio Hospital: Satellite stations	1.5:1	1.8:1	9.3:1	6.4:1	<b>1.8:1</b>
<b>HD shifts / week</b>					
Unit median (range)	891	69	175	48	<b>1,183</b>
Unit median (range)	18 (12-24)	12 (12-18)	18 (12-19)	18 (12-18)	<b>18 (12-24)</b>

**Table 3.6 Renal unit facilities in the UK – 31/12/1998**

<b>Satellite units:</b>	<b>England</b>	<b>Wales</b>	<b>Scotland</b>	<b>N. Ireland</b>	<b>Total UK</b>
Current satellites	73	4	5	1	<b>83</b>
No. units with current satellites	36	2	3	1	<b>42</b>
range per renal unit	0-5	0-3	0-2	0-1	<b>0-5</b>
Planned new satellites	28	2	5	0	<b>35</b>
No. Units with planned satellites	25	2	4	0	<b>31</b>
No. of units without satellites planning to start a satellite centre	7	1	3	0	<b>11</b>
Total patients in satellite units	2,847	194	102	39	<b>3,182</b>
Median per satellite (range)	35 (6-160)	49 (36-60)	16 (3-52)	39	<b>36 (3-160)</b>
Total HD stations in satellite unit	761	47	24	10	<b>842</b>
Median per satellite (range)	8 (3-41)	13(9-13)	4 (2-9)	10	<b>9 (2-41)</b>

**Table 3.7 Satellite dialysis units in the UK – 31/12/1998**

### **Changes in renal facilities in England and Wales 1993-1998**

Despite the large growth in patient numbers there has been no increase in the number of renal units in England and Wales between 1993 –1998 (Table 3.7). The number of renal units per million population is lower in England (1.1) than in Scotland (2.1), Wales (1.7) or Northern Ireland (1.8) (Table 3.6). The expansion in patient numbers has been accommodated by increasing the number of haemodialysis stations available within main renal units (from 932 stations in 1993 to 1890 stations in 1998) and the number of shifts worked. In England and Wales there has also been a massive expansion of satellite unit provision accounting for 35%



of haemodialysis, with an expansion both in the numbers (8%) and size (75% increase in number of stations) since 1995 (Tables 3.7, 3.8, 3.9).

	England 1993	England 1995	England 1998	Wales 1995	Wales 1998
Main renal units	52	51*	52	5	5
Total HD stations	932	1,423	1,890	97	130
Unit no fixed of stations median (range)	15 (3-55)	23 (7-86)	19 (7-55)	13 (10-35)	16 (10-23)
Fixed stations	743	832	1021	65	83
Satellite stations	189	472	761	28	47
Temporary stations	N/A	119	108	4	0
HD shifts / week	694	856	891	62	69
Unit median (range)	12 (0-31)	18 (8-35)	18 (12-24)	16 (12-18)	12 (12-18)

\* Facilities data based on returns from 50 renal units with 2 unit missing

**Table 3.8 Changes in renal unit facilities in England 1993-98 and Wales 1995-98**

<b>Satellite units:</b>	England 1993	England 1995	England 1998	Wales 1995	Wales 1998
Current satellites	36	60	73	3	4
No. units with satellites	17	30	36	2	2
range per unit	1-6	1-5	1-5	1-2	1-3
Planned satellites	14	37	28	5	2
No. units with planned satellites	9	28	25	5	2
No. of planned satellites where unit has no existing satellites	5	8	7	1	1
Total patients in satellite units	476	1476	2,847	64	194
Median per satellite (range)	15 (1-41)	24 (1-68)	35 (6-160)	32 (25-39)	49 (36-60)
Total HD stations in satellite unit	189	472	761	28	47
Median per satellite (range)	6 (2-10)	7 (2-31)	8 (3-41)	8 (6-14)	13 (9-13)

**Table 3.9 Changes in satellite haemodialysis provision in England & Wales**

In England whilst the number of haemodialysis patients has doubled, there has been no increase in the number of renal units, they have simply become larger, by nearly 40%. The number of satellite units has doubled in England between 1993 and 1995 with a trebling of the number of haemodialysis stations available in them.

### **Staffing in renal units**

Details of staffing in renal units are shown in Tables 3.10, 3.11 and 3.12. Relating the changes in whole time equivalent (WTE) staffing in England to the changes in patient numbers, there has been very little change in the ratio of renal replacement therapy patients or dialysis patients per consultant nephrologist. The ratio of one consultant nephrologist per 70 dialysis patients has remained unchanged in England since 1993. Northern Ireland had one nephrology consultant WTE per 55 dialysis patients whereas Scotland (82), England (95) and Wales (113) had less number of consultants WTE per dialysis patient. Scotland had a higher

ratio of trained to untrained nursing staff (7.2) than England (2.6) and Wales (2.5). We also observed a higher proportion of non-consultant grade physicians in Wales.

	England	Scotland	Wales	N. Ireland	<b>UK</b>
	1998	1998	1998	1998	<b>1998</b>
<b>Consultant nephrologists:</b>					
Numbers	192	33	12	9	<b>246</b>
Number p.m.p.	3.9	6.4	4.1	5.3	<b>4.2</b>
No. of units	52	11	5	3	<b>71</b>
Average per unit	3.7	3.0	2.4	3	<b>3.5</b>
WTE nephrology*	139.7	18.1	6.8	7.9	<b>172.5</b>
WTE p.m.p.	2.8	3.5	2.3	4.7	<b>2.9</b>
<b>Transplant surgeons:</b>					
Numbers	69	12	3	1	<b>85</b>
Number p.m.p.	1.4	2.3	1.0	0.6	<b>1.4</b>
No. of units	24	3	1	1	<b>31</b>
WTE transplant surgeons**	35.8	3.5	2.1	1.1	<b>42.5</b>
WTE p.m.p.	0.7	0.7	0.7	0.7	<b>0.7</b>
<b>Associate specialists:</b>					
Staff Grade	13	1	5	0	<b>19</b>
Clinical Assistants	18	8	1	0	<b>27</b>
Senior Registrars/Lecturers	7	0	2	0	<b>9</b>
Clinical Research Fellows	9	1	0	1	<b>11</b>
Registrars/Lecturers	49	8	0	2	<b>59</b>
Senior house officers	117	15	8	2	<b>142</b>
House officers	144	25	11	6	<b>186</b>
	35	4	3	3	<b>45</b>

\* renal units varied in the number of sessions included in a full time week - 10.64 sessions was taken as the weighted average.

\*\* transplant units varied in the number of sessions included in a full time week -10.43 sessions was taken as the weighted average.

**Table 3.10 Medical staffing in renal units in the UK 1998**

	England	Scotland	Wales	N. Ireland	UK
<b>Nursing Staff:</b>					
WTE	1555.6	422	74.8	87.4	2139.8
WTE per million population	31	82	26	52	36
No. of units	52	11	5	3	71
Median (range)	22 (9.5-142.8)	3 (10.7-108)	14 (11-20.8)	15 (11-61.4)	21.6 (9.2-142.8)
% of nurses with ENB qualification	53%	NA	49%	46%	52%
Ratio of nurses to main unit HD patients	0.3	0.5	0.3	0.3	0.5
Ratio of nurses to non nursing trained staff	2.6	7.2	2.5	4.6	3
<b>Non nursing trained staff:</b>					
WTE	606.6	58.5	30	19	714.1
WTE per million population	12	11	10	11	12
No. of units	52	11	5	3	71
Median (range)	8.2 (0-76.9)	5.8 (0-12)	5 (3-10)	5.8 (0-12)	8 (0-76.9)

	England	Scotland	Wales	N. Ireland	UK
Dieticians numbers WTE	88.4	14.3	5.5	4.2	112.4
No. of units	52	11	5	3	71
Average per unit	1.7	1.3	1.1	1.4	1.6
Social workers numbers WTE	42.6	5.4	3.8	3.1	54.9
No. of units	52	11	5	3	71
Average per unit	0.8	0.5	0.8	1	0.8
Technicians numbers WTE	150	21.5	8	8.3	187.8
No. of units	52	11	5	3	71
Average per unit	2.9	2	1.6	2.8	2.6

**Table 3.11 Professions allied to medicine staffing in the UK 31/12/1998**

### **Changes in staffing in England and Wales 1993-1998**

	England 1993	England 1995	England 1998	Wales 1995	Wales 1998
<b>Consultant nephrologists:</b>					
Numbers	129	151	<b>192</b>	11	<b>12</b>
No. of units	52	50	<b>52</b>	5	<b>5</b>
Average per unit	2.5	3.0	<b>3.7</b>	2.2	<b>2.4</b>
WTE nephrology*	-	98.4	<b>139.7</b>	5.5	<b>6.8</b>
<b>Transplant surgeons:</b>					
Numbers	60	55	<b>69</b>	2	<b>3</b>
No. of units	28	24	<b>24</b>	1	<b>1</b>
WTE transplant surgeons <sup>s</sup>	-	24.4	<b>35.8</b>	1.4	<b>2.1</b>
Associate specialists	8	9	<b>13</b>	3	<b>5</b>
Staff Grade	8	15	<b>18</b>	2	<b>1</b>
Clinical Assistants	13	13	<b>7</b>	5	<b>2</b>
Senior Registrars/Lecturers	37	36	<b>9</b>	2	<b>0</b>
Clinical Research Fellows	25	35	<b>49</b>	0	<b>0</b>
Registrars/Lecturers	62	70	<b>117</b>	4	<b>8</b>
SHOs	122	131	<b>144</b>	10	<b>11</b>
HO	29	27	<b>35</b>	2	<b>3</b>
<b>Dieticians numbers WTE</b>	-	70.5	<b>88.4</b>	5	<b>5.5</b>
No. of units	-	49	<b>52</b>	5	<b>5</b>
Average per unit	-	1.4	<b>1.7</b>	1	<b>1.1</b>
<b>Social workers numbers WTE</b>	-	32.9	<b>42.6</b>	2.7	<b>3.8</b>
No. of units	-	49	<b>52</b>	5	<b>5</b>
Average per unit	-	0.7	<b>0.8</b>	2.7	<b>0.8</b>
<b>Technicians numbers WTE</b>	-	156.5	<b>150</b>	11	<b>8</b>
No. of units	-	49	<b>52</b>	5	<b>5</b>
Average per unit	-	3.2	<b>2.9</b>	2.2	<b>1.6</b>

\* Units varied in the number of sessions included in a week - 10.65 sessions was taken as the weighted average for 1995 and 10.64 for 1998.

\*\* Transplant units varied in the number of sessions included in a week -10.62 sessions was taken as the weighted average for 1995 and 10.43 for 1998.

**Table 3.12 Changes in staffing in renal units in England & Wales 1993-8**

## Processes of care

Some information on processes of care is listed in Tables 3.13-3.15. A large number of haemodialysis patients in Northern Ireland are still retained on twice weekly dialysis. The reasons for this are not clear. As reported in many other studies haemodialysis patients are more likely to need erythropoietin than peritoneal dialysis patients.

	England	Scotland	Wales	N. Ireland	UK
Process measures	1998	1998	1998	1998	1998
% of dialysis patients on hospital/satellite HD	58%	66%	59%	83%	59%
Unit median (range)	58% (30-100%)	67% (40-77%)	62% (56-69%)	N/A	61% (30-100%)
Units	52	11	5	3	71
% of HD patients on bicarbonate	99.6%	100%	98%	100%	99.6%
Unit median (range)	100% (90-100%)	100% (100-100%)	100% (94-100%)	N/A	100%(90-100%)
Units	52	11	5	3	71
% of HD patients on Erythropoietin (95% CI)	80% (79-81%)	79% (76-81%)	87% (84-90%)	87% (83-90%)	80% (80-81%)
Unit median (range)	80% (10-99%)	80% (50-99%)	88% (83-90%)	N/A	83% (10-100%)
Units	51	11	5	3	70
% of HD patients on thrice weekly	92%	99.8%	96%	65%	92%
Unit median (range)	96% (14-100%)	100% (99-100%)	99% (92-100%)	N/A	97% (14-100%)
Units	51	10	5	3	69
% of HD patients using : (95% CI)					
Standard membrane	10% (9-11%)	9% (7-11%)	0%	0%	9% (8-9%)
Modified cellulose	53% (52-54%)	47% (44-50%)	17% (14-20%)	86% (82-89%)	52% (51-53%)
Synthetic membrane	38% (36-39%)	45% (41-48%)	83% (80-87%)	14% (11-18%)	39% (39-41%)
Units	50	10	5	3	68
% of CAPD patients with disconnect (95% CI)	93% (93-94%)	100% (100-100%)	90% (86-94%)	100% (100-100%)	94% (93-94%)
Unit median (range)	100% (0-100%)	100% (100-100%)	100% (72-100%)	N/A	100% (0-100%)
Units	52	11	5	3	71
% of PD patients on Erythropoietin (95% CI)	64% (63-66%)	64% (59-68%)	56% (50-61%)	55% (44-66%)	64% (62-65%)
Unit median (range)	62% (10-100%)	60% (25-90%)	62% (29-100%)	N/A	61% (10-100%)
Units	51	10	5	3	69

HD=haemodialysis, PD =peritoneal dialysis

**Table 3.13 Process measures of dialysis care for renal units in the UK 1998**

### **Changes in processes of care in England and Wales 1993-1998**

Tables 3.14 and 3.15 show a steady improvement in the measured processes of care in England and Wales from 1993 to 1998.

Process measures	England 1993	England 1995	England 1998
% of HD patients on bicarbonate	71%	89%	99.6%
Unit median (range)	87% (0-100%)	100% (44-100%)	100% (90-100%)
Units	51	47	52
% of all dialysis patients on Erythropoietin	43%	59%	74%
Unit median (range)	42% (12-74%)	60% (25-83%)	75% (10-97%)
Units	52	48	50
% of PD patients with disconnect catheters	64%	79%	93%
Unit median (range)	79% (0-100%)	92% (0-100%)	100% (0-100%)
Units	51	46	52
% of HD patients on thrice weekly	75%	82%	92%
Unit median (range)	86% (0-100%)	90% (10-100%)	96% (14-100%)
Units	52	48	51
% of HD patients using			
standard membrane	-	29.5%	10%
modified cellulose	-	45.5%	53%
synthetic membrane	-	25%	37%
Units	-	47	50

HD=haemodialysis, PD =peritoneal dialysis

**Table 3.14 Changes in process measures of dialysis care in England 1993-1998**

Process measures	Wales 1995	Wales 1998
% of HD patients on bicarbonate	77%	98.4%
Unit median (range)	88% (58-100%)	100% (94-100%)
Units	5	5
% of all dialysis patients on Erythropoietin	48%	75%
Unit median (range)	58% (32-66%)	75% (67-92%)
Units	4	5
% of PD patients with disconnect catheters	64%	90%
Unit median (range)	100% (46-100%)	100%(72-100%)
Units	5	5
% of HD patients on thrice weekly	77%	96%
Unit median (range)	88% (53-98%)	99%(92-100%)
Units	5	5
% of dialysis patients on	52%	59%

Process measures	Wales 1995	Wales 1998
hospital/satellite HD		
Unit median (range)	56% (48-74%)	62% (56-69%)
Units	4	5
% of HD patients using		
standard membrane	44%	0%
modified cellulose	29%	17%
synthetic membrane	27%	83%
Units	4	5

HD=haemodialysis, PD =peritoneal dialysis

**Table 3.15 Changes in process measures of dialysis in Wales 1995-98**

### ***Factors restricting development of renal services***

The questionnaire contained a section requesting information on factors which had constrained what was considered necessary development to meet the needs of the local population. The replies are summarised below in Table 3.16. These constraining factors are more or less unchanged since 1995.

Constraining factor	% of units
Capital funding	77
Physical space	74
Revenue funding	70
Nursing staff	66
Access provision	43
Medical manpower	36
Surgical staff	24
Nephrology consultant recruitment	14

**Table 3.16 Constraining factors (of the responding units)**

The number of units responding to each question varied between 63 and 66.

### ***Regional Comparisons***

The prevalence and acceptance rates for patients on renal therapy in different regions in England and countries are shown in Tables 3.17 and 3.18 and illustrated in Figure 3.3. These data do not take account of cross-regional boundary flows, nor differences in the key population characteristics such as age and ethnic minority distribution.

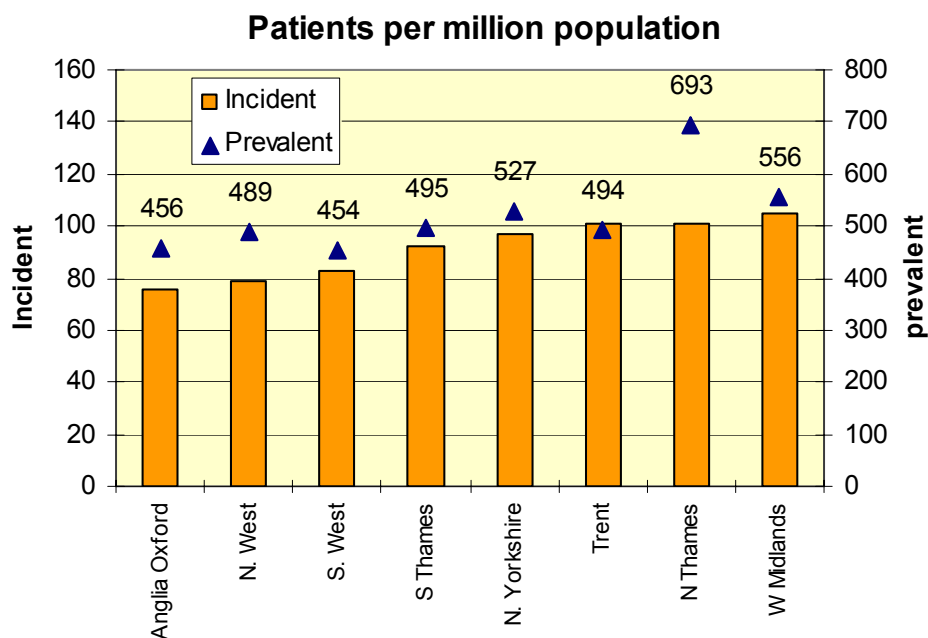
Region/Country	Acceptance (pmp)	Prevalence (pmp)
South West	83	454
Anglia Oxford	76	456
North West	79	489
S Thames	92	495
Trent	101	494

Northern Yorkshire	97	527
W Midlands	105	556
N Thames	107	693
England	92	523
Scotland	105	546
Wales	128	585
N. Ireland	107	439

**Table 3.17 Regional treatment rates 1998 pmp**

Region/Country	Acceptances (pmp)		Prevalent patients (pmp)	
	1995	1998	1995	1998
South West	72	83	381	454
Anglia Oxford	64	76	425	456
North West	84	79	441	489
S Thames	76	92	420	495
Trent	84	101	470	494
N Yorkshire	80	97	421	527
W Midlands	92	105	470	556
N Thames	105	107	608	693
<b>England</b>	<b>82</b>	<b>92</b>	<b>458</b>	<b>523</b>
<b>Wales</b>	<b>109</b>	<b>128</b>	<b>487</b>	<b>585</b>

**Table 3.18: Changes in regional treatment rates p.m.p. 1995-8**



**Figure 3.3 Incidence and prevalence rates (p.m.p.) of RRT patients by region**

Some comparisons between regions in the facilities for dialysis are shown in Table 3.19. There are considerable disparities, which are not easily explained on the basis of age distribution or ethnic mix.

	<i>Unit s</i>	<i>Satellit es</i>	<b>HD stations* pmp (Main units)</b>	<b>HD stations pmp (Satellite units)</b>	<b>WTE consultant Nephrologist pmp</b>
South West	7	13	18	16	2.8
Anglia Oxford	5	4	16	7	1.8
N Thames	8	11	33	26	3.4
S Thames	6	7	22	8	3.5
N Yorkshire	10	11	27	12	2.9
North West	5	13	15	16	2.6
Trent	4	7	23	13	2.2
W Midlands	7	7	28	24	3.4
England	52	73	23	15	2.8
Wales	5	4	28	16	2.3
Scotland	11	5	44	5	3.5
N. Ireland	3	1	38	6	4.7

*\*figure includes temporary stations*

**Table 3.19 Regional rates of supply of RRT facilities and staff 31/12/1998**

## ***Prevalence of hepatitis in patients on renal replacement therapy.***

### ***Hepatitis C***

Renal units reported they had between 0% and 7% of patients as hepatitis C positive. Overall less than 2% of renal replacement therapy patients in the UK are hepatitis C positive.

### ***Hepatitis B***

Renal units reported they had between 0 and 5% of patients as hepatitis B antigen positive, with the large majority having no positive patients. Overall less than 1% of UK patients on renal replacement therapy are hepatitis B positive.



## **Discussion**

There have been significant trends in the type of patients being treated by RRT with more patients being treated who are elderly and/or with co-morbidity.

The prevalent patients alive on renal replacement therapy seems to be growing at around 4-6% per annum. In England the absolute and relative growth rate is greatest for haemodialysis patients, especially in satellite units. Of the 3599 increased number of haemodialysis patients from 1993 to 1998, 66% were in satellite units. This is 37% of the total increase in RRT patients. Whilst home haemodialysis is still declining, home based therapy, which included most forms of peritoneal dialysis, still contributes a substantial proportion of the total (40%) (Table 3.3). With the growth of satellite units, which provide treatment nearer to patient's homes, treatment may be generally more convenient for patients.

The proportion of patients with a functioning transplant has fallen to below 50% for the first time. The proportion of patients with a functioning renal transplant is the result of the balance between the rate of renal transplantation and the rate of acceptance of new patients. Organ donor rates in the UK have fallen slightly in recent years with 7% less cadaveric transplants in 1998 than in 1997. Although there has been a 40% increase in live donor renal transplantation from 1997 to 1998, the overall renal transplant rate has declined by 2%.

The size of renal units varies considerably (Table 3.6). In Scotland there are more units per million population, possibly as a result of a widely scattered population. The size of satellite units is highly variable (Table 3.7). The pattern of care in satellite units varies considerably, from units which have near permanent medical attendance to those which have infrequent regular visits from a doctor. Over half the main renal units now have satellite haemodialysis units (42/71), with more planned, such that 53 of the 71 units should have satellites within three or four years. The planned expansion of satellite units reported in 1995 has not been fully realised. Only 14 of the 33 satellite units then planned came to fruition in the subsequent three years. This major growth area of dialysis has never been systematically studied, but is currently the subject of review in a project funded by the Department of Health's Health Technology Assessment R&D scheme and carried out with support from the Renal Registry.

Some satellites, especially in England, are larger than many main renal units, with up to 41 dialysis stations. It may not be appropriate for such large units to remain without full support. The NHS may need to consider employing additional nephrologists to establish these large satellites as independent renal units.

Relating the changes in WTE staffing in England to the changes in dialysis patient numbers, there has been very little change in the ratio of dialysis patients per consultant, but the number of non-consultant grade nephrology staff has not risen proportionately (Table 3.20). However the patients now being treated are older, with more co-morbidity and consume more time than those being treated in the early 90's. Furthermore it was demonstrated that nephrology staffing in the UK in 1991 lagged well behind that in other developed countries.

There does not appear to have been any significant catch up since then. It appears that Scotland has more nephrologists per million population than England or Wales (Table 3.10).

	1993	1998	% increase
Consultant nephrologists	129	192	49
Non-Consultant nephrologists	29	38	31
Trainee nephrologists	99	126	27
Dialysis Patients	9,045	13,405	48

**Table 3.20 Changes in patient number and medical staff in England 1993-98**

There were no sequential data available on nursing staff. The 1995 review did show qualitatively that nursing shortages were a major barrier to expansion, and this survey shows that this is now an even greater problem.

From the information on processes of care in Tables 3.13, 3.14, and 3.15 it can be seen that there is a welcome shift towards evidence based practice, with use of bicarbonate haemodialysis and disconnect peritoneal dialysis. The shift from standard cuprophane and cellulose membranes to synthetic membranes reflects the increasing evidence that synthetic membranes induce less inflammatory response, and are likely to lead to a reduction in some of the long-term complications of dialysis, particularly joint and other problems related to dialysis amyloid.

The regional variation in acceptance and stock rates seen in Tables 3.17 and 3.18 should be interpreted with caution as some regions, such as London with high ethnic minority groups, or others with a disproportionately elderly population, would be expected to have higher treatment rates than others. The provision of facilities per million population (Table 3.19) also shows considerable variation. This partly reflects historical patterns of development of renal services but over time provision should become more in line with population need.

Individual renal units appear to be working at a faster pace with more shifts per day, and rising numbers of patients in both satellite and main units. International comparisons on staffing suggest that the provision of nephrologists in the UK is well below norms found in other European countries

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## Chapter 4: New Adult Patients Starting Renal Replacement Therapy In 1999

### Summary

The estimated rate of adult patients starting renal replacement therapy (RRT) in the UK is 90 pmp indicating that approximately 5350 patients started RRT in 1999.

Haemodialysis was the modality of RRT at a day 90 for 58.8% of dialysis patients in England & Wales compared with 66.8% in Scotland

By the end of the first year 16% of patients starting on PD had changed to HD

The 90 day survival is 95% (95%CI 94-97%) for those aged less than 65 and 81% (95%CI 78-83%) for patients aged 65 and over.

The one year survival is 88% (95%CI 86-89%) for those aged less than 65 and 65% (95%CI 62-68%) for patients aged 65 and over.

The one year survival of the 1998 patient cohort on RRT was the same as the 1997 patient cohort even though there were 2 1/2 times the number of patients. This was also true when comparing the two year survival with that of previous Reports.

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

In addition to bringing the information on demographics provided in previous years up to date, this chapter will give more detail on one and two year survival for the Registry patients. Where relevant, Registry information will be compared with the 1998 National Renal Survey in which details of activity, staffing and service provision were obtained from all 71 UK Units during 1998.

The 1999 data were from 35 renal units covering 47% of the UK, including all 11 adult Scottish Units, and 23 (40%) of the 57 Units in England and Wales (Table 4.1).

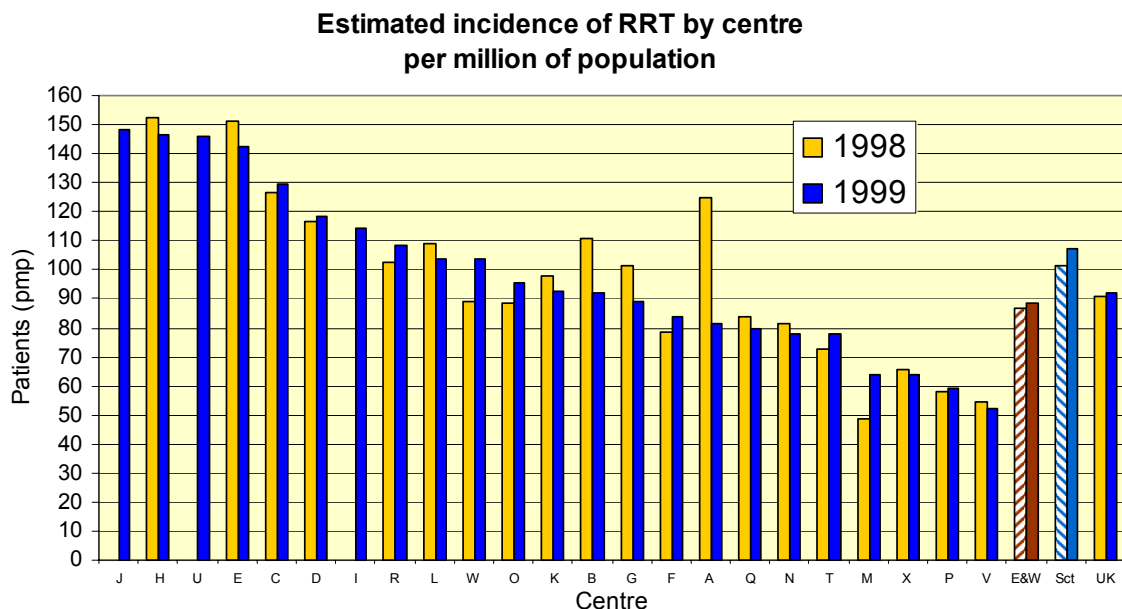
	<b>England &amp; Wales</b>	<b>Scotland</b>	<b>Estimated UK</b>
<b>No. of Units</b>	23	11	
<b>No. of new patients</b>	1998	546	5350
<b>Catchment population million</b>	22.5	5.1	
<b>New patients p.m.p. (95% C.I.)</b>	88.7 (84.6 – 92.8)	107.1 (98.3 – 116.4)	90.4
<b>New patients per Unit</b>	86.9	49.6	

**Table 4.1 Summary of new adult patients accepted during 1999**

## Acceptance Rates

The acceptance rate for Scotland has increased from 101 in 1998 to 107 p.m.p in 1999, although this is still within the 95% confidence interval from last year. These figures are accurate as all Scottish Units are included in the Registry. The estimated acceptance rate for England & Wales increased from 86.8 in 1998 to 88.7 p.m.p in 1999 but these figures are less reliable than those for Scotland because the catchment populations are less well defined, and the pool from which patients are drawn differs from year to year as more units join the Registry. The incidence of 86.8 p.m.p calculated by the Registry based on the 19 centres from England & Wales who contributed to the Registry during 1998 should be compared to that of 94.6 p.m.p obtained in the 1998 UK Renal Survey, which included all centres in England & Wales. The discrepancy between these two figures is probably caused by the higher acceptance rates in the London area due to the high ethnic minority population. London is relatively poorly represented in the Registry. Nevertheless the centres contributing to the Registry include a number of cities, large and small, in various parts of the country, with varying ethnic minority populations. Although there may be small errors in extrapolating epidemiological data from the Registry to the whole UK, the information appears to be largely representative of British nephrology, and will be more accurate as more units join the Registry

As shown in last years report, there is a wide variation in estimated acceptance rates between centres (figure 4.1). Once again it is stressed that these calculations are based on population estimates given by each centre, which may well be a major cause for the wide variation because of the unknown percentage of cross-boundary flow. Other reasons for this variation include differing population needs due to age and ethnicity, differing referral practices to the renal unit, and differing policies for acceptance for therapy which in some cases are driven by resource limitations.



**Figure 4.1** Estimated new patients starting RRT by centre per million of population

The changes in acceptance rates from 1998 to 1999 should be interpreted with caution from the point of view of individual renal units where the numbers may be small and confidence intervals large. When comparing the year on year national figures the possible effect of the additional centres who joined the Registry in 1999 must be borne in mind.

Calculation of incidence rates for the Scottish centres is not possible as the catchment populations by centre are not available.

When comparing the catchment data supplied in this report with that calculated by the National Review in 1992 centres B, C, F, G, H, I, J, K, M, P, Q, R and X have some discrepancy. Some of these centres appear as an over-estimate and others an under-estimate. The overall summation of these discrepancies appear to cancel each other out and does not change the total Registry coverage of 22.5 million.

Centre A is one of the smaller centres and the variation is within the 95% confidence interval..

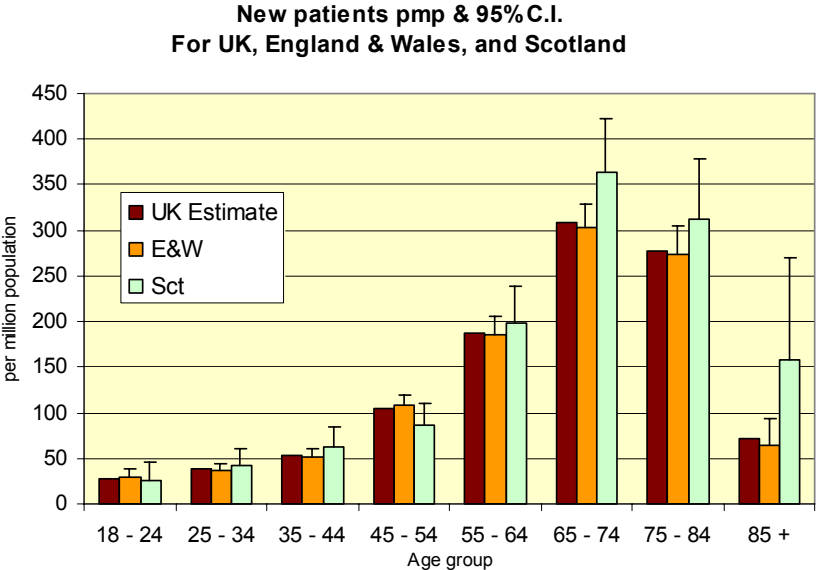
Due to incomplete geographical coverage, it has not been possible to analyse acceptance rates by district health authority using postcode information. Each year as more renal units are included in the Registry there will be larger contiguous areas of the UK covered. The possible errors due to cross boundary flow and population estimates will be smaller, and the calculation of crude and standardised acceptance rates for individual Health Authorities from post codes, and age and national /regional age and ethnic specific rates, will be more accurate.

**Incidence rate of RRT per million population by age**

In 1999 the Registry covered an approximate population in England & Wales of 22 million. Data produced by the Office for National Statistics have been used to generate an approximate prevalent age distribution for England & Wales. The distributions for Scotland were obtained from the General Register Office for Scotland. The age distribution of the whole population in England & Wales compared with Scotland is fairly similar (table 4.2)

Age	18-24	25-34	35-44	45-54	55-64	65-74	75-84	85+
E&W	8.3	15.6	14.3	13.2	9.9	8.4	5.5	1.9
Scot	8.6	14.8	14.8	12.7	10.3	9.0	6.4	1.6

**Table 4.2 UK population distribution by age group (% of total population)**



**Figure 4.2 Estimated incidence per million population by age**

The underlying assumption by the Registry in calculation of the acceptance rates for RRT shown in figure 4.2 is that the areas covered by the Registry have a similar age distribution to the overall population for England and Wales. The upper 95% confidence intervals are included. The differences between Scotland and England & Wales are not significant in any of the age groups. The acceptance rates peak in the 65-74 age group and then falls, which is contrary to the rising incidence of ESRF with age indicating the unmet need in the 65+ age group.

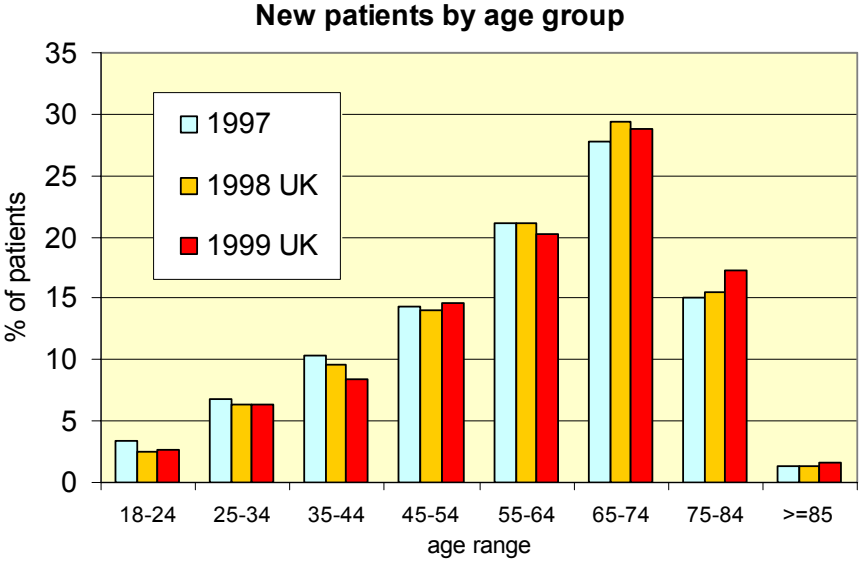


Figure 4.3 New RRT patients by age group for the UK

In England & Wales 44% of patients are over 65 compared with 50% in Scotland and 1 in 6 over 75 years of age at the start of treatment (Figures 4.2 & 4.3). In England and Wales the median age of patients starting renal replacement therapy in 1999 remained unchanged at 63.0, although in Scotland it increased from 64.0 to 65.0 years (figure 4.4).

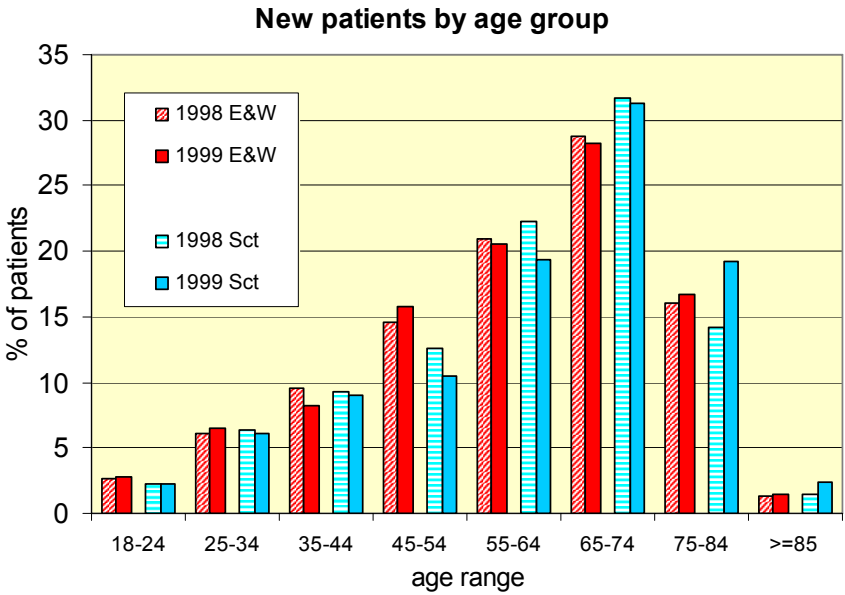


Figure 4.4 Changes in new RRT patients by age group – Scotland with England & Wales

There was a significant difference in the median age between England & Wales and Scotland (Chi squared  $p < 0.01$ ) There was also a significant variation in median age between centres within England & Wales (Chi squared  $p < 0.005$ ) shown in Figure 4.5. There was no significant variation in median age within Scotland (Chi squared  $p = .33$ ). Perhaps surprisingly, there was no relationship between median age and acceptance rates (Figure 4.6).

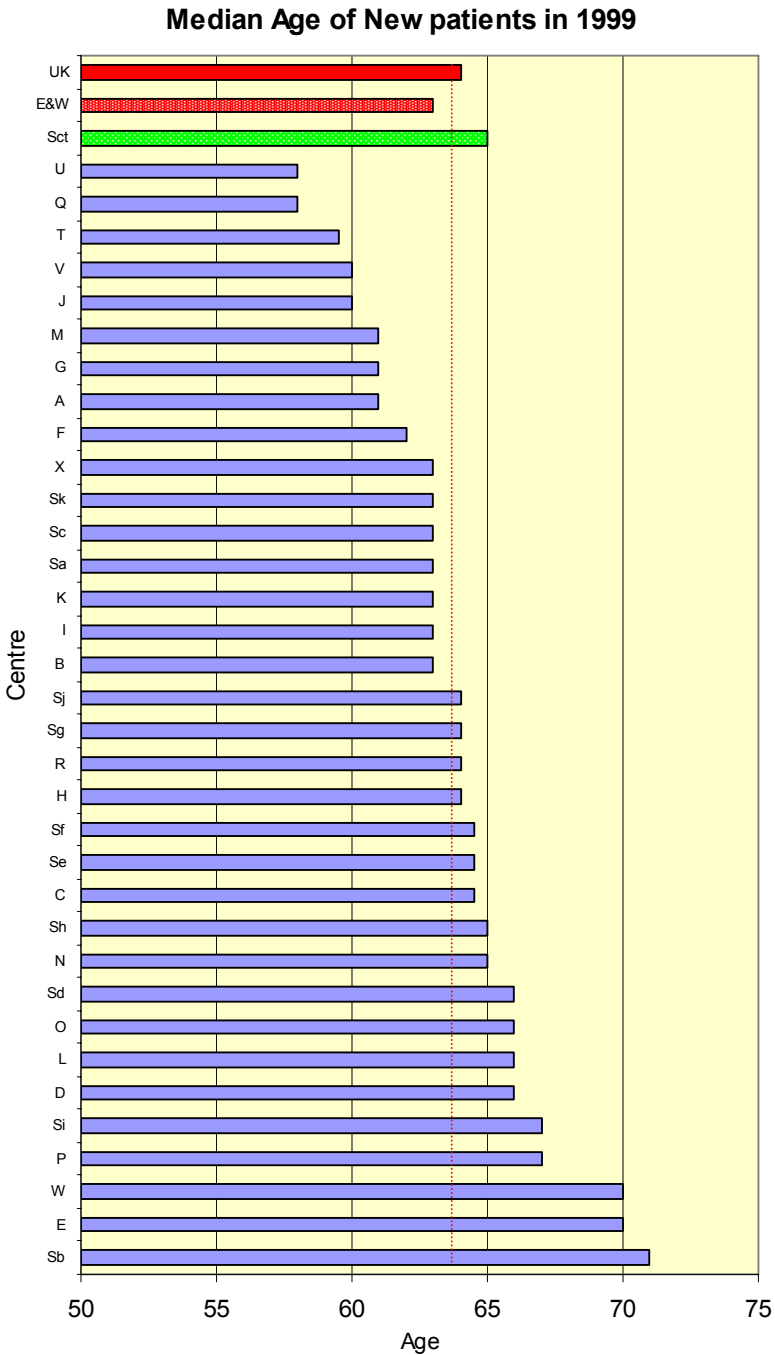


Figure 4.5 Median age of new patients in each unit

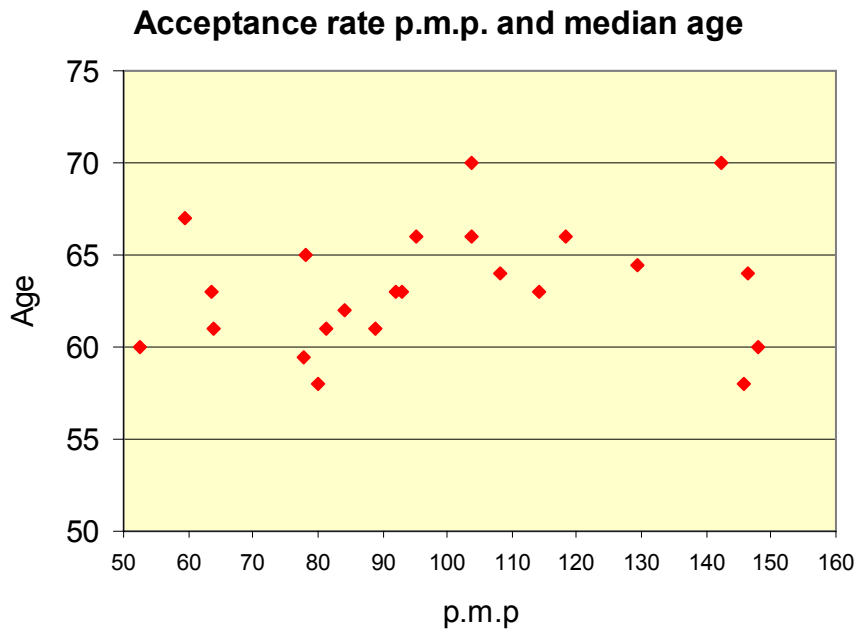


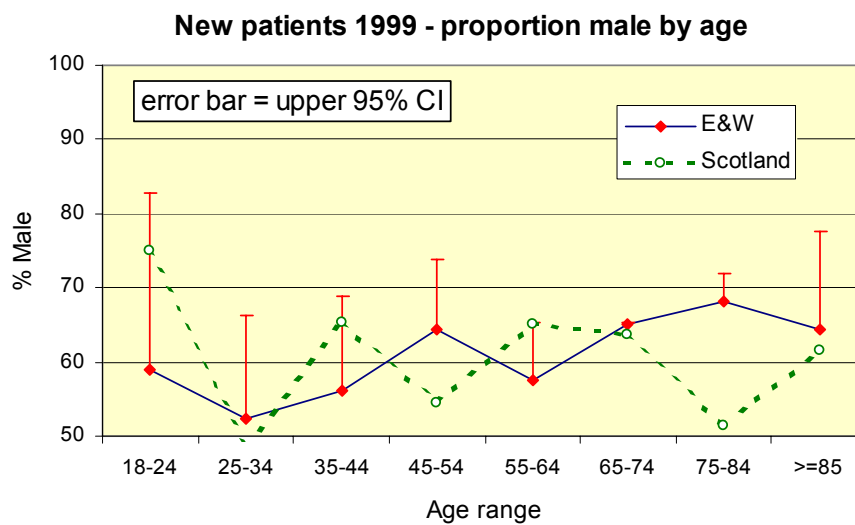
Figure 4.6 Estimated acceptance rate p.m.p. and age

### Gender

Year	1997	1998	1999
England & Wales	63.1	62.8	62.2
Scotland		59.3	60.1

Table 4.3 Percentage of males accepted for RRT

From 1997 – 99 there was no change in the proportion of males starting renal replacement therapy (table 4.3)



For Scotland there are small numbers in each age band. There are thus wide confidence limits, and no significance difference from England and Wales.

Figure 4.7 New patients 1999 – proportion male by age



## Ethnicity

Centre	%sent	White	Black	Asian	Chinese	Other
Sheffield	100	94	2	2	1	1
Nottingham	100	91	5	3		1
Stourbridge	100	85		15		
Birmingham Heartlands	100	76	3	18	2	1
Gloucester	98	100				
Plymouth	98	95	3	2		
Leicester	98	87	1	10		2
Sunderland	93	98			2	
Carshalton	93	76	4	6		14
Exeter	88	100				
Coventry	88	81	5	14		
Bristol	87	90	6	2	2	
Leeds, St James'	79	90	7	3		
Middlesbrough	65	86		7		7
Hull	2	2				
Cardiff	0					
Carlisle	0					
Oxford	0					
Preston	0					
Southend	0					
Stevenage	0					
Wolverhampton	0					
Wrexham	0					
<b>England</b>	<b>66</b>					

**Table 4.4 Ethnicity by centre**

In those centres which sent ethnicity data, 12% of patients were from ethnic minorities. This is similar to the total of 14% in the 1998 cohort. Neither Scotland nor Wales collect ethnicity data within the health service as a matter of policy.

The median age of ethnic minority patients was 59.0 years (n=129) compared with 64.0 (n=1034) for white patients in England.

Data on ethnicity for England were missing in 34% of patients. The number of centres providing information on at least 85% of patients increased from 6 to 12 including 2 centres which provided no data last year. Seven centres in England provided no data or virtually none and this included all 4 of the new centres. All centres in the UK are encouraged to provide these data, which are very important for relating acceptance rates to local populations and planning service provision, and also for studying the pattern of disease in different ethnic populations.

## Primary Renal Diagnosis

Diagnosis	E&W < 65	Scot <65	E&W ≥ 65	Scot ≥65	M:F (UK)
Aetiology uncertain and Glomerulonephritis not proven	16	13	23	31	1.6
Glomerulonephritis	13	15	6	7	2.2
Diabetes	20	21	10	12	1.4
Polycystic Kidney	9	10	3	2	1.1
Pyelonephritis	9	11	7	6	1.3
Renal Vascular disease	3	2	12	14	2.7
Hypertension	4	5	4	7	2.2
Other	12	14	12	9	1.5
No diagnosis sent	14	10	23	11	1.7
Total patients	1124	275	874	271	1.4

**Table 4.5 % Primary renal diagnosis by age, and gender ratios**

For the U.K. as a whole the single most common diagnosis was diabetic nephropathy (16%); this was even more commonly reported in those under 65 (20%). In the ethnic minority populations this accounted for 29% starting renal replacement therapy in 1999 and 32% including all those known to be from ethnic minorities who started in 1997-99. Once again there was a high proportion of diagnoses not returned, especially amongst the over 65 years old patients in England & Wales.

Unit	Not sent	Aetiology unc. Glomer. NP	GN	Diabetes	Polycystic Kidney	Pyelo-nephritis	Reno-vasc disease	Hyper tension	Other
A	0	23	15	19		12	23		8
B	37	15	13	10	4	8	1	4	8
C	18	20	9	20	5	14		7	7
D	0	45	8	10	6	10	10	1	10
E	14	19	8	17	6	6	9	2	19
F	7	30	10	9	3	6	8	1	28
G	8	28	10	16	4	11	9	3	11
H	1	21	10	19	7	10	10	7	16
I	0	30	15	23	8	8	15		3
J	0	16	4	28	7	12	9	12	12
K	0	18	10	15	8	10	5	15	18
L	42	17	13	15	7	2	1	1	2
M	2	16	9	26	8	5	6	9	20
N	12	22	13	19	6	9	6	1	13
O	53	6	5	14	2	5	1		14
P	72	6	2	8	2	2	4		5
Q	28	12	13	14	13	7	3	1	10
R	1	17	10	20	3	10	12	9	18
Sa	0	16	19	10	12	8	6	17	12
Sb	12	31	5	16	4	4	9	4	14
Sc	59	12	12			6	6	6	0
Sd	0	32	8	15	4	10	10	2	19
Se	2	24	9	28	9	11	4	7	7

Unit	Not sent	Aetiology unc. Glomer. NP	GN	Diabetes	Polycystic Kidney	Pyelo-nephritis	Reno-vasc disease	Hyper tension	Other
Sf	100								
Sg	0	35	11	19	11	8	5	3	8
Sh	0	24	14	24		10	10	10	7
Si	7	20		20	7	13	27	7	0
Sj	4	21	13	25	4	8	8	4	15
Sk	0	11	18	19	9	12	11	7	14
T	0	15	12	18	4	13	9	13	17
U	63	8	2	10	6	6			6
V	5	20	14	11	9	4	13	8	16
W	12	33	9	7	7	9	14	4	5
X	9	23	11	15	11	14	3	3	11
Sct	10	22	11	16	6	8	8	6	12
E&W	18	19	10	16	6	8	7	4	12
<b>UK</b>	<b>16</b>	<b>20</b>	<b>10</b>	<b>16</b>	<b>6</b>	<b>8</b>	<b>7</b>	<b>5</b>	<b>12</b>

**Table 4.6 Percentage diagnostic distribution of new RRT patients by unit**

This year the information is shown by individual centre (Table 4.6). The EDTA diagnostic coding categories for primary renal disease are used by all but one centre. This centre uses ICD9 coding which has been mapped at the Registry to EDTA. In the absence of reliable definitions of most diagnoses, except for biopsy proven glomerulonephritis, polycystic disease and to a lesser extent diabetic nephropathy and pyelonephritis, the variation between centres may reflect little more than the difficulty in categorising patients. This illustrates the need for more reliable definitions to enable meaningful comparison of outcomes in relation to underlying disease. These difficulties are compounded by the fact that many patients have multiple problems and there is individual variation in the use of invasive investigations to obtain a diagnosis in a predominantly elderly population.

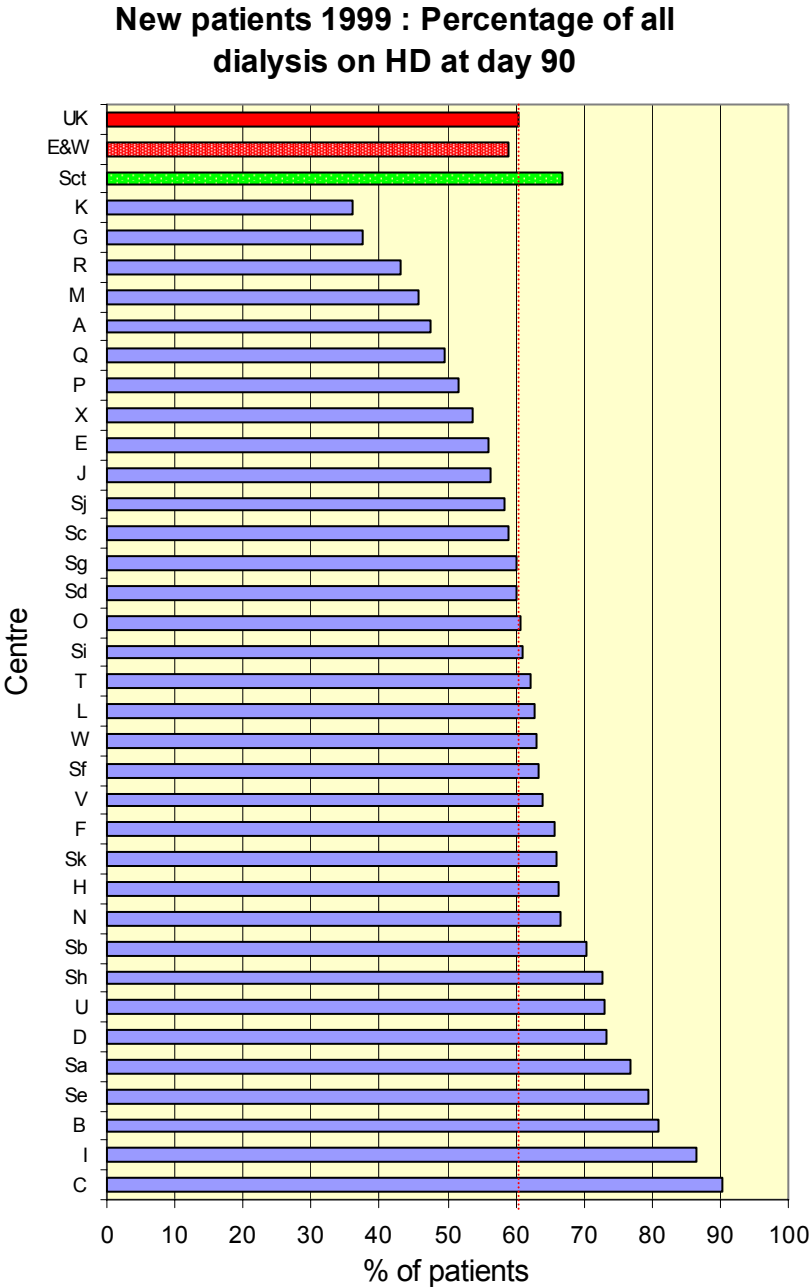
Nevertheless there was a large variation from 7% - 28% in the reporting of diabetic nephropathy as the cause of end stage renal failure. With the Black and Asian population having a much higher incidence of diabetes than the rest of the population, the variation in ethnic minority mix will account for some of these differences.

### ***Treatment modality***

In 1999 haemodialysis was the very first modality of RRT for 58.6% of patients in England & Wales (57.7% in 1998) compared with 67.6% in Scotland (67.0% in 1998). Calculated as the percentage all dialysis patients 59.7% started on haemodialysis in England & Wales compared with 69.0% in Scotland. In many cases this was temporary haemodialysis whilst peritoneal dialysis was being established. The Registry therefore looks at the modality on day 90 as being more indicative of the elective modality for patients.

Haemodialysis was the modality of RRT at a day 90 for 58.8% of dialysis patients in England & Wales compared with 66.8% in Scotland (Figure 4.8). This is little changed from the initial treatment modality in England & Wales and Scotland respectively. The lack of change in these figures is probably hidden by the increased death rate in the haemodialysis patients (older patient group) and also the failure of PD in some patients.

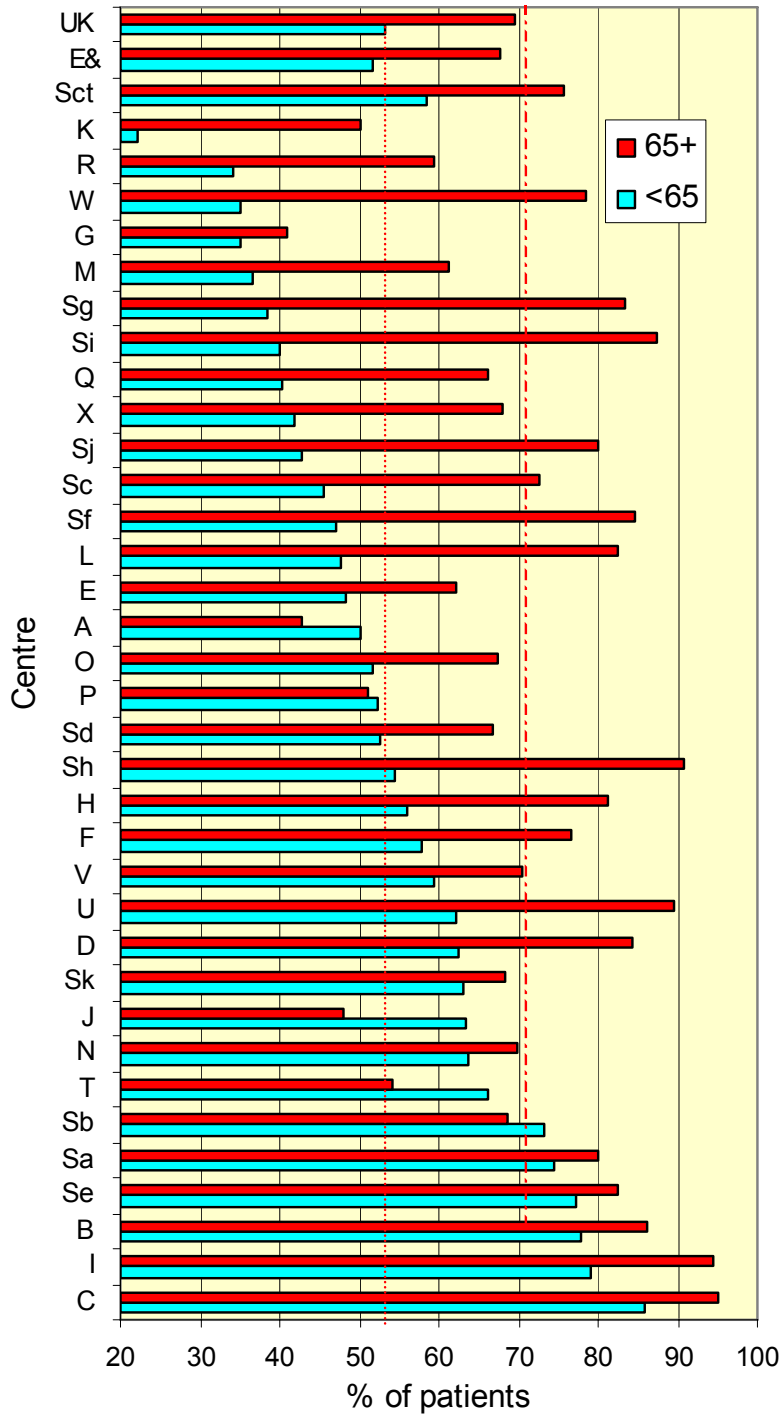
By day 90, only 2.6% of 1999 patient cohort in England & Wales had received a transplant compared with 3.9% in 1998 while the corresponding figures for Scotland were 2.0% in 1999 and 0.9% in 1998.



**Figure 4.8 Percentage of patients established on HD at day 90 by centre**

There were significant differences between individual Units within England & Wales (chi squared  $p < 0.001$ ) in the percentage of patients on haemodialysis. This was not a significant difference within Scotland (chi squared  $p < 0.05$ ). Peritoneal dialysis is more likely to be used in younger than older patients. Possible reasons for these differences include availability of treatment, patient and clinician preferences as well as differences in age and ethnicity.

**New patients : Percentage of all dialysis patients on haemodialysis on day 90, by age**



**Figure 4.9 Percentage of patients established on HD at day 90 by centre and by age**  
 By day 90, 9.9% of patients in England & Wales had died (9.6% in 1998) compared with 12.7% for Scotland (13.6% in 1998).

## **The first change of treatment modality**

This analysis includes the 2065 patients from the 19 E&W centres and 11 Scottish centres who started RRT on dialysis in 1998 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**

<b>Haemodialysis Modality</b>	<i>No of patients</i>	<i>Percentage</i>
Remains on HD	849	70
Changed to PD	54	4
Transplanted	55	5
Transferred out elsewhere	9	0.7
Recovered	14	1.2
Stopped Treatment (died)	2	0.2
Died (no change in modality)	229	19

**Table 4.7 HD patients at 90 days: changes in modality in subsequent year**

The results in table 4.7 are almost identical to those in the 1998 Report although only 4% changed to PD in the first year rather than the 6% reported previously

<b>Peritoneal Dialysis Modality</b>	<i>No of patients</i>	<i>Percentage</i>
Remains on PD	545	64
Change to HD	135	16
Transplanted	76	9
Transferred out elsewhere	7	0.8
Recovered	1	0.1
Stopped Treatment (died)	6	0.7
Died (no change in modality)	83	10

**Table 4.8 PD patients at 90 days: changes in modality in one year**

The results in table 4.8 are identical to those in the 1999 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 1997 had a full annual cohort of patients available for a 2 year follow up period. The analysis includes 773 patients.

### **Patients who were on haemodialysis after the first 90 days**

These figures are similar to those in last years 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. This fall is accounted for by the increased waiting lists for transplantation without a corresponding increase in the transplant rate.

<b>First Change in Modality</b>	<b>At end of 1 year</b>		<b>At end of 2 years</b>	
	<b>No. of Patients</b>	<b>% of Patients</b>	<b>No. of Patients</b>	<b>% of Patients</b>
Remains on HD	330	69	233	49
Changed to PD	28	6	31	7
Transplanted	16	3	35	7
Transferred out elsewhere	3	0.6	14	3
Recovered	4	0.8	5	1
Stopped Treatment (died)	4	0.8	4	0.8
Died (with no change in modality)	91	19	154	32
<b>Total</b>	<b>476</b>		<b>476</b>	

**Table 4.9 Changes in modality over the first 2 years for patients on HD**

***Patients who were on peritoneal dialysis after the first 90 days***

<b>First Change in Modality</b>	<b>At end of 1 year</b>		<b>At end of 2 years</b>	
	<b>No. of Patients</b>	<b>% of Patients</b>	<b>No. of Patients</b>	<b>% of Patients</b>
Remains on PD	196	66	122	41
Changed to HD	50	17	74	25
Transplanted	22	7	37	13
Transferred out	2	0.7	10	0
Recovered	1	0.3	1	0.3
Stopped Treatment (died)	0	0	0	0
Died (with no change in modality)	26	9	53	18
<b>Total</b>	<b>297</b>		<b>297</b>	

**Table 4.10 Changes in modality over the first 2 years for patients on PD**

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%. 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 25% 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.

***New patient survival***

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

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

## **Analysis criteria**

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

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

In the analysis against the Renal Association Standard patients were only included if they were aged between 18 and 55 when they started renal replacement therapy.

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

Analysis of patients with ‘All Diseases Except Diabetes’ also excluded patients with no diagnosis recorded.

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

For the analysis by modality of patients on haemodialysis and peritoneal dialysis, patients were censored when they changed treatment modality - even if the change in treatment modality only lasted a day. Patients were classified according to their starting treatment modality – even if they only remained on their starting treatment modality for a day. Note that if a patient transfers out and then back into the centre later then it is assumed that the patient has remained on the same modality unless the timeline shows otherwise.

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

## **Comparison with the Standard recommendation**

This analysis includes the cohort of 2347 patients from the 19 E&W centres and 11 Scottish centres who started RRT between 1/1/1998 and the 31/12/1998. The previous annual cohort of 984 patients is compared and then incorporated for further analysis. Results are shown in table 4.11.

<b>First Treatment</b>	<b>Patients 18-55 - One Year Survival (95% CI)</b>			
	<i>Standard Primary Renal Disease</i>		<b>All Diseases Except Diabetes</b>	
	<b>1998</b>	<b>1997 &amp; 1998</b>	<b>1998</b>	<b>1997 &amp; 1998</b>
All	95.8 (94.3 - 97.4)	96.0 (94.6 - 97.4)	94.4 (91.7 – 97.1)	93.8 (92.3 - 95.3)
Haemodialysis	92.7 (89.7 - 95.8)	93.1 (90.4 - 95.9)	88.6 (85.4 – 91.8)	89.5 (86.7 - 92.3)
Peritoneal dialysis	98.0 (96.0 - 100)	97.9 (96.0 - 99.7)	97.6 (95.7 – 99.5)	97.3 (95.4 - 99.2)

**Table 4.11 One Year Patients Survival – patients age 18-55**

These data are well within the Renal Association Standard and within the 95% confidence intervals of the previous year’s data. As the numbers of deaths are small in these categories, the data for 1997 and 1998 patient cohort have been combined to provide a more accurate figure and narrow the confidence intervals. The apparent better survival on peritoneal dialysis



is unlikely to reflect differential benefits of the treatment, as the patients are a selected group and are younger than those on haemodialysis.

### **Survival of all new patients – further analysis**

Results are shown in tables 4.12 to 4.14

	<b>1998 Deaths No of Patients</b>	<b>1998 KM Survival</b>	<b>1998 K-M 95% C I</b>	<b>1997-8 KM Survival</b>	<b>1997-8 K-M 95% C I</b>
< 65	65/1268	0.95	(0.94 - 0.97)	0.95	(0.94 - 0.96)
≥ 65	206/1079	0.80	(0.78 - 0.83)	0.81	(0.78 - 0.83)
All	271/2347	0.88	(0.87- 0.90)	0.89	(0.87 - 0.90)

**Table 4.12 Ninety day survival of 1998 and combined 1997-8 cohort patients**

These 1998 patient cohort results are similar to those of 1997 produced in the 1999 Registry report, with 89% survival in the first ninety days.

### **One year survival**

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 were calculated by adding up for each patient the number of days at risk (until they died or transferred out) and dividing by 365. Results are shown in tables 4.13 and 4.14

	<b>At 3 months 1998 cohort</b>		<b>At one year 1998 cohort</b>		<b>Death Rate Per 100 Patient Years</b>
<b>Deaths</b>	<b>Deaths</b>	<b>KM</b>	<b>K-M</b>		
<b>/Patients</b>	<b>/Patients</b>	<b>Survival</b>	<b>95% CI</b>		
< 65	65/1268	156/1268	0.88	(0.86 - 0.89)	13.5
≥65	206/1079	375/1079	0.65	(0.62 - 0.68)	46.3
All	271/2347	531/2347	0.77	(0.75 - 0.79)	27.0

**Table 4.13 One year survival of new patients, by age at start of therapy in 1998**

	<b>At 3 months 1997 cohort</b>		<b>At one year 1997 cohort</b>		<b>Death Rate Per 100 Patient Years</b>
<b>Deaths</b>	<b>Deaths</b>	<b>KM</b>	<b>K-M</b>		
<b>/Patients</b>	<b>/Patients</b>	<b>Survival</b>	<b>95% CI</b>		
< 65	29/547	68/547	0.87	0.85 - 0.90	13.6
≥65	81/437	151/437	0.65	0.61 – 0.70	45.7
All	110/984	219/984	0.78	0.75 – 0.80	26.3

**Table 4.14 One year survival of new patients from 1997**

There are over twice the number of patients included in this analysis than in the 1999 Report, with similar results. This consistency suggests the Registry data are representative of the UK as a whole.

### **Two year survival**

Only centres on the Registry in 1997 which had a full annual cohort of patients available for a 2 year follow up period ending 31/12/1999 were included. The analysis includes 987 patients and is shown in figure 4.15.

	Deaths / No of Patients			KM Survival Analysis		K-M 95% Confidence Interval
	3/12	1 year	2 years	1 year	2 year	2 year survival
<65	29	67	114/552	0.90	0.83	(0.79 - 0.87)
≥ 65	84	153	258/435	0.68	0.48	(0.43 - 0.53)
All	113/987	220/987	372/987	0.82	0.67	(0.65 - 0.70)

**Table 4.15 Two year survival of 1997 cohort patients**

### **Comment**

These survival data are similar to that in the previous report. In a further 2 years a trend analysis will be possible to identify any changes in these patterns.

Comparisons of survival in different units are not shown at this point. To perform such comparisons it is essential to understand the influence of factors such as age, gender, social deprivation, and primary diagnosis on outcomes. One can then adjust the measured outcomes of each unit for these factors. In chapter 16 there is further analysis of factors influencing survival enabling some of these adjustments to be made. Appropriately adjusted survival for each renal unit is then presented.

## Chapter 5: All Patients Receiving Renal Replacement Therapy In 1999

### Summary

#### Point prevalence.

On December 31<sup>st</sup> 1999 14772 patients receiving Renal Replacement Therapy from 35 renal units were enrolled in the Renal Registry. The number of patients in units with data for both 1998 and 1999, increased by 4.3% during 1999. For individual English and Welsh units, estimated dialysis prevalence varied from 491 to 198 pmp. In England and Wales, the average number of patients on RRT in each unit was 486; in Scotland, it was 260.

#### Prevalent age.

The median age for all patients on treatment on 31/12/99 was 54 years, unchanged from the previous year. The median age of patients on peritoneal dialysis remains lower than that of those on haemodialysis at 59 as against 62 years.

The median age for prevalent patients in Scotland was lower than in England & Wales. In the UK as a whole, 28.7% of patients were aged 65 or over and 9.4% were over the age of 75. The median age varied significantly between units with a range of 57 to 68 years.

#### Gender of RRT patients

61% of all patients on treatment were male: this preponderance occurs at all ages. Of the small number of patients aged over 85, 72% were male.

#### Ethnicity

Data on ethnicity for existing patients remains patchy, particularly since in Scotland and Wales, it is not health service policy to collect ethnicity data. From the available data, the median age of patients from the ethnic minority population starting RRT is lower than that of the white population, but prevalent ethnic minority patients are older (55.6 years compared with a median age of 54 for all prevalent patients). The gender ratio in the ethnic minority group was the same as for the white population, 62% being male. Although the main ethnic minority in the UK is of Indo-Asian origin, this higher median age of prevalent ethnic patients may indicate a similar higher survival rate to that shown in the USA for the black, when compared with the white, RRT population.

33% of prevalent ethnic minority dialysis patients were on PD. This is of interest since there have been reports of difficulties in establishing such patients on peritoneal dialysis..

#### Primary renal disease

The most common primary renal disease recorded for prevalent patients under 65 years old was glomerulonephritis. In as many as 30.7% of those over 65 it was not possible to give a diagnosis.

#### Diabetes

This accounted 16% in current incident patients, but just over 10% of all prevalent patients; and for 13% of patients on HD, 16% of those on PD and 16% of patients with a working transplant. Of those classified as Type I diabetics, 46% under 65 years old were on PD compared with 28% of Type 2 diabetics and 33% of the under 65 non-diabetics. In the over

65-year-old patients, use of PD was less common. Analysis suggests that the classification of diabetic patients as Type 1 and Type 2 is not uniform at present and this has some influence on the data.

### Dialysis modality

In England & Wales 66% of dialysis patients were on haemodialysis compared with 73% in Scotland. 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. So few patients are now on “standard” CAPD that it should no longer be called “standard”. “Connect PD” may be a better term.

The percentage of patients on haemodialysis treated at home or in satellite units in England & Wales was 38% compared with 28% last year, while in Scotland it fell from 8% to 5%.

In England & Wales 66% of dialysis patients were on haemodialysis compared with 73% in Scotland.

Both England & Wales and Scotland show an increasing percentage of patients being treated with haemodialysis, with the steepest rise being since 1995. England & Wales still have a lower percentage of patients on haemodialysis than Scotland and this difference in service provision now exceeds that of 1995

### Patient survival

The one-year survival of all patients established on renal replacement therapy for at least 90 days on 1/1/1999 was 83.7% for the UK; it was 84.8% for England and Wales but 78.8% for Scotland. These survival differences are present across the age spectrum and for 2-year survival also. There is a weak similar trend for transplant patients. The lower survival of Scottish patients on RRT may reflect the generally lower survival of the Scottish population itself, rather than any factor related to RRT.

## ***Introduction***

On December 31<sup>st</sup> 1999 14772 patients receiving Renal Replacement Therapy from 35 renal units were enrolled in the Renal Registry. This chapter describes their demographic details, diagnosis and treatment, and gives a detailed analysis of the 1-year and 2-year survival of patients who had been established for at least 3 months on RRT on 31/12/98 and 31/12/97 respectively.

## ***Prevalence Rates***

As noted in chapter 4, calculations of prevalence for England & Wales must be interpreted with caution as they are based on estimated catchment populations.

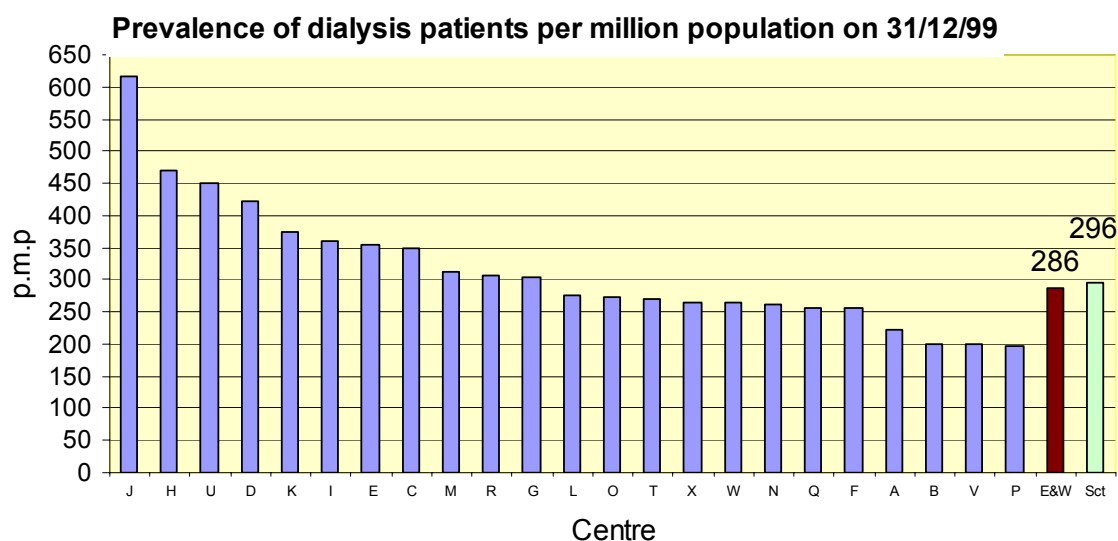
Summary figures are shown in table 5.1.

	England & Wales	Scotland	Estimated UK
No. of units	23	11	
No. of patients	11897	2875	31500*
Population (m)	22.5*	5.1	59.2
Patients (pmp)	528*	563	531*
Mean Pats/unit	486	260	

\* = estimated figures

**Table 5.1 Summary of adult patients registered and total population covered**

Potential errors are larger when assessing individual centres where numbers are smaller and inaccuracies in estimating catchment populations and the possibilities of cross-boundary flow of patients may have significant effects. Transplantation presents further difficulties as some transplant centres follow patients longer than others before transferring care back to the parent renal unit, and catchment populations do not take this into account. For this reason comparisons between individual units are made only for dialysis therapy. Figure 5.1 therefore only includes dialysis patients: it demonstrates wide variations in dialysis prevalence between individual units from 419 pmp to 198 pmp. The estimated prevalence for individual renal units within Scotland has not been shown, as the population coverage for each unit was not available.



**Figure 5.1 Estimated dialysis prevalence per million population by centre**

Comparing centres in England & Wales where the Registry has data for 1998 and 1999 the prevalence rate has risen from 516 pmp to 528 pmp. It may be noted that the 1998 prevalence of 516 pmp is at variance from the reported prevalence of 528 in the 1999 Report. This is because an additional centre with a very low prevalence rate has contributed 1998 data since the Report was published.

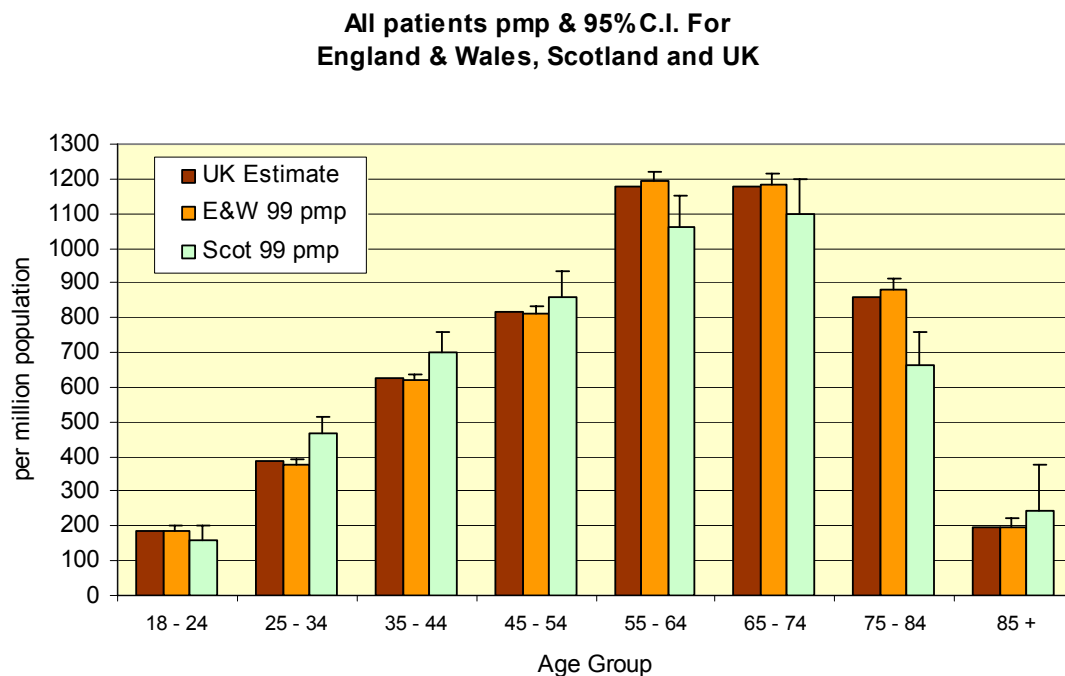
## Age

The median age for all patients on treatment on 31/12/99 was 54 years (Table 5.2), which is unchanged from the previous year. The median age of patients on peritoneal dialysis remains lower than those on haemodialysis.

	Transplants	Peritoneal dialysis	Haemodialysis	All
England & Wales	49	59	62	54
Scotland	47	57	61	52
All	48	59	62	54

**Table 5.2 Median age and treatment modality**

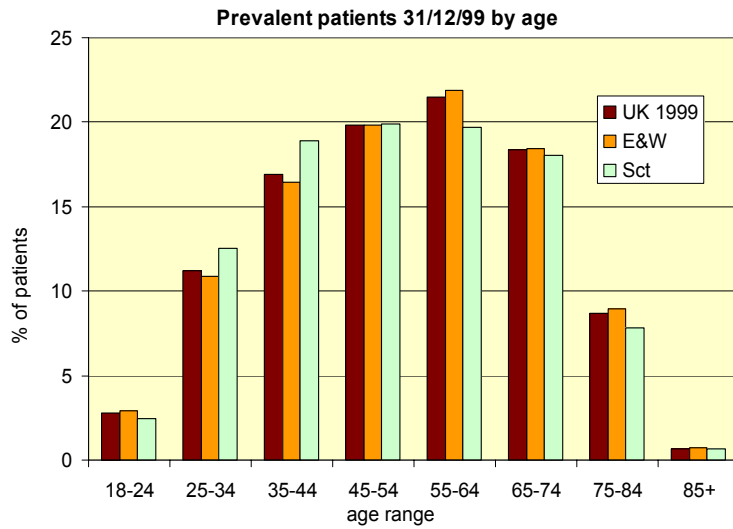
The median age for prevalent patients in Scotland was lower than in England & Wales: this is also evident from the age profile of patients shown in Figures 5.1 and 5.2. In the UK, 28.7% of patients were aged 65 or over and 9.4% were over the age of 75.



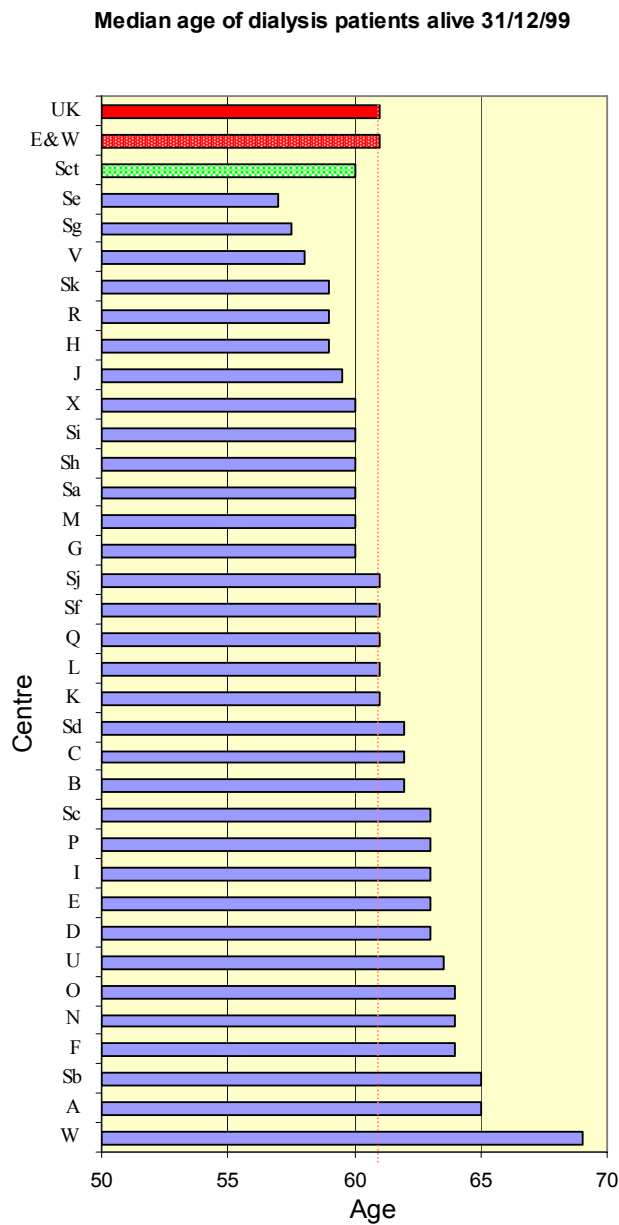
The upper 95% confidence limits are shown.

**Figure 5.2a Prevalence rates p.m.p. for RRT by age**

Data produced by the Office for National Statistics and the General Register Office for Scotland have been used to generate an approximate prevalent age distribution (Figures 5.2a & b). For England & Wales, the main underlying assumption in the calculation is that the areas covered by the Registry have a similar age distribution to the overall population for England & Wales. An additional assumption is that the estimate of the Registry catchment population is a reasonable approximation. The UK estimate relies on the prevalence rate in the rest of the country being similar to that of the Registry. The latter assumption seems reasonable as in 1998 the Registry prevalence was 528 pmp for England & Wales (or 516 as recalculated in this report) compared with 527 pmp calculated by the 1998 national renal survey. The 95% confidence intervals are included.



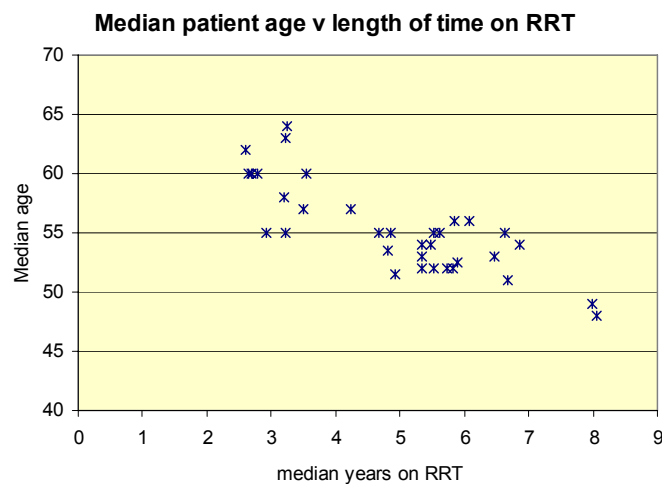
**Figure 5.2b Age profile of prevalent patients**



**Figure 5.3 Median age of dialysis patients alive 31.12.99**

Figure 5.3 demonstrates the wide variation in median age of dialysis patients in individual units. Possible reasons for this include differences in local populations, referral and acceptance policies, survival rates and available resources.

There was a significant difference of the median age within England & Wales (chi squared  $p < 0.0001$ ) and also within Scotland (chi squared  $p < 0.0001$ ).

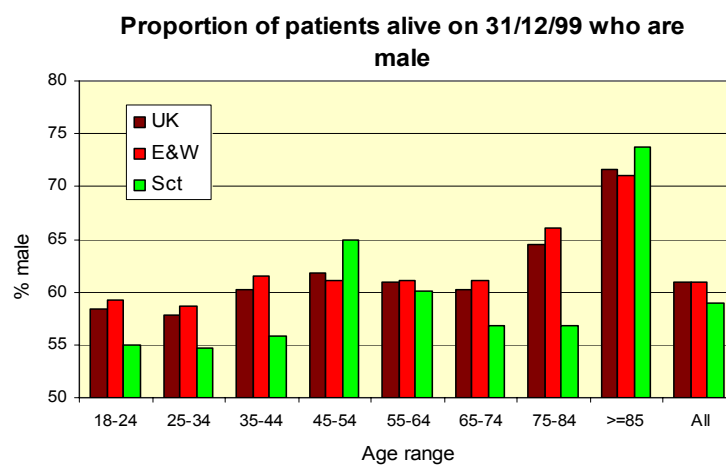


**Figure 5.4 Median age at each centre and length of time on RRT in the UK**

In figure 5.4, the median age of non-diabetic patients at each centre has been plotted against the median length of time on renal replacement therapy. The low median age and long median length of time on RRT is related to a large transplant population.

## Gender

Overall 61% of all patients on treatment were male: the male preponderance occurs at all ages (Figure 5.5). In particular, of the 102 patients who were over 85 on 31.12.99, 72% were male compared with 62% in the previous year. 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 5.5 Percentage of male patients according to age**



## Ethnicity

With some exceptions (notably Exeter) few units managed to improve the data on ethnicity for existing patients. 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, 7 provided little or no data at all while information was complete on at least 86% of patients in 14 units (Table 5.3).

	<b>% with data complete</b>	<b>% White</b>	<b>% Black</b>	<b>% Asian</b>	<b>% Chinese</b>	<b>% Other</b>
Sheffield	99.8	94.2	1.5	2.9	0.9	0.6
Birmingham Heartlands	99.2	74.9	4.6	19.0	0.8	0.8
Stourbridge	99.2	88.9	1.7	8.9	0.4	
Plymouth	98.7	98.2	0.5		0.5	0.8
Carshalton	98.5	71.0	4.5	4.3	0.6	19.6
Leeds, St James'	97.5	89.4	2.6	7.7		0.3
Sunderland	97.4	98.2	0.9		0.4	0.4
Exeter	96.4	99.8	0.2			
Coventry	95.3	80.9	3.0	15.5	0.6	
Bristol	94.7	93.0	3.1	1.8	1.2	0.9
Middlesbrough	92.1	95.3		3.4		1.3
Nottingham	89.6	89.0	4.7	5.8		0.5
Gloucester	88.2	100.0				
Leicester	86.4	80.7	2.4	13.8	0.2	2.9
Cardiff	14.8	97.9		2.1		
Carlisle	0					
Hull	0					
Oxford	0					
Preston	0					
Southend	0					
Stevenage	0					
Wolverhampton	0					
Wrexham	0					
England	66.0					

**Table 5.3 Ethnicity**

The median age of the ethnic minority patients was slightly older at 55.6 years compared with a median age of 54 over all patients. When compared with the younger median age of ethnic patients starting RRT this higher median age of prevalent ethnic patients may indicate a similar higher survival rate to that shown in the USA black RRT population when compared with the white population. The gender ratio in the ethnic minority group was the same as for the white population with 62% of patients male.

Within the ethnic minorities group 67% of dialysis patients were on HD which was similar to the percentage for non-ethnic population in England & Wales, although 78% of these were on hospital HD. The acceptance of PD is surprising as several units have reported difficulties in establishing patients on peritoneal dialysis particularly with most units having PD education programmes only available in English.

## Primary Renal Disease

Details of primary renal disease, based on the original EDTA coding classification are shown in Table 5.4. Unlike incident patients, in those under 65 years old the single most common diagnosis was glomerulonephritis, followed by pyelonephritis (which includes outflow obstruction). In as many as 30.7% 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
<b>Aetiology uncertain *</b>	23.5	13-29	21.6	30.7	1.7
<b>Glomerulonephritis**</b>	15.5	7-21	17.4	8.3	2.3
<b>Pyelonephritis</b>	15.2	7-21	16.2	10.7	1.0
<b>Diabetes</b>	10.1	7-18	10.1	10.5	1.5
Type I	7.3		8.5	4.0	
Type II	2.7		1.8	5.4	
<b>Polycystic Kidney</b>	3.2	7-13	10.6	4.9	2.1
<b>Hypertension</b>	5.2	2-14	5.2	5.6	2.6
<b>Renal Vascular disease</b>	9.4	1-10	1.7	9.6	1.1
<b>Not sent</b>	4.6	0-47	3.1	9.9	1.7
<b>Other</b>	13.3	4-19	14.1	9.9	1.3
<b>All Patients Total</b>	14072		10285	3787	

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

\*\* - biopsy proven.

**Table 5.4 Primary renal disease in all patients, and according to age and gender**

Centre J which has the highest incidence rate of renal replacement therapy in the UK at 194 pmp has 18% of all patients who are diabetic and 28% of all patients starting renal replacement therapy are diabetic.

## Diabetes

Diabetes was recorded as the primary diagnosis in 10% of all prevalent patients, and in 13% of patients on HD, 16% of those on PD and 16% of patients with a working transplant. The median ages are shown in Table 5.5

<b>England and Wales</b>	<b>Type 1</b>	51.0
	<b>Type 2</b>	65.0
<b>Scotland</b>	<b>Type 1</b>	48.0
	<b>Type 2</b>	66.5

**Table 5.5 Median age of prevalent diabetics**

There was an apparent difference between England & Wales and Scotland in the percentage of diabetics with a transplant (Table 5.6). When type 1 and type 2 diabetics were grouped together these differences disappeared with 29% transplanted in E&W and 31% in Scotland. The apparent differences in treatment may be partly explained by variation in the categorisation of type of diabetes.

	% HD	% PD	% Transplanted
E&W diabetic type 1	36.7	29.9	33.4
E&W diabetic type 2	62.0	22.7	15.3
Sct diabetic type 1	34.8	22.9	42.4
Sct diabetic type 2	75.0	21.4	3.6

**Table 5.6 Treatment according to type of diabetes and country**

5.7 a	Type I	Type II	Non-Diabetics
Number	1084	405	12151
M : F ratio	1.5	1.7	1.55
Median Age on 31/12/99	50	66	54
Median Age started ESRF	46	63	46
Median years on treatment	2.6	2.0	5.5
% HD	36	65	34
% PD	29	22	15
% transplant	35	13	51

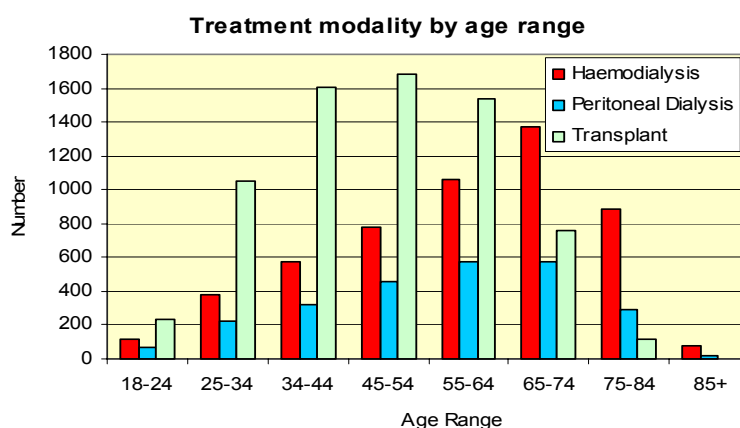
5.7 b	Type I	Type II	Non-diabetics	Type I	Type II	Non-diabetics
	< 65	< 65	< 65	≥ 65	≥ 65	≥ 65
Number	913	186	9186	171	219	3397
% HD	32	61	26	61	74	55
% PD	28	24	13	30	21	21
% transplant	40	22	61	9	5	24

**Tables 5.7a and 5.7b Type of diabetes – age, sex ratio, treatment**

Of those Type I diabetics on dialysis under 65, 46% are on PD compared with 33% of the under 65 non-diabetics and 28% in the Type 2 diabetics. In the over 65s use of PD was less common although still more common in the Type I diabetics at 33% compared with 28% in non-diabetics and 22% in Type 2 diabetics

## Modalities of Treatment

In England & Wales 66% of dialysis patients were on haemodialysis compared with 73% in Scotland. The variation in patterns of treatment with age are shown in Figures 5.6 and Table 5.8. 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.



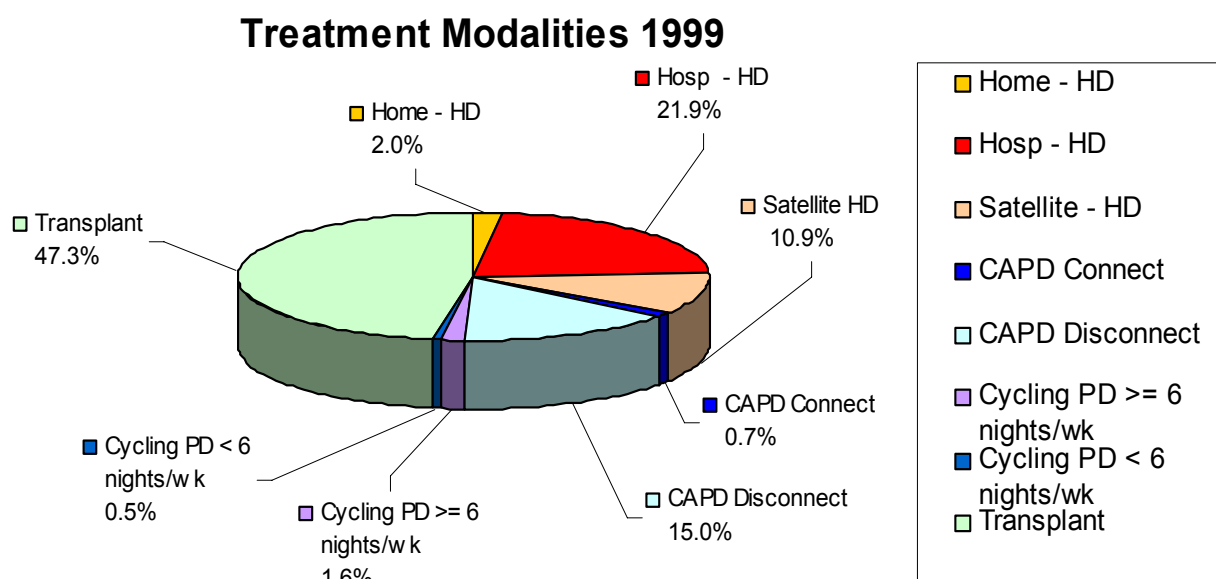
**Figure 5.6 Patients in each modality according to age**

	18-24	25-34	34-44	45-54	55-64	65-74	75-84	85+
Haemodialysis	27	23	23	27	33	51	69	78
Peritoneal Dialysis	16	14	13	16	18	21	23	21
Transplant	57	64	64	58	48	28	9	1

**Table 5.8 Percentage modality according to age**

The proportion of patients treated by the various types of dialysis is shown in Figure 5.7. So few patients are now on “standard” CAPD that it should no longer be called “standard”. “Connect PD” may be a better term.

Compared with the 1999 Report there has been an increase in the proportion of patients treated at satellite units (5.6% to 10.9%) and of patients treated by cycling PD (1.0% to 2.1%). The percentage of patients with a transplant fell from 49.9% to 47.3% during this



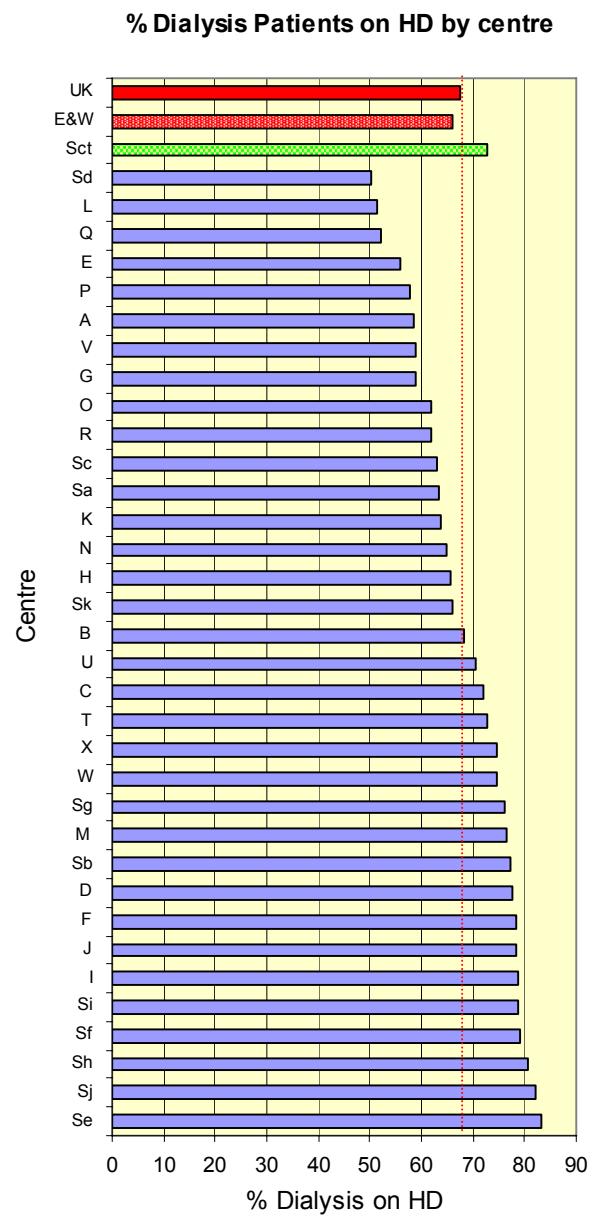
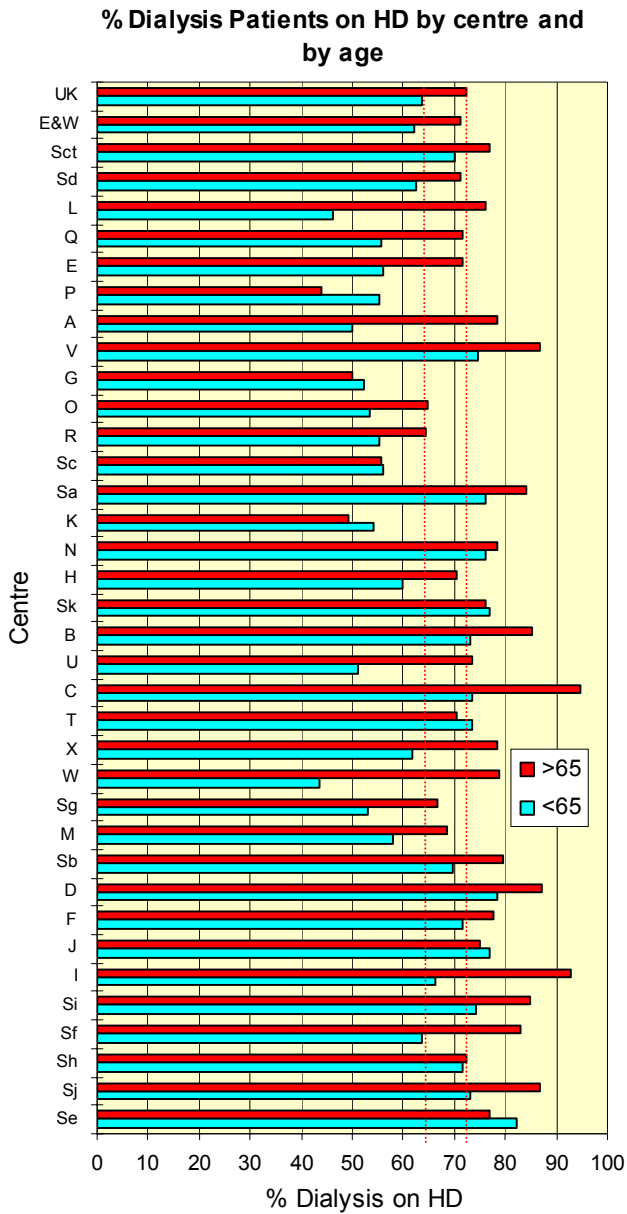
time.

**Figure 5.7 Percentage of patients on each dialysis modality**

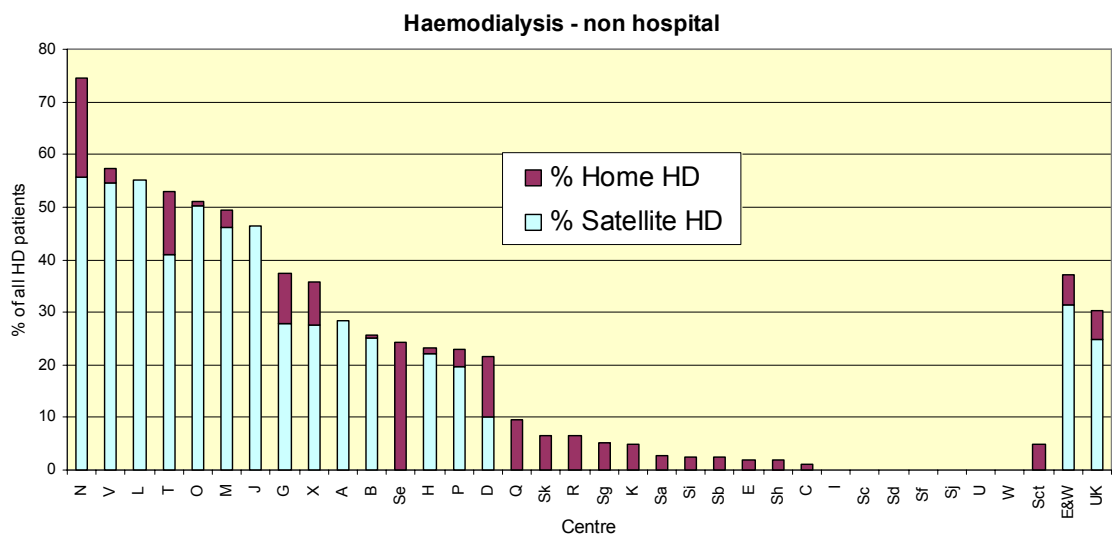
### Haemodialysis

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 5.8)

The percentage of patients on haemodialysis treated in satellite units in England & Wales was 31% compared with 17% in last years data, (Figure 5.9). Home haemodialysis fell from 7.5% to 5.7%. These data for 1999 include the four additional centres included in the Registry this year.

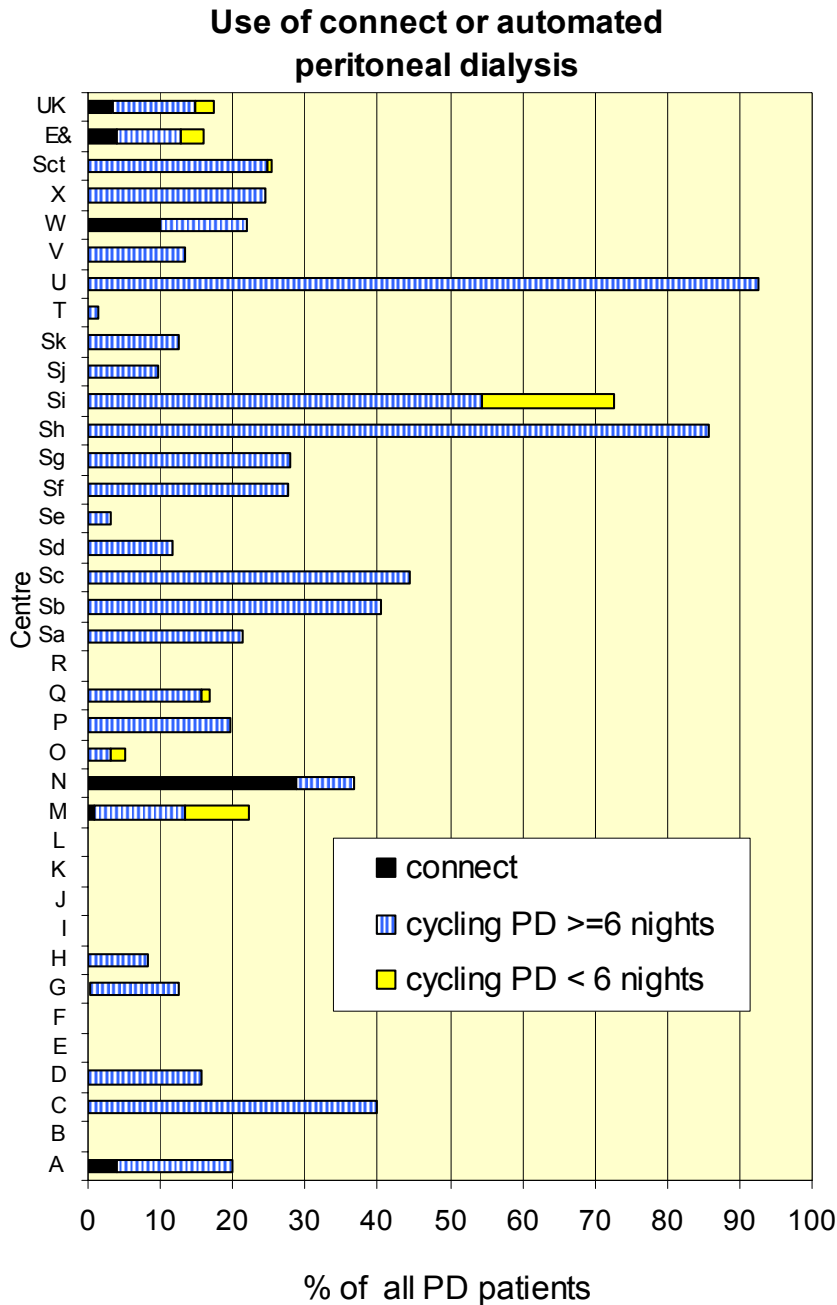


**Figure 5.8** Proportion of patients treated by HD according to centre and age.



**Figure 5.9** Percentage of haemodialysis patients treated at home and in satellite units

## Peritoneal Dialysis



**Figure 5.10 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 5.10. Connect PD was used by 29% of PD patients in one centre, by 10% in another and by less than 5% in another 2 centres. It was not used at all in the remaining centres, including all the Scottish units. Cycling PD was more widely used in Scotland than in England and Wales. There was a wide variation in the percentage of patients treated with one or other form of cycling PD; in 3 centres it was used for the majority of patients whereas 10 units had very few or none at all on this treatment.

A relatively high proportion of patients with a primary diagnosis of diabetes (38%) was treated by peritoneal dialysis as shown on Table 5.9. This may partly relate to the younger age of diabetic patients, as PD is more common in younger than older patients.

Diagnosis	% on PD
Diabetes	38
Aetiology uncertain *	34
Glomerulonephritis	33
Polycystic Kidney	27
Pyelonephritis	31
Hypertension	29
Renal Vascular disease	25
Other	30
Not sent	38

\* = Includes patients listed as “glomerulonephritis not biopsy proven

**Table 5.9 Proportion of patients on PD by diagnostic category.**

### **Modality and gender**

There were no differences in type of treatment according to gender (Table 5.10) except that of all dialysis patients 4.5% of males are on home haemodialysis compared with 2.5% of females.

		%HD	%PD	% Trans
Scotland	Male	38	14	49
	Female	39	15	46
England and Wales	Male	36	17	47
	Female	34	19	47
UK	Male	36	16	48
	Female	35	18	47

**Table 5.10 Treatment modality and gender**

### **Change in treatment modalities 1998 –1999**

	% HD Home	% HD Hospital	% HD Satellite	% HD Total	% PD standard	% PD Disconnect	% PD cycling	% PD Total	% with Transplant
1 <sup>st</sup> qtr 1998	2.5	22.6	6.6	31.7	0.9	16.8	1.2	18.9	49.4
1 <sup>st</sup> qtr 1999	2.4	23.0	7.6	33.0	1.2	15.7	1.1	18.0	49.0
4 <sup>th</sup> qtr 1999	2.2	21.0	10.7	33.9	0.8	14.9	1.8	17.5	48.6

**Table 5.11 Proportion of patients with different modalities of RRT 1999 and 1998**

	HD	PD	Transplant
4 <sup>th</sup> qtr 1998	3508	1986	5268
4 <sup>th</sup> qtr 1999	3783	1989	5448

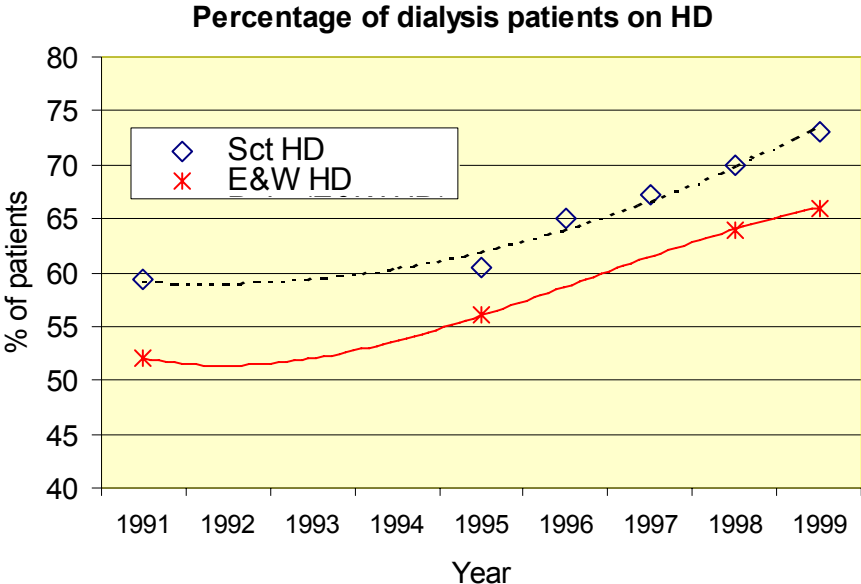
**Table 5.12 Number of patients with different modalities of RRT 1998 and 1999 in same centres**

Comparing only the 20 England & Wales centres where there were data for both 1998 and 1999, there was a 4.2% overall increase in percentage of patients. These data divided into a 3.4% increase in the number of transplant patients within 12 months. This compares with the 2.5% increase shown last year comparing a much smaller number of centres from 1997 – 1998.

Similarly there was a 5% overall increase in the total numbers of patients on dialysis over the 12 month period. This was almost totally due to an increase of 7.8% in the number of patients on haemodialysis with the total number of patients on peritoneal dialysis remaining static.

**Long term trends**

In England & Wales 66% of dialysis patients were on haemodialysis compared with 73% in Scotland.



**Figure 5.11 Percentage of dialysis patients on haemodialysis by year**

Both England & Wales and Scotland show an increasing percentage of patients being treated with haemodialysis, with the steepest rise being since 1995. England & Wales still have a lower percentage of patients on haemodialysis than Scotland and this difference in provision of haemodialysis facilities now exceeds that in 1995. The England data for 1992 and 1995 were from the national review. As the Registry only covered 9 centres in 1997 these data for England have not been included.

**Survival on renal replacement therapy**

This section analyses the one-year survival of all patients established on renal replacement therapy for at least 90 days on 1/1/1999, and the two-year survival of similar patients alive on 1/1/1998.



	<b>E&amp;W 1998</b>	<b>E&amp;W 1999</b>	<b>Scot 1999</b>	<b>UK 1999</b>
<b>No. of patients</b>	4554	5622	1353	6975
<b>No of deaths</b>	706	820	272	1092
<b>Death rate</b>	17.8	16.7	23.2	18.0
<b>(95% CI)</b>	16.5 – 19.1	15.6 – 17.9	20.5 – 26.1	16.9 - 19.1
<b>K-M 1 yr survival</b>	83.8	84.8	78.8	83.7
<b>(95% CI)</b>	82.6 – 84.8	83.8 - 85.8	76.6 - 81.	82.8 - 84.6

**Table 5.13a Survival during 1999 of dialysis patients alive on 1/1/1999**

	<b>Transplant censored at dialysis</b>			<b>Transplant including dialysis returns</b>		
	<b>E&amp;W</b>	<b>Scot</b>	<b>UK</b>	<b>E&amp;W</b>	<b>Scot</b>	<b>UK</b>
<b>No. of patients</b>	5228	1259	6487	5228	1259	6487
<b>No of deaths</b>	138	35	173	149	38	187
<b>Death rate</b>	2.7	2.9	2.8	2.9	3.1	2.9
<b>(95% CI)</b>	2.3 - 3.2	2.0 - 4.0	2.4 - 3.2	2.5 - 3.4	2.2 - 4.2	2.6 - 3.3
<b>K-M 1 yr survival</b>	97.3	97.2	97.3	97.2	97.0	97.2
<b>(95% CI)</b>	96.9 - 97.8	96.3 - 98.0	96.9 - 97.8	96.7 - 97.8	96.3 - 97.7	96.7 - 97.6

**Table 5.13b Survival during 1999 of transplant patients alive on 1/1/1999**

Transplanted patients have a lower mortality than dialysis patients, but these patients are a selected younger fit population with a median age of 48 years compared with 55 years in the dialysis population. Comparing transplant patients with non-diabetic dialysis patients aged less than 55 (Table 5.16) there is still a lower mortality with a 97.3% v 94.2% survival during 1999. This will be partly related to selective transplantation of fitter patients with less comorbidity.

Scotland has a higher mortality of dialysis patients than England & Wales (Table 5.13a) even though the median ages of patients are similar (55 years England & Wales v 54 years Scotland). There is a weak similar trend for transplant patients. This was analysed further.

The analysis was repeated separately for dialysis patients aged under 65 on 1/1/1999 and for patients aged 65 or more on 1/1/1999 (Table 5.14). This also showed a difference in survival comparing England & Wales with Scotland in both groups. This may have been related to the percentage of diabetic patients so the analysis was repeated for the diabetic and non-diabetic patients (Table 5.15a & 5.15b). The England and Wales figures for 1999 were within the 95% confidence limits of the results from 1998, suggesting no overall change in survival.

	<b>Dialysis aged less than 65</b>			<b>Dialysis aged 65 and over</b>		
	<b>E&amp;W</b>	<b>Scot</b>	<b>UK</b>	<b>E&amp;W</b>	<b>Scot</b>	<b>UK</b>
<b>No. of patients</b>	3338	847	4185	2284	506	2790
<b>No of deaths</b>	298	106	404	522	166	688
<b>Death rate</b>	10.1	14.2	10.9	26.7	39.0	28.9
<b>(95% CI)</b>	9.0 - 11.3	11.6 - 17.2	9.9 - 12.0	24.5 - 29.1	33.3 - 45.5	26.8 - 31.2
<b>K-M 1 yr survival</b>	90.5	76.9	89.7	76.9	66.8	75.1
<b>(95% CI)</b>	89.5 - 91.5	75.0 – 78.8	88.8 - 90.6	75.2 - 78.6	65.1 - 68.5	73.5 - 76.7

**Table 5.14 Survival during 1999 of dialysis patients alive on 1/1/1999 by age**

	Diabetic < 65			Non-diabetic < 65c		
	E&W	Scot	UK	E&W	Scot	UK
No. of patients	479	108	587	2799	710	3509
No of deaths	85	19	104	211	83	294
Death rate 1999 (95% CI)	20.4 16.3–25.2	19.4 11.7–30.4	20.2 16.5–24.5	8.5 7.4–9.7	13.3 10.60–16.5	9.5 8.4–10.6
K-M 1 yr survival (95% CI) 1999	81.8 78.6–85.1	82.0 74.2–89.8	81.8 78.6–85.1	91.9 90.9–92.9	87.3 85.4–89.2	91.0 90.0–92.0
K-M 1 yr survival (95% CI) 1998	80.5 76.2–84.8			91.4 90.2–92.6		

Table 5.15a Survival of dialysis patients aged < 65

	Diabetic ≥ 65			Non-diabetic ≥ 65c		
	E&W	Scot	UK	E&W	Scot	UK
No. of patients	255	59	314	1923	437	2360
No of deaths	73	22	95	431	138	569
Death rate 1999 (95% CI)	35.4 27.8–44.6	48.2 30.2–73.1	37.8 30.5–46.2	26.1 23.7–28.6	37.0 31.1–43.7	28.1 25.8–30.5
K-M 1 yr survival (95% CI) 1999	70.9 65.2–76.6	62.3 49.6–75.0	69.3 64.1–74.6	77.4 75.4–79.4	68.0 63.5–72.5	75.7 73.9–77.5
K-M 1 yr survival (95% CI) 1998	74.5 67.9–81.			76.6 74.5–78.7		

Table 5.15b Survival during 1999 of dialysis patients aged ≥65

The survival of diabetic dialysis patients for all age groups was not significantly different for England & Wales compared with Scotland. There was a significant difference in survival for non-diabetic patients. This difference in mortality remained consistent when analysed by 10-year age band (Table 5.16).

	<55 non diabetic			55- 64 non diabetic		
	E&W	Scot	UK	E&W	Scot	UK
No. of patients	1853	488	2341	946	221	1167
No of deaths	100	41	141	111	42	153
Death rate (95% CI)	6.1 5.0–7.4	9.6 6.9–13.0	6.8 5.8–8.1	13.1 10.8–15.8	21.7 15.6–29.4	14.7 12.5–17.2
K-M 1 yr survival (95% CI)	94.2 93.1–95.3	90.7 87.9–93.5	93.4 92.4–94.5	87.7 85.6–89.8	80.2 74.7–85.7	86.3 84.3–88.3
	65 -74 non diabetic			≥75 non diabetic		
	E&W	Scot	UK	E&W	Scot	UK
No. of patients	1137	279	1416	784	158	944
No of deaths	235	77	312	196	61	257
Death rate (95% CI)	23.5 20.9–22.1	31.5 24.9–39.4	25.4 22.7–28.4	29.2 25.3–33.6	47.5 36.3–61.0	32.3 28.4–36.3
K-M 1 yr survival (95% CI)	79.1 76.1–82.2	71.9 66.4–77.3	77.7 75.7–79.7	75.0 70.8–79.2	64.6 55.6–73.6	72.7 69.8–75.6

Table 5.16 Survival during 1999 of non-diabetic dialysis patients by age

The general population of Scotland is known to have more ill health than England & Wales, reflected in a higher all cause mortality and particularly cardio-vascular disease mortality<sup>1,2</sup>. The table below shows the all cause mortality rate per 1,000 population for the general population of England & Wales and Scotland in 1998. The data was supplied by the Office for National Statistics and the Register General Office of Scotland.

Age group	45-54	55-64	65-74	75-84	85+
Deaths per 1,000 E&W	3.3	9.0	25.7	64.5	160.9
Deaths per 1,000 Scotland	4.4	11.8	31.0	71.0	180.9
Excess mortality in Scotland	33.3	31.1	20.6	10.1	12.4

**Table 5.17 Mortality in the general UK population**

Thus the slightly higher dialysis mortality in Scotland reflects the increased mortality in the population from which the dialysis patients are drawn, and is unlikely to indicate anything about the quality of renal care. This analysis emphasises the need to consider the characteristics of the general population from which patients come when considering or comparing outcomes of treatment.

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## 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 not yet been implemented. This standardisation is essential to permit meaningful comparative audit among participating renal units. Within Scotland, where a uniform method of post dialysis sampling has been put in place, there is still a wide variation of 57-90% in the percentage of patients at centres achieving a urea reduction ratio (URR) greater than 65%.

Due to 'population distribution curves', centres will need to reach a median URR of 75% for almost all patients to have a URR >65%.

A cross sectional analysis of patients in 1999 showed there was a continuing rise in URRs over the 2 years from starting dialysis. This rose from 40% achieving a URR > 65% in the first 6 months to 70% achieving this at 2 years.

Within England and Wales, there has been a year on year increase in dialysis adequacy over the three 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 "*Twice weekly haemodialysis is not recommended except where there is good preservation of renal function.*"

The majority of patients in Registry units (94%) received thrice weekly dialysis. Many units have a small proportion of patients (<6%), often with some residual renal function, who dialyse twice weekly. Centre P had the largest proportion of patients (20%) on twice weekly dialysis, due to limited facilities (including staff) and financial constraints.

### Solute clearance Standards

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

*A urea reduction ratio > 65%*

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

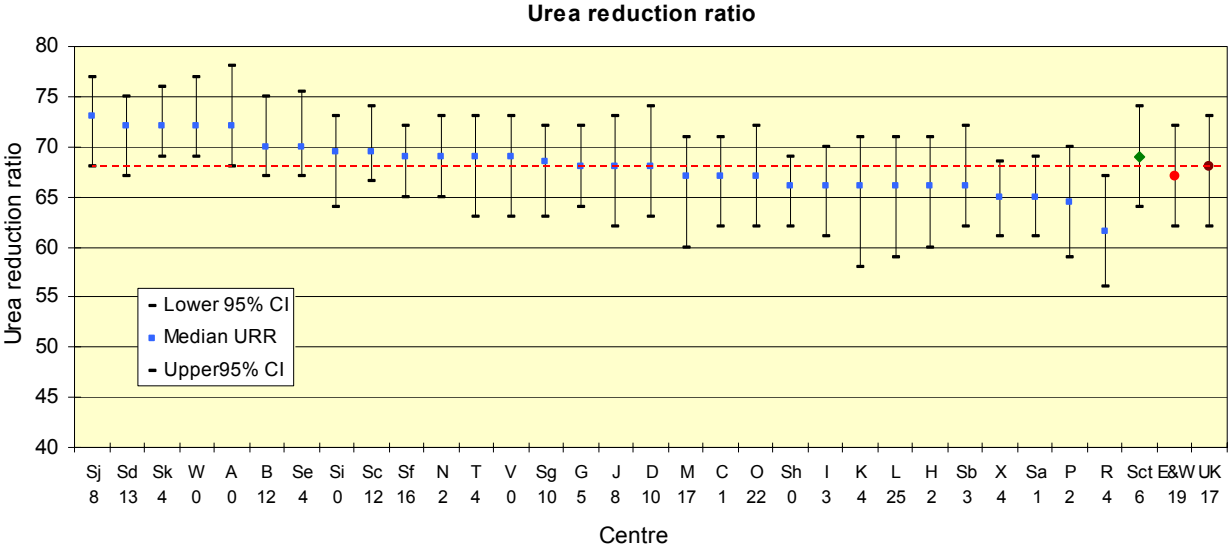
The Standards document considers both Kt/V and Urea Reduction Ratio (URR) as indicators of adequacy of haemodialysis. Several different methods are in use for calculating Kt/V and they give results which vary significantly. For meaningful comparisons, the Registry would need to calculate Kt/V by a single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

**Interpretation of results**

At present, post dialysis sampling methodology is not uniform across units. A caveat similar to that in the 1999 Report is still placed over the interpretation of the URR results. For convenient reference, the discussion presented in the 1999 report has been reproduced at the end of this chapter.

There has been no large move by all centres to a single “post urea” measurement standard. In 1999 some of the centres in England have moved to the Mactier “stop-dialysate-flow” method used by all the Scottish renal units. Use of the Mactier method has been shown to produce a lower URR than the two other main methods in use. This does cause an apparent reduction of achievement of the standard by the centre compared to a centre using the Renal Association recommended “slow flow” method.

**Centre achievement of the Standard**



**Figure 6.1 Percentage patients with URR ≥ 65% in the last quarter of 1999**

The data above excludes patients known to be on home haemodialysis or dialysing less than three times per week in the last quarter of 1999. The individual centre data from Scotland has also been included this year. Centres F and U have been excluded due to incompleteness of data.

### Urea Reduction ratio

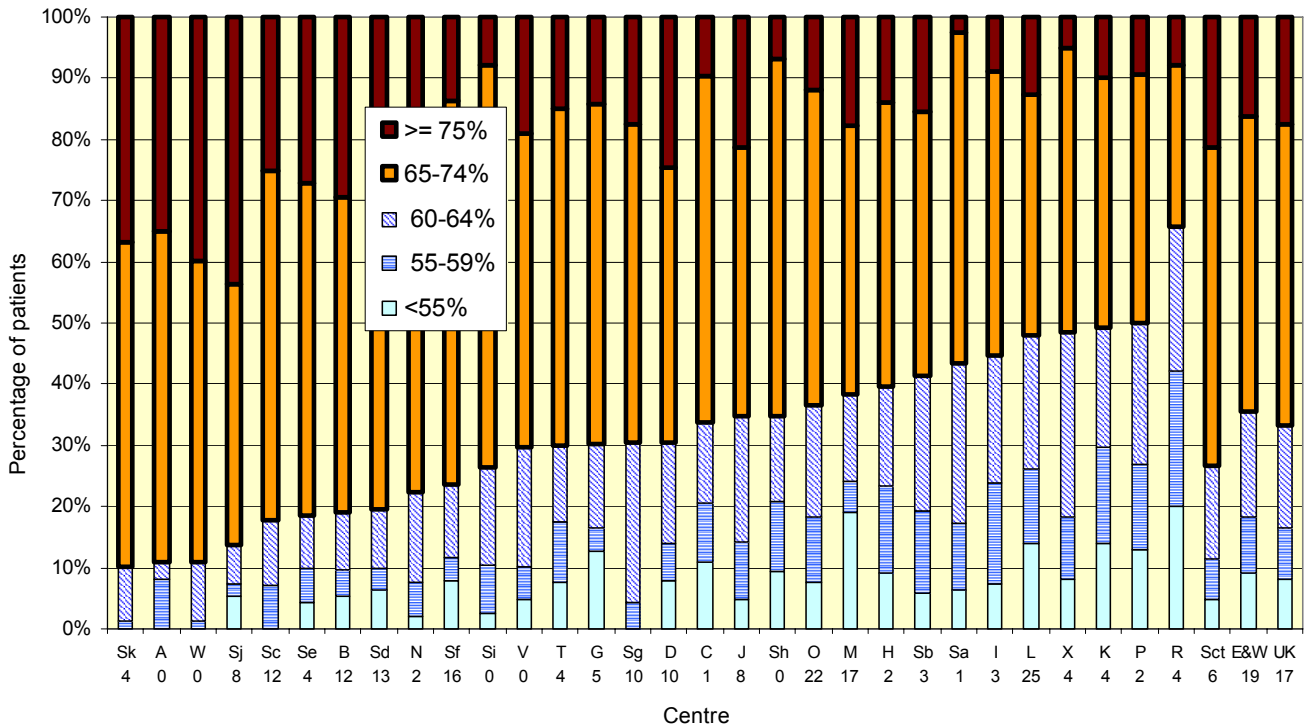
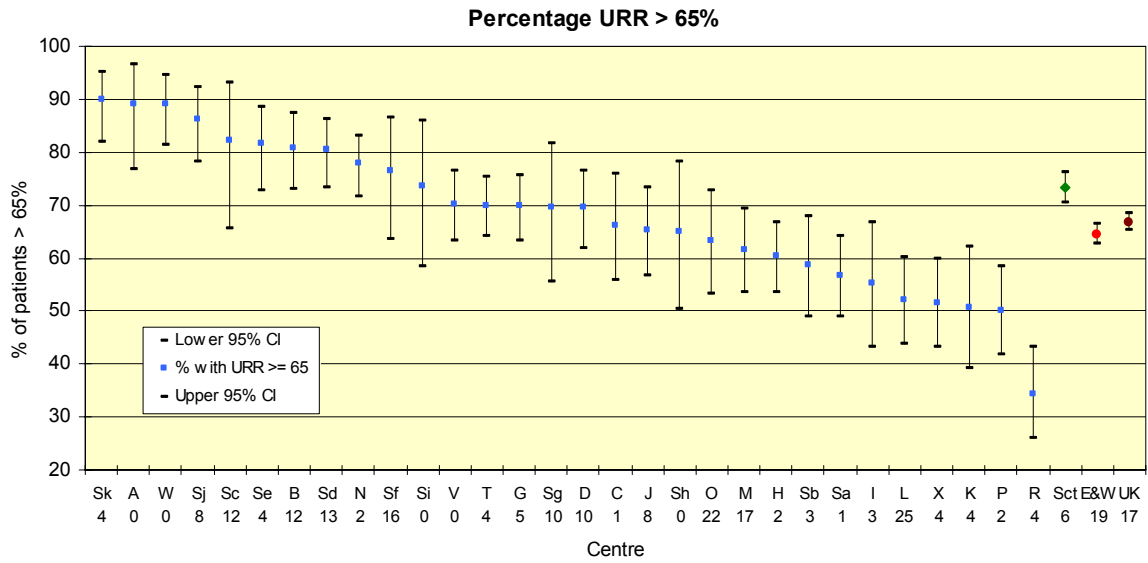


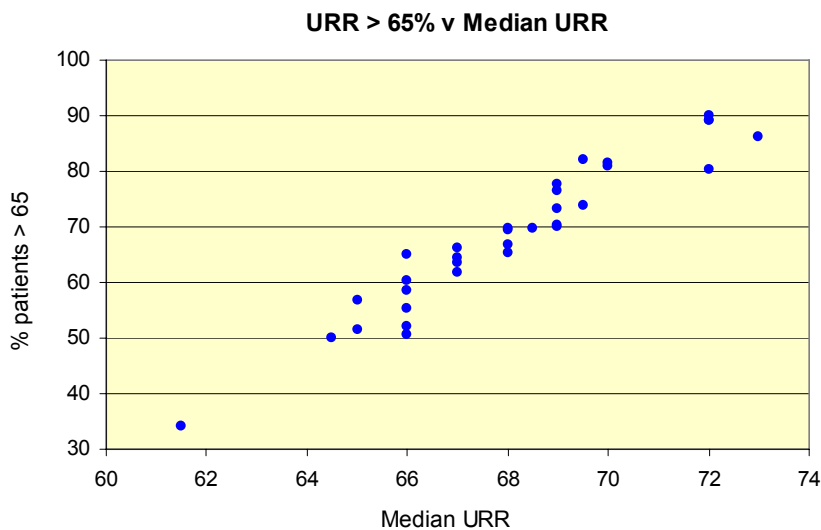
Figure 6.2 Urea reduction ratio distribution

There is wide variation between units, in the proportion of patients who achieve the current minimum Standard URR. For England and Wales, the percentage of hospital haemodialysis patients with a compliant URR (>65%) averaged 65% for all of the 19 units which was improved from 54% at the start of 1998 and 57% in the last quarter of 1998. There was still a wide variation between centres from 89% to 34% (97% - 28% in 1998). The results for England & Wales are significantly lower than Scotland which achieved a URR of >65% in 73% of patients (71% in 1998) with a variation between centres of 90% - 57%.

Centre R indicate most patients in 1998 were on 3 hours dialysis due to lack of funding. In 1999 these hours were being increased and the data shows some improvement from 1998. The URR calculation does not include residual renal function and so underestimates the true clearance. We have chosen to use it because it permits comparison across centres from the data which is collected at present.



**Figure 6.1b Achievement of the RA Standard for haemodialysis**



**Figure 6.3 URR achievement and median URR**

The above figure of median URR v percentage of patients achieving the Standard reveals a linear relationship, although it would be expected to tail off at the top end as a URR of >65% may well not be achievable in 100% of patients. It provides a strong indication that with current practice, a centre would have to reach a median URR of 75% for almost all patients to achieve a URR of >65%. This is even true for the USA with a different frequency distribution curve and 73% of patients with a URR >65% with a mean URR of 69%.

### ***Change in URR during 1998-99***

Overall the URRs increased in 1999 although, in England & Wales, the URR still lagged behind levels achieved in Scotland and the USA.



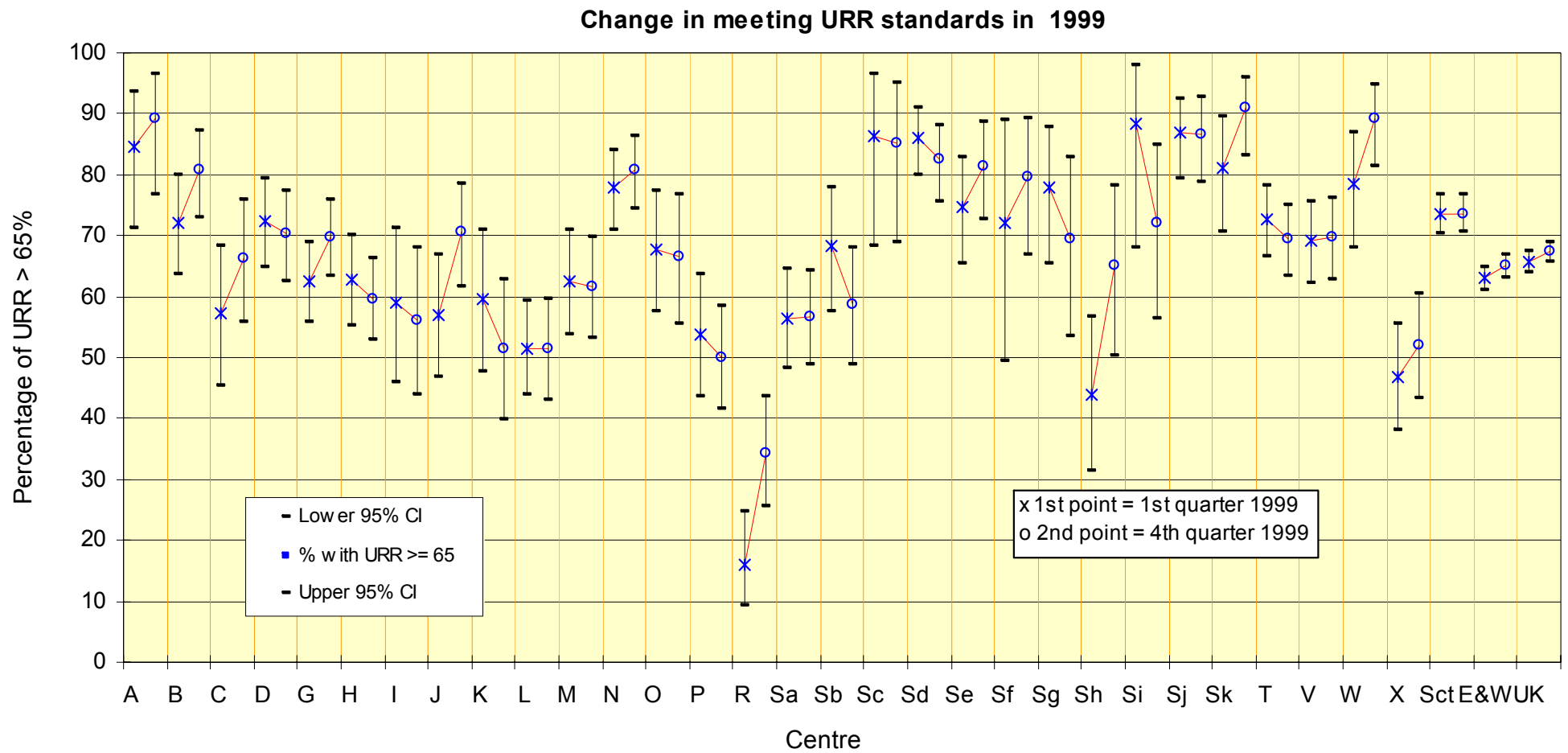
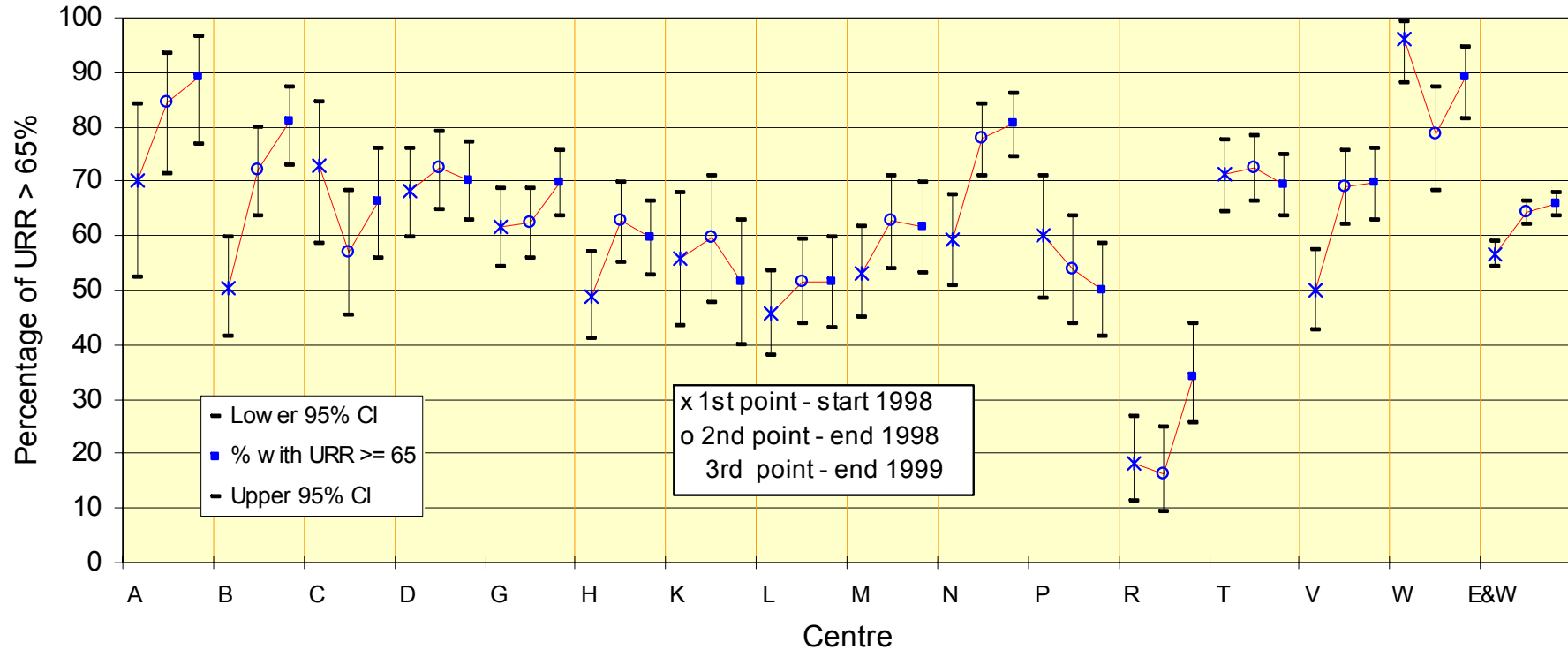


Figure 6.4 Change in meeting URR standard in 1999

### Change in meeting URR standards in 1998-99

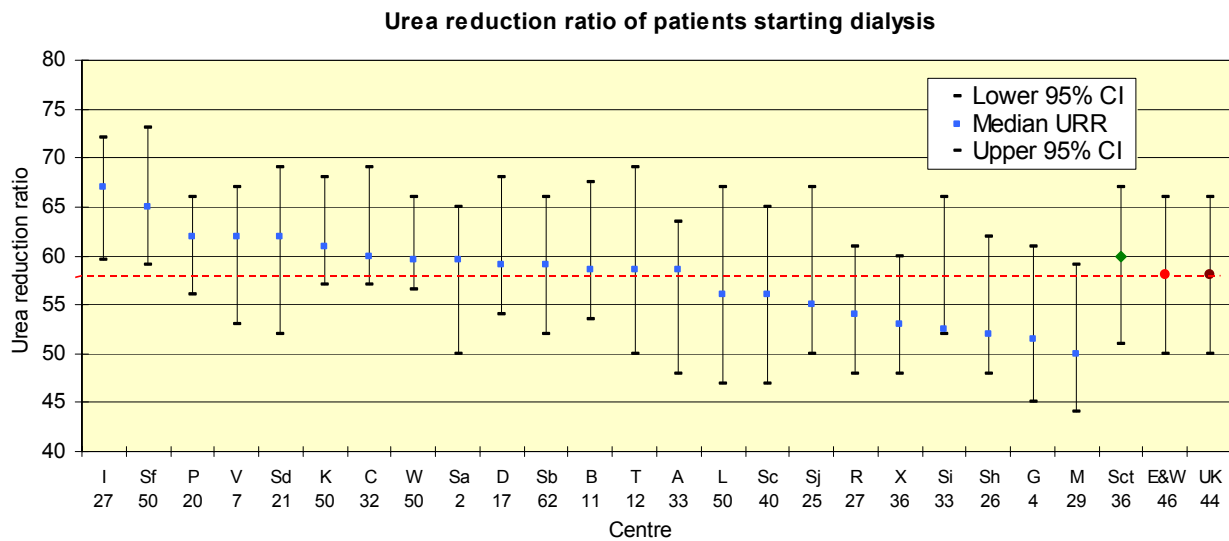


**Figure 6.5** Change in meeting URR standard over 2 years.

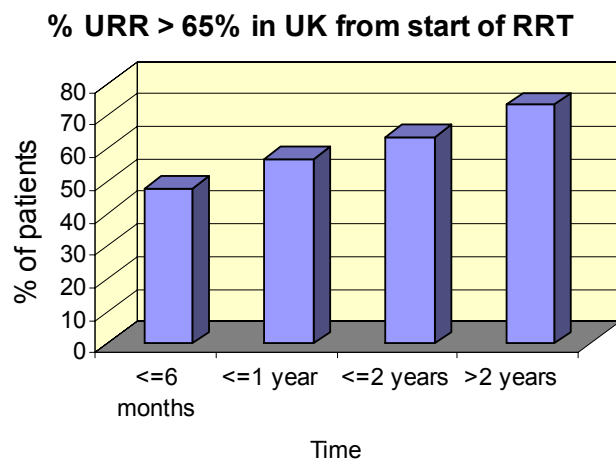
The two-year changes exclude the Scottish data as these data were not available in 1998. There is an overall increase in achievement of a URR > 65% although centre P shows a drop. Personal communication with this centre indicates that this is due to both nursing and medical staff shortage leaving inadequate time for patient supervision.

Centre T was the best performing centre in 1998 but with improvements from all other centres, there were 6 centres with a higher URR than T. At the start of 1998, 4 centres in England and Wales had greater than 70% of patients with a URR of >65, while by the end of 1999 this had increased to 8 centres.

## Achievement of standards in patients starting haemodialysis in 1999



**Figure 6.6 Achievement of URR within the 1st three months of HD**



excludes patients on <3 x week dialysis

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

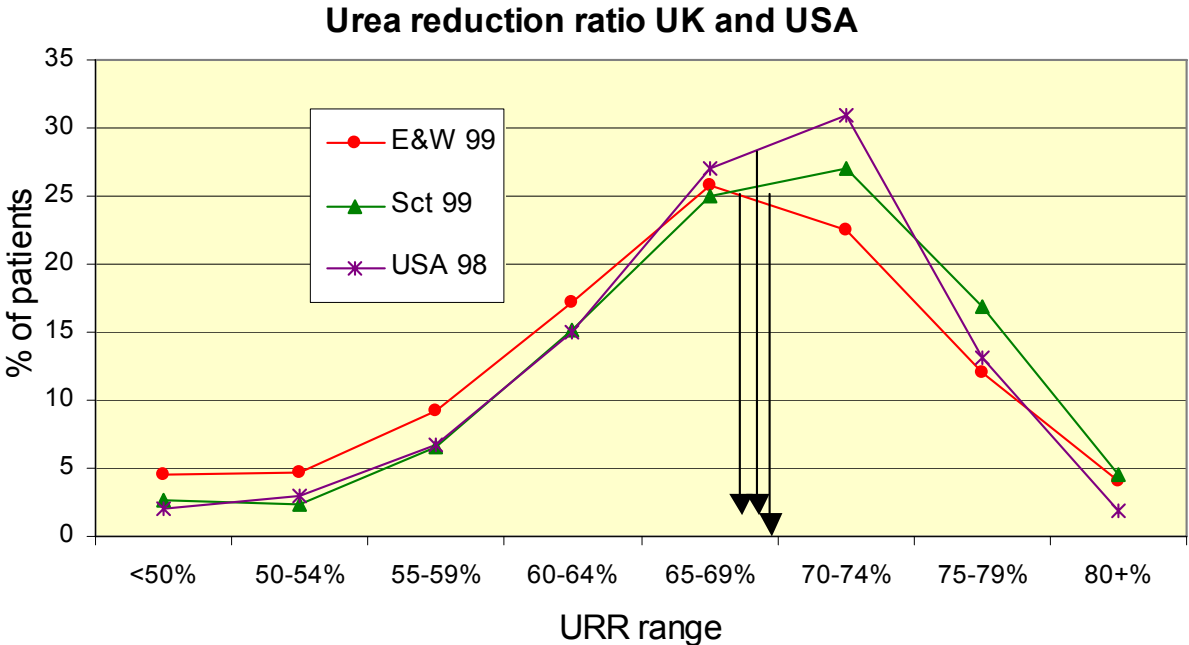
As expected, URRs were lower in patients starting dialysis than those of all HD patients at the same unit (which excludes patients within the first 3 months). This is probably partly due to a degree of residual renal function. URRs slowly increased with time on RRT with the median URR changing from 64% in the first 6 months to 69% at 2 years. How much of this increase in the URR is due to exclusion of those patients who died, and may have had a lower URR than the survivors, is unknown at present but will be analysed at a latter date by the Registry.

All these data excluded any patients known not to be on thrice weekly dialysis. Starting patients on dialysis earlier than another centre could lead to one centre having a greater proportion of patients at one year with significant residual renal function and apparent lower achievement of the URR Standard. With the known pressure on haemodialysis facilities within England and Wales, there are unlikely to be a large number of patients on thrice weekly dialysis with significant residual renal function. Only one Registry centre is known to

start most patients on dialysis when they still have significant renal function. At this centre these patients start on once a week dialysis and would be excluded from this analysis.

**International Comparison**

The US data were supplied by the healthcare finance association (HCFA <http://www.hcfa.gov/quality/3h.htm>). The US data are from a random sample of about 400 patients from each of the 18 dialysis networks and include 6,200 patients. The US data exclude patients within the first 6 months of dialysis (compared with 3 months in the UK). The vertical lines in Figure 6.8 shows the median URR. Due to the steepness of the curve at this point the median URR were similar at 67%, 69%, 68% for England & Wales, Scotland and USA respectively, although the percentage of patients achieving a URR > 65% were 65%, 73% and 73%.



\* US data excludes patients in the first 6 months of RRT.

**Figure 6.8 Urea reduction ratios in UK and USA**

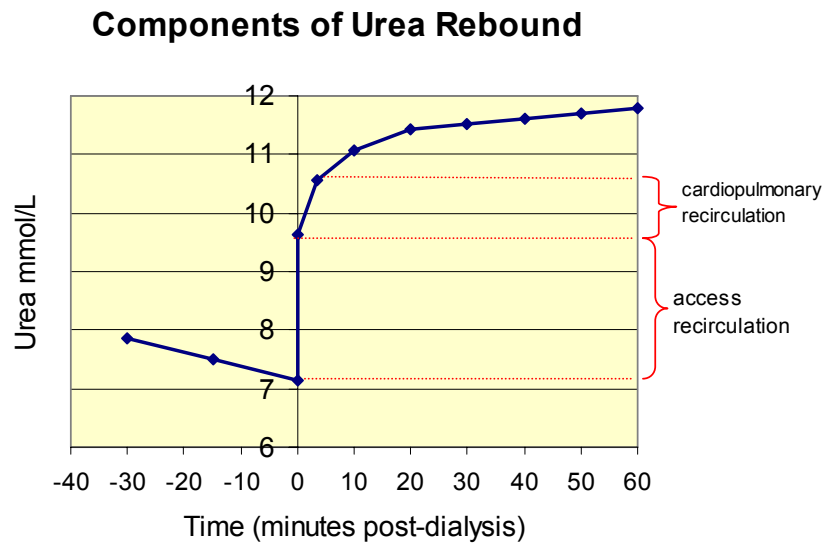
The figure indicates that only a small shift is required in the median URR in England & Wales to achieve the same percentage of patients with a URR > 65% as in the USA.

**Interpretation of results (Reproduced from 1999 report)**

**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 6.9 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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## Chapter 7: Haemoglobin and related variables

This chapter describes the position at the end of 1999 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

- Of the 22 renal units in England and Wales with adequate data returns, the Renal Association standard for haemoglobin in dialysis patients of 85% with haemoglobin of at least 10 g/dl was achieved by 2 units for haemodialysis patients, and 9 for peritoneal dialysis patients.
- Overall haemoglobin levels improved with 72% of haemodialysis patients and 80% of peritoneal dialysis patients in England and Wales achieving a haemoglobin of 10g/dl or more. This improvement was reflected by an improvement in the performance of most individual renal units.
- Serum ferritin concentrations were above 100mcg/l in 88% of haemodialysis patients in renal units in England & Wales (unit range 67-100%), and 80% of peritoneal dialysis patients.(unit range 63% -93%). It appears that the most efficient use of erythropoietin therapy is not being obtained in many units.
- Erythropoietin is given to 86% (range between renal units of 79% to 97%) of haemodialysis patients and 63% (36% to 88%) of peritoneal dialysis patients.
- An haemoglobin  $\geq 10$ g/dl was obtained without the use of erythropoietin in between 2% and 16% of haemodialysis patients in different renal units, and between 12% and 45% of peritoneal dialysis patients. The factors determining this variation are not clear. There was no clear relationship of haemoglobin of erythropoietin usage to age, but women had lower haemoglobin concentrations and were more likely to be on erythropoietin than men.

The management plans being used in different units with varying degrees of success are not influencing the spread of haemoglobin concentrations within the unit. Thus there is no evidence of successful targeting of a particular haemoglobin concentration. The maintenance of a broad spread of haemoglobin concentrations, even as haemoglobin concentrations on average are rising, is contributed to by the demonstrated variability of individual's haemoglobin concentrations.

## ***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 1999 was used in the analysis.

Data from centres were only included for statistical analysis if there was more than 75% data completeness. Centres with less than 50% completeness of data were not shown on the 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 units 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. The data for haemodialysis and peritoneal dialysis patients is presented in figures 1- 6 and tables 1 and 2.

A higher proportion of patients on peritoneal dialysis than on haemodialysis achieved the Renal Association Standard. In 1999 80% of peritoneal dialysis patients and 72% of haemodialysis patients in England and Wales had haemoglobin of 10g/dl or more (78% and 69% respectively in 1998).

Two centres achieved the Standard for patients on haemodialysis and in an additional three centres the 95% C.I. also included the 85% achievement Standard. This is unchanged compared to 1998.

Nine centres achieved the haemoglobin Standard for patients on peritoneal dialysis with an additional six centres having a 95% C.I which includes the Standard. In 1998 for patients on peritoneal dialysis, five centres achieved the Standard.

<b>Centre</b>	<b>% data return</b>	<b>Median Hb g/dl</b>	<b>90% range</b>	<b>Quartile range</b>	<b>% Hb ≥ 10 g/dl</b>	<b>Mean Hb g/dl</b>	<b>Standard deviation</b>
A	100	11.4	8.9-13.2	10.5-12.2	87	11.2	1.2
B	94	10.9	7.8-13.6	9.7-12.2	68	10.8	1.8
C	97	10.6	8.1-12.9	9.4-11.5	64	10.5	1.6
D	84	10.4	7.4-13.1	9.3-11.6	60	10.3	1.8
F	98	11.6	9.2-13.8	10.6-12.4	88	11.4	1.4
G	92	10.9	8.5-13.7	9.9-12.1	72	11.0	1.7
H	99	10.4	7.6-13.3	9.2-11.4	60	10.4	1.7
I	99	11.0	7.7-13.3	10.2-12.0	78	10.9	1.6
J	100	11.2	8.3-13.7	9.9-12.1	74	11.0	1.7
K	97	10.4	8.4-12.6	9.6-11.2	66	10.5	1.3
L	88	11.0	8.1-13.6	9.9-11.9	74	10.9	1.7
M	83	10.8	8.4-13.7	9.6-12.1	69	10.8	1.6
N	100	11.0	8.6-13.4	10.1-12.1	76	11.0	1.5
<b>Centre</b>	<b>% data</b>	<b>Median</b>	<b>90%</b>	<b>Quartile</b>	<b>% Hb ≥</b>	<b>Mean</b>	<b>Standard</b>

	return	Hb g/dl	range	range	10 g/dl	Hb g/dl	deviation
O	100	11.3	8.7-13.5	10.3-12.3	82	11.2	1.5
P	100	10.9	8.8-15.0	9.8-12.2	73	11.1	1.7
Q	99	11.4	8.5-13.9	10.0-12.4	77	11.2	1.7
R	98	10.8	8.4-14.0	9.9-11.9	73	10.9	1.7
T	96	11.0	8.4-13.7	10.0-12.1	75	11.0	1.6
U	82	10.6	8.2-13.0	9.6-11.6	72	10.6	1.4
V	100	11.5	8.7-14.1	10.5-12.3	84	11.5	1.5
W	99	10.1	8.0-12.3	8.8-11.0	56	10.0	1.4
X	100	10.7	8.6-13.2	9.7-11.8	68	10.7	1.4
<b>E&amp;W</b>	<b>94</b>	<b>10.9</b>	<b>8.3-13.6</b>	<b>9.8-12.0</b>	<b>73</b>	<b>10.9</b>	<b>1.6</b>
<b>Scot.</b>	<b>94</b>	<b>11.0</b>	<b>7.8-13.5</b>	<b>9.7-12.1</b>	<b>70</b>	<b>10.8</b>	<b>1.7</b>

Table 7.1 Haemoglobin data for patients on haemodialysis

Haemoglobin distribution : haemodialysis

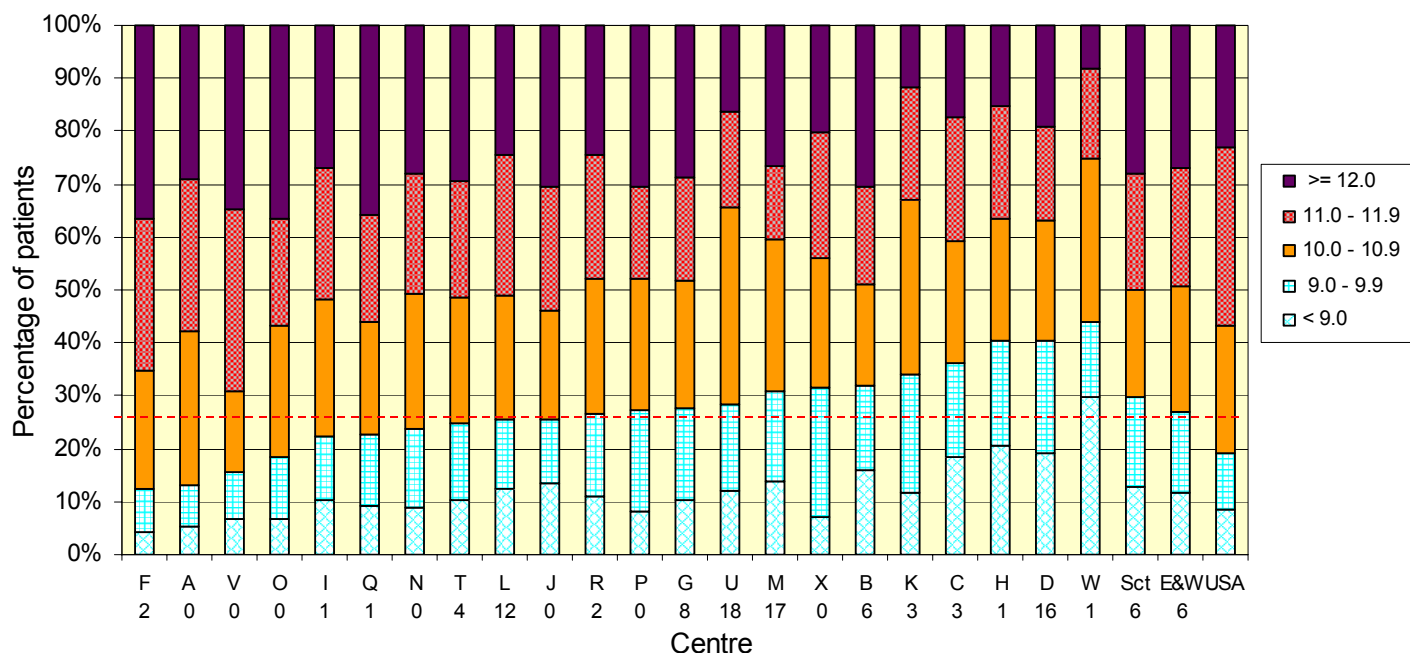


Figure 7.1 Haemoglobin patients on HD by 1g/dl bands

Figure 7.1 shows the spread of data by 1g/dl bands. The centres are ordered by increasing percentage with a haemoglobin  $\geq 10$  g/dl, with centres to the left having the highest percentage.

### Percentage haemoglobin > 10 g/dL : haemodialysis

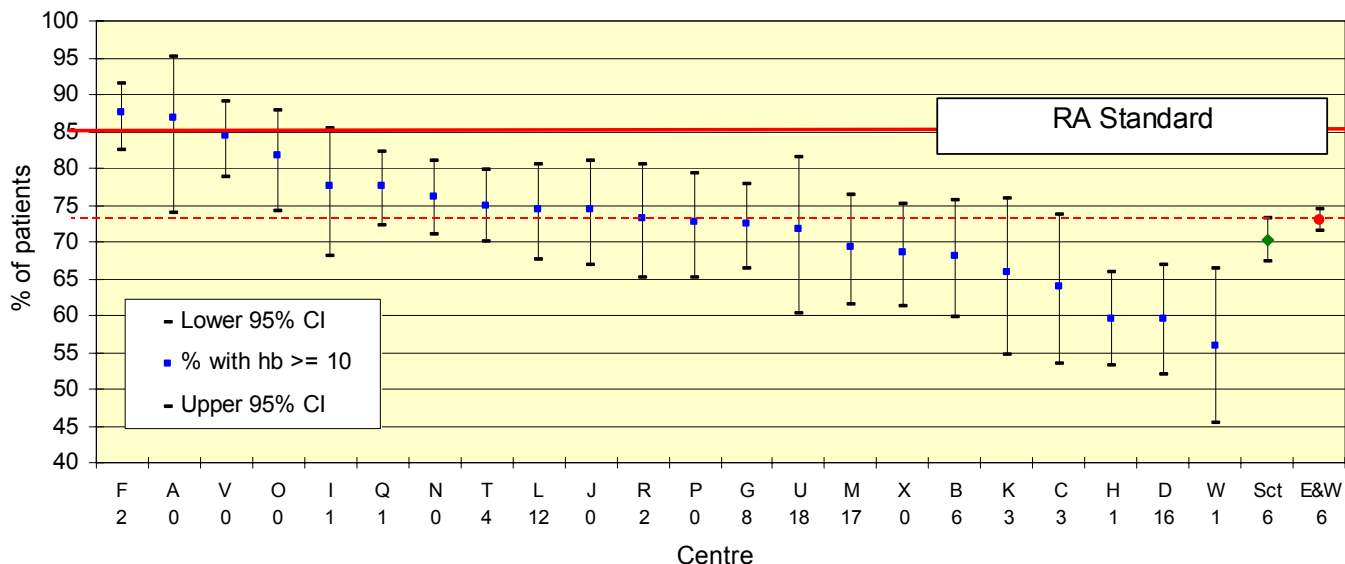


Figure 7.2 Percentage of HD patients by centre achieving the RA Standard

### Haemoglobin : haemodialysis

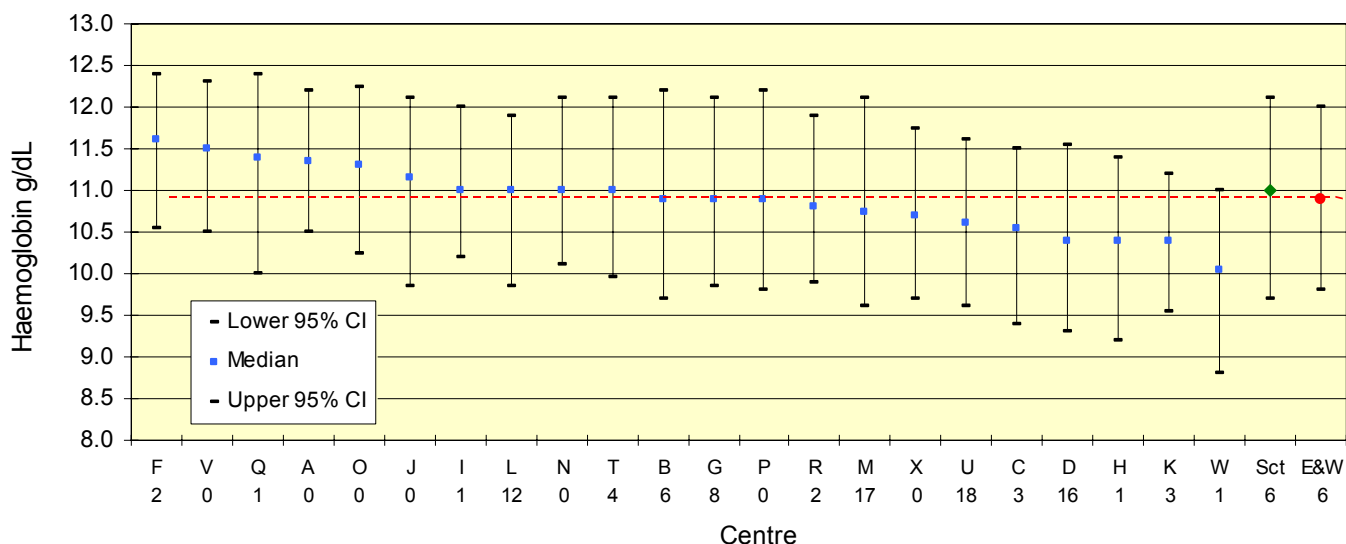


Figure 7.3 Haemoglobin median and quartile range for haemodialysis patients

Centre	% data return	Median Hb g/dl	90% range	Quartile range	% Hb ≥ 10 g/dl	Mean Hb g/dl	Standard deviation
A	100	12.1	10.1-15.4	11.0-13.5	95	12.3	1.6
B	94	11.4	8.8-13.2	9.9-12.1	74	11.0	1.4
C	100	12.0	9.0-15.1	11.4-13.3	88	12.1	1.7
D	100	11.5	9.4-14.3	10.4-12.6	84	11.6	1.6
F	99	11.8	9.5-14.8	11.0-13.0	95	12.0	1.6
G	97	11.3	8.8-13.8	10.2-12.2	79	11.2	1.6
H	100	10.9	8.2-13.2	9.7-11.7	71	10.8	1.4
J	100	12.1	9.1-14.3	10.4-13.1	84	11.8	1.9
K	99	11.3	9.2-13.6	10.5-12.3	86	11.4	1.4
L	97	10.8	7.3-14.4	9.7-12.4	69	11.0	2.2
M	99	11.6	8.0-15.0	10.6-12.7	80	11.6	1.9
N	100	11.8	9.6-14.1	10.6-12.4	88	11.6	1.4
O	99	11.6	9.5-14.5	10.9-12.7	87	11.8	1.6
P	97	11.5	9.1-14.1	10.7-12.4	87	11.6	1.4

Centre	% data return	Median Hb g/dl	90% range	Quartile range	% Hb ≥ 10 g/dl	Mean Hb g/dl	Standard deviation
Q	99	11.6	8.2-14.2	10.6-12.7	81	11.5	1.9
R	98	11.4	8.8-13.4	10.6-12.1	84	11.3	1.3
T	99	10.7	8.0-13.8	9.6-12.4	68	10.8	1.9
U	93	11.6	9.7-13.3	10.8-12.1	88	11.5	1.1
V	98	12.1	9.2-14.6	11.3-12.9	93	12.1	1.6
W	98	10.3	7.1-12.9	9.2-11.3	59	10.3	1.6
X	98	10.7	8.5-13.7	9.8-11.9	67	10.9	1.7
<b>E&amp;W</b>	<b>95</b>	<b>11.4</b>	<b>8.6-14.1</b>	<b>10.3-12.4</b>	<b>80</b>	<b>11.3</b>	<b>1.7</b>
<b>Scot</b>	<b>90</b>	<b>11.2</b>	<b>8.5-14.1</b>	<b>10.1-12.4</b>	<b>77</b>	<b>11.2</b>	<b>1.8</b>

Table 7.2 Haemoglobin data for patients on peritoneal dialysis

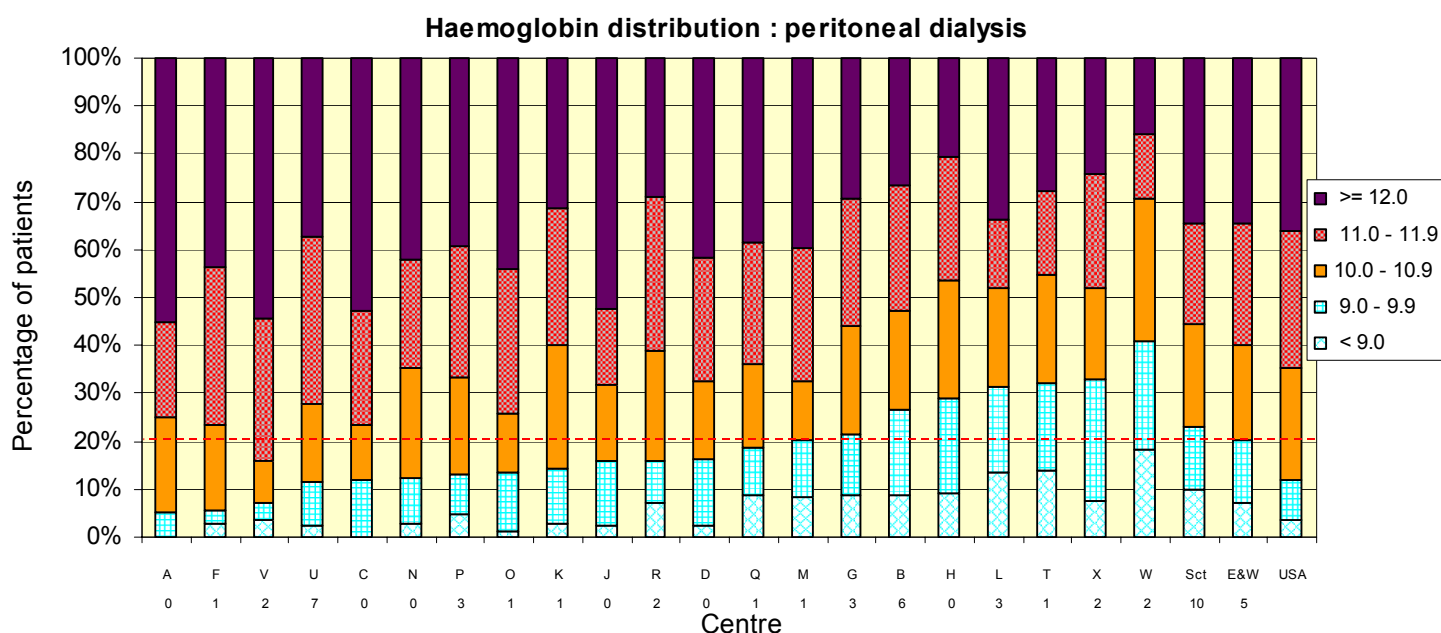


Figure 7.4 Distribution of haemoglobin for patients on PD by 1g/dl bands

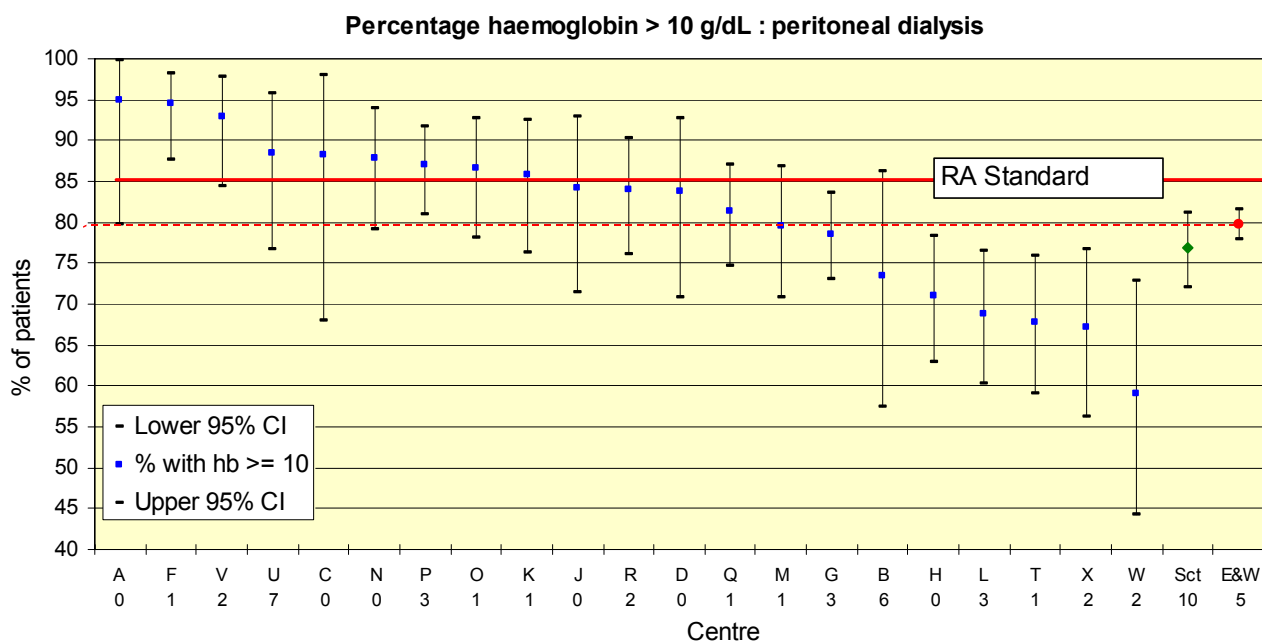
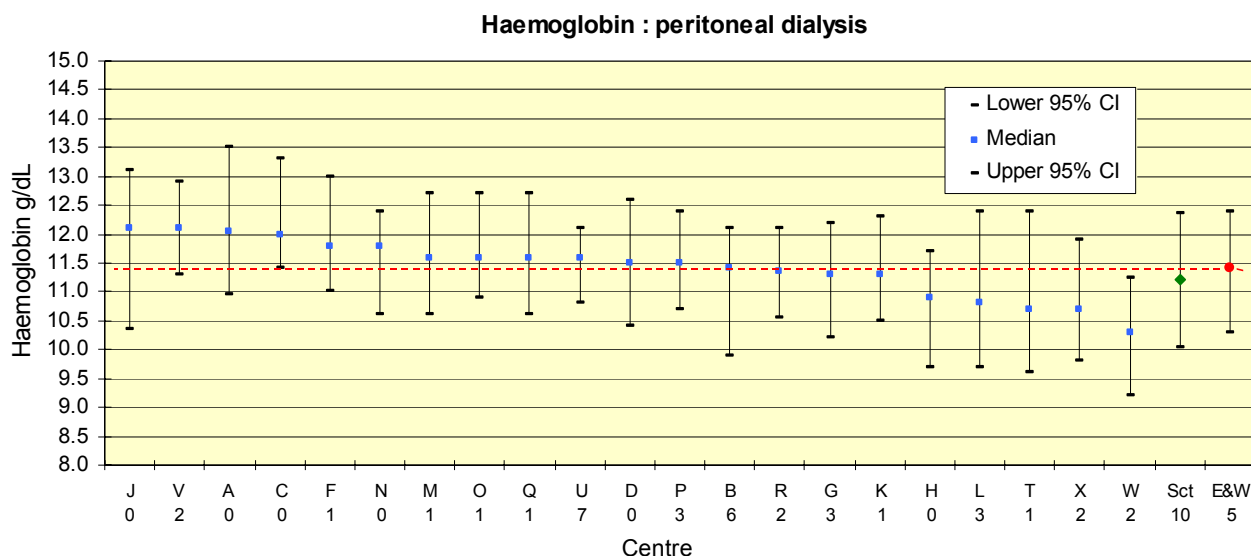


Figure 7.5 Percentage of PD patients by centre achieving the RA Standard



**Figure 7.6 Median haemoglobin on peritoneal dialysis**

### ***Factors influencing haemoglobin***

Erythropoietin prescription and iron stores influence haemoglobin concentration and data on these variables are presented in this report. Other influences are less certain.

### ***Haemoglobin and serum ferritin***

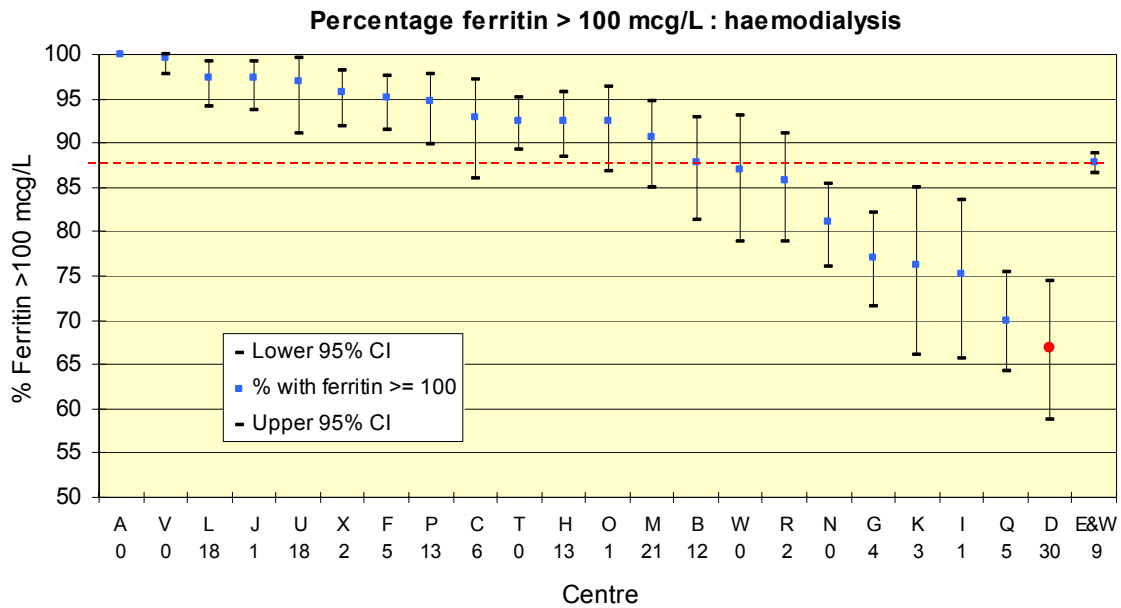
Centres use different variables as measures of iron stores: serum ferritin is most commonly used. For this report, serum ferritin levels have been analysed and are shown in tables 7.3 and 7.4. As with haemoglobin the distribution of serum ferritin concentrations is represented by the inter-quartile and 90% ranges. The percentage with serum ferritin over 100 mcg/l can be compared between units using 95% confidence intervals.

Centre	% data return	Median ferritin	90% range	Quartile range	% ferritin $\geq$ 100 $\mu$ g/l
A	100	496	191-1273	371-688	100
B	88	340	62-1367	181-702	88
C	94	420	75-1790	263-709	93
D	70	132	27-652	73-253	67
E	22	*	*	*	*
F	95	483	102-1337	288-732	95
G	96	182	43-957	106-310	77
H	87	286	94-801	204-436	93
I	99	157	32-493	103-257	75
J	99	411	125-990	283-558	97
K	97	211	23-929	105-342	76
L	82	713	173-1798	422-1133	97
M	79	321	73-813	180-503	91
N	100	222	36-682	122-382	81
O	99	239	66-1000	165-335	92
P	87	345	92-861	200-497	95
Q	95	158	25-782	84-267	70
R	98	244	57-1012	158-388	86
T	100	484	63-1144	320-756	93

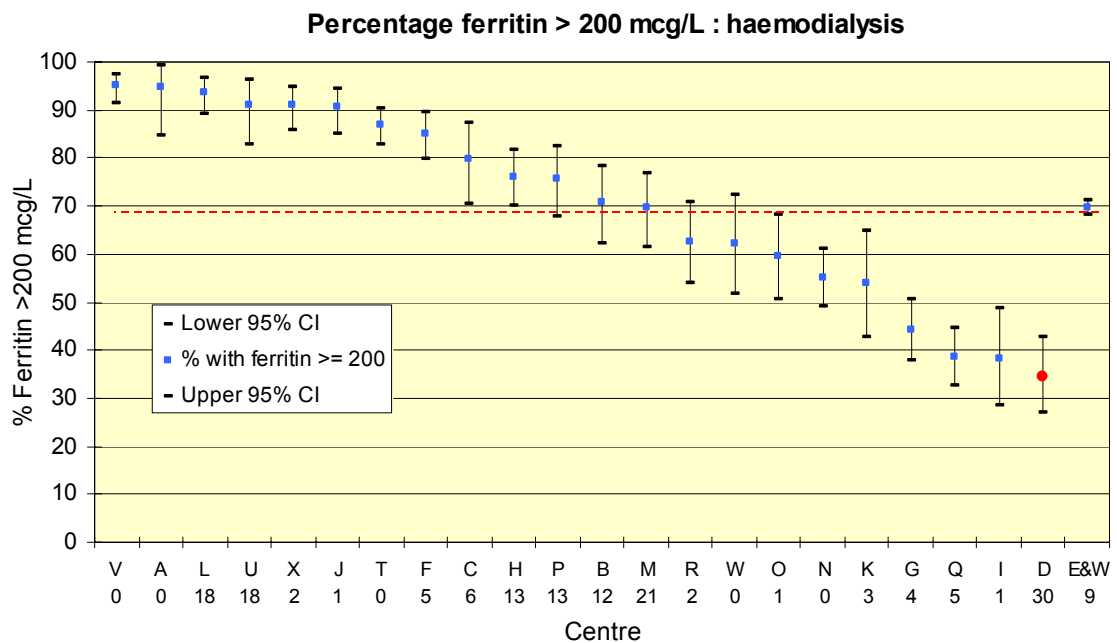
Centre	% data return	Median ferritin	90% range	Quartile range	% ferritin $\geq$ 100 $\mu$ g/l
U	82	403	157-849	298-561	97
V	100	517	186-891	411-647	99
W	100	236	56-831	151-409	87
X	98	407	127-832	321-554	96
E & W	91	316	55-1094	171-535	88

\* insufficient data

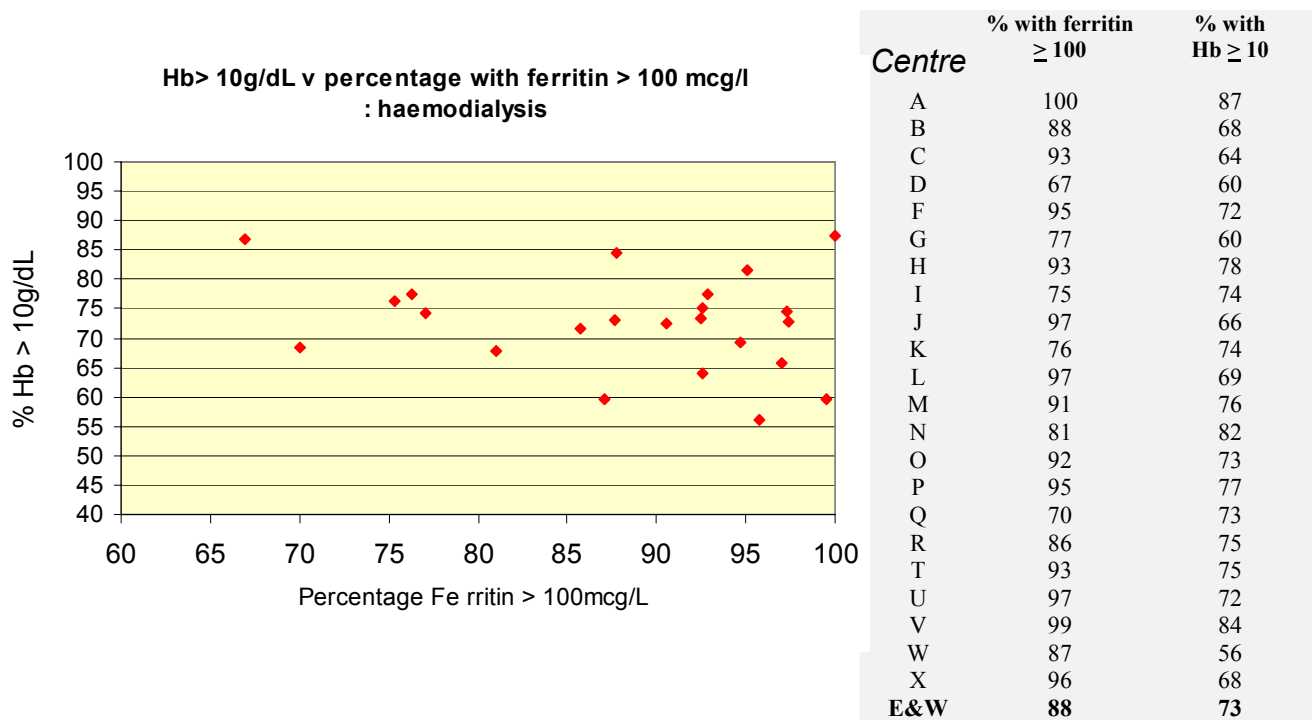
**Table 7.3 Serum Ferritin concentration in haemodialysis patients**



**Figure 7.7 Percentage of HD patients with serum ferritin > 100 mcg/l.**



**Figure 7.8 Percentage serum ferritin > 200 mcg/l on HD**

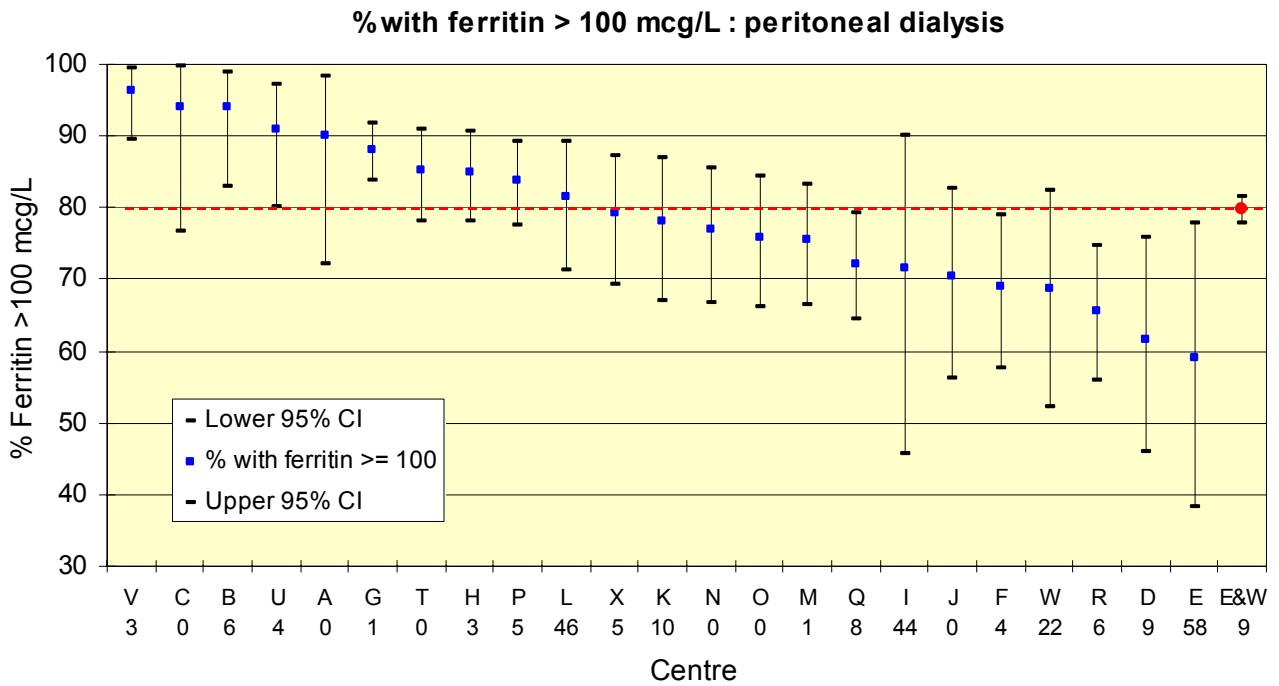


**Figure 7.9 Haemoglobin > 10 g/dl vs. serum ferritin > 100 mcg/l on haemodialysis**

Centre	% data return	Median ferritin µg/l	90% range	Quartile range	% ferritin > 100µg/l
A	100	508	14-1043	426-636	90
B	94	434	93-1226	243-669	94
C	100	515	61-1472	362-825	94
D	91	136	21-403	77-222	62
E	42	*	*	*	*
F	96	138	29-516	85-323	69
G	99	263	48-1101	156-462	88
H	97	177	46-836	122-323	85
I	56	192	51-538	99-246	71
J	100	188	21-478	65-335	70
K	90	208	37-793	111-372	78
L	54	312	47-1251	141-506	81
M	99	186	37-678	100-370	76
N	100	193	42-483	114-292	77
O	100	211	26-749	103-344	76
P	95	269	61-795	162-422	84
Q	92	174	31-718	94-304	72
R	94	152	22-521	69-242	66
T	100	305	54-1085	158-432	85
U	96	282	37-606	137-389	91
V	97	326	118-806	215-510	96
W	78	160	25-643	89-254	69
X	95	222	38-1129	110-360	79
<b>E &amp; W</b>	<b>91</b>	<b>226</b>	<b>37-817</b>	<b>117-392</b>	<b>80</b>

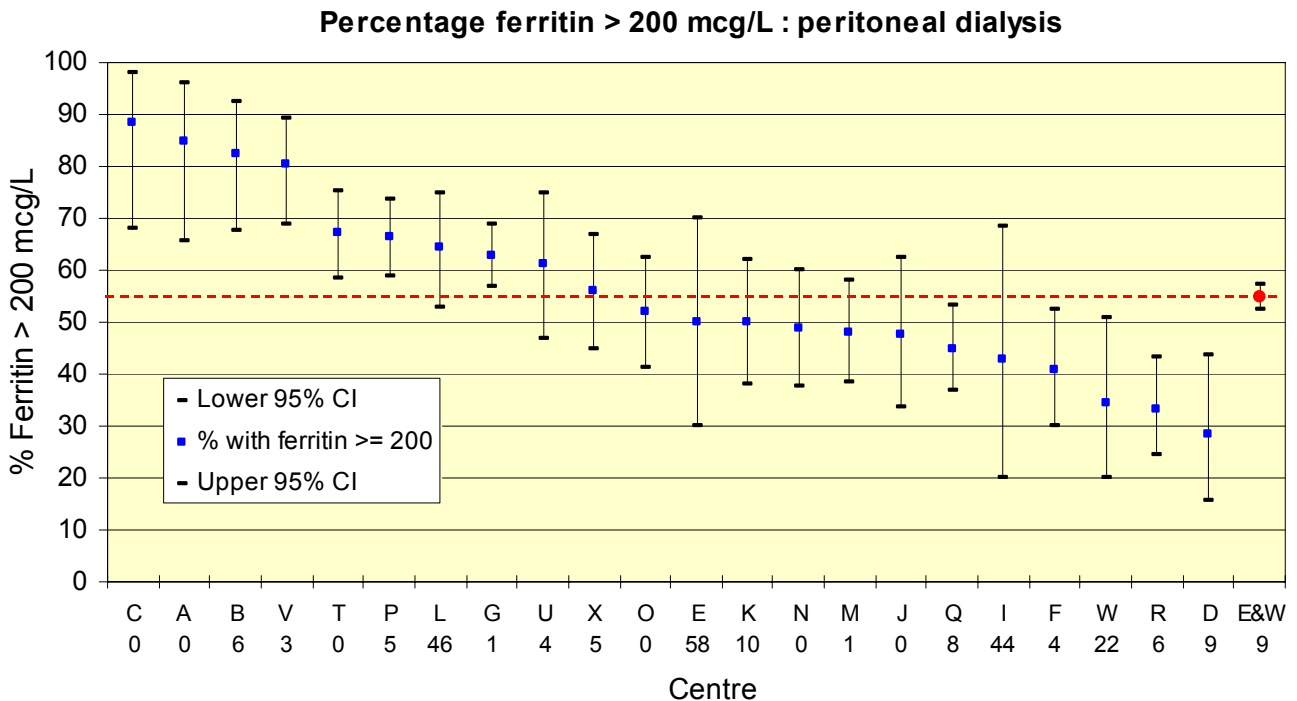
**Table 7.4 Ferritin concentrations in peritoneal dialysis patients**





**Figure 7.10 Percentage serum ferritin > 100 mcg/l on peritoneal dialysis**

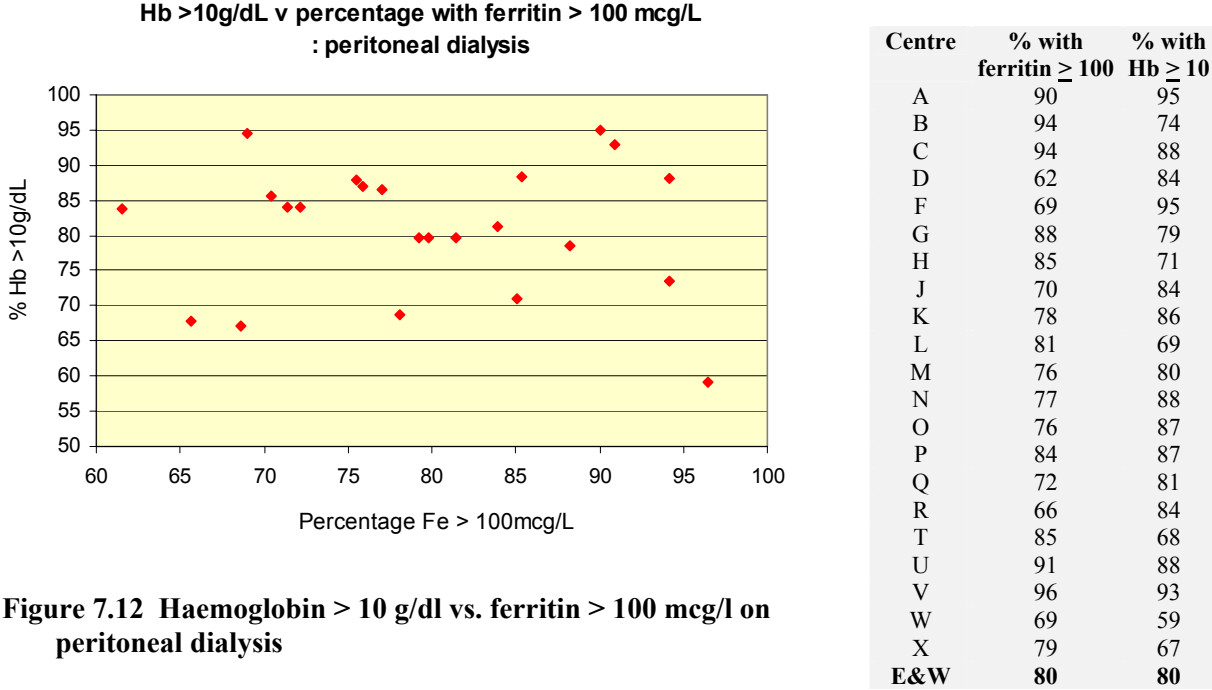
The numbers under each centre on the graph show the percentage of missing ferritin data over 9 months, for that unit. Error bars represent 95% confidence intervals.



**Figure 7.11 Percentage serum ferritin > 200 mcg/l on peritoneal dialysis**

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

There was no clear correlation between the percentage of patients with serum ferritin over 100 mcg/l and achievement of the Real Association Standard for haemoglobin in either haemodialysis or peritoneal dialysis patients (figures 7. 9 and 7.12).



**Figure 7.12 Haemoglobin > 10 g/dl vs. ferritin > 100 mcg/l on peritoneal dialysis**

**Haemoglobin and erythropoietin**

Many centres do not record prescription of erythropoietin on their IT systems or do so only partially. Partial recording has been identified during the analysis, confirmed with the centre and excluded from the analysis. Most centres only record whether an individual was prescribed erythropoietin and failure to record is assumed to mean that erythropoietin has not been prescribed. This year 9 centres submitted data on erythropoietin prescribing compared to 8 in last year’s report. The rates of prescription of erythropoietin are shown in tables 7.5 and 7.6.

If centres work to a minimum haemoglobin of 10g/dl then it might be presumed that patients with a haemoglobin less than this level should be prescribed erythropoietin. Rates of erythropoietin prescription to patients with haemoglobin less than 10g/dl may be useful in determining whether there are specific groups to which there is a relative reluctance to prescribe erythropoietin. For example there are some centres that have lower rates of erythropoietin prescribing for patients on peritoneal dialysis with haemoglobin less than 10g/dl than for haemodialysis patients.

Some patients on dialysis maintain adequate haemoglobin concentrations without the need for erythropoietin prescription. This is reported in tables 7.5 and 7.6 as the percentage of patients with a haemoglobin over 10g/dl but not requiring erythropoietin. This measure might be indicative of whether the overall management in a centre (excluding erythropoietin prescription) is conducive to high haemoglobin and may help explain some of the differences between units. For example centre C uses relatively high doses of erythropoietin in a high proportion of patients and has good serum levels of ferritin but still only achieves 64% of haemodialysis patients with a haemoglobin over 10g/dl. Only 2% of patients in centre C have

a haemoglobin over 10g/dl without the need for erythropoietin. As expected a higher percentage of peritoneal dialysis patients maintain adequate haemoglobin without erythropoietin than haemodialysis patients.

Centre	% on epo	Mean weekly dose for pats on epo	Median dose for pats on epo	Hb < 10g/dl % on epo	Hb ≥10 g/dl % not on epo
B	86	5920	6000	93	8
C	97	7470	8000	100	2
G	84	6720	6000	88	11
J	93	8690	8000	97	7
K	85	6000	4000	77	5
N	87	6870	6000	97	12
R	84	6880	6000	91	13
T	79	5600	6000	80	16
W	89	7660	8000	89	6
<b>E &amp; W</b>	<b>86</b>	<b>6750</b>	<b>6000</b>	<b>90</b>	<b>10</b>

**Table 7.5 Erythropoietin prescribing in haemodialysis patients**

Centre	% on epo	Mean weekly dose for pats on epo	Median dose for pats on epo	Hb < 10g/dl % on epo	Hb ≥10 g/dl % not on epo
B	61	4910	6000	78	29
C	88	3670	4000	100	12
G	77	4550	4000	74	18
J	75	4520	4000	100	25
K	62	4410	4000	90	36
N	58	4400	4000	100	42
R	64	5170	4000	75	31
T	36	4770	4000	43	45
W	49	4320	4000	67	39
<b>E &amp; W</b>	<b>63</b>	<b>4600</b>	<b>4000</b>	<b>70</b>	<b>30</b>

**Table 7.6 Erythropoietin prescribing in peritoneal dialysis patients and weekly dose**

### ***Erythropoietin and time on renal replacement therapy***

Table 7.7 shows that with increasing time on peritoneal dialysis there is an increase in proportion treated with erythropoietin but in haemodialysis patients there is little change in erythropoietin prescription with time.

Time on treatment	< 1year	1-2 years	2-3 years	3-5 years	5-10 years	>10 years
<b>Haemodialysis % patients</b>	82 (200)	92 (261)	85 (159)	89 (219)	84 (218)	80 (185)
<b>Peritoneal dialysis %</b>	49 (98)	67 (126)	60 (57)	68 (84)	73 (66)	79 (31)

Brackets indicate total numbers

**Table 7.7 Percentage of patients prescribed erythropoietin against time on RRT**

## Age and anaemia management

Data on erythropoietin prescribing and age was available from 1500 haemodialysis and 744 peritoneal dialysis patients.

### Haemodialysis

Age group (years)	18-34	35-44	45-54	55-64	65-74	75+
% on epo	89 (121)	83 (151)	83 (203)	83 (262)	89 (320)	88 (229)
% Hb >10 no epo	7 (9)	12 (22)	14 (34)	14 (44)	7 (26)	7 (17)
% Hb <10 on epo	95 (36)	86 (43)	90 (70)	93 (79)	89 (82)	87 (59)

Brackets indicate total numbers.

**Table 7.8 Erythropoietin prescription by age in haemodialysis patients**

No definite trends in use of erythropoietin prescription with age are evident although the data may indicate less use of erythropoietin in middle ages compared with both the young and elderly. This data is consistent with that reported for 1998. There is also a suggestion from the data that there are fewer patients with adequate haemoglobin without the need for erythropoietin among the young and elderly compared to the middle aged although the number of patients is small.

### Peritoneal dialysis

Age group (years)	18-34	35-44	45-54	55-64	65-74	75+
% on epo	58 (36)	73 (66)	70 (94)	55(102)	61 (112)	67 (59)
% Hb>10 no epo	26 (16)	17 (15)	29 (38)	35 (64)	35 (64)	29 (25)
% Hb<10 on epo	44 (7)	76 (28)	89 (25)	59 (23)	67 (16)	86 (12)

Brackets indicate total numbers

**Table 7.9 Erythropoietin prescription by age in peritoneal dialysis patients**

It is difficult to draw conclusions from the data on erythropoietin prescribing in peritoneal dialysis because of the relatively small number of patients. The apparent low levels of erythropoietin prescribing in the young even when the haemoglobin is less than 10g/dl was not seen in the data from 1998 and is of uncertain significance.

## Erythropoietin prescription and gender

### Haemodialysis

The 1999 and 1998 Registry reports demonstrated that as in the normal population females on dialysis had lower haemoglobin than males. The data presented in table 7.10 confirms that fewer females have haemoglobin  $\geq 10$ g/dl without erythropoietin than males. Females are prescribed erythropoietin appropriately as demonstrated by a higher proportion of females than males prescribed erythropoietin in the population as a whole. Amongst haemodialysis

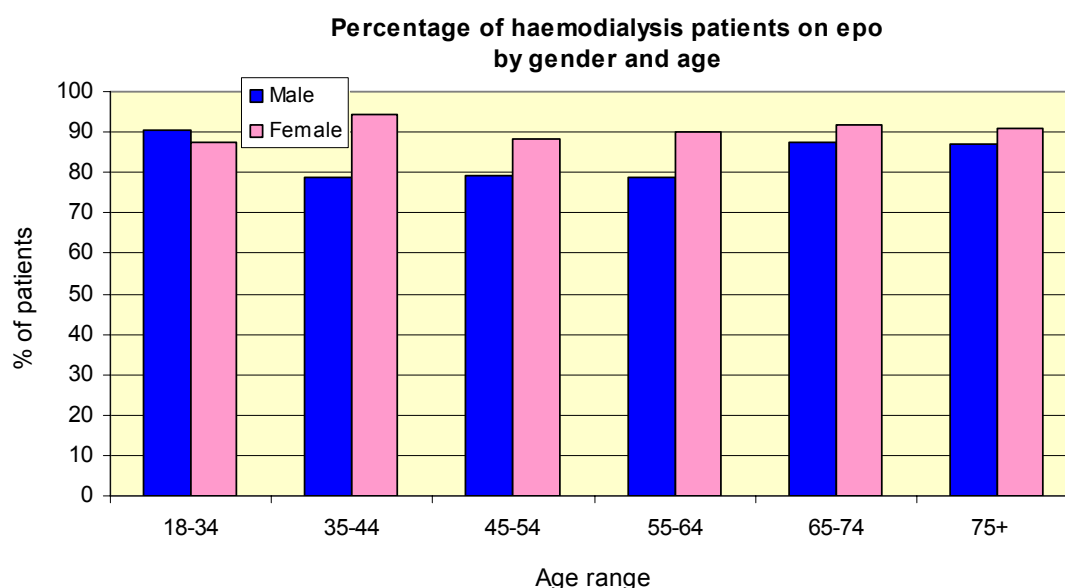
patients with a haemoglobin < 10g/dl, a higher proportion of males did not receive erythropoietin than females.

Gender	mean Hb g/dl	Standard deviation	% on epo	% Hb < 10 g/dl on epo	% Hb>10g/dl without epo
Male	11.0	1.64	83 (801)	87 (211)	13 (120)
Female	10.8	1.58	90 (485)	93 (158)	6 (32)

Numbers in brackets are the total number of patients

**Table 7.10 Haemoglobin and gender in HD patients**

In 1999 the mean haemoglobin has risen from the 1998 figure of 10.9 g/dl for males and 10.6 g/dl for females. Similar to last year, the mean haemoglobin of men on haemodialysis was significantly higher than women, (Chi squared, p=0.004).



**Figure 7.13 Percentage of haemodialysis patients on epo by age and gender**

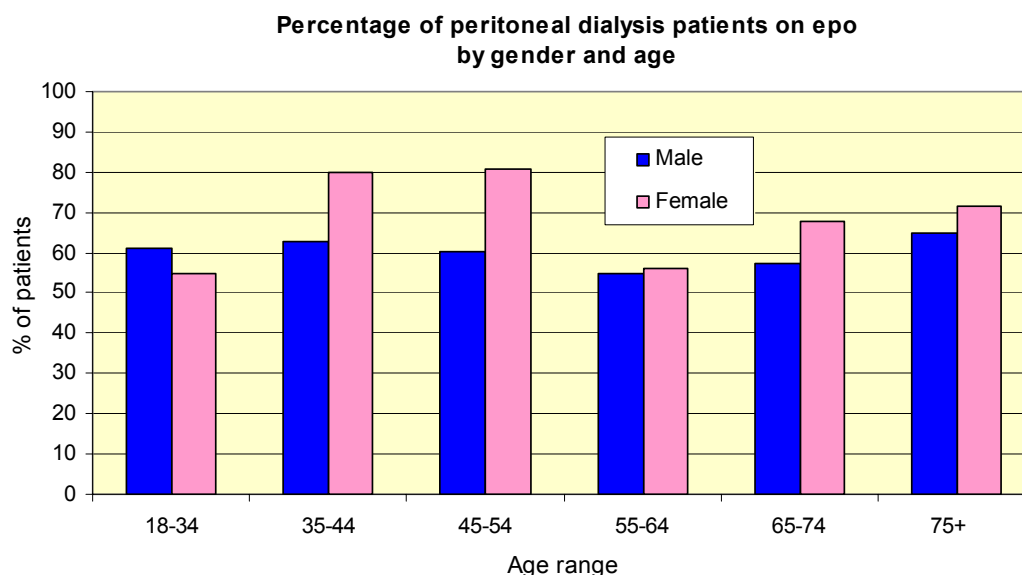
### ***Peritoneal dialysis***

Gender	mean Hb g/dl	Standard deviation	% on epo	Hb < 10 g/dl % on epo	% Hb>10g/dl without epo
Male	11.5	1.70	59 (257)	64 (48)	35 (151)
Female	11.1	1.69	69 (212)	76 (63)	24 (71)

Numbers in brackets are the total number of patients

**Table 7.11 Haemoglobin and gender in peritoneal dialysis patients**

In 1999 the mean haemoglobin has risen from the 1998 figure of 11.2 g/dl for males and 10.8 g/dl for females. Similar to last year, the mean haemoglobin of men on peritoneal dialysis was significantly higher (chi squared p=0.001).

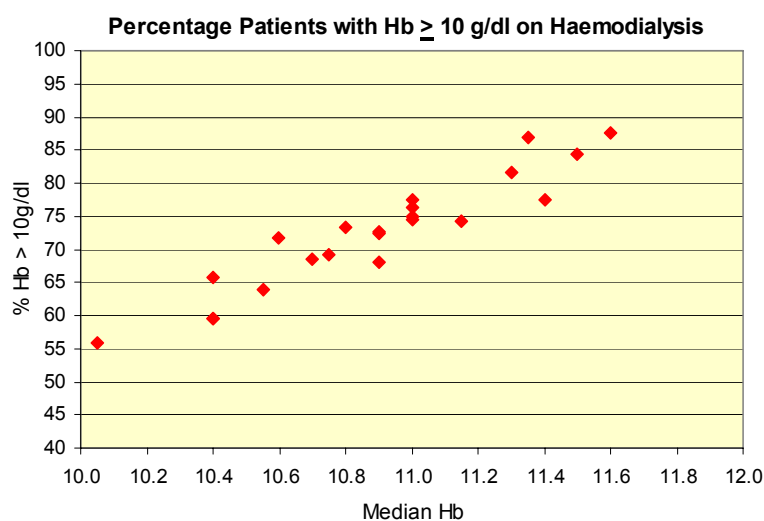


**Figure 7.14** Percentage of peritoneal dialysis patients on epo by age

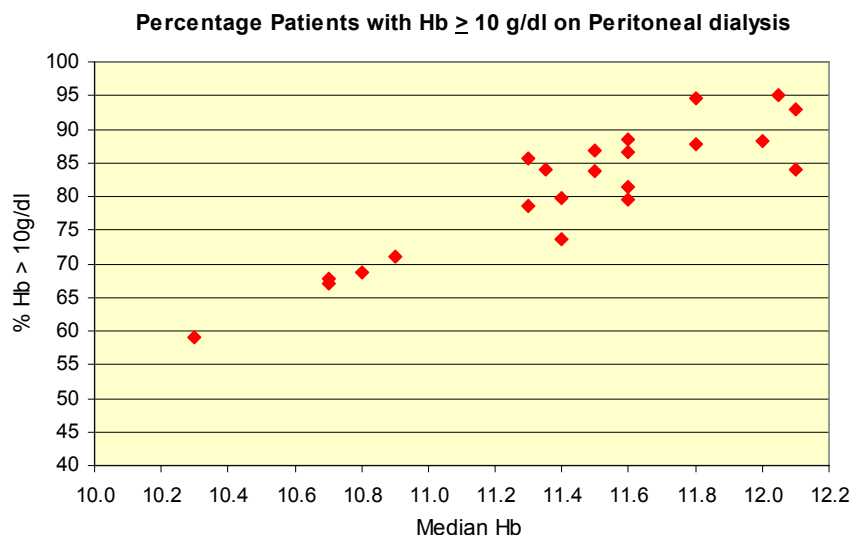
### ***Compliance with Renal Association standards and median haemoglobin***

As in previous reports figure 7.15 demonstrates a linear relationship between median haemoglobin and percentage achievement of the Renal Association recommended level of 10g/dl. There is no evidence that the spread of data in units with higher achievement of the recommended level is different from that with lower levels. The data show that in current practice units which have a high achievement of the Renal Association haemoglobin standard have proportionately high median haemoglobins. There is no evidence that they have successful targeting strategies.

A similar relationship is shown by the Healthcare Finance Administration data from USA where an average haemoglobin of 11.1g/dl was achieved across all the renal networks in October 1998 with 78% of patients having a haemoglobin above 10g/dl.



**Figure 7.15** Percent Hb above 10g/dl and median Hb in individual centres (HD)



**Figure 7.16 Percent Hb above 10g/dl and median Hb in individual centres (PD)**

### ***Changes in Haemoglobin over Time***

The Renal Registry collects individual patient data which allows analysis of changes over time within centres as a whole and also longitudinal changes over time for individual patients.

#### ***Data selection***

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

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

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

### ***Haemoglobin at start of dialysis***

<b>Centre</b>	<b>% data return</b>	<b>Median Hb g/dl</b>	<b>90% range</b>	<b>Quartile range</b>	<b>%Hb &gt; 10g/dL</b>
A	96	11.0	9.5-12.8	10.7-11.9	84
B	96	8.7	6.3-11.3	7.5-9.7	15
C	91	9.4	7.4-12.2	8.7-10.4	38
D	86	9.5	7.0-12.4	7.9-10.5	36
E	27				
F	93	9.9	6.7-13.6	8.8-11.2	49
G	93	10.2	8.3-12.8	9.5-11.3	59
H	98	9.3	7.6-11.7	8.7-10.2	33
I	95	9.5	6.6-13.0	8.6-10.2	37

J	91	10.0	6.8-13.7	9.1-10.9	50
K	100	10.1	8.3-13.0	9.3-11.7	56
L	100	9.5	7.1-12.6	8.7-10.7	39
M	97	9.4	6.9-13.2	8.2-10.7	36
N	96	9.9	7.9-12.9	9.1-11.1	48
O	100	9.8	7.6-11.8	9.1-10.8	49
P	98	9.9	7.9-12.0	8.9-10.8	49
Q	97	10.2	7.6-13.0	9.1-11.4	56
R	82	9.9	8.0-12.4	9.2-11.1	49
T	90	9.3	7.2-11.8	8.4-10.2	31
U	71	9.5	7.0-12.6	8.4-10.2	36
V	100	9.8	7.3-12.3	9.0-10.7	41
W	98	9.1	7.0-11.9	8.3-10.2	29
X	94	9.4	7.3-11.9	8.3-10.5	34
Sct	61	9.5	7.1-12.3	8.6-10.5	39
E&W	92	9.7	7.2-12.4	8.7-10.8	43

Table 7.12 Haemoglobin at start of dialysis

Median Haemoglobin and range : At start of ESRF

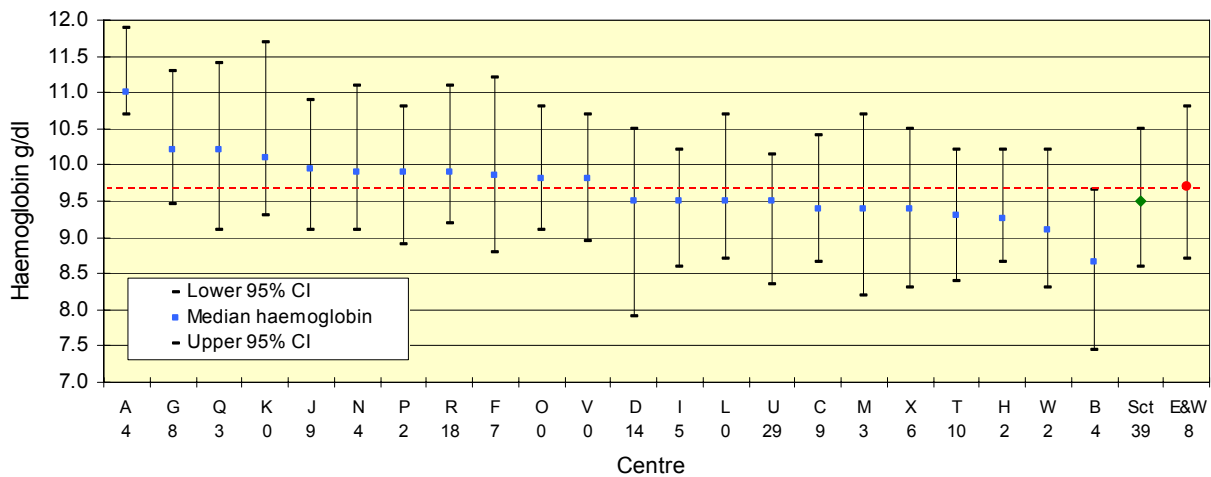


Figure 7.17 Median haemoglobin and 90% range at start of dialysis treatment

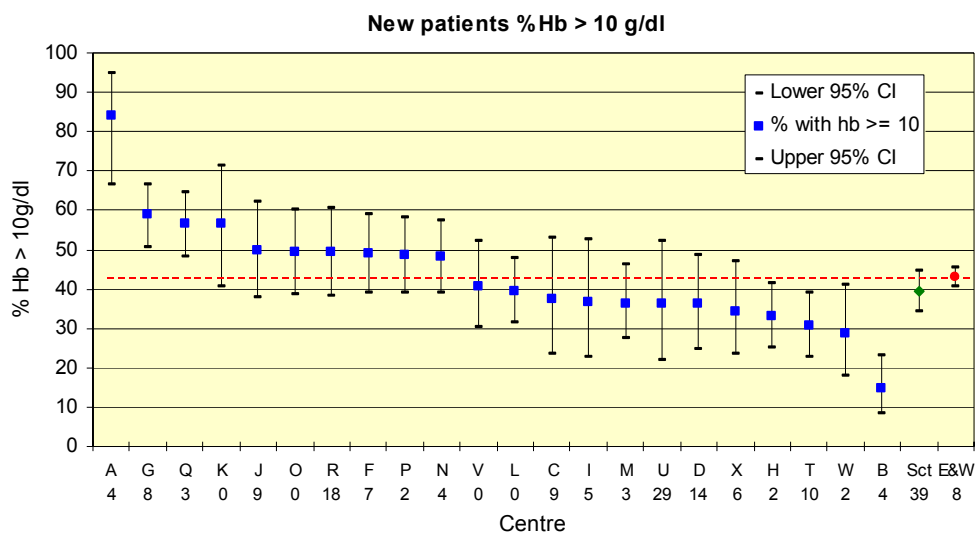
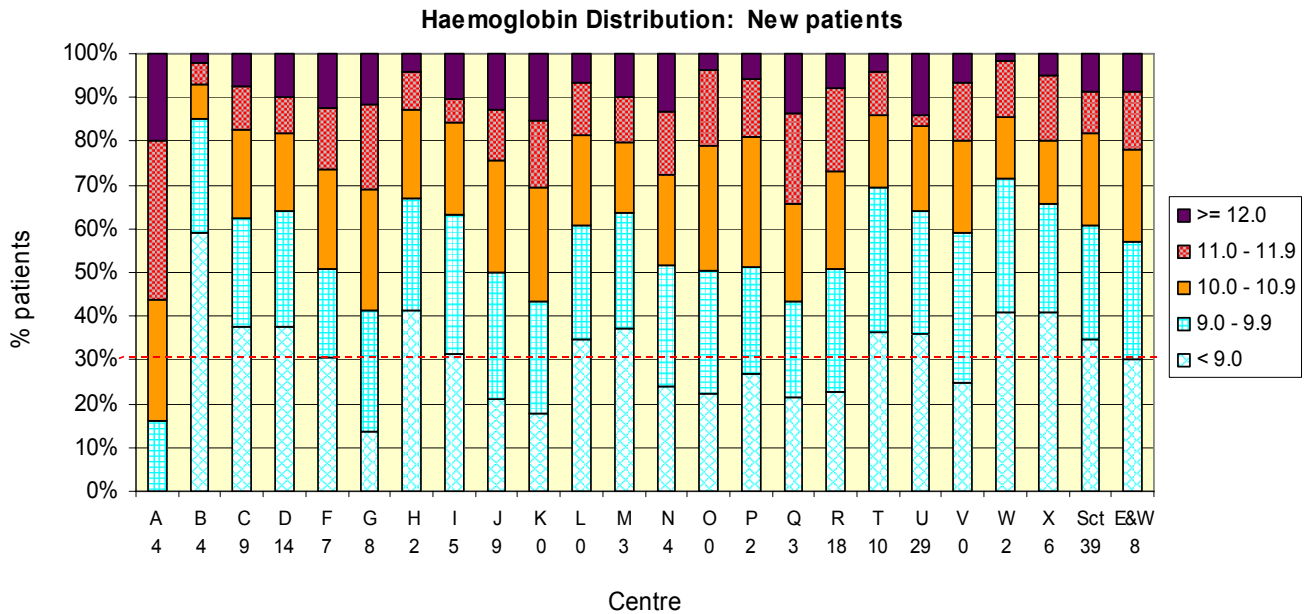
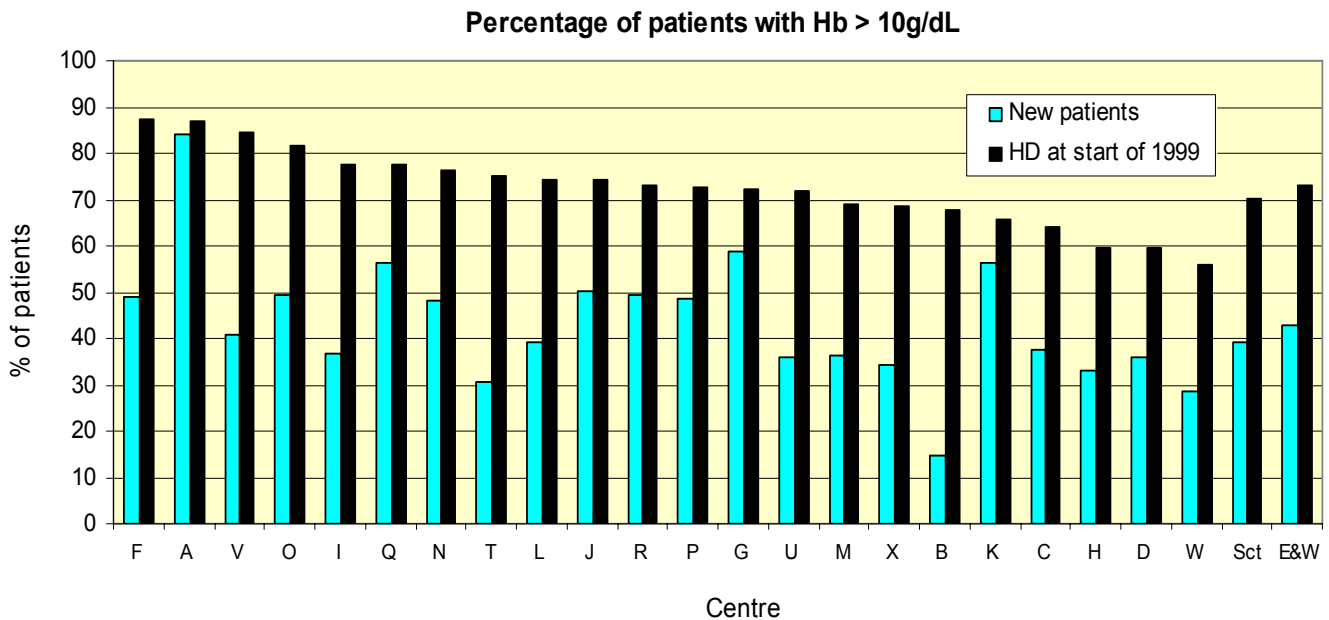


Figure 7.18 Percentage haemoglobin  $\geq$  10g/dl for new patients





**Figure 7.19** Haemoglobin distribution at start of dialysis



**Figure 7.20** Percentage with haemoglobin > 10g/dL: new and prevalent patients

### **Changes in haemoglobin of prevalent patients 1998-1999**

This data relates to all patients alive on dialysis at selected time points. Data over 2 years is available from centres which sent returns to the Registry in 1998. The data for England and Wales are summarised in table 7.13

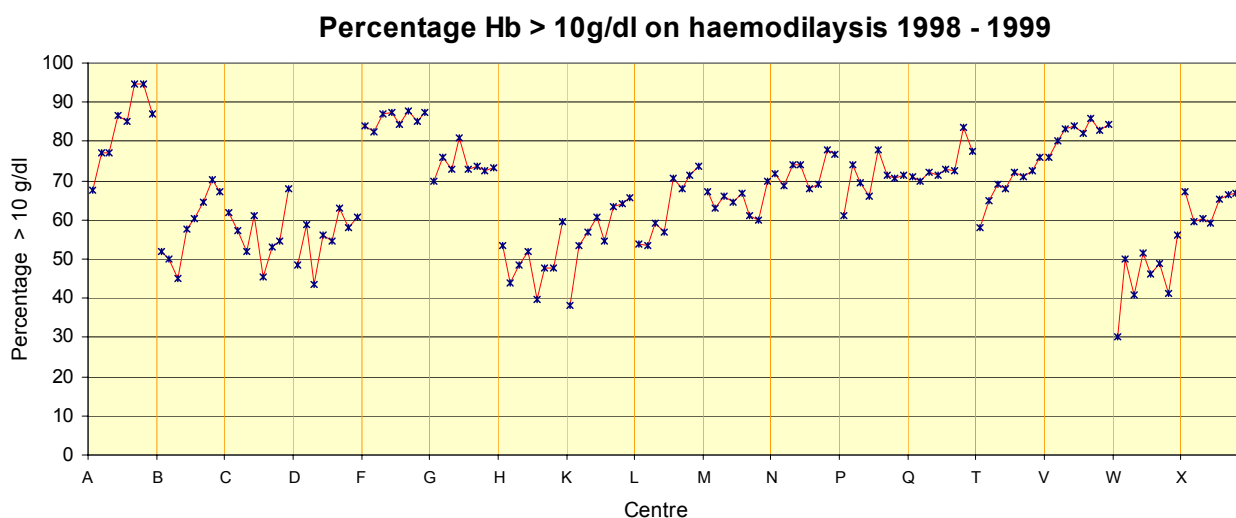
	Mean	SD	Median	90% Range	Quartile Range	%Hb $\geq 10\text{g/dl}$
<b>Haemodialysis</b>						
Qtr 1 1998	10.6	1.8	10.5	7.7-13.5	9.4-11.7	64
Qtr 1 1999	10.7	1.7	10.7	7.9-13.6	9.6-11.8	67
Qtr 4 1999	10.9	1.6	10.9	8.3-13.6	9.8-12.0	73
<b>Peritoneal dialysis</b>						
Qtr 1 1998	10.9	1.7	10.9	8.1-13.7	9.8-12.0	71
Qtr 1 1999	11.1	1.7	11.0	8.3-13.9	10.0-12.1	76
Qtr 4 1999	11.3	1.7	11.3	8.5-14.0	10.2-12.4	79

**Table 7.13** Change in Hb for all centres in 1st qtr. of 1998, 1999 and 4th qtr. of 1999

For the haemodialysis and peritoneal dialysis populations there has been continued increase in mean haemoglobin, median haemoglobin and percent with haemoglobin greater than 10g/dl. Similar increases were shown between 1997 and 1998 in last years report. 1997 data has not been included in this years report because relatively few (8) centres returned data to the Registry for 1997.

### Haemodialysis

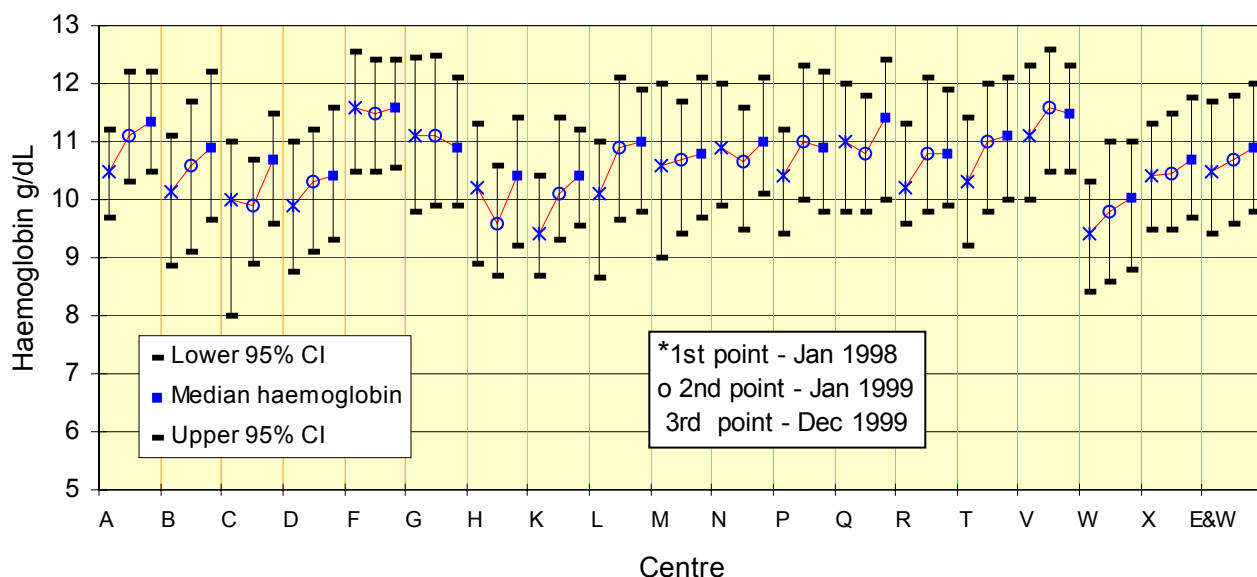
Figure 7.21 shows the percentage haemoglobin greater than 10g/dl for haemodialysis patients in each quarterly return from those centres that returned data in 1998 and 1999.



**Figure 7.21** Hb  $\geq 10$  g/dl from 1997 to end 1998, on haemodialysis

In every centre the percent with haemoglobin greater than or equal to 10g/dl was higher in the last quarter of 1999 than in the first quarter of 1998. Some centres showed large increases whereas in other centres the results were more stable though still below the Renal Association standard.

**Median haemoglobin from start 1998 to end of 1999 by centre :  
haemodialysis:**



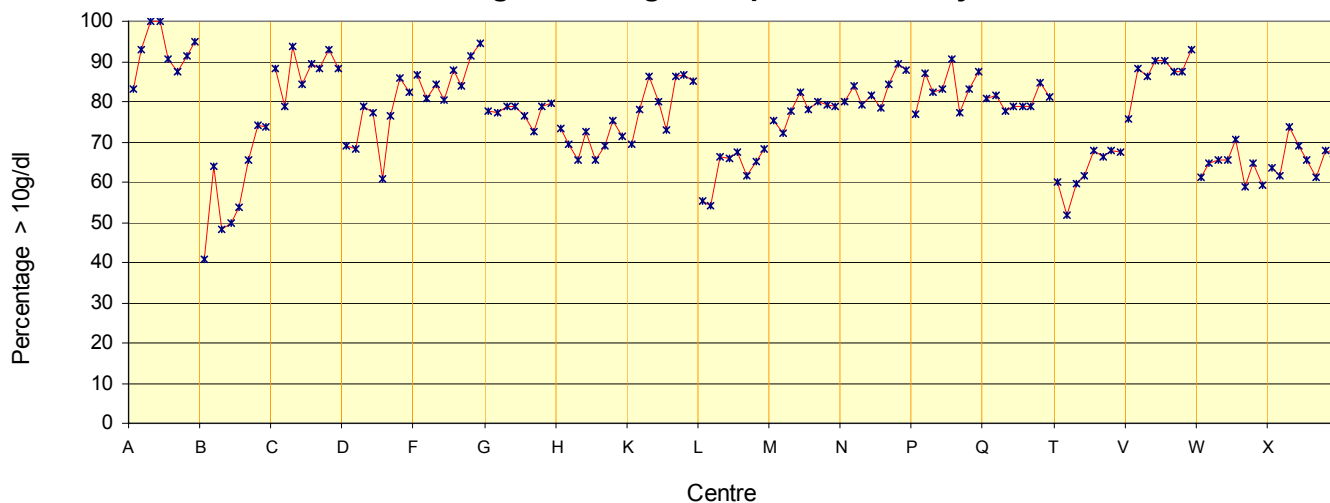
**Figure 7.22 Median haemoglobin 1997-1998 on haemodialysis**

Data presented for each centre are, in sequence, from the end of 1<sup>st</sup> quarter 1997, 1<sup>st</sup> quarter 1998 and the 4<sup>th</sup> quarter 1998

Median haemoglobin increased for haemodialysis patients in all but 2 centres from the first quarter of 1998 to the last quarter of 1999. Centre F had a stable median and centre G a small fall in median haemoglobin, in both these centres there was a small increase in percent greater than or equal to 10g/dl.

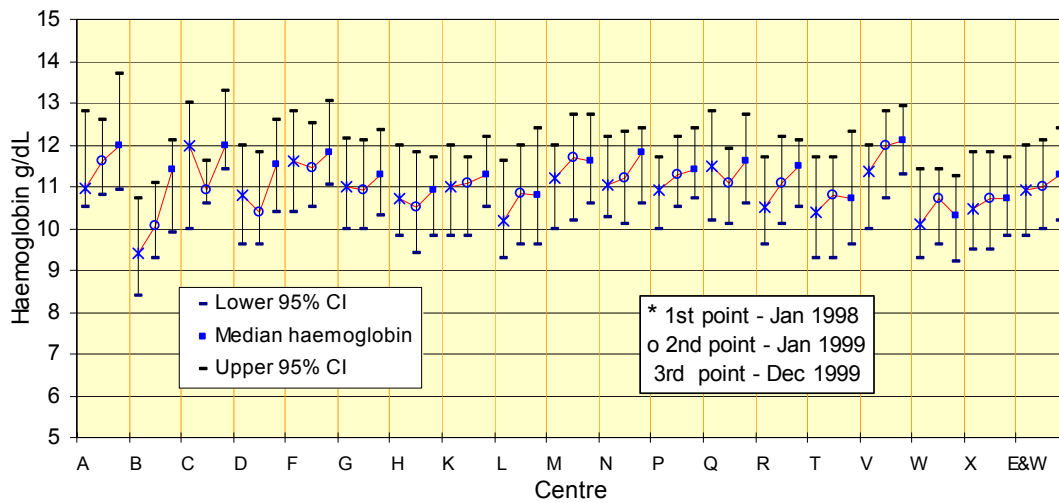
**Peritoneal dialysis**

**Percentage Hb > 10g/dl on peritoneal dialysis 1998-1999**



**Figure 7.23 Percentage with Hb  $\geq$  10g/dl 1998 to end 1999, on Peritoneal dialysis**

**Median haemoglobin from start 1998 to end of 1999 by centre :  
peritoneal dialysis**



**Figure 7.24 Median haemoglobin 1998- 1999 on peritoneal dialysis**

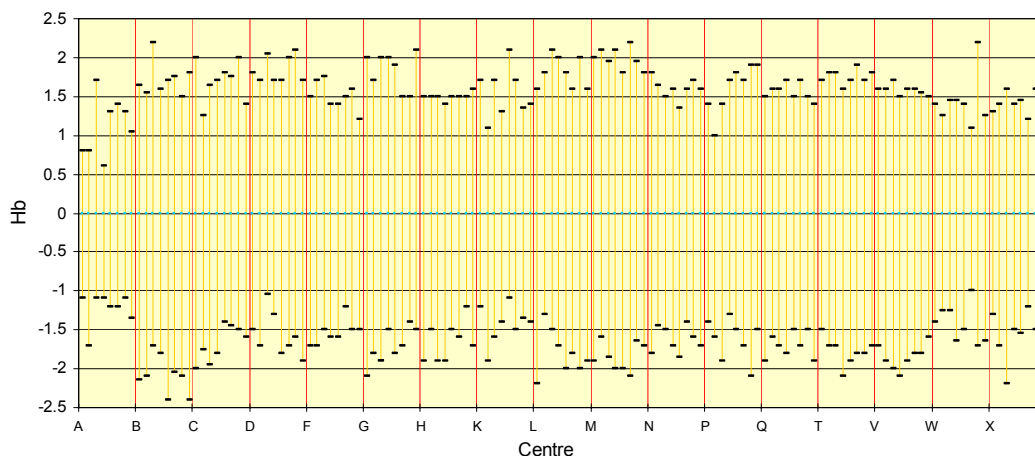
Data presented for each centre are, in sequence, from the end of 1<sup>st</sup> quarter 1997, 1<sup>st</sup> quarter 1998 and the 4<sup>th</sup> quarter 1998

In 15 out of 17 centres there was an increase in the percentage of peritoneal dialysis patients with haemoglobin greater than or equal to 10g/dl between the first quarter of 1998 and the last quarter of 1999. This resulted in an increase for England and Wales from 76 to 79% over this time period. Median haemoglobins are shown in the figure below and demonstrate modest increases in most centres

Figures 7.25 and 7.26 show the inter-quantile range between the 15<sup>th</sup> and 85<sup>th</sup> percentiles at each quarter of 1998 and 1999 for haemodialysis and peritoneal dialysis. This range has been chosen as a measure of the spread of data to exclude outliers. There is no clear trend to narrowing of the inter-quantile range suggesting that centres are not successfully targeting particular haemoglobin levels.

**Figure 7.25 15 to 85% quantiles for median Hb on HD at each quarter from 1st 1998 to 4th**

**Hb quantiles on haemodialysis 1998 - 1999**



**1999.**

Median value is normalised to zero to allow comparison of quantiles at each quarter.

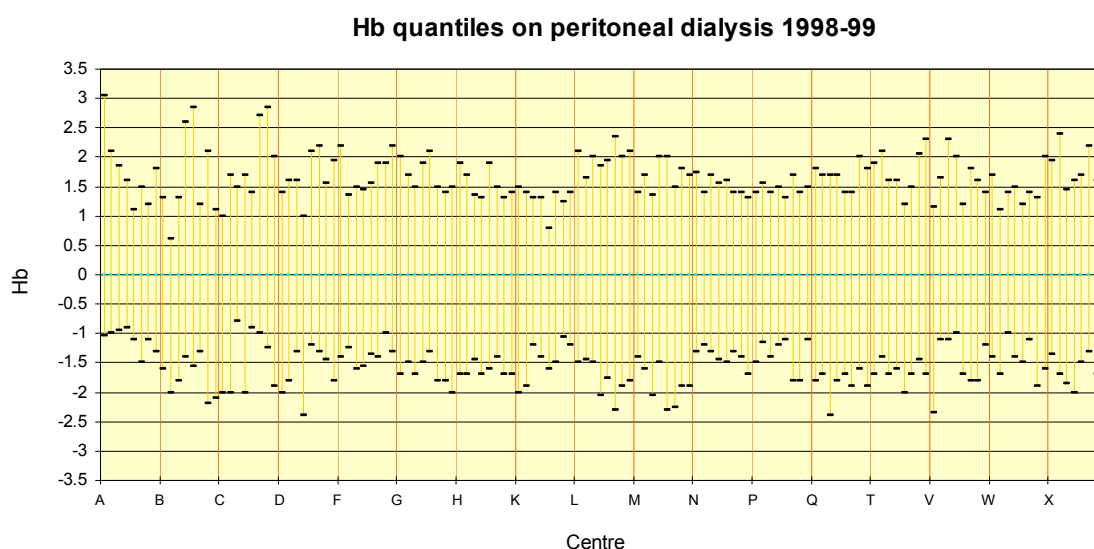


Figure 7.26 15 to 85% quantiles for median Hb on PD at each quarter from 1st 1998 to 4th 1999.

Median value is normalised to zero to allow comparison of quantiles at each quarter

### Change in haemoglobin achieved through 1999

Four units that returned data in 1999 had not done so in 1998 and were not included in the above analysis. To include those units in data on changes over time the following analysis compares data from the first quarter of 1999 with the fourth quarter of 1999 for those 22 centres that submitted sufficient data in 1999.

The data are summarised in table 7.14.

	Mean	SD	Median	90% Range	Quartile Range	% $\geq 10\text{g/dl}$
<b>Haemodialysis</b>						
Qtr 1 1999	10.7	1.7	10.7	8.0-13.6	9.6-11.9	68
Qtr 4 1999	10.9	1.6	10.9	8.3-13.6	9.9-12.1	73
<b>Peritoneal dialysis</b>						
Qtr 1 1999	11.1	1.7	11.1	8.4-14.0	10.1-12.1	79
Qtr 4 1999	11.3	1.7	11.4	8.6-14.0	10.3-12.4	82

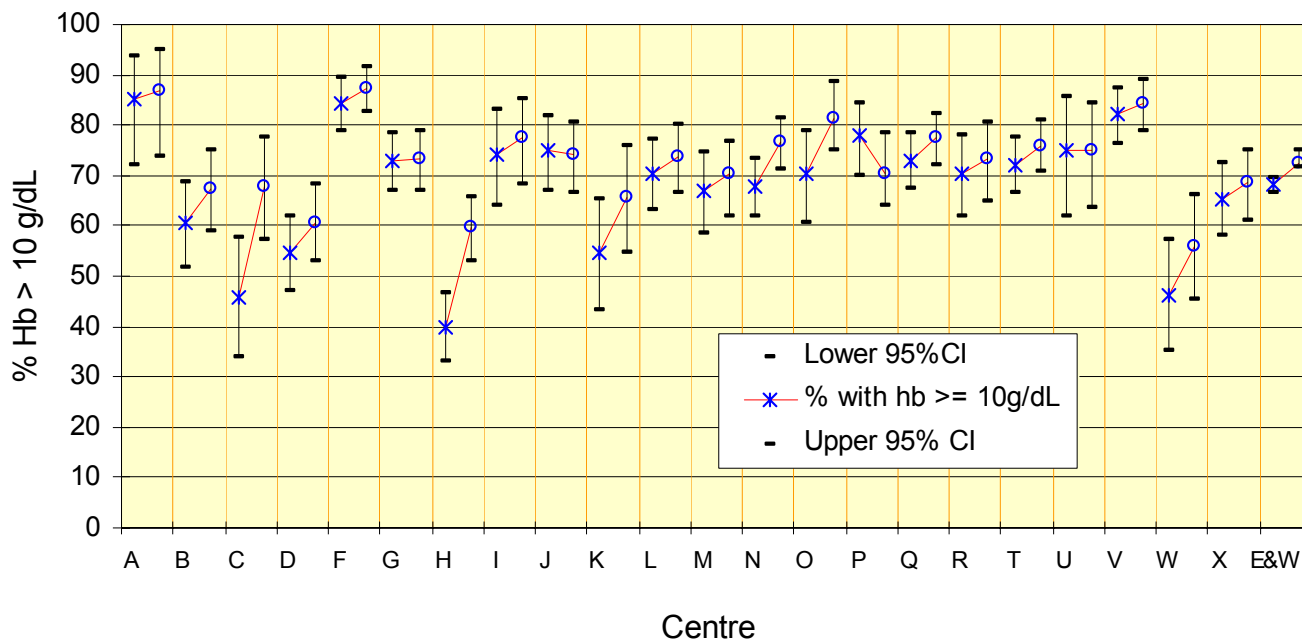
Table 7.14 Change in Hb for all centres returning data in 1<sup>st</sup> and 4<sup>th</sup> quarter of 1998.

### Haemodialysis

During 1998 18 of 22 centres recorded an increase in the percentage of haemodialysis patients with haemoglobin of 10g/dl or more between the 1<sup>st</sup> and 4<sup>th</sup> quarters. In 16 of 22 centres there was an increase in median haemoglobin.

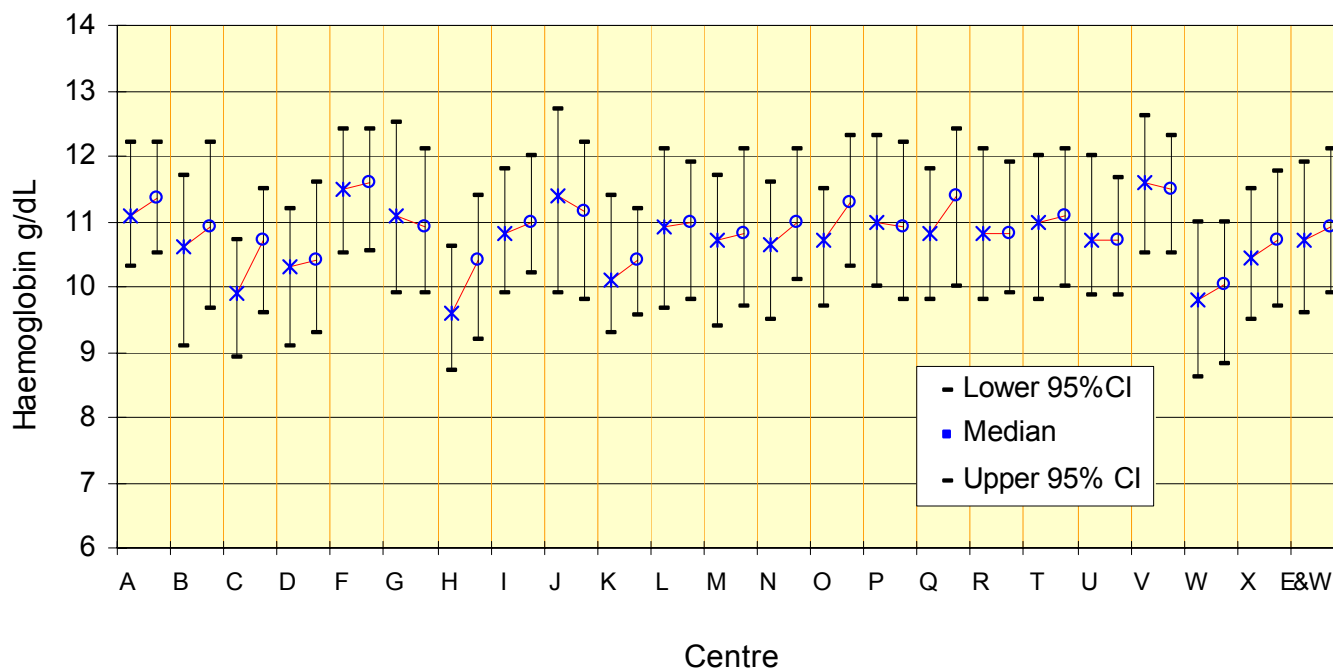
In peritoneal dialysis patients 16 of 22 centres recorded an increase in the percentage of patients with haemoglobin of 10g/dl or more between the 1<sup>st</sup> and 4<sup>th</sup> quarters of 1998. In 15 of 22 there was an increase in median haemoglobin.

**Haemoglobin > 10 g/dL at start and end of 1999 by centre : haemodialysis**



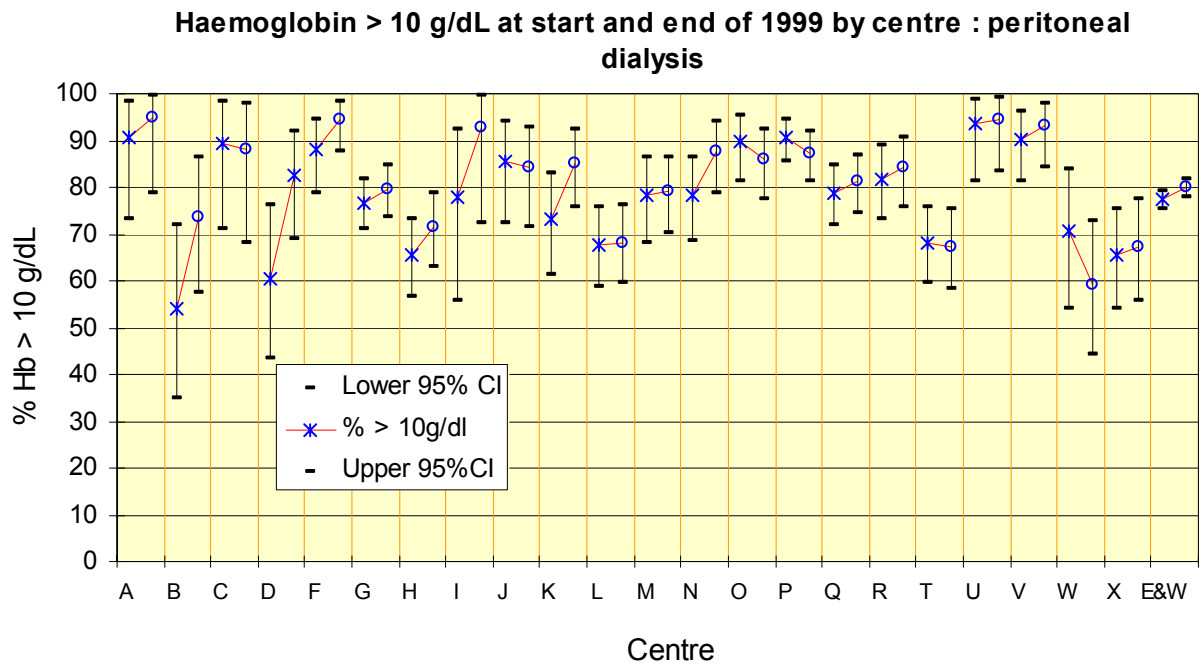
**Figure 7.27 Hb > 10g/dl at start and end of 1999, on Haemodialysis**  
Data from each centre are from the end of the first and fourth quarters of 1999

**Median haemoglobin at start and end of 1999 by centre : haemodialysis**

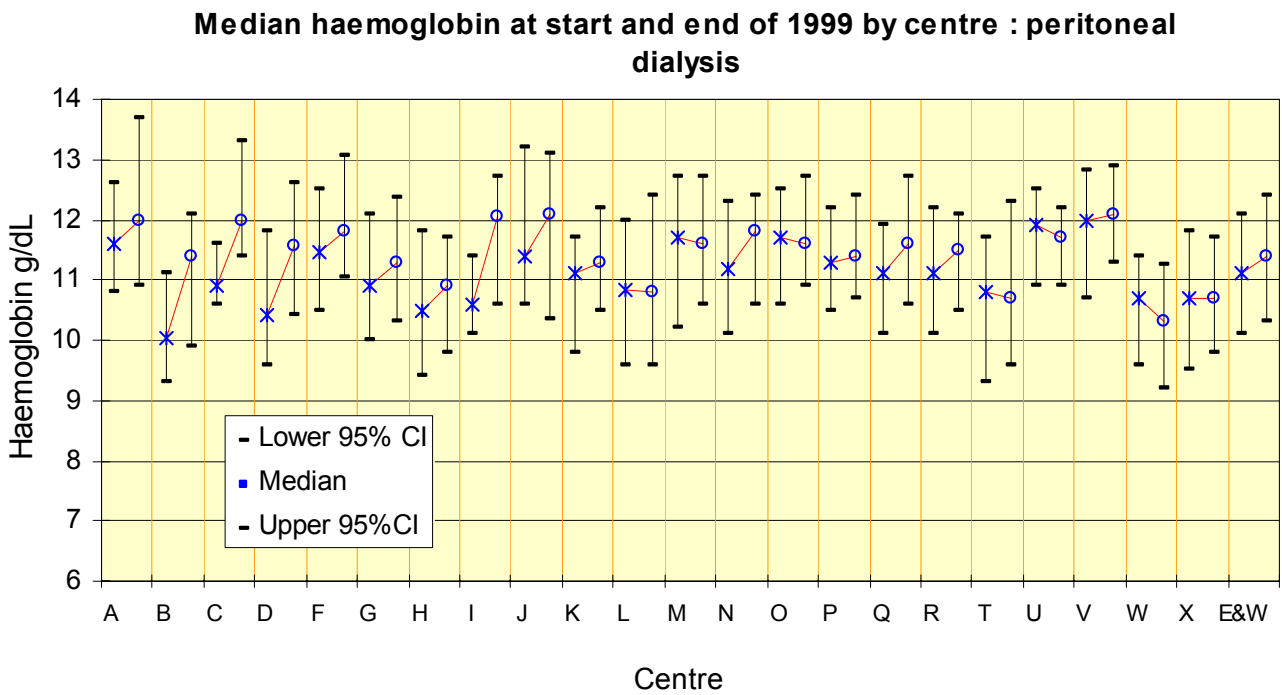


**Figure 7.28 Median Haemoglobin, Haemodialysis, start and end of 1999**  
Data from each centre are from the end of the first and fourth quarters of 1999

**Peritoneal dialysis**



**Figure 7.29 Hb > 10g/dl at start and end of 1999, on Peritoneal Dialysis**  
 Data from each centre are from the end of the first and fourth quarters of 1999



**Figure 7.30 Peritoneal Dialysis results at start and end of 1999**  
 Data from each centre are from the end of the first and fourth quarters of 1999

## Analysis of changes in haemoglobin of individuals during 1999

The data presented above could be interpreted as showing populations with relatively stable haemoglobin concentrations albeit in the context of an increasing trend. The collection of individual patient data by the Registry provides an opportunity to examine the variability of individuals haemoglobin concentration which may be important in devising management strategies to improve compliance with the Renal Association standards. Figure y.15 shows the haemoglobin distributions for all patients on the Registry in the first quarter of 1999. The haemoglobin bands for the 4<sup>th</sup> quarter of 1999 are further subdivided to indicate the haemoglobin that the same individuals had in the 1<sup>st</sup> quarter and also those patients that had started dialysis during the year. A complex picture emerges. Individuals within each band at the beginning of 1999 are distributed through every band at the end of the year. The populations within each band at start and end of the year are therefore quite different and great variability of individuals haemoglobin concentrations is demonstrated.

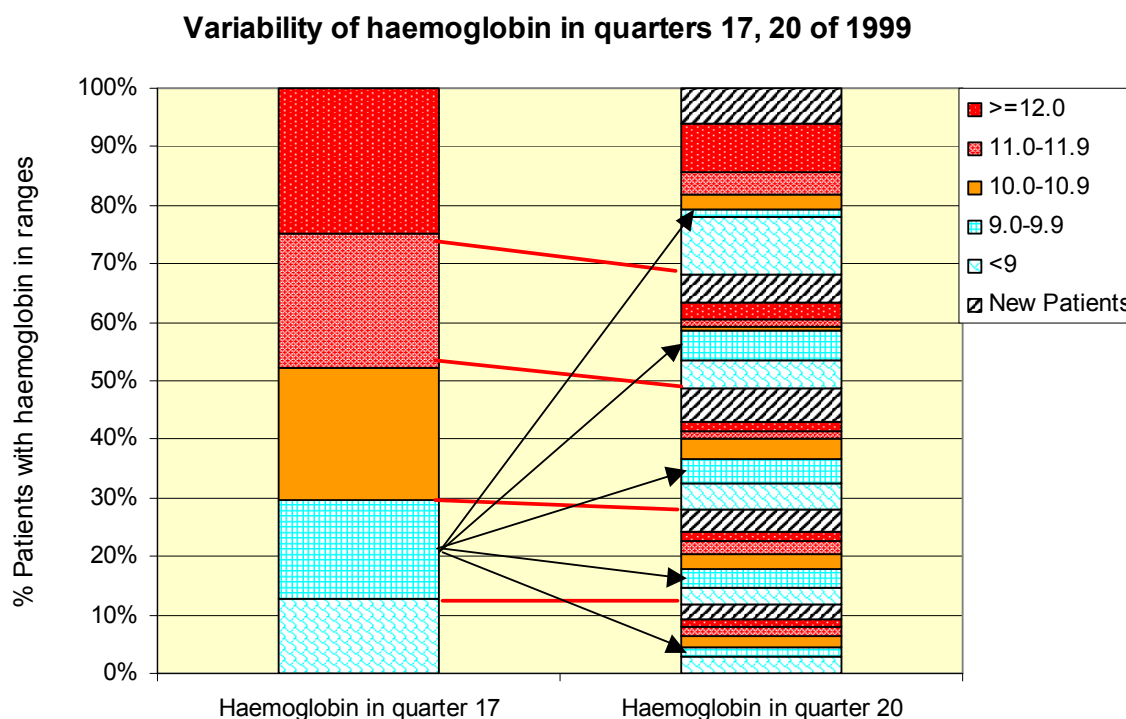


Figure 7.31 Change of haemoglobin in individuals from 1st to 4th quarters of 1999

## Conclusion

The previously reported improvements in achievement of the Renal Association standards for management of anaemia were continued in the data returned in 1999. There remain wide variations between centres in the haemoglobin levels recorded for their patients. There is further evidence that to achieve more than 85% of patients with haemoglobin at least 10g/dl requires a median haemoglobin for the centre as a whole above 11g/dl. The two centres that



achieved the Renal Association standard for haemoglobin in haemodialysis had median haemoglobins of 11.4 g/dl and 11.6 g/dl.

Iron stores as judged by serum ferritin were well maintained in most centres but there remain significant numbers of patients with ferritin less than 100µg/l. Some of these will have well maintained haemoglobin levels without requiring erythropoietin and will therefore be considered to have adequate iron stores. In others there may be an opportunity to increase haemoglobin levels and use of erythropoietin more efficiently by increasing iron stores.

It is difficult to adequately interpret data on haemoglobin concentrations without detailed information on erythropoietin prescribing. It is hoped that centres will increase their efforts to make this data available to the Registry.

There remains wide variation between centres in the haemoglobin concentration of patients on starting dialysis presumably reflecting differences in use of erythropoietin in pre-dialysis patients although differences in late referral rates may also contribute. In the great majority of centres there is increasing achievement of the Renal Association Standard haemoglobin level and increase in the centre median haemoglobin. There is no evidence that the management plans that are being used to bring about these improvements are reducing the spread of data. There is therefore no evidence of successful targeting of a particular haemoglobin concentration. The maintenance of a broad spread of haemoglobin concentrations even as haemoglobin concentrations on average are rising is contributed to by the demonstrated variability of individuals' haemoglobin concentrations. Some of this variability maybe slow in onset allowing time for intervention but other factors such as intercurrent illness may cause an unpredictable and rapid fall of haemoglobin concentration that cannot be prevented. These influences are likely to impact upon a centre's ability to obtain the Renal Association standards for haemoglobin.



## **Chapter 8: Serum Calcium, Phosphate and Parathyroid Hormone**

### ***Summary***

Control of serum calcium varies widely among units. Non-compliance with the target range may be due to either hypo- or hypercalcaemia,

There are continuing problems with comparative audit of corrected serum calcium due to difficulties with albumin measurements. Reliance on the BCG method to measure serum albumin (which over-estimates serum albumin) to correct calcium, may be concealing hypercalcaemia. Use of uncorrected calcium concentrations may help comparative audit and should be further explored.

Many centres have difficulty achieving the target phosphate concentrations for the majority of patients. These targets may not be achievable with current phosphate binders and dialysis regimes.

There are significant differences in control of serum phosphate between centres.

There is significant variation in control of hyperparathyroidism among centres and between modalities within some centres. Much could be learned from detailed comparisons between the centres of the approaches to the prevention and treatment of hyperparathyroidism.

### ***Introduction***

The control of calcium, phosphate and parathyroid hormone activity in patients receiving renal replacement therapy is important in preventing progressive renal osteodystrophy and ectopic calcification. There is also evidence that poor control of calcium/phosphate metabolism may accelerate cardiac and vascular disease. Recommended target concentrations for all of these analytes are published in the Renal Association standards document.

### ***Harmonisation of laboratory data between hospitals***

Previous Registry reports have considered in detail the problems arising from inter-laboratory variation. The Registry continues to work with the Association of Clinical Biochemists and the UK NEQAS scheme to minimise the effect of analytical factors on comparative audit. Where NEQAS data was available, calcium and phosphate have been corrected by a 'harmonisation' factor. There are particular problem with calcium measurements when correcting for serum albumin. This relates to the different methodologies for measuring serum albumin and the different formulae applied to correct to a standard albumin concentration. This is considered in greater detail in chapter 9.

## Serum calcium

### Measurement of serum calcium

Centre	Method	Uncorrected range	Corrected range	Correction formula
A	Arsenazo	2.10-2.60	2.10-2.60	+0.02(40-Alb)
B	Arsenazo	2.10-2.60	Not reported	+0.02(40-Alb)
C	CPC	2.12-2.65	Not reported	Not Reported
D	CPC	2.05- 2.60	2.05- 2.60	+0.025(40-Alb)
E	CPC	2.12-2.55	2.12-2.55	+0.025(40-Alb)
F	Electrode	2.20-2.80	2.20-2.80	+0.025(40-Alb)
G	Arsenazo	2.10-2.60	2.10-2.60	+0.2(40-Alb)
H	Arsenazo	2.20-2.60	2.20-2.60	+0.017(43-Alb)
I	Arsenazo	2.20-2.60		-((0.0175xALb)+0.7)
J	Arsenazo	2.00-2.60	2.10-2.5	Not Reported
K	Arsenazo	2.20-2.60	Not reported	Not Reported
L	CPC	2.20-2.60		+0.02(40-Alb)
M	CPC	2.18-2.63		+(0.02(40-Alb)
N	CPC	2.10-2.65		+0.02(40-Alb)
O	Arsenazo	2.20-2.62	2.20-2.62	+0.02(40-Alb)
P	CPC	2.20-2.60	2.20-2.60	+0.02(40-Alb)
Q	Arsenazo	2.12-2.62	Not reported	Not Reported
R	Arsenazo	2.22-2.58	2.22-2.58	-((0.0116xAlb) +0.4652)
T	CPC	2.05-2.65	2.10-2.60	+ (40-Alb)0.02
U	Electrode	2.10-2.65	2.10-2.65	-((0.017xALb)+0.692)
V	CPC	2.20-2.60	2.20-2.60	+0.016(46-Alb)
W	Electrode	2.13-2.63		+0.02(40-Alb)
X	Electrode	2.20-2.60	2.20-2.60	+(-0.016 alb)+0.59

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

**Table 8.1 Laboratory methodologies for serum calcium**

The different laboratory methodologies, normal ranges and correction formulae are given in table 8.1. The Registry calculated serum calcium concentrations corrected for serum albumin from uncorrected calcium data using a standard formula :-

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

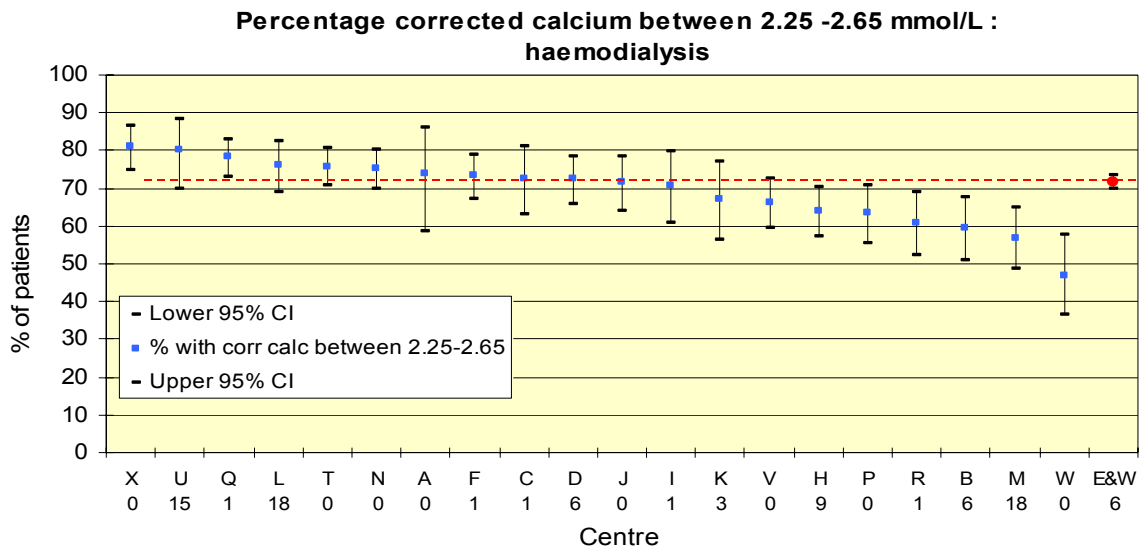
Where only corrected calcium was reported by the local laboratory, this was first uncorrected using the local formula then corrected using 'standard' registry formula. The target range for corrected calcium was set at 2.25-2.65 mmol/l.

### Corrected serum calcium

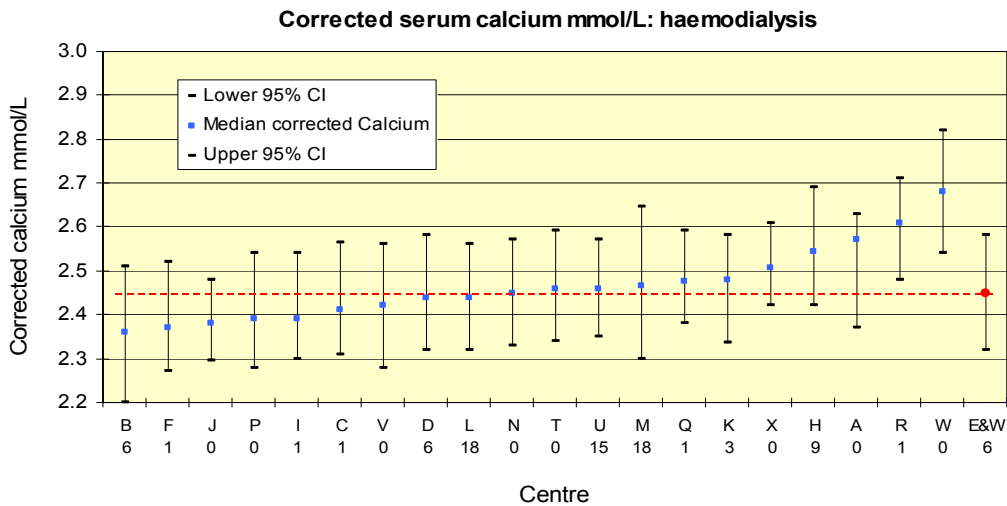
The Renal Standards document recommends that *total calcium should fall within the normal range quoted by the local pathology laboratory, corrected for serum albumin concentration.*

## Haemodialysis

The percentage of haemodialysis patients within the target range (2.26-2.65mmol/l) varied widely among centres from >80% to <50% (figure8.1). Centre W with the lowest % of patients within target range had the highest median calcium concentration (figure8.2). However, the results for this centre are markedly affected by correction for albumin (see also chapter 9). Poor compliance with the standard may be due to either relative hypocalcaemia (centre B) or hypercalcaemia (centre R).

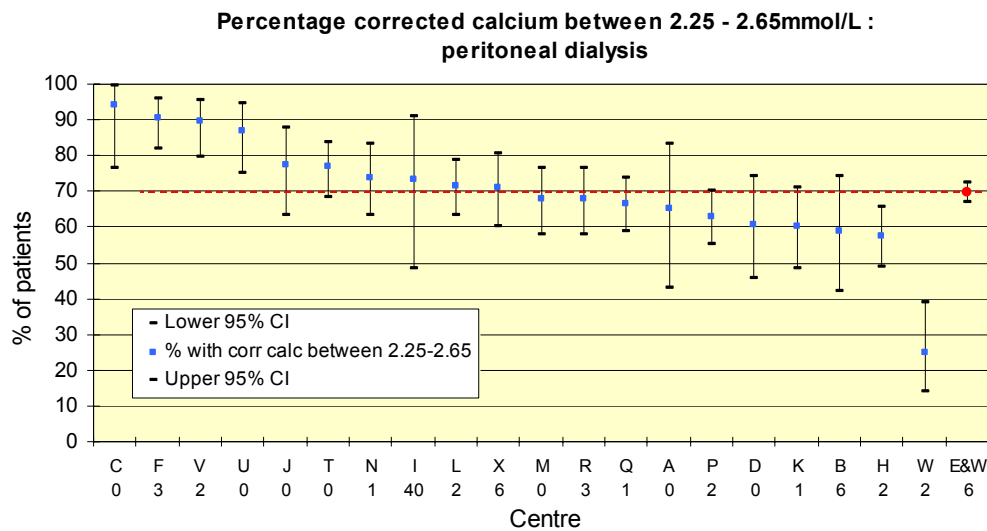


**Figure 8.1 Percentage corrected serum calcium within 2.25-2.65 mmol/L on HD**



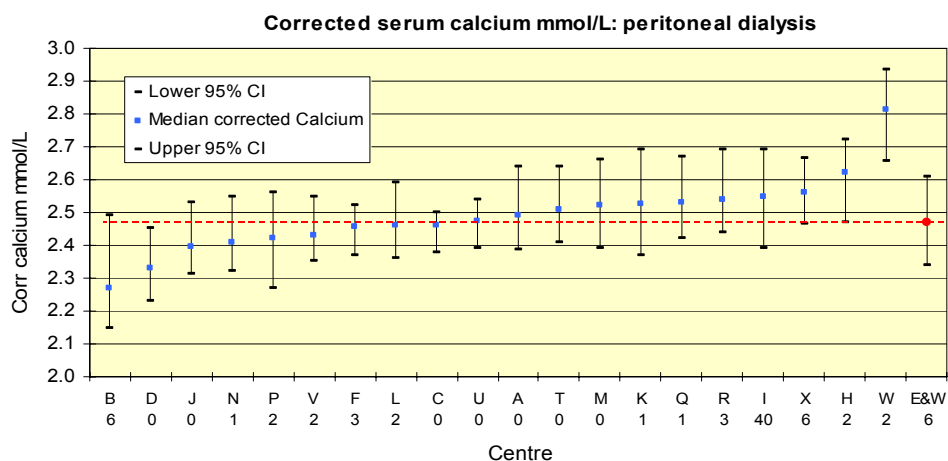
**Figure 8.2 Median corrected serum calcium on haemodialysis**

## Peritoneal dialysis



**Figure 8.3 Percentage corrected serum calcium in range 2.25-2.65 mmol/L: on PD**

Results for peritoneal dialysis patients were very similar to those for haemodialysis patients (figures 8.3, 8.4). Excluding centre W, whose results seem to be outlying, largely through problems with correction for albumin, the compliance with target calcium varied from 95% to <60% (figure 8.3). Again either low or high median calcium could be associated with poor achievement of target (figure 8.4). For both haemodialysis and peritoneal dialysis, approximately 70% of patients in England and Wales had calcium concentrations within the suggested range.

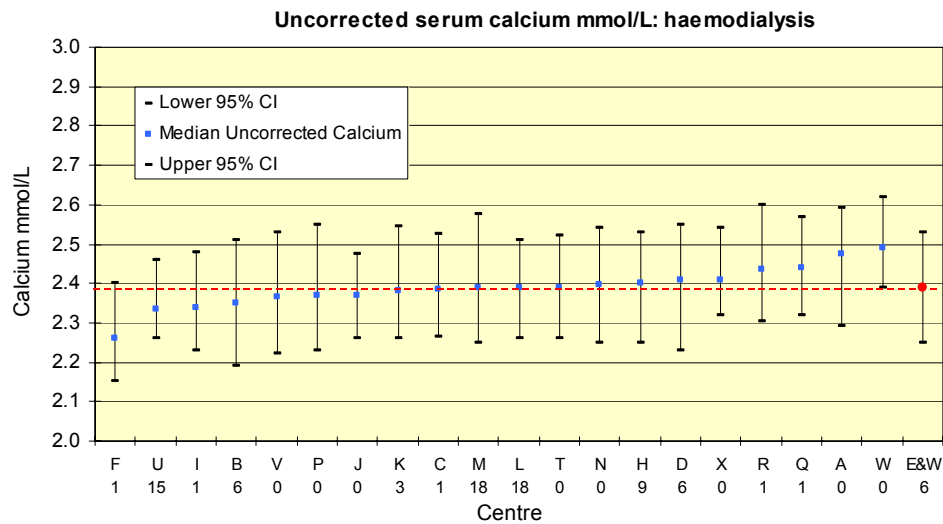


**Figure 8.4 Median corrected serum calcium on peritoneal dialysis**

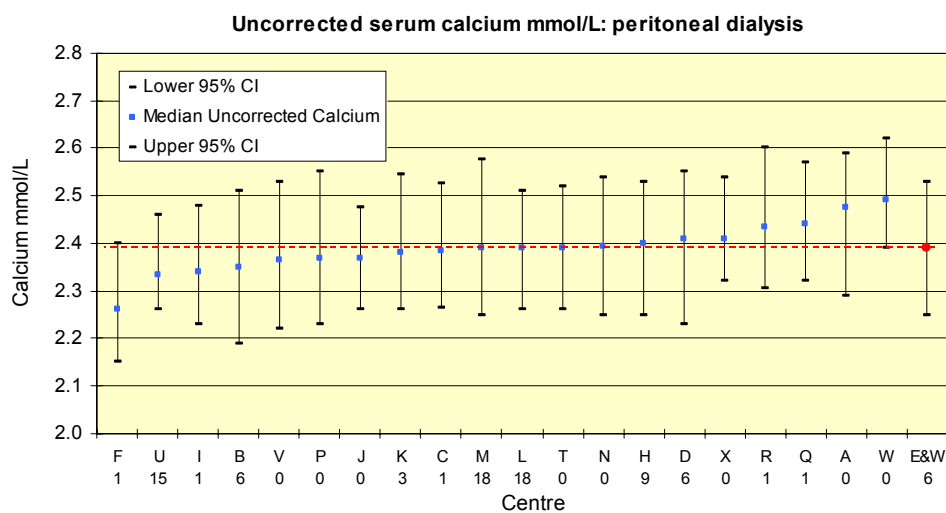
## Uncorrected serum calcium

Using uncorrected calcium concentration would remove some of the complications related to serum albumin assay techniques and correction formula. The data for both haemodialysis and

peritoneal dialysis patients are shown in figures 8.5 and 8.6. These show less variation between units. Centre W, which has low serum albumin as measured by the BCP method, and therefore high corrected serum calcium, still has relatively high serum calcium but is no longer an outlier. If widespread reliable direct serum ionised calcium measurement is not possible, uncorrected serum calcium may be more meaningful for comparative audit in future years. This is being discussed with the Association of Clinical Biochemists and is the subject of further work.



**Figure 8.5 Median uncorrected serum calcium on haemodialysis**



**Figure 8.6 Median uncorrected serum calcium on peritoneal dialysis**

## Serum phosphate

The methodologies for measuring serum phosphate are listed in table 8.2. Note the variation in quoted normal range for laboratories using the same method of measurement.

## Measurement of phosphate

Centre	Methodology	Lab reference Range mmol/L
A	PMb	0.90-1.50
B	PMb	0.74-1.40
C	PMb	0.80-1.40
D	PMb	0.80-1.45
E	PMb	0.80-1.40
F	PMb	1.40-2.20
G	PMb	0.80-1.40
H	PMb	0.80-1.40
I	Fish/Sub	0.80-1.40
J	PMb	0.80-1.40
K	PMb	0.80-1.40
L	PMb	0.80-1.45
M	PMb	0.80-1.45
N	PMb	0.75-1.35
O	PMb	0.80-1.45
P	PMb	0.80-1.40
Q	PMb	0.80-1.45
R	PMb	0.75-1.40
T	PMb	0.80-1.45
U	PMb	0.80-1.40
V	PMb	0.80-1.30
W	PMb	0.82-1.55
X	PMb	0.70-1.40

Conversion factor mg/dl = mmol/L x 3.1

Table 8.2 Methodologies for measurement of serum phosphate

## Haemodialysis

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

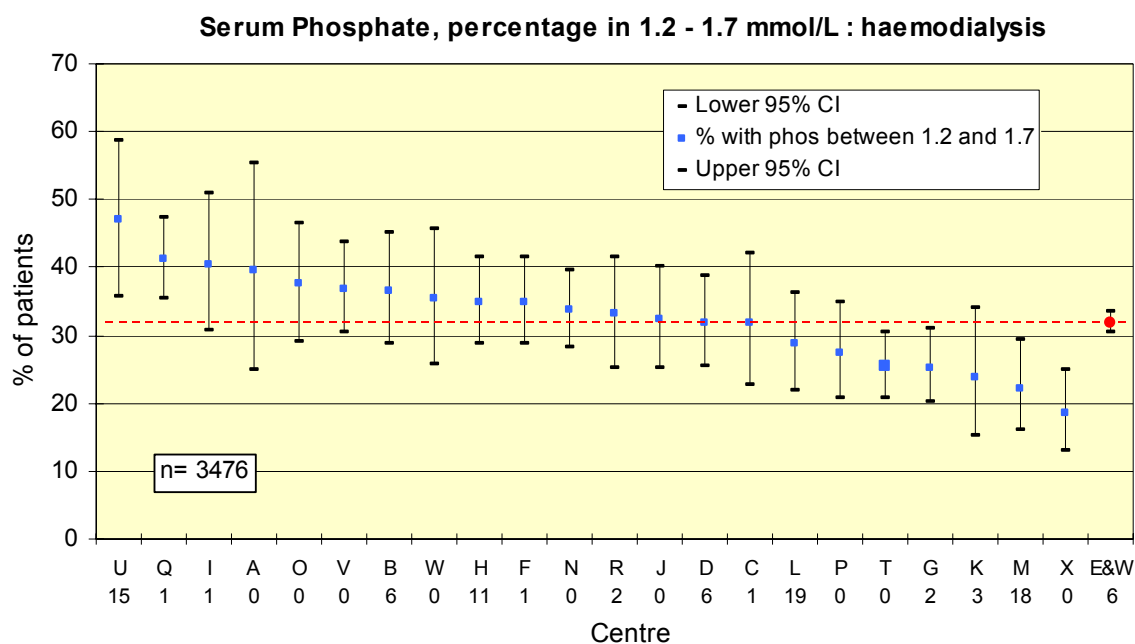
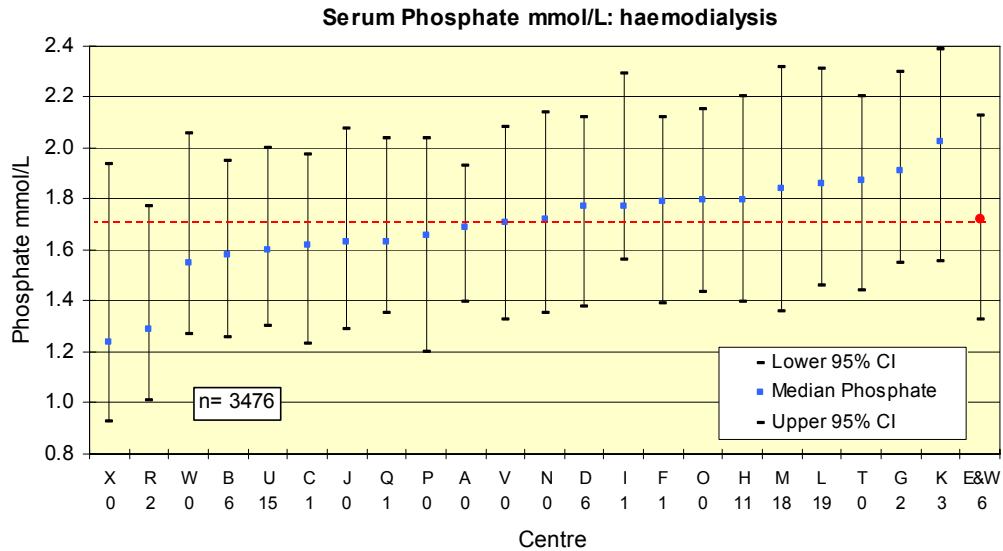


Figure 8.7 Percentage patients with phosphate between 1.2 and 1.7 mmol/L: - HD





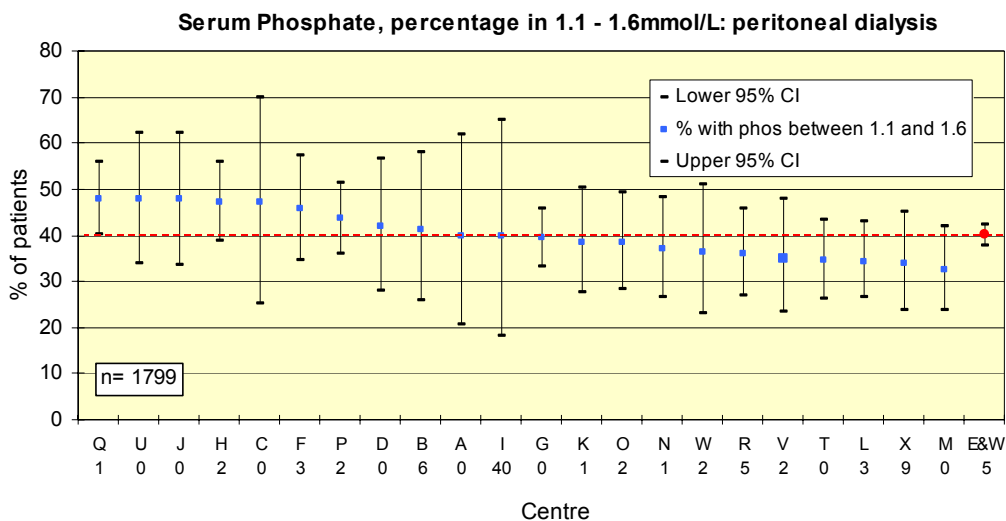
**Figure 8.8 Median serum phosphate on haemodialysis**

Most centres have difficulty in achieving the suggested standards for phosphate for both haemodialysis (1.1-1.7mmol/l) (figures 8.7, 8.8) and peritoneal dialysis (1.1-1.6mmol/l) (figures 8.9,8.10). Even the best performing centre had <50% of haemodialysis patients within the target range. Overall, for England and Wales only on third of haemodialysis patients had control of serum phosphate within the suggested standard range (figure8.7). Haemodialysis results from centre X should be ignored as on investigation they were post-dialysis samples. Centre X has now instituted a laboratory flag to indicate a post dialysis sample and this is stored on the renal system.

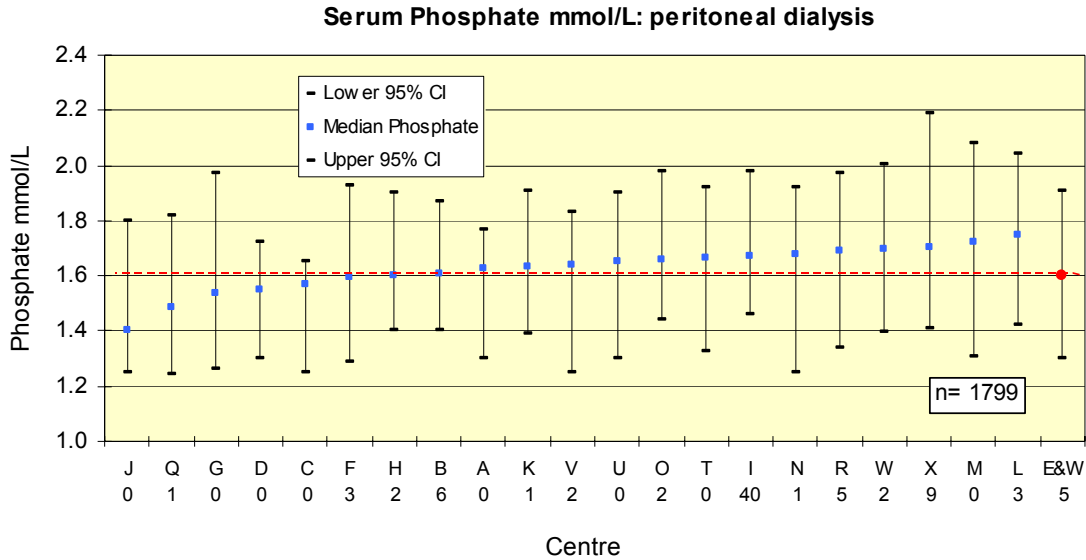
### Peritoneal dialysis

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

The results for peritoneal dialysis patients are shown in figures 8.9 and 8.10



**Figure 8.9 Percentage patients with serum phosphate between 1.1 and 1.6 mmol/L: PD**



**Figure 8.10 Median serum phosphate on peritoneal dialysis**

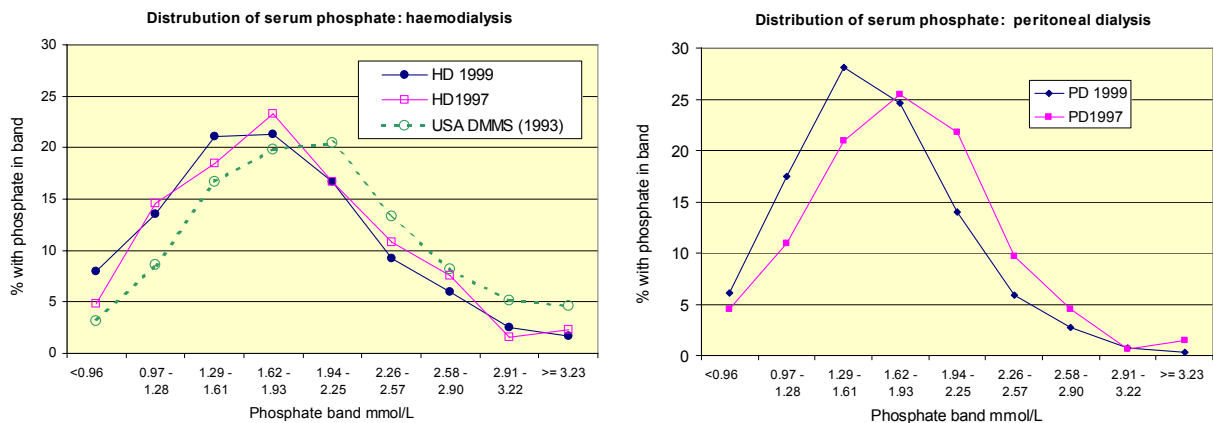
**Significance of differences in serum phosphate between centres.**

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

For patients on HD, the percentage of patients with phosphate  $\leq 1.70$  mmol/L differed significantly between centres ( $X^2 = 129.8$ , d.f. = 21,  $p < 0.001$ ).

For patients on PD, the percentage of patients with phosphate  $\leq 1.60$  mmol/L differed significantly between centres ( $X^2 = 46.3$ , d.f. = 21,  $p < 0.001$ ).

**Changes in serum phosphate 1998 – 1999**

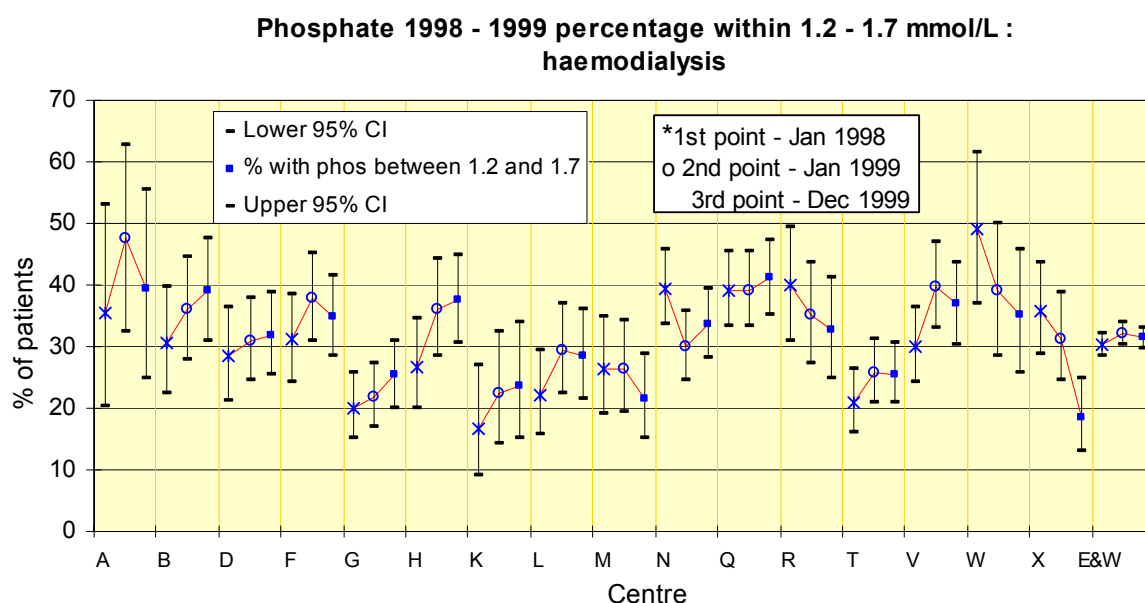


**Figure 8.11 Serum phosphate distribution by year**

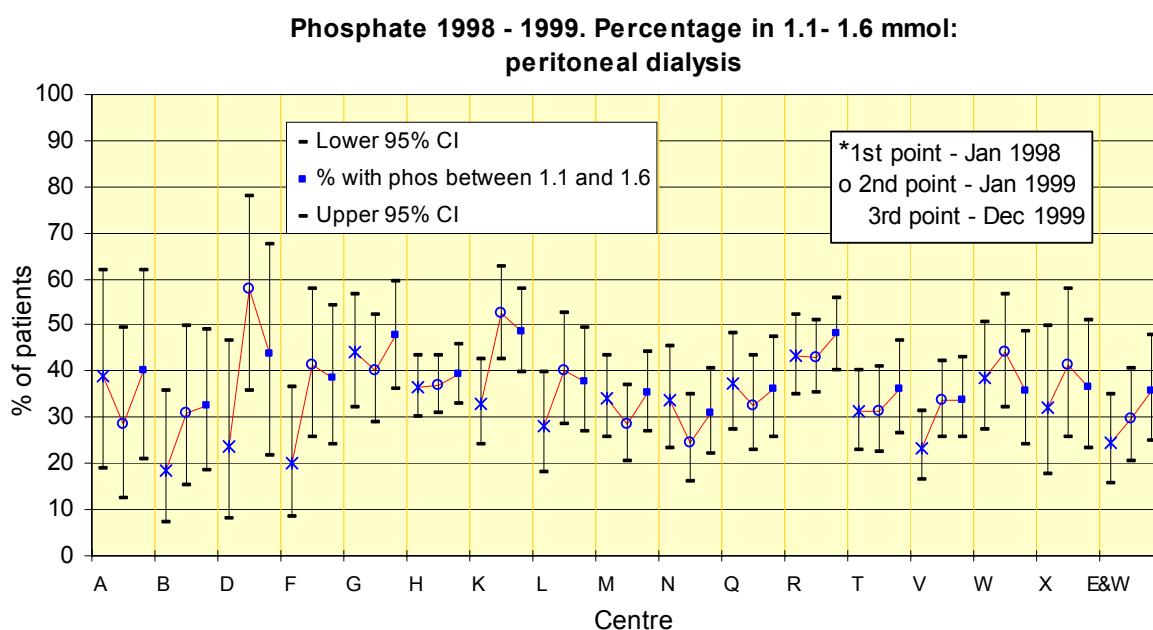
Formula to convert from mmol/L to mg/dl is: - mg/dl = mmol/L x 3.1

The Registry now has serial data on phosphate control. This is compared with data from USRDS in figure 8.11. There is an improvement with time for peritoneal dialysis patients but not for haemodialysis patients

However, there is considerable variation among units with some appearing to improve and others with deteriorating results (figs 8.12 and 8.13). There was no overall change in the proportion of patients with a high serum phosphate.



**Figure 8.12 Change in % phosphate 1998 – 1999 in range 1.2-1.7 mmol/L: haemodialysis**



**Figure 8.13 Change in phosphate 1998-1999 between 1.1 and 1.6 mmol/L: peritoneal dialysis**

## Serum parathyroid hormone

Different laboratories use different methodologies for PTH. Even where laboratories use the same assay method local normal ranges vary as shown in table 8.3. For consistency a value of 23pmmol/l has been taken as the upper limit of the standard suggested by the Renal Association, as this is 3x the most commonly quoted upper limit of normal.

Centre	Methodology	Lab ref Range	3 x upper ref. Range
A	Elecsys	15-65 ng/L	20
B	DPC	12-72 ng/L	23
C	DPC	1.3-7.6 pmol/L	23
D	Birmingham S.O	12-72 ng/L	23
E	DPC	12-72 ng/L	23
F	INCSTAR/DPC	10-55/11-62 ng/L	18./20
G	DPC	1.3-7.6 pmol/L	23
H	DPC	12-72 ng/L	23
I	Chiron	10-65 ng/L	16
J	DPC	12-72 ng/L	23
K	DPC	1.3-7.6 pmol/L	23
L	Nichols	0.9-5.4 pmol/L	16
M	DPC	10-70 ng/L	22
N	Chiron	<4.0 pmol/L	23
O	DPC	1.3-7.6 pmol/L	23
P	DPC	10-65 ng/L	20
Q	Nichols	1.0-6.1 pmol/L	18
R	IDS	1.1-4.2 pmol/l	13
T	Nichols	Oct-50	20
U	Nichols	0.9-5.4 pmol/L	16
V	Nichols	10-65 ng/L	20
W	Nichols	0.9-5.4 pmol/L	16
X	DPC	12-72 ng/L	23

Conversion factor: ng/L = pmol/L x 9.5

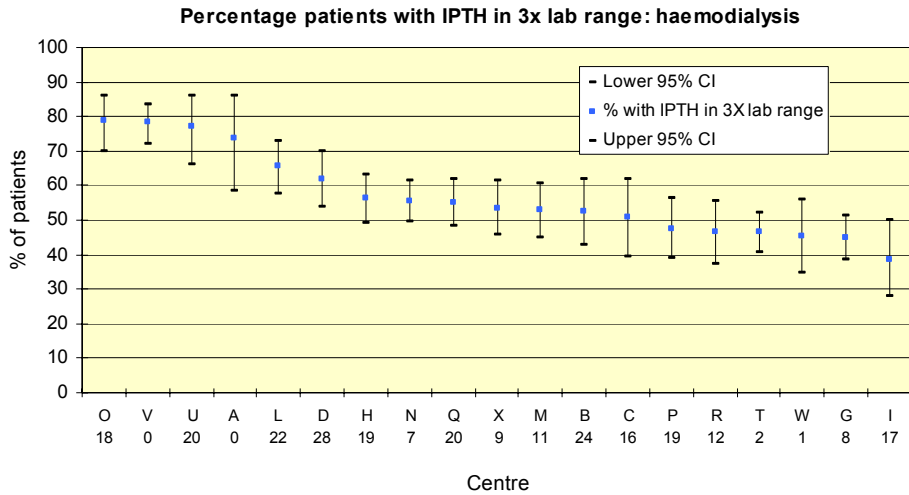
**Table 8.3 Laboratory methodology for serum iPTH**

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

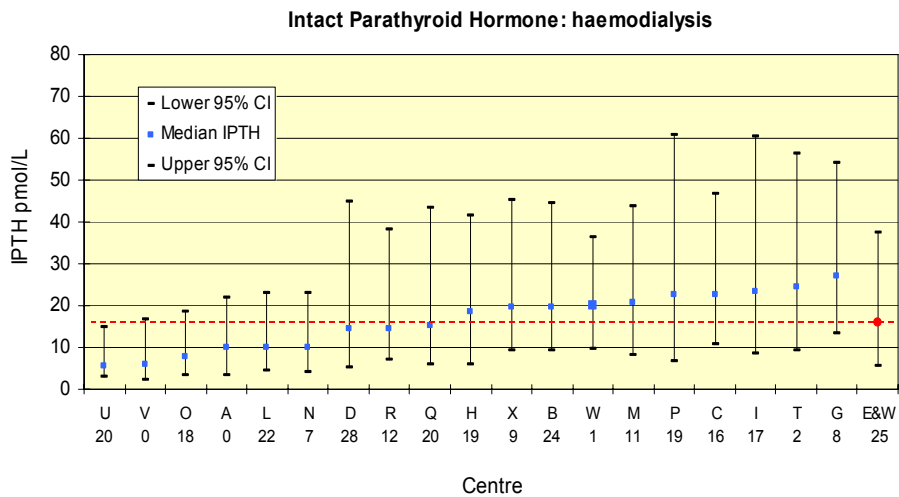
As in the 1999 Registry report perhaps the most notable fact was the percentage of patients with no PTH data (defined as no value in the previous 9 months). This ranged from 0-28% for haemodialysis, 0-46% for peritoneal dialysis and overall approximately 25% of patients had missing data.

### Haemodialysis

The percentage of haemodialysis patients with iPTH <23pmol/l varied from over 80% to <50% (figure 8.14). There was also considerable variation in median serum iPTH concentrations (figure 8.15). This probably reflects differences in approaches to the prevention and management of hyperparathyroidism.

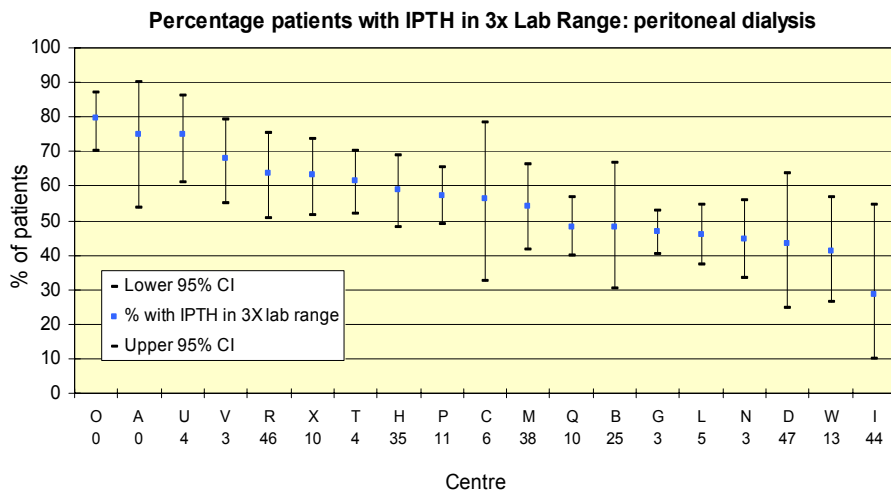


**Figure 8.14 Percentage patients with serum iPTH in 3x lab range on HD**



**Figure 8.15 Median intact serum parathyroid hormone on HD**

**Peritoneal dialysis**



**Figure 8.16 Percentage patients with serum iPTH in 3x lab range on PD**

There is an even wider variation between units for achievement of the serum iPTH standard in peritoneal dialysis patients than in haemodialysis patients (figure 8.16).

The variation in median iPTH achieved is shown in figure 8.17. As in haemodialysis patients this appears to reflect differing attitudes to control of hyperparathyroidism. Some of the units with relatively low achievement of the standard in haemodialysis patients have much higher relative achievement in peritoneal dialysis patients. This suggests that practices and attitudes may differ within units for the two modalities of dialysis.

The median serum iPTH achieved in peritoneal dialysis patients in each unit are shown in figure 8.17.

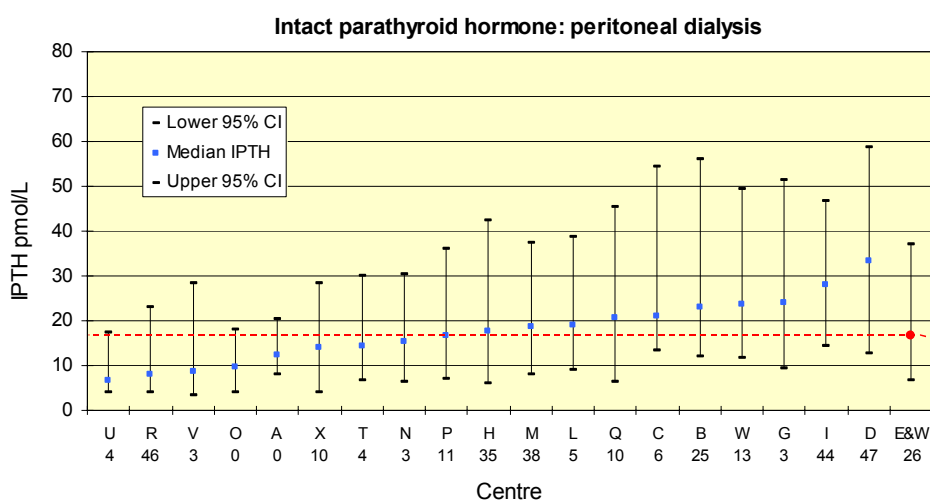


Figure 8.17 Median serum intact parathyroid hormone on peritoneal dialysis

### Significance of differences in serum iPTH between centres.

A chi-squared test was used to determine whether the percentage of patients with iPTH  $\leq 22.8$  pmol/L differed between centres.

For patients on HD, the percentage of patients with PTH  $\leq 22.8$  pmol/L differed significantly between centres ( $X^2 = 239.5$ , d.f. = 18,  $p < 0.001$ ).

For patients on PD, the percentage of patients with PTH  $\leq 22.8$  pmol/L differed significantly between centres ( $X^2 = 88.8$ , d.f. = 18,  $p < 0.001$ ).

### Conclusions

1. Control of serum calcium varies widely among units and compliance with the target range may be due to either hypo- or hyper-calcaemia
2. There are continuing problems with comparative audit of corrected serum calcium due to the difficulties with albumin measurements. Use of uncorrected calcium concentrations may solve this and should be further explored.

3. Many centres have difficulty achieving the target phosphate concentrations for the majority of patients. These targets may not be achievable with current phosphate binders and dialysis regimes.
4. The variation in control of hyperparathyroidism among centres and between modalities within each centre may reflect different policies. Much could be learned from detailed comparisons of the approaches to the prevention and treatment of hyperparathyroidism between the centres at each end of range.

The Renal Association Standards Committee is currently preparing a new standards document, and is considering several changes. The difficulties regarding different methods for measurement of albumin and the effect on corrected serum calcium will be taken into account. A higher upper limit for the serum phosphate standard is being considered. The recommendations for serum iPTH may also be more liberal.





## Chapter 9: Serum Albumin and Serum Bicarbonate

### Serum Albumin

#### Albumin measurement

In general serum albumin is measured by one of two methods, both of which utilise a colour change induced by a dye binding to albumin.

**Bromocresol Green (BCG)** is the most commonly used method but this has been criticised for the fact the BCG binds to a range of proteins other than albumin such that at low albumin concentrations there may be a significant overestimation of the albumin concentration

**Bromocresol Purple (BCP)** is slightly more expensive than BCG and is available on fewer clinical laboratory analysers. The advantage of BCP is that it predominantly binds to albumin and thus gives a more accurate measure of albumin concentrations especially below 30g/L

**Immunoassay.** The reference procedure for serum albumin measurement is to use a specific antibody along with either immunonephelometric or immunoturbidimetric detection.

Most of the above statements with regards the relative performance of BCG and BCP hold in true even in uremic serum where uremic toxins (unknown) bind to albumin and alter the ability of other substances to bind such as drugs and dyes such as BCP and BCG. This has recently been confirmed in two studies one published in NDT (Carfray A, Patel K, Whitaker P, Garrick P, Griffiths GJ, Warwick GL. Albumin as an outcome measure in haemodialysis patients: the effects of variation in assay method. *Nephrol Dialysis Transplant* 2000, 15, 1819-1822.) and one by the Laboratory supporting Unit "W" which has recently changed from BCG to BCP. This laboratory was concerned to investigate the difference in results found in their renal patients but not apparent in other patient populations which formed the majority of their clinical workload.

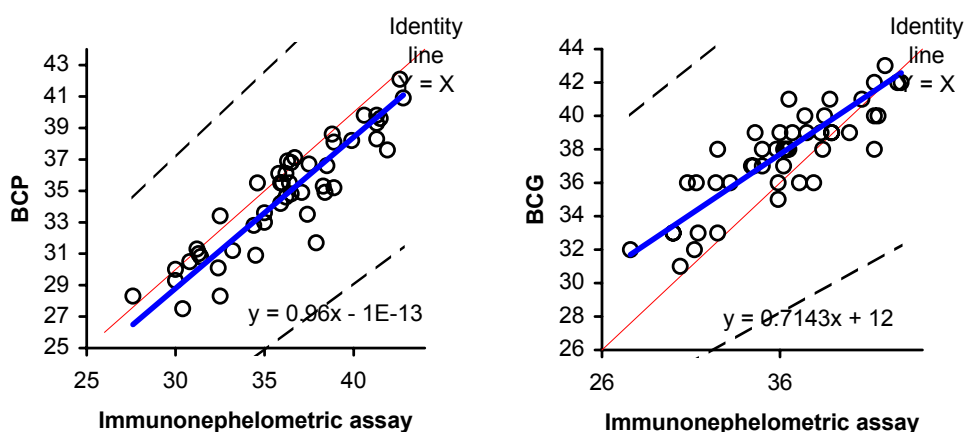


Figure 9.1 Comparison of methods of measuring albumin

BCP and BCG assays are compared with an albumin immunoassay in sera taken from patients on haemodialysis. Results are scattered around the line of identity indicating no significant

difference for BCP but deviate significantly for BCG. This data would suggest that BCP should be preferred to BCG methods for the monitoring of renal patients.

The remaining issue for albumin from previous Registry reports was the variation in reference ranges reported by laboratories and the different sources that had been used to obtain them. In principal and supported by most manufacturers and published sources there should be no large difference in the reference ranges that would be appropriate for use with BCG and BCP methodologies.

Indeed Unit W's laboratory provided information that

- BCG assay reference range (locally determined) was 35-53 g/L.
- BCP assay reference range (Manufacturers) was 34 – 48 g/L
- Immuno-turbidimetric assay reference range (Manufacturers) was 34-47 g/L

Whilst slight differences can be expected ( $\pm 1$ g/L) there seems no particular reason why two laboratories (one BCG and the other BCP using) should have reference ranges down to 30 g/L. It could be suggested that in order to assess compliance with a standard a fixed reference range of 35-50 should be applied to all units as has been tried here.

Unit	Method	Reference Range (g/L)
A	BCG	36-47
B	BCG	35-50
C	BCG	34-50
D	BCG	35-48
E	BCG	35-50
F	BCP	35-50
G	BCG	35-55
H	BCP	30-52
I	BCG	35-50
J	BCG	36-52
K	BCG	35-47
L	BCG	35-50
M	BCG	35-55
N	BCG	35-50
O	BCG	30-48
P	BCG	35-50
Q	BCG	35-50
R	BCP	34-48
T	BCG	36-50
U	BCG	35-50
V	BCG	37-49
W	BCP	35-53
X	BCP	36-50

Conversion g/dl = g/L x 0.1

**Table 9.1 Methods and ranges of albumin measurement**

To study the influence of albumin assay methodology on the distribution of results for centres a different symbol has been used to highlight those supported by laboratories using BCP methodology (● )

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

### Haemodialysis

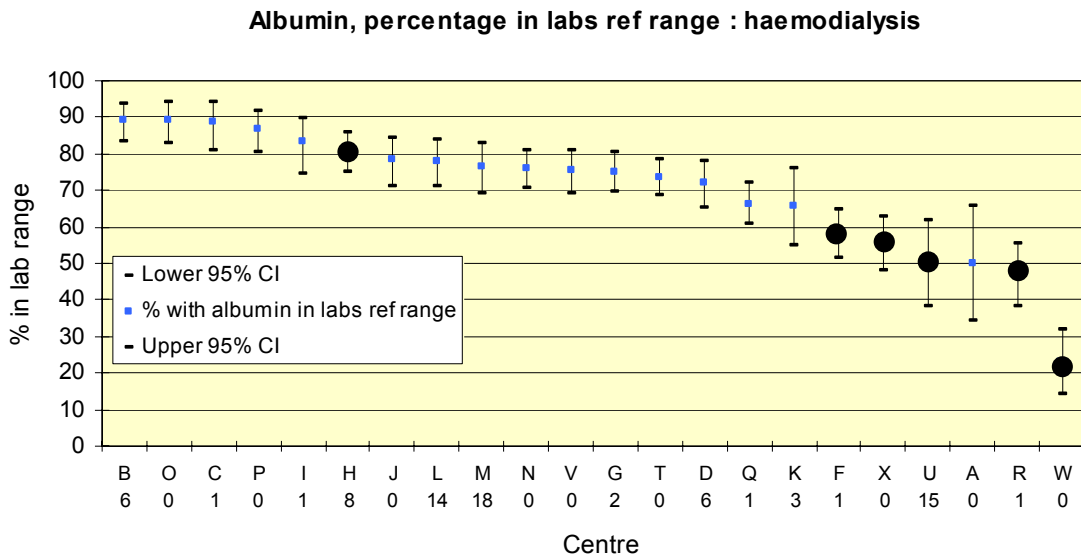


Figure 9.2 Percentage albumin in laboratory reference range on haemodialysis

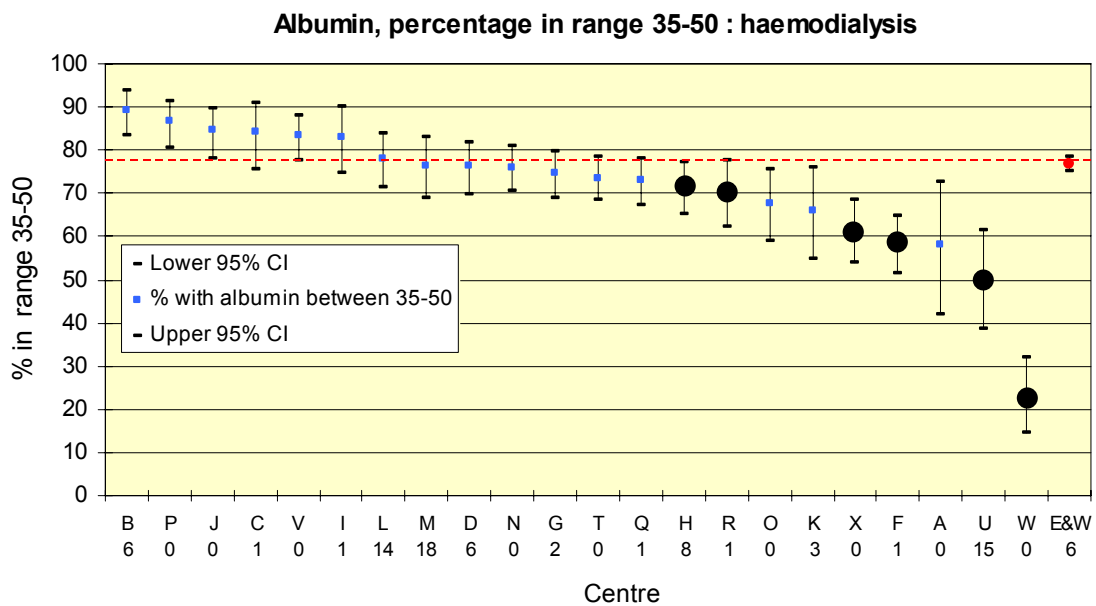
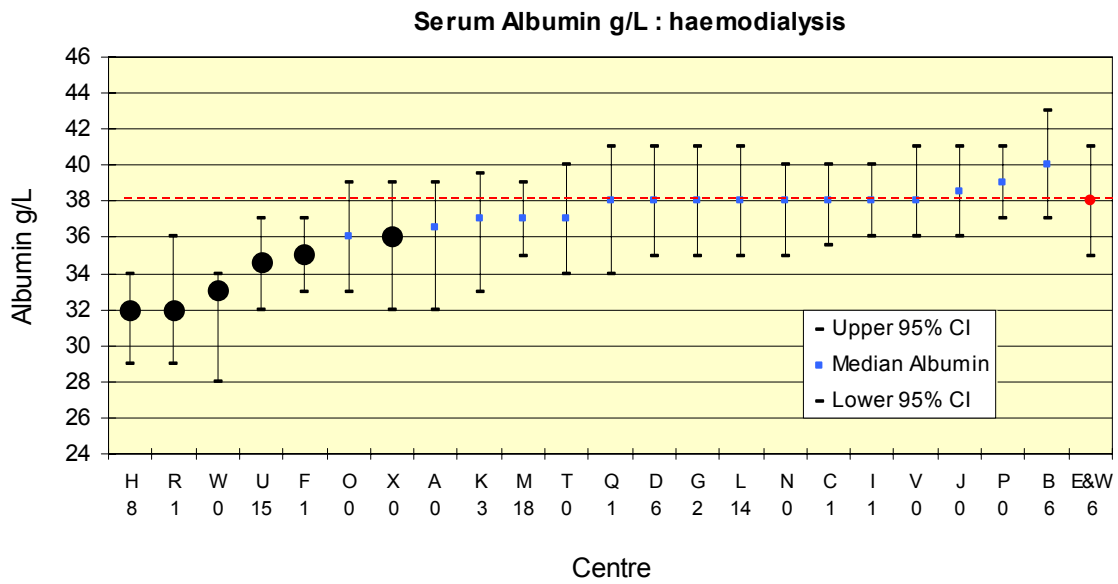
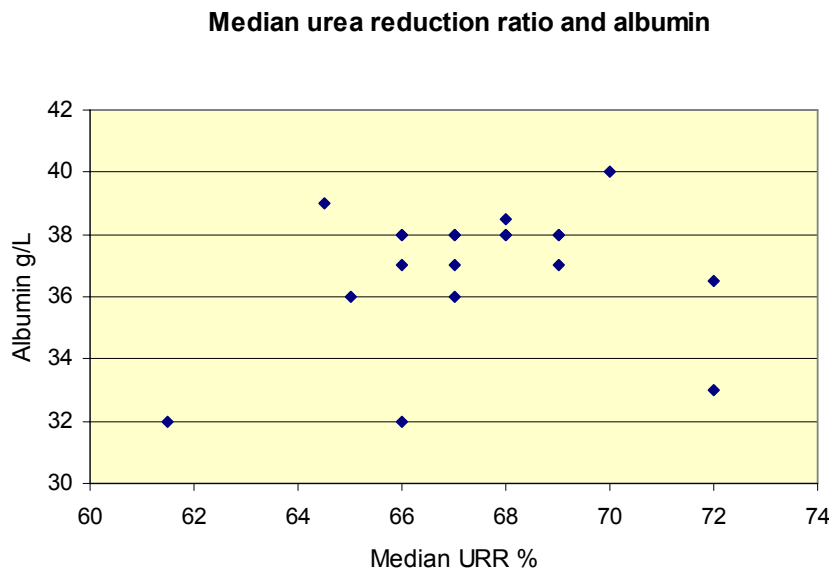


Figure 9.3 Percentage albumin in range 35-50 g/L on haemodialysis



**Figure 9.4 Serum albumin on haemodialysis**

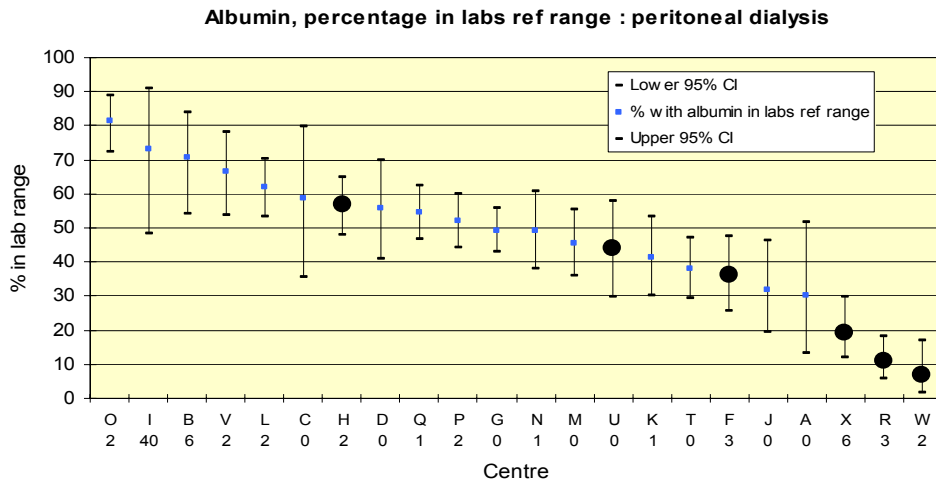
There was variation in median serum albumin both within the BCP group (32-36 mmol/L) and within BCG group (36-40 mmol/L). For patients on HD and laboratories using the BCP methodology, the percentage of patients with albumin greater than or equal to the labs lower reference range limit differed significantly between centres ( $X^2 = 305.9$ , d.f. = 20,  $p < 0.001$ ). This analysis was not performed for the 6 centres using BCP.



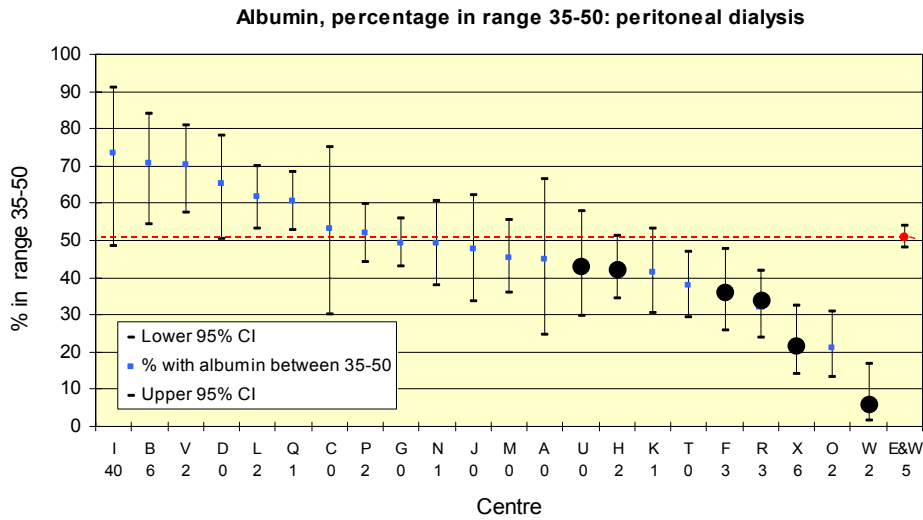
**Figure 9.5 Median urea reduction ratio and albumin**

Although figure 9.5 includes centres using BCP, even after excluding these centres, there was no relationship between the median urea reduction ratio achieved by each centre and the median serum albumin.

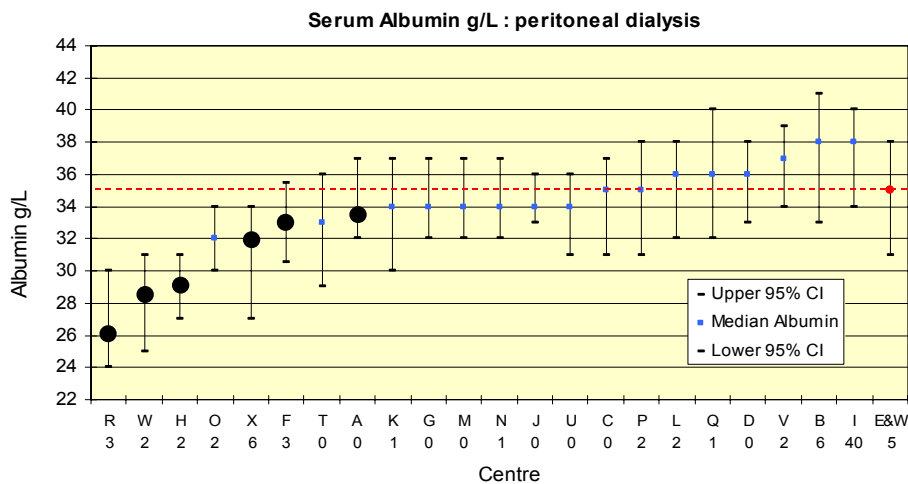
## Peritoneal dialysis



**Figure 9.6 Percentage albumin in laboratory reference range on peritoneal dialysis**



**Figure 9.7 Percentage albumin in range 35-50 g/L on peritoneal dialysis**



**Figure 9.8 Serum albumin on peritoneal dialysis**

For patients on PD and laboratories using the BCG method, the percentage of patients with albumin greater than or equal to the labs lower reference range limit differed significantly between centres ( $X^2 = 200.4$ , d.f. = 21,  $p < 0.001$ )

### Discussion

The BCP using Centres are clearly grouped towards one side of the figures. The relative positions can be modulated by applying different reference ranges (particularly centres H and O) but it is clear that not all the variation in albumin concentration is due to methodological factors as the median serum albumin varied from 28-34 mmol/L in the BCP group.

### Changes in albumin 1998-1999 Haemodialysis

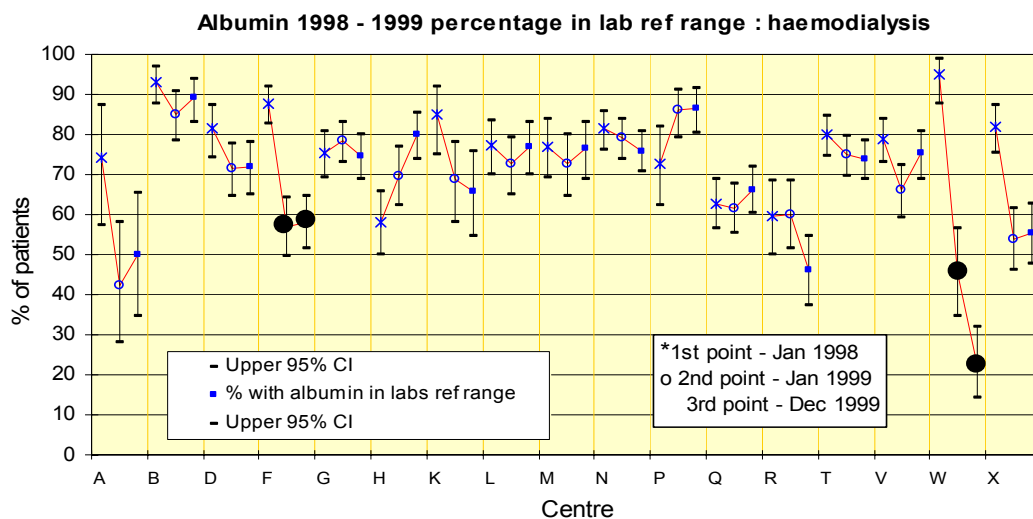


Figure 9.9 Percentage albumin in lab reference range on haemodialysis, 1998-1999

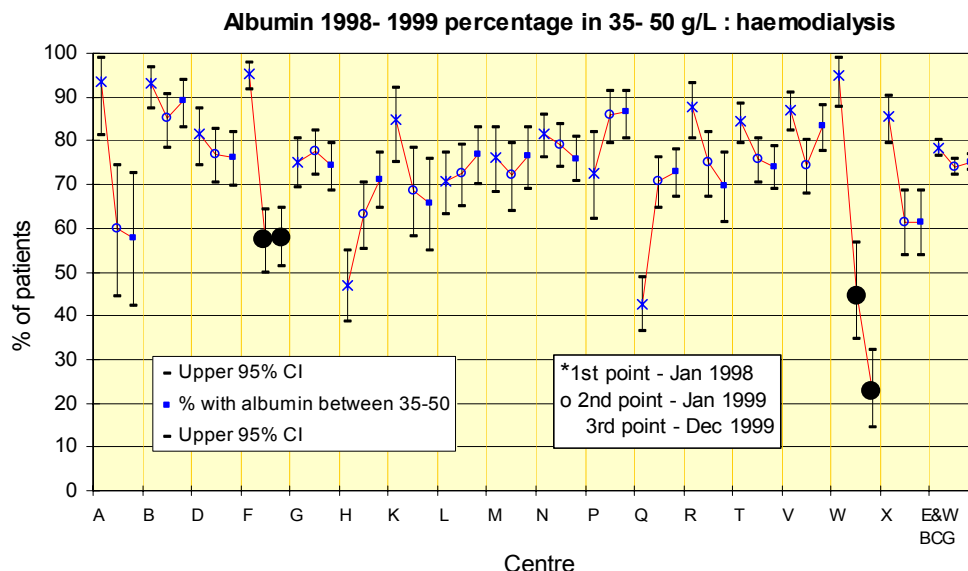
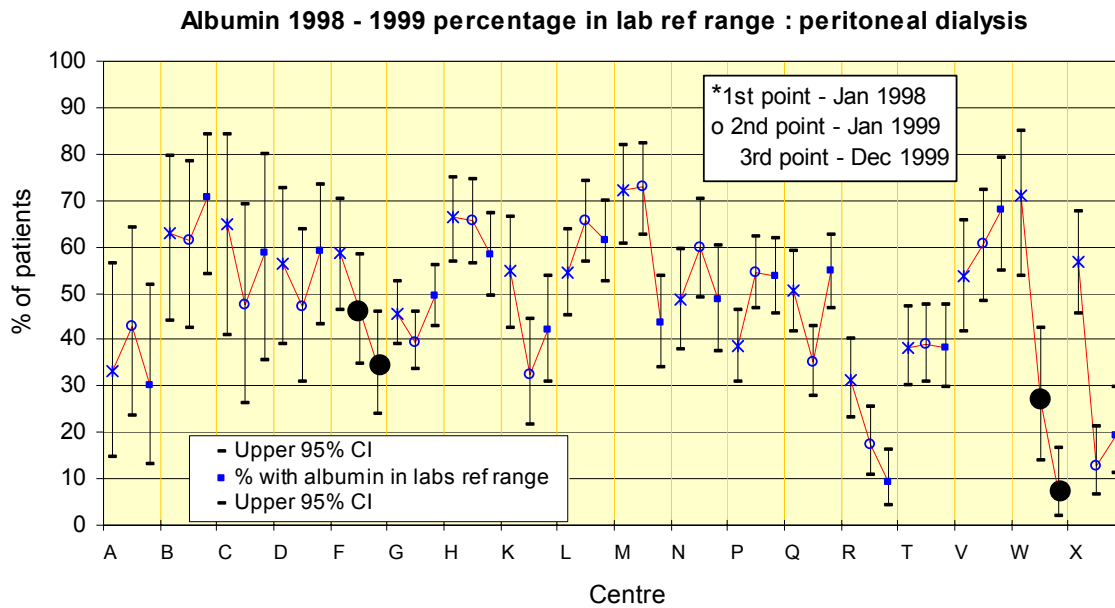


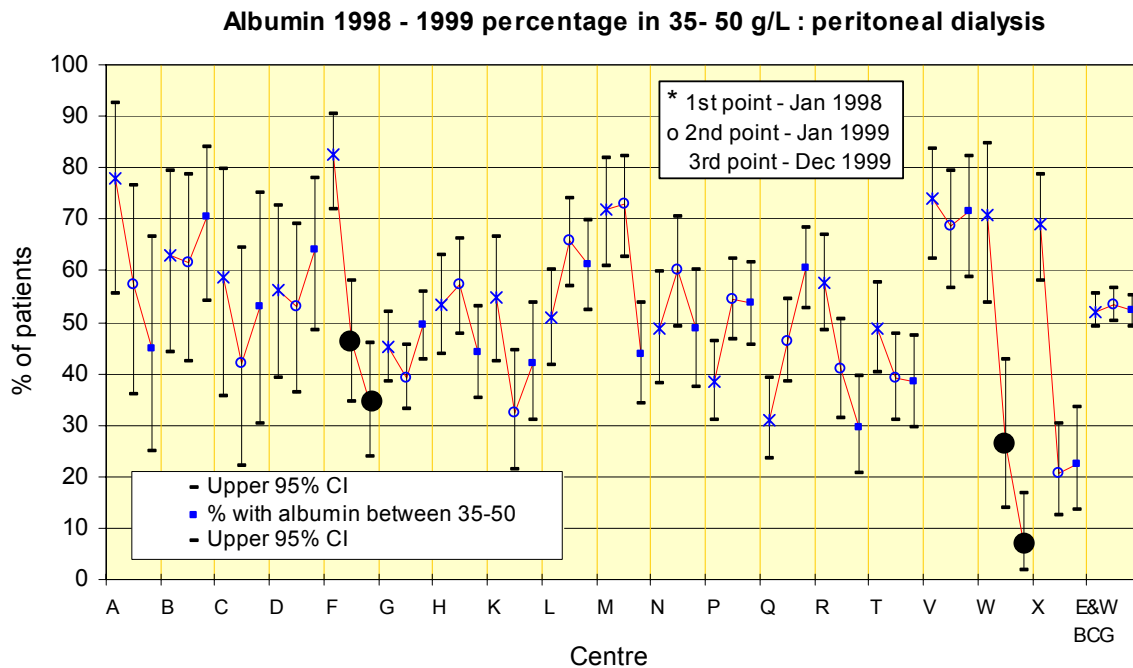
Figure 9.10 Percentage albumin in range 35-50 g/L on haemodialysis, 1998-1999

Two laboratories have changed from BCG in 1998 to BCP in 1999 and this is reflected in the large shifts in albumin concentration shown above and in the following diagrams. Only these two changes are identified (●).

## Peritoneal dialysis

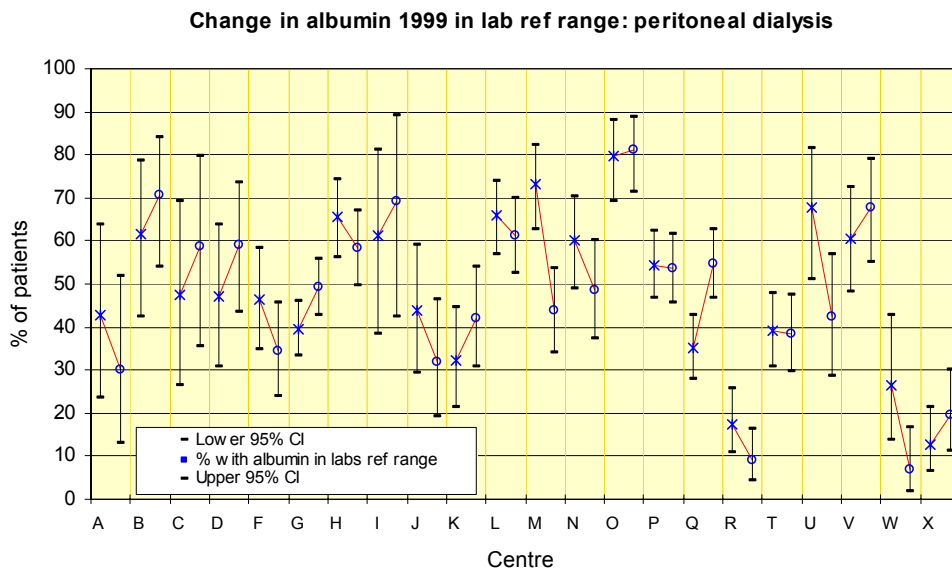


**Figure 9.11 Percentage albumin in laboratory reference range on peritoneal dialysis, 1998-1999**

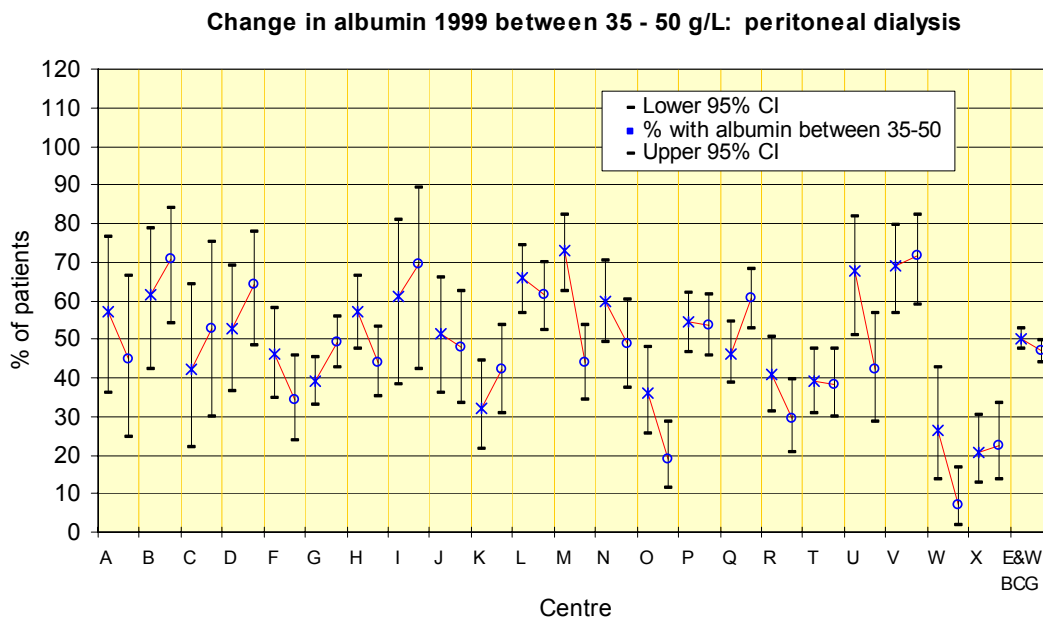


**Figure 9.12 Percentage albumin in range 35-50 g/L on peritoneal dialysis, 1998-1999**

## Change in albumin for 1999



**Figure 9.13** Change in albumin in laboratory reference range on peritoneal dialysis, 1999



**Figure 9.14** Change in albumin between 35-50 g/L on peritoneal dialysis, 1999

### Discussion

Methodological change can clearly cause large shifts in the median albumin concentration for a unit. However not all centres had a methodological change and this data confirms that there are genuine differences in the albumin concentrations between centres and also changes over time. Shifts in median serum albumin over 2 years were more apparent for patients on peritoneal dialysis and explanations for these factors will be sought.



## Conclusions

- Centres using BCP form a distinct grouping due to albumin assay methodology rather than clinical factors.
- BCP assay for serum albumin measurement should be recommended on uraemic sera.
- Reference ranges for BCG and BCP users should be identical
- Previously reported differences (Registry Report 1998) in interference in albumin methods in sera from haemodialysis vs peritoneal dialysis patients are probably due the different median albumin concentrations in these populations. At lower albumin concentrations (ie in PD patients) the BCG assay will show greater differences to the BCP assay due to interference from non-albumin proteins.
- Whilst compliance with RA standards is difficult to assess it is clear that clinical factors are responsible for a significant proportion of the changes in albumin concentration.

## Serum Bicarbonate

### Bicarbonate measurement

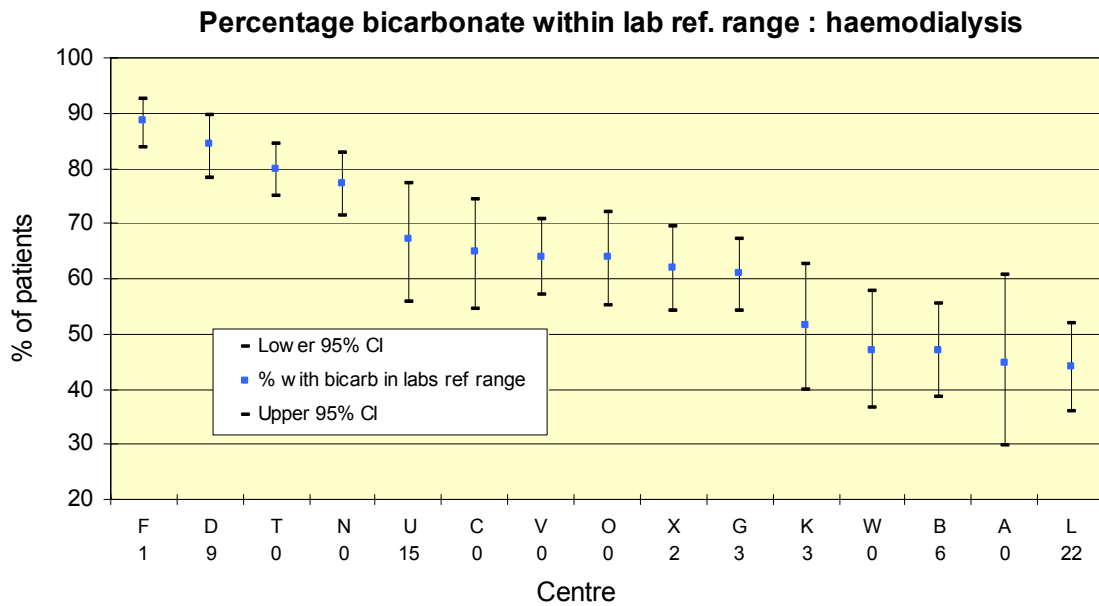
As can be seen from Table 9.2 there are two main methodologies in use for the measurement of bicarbonate. There is some variation in reference ranges but this is probably not the main factor that will determine the distribution of results between centres. Bicarbonate is a relatively unstable anion and concentration changes will result from delayed analysis as can happen with samples sent from General Practitioners, home haemodialysis and possibly satellite dialysis units. Home haemodialysis patients have been excluded from the haemodialysis analysis. Another factor that will alter bicarbonate distributions will be the proportion of patients receiving acetate dialysis solutions.

Centre	Methodology	Ref range mmol/L
A	PEPC	23-30
B	PEPC	22-29
C	PEPC	23-30
D	PEPC	22-30
E	PEPC	23-31
F	Electrode	20-30
G	PEPC	22-30
H	PEPC	19-28
I	PEPC	22-30
J	PEPC	23-29
K	PEPC	22-29
L	PEPC	22-30
M	Electrode	19-32
N	PEPC	20-29
O	Electrode	23-30
P	PEPC	24-30
Q	PEPC	24-30
R	PEPC	24-30
T	PEPC	22-31
U	Electrode	21-30
V	PEPC	20-28
W	Electrode	24-32
X	Electrode	22-31

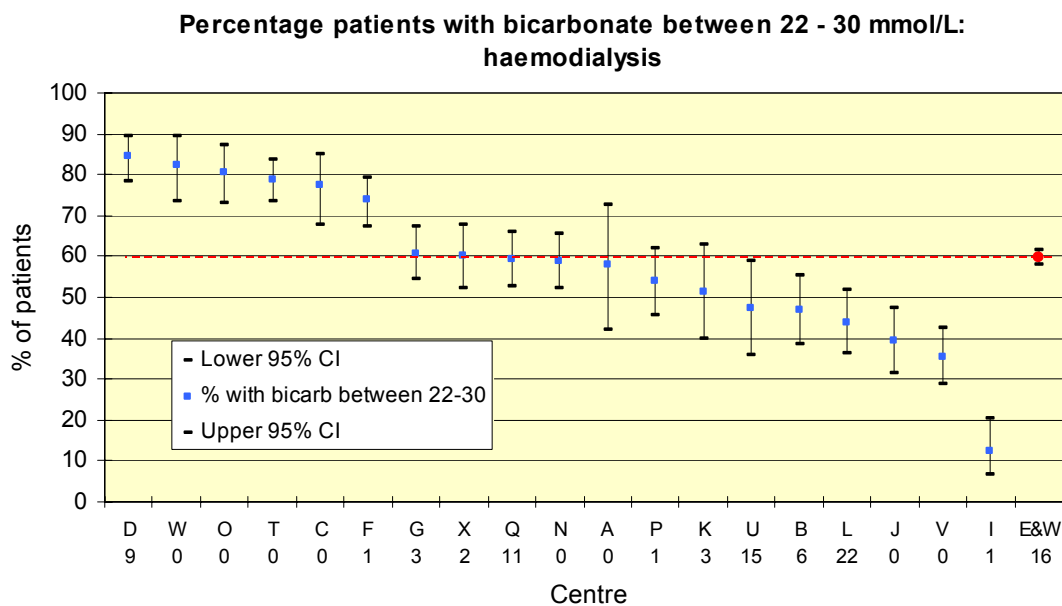
**Table 9.2 Bicarbonate methodology and reference ranges**

## Haemodialysis

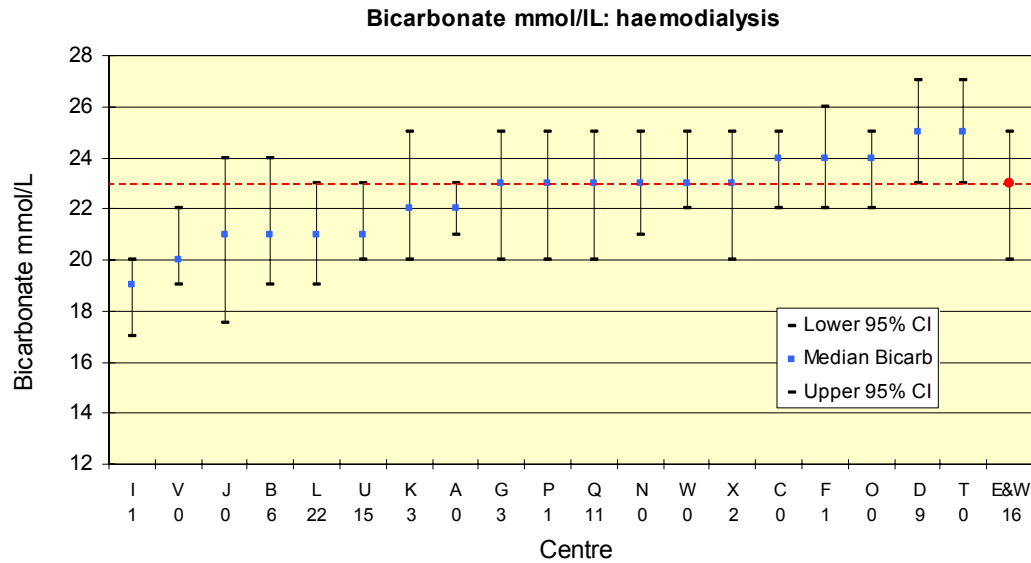
The Renal Association Standard is that all patients *should be within the local normal range*.



**Figure 9.15 Percentage bicarbonate in laboratory reference range on haemodialysis**  
Bicarbonate was not available from centre E, and their was greater than 50% missing data from centres M and R



**Figure 9.16 Percentage patients with bicarbonate in range 22-30 mmol/L on HD**



**Figure 9.17 Median bicarbonate (mmol/L) on haemodialysis**

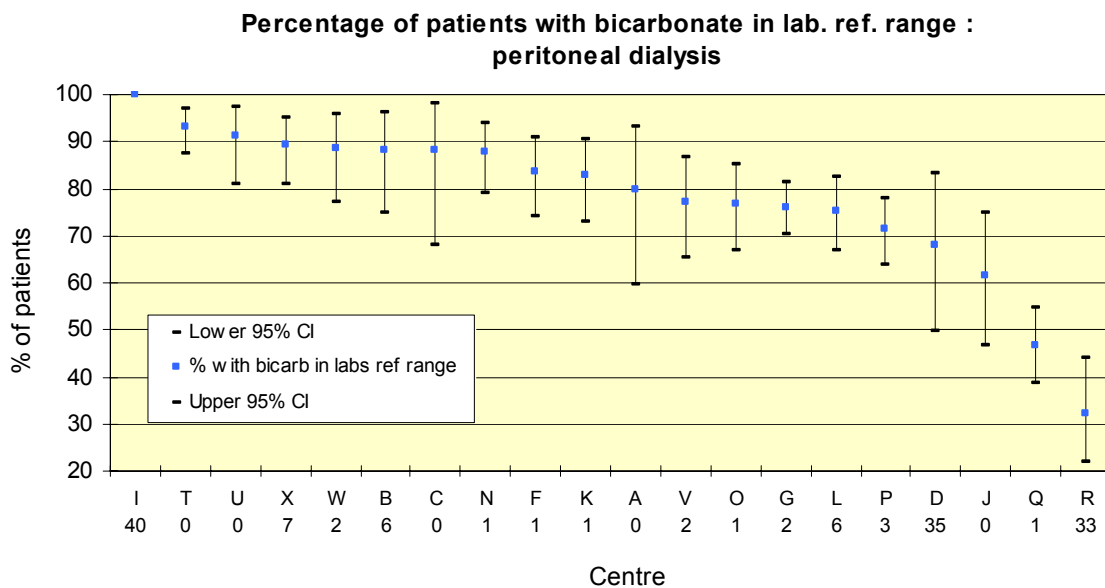
Median serum bicarbonate varied from 18 –25 between centres. For patients on HD, the percentage of patients with bicarbonate within the Standard differed significantly between centres ( $X^2 = 305.9$ , d.f. = 21,  $p < 0.001$ ).

**Discussion**

There is a wide variation in median bicarbonate concentrations of 18-25 mmol/L, between centres. The relative distribution of centres is however not materially altered by applying a reference range factor whether local or Registry assigned (22-30 mmol/L).

**Peritoneal dialysis**

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



**Figure 9.18 Percentage patients with bicarbonate in laboratory reference range on PD**

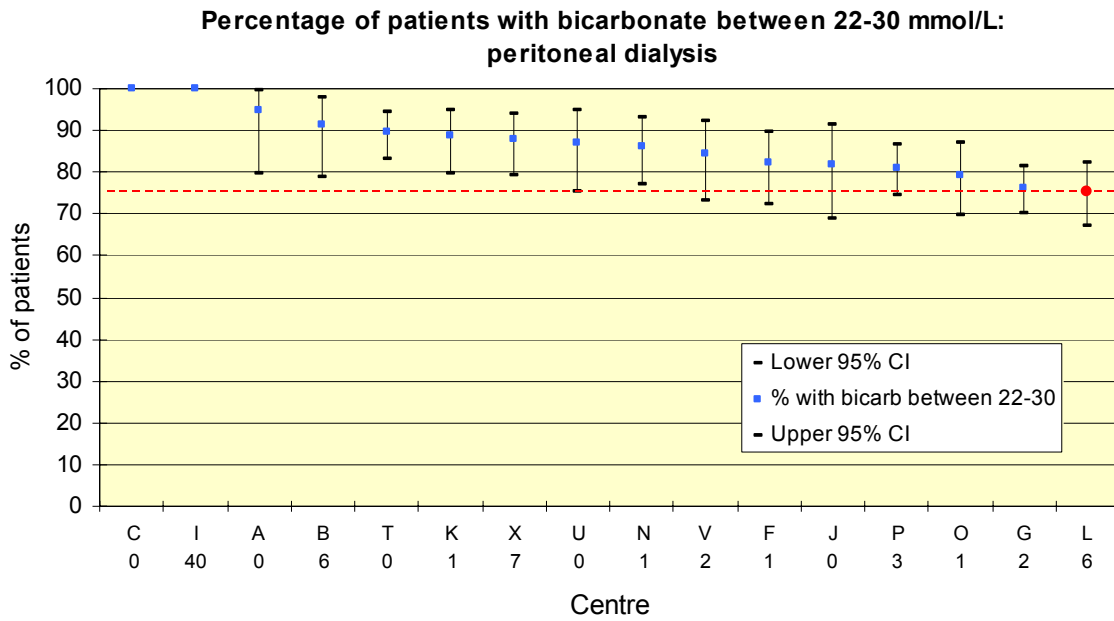


Figure 9.19 Percentage patients with bicarbonate in range 22-30 mmol/L on PD

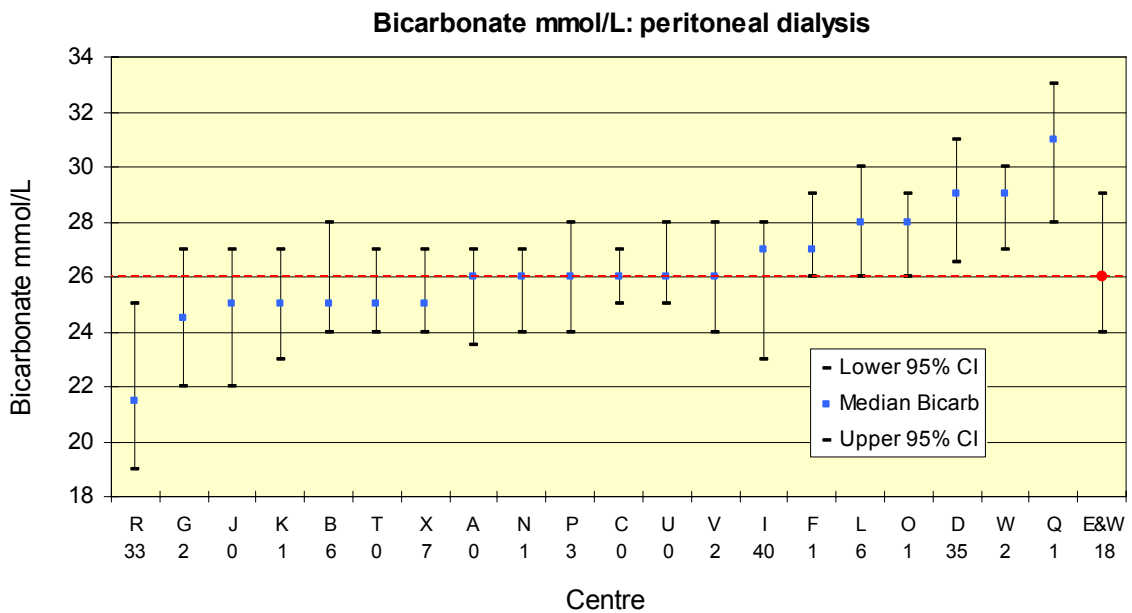


Figure 9.20 Bicarbonate (mmol/L) on peritoneal dialysis

For patients on PD, the percentage of patients with bicarbonate within the Standard differed significantly between centres ( $X^2 = 195.8$ , d.f. = 19,  $p < 0.001$ )

### Discussion

Bicarbonate concentrations appear even more variable in peritoneal dialysis patients, albeit the concentration range is different (21-31 mmol/L). Again use of reference ranges makes little difference to the relative distribution of centres. A more in depth investigation of the usage of dialysate solutions and the delays in sample analysis is required to ascertain the significance of these differences to patient outcomes.



## **Chapter 10: Factors which may influence cardiovascular disease – blood pressure and serum cholesterol**

The majority of patients on renal replacement therapy will die of some form of cardiovascular disease, so factors which influence its development must be major targets for audit and intervention. This chapter considers two of the major determinants of cardiovascular disease in the general population, hypertension and serum cholesterol. The precise importance of these factors in patients on renal replacement therapy is uncertain, as there are other important influences in this situation which can cause vascular damage, and the vascular abnormalities are not necessarily the same as in people without renal failure. In particular, there is marked vascular calcification and vascular rigidity. The abnormalities of calcium and phosphate metabolism, and the measures taken to correct these, may play a dominant role in vascular disease in renal failure.

### ***Blood pressure***

#### ***Introduction***

The current Renal Association Standards Document recommends similar blood pressure control for haemodialysis and peritoneal dialysis patients, although no standard is recommended for transplant patients. The standards for systolic and diastolic blood pressure vary in relation to age, although current available evidence does not support this differentiation. It has been shown in the general population that the absolute benefits of blood pressure reduction are greater in elderly than in younger patients, due to their higher baseline risk, and that hypertension in patients up to the age of 80 can be safely treated with good results<sup>1</sup>.

The current standards for control of hypertension published in 1997 are:

**Age <60: BP < 140/90 mmHg. (predialysis for haemodialysis patients).**

**Age ≥60: BP < 160/90 mmHg. (predialysis for haemodialysis patients).**

**(Korotkoff V if auscultation is used.)**

In the proposals under discussion for the next standards document, the age variation is not maintained, and a lower standard of 130/80 mmHg is being considered for peritoneal dialysis patients.

Studies in renal replacement therapy do not show the relationship between achieved blood pressure control and outcome seen in the general population. In some studies apparently good blood pressure control is associated with poor outcome. There are factors in renal replacement therapy which may account for this:

- “Good” control groups include patients with established heart disease and poor myocardial function, either as a result of years of chronic renal failure and hypertension, or because vascular disease was the primary cause of renal failure. These patients do not have good blood pressure control, but poor cardiac function.

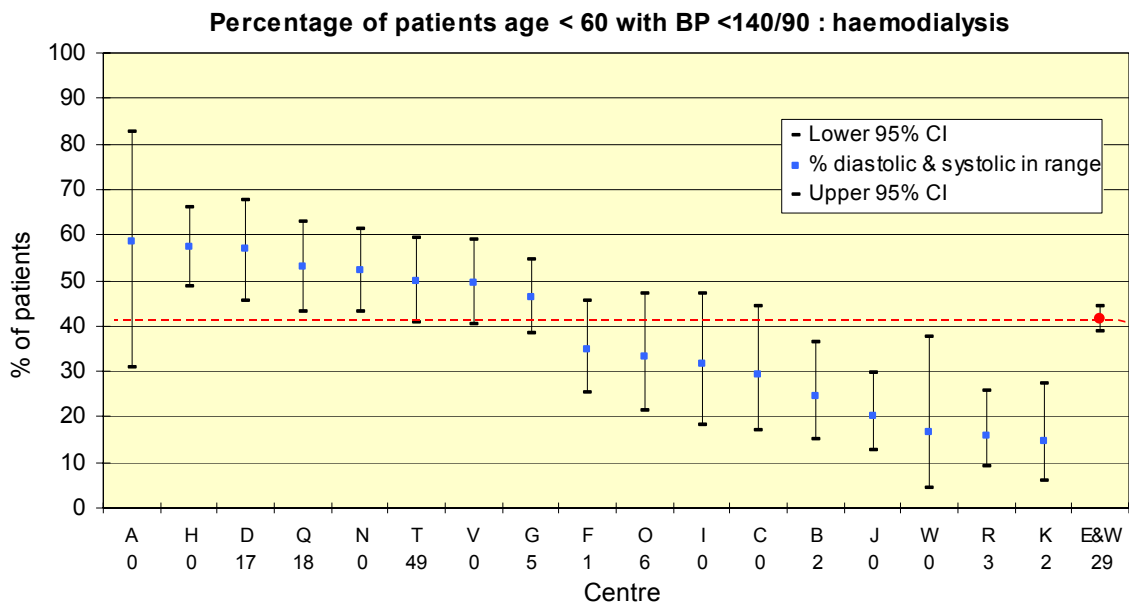
- The major factor driving hypertension in many dialysis patients is inadequate control of salt and water status. Patients will be hypertensive unless they already have impaired cardiac function.
- Those who can tolerate anti-hypertensive drugs without symptomatic hypotension during or between dialysis sessions have less severe cardiac disease.

The studies of the relationship between hypertension and outcome in renal replacement therapy have been short-term. It is probable that hypertension, often sustained over many years longer than the observation periods of the studies, is a major cause of cardiac damage and eventually of cardiac failure, low blood pressure, and death. A recent paper supports this interpretation: in a single centre study, early mortality was associated with low diastolic blood pressure, but late mortality was associated with high systolic blood pressure<sup>2</sup>. However, there have been no controlled trials examining the effect of blood pressure reduction, however achieved, on outcome in haemodialysis patients. In the light of this, the comparative results on blood pressure control presented here must be interpreted with extreme caution.

Perhaps the most remarkable observation in the results presented below, whatever the measured blood pressure indicates, is the enormous variation between renal units in blood pressure control achieved.

### **Achievement of combined systolic and diastolic standard**

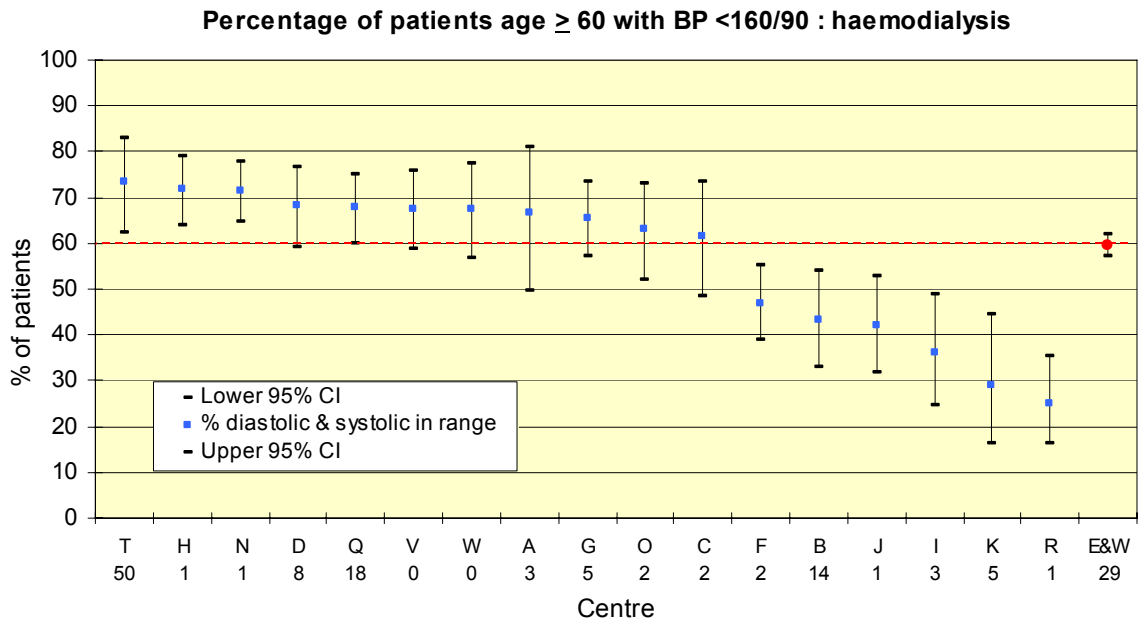
#### *Haemodialysis*



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

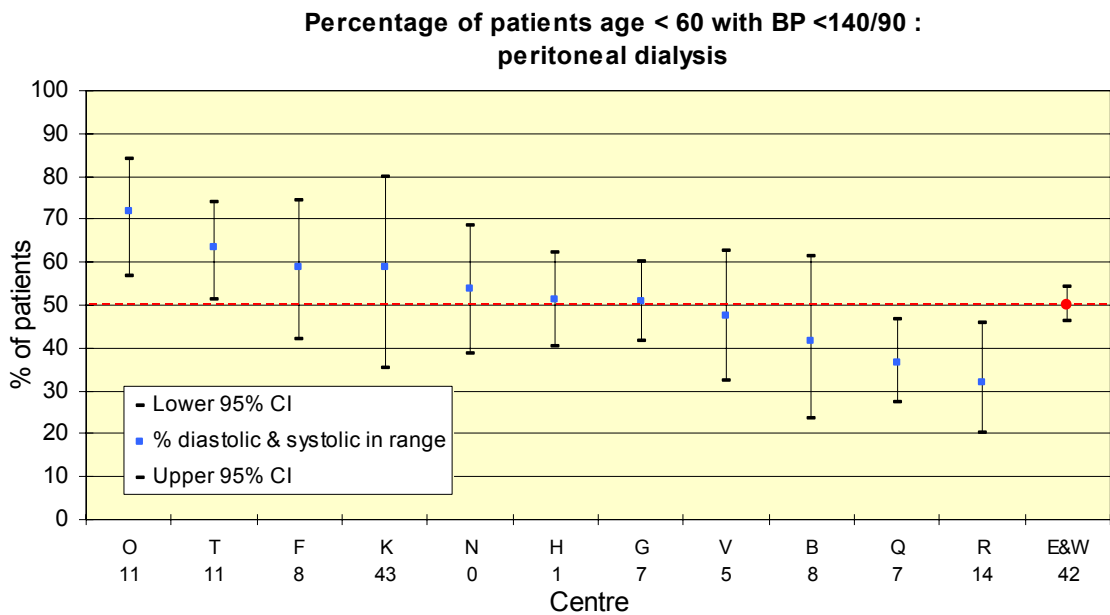
For patients on HD, the percentage of patients aged < 60 with a combined systolic blood pressure < 140 mm Hg and diastolic pressure < 90 mm Hg was found to differ significantly between centres ( $X^2 = 105.6$ , d.f. = 16,  $p < 0.001$ ). This was also significant in patients aged  $\geq 60$  with a combined systolic pressure < 160 mm Hg and diastolic pressure < 90 mm Hg ( $X^2 = 135.5$ , d.f. = 16,  $p < 0.001$ ).





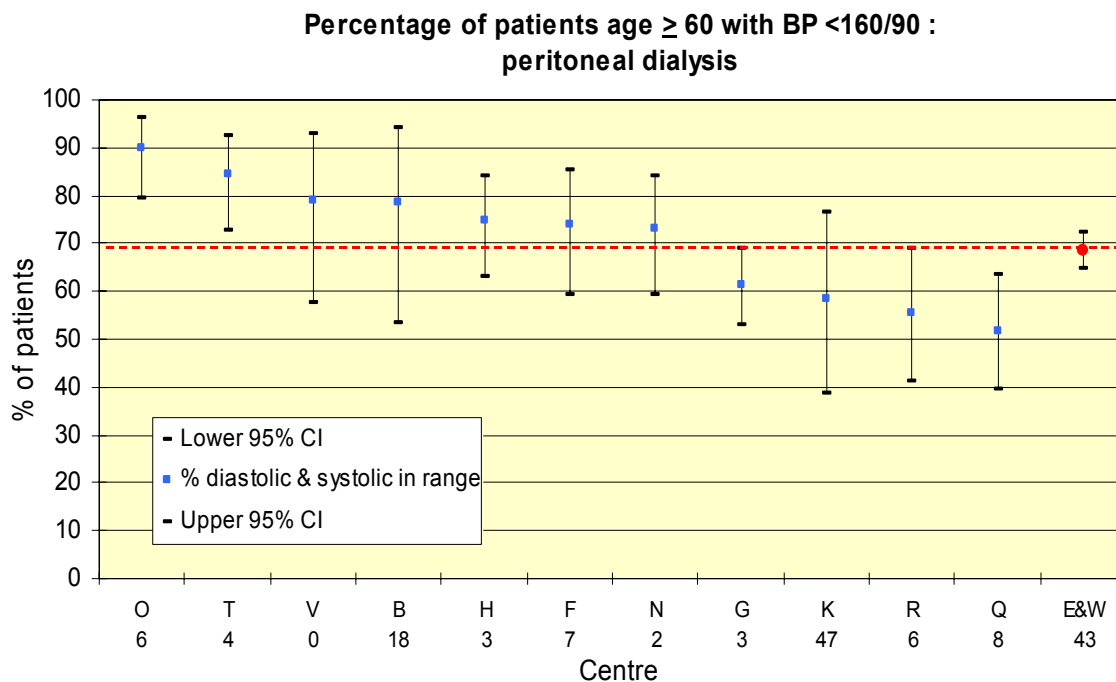
**Figure 10.2** Percentage of patients age  $\geq 60$  with BP  $\leq 160/90$  on haemodialysis

*Peritoneal dialysis*



**Figure 10.3** Percentage of patients age  $< 60$  with BP  $< 140/90$  on PD

For patients on peritoneal dialysis, the percentage of patients aged  $< 60$  with a combined systolic blood pressure  $< 140$  mm Hg and diastolic pressure  $< 90$  mm Hg was found to differ significantly between centres ( $X^2 = X^2 = 28.0$ , d.f. = 10,  $p < 0.001$ ). This was also significant in patients aged  $\geq 60$  with a combined systolic pressure  $< 160$  mm Hg and diastolic pressure  $< 90$  mm Hg ( $X^2 = 37.1$ , d.f. = 10,  $p = 0.005$ ).



**Figure 10.4 Percentage of patients age  $\geq 60$  with BP < 160/90 on PD**

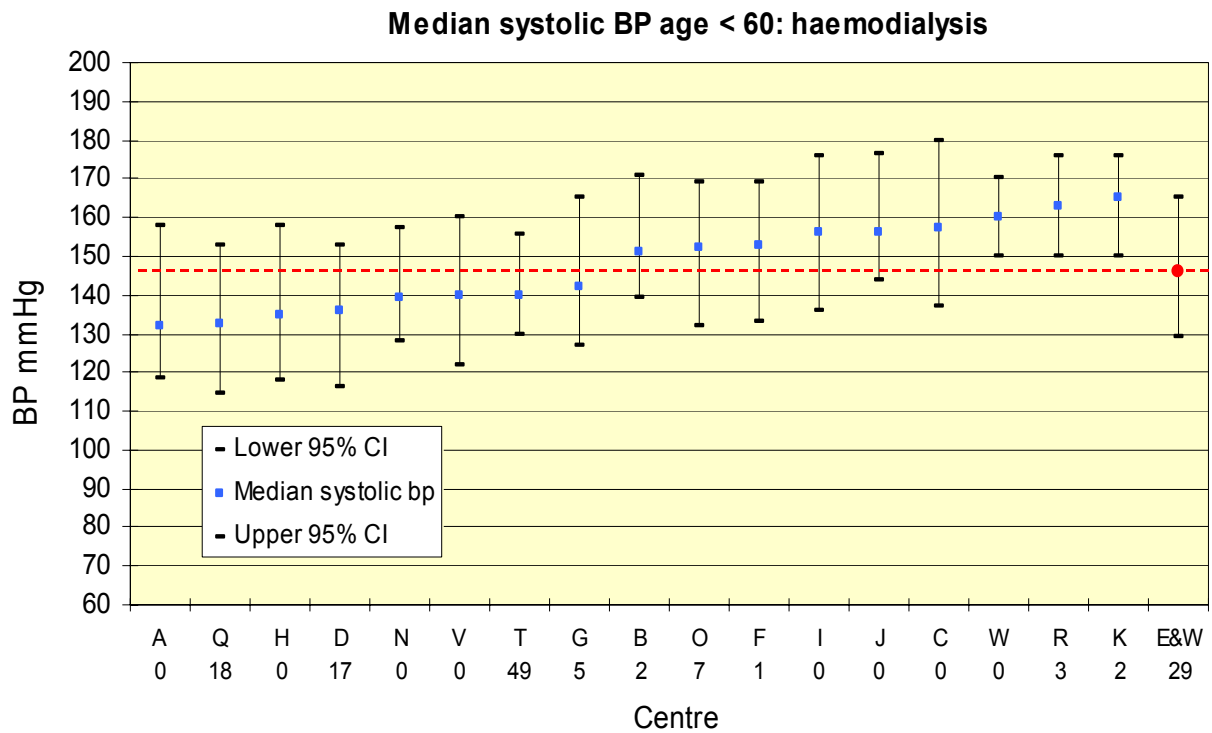
Figures 10.1-10.4 show wide variation between units in percentage of patients within the blood pressure standard.

The standard is achieved more frequently in peritoneal dialysis patients than in haemodialysis patients. The variation for younger haemodialysis patients is from 15% to 60% of patients in individual centres meeting the standard, average 41%: for older haemodialysis patients the corresponding figures are 25% to 73%, average 60%. For younger peritoneal dialysis patients the variation is from 32% to 71% of patients achieving the standard, average 60%: for older peritoneal dialysis patients the figures are from 52% to 90%, average 79%. More older patients achieve the standard than younger patients, because the standard for older patients is less rigorous.

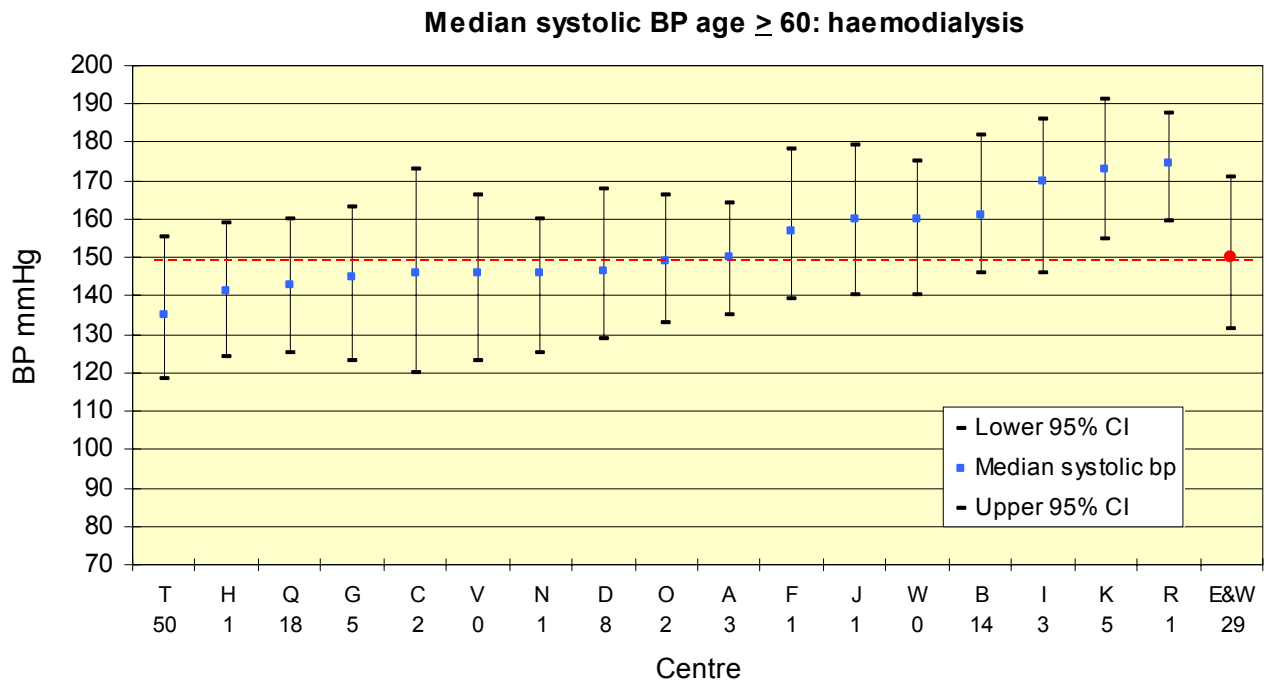
### **Systolic pressure alone**

In the general population systolic pressure is an indicator of vascular risk. Many elderly patients have isolated systolic hypertension. There is benefit from reducing systolic blood pressure in the elderly general population<sup>3</sup>, but this has not been specifically examined in renal replacement therapy. The appropriate approach to systolic hypertension in the elderly dialysis patient is therefore unclear.

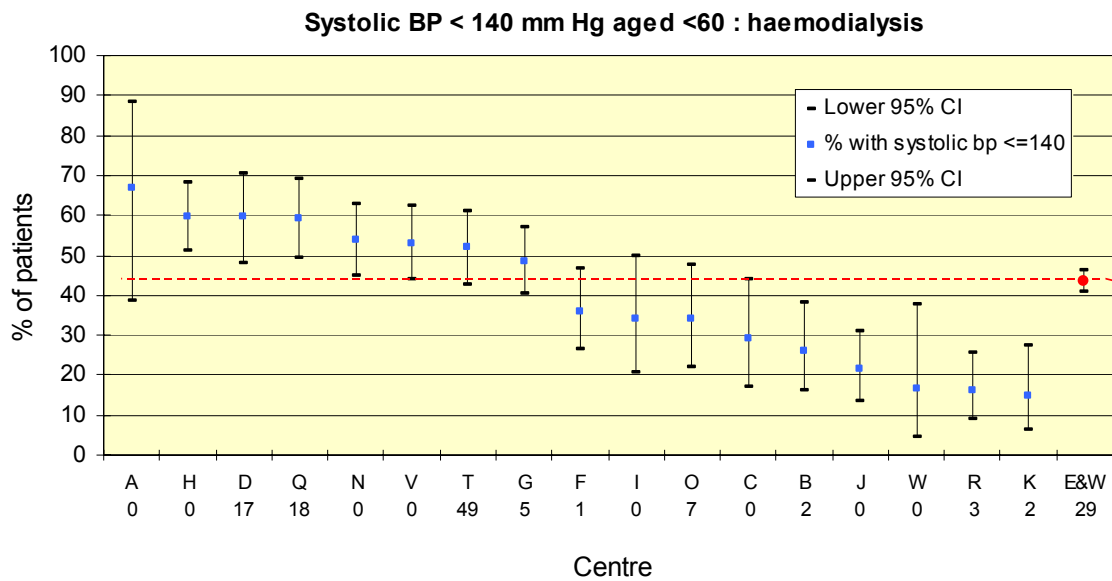
## Haemodialysis



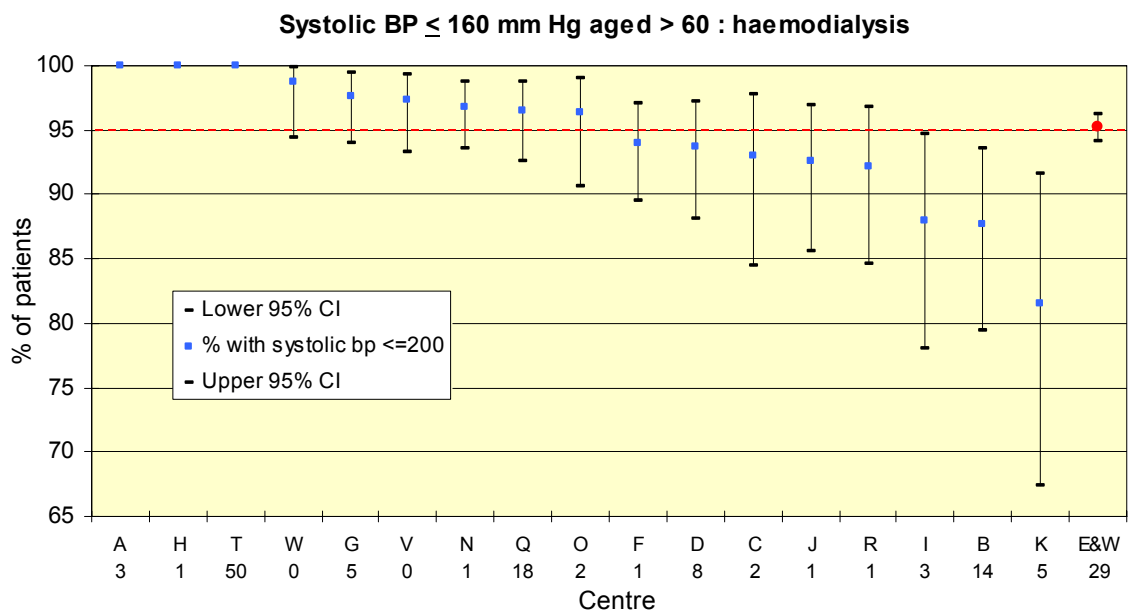
**Figure 10.5 Median systolic blood pressure age < 60 on haemodialysis**



**Figure 10.6 Median systolic blood pressure age  $\geq$  60 on haemodialysis**



**Figure 10.7 Percentage of patients with systolic BP  $\leq$  140 mm Hg aged < 60 on HD**



**Figure 10.8 Percentage of patients with systolic BP  $\leq$  160 mm Hg aged  $\geq$  60 on HD**

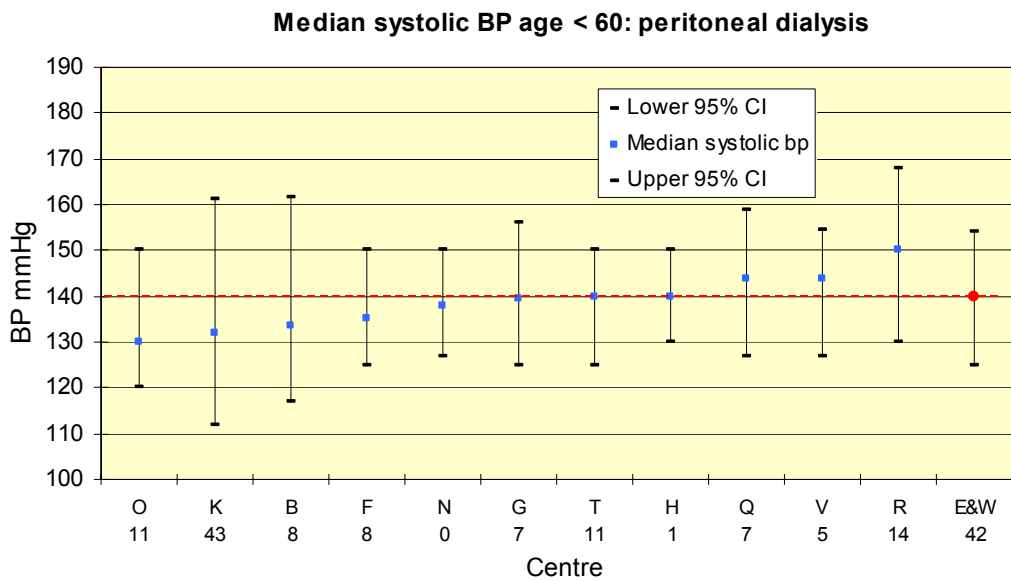
The percentage of elderly haemodialysis patients achieving the systolic standard is higher (centre variation from 83% to 100%, mean 95%) than younger patients (variation from 15% to 68%, mean 44%), as the standard is more liberal in this age group. The median blood pressure obtained in the two groups is similar (148 mm/Hg in the younger patients, 150 mm/Hg in the older patients) (figures 10.5 – 10.8).

For patients on HD, the percentage of patients aged < 60 with a systolic blood pressure < 140 mm Hg was found to differ significantly between centres ( $X^2 = 121$ , d.f. = 16,  $p < 0.001$ ). This was also significant in patients aged  $\geq 60$  ( $X^2 = 55.6$ , d.f. = 16,  $p < 0.001$ ).

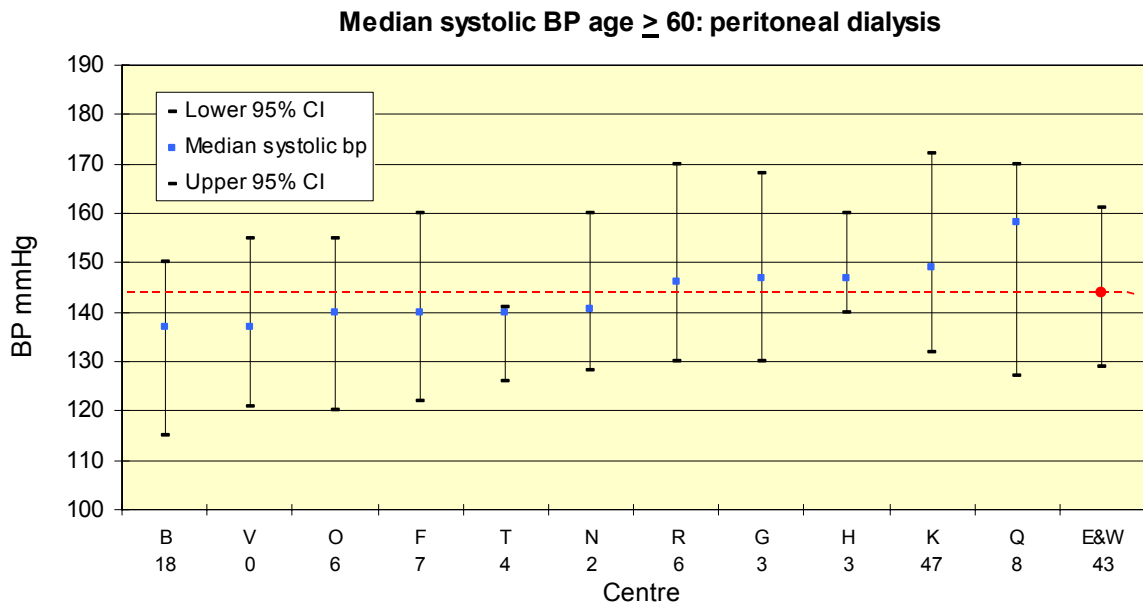
### Peritoneal dialysis

Similar relationships are seen in peritoneal dialysis patients (figures 10.9 - 10.12), but overall blood pressure control was better in patients on PD (median systolic pressure 140 mm/Hg in the younger patients, 143 mm/Hg in the older, with 55% and 98% patients achieving the standard in each age group).

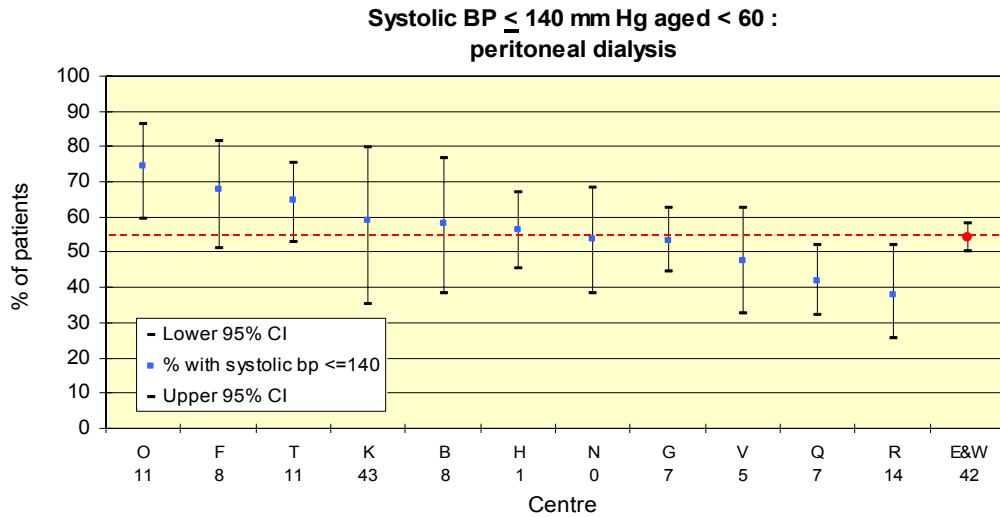
A significance level of 0.01 has been used within the biochemistry and blood pressure chapters due to the large number of tests. At this significance level, the percentage of patients aged < 60 with a systolic blood pressure < 140 mm Hg was just found to differ significantly between centres ( $X^2 = 24$ , d.f. = 10,  $p < 0.008$ ). This was **NOT** significant in patients aged  $\geq 60$  ( $X^2 = 17$ , d.f. = 10,  $p = 0.07$ ).



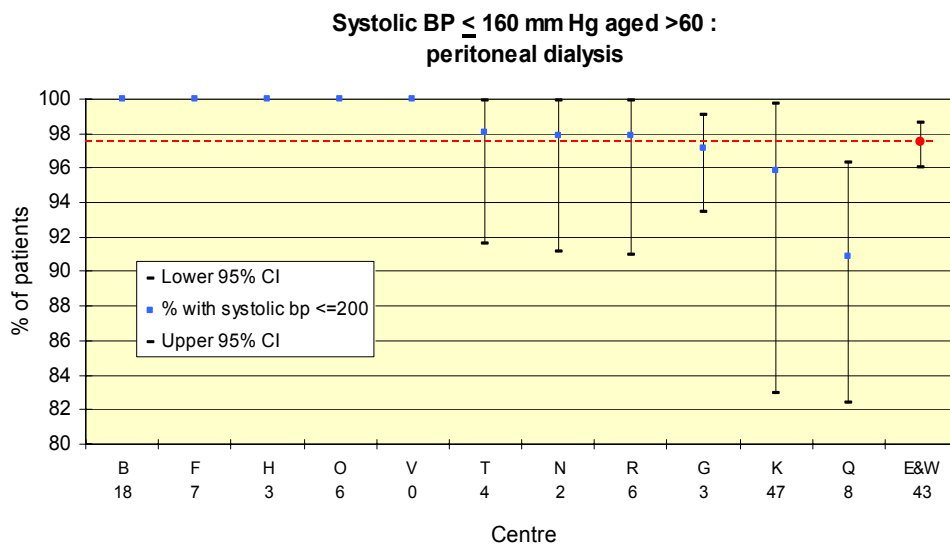
**Figure 10.9 Median systolic blood pressure age < 60 on peritoneal dialysis**



**Figure 10.10 Median systolic blood pressure age  $\geq 60$  on peritoneal dialysis**



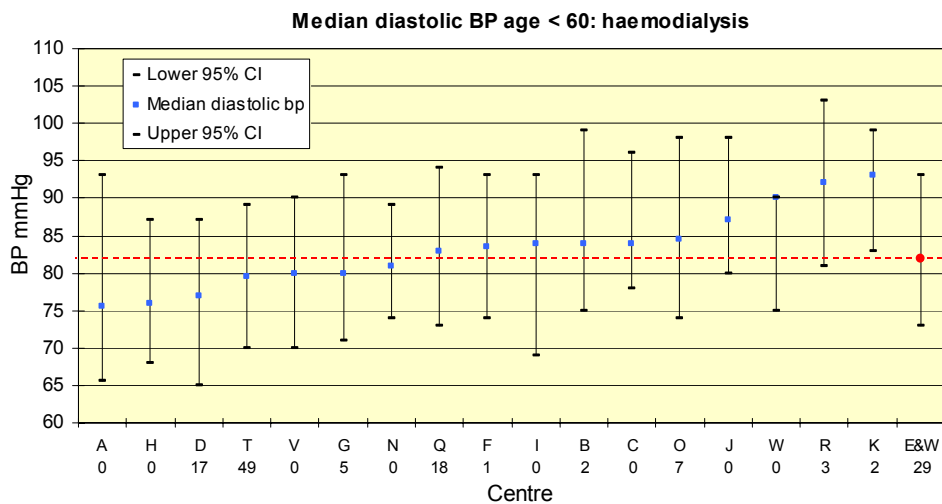
**Figure 10.11 Percentage of patients with systolic BP  $<$  140 mm Hg age  $<$  60: PD**



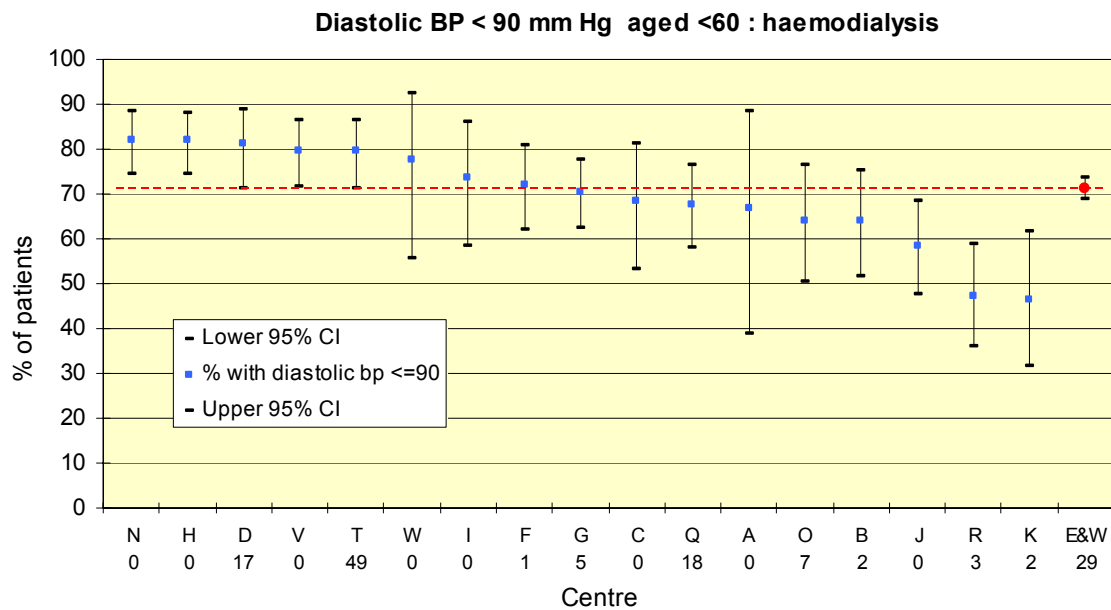
**Figure 10.12 Percentage of patients with systolic BP  $<$  160 mm HG age  $>$  60: PD**

**Diastolic pressure alone**

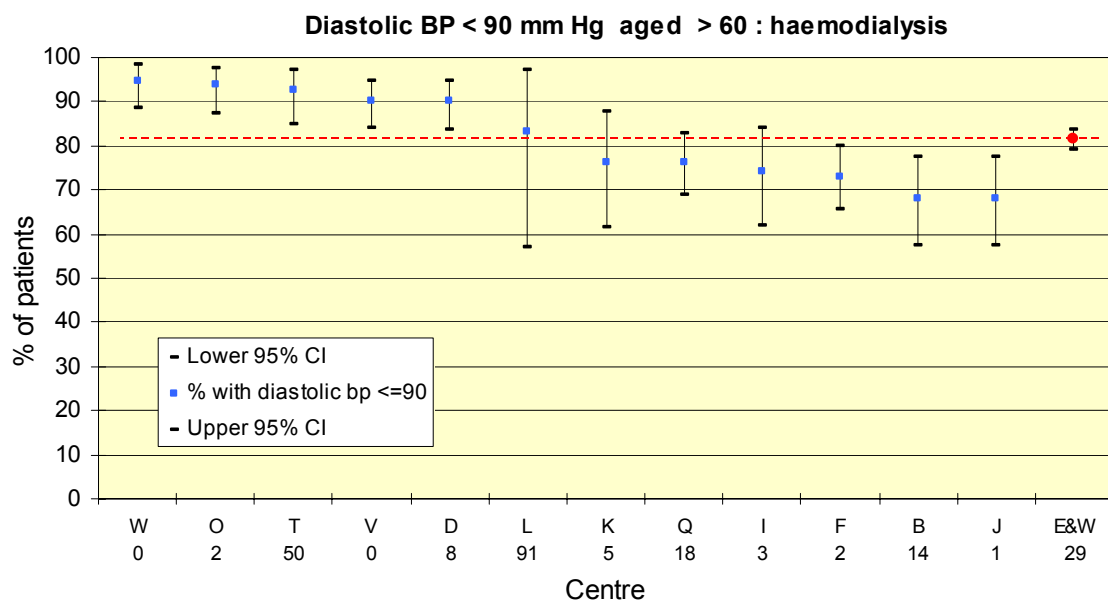
**Haemodialysis**



**Figure 10.13 Median diastolic blood pressure age  $<$  60 on haemodialysis**



**Figure 10.14** Percentage of patients age < 60 with diastolic BP ≤ 90 mmHg on HD



**Figure 10.15** Percentage of patients age ≥ 60 with diastolic BP < 90 mmHg on HD

The median diastolic pressure of younger haemodialysis patients (84 mm/Hg) is higher than that of older haemodialysis patients (82 mm/Hg), (figures 10.13 – 10.15), and similar in peritoneal dialysis patients (figures 10.16 – 10.19). Thus fewer younger patients achieve the standard value (71% vs 81% in haemodialysis, 77% versus 82% in peritoneal dialysis). Overall results are again better in peritoneal dialysis patients.

For patients on HD, the percentage of patients aged < 60 with a diastolic blood pressure < 90 mm Hg was found to differ significantly between centres ( $X^2 = 69$ , d.f. = 16,  $p < 0.001$ ). This was also significant in patients aged ≥ 60 ( $X^2 = 68$ , d.f. = 11,  $p < 0.001$ ).

Peritoneal dialysis

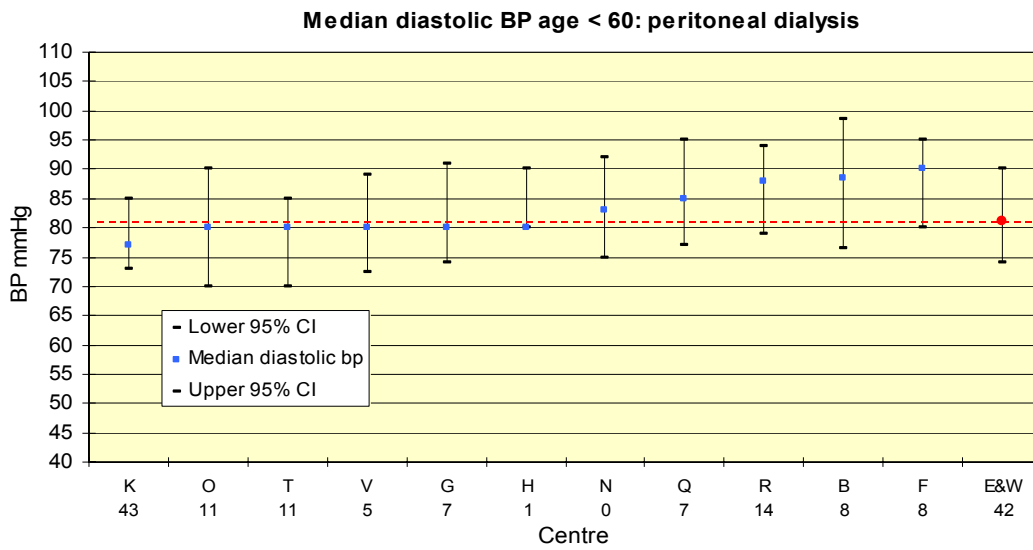


Figure 10.16 Median diastolic blood pressure age < 60 on PD

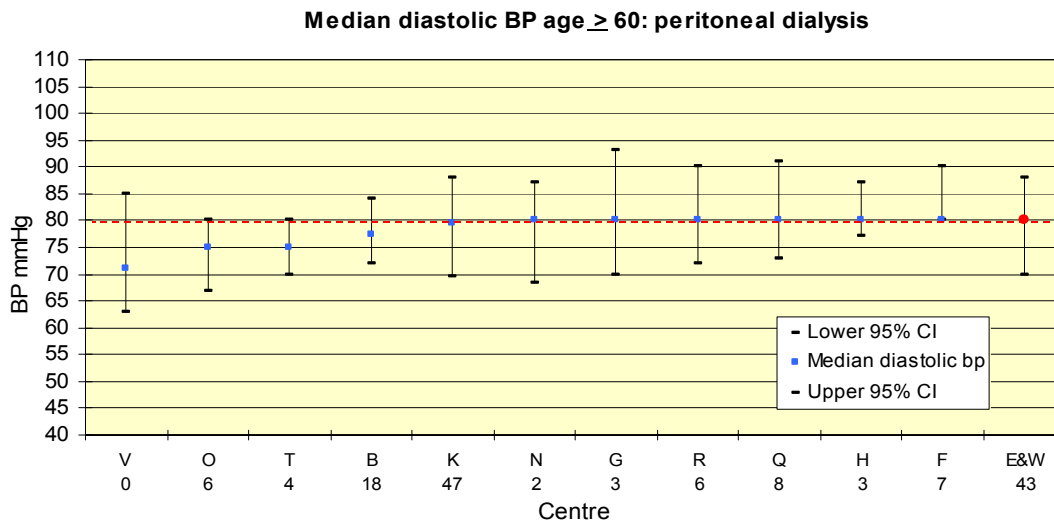


Figure 10.17 Median diastolic blood pressure age ≥ 60 on peritoneal dialysis

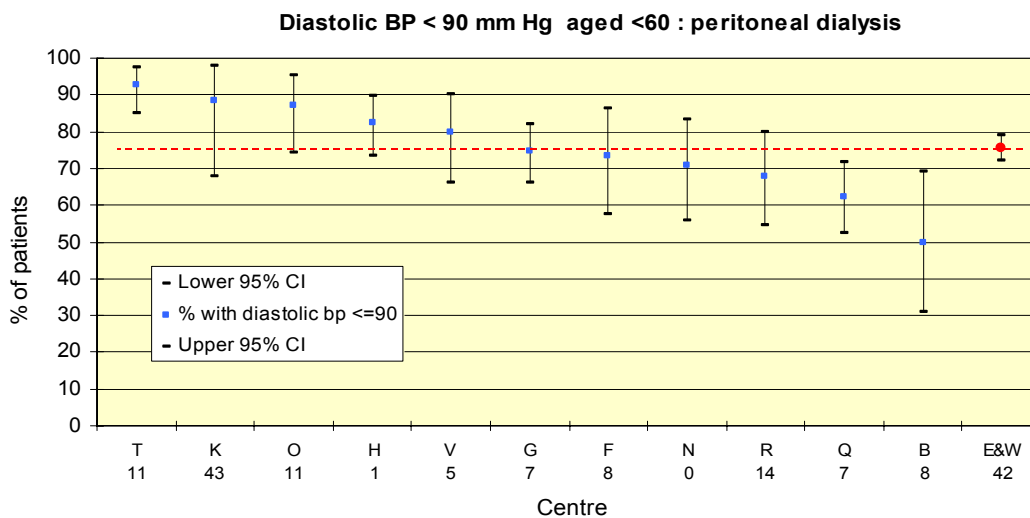


Figure 10.18 Percentage patients age < 60 with diastolic BP ≤ 90 mmHg on PD



For patients on PD, the percentage of patients aged < 60 with a diastolic blood pressure < 90 mm Hg was found to differ significantly between centres ( $X^2 = 37$ , d.f. = 10,  $p < 0.001$ ). This was also significant in patients aged  $\geq 60$  ( $X^2 = 26$ , d.f. = 11,  $p < 0.003$ ).

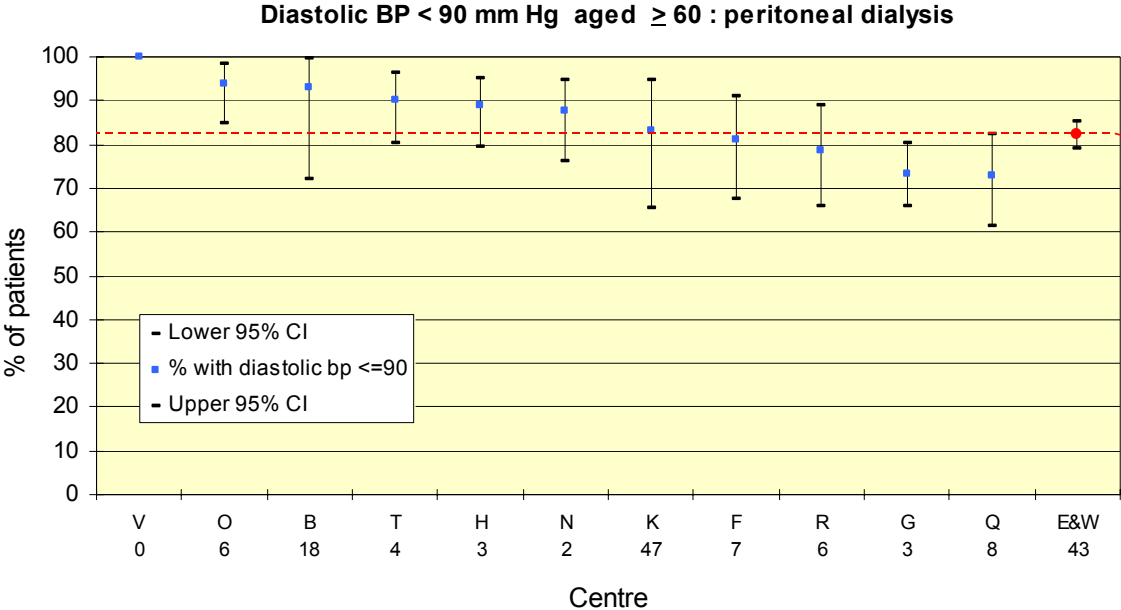


Figure 10.19 Percentage patients age  $\geq 60$  with diastolic BP < 90 mmHg on PD

**Mean arterial pressure**

Mean arterial pressure is calculated as diastolic pressure plus one-third the difference between systolic and diastolic pressures. The standards for systolic and diastolic blood pressure are equivalent to a mean arterial pressure of 106.7mmHg in those under 60 and 113.3mmHg in older patients.

**Haemodialysis**

Results are shown in figures 10.20 – 10.23

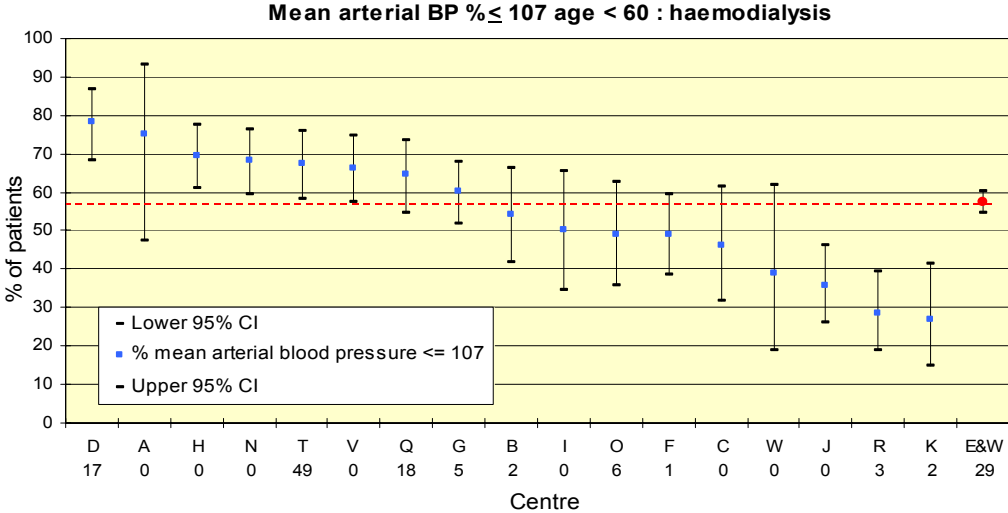


Figure 10.20 Percentage patients age < 60 with mean arterial BP < 107 on HD

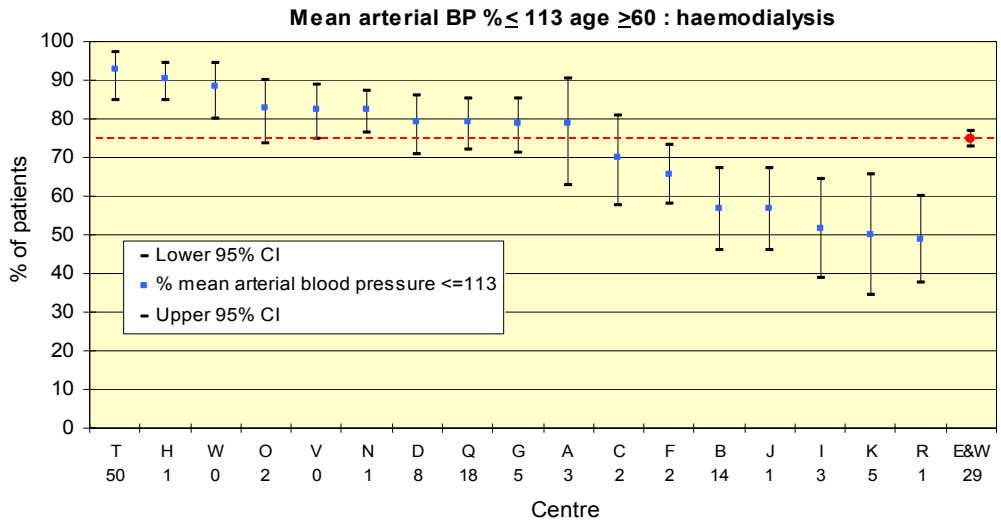


Figure 10.21 Percentage patients age ≥ 60 with mean arterial BP < 113 on HD

Peritoneal dialysis

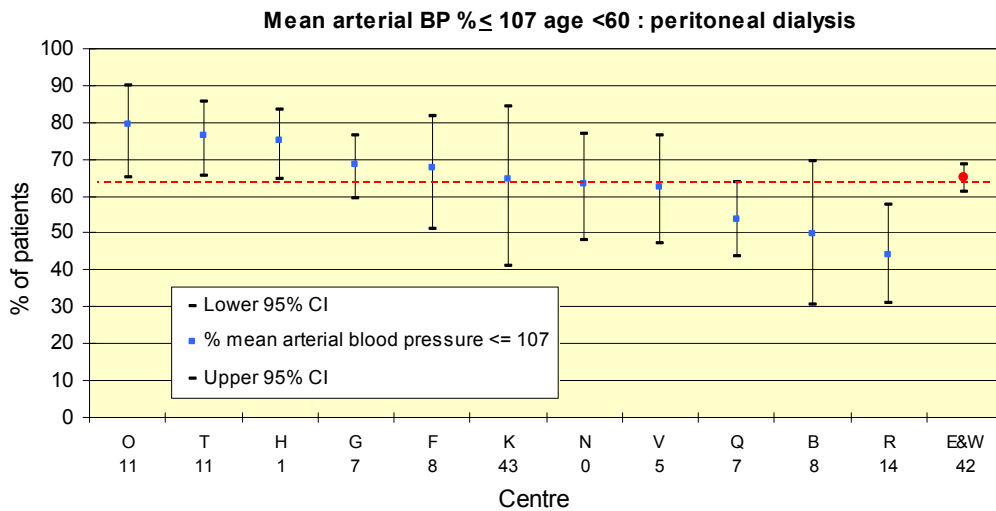


Figure 10.22 Percentage patients age < 60 with mean arterial BP < 107 PD

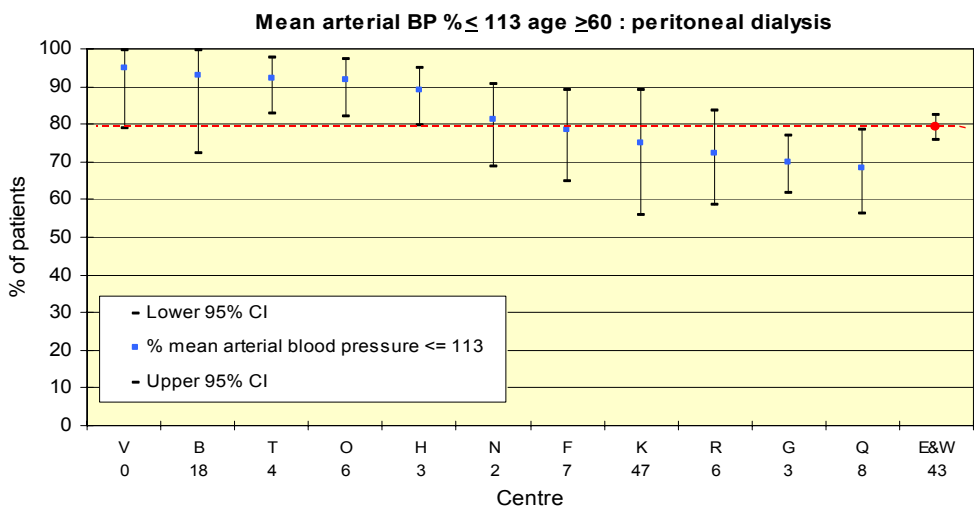


Figure 10.23 Percentage patients age ≥ 60 with mean arterial BP < 113 on PD

Of younger haemodialysis patients, 56% achieve this nominal standard compared with 75% of older patients. For peritoneal dialysis the figures are 66% and 80% respectively.

Patients aged  $\geq 60$  years had the same mean arterial pressure as those  $< 60$  years (103 mm Hg for patients on haemodialysis and 101 mm Hg on peritoneal dialysis). The prognostic significance of mean arterial pressure is doubtful.

Recent studies have shown that increased pulse pressure, a result of decreased conduit artery compliance, is a much more powerful risk factor for death in the general population than systolic or diastolic blood pressure<sup>4-9</sup>. For patients with the same mean arterial pressure prognosis may be very different depending on the pulse pressure. Increased pulse pressure is common in dialysis patients<sup>10</sup>, and increased pulse wave velocity, a more direct marker of decreased conduit artery compliance, has been associated with poor outcome in dialysis patients<sup>11</sup>. Studies examining the effects of anti-hypertensive strategies aimed at reducing pulse pressure, and the effects of such treatment strategies on outcome, are required both in the general population and in patients on dialysis<sup>12</sup>.

### ***Further problems***

#### ***Pre-dialysis or post-dialysis measurements?***

Most studies of blood pressure in haemodialysis patients have used pre-dialysis blood pressure measurements. This is what the Registry has analysed in haemodialysis patients, although post-dialysis blood pressure records have been collected from some renal units.

Predialysis pressure may not be the most appropriate to study. Two recent large studies showed no increase in cardiovascular mortality with increasing pre-dialysis blood pressure, but did find increasing mortality at the higher levels of post-dialysis blood pressure<sup>13,14</sup>. There is a rapid rise in blood pressure a few hours before each haemodialysis session<sup>15,16</sup>, and several ambulatory blood pressure monitoring studies<sup>15-17</sup> have shown a closer relationship between mean ambulatory blood pressure and post-dialysis blood pressure than with pre-dialysis blood pressure. The closest estimate of the ambulatory blood pressure may be obtained by measuring blood pressure 20 minutes after completion of dialysis<sup>16</sup>, but this is impractical in routine practice, and a measurement shortly after completion of dialysis has to be acceptable, despite the concern that this may be influenced unduly by haemodynamic instability caused by continued equilibration between the blood volume and the interstitial compartment. Mean ambulatory systolic pressure may be more closely related to the predialysis measurement, and diastolic pressure to the post-dialysis measurement<sup>18</sup>.

#### ***Measurement of blood pressure***

In the management of essential hypertension, the need for care in the interpretation of blood pressure measurements, and the unreliability of casual measurements taken while the patient is stressed or anxious, are well recognised. In clinical practice, pre-dialysis blood pressure is often measured in conditions far removed from those recommended for the measurement of resting blood pressure. Pressures recorded are often from casual, hurried, measurements of

blood pressure in a stressed patient just prior to the commencement of dialysis (involving needling of the fistula). Such readings may be expected to give misleadingly high readings. Renal registry blood pressure records will be from a variety of techniques and conditions of blood pressure measurement.

### ***Relationship of measured blood pressure to outcomes***

The lack of the expected relationship between hypertension and outcome in renal replacement therapy has already been considered. This is not entirely surprising. Techniques and conditions of blood pressure measurement vary considerably. The vascular disease in renal failure differs significantly from that usually seen in the general population. The measured blood pressure reflects many things including myocardial function, arterial rigidity and resistance, fluid overload, and hypotensive treatment given. Treatment of hypertension may be by drugs (some of which are cardio-protective), salt and water control, and possibly by interventions which may have unknown benefits, such as long haemodialysis. Different interventions may not be of equivalent benefit. Given all these confounding factors it might be considered surprising if any relationships were found between registry blood pressure measurement and outcome. A preliminary analysis of the relationship between measured blood pressure and outcome is presented in chapter 18. As in several other studies higher blood pressures are associated with better outcomes over a short time scale. The relationship is strongest for diastolic pressures and weakest for mean arterial pressures.

## ***Serum Cholesterol***

### ***Introduction***

There are difficulties in making firm recommendations on desirable serum cholesterol in renal replacement therapy. Although cardiovascular disease is an important cause of premature mortality in patients on dialysis, the patterns of disease differ from the general population. There is less contribution from acute myocardial infarction and cerebrovascular disease, and a greater incidence of sudden cardiac death, hypertensive heart failure, altered myocardial capillary density, increased cellular susceptibility to ischaemia, and endocarditis. The risk factors for atherosclerosis in dialysis patients are different from those in the general population. The effects of peroxidation and carbamylation of lipoprotein particles, hyperhomocystinaemia, and many other “non-classical” risk factors may confound the contribution from traditional risk factors such as hypertension and hyperlipidaemia. Large-scale epidemiological studies in haemodialysis patients have, shown an inverse or U-shaped relationship between serum cholesterol and subsequent mortality<sup>19-23</sup>. This probably reflects the effects of malnutrition and/or a chronic inflammatory response in ill patients causing low serum cholesterol. Nevertheless some studies have, found an association between ischaemia heart disease and dyslipidaemia in dialysis patients, and in CAPD patients a direct correlation between total cholesterol or total: HDL cholesterol ratio and survival<sup>24,25</sup>, has been observed.

***The current renal standards document does not contain any recommendations on control of serum cholesterol.***

The Standards committee is considering a revision which recommends that hyperlipidaemia in dialysis patients with a history of cardiac or vascular disease should be treated along the lines of the published national guidelines for secondary prevention. This means aiming for a total:HDL cholesterol ratio of < 5.0, or serum cholesterol below 5.0 mmol/L. For effective audit of this, renal units will need to record on their databases symptoms of vascular disease and vascular events so that such patients can be identified.

**Methods**

The Renal Registry is able to harmonise cholesterol data to facilitate direct comparisons of measurements between centres. The Renal Registry has analysed the most recent cholesterol data over one year as many centres only measure this annually. Some centres may not regularly repeat measurement if a result is normal without use of a lipid-lowering agent. The treatment modality was defined on 31/12/99, although some patients may have changed modality over the course of the preceding year.

The analysis has been performed around levels of serum cholesterol  $\leq 5.0$  mmol/L for men and women, in accordance with the recommendations for primary prevention by the ‘Joint British recommendations on prevention of coronary heart disease in clinical practice’<sup>26</sup>. These recommendations categorise renal failure patients to be high risk individuals.

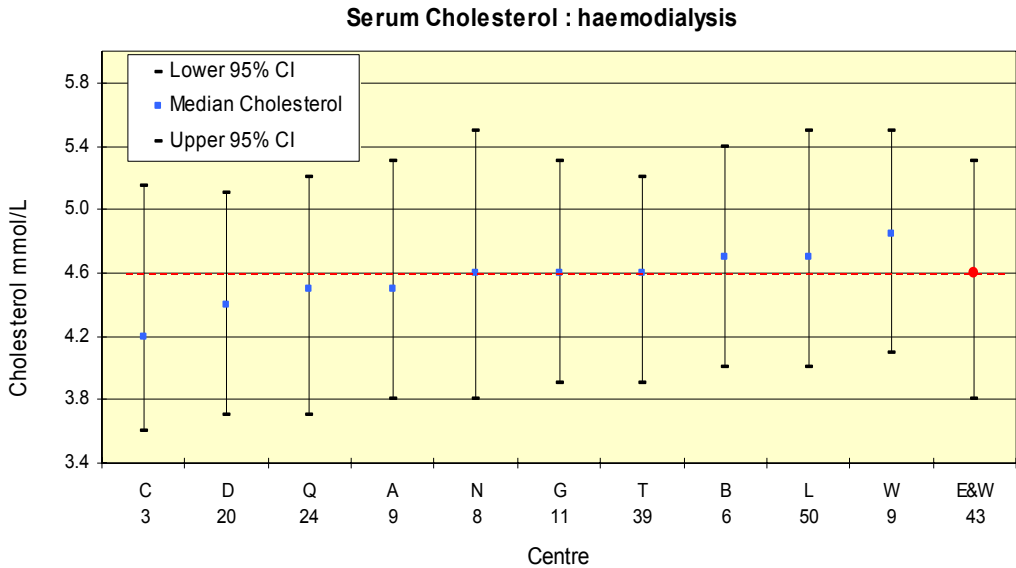
Data on serum cholesterol in dialysis patients are presented below.

**Results**

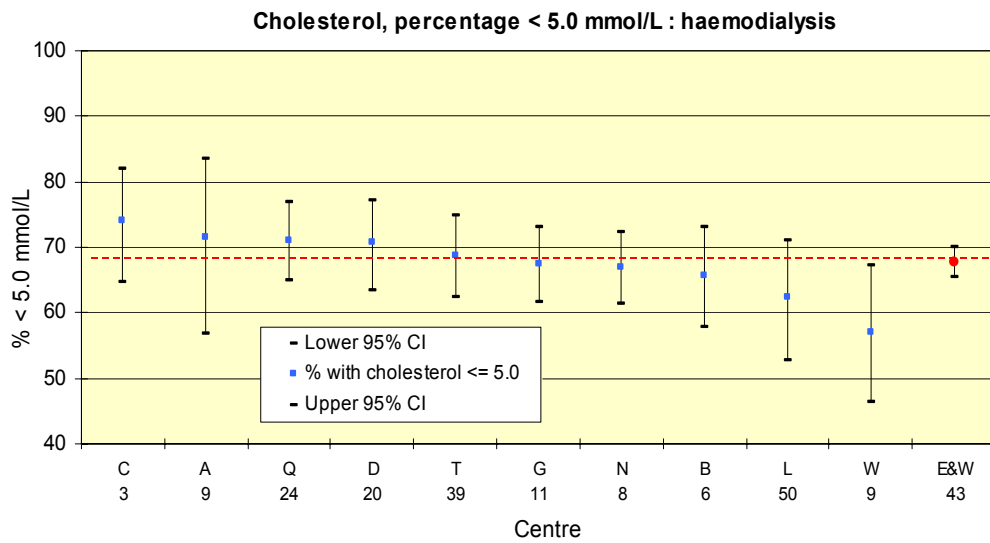
All results are presented using laboratory harmonised serum cholesterol.

**Haemodialysis**

Serum cholesterol results for patients on haemodialysis are shown in figures 10.24 and 10.25.



**Figure 10.24 Median serum cholesterol (mmol/L) on haemodialysis**

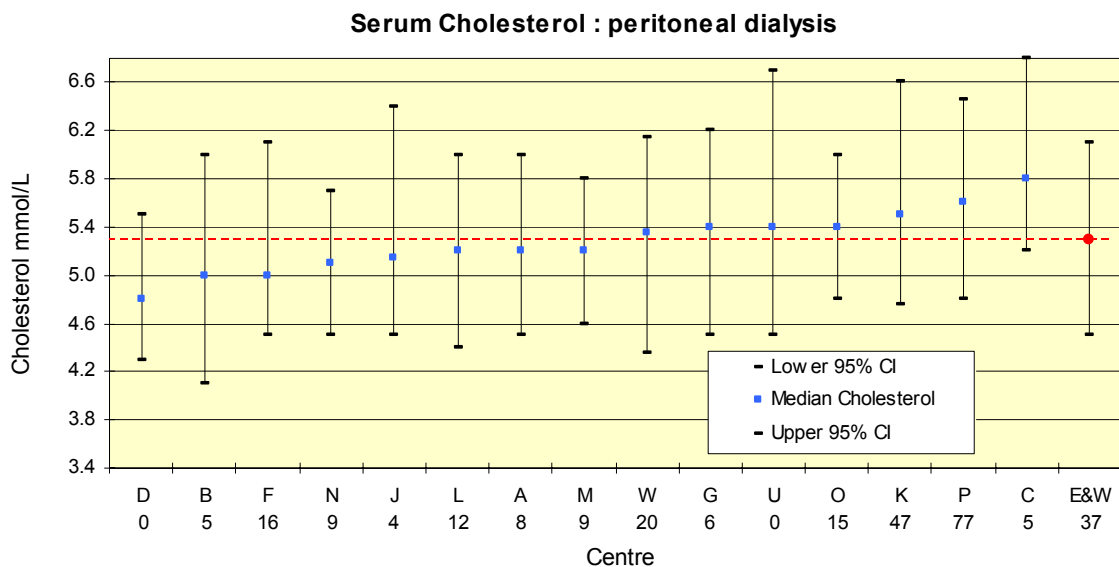


**Figure 10.25** Percentage cholesterol  $\leq 5.0$  mmol/L on haemodialysis

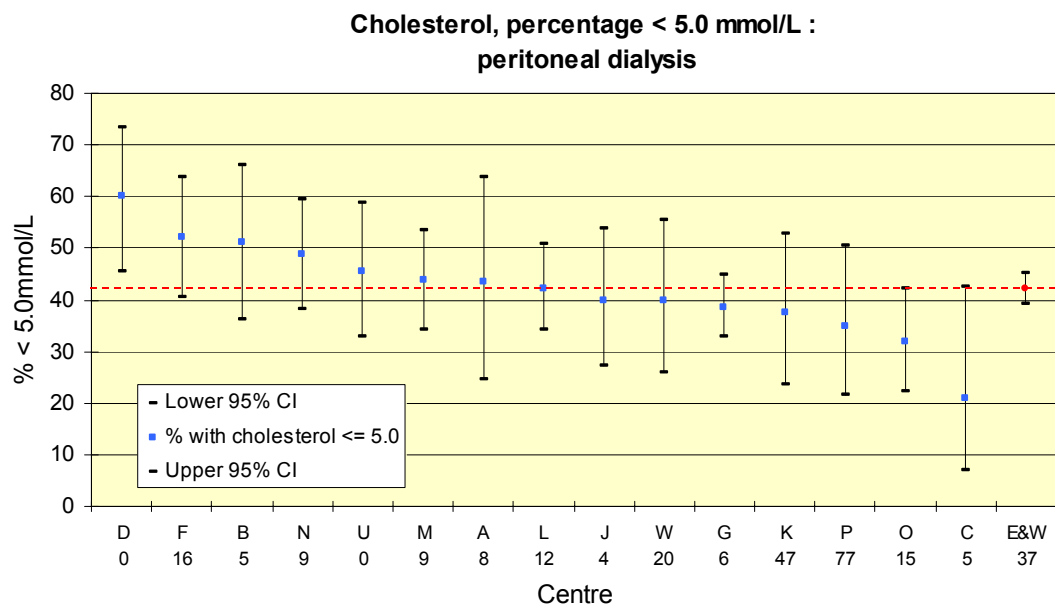
A chi-squared test was used to determine whether the percentage of patients with cholesterol  $\leq 5.0$  differed between centres. For patients on haemodialysis, the percentage of patients with cholesterol  $\leq 5.0$  did **NOT** differ significantly between centres ( $X^2 = 10.2$ , d.f. = 9,  $p=0.337$ ).

### Peritoneal dialysis

Serum cholesterol results for patients on peritoneal dialysis are shown in figures 10.26 and 10.27.



**Figure 10.26** Serum cholesterol (mmol/L) on peritoneal dialysis



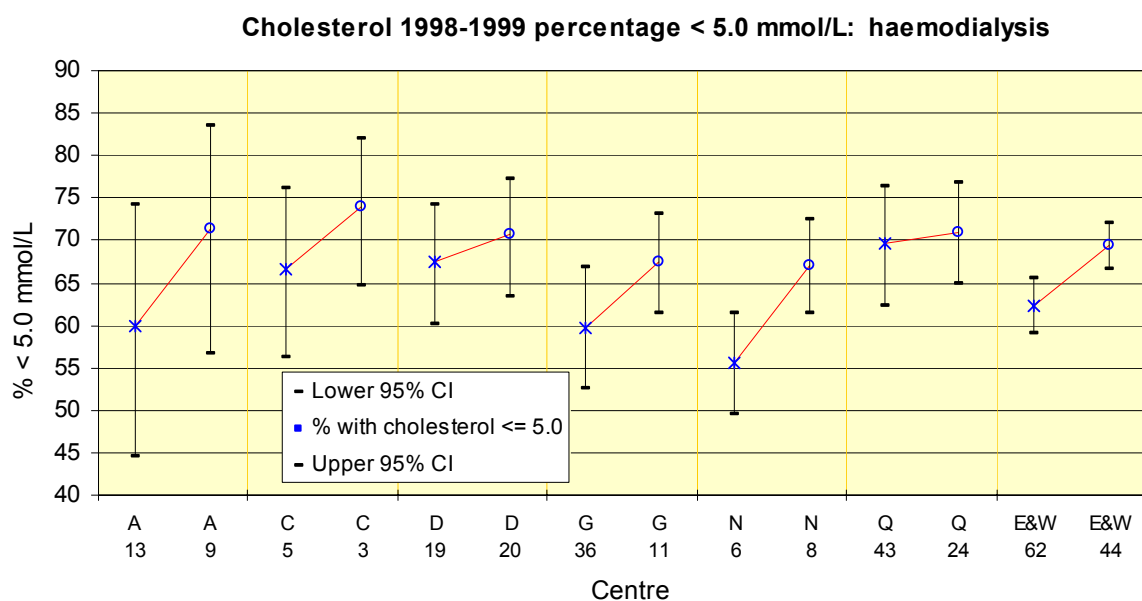
**Figure 10.27 Percentage cholesterol ≤ 5.0 mmol/L on peritoneal dialysis**

For patients on peritoneal dialysis, the percentage of patients with cholesterol ≤ 5.0 was **NOT** found to differ significantly between centres ( $X^2 = 21.7$ , d.f. = 14,  $p=0.085$ ).

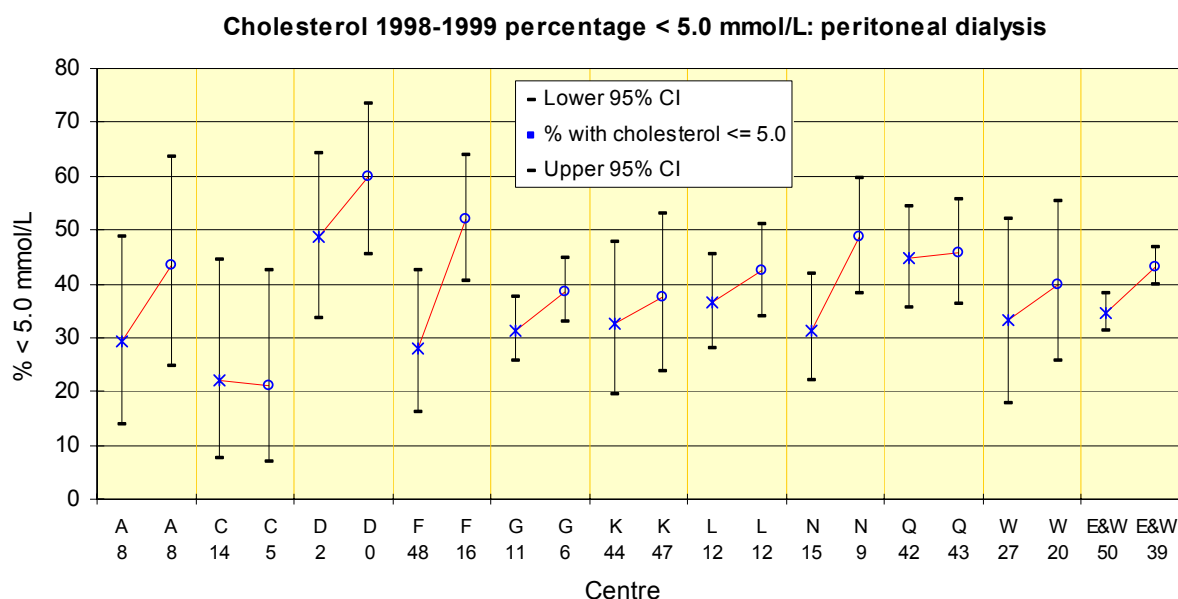
The dialysis population differed from the transplant population which did show a significant difference ( $p < 0.001$ ) in serum cholesterol between centres in these patients.

### **Change in cholesterol 1998–1999**

Changes in percentage of patients with serum cholesterol below 5.0 mol/l from 1998 to 1999 are shown in figures 10.28 and 10.29 for the ten renal units from which results are available.



**Figure 10.28 Percentage cholesterol ≤ 5.0 mmol/L on haemodialysis, 1998-1999**



**Figure 10.29 Percentage cholesterol  $\leq 5.0$  mmol/L on peritoneal dialysis, 1998-1999**

It appears that serum cholesterol is maintained at a lower level in haemodialysis patients than in peritoneal dialysis patients. Serum cholesterol control in all ten units appears to have improved except for peritoneal dialysis patients in unit C.

### **Clinical trial of cholesterol lowering in CRF**

To answer some of these questions on the importance of serum cholesterol in patients with renal failure, the clinical trials committee of the Renal Association has set up a trial on the use of statins in chronic renal failure. The Heart and Renal Protection pilot study (HARP), assessing the safety and efficacy of a statin + aspirin in these patients, has just completed enrolment. Towards the middle of 2001 the pilot study will be extended to a full-scale trial. Interested centres wanting further information should contact the Clinical Trials Support Unit in Oxford on 0800-585323 (Freefone) or 01865 240972

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## **Chapter 11: Renal Transplantation**

### ***Summary***

Variation exists between centres with respect to access to renal transplantation for patients receiving renal replacement therapy

There appears to be a marked difference between centres in attitude towards transplanting diabetics.

The annual death rate of patients with established renal transplants is low at 2.9% for the whole UK (including patients with failed grafts returning to dialysis).

3.1% of all patients starting dialysis in the UK in 1999 were patients with failed transplants.

The quality of transplant function differs significantly between centres, as does the haemoglobin level.

Differences in modifiable risk factors for cardiovascular disease such as serum cholesterol and blood pressure also exist. Control of these factors is often poor.

In some centres up to 50% of patients did not have a blood pressure or serum cholesterol measurement returned to the Registry for 1999.

### ***Introduction***

A chapter combining data with UK Transplant is presented in Chapter 20. This chapter is written using data from the Renal Registry, with an emphasis on access to transplantation, quality of transplant function, haemoglobin and potentially modifiable cardiovascular risk factors such as blood pressure and cholesterol.

### ***Transplants performed 1999***

Once again, the intention is to provide data on transplant activity for patients on Renal Replacement Therapy in units participating in the Registry. Thus, data on patients transferring in from non-registry units specifically for transplantation are excluded, but data on patients from registry units transferring to non-registry units for transplantation are included.

During 1999, 651 patients under follow up in participating units received a renal transplant. Details are given in tables 11.1 and 11.2.

In 1999, 64.7% of newly transplanted patients in the UK were male and 35 % female (0.3% unknown). The gender distributions for both England and Wales and Scotland were similar. Table 11.2 shows the primary renal diagnosis in newly transplanted patients mirrors that in the established transplant population.

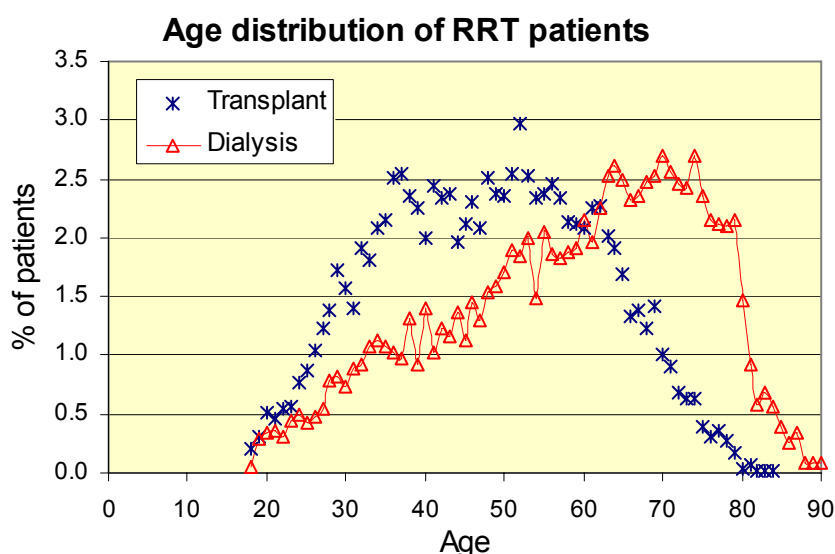
	Median age	Number
E&W (23 renal units)	43	506
Scotland (all units)	42	145
<b>Total Registry</b>	<b>43</b>	<b>651</b>

**Table 11.1 New transplants from the Registry 1999**

	New transplants in 1999		Established transplants 1/1/99	
	%	No	%	No
Aetiology unc. /Glomer. NP	20.4	133	23.0	1607
Glomerulonephritis	22.1	144	18.5	1295
Pyelonephritis	16.3	106	18.6	1302
Diabetes	7.8	51	6.2	433
Renal Vascular disease	0.9	6	1.2	85
Hypertension	3.5	23	4.9	343
Polycystic Kidney	10.9	71	11.5	803
Not sent	4.1	27	2.0	143
Other	13.8	90	14.0	975

**Table 11.2 Primary diagnosis of transplant patients in the UK**

### ***Patients with established renal transplants***



**Figure 11.1 Age histogram of dialysis and transplant patients**

The age distribution of the prevalent transplant patients for 1999 is shown in figure 11.1. The median age was 43 years compared with 61 years for the dialysis population from which they were drawn. The age distribution is consistent with the previous years report. In the UK 13% of prevalent and 5% of new transplant patients were over 65 years.

The proportion of prevalent patients aged less than 65 years receiving renal replacement therapy according to treatment modality at the end of 1999 is shown for each participating centre in figure 11.2. This age cut off is used, as most patients receiving a renal transplant for

the first time are less than 65 years old. All but 3 centres provide care for renal transplant recipients. The proportion of RRT stock composed of transplant patients for each centre varies between 14-80%. Overall for the UK, 57% of the RRT stock under the age of 65 years is made up by transplant patients. If all patients receiving RRT are included (i.e. those over 65 years old as well), this proportion falls to 47%.

For individual Registry units, the proportion of the prevalent dialysis patients under 65 years old that had ever had a renal transplant is illustrated in figure 11.3. These figures are an underestimate, as some patients had no information regarding previous transplantation when transferring in on dialysis from a non-registry unit, and are treated as unknown. In spite of this, there are wide variations (4.2-34.3%) between centres in apparent access to transplantation. Plausible explanations for these variations include a difference in the age of units. Patients in older units are likely to have had a longer exposure to possible transplantation than in newer units and older units are likely to have a larger stock of transplant patients. In addition there may be differences in the proportion of prevalent dialysis patients made up by ethnic minorities (harder to HLA match and thus transplant) as well as differences in selection criteria for accepting patients onto the waiting list. With more complete returns from participating centres, the Registry should have sufficient data in the future to test some of these hypotheses.

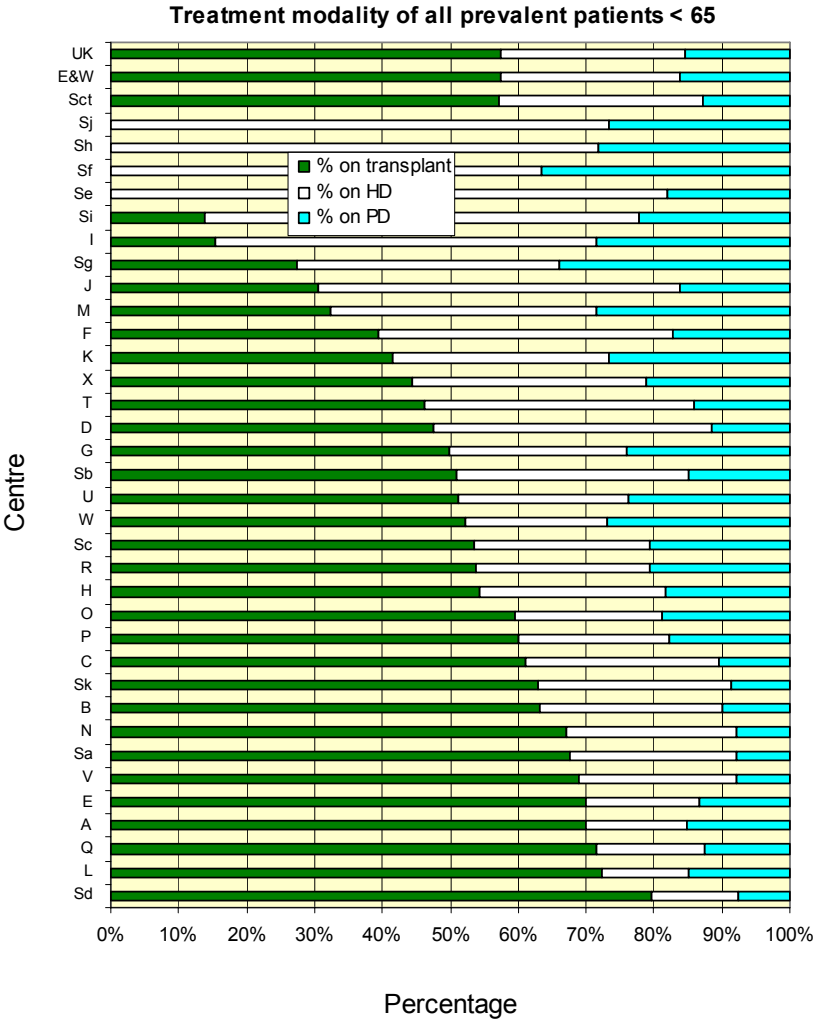
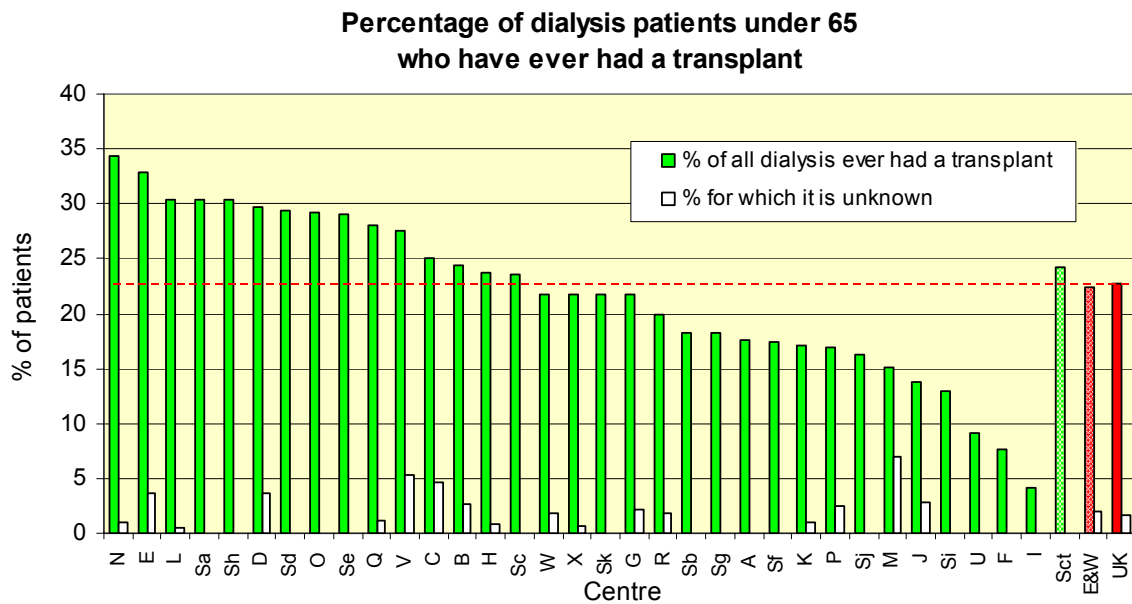


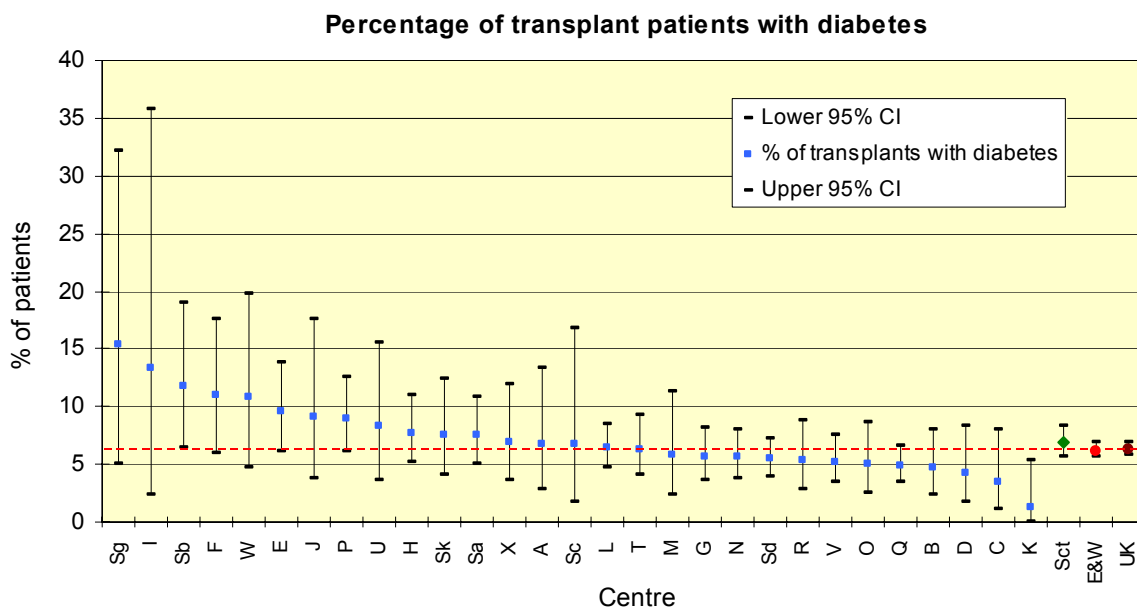
Figure 11.2 Treatment modality of all prevalent patients < 65



**Figure 11.3 Percentage of prevalent dialysis patients age <65 years who have ever received a renal transplant**

### ***Transplantation in patients with diabetes mellitus***

The recently published European Best Practice Guidelines for Renal Transplantation advise that “Kidney transplantation should be considered as the first therapeutic choice for all suitable patients with end-stage renal disease due to diabetes mellitus, because kidney transplantation is able to significantly extend survival as compared with dialysis (Evidence level B)”<sup>1</sup>. Figure 11.4 shows the proportion of all patients in each registry centre with a functioning renal transplant on 31/12/99 whose primary diagnosis was diabetes mellitus.



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

In addition, the proportion of patients with a primary diagnosis of diabetes mellitus at each centre whose renal replacement therapy on 31/12/99 was with a functioning renal transplant is illustrated in figure 11.5.

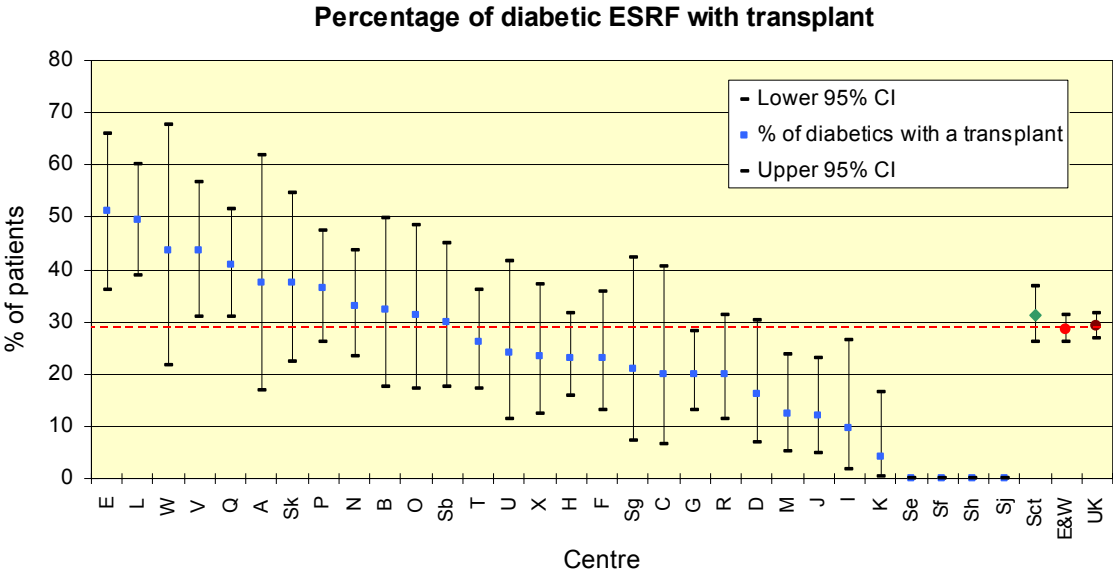


Figure 11.5 Percentage of diabetic ESRF patients with a transplant, by centre

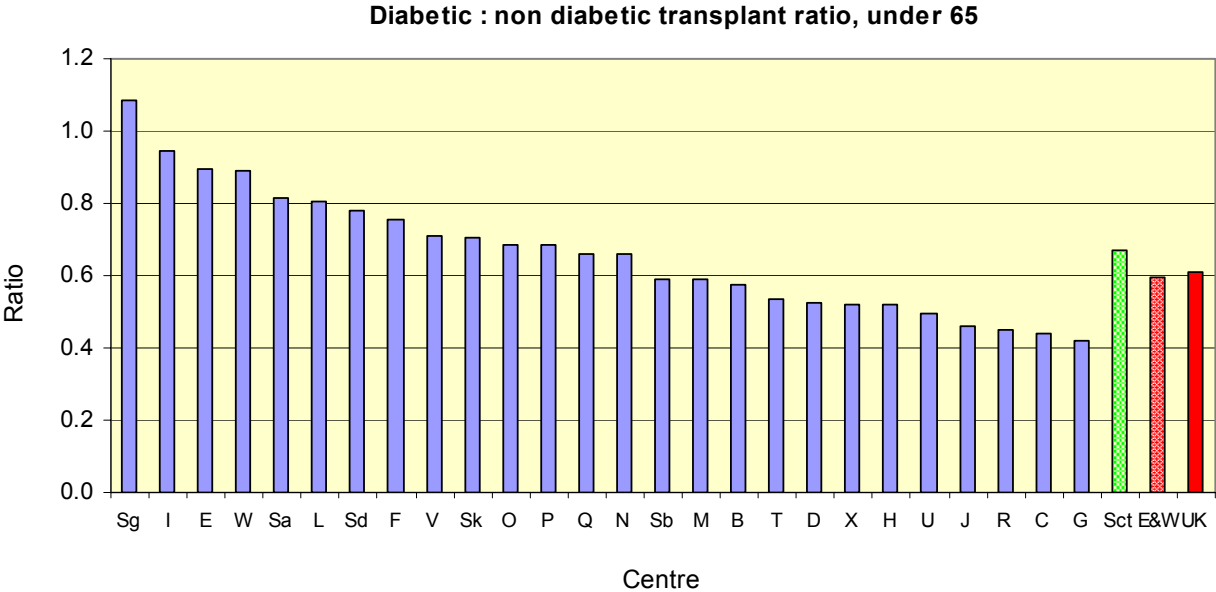


Figure 11.6 Ratio of % patients with a transplant under 65, diabetics : non-diabetics

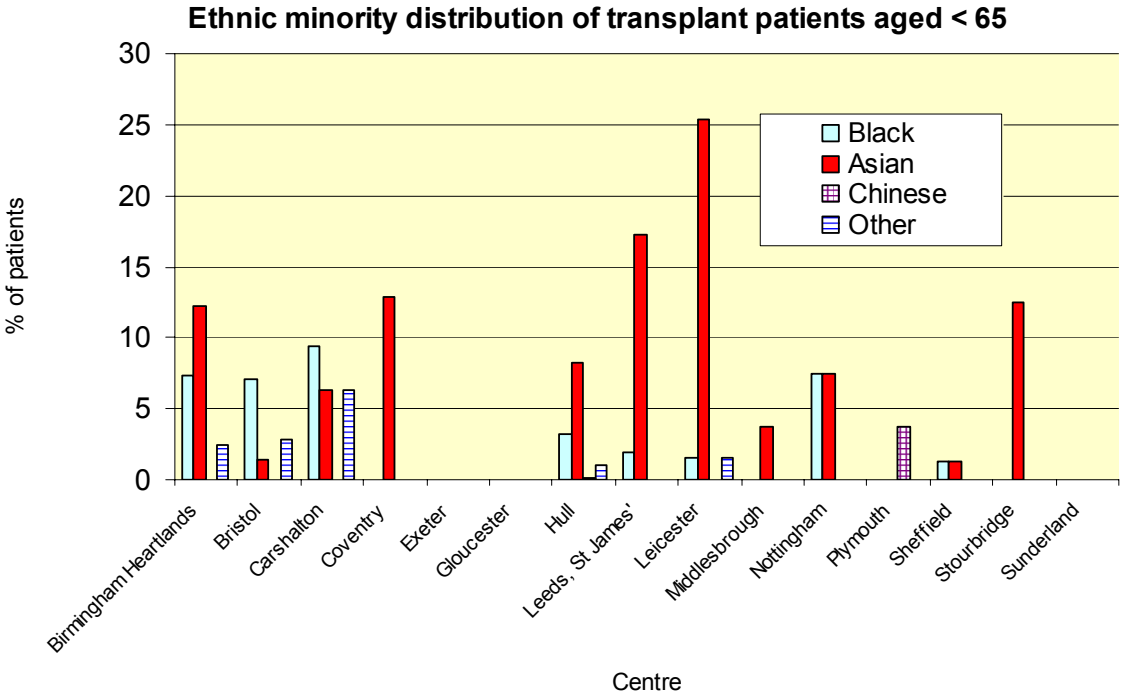
There is a wide variation (0-51.2%) between centres in the proportion of diabetic patients with end-stage renal failure that have a transplant. In order to explore a possible difference in access to transplantation for diabetic patients between centres, the proportion of transplanted diabetic patients and transplanted non-diabetic patients under 65 was expressed as a ratio for each centre (figure 11.6). This age limit was used in an effort to make the populations comparable, as most patients receiving a transplant are under 65, and diabetic patients on RRT have a lower median age than other patients. Centres with fewer than 20 diabetic patients aged under 65 have been excluded from the figure.

To identify reasons for these observed differences between centres, a number of variables would need to be examined. These include the overall percentage of live RRT patients with diabetes, the median age of this diabetic cohort, and the percentage of the cohort originating from ethnic minorities (and thus likely to experience difficulty in HLA matching). Some of the difference in the proportion of transplant patients with a primary diagnosis of diabetes mellitus observed between centres could be accounted for by differences in these variables.

Overall, RRT patients with diabetes mellitus seem less likely to receive a transplant than other patients on RRT presumably due to significant co-morbidity making them less suitable for transplantation. However, attitudes towards transplantation of diabetic patients appear to differ between units.

**Ethnicity**

Figures 11.7 and 11.8 compare the ethnic minority distribution for each centre of prevalent renal transplant patients (end of 1999) under age 65 and renal replacement therapy patients under 65 who have never received a transplant.



**Figure 11.7 Ethnic minority distribution of transplant patients < 65 by centre**

The centre names are shown to preserve anonymity so that the centres with a percentage of ethnic minorities cannot be identified from the prevalence chapter.



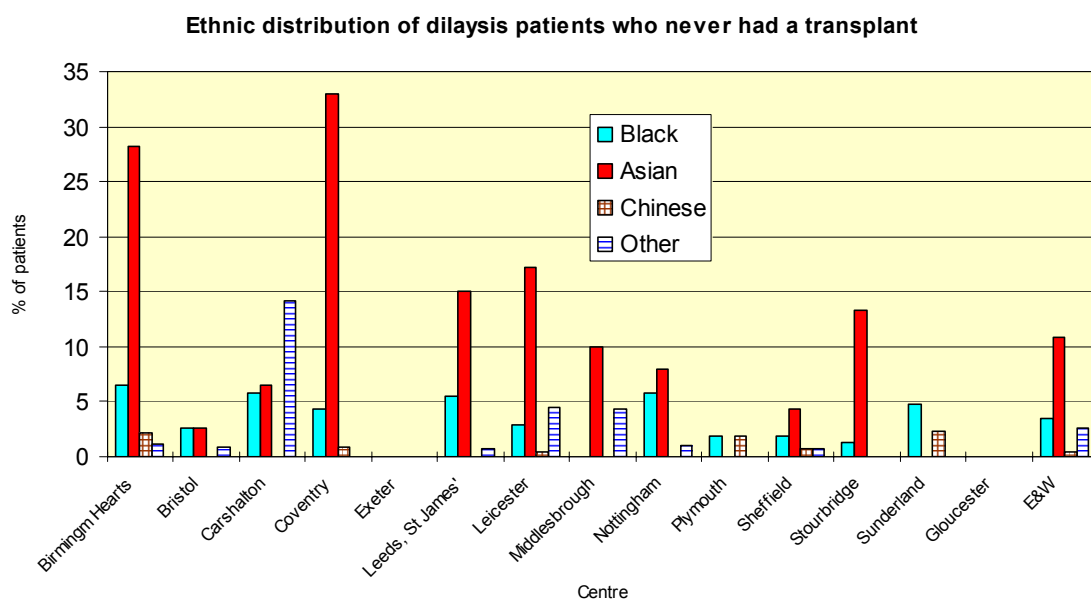


Figure 11.8 Ethnic minority distribution of dialysis patients who have never had a transplant

### Failed transplants

Within the participating centres, 3% of all patients commencing dialysis in 1999 were patients whose renal transplants had failed during the year as opposed to new patients on Renal Replacement Therapy. The percentage in Scotland was 3.4% and for the UK as a whole it was 3.1%. In last year's report it was incorrectly stated that 9% of all patients commencing dialysis in 1998 were individuals with failed transplants. The correct figures should have been 3.1% for England and Wales and 3.2% for the UK as a whole.

### Survival of patients with established renal transplants

Table 11.3 shows the one-year patient survival for established transplant patients alive on 1/1/99. Patients who had been transplanted within six months prior to this date were excluded from these figures as they were still considered to be in the post-operative high-risk period. Survival was calculated both censoring at return to dialysis and with continuing follow-up of patients after return to dialysis (Table 11.3). The overall annual death rate for the UK is 2.8% (censored at dialysis).

	Transplant censored at dialysis			Transplant including dialysis returns		
	E&W	Scot	UK	E&W	Scot	UK
<b>No. of patients</b>	5228	1259	6487	5228	1259	6487
<b>No of deaths</b>	138	35	173	149	38	187
<b>Death rate</b>	2.7	2.9	2.8	2.9	3.1	2.9
<b>(95% CI)</b>	2.3 - 3.2	2.0 - 4.0	2.4 - 3.2	2.5 - 3.4	2.2 - 4.2	2.6 - 3.3
<b>K-M 1 yr survival</b>	97.3	97.2	97.3	97.2	97.0	97.2
<b>(95% CI)</b>	96.9 - 97.8	96.3 - 98.0	96.9 - 97.8	96.7 - 97.8	96.3 - 97.7	96.7 - 97.6

Table 11.3 Survival during 1999 of established transplant patients alive 1.1.99

## Quality of transplant function

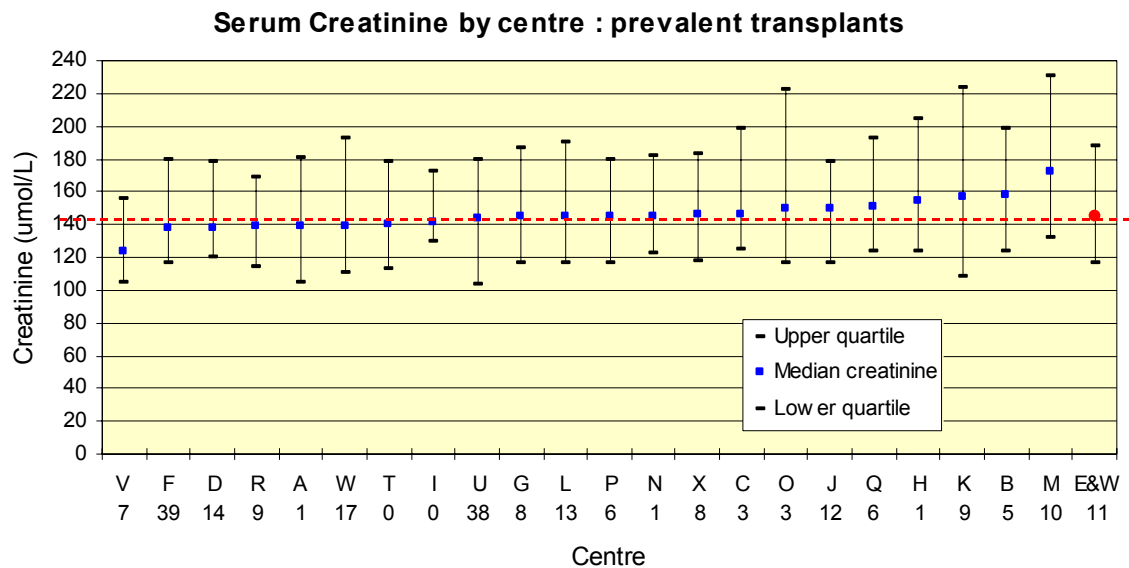
This analysis considered transplant patients on 31/12/1999 whose transplant had been functioning for at least one year. The most recent serum creatinine within 6 months was used in the analysis. The relationship between primary diagnosis and graft function is shown in Table 11.4

Diagnosis	% with creatinine < 200 (no of pts)
Aetiology uncertain*	80.3 (902)
Glomerulonephritis	75.6 (591)
Pyelonephritis	77.4 (590)
Diabetes	72.3 (192)
Renal Vascular disease	88.6 (48)
Hypertension	75.3 (182)
Polycystic Kidney	82.5 (431)
Not sent	82.1 (49)
Other	78.0 (480)

\* Includes "glomerulonephritis– not histologically proven"

**Table 11.4 Relationship between transplant function and primary renal diagnosis**

For each centre the median serum creatinine of prevalent transplant recipients was similar (Figure 11.9).



**Figure 11.9 Median serum creatinine of prevalent transplant patients, by centre**

However, figure 11.10 shows the percentage of established transplant patients with a serum creatinine greater than 250 micromoles/l for each unit. The differences between units are significant but unexplained although they may include differences in immunosuppressive protocols and attitude to use of marginal donors.

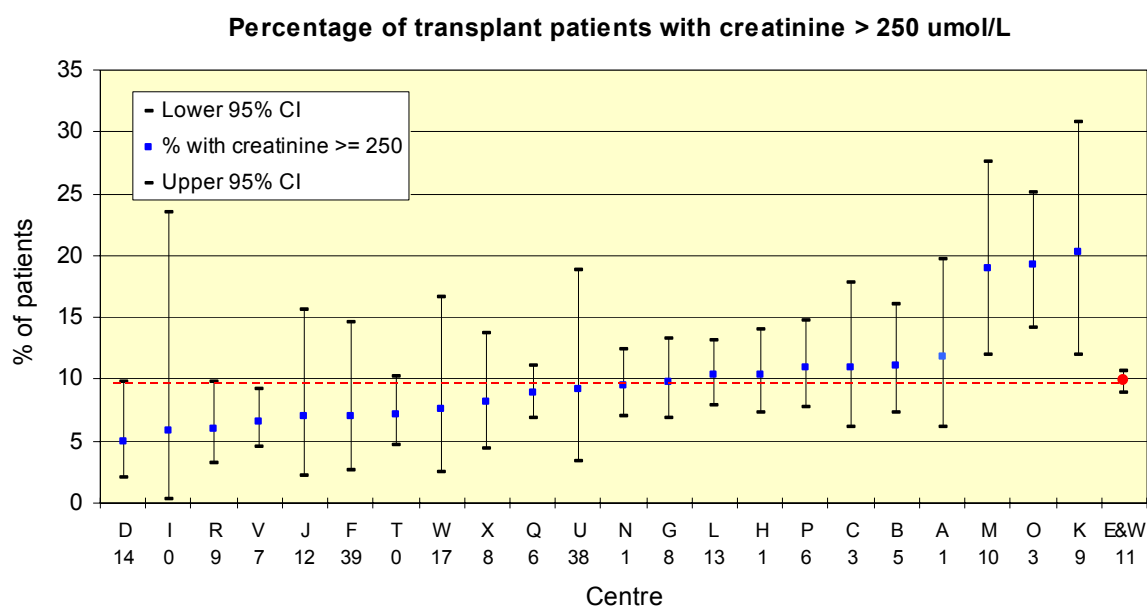


Figure 11.10 Percentage of established transplant patients with serum creatinine >250 umols/l

### Haemoglobin in transplanted patients

There are no recommended haemoglobin standards for renal transplant patients.

Haemoglobin concentrations of 5630 transplant patients in England and Wales were available for analysis. Results are shown in figures 11.11 and 11.12. Overall, 7.6% of these patients had a haemoglobin level less than 10 g/d and 2% less than 9 g/dl. These values are similar to last year's haemoglobin data when 6.1% and 2% of transplant patients had haemoglobin concentrations less than 10g/dl and 9g/dl respectively.

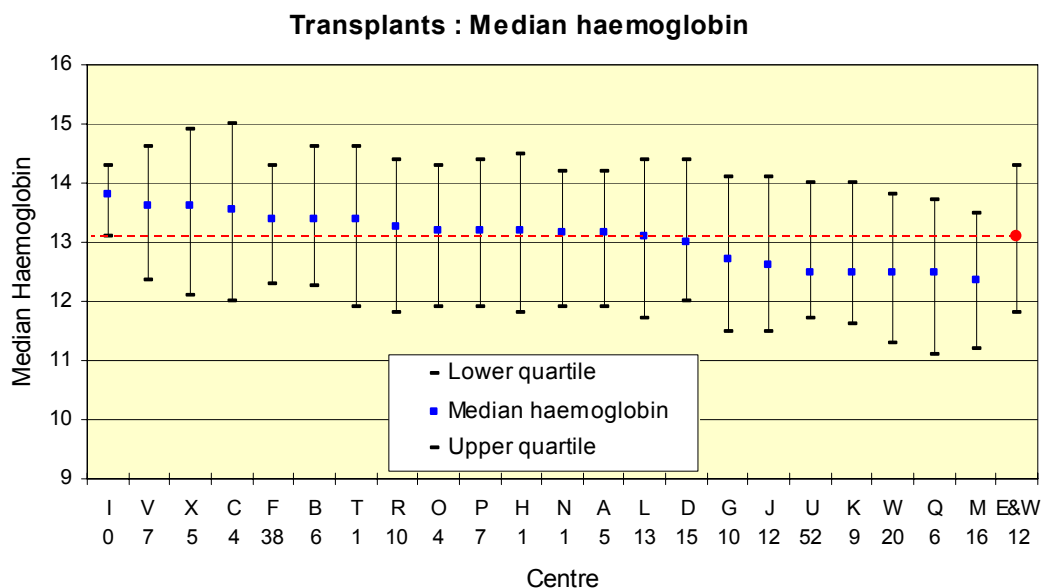
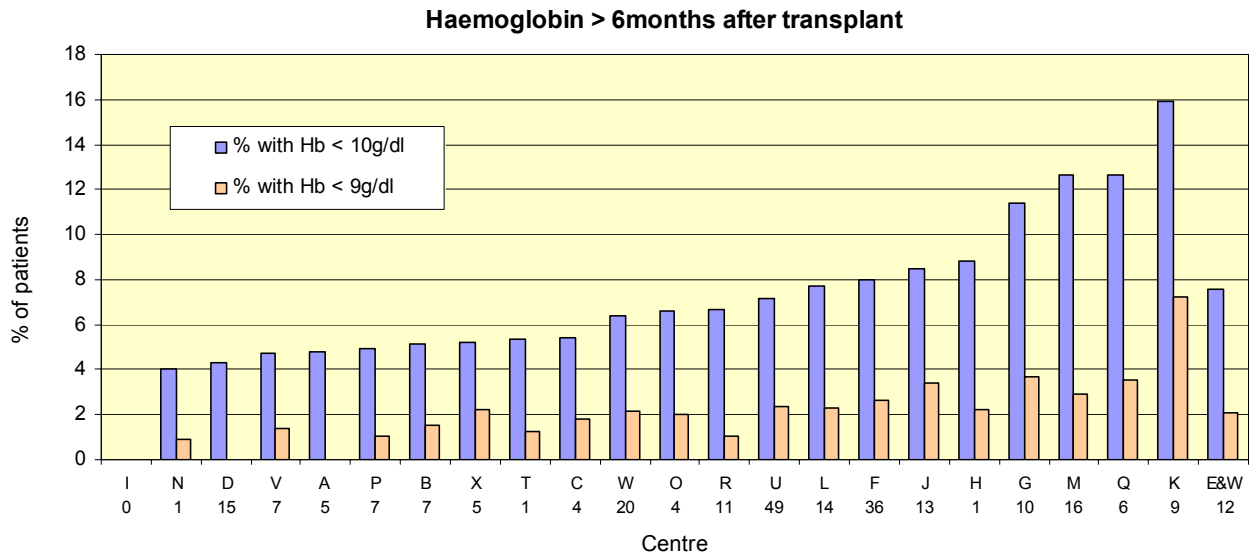


Figure 11.11 Median haemoglobin of transplant patients by centre

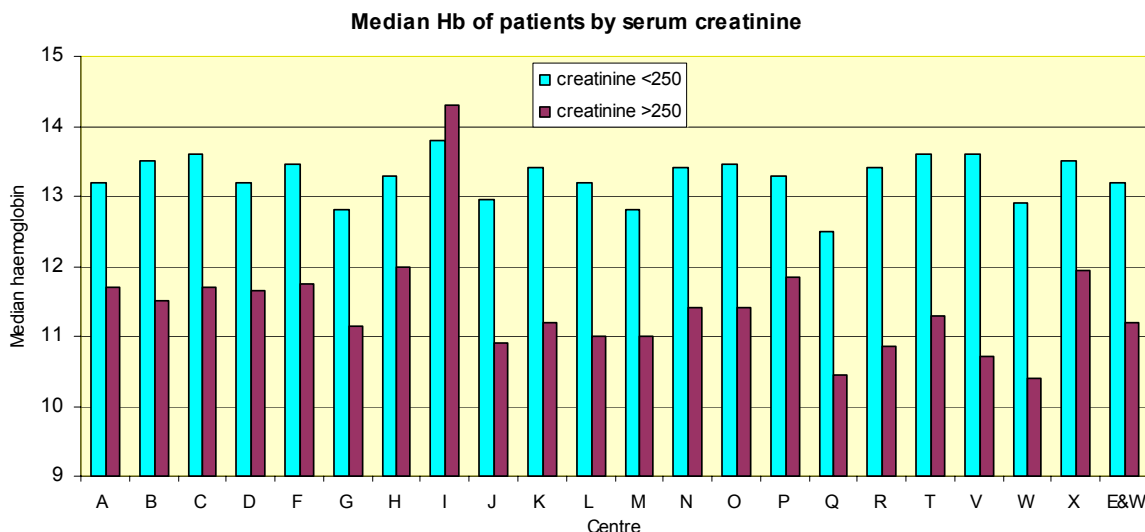
Figure 11.11 shows the median haemoglobin for prevalent transplant patients according to registry centre.

Figure 11.12 shows the percentage of transplant patients in each participating Registry unit with a haemoglobin concentration less than 10g/dL and 9g/dL respectively, at least 6 months after transplantation. The variation of 0-16% between centres (3-9% in 1998) with Hb <10g/dL is unexplained. Centre I is one of the small centres on the Registry. The possible reasons include quality of graft function, type of immunosuppression (use of azathioprine and mycophenolate mofetil) and use of erythropoietin when there are failing grafts.



**Figure 11.12 Haemoglobin achieved in established transplant patients – by centre**

Figure 11.13 shows the relationship between median haemoglobin and serum creatinine in transplant recipients at each centre.



**Figure 11.13 Median Hb of patients with serum creatinine greater and less than 250 umol/l**

As expected haemoglobin was lower in women and in patients with a higher serum creatinine (Table 11.5).

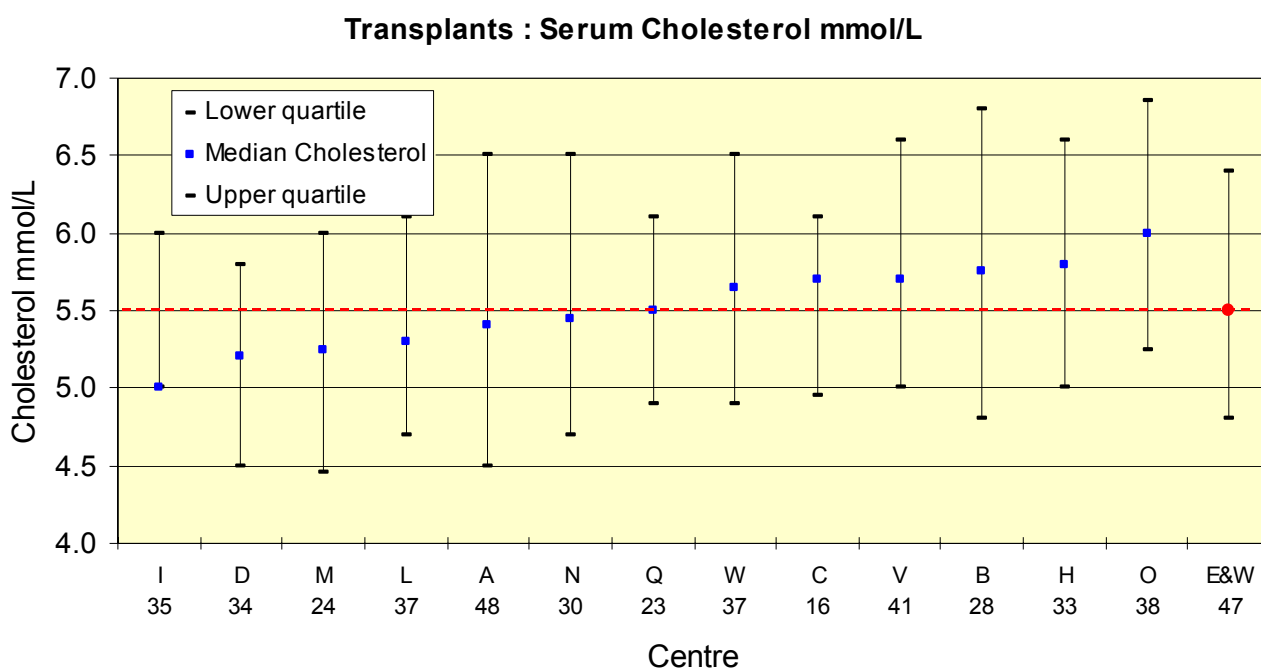
		Haemoglobin							No. with data
Gender	Creatinine	Mean Hb	Std dev	5th centile	Lower quartile	Median Hb	Upper quartile	95th centile	
Male	<250	13.6	1.7	10.7	12.5	13.7	14.8	16.2	2150
Male	250+	11.5	1.9	8.6	10.2	11.4	12.8	14.7	294
Female	<250	12.5	1.6	10.0	11.4	12.5	13.6	15.0	1417
Female	250+	10.9	1.5	8.7	9.7	10.9	11.9	13.4	124

**Table 11.5 Transplant patients: relationship between haemoglobin, creatinine and gender.**

## Serum cholesterol

This analysis considered all transplant patients on the 31/12/1999 whose grafts had been functioning for at least one year. The most recent serum cholesterol over a 12-month period was used and the cholesterol was harmonised for inter-laboratory variation. Results were available from 3060 patients. In 47% of established transplant patients serum cholesterol had not been recorded in the last year.

The distribution of serum cholesterol in prevalent transplant recipients according to centre is shown in figure 11.14



**Figure 11.14 Median Serum cholesterol for transplant patients – by centre**

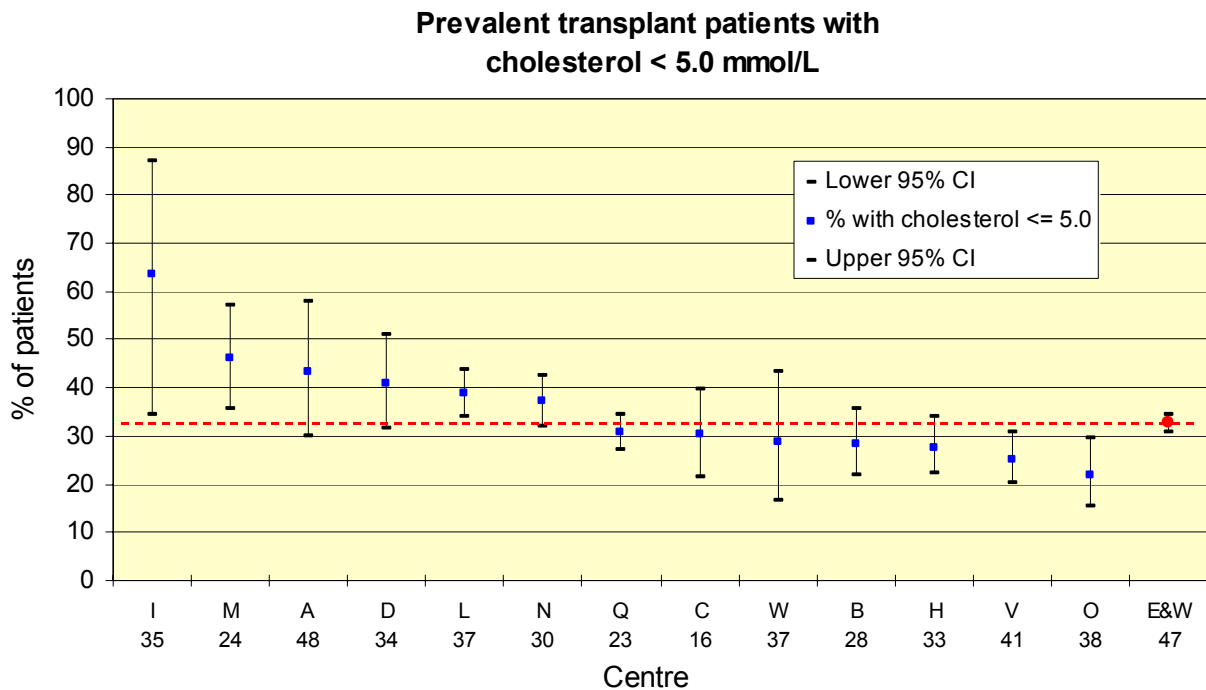
In most units the median serum cholesterol is above the recommended level for primary prevention in the high-risk non-transplant population (5.0 mmol/L)<sup>2</sup>.

Table 11.6 shows that there is no relationship between serum cholesterol and transplant function.

Serum Creatinine	Serum cholesterol					No. with data
	5th centile	Lower quartile	Median cholesterol	Upper quartile	95th centile	
<150	3.9	4.8	5.5	6.3	7.5	1630
150-250	3.9	4.8	5.6	6.4	7.7	1125
250+	3.6	4.7	5.5	6.5	8.3	305

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

Figure 11.15 shows the percentage of prevalent transplant patients for each registry centre with a serum cholesterol level below 5.0 mmol/l.



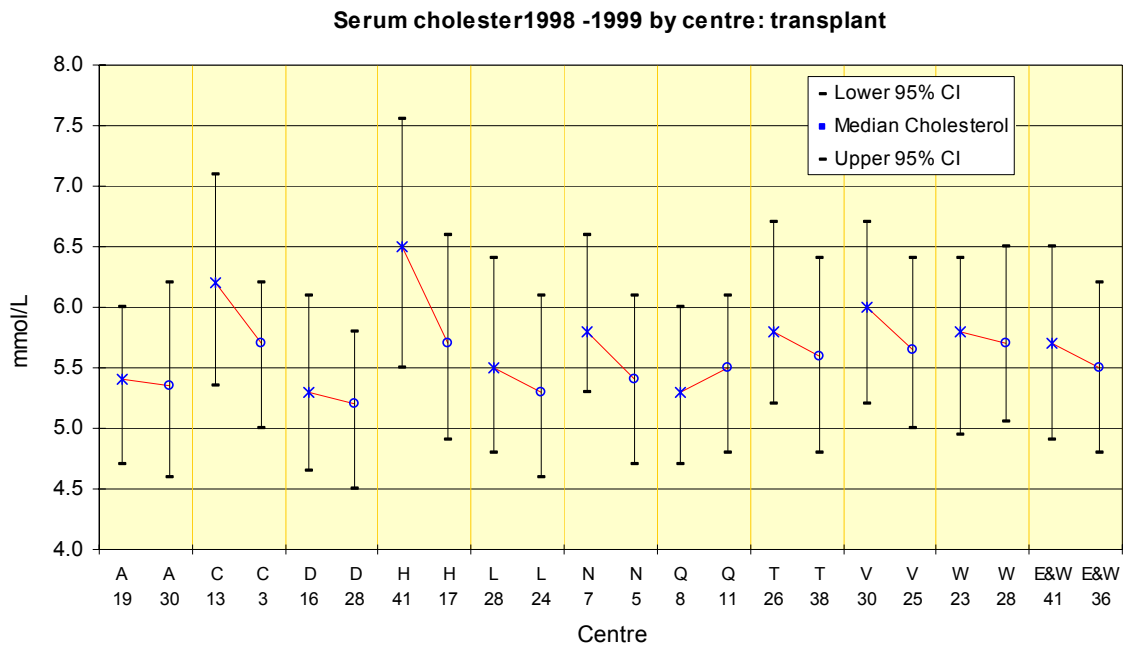
**Figure 11.15 Percentage of transplant patients with cholesterol  $\leq 5.0$  mmol/L**

Given that death from cardiovascular disease in the UK transplant population is 8-10 times more common than in the age and sex- matched general population<sup>3</sup>, this is an important modifiable risk factor that in some centres appears to be ignored. This is reinforced by the percentage of patients with no data, the number shown below each centre in figure 11.15. In many centres, no measurement has been made in a significant proportion of patients over the preceding 12 months.

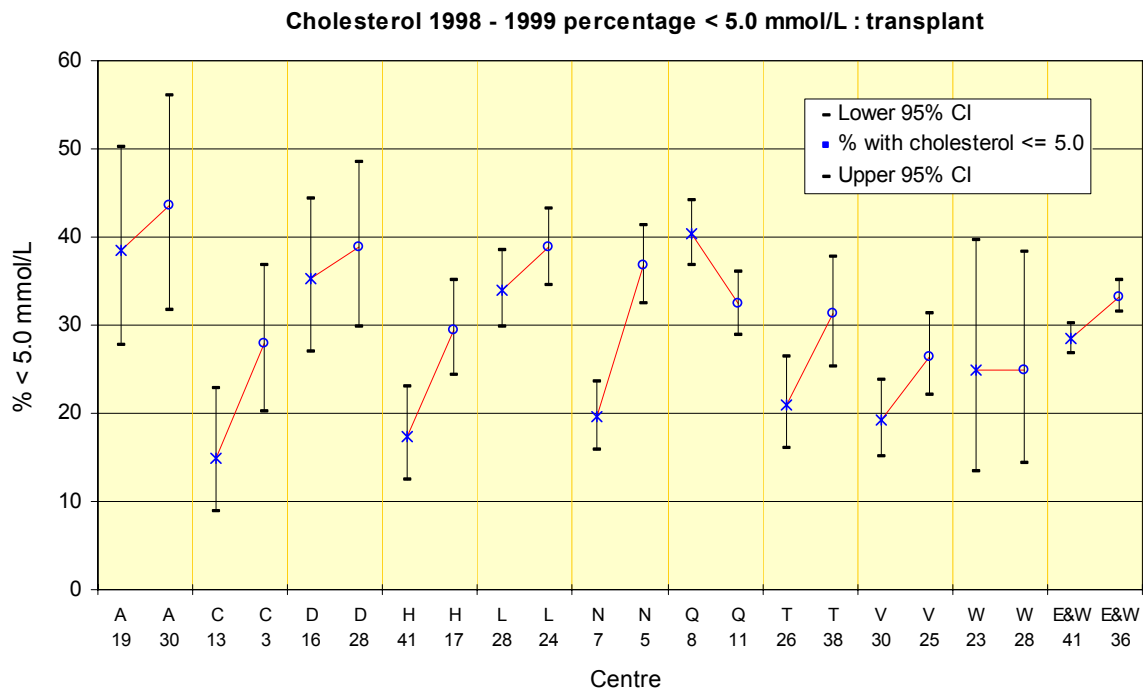
A chi-squared test was used to determine whether the percentage of patients with a serum cholesterol  $\leq 5.0$  mmol/L differed between centres. The percentage of patients with serum cholesterol  $\leq 5.0$  mmol/L was found to vary significantly between centres ( $X^2 = 45.8$ , d.f. = 12,  $p < 0.001$ ). In comparison there was no significant variation of serum cholesterol between centres in the dialysis population.

## Changes in serum cholesterol 1998-99

Compared with 1998 data, there was no overall significant change in median serum cholesterol although there was a trend towards a lower level (figure 11.16). There was a fall in median serum cholesterol in most centres. Similarly from 1998 to 1999, apart from one centre, there was an improvement within centres in the percentage of patients with serum cholesterol  $\leq 5.0$  mmol/l 99 (figure 11.17). In a few centres, the change was significant.



**Figure 11.16 Median serum cholesterol, mmol/L, in transplant patients by centre 1998-9**



**Figure 11.17 Percentage transplant patients with a serum cholesterol  $\leq 5.0$  mmol/l in 1998-9**

## Blood pressure

Neither the Renal Association nor the British Transplantation Society has recommended standards for blood pressure control in transplanted patients. In the following analysis the standards recommended for dialysis patients have been adopted (<140/90mmHg age <60 years, <160/90mmHg age  $\geq$ 60 years). The acceptance of higher blood pressure in the elderly may not be appropriate (British Hypertension Society guidelines)<sup>4</sup>.

There may be errors due to incomplete data. Table 11.7 shows the percentage of renal transplant recipients with blood pressure data. Disappointingly, the completeness of blood pressure returns has fallen somewhat compared with 1998 when data on 50% of patients aged <60 years and 47% of patients aged >60 years were available.

<b>% with BP return from last 6 months</b>		
<b>Centre</b>	<b>Age &lt; 60</b>	<b>Age &gt; 60</b>
A	0	0
B	42	42
C	0	0
D	2	0
E	0	0
F	0	0
G	86	84
H	99	98
I	0	0
J	0	0
K	78	81
L	85	85
M	0	0
N	56	47
O	6	2
P	0	0
Q	33	37
R	88	84
T	4	3
U	0	0
V	89	98
W	0	0
X	1	0
<b>E&amp;W</b>	<b>45</b>	<b>44</b>

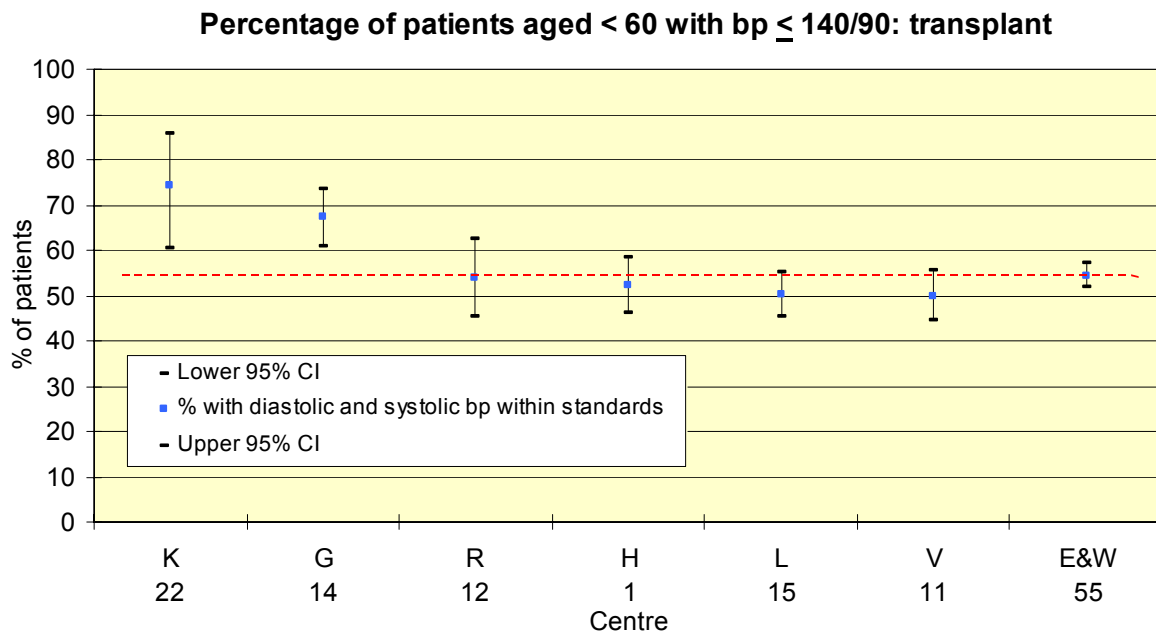
**Table 11.7 Completeness of BP returns for transplant patients**

Blood pressure recordings may also be subject to a variety of biases. Fit patients with infrequent clinic attendance will have infrequent BP assessment. High BP readings may be selectively included or excluded from computer records depending on operator bias. The following data must be interpreted with this in mind.

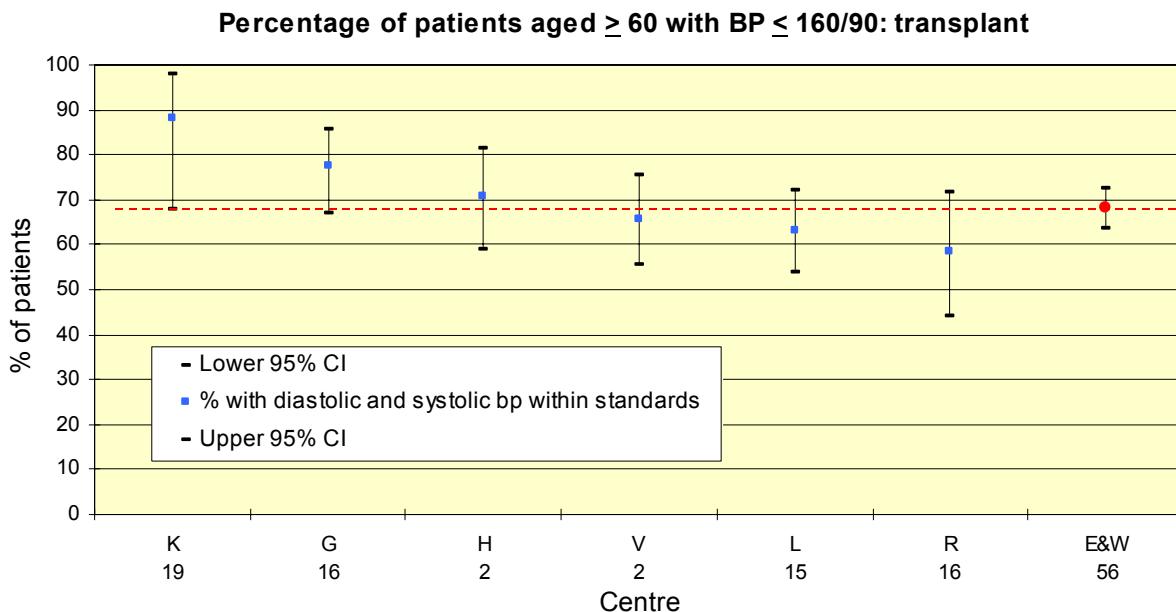
Figures 11.18 and 11.19 show the proportion of transplant patients achieving the Renal Association standards in each centre for those aged less than 60 years and those aged 60 years or older respectively.



Because the blood pressure target for older patients is less stringent, a greater proportion of older patients achieved the blood pressure standards overall; 68.2% vs 53.3% in the older and younger age groups respectively.



**Figure 11.18 % patients under 60 with systolic and diastolic BP below 140/90 mmHg**



**Figure 11.19 % patients over 60 with systolic and diastolic BP below 160/90 mmHg**

Figures 11.20-11.27 show the systolic and diastolic blood pressure for each age range by centre together with the proportion of patients achieving the Renal Association Standards for each measure. The overall median diastolic pressure in those below and above age 60 is similar at 80 mmHg. and 81 mmHg respectively. The overall median systolic pressure is higher in those aged over 60 years at 150 mmHg compared with 138 mmHg in the younger age group.

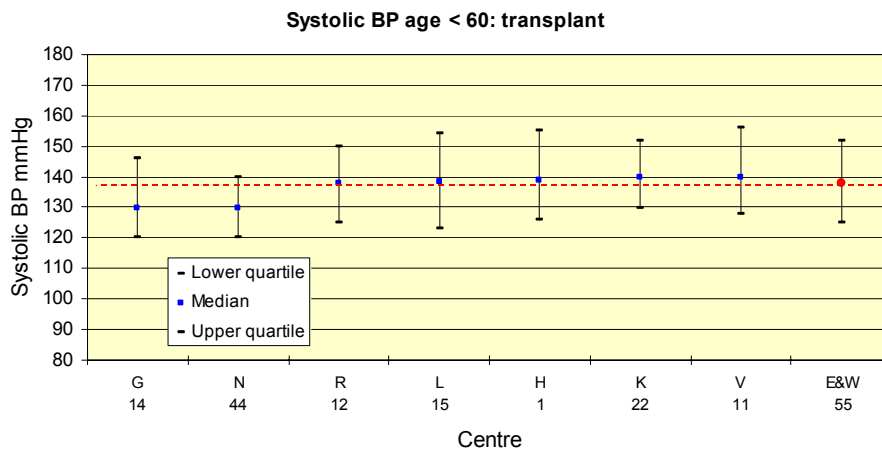


Figure 11.20 Transplant patients under 60: median systolic pressure

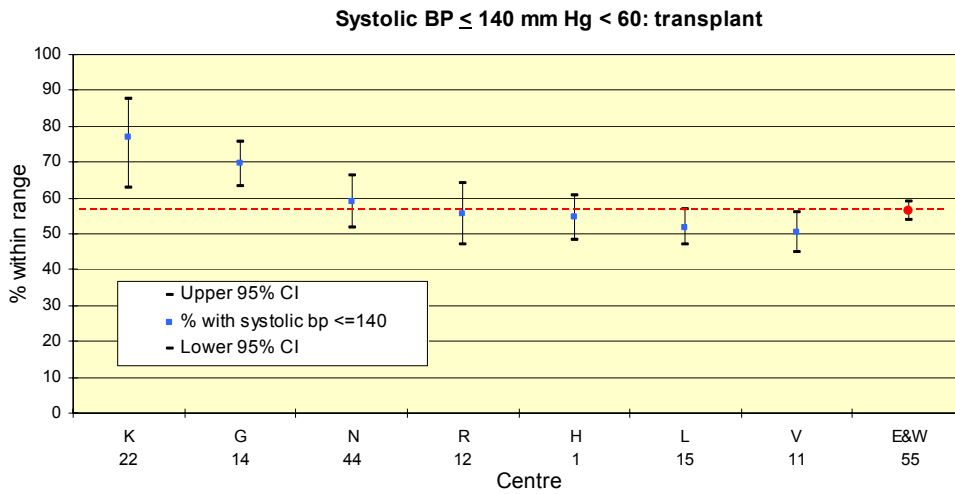


Figure 11.21 Percentage transplant patients under 60 with systolic BP <140 mmHg

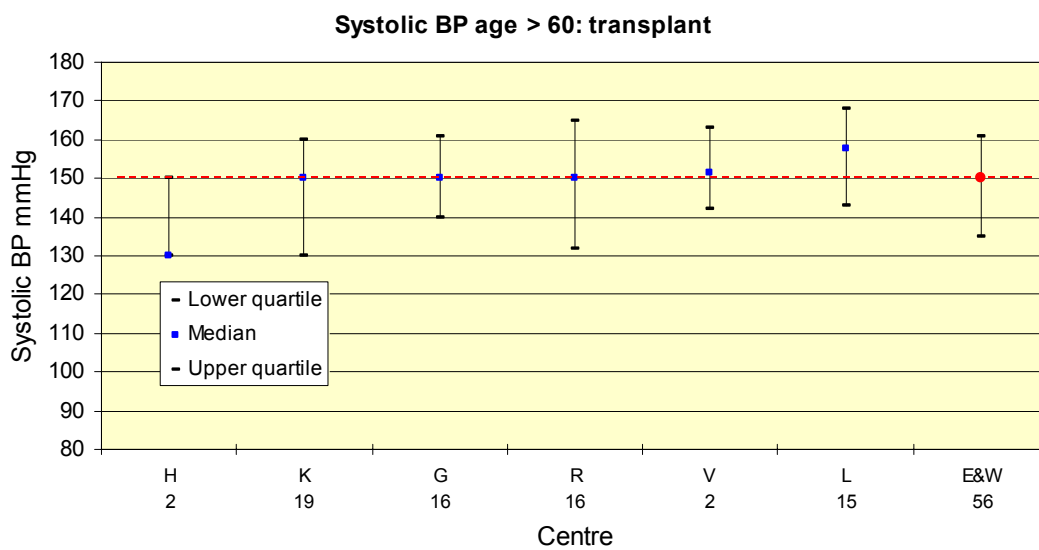


Figure 11.22 Transplant patients over 60: median systolic pressure

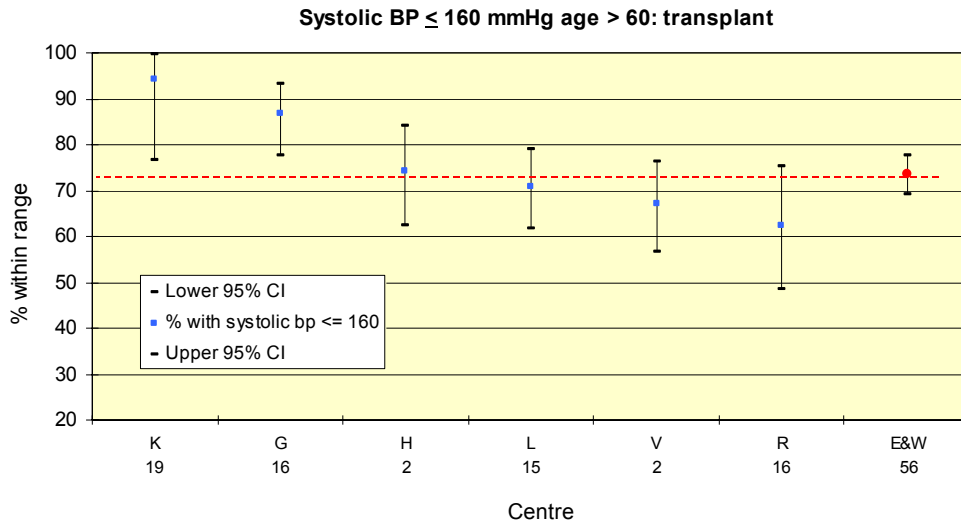


Figure 11.23 % patients over 60 with systolic BP <160 mmHg

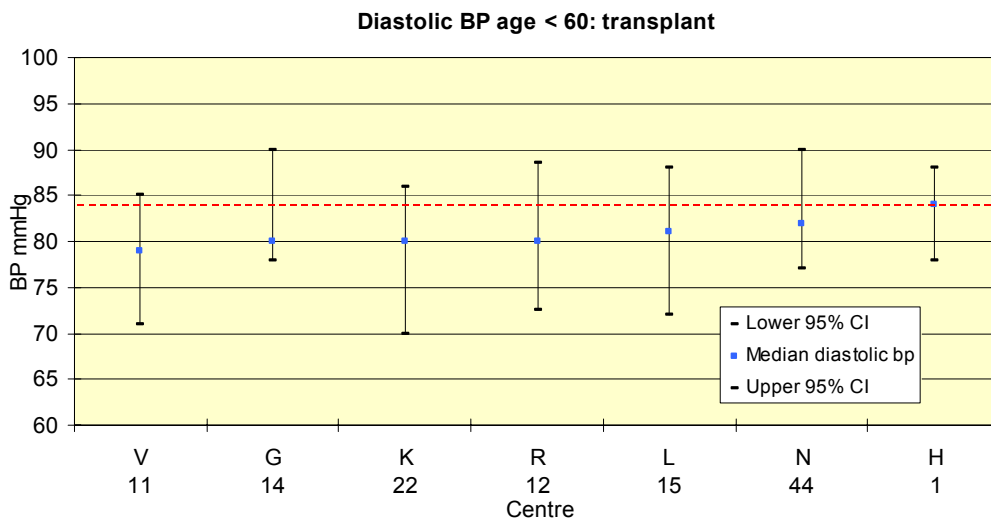


Figure 11.24 Transplant patients under 60; median diastolic pressure

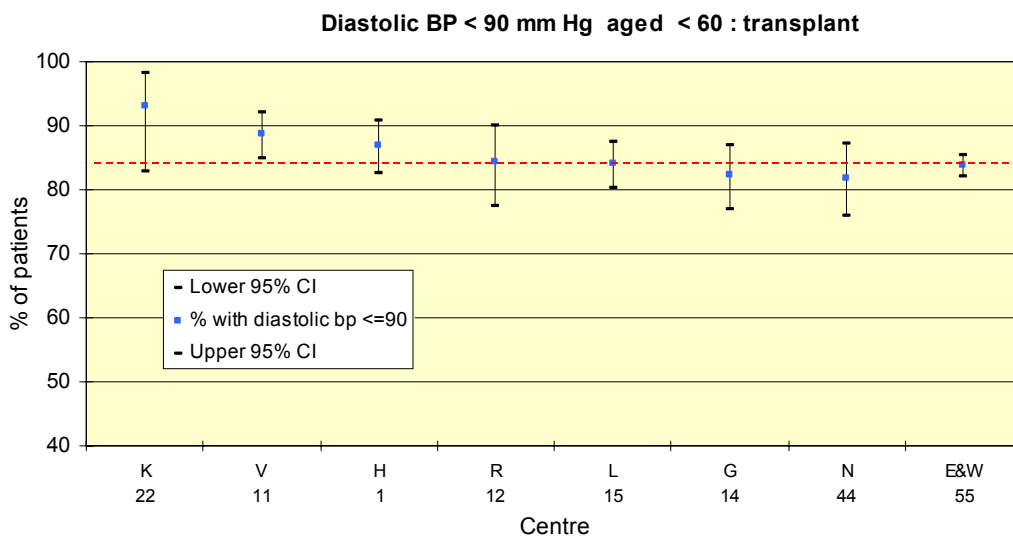
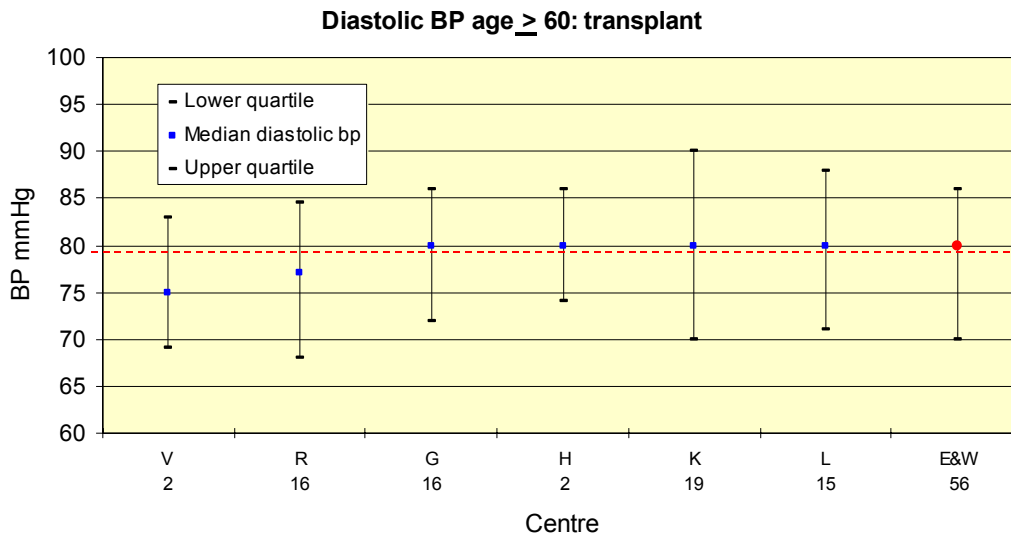
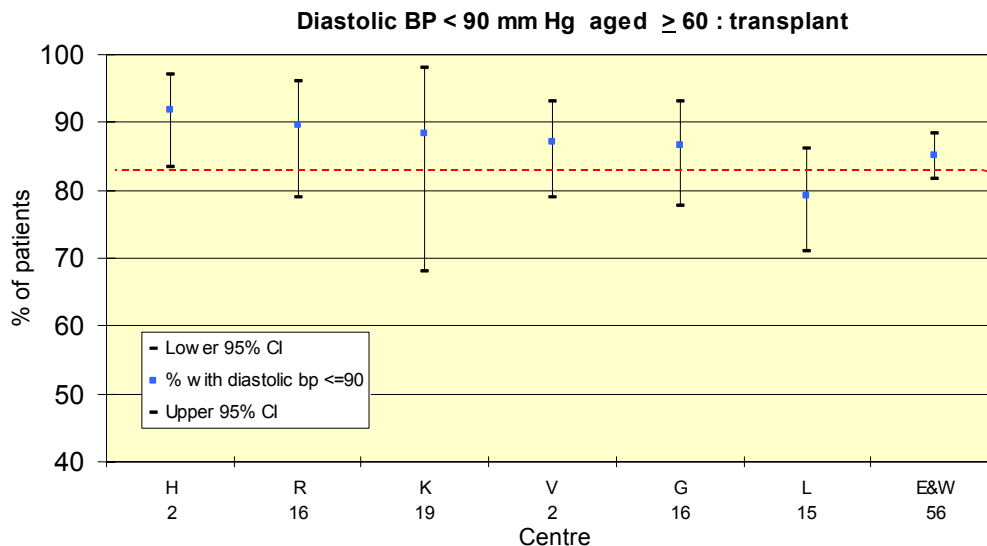


Figure 11.25 % patients under 60 with diastolic BP <90mmHg



**Figure 11.26 Transplant patients over 60: median diastolic pressure**



**Figure 11.27 % patients over 60 with diastolic BP <90mHg**

The relationship between systolic, diastolic and mean arterial blood pressure and transplant function as reflected by serum creatinine is shown in Table 11.8. It is not possible to determine whether higher blood pressure causes or results in poorer graft function. As the Registry collects further sequential data on these patients, the relationship of blood pressure both before and after transplantation to graft and patient survival will be investigated.

Serum Creatinine	Median mean arterial BP	Median Systolic BP	Median Diastolic BP
< 150 mmol/L	99.0	139.0	80.0
150-250 mmol/L	102.0	143.0	81.0
> 250 mmol/L	105.0	149.0	82.0

**Table 11.8 Relationship between BP and graft function in transplant patients in E&W.**

## **Conclusion**

Once again this report has concentrated on providing data on renal transplant patients that are not available from other sources or registries.

Variation exists between centres with respect to access to renal transplantation for both stock patients receiving renal replacement therapy as well as patients whose primary diagnosis is diabetes mellitus. In future reports it may be possible to obtain additional and more complete information (e.g. ethnicity) that could enable reasons for these differences to be examined in more detail.

The annual death rate of patients with established renal transplants is low at 2.9% for the whole UK (including patients with failed grafts returning to dialysis).

3.1% of all patients starting dialysis in the UK in 1999 were patients with failed transplants. This proportion is likely to vary substantially between units depending on the size of the stock transplant population.

The quality of transplant function differs significantly between centres, as does the haemoglobin level. Differences in modifiable risk factors for cardiovascular disease such as serum cholesterol and blood pressure also exist.

More sequential data will be available in the future and should enable individual centres to monitor the impact of new policies and protocols as well as allow comparison in outcome with other centres.

## **References**

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2. Wood D, Durrington P, Poulter N, McInnes G, Rees A, Wray R. (1998). "Joint British recommendations on prevention of coronary heart disease in clinical practice." *Heart* 80(2): S1-S29.
3. Raine AEG, McMahon. S, Selwood NH, Wing AJ, Brunner FP. (1991). "Mortality from myocardial infarction in patients on renal replacement therapy in the UK." *Nephrology Dialysis Transplantation* **6**: 902
4. Ramsay LE, Williams B, Johnston DG, MacGregor GA, Poston L, Potter JF, Poulter NR, Russell G. (1999). "Guidelines for the management of hypertension: report of the third working party



## Chapter 12: Co-morbidity of new patients

### Summary

The most pressing need for the Registry is to improve the returns of co-morbidity data from patients starting renal replacement therapy. Without good co-morbidity data the value of survival analysis and comparative audit of groups of apparently similar patients will be greatly reduced.

Only 3 units sent significant amounts of data, and even from these completeness was inadequate for analysis.

### Co-morbidity returns

As can be seen from table 12.1 return of co-morbidity data of new patients in 1999 was very poor. Only 3 units sent significant amounts of data, and even from these completeness was adequate for analysis only from centre G.

Treatment Centre	% of patients with complete data
G	78.13
H	23.81
N	64.96
O	12.35

No other centre returned significant amounts of data.

**Table 12.1 Data returns from centres of co-morbidity at start of renal replacement therapy**

**In the 1999 Registry Report, collection of co-morbidity was introduced for patients starting renal replacement therapy in 1998. Four of the Registry centres managed to send some data and the report presented some comment on this. Feedback to the user group meeting in January 2000 was too late to affect the completeness of co-morbidity data for this years report on patients starting RRT in 1999. It is hoped the returns for the year 2000 are improved.**

In view of the incomplete data return no analysis is made of co- morbidity of new patients in 1999.

### Co-morbidity definitions

#### Angina

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

#### Previous MI within last 3 months

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

**Previous MI > 3 months ago**

From time of start of renal replacement therapy.

**Previous CABG or coronary angioplasty****Cerebrovascular disease**

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

**Diabetes (not causing ESRF)**

This includes diet controlled diabetics.

**Chronic Obstructive Pulmonary Disease**

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

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

**Liver Disease**

Persistent enzyme evidence of hepatic dysfunction OR Biospy evidence OR HbeAg or hepatitis C antigen (polymerase chain reaction) positive serology

**Malignancy**

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

**Claudication**

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

**Ischaemic / Neuropathic ulcers**

Current presence of these ulcers.

**Angioplasty (non coronary)****Amputation for Peripheral Vascular Disease****Smoking**

Current smoker or history within the last year.

A screen as shown in figure 12.1 is provided for participants to place on their data systems to facilitate easy entry.



## Co-morbidity Screen

<input type="checkbox"/> Angina	<input type="checkbox"/> Claudication
<input type="checkbox"/> Previous MI within last 3 months	<input type="checkbox"/> Ischaemic / Neuropathic ulcers
<input type="checkbox"/> Previous MI > 3 months ago	<input type="checkbox"/> Angioplasty (non coronary)
<input type="checkbox"/> Previous CABG or coronary angioplasty	<input type="checkbox"/> Amputation for Periph Vasc Dis
<input type="checkbox"/> Cerebrovascular disease	<input type="checkbox"/> Smoking
<input type="checkbox"/> Diabetes (not causing ESRF)	

Figure 12.1 A typical co-morbidity entry screen

### Comment

Collection of co-morbidity data is essential for the Registry to carry out survival analysis, to assess national outcomes, and for comparative audit between centres. Co-morbidity data is sought from all new patients currently starting renal replacement therapy. It has not been requested from existing patients when renal units first join the Registry.

As has been shown in this year's report in Chapter 5, there is a differential in survival of prevalent patients between Scotland and England & Wales. The probable explanation for this is the higher cardiovascular mortality rate in Scotland. This may also be part of the reason for the differential survival between centres within England & Wales. Without good co-morbidity data to enable comparisons of groups of similar patients, the value of these analyses will be greatly reduced.

The USRDS has increased accuracy of co-morbidity returns by classifying patients without any co-morbidity return as having zero co-morbidity. This when included as adjustment factor in survival for that centre shows the centre to have poorer survival compared to another centre with high co-morbidity completeness, as many of these patients will have some co-morbidity. The UK Registry will consider this proposal when more centres start to return co-morbidity.



## Chapter 13: Performance Against Renal Association Standards

### Introduction

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

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

**Table 13.1 Renal Association Standards**

Data are included for the last quarter of 1999. Patients were excluded if they had not been on renal replacement therapy for at least three months or if they had transferred unit or changed dialysis modality in the three month period prior to data sampling. This ensures that the results for a unit reflect stable treatment patterns and are not adversely affected by new patients which the unit has not had chance to treat effectively.

The problems of comparing biochemical variables such as albumin, calcium and bicarbonate identified in the 1998 and 1999 report still apply; and comparative data must be interpreted with caution. Achievement of Standards defined around the local laboratory reference range is dependent on the source of derivation for the reference range. Biochemical data have been harmonised as described previously. The harmonisation constants for an individual laboratory change year on year and are monitored. The urea reduction ratios may be influenced by post-dialysis sampling techniques; this is discussed again this year in detail in chapter 6.

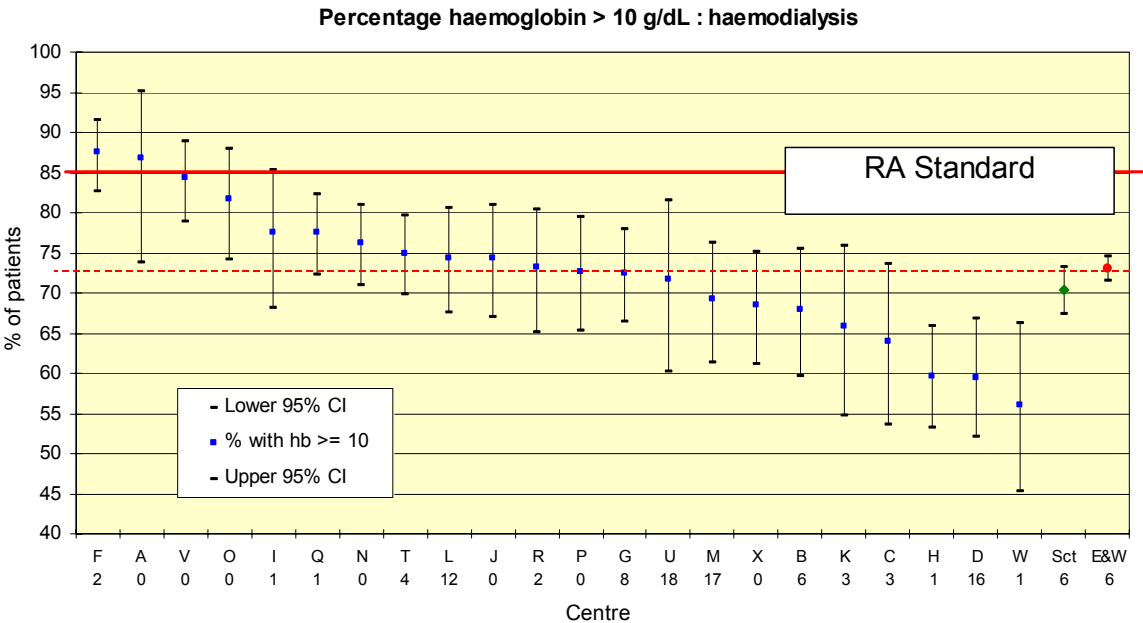
Results have been ranked in order of performance purely for clarity of presentation, otherwise the figures would be difficult to read. The ranking does not necessarily imply significant differences in the performance of different units and the significance of the ranking order has not been tested.. The 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.

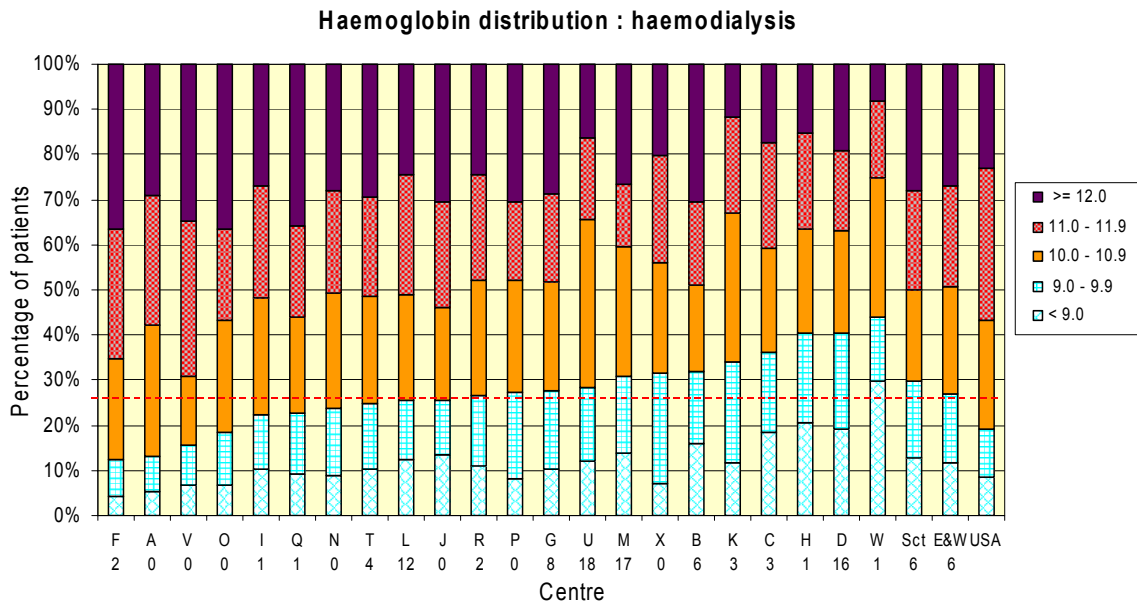
**Overview of presentation**

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 25<sup>th</sup> and 75<sup>th</sup> centiles for the unit are included. Figures showing the percentage within a range (as defined by the Renal Association Standard or a Renal Registry defined range) also include the 95% confidence interval calculated for this figure. Data completeness is indicated by the percentage missing figure below the unit code letter.

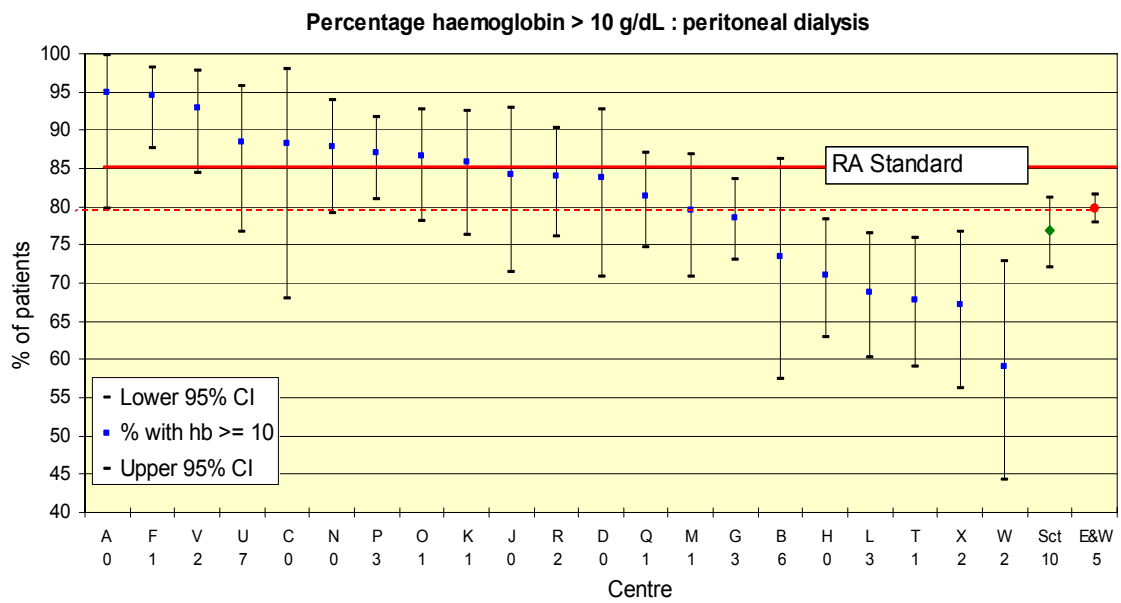
**Haemoglobin**



**Figure 13.1 Haemoglobin Percentage of HD patients achieving the RA Standard**



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



**Figure 13.3 Percentage of PD patients by centre achieving the RA Standard**

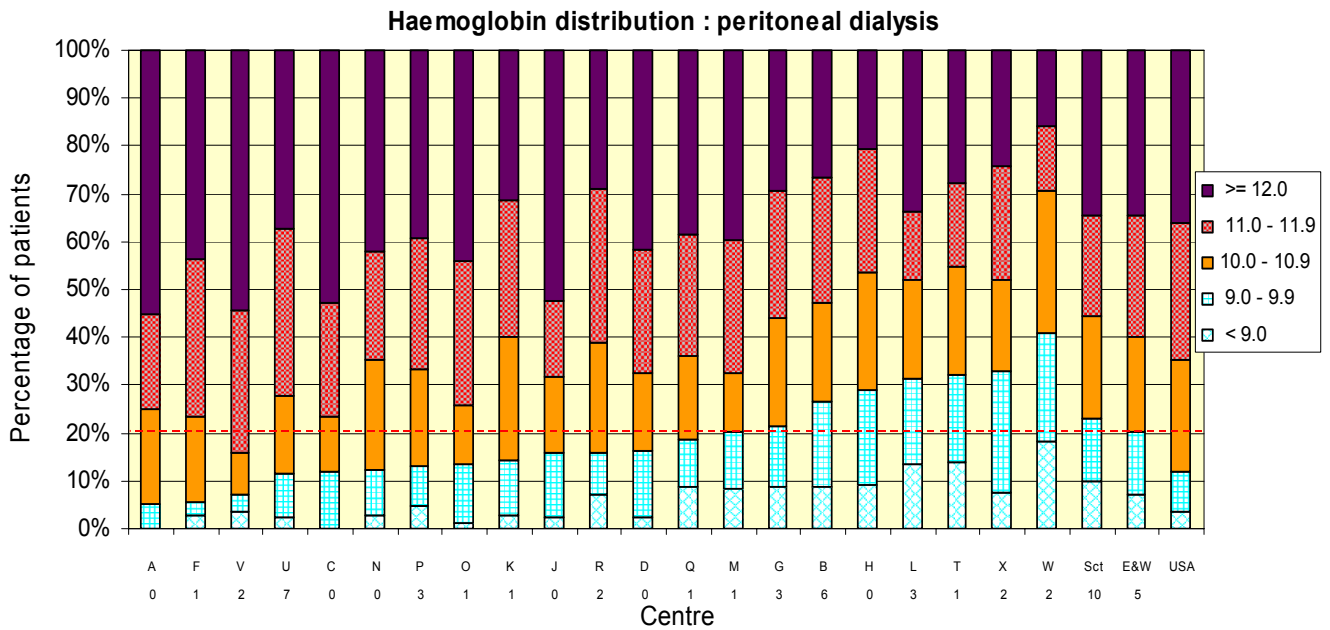


Figure 13.4 Distribution of haemoglobin for patients on PD by 1g/dl bands

## Serum Albumin

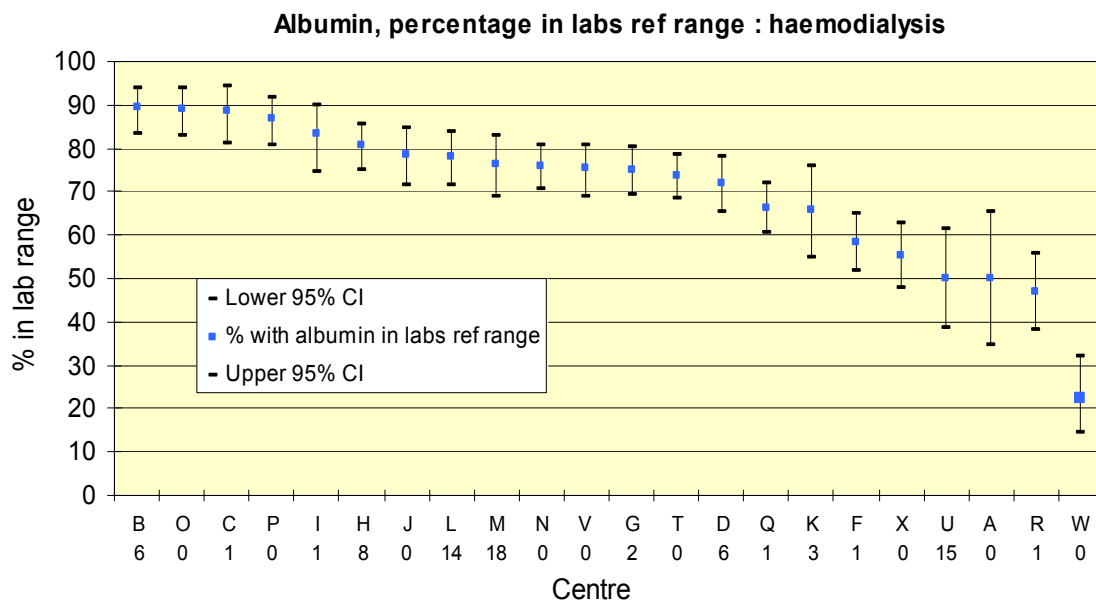


Figure 13.5 Percentage albumin in lab reference range for haemodialysis

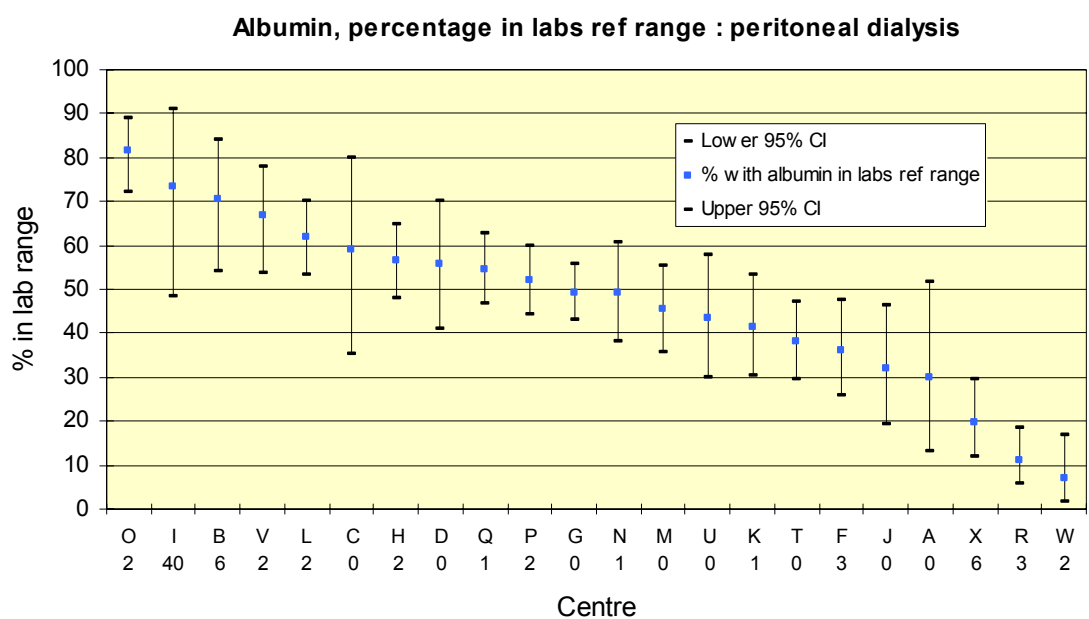


Figure 13.6 Percentage albumin in lab reference range for peritoneal dialysis

## Serum Bicarbonate

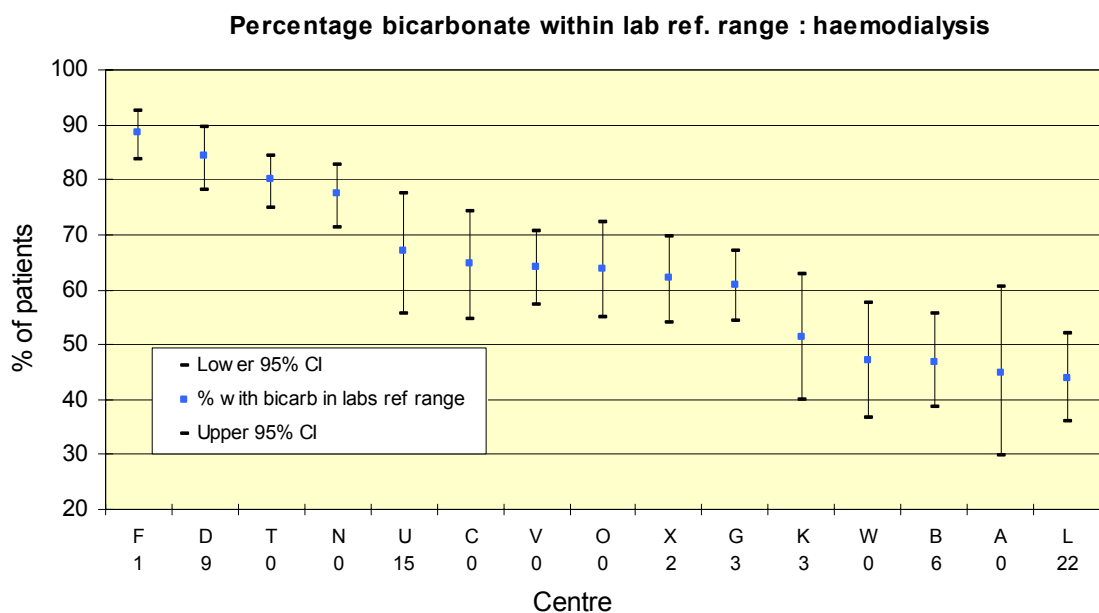
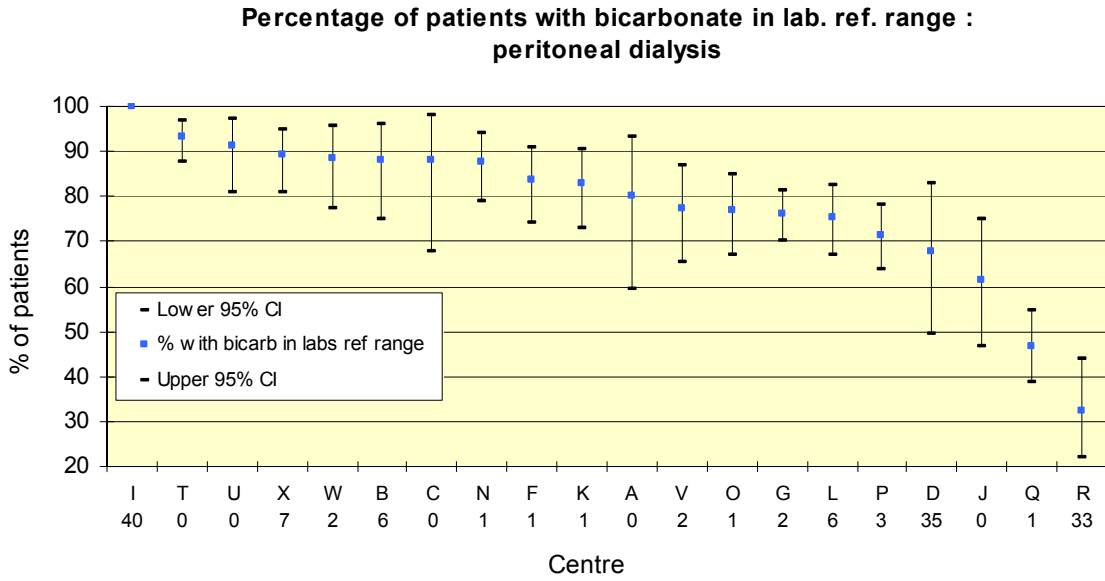
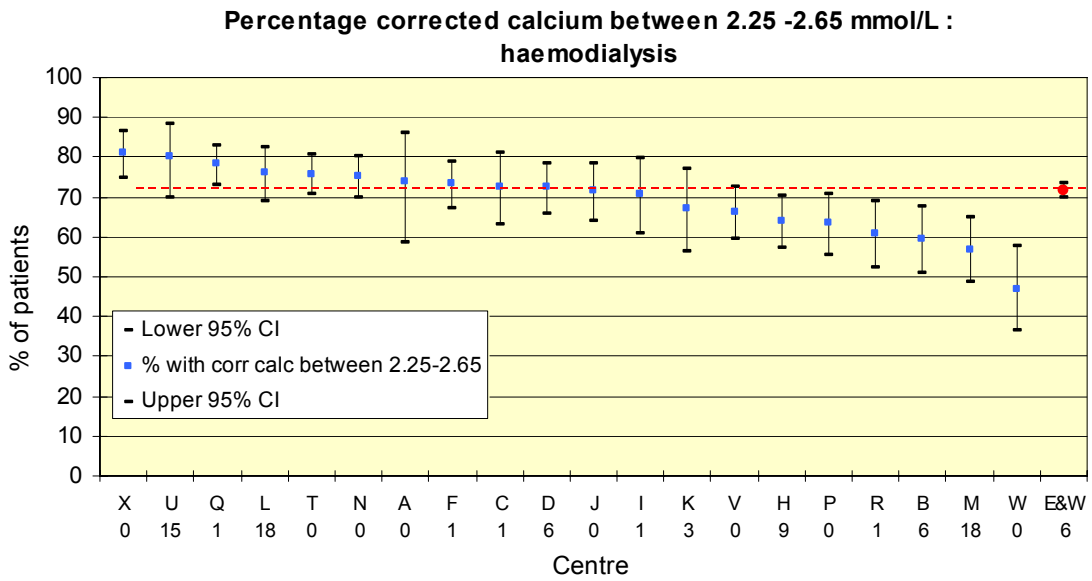


Figure 13.7 Percentage bicarbonate in lab reference range for haemodialysis



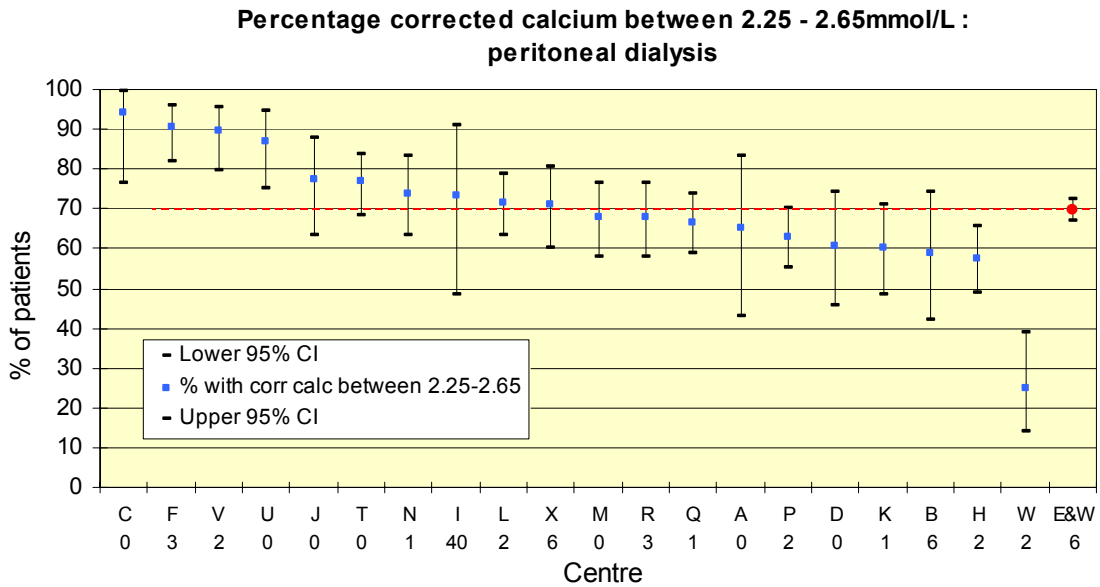
**Figure 13.8 Percentage bicarbonate in lab reference range for peritoneal dialysis**

### **Serum Calcium**



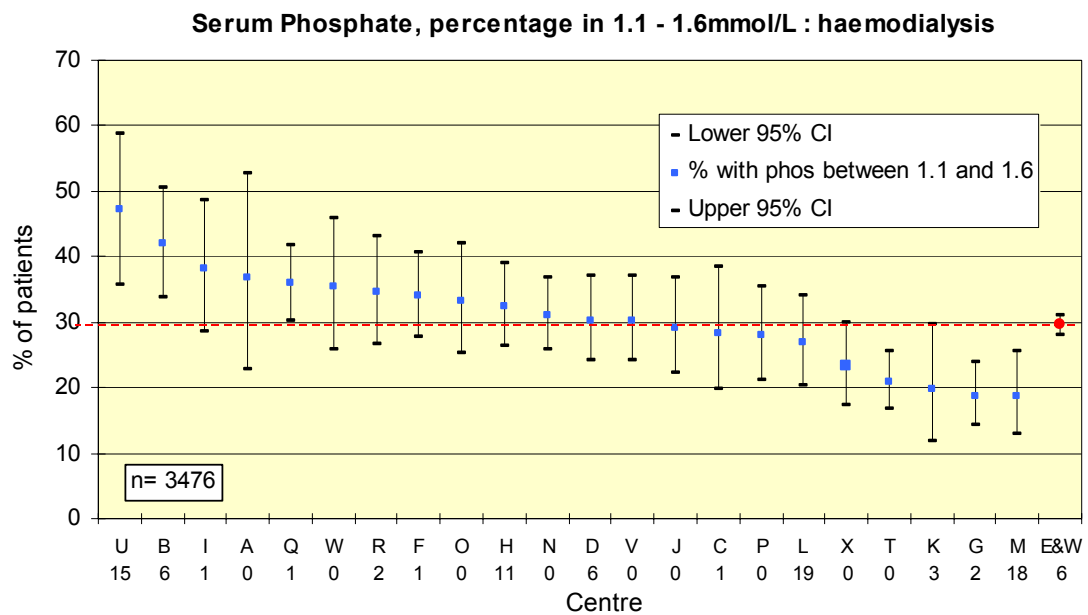
**Figure 13.9 Percentage corrected calcium in 2.25-2.65 for haemodialysis**





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

### Serum Phosphate



**Figure 13.11** Percentage serum phosphate in range 1.1-1.6 for haemodialysis

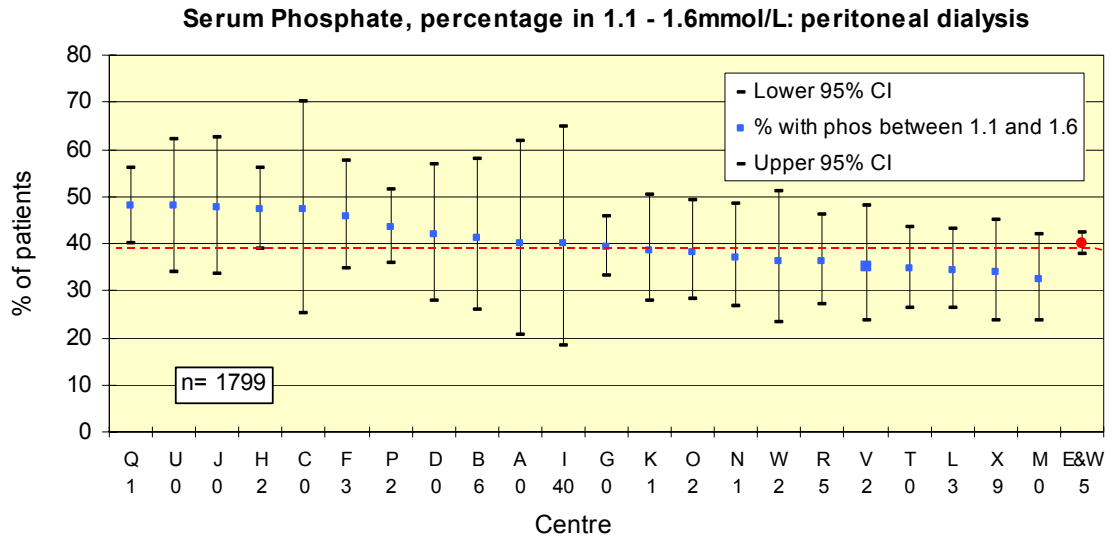


Figure 13.12 Percentage serum phosphate in range 1.1-1.6 for peritoneal dialysis

### Intact parathyroid hormone

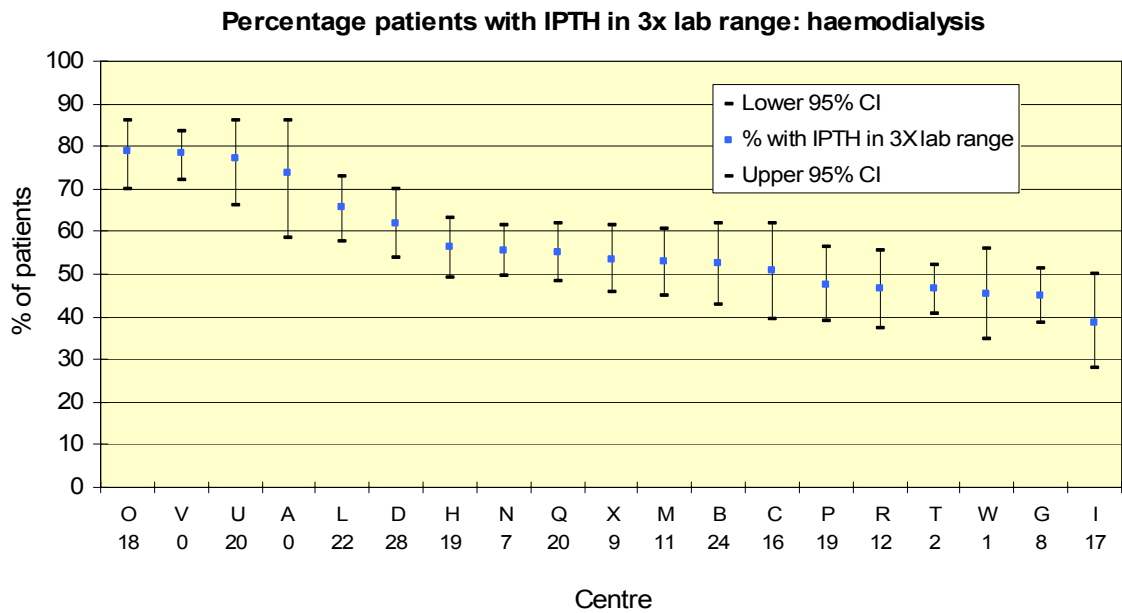
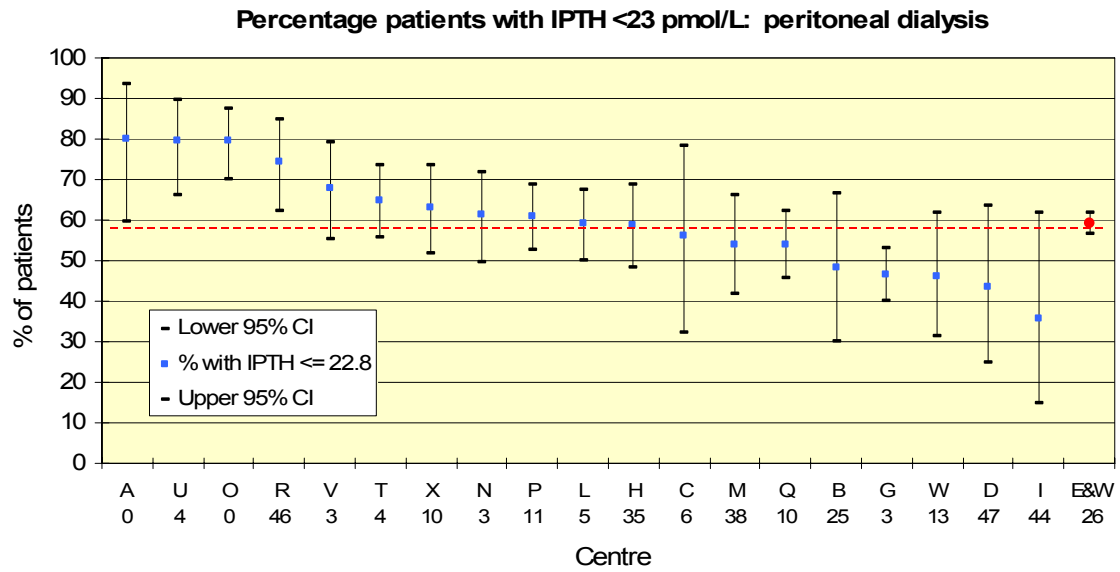
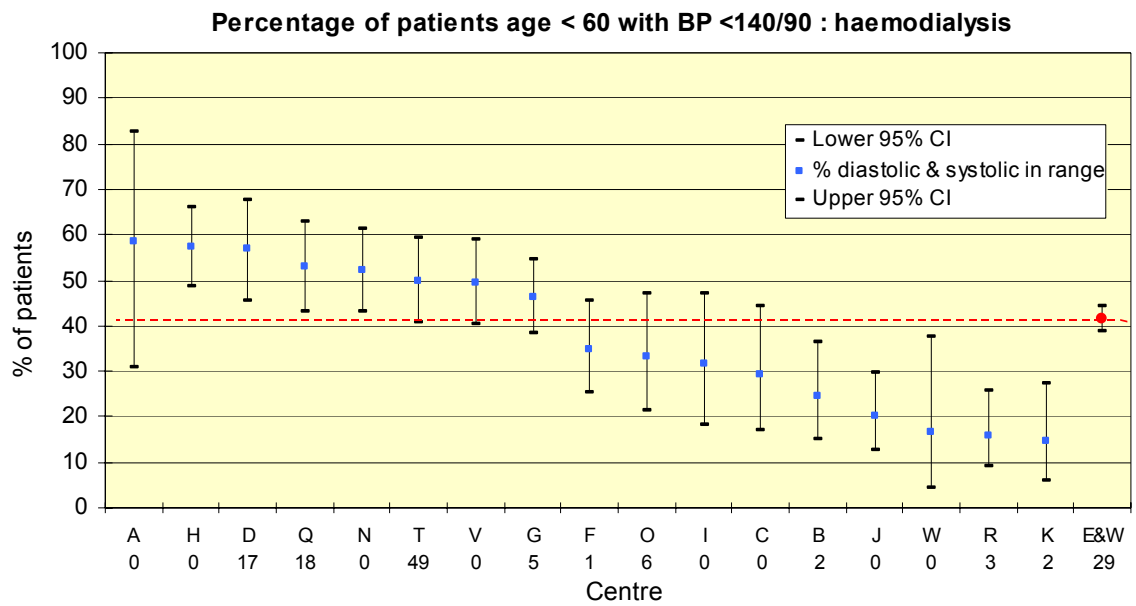


Figure 13.13 Percentage patients with iPTH in 3x lab range on haemodialysis

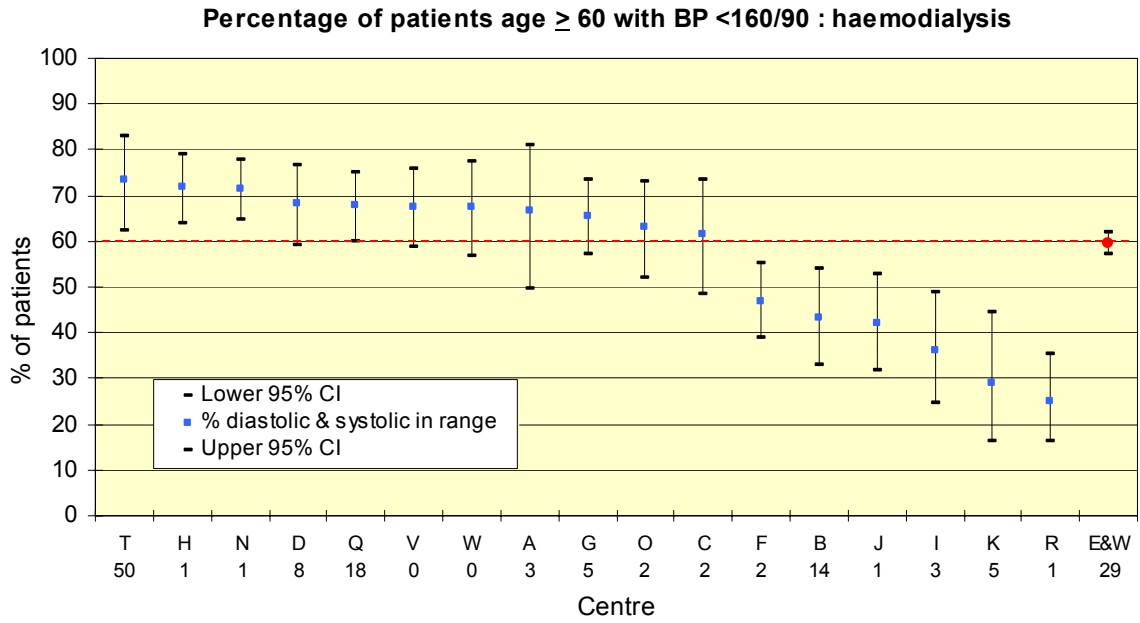


**Figure 13.14 Percentage patients with iPTH in 3x lab range on peritoneal dialysis**

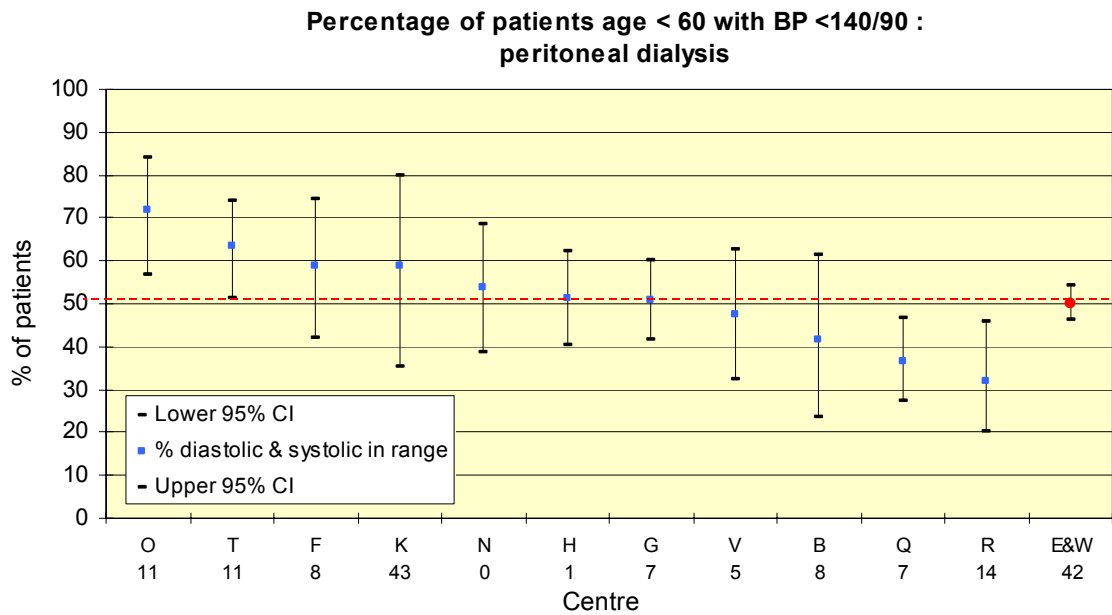
### Blood Pressure



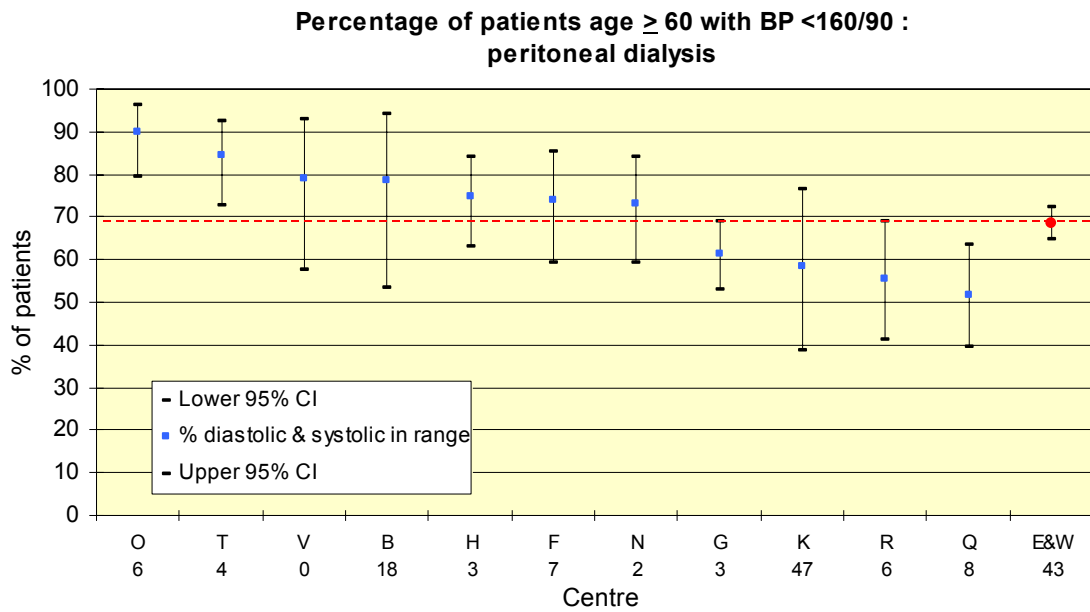
**Figure 13.15 Percentage haemodialysis patients age < 60 with BP in RA Standard range**



**Figure 13.16 Percentage patients age  $> 60$  with BP in RA Standard on haemodialysis**

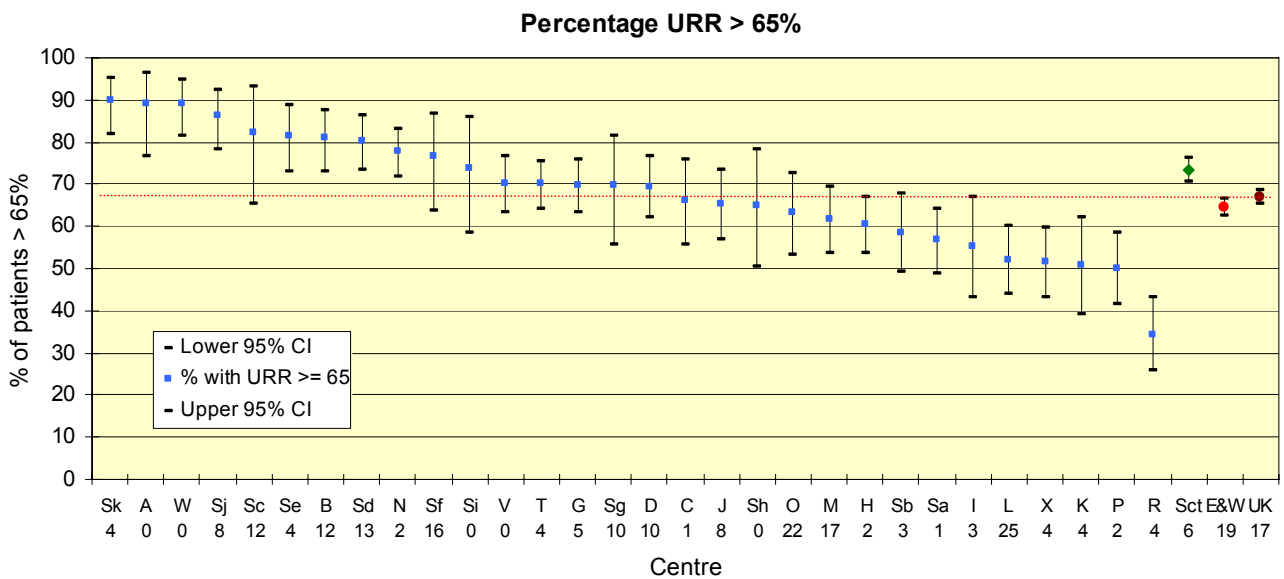


**Figure 13.17 Percentage pts age  $< 60$  with BP in RA Standard on peritoneal dialysis**



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

### Dialysis Adequacy



**Figure 13.19** Percentage URR > 65%

## **Statistical analysis**

### **Methodology**

Chi-squared tests were used to see whether the percentage of patients with data in a given range varied significantly between centres. 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  $\geq 10$ g/dl differed between centres.

For patients on HD, the percentage of patients with haemoglobin  $\geq 10$ g/dl was found to differ significantly between centres ( $X^2 = 108.4$ , d.f. = 21,  $p < 0.001$ ).

For patients on PD, the percentage of patients with haemoglobin  $\geq 10$ g/dl was found to differ significantly between centres ( $X^2 = 81.9$ , d.f. = 20,  $p < 0.001$ ).

#### **Ferritin**

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

For patients on HD, the percentage of patients with ferritin  $\geq 100$  was found to differ significantly between centres ( $X^2 = 292.2$ , d.f. = 21,  $p < 0.001$ ).

For patients on PD, the percentage of patients with ferritin  $\geq 100$  was found to differ significantly between centres ( $X^2 = 81.3$ , d.f. = 22,  $p < 0.001$ ).

#### **Albumin**

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

For patients on HD, the percentage of patients with albumin greater than or equal to the labs lower reference range limit differed significantly between centres ( $X^2 = 305.9$ , d.f. = 20,  $p < 0.001$ ).

For patients on PD, the percentage of patients with albumin greater than or equal to the labs lower reference range limit differed significantly between centres ( $X^2 = 200.4$ , d.f. = 21,  $p < 0.001$ ).

#### **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 ( $X^2 = 305.9$ , d.f. = 21,  $p < 0.001$ ).

For patients on PD, the percentage of patients with bicarbonate within the Standard differed significantly between centres ( $X^2 = 195.8$ , 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  $\leq 1.70$  mmol/L differed between centres. For patients on PD, a chi-squared test was used to determine whether the percentage of patients with phosphate  $\leq 1.60$  mmol/L differed between centres. Note that the analysis considered lab-harmonised phosphate.

For patients on HD, the percentage of patients with phosphate  $\leq 1.70$  mmol/L differed significantly between centres ( $X^2 = 129.8$ , d.f. = 21,  $p < 0.001$ ). [Note this does not fit in with text in the Report for phosphate.]

For patients on PD, the percentage of patients with phosphate  $\leq 1.60$  mmol/L differed significantly between centres ( $X^2 = 46.3$ , d.f. = 21,  $p < 0.001$ ). [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  $\leq 22.8$  pmol/L differed between centres. Note that the analysis considered lab harmonised PTH.

For patients on HD, the percentage of patients with PTH  $\leq 22.8$  pmol/L differed significantly between centres ( $X^2 = 239.5$ , d.f. = 18,  $p < 0.001$ ).

For patients on PD, the percentage of patients with PTH  $\leq 22.8$  pmol/L differed significantly between centres ( $X^2 = 88.8$ , d.f. = 18,  $p < 0.001$ ).

### *URR*

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

The percentage of patients with URR  $\geq 65\%$  was found to vary significantly between centres ( $X^2 = 242.9$ , d.f. = 29,  $p < 0.001$ ).

### *Blood Pressure*

A chi-squared test was used to determine whether the percentage of patients with both systolic and diastolic blood pressure within range differed between centres. Note that the analysis for transplant patients excluded patients who had a transplant in 1999.

For patients on HD, aged 60 or more, the percentage of patients reaching the Standard for both systolic and diastolic blood pressure differed significantly between centres ( $X^2 = 135.5$ , d.f. = 16,  $p < 0.001$ ).

For patients on HD, aged under 60, the percentage of patients reaching the Standard for both systolic and diastolic blood pressure differed significantly between centres ( $X^2 = 105.6$ , d.f. = 16,  $p < 0.001$ ).

For patients on PD, aged 60 or more, the percentage of patients reaching the Standard for both systolic and diastolic blood pressure differed significantly between centres ( $X^2 = 37.1$ , d.f. = 10,  $p = 0.005$ ).

For patients on PD, aged under 60, the percentage of patients reaching the Standard for both systolic and diastolic blood pressure differed significantly between centres ( $X^2 = 28.0$ , d.f. = 10,  $p < 0.001$ ).



# Chapter 14: International Comparisons with UK Renal Registry Data

## Incidence & prevalence

Country	Year	Population	Prevalent ESRF p.m.p.	Prevalent Dialysis p.m.p.	Incident p.m.p.	% incident ESRD with diabetes
Australia	1998	18,750,982	555	295	85	22
Austria	1998	8,091,000	668	349	125	31
Canada	1997	30,286,268	609	371	152	29
Germany	1998	82,037,000	764	585	148	35
Italy	1997	57,563,356	757	589	119	15
Netherlands	1998	15,654,192	583	290	93	16
New Zealand	1998	3,792,000	541	295	96	44
Norway	1998	4,445,000	526	123	91	10
Sweden	1998	8,854,322	668	304	119	23
<b>U.K.</b>	<b>1998</b>	<b>59,236,522</b>	<b>534</b>	<b>273</b>	<b>97</b>	<b>19</b>
USA	1998	270,299,000	1,177	909.8	320	40

Table 14.1 Prevalence and incidence of RRT in several countries

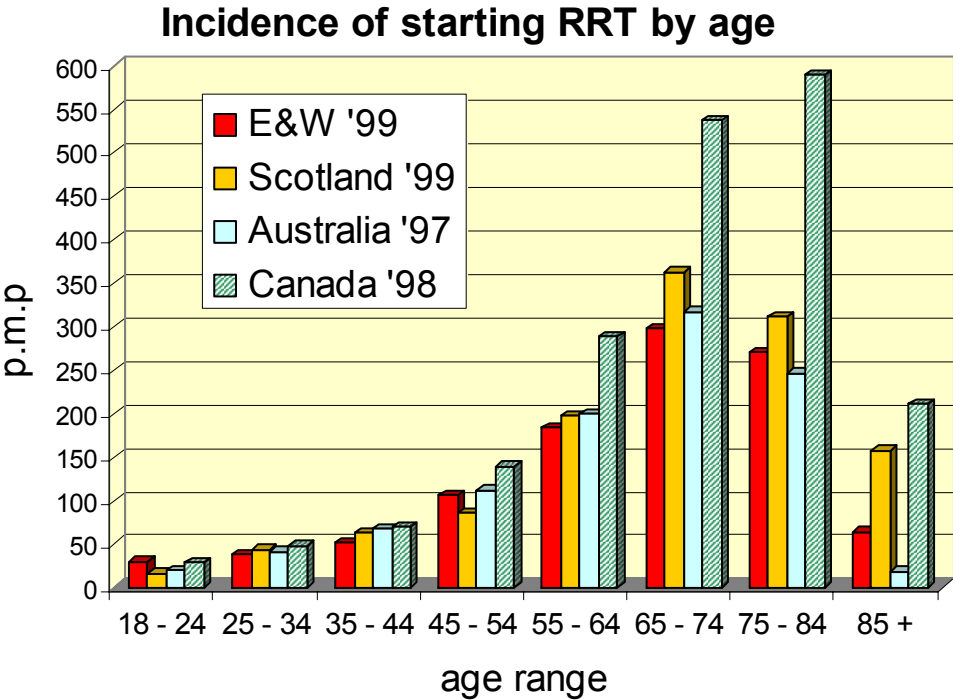
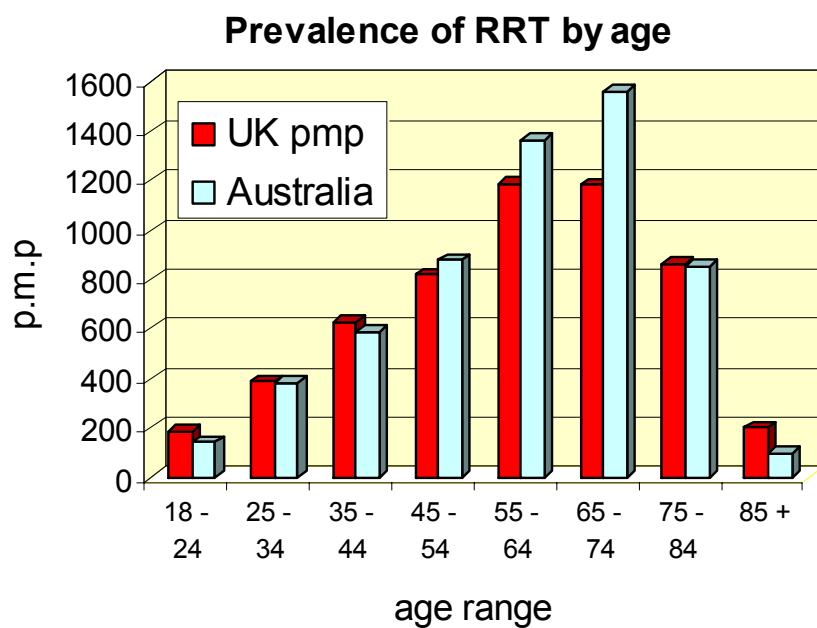


Figure 14.1 Incidence of renal replacement therapy by age group



**Figure 14.2** Prevalence of renal replacement therapy by age group

### ***Treatment modalities***

Country	Year	% unit HD	%CAPD/CCPD	% Home HD	% Transplanted	New Transplant	Tx living donor
Australia	1998	60	28	12	47	517	160
Austria	1998	92	8	0.2	47	375	50
Canada	1997	66	30	4	39	1,010	285
Germany	1998	93	6	1	23	2,340	343
Italy	1997	86	10	4	20	1,190	-
Netherlands	1998	68	30	2	50	480	95
New Zealand	1998	26	56	18	46	106	31
Norway	1998	81	18	1	77	203	78
Sweden	1998	87	12	1	54	356	120
<b>U.K.</b>	<b>1998</b>	<b>60</b>	<b>36</b>	<b>4</b>	<b>48</b>	<b>1,349</b>	<b>247</b>
USA	1998	89	10.2	1.3	29	12,956	4,026

**Table 14.2** Modality pattern in several countries

## Transplantation

Waiting list as percentage of all dialysis patients by age group on 1/1/1999

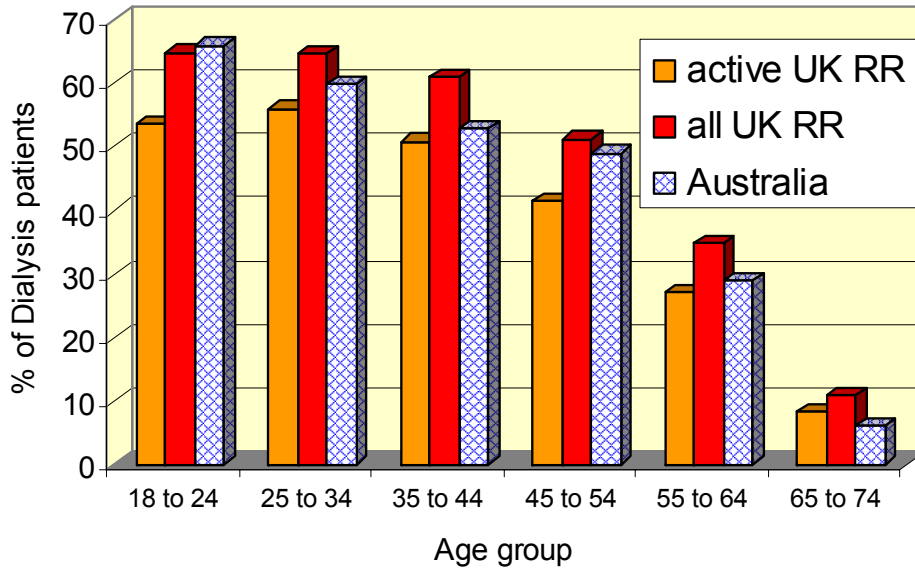


Figure 14.3 Transplant waiting list by age group

## Urea reduction ratio in haemodialysis

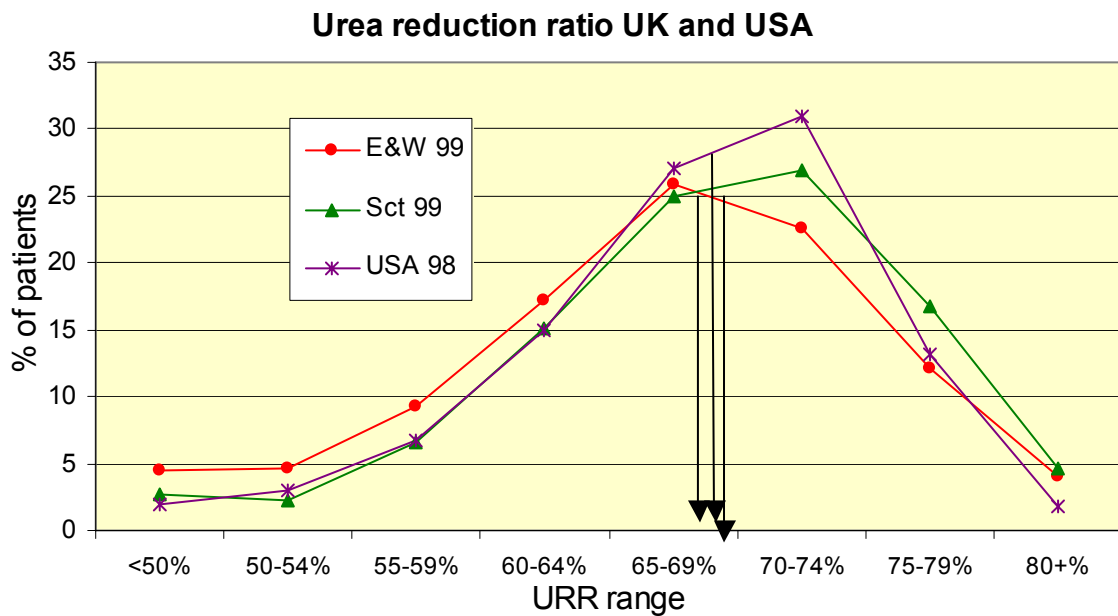


Figure 14.4 URR in the UK and USA

## Renal Anaemia

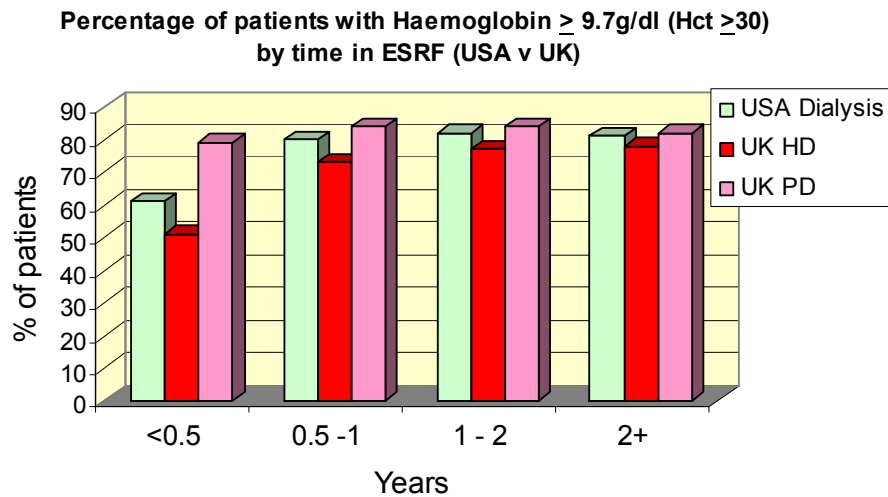


Figure 14.5 Haemoglobin  $>$  9.7 g/dl comparison of UK vs. USA by time in ESRF

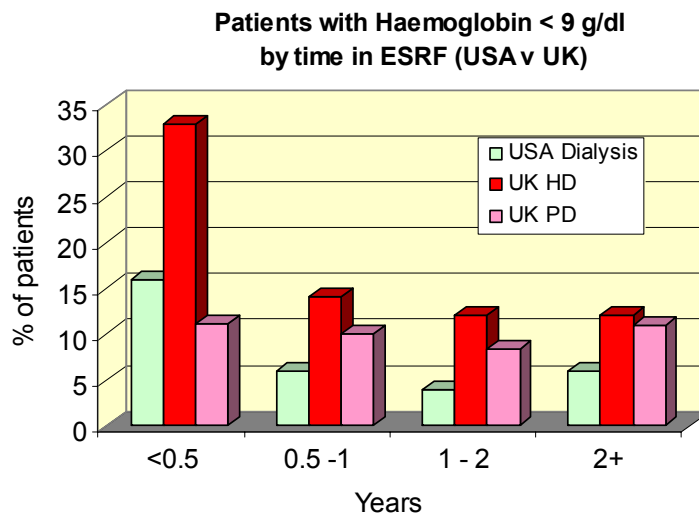


Figure 14.6 Haemoglobin  $<$  9 g/dl comparison of UK vs. USA by time in ESRF

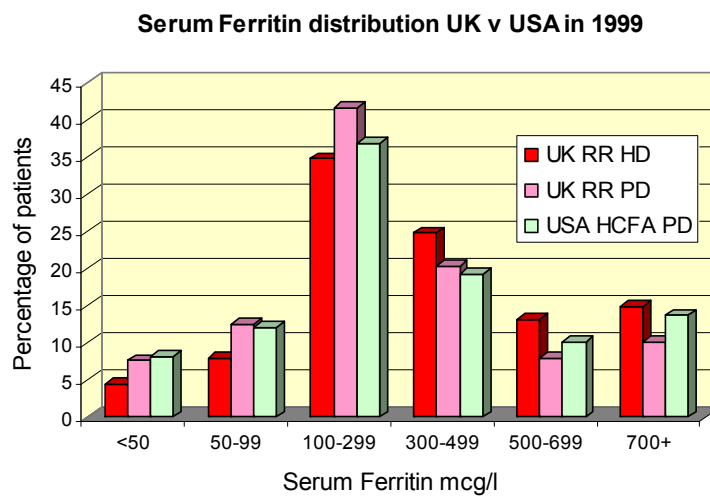


Figure 14.7 Serum Ferritin distribution UK vs. USA in 1999

## **Chapter 15: Report of the Paediatric Renal Registry**

Compiled by Dr M.A. Lewis and Mrs Jo Shaw

### **Summary**

The data collected for this report were from a single time point between September 1999 to May 2000 and represents the first set of dynamic data returns. Data were analysed from 621 patients. There were 755 patients entered on to the database when it was initiated in 1999. The data analysed in this report is incomplete but in future years we aim to report on more complete data as the process of data entry improves

Transplantation is the treatment modality of choice for paediatric patients and cross sectional analysis reveals 76% of patients had a functioning graft. Of. This group, 405 (86.7%) were cadaveric and 62 (13.3%) from living related donors There was a significant increase in live related grafts, 30% in the last year compared to 10% previously. 103 (22%) patients had pre-emptive grafts. 83 (17.8%) of 467 grafts had been performed in the previous 12 months. Graft outcome was excellent with over 85% having very good function (GFR > 40mls/min/1.73 m<sup>2</sup>) and only 1.6 % having poor function with the likely need for return to dialysis soon.

Although over the age of five years the ratio of dialysis to transplanted patients is 4:1, under the age of five years there are more children on dialysis than transplanted. This group of children in particular require enormous support from all members of the multi-disciplinary team Of the 148 patients on dialysis 94 (63.5%) were on peritoneal dialysis. Of those on peritoneal dialysis 88.4% were on automated cycling dialysis as opposed to CAPD.

Comparing the prevalence and treatment modality of children receiving renal replacement therapy with that reported in 1992 BAPN report 'The provision of services in the United Kingdom for Children and adolescents with renal disease' there has been a 23% increase in the numbers of children receiving treatment. Although there has been a fall in the proportion of children on dialysis from 34% to 25% there has been an increase in the proportion of children on haemodialysis from 26% of the dialysis population to 41%. This could have significant resource implication.

Normalisation of growth and nutritional status are important goals of treatment in children. 37.5% of patients on PD and 43.8% of those on HD were less than 2 s.d. below the mean for height. 20.6% of dialysis patients were receiving growth hormone. Linear growth was improved with transplantation with 29% of those with functioning grafts being less than 2 s.d. below the mean for height

Most dialysis patients had a normal BMI, only 4.4% being less than 2 s.d. below the mean.. However 23% of patients with a functioning graft had a body mass index (BMI) of >2 s.d. above the mean. 4.3% had a BMI >3 s.d. above the mean. This is an area of particular concern for long term morbidity and needs further evaluation.

**Introduction.**

The incidence, prevalence and geographical distribution of renal failure in childhood make it an excellent candidate for specialty advancement through the use of a national registry. Data from national registries can be presented in a number of ways. There can be presentations on a cross-sectional basis of incidence, prevalence and patient demography. Data on management can be presented cross-sectionally across the population or longitudinally following patient progress. Longitudinal studies can encompass all aspects for the whole population or can be split to look at specific factors in specific subgroups. Last year we reported on the demography of renal failure in childhood looking specifically at the incidence and prevalence of renal failure according to age and diagnosis. We reported details on presentation and initial treatment. This year we are again taking a cross-sectional view, but this time at current treatment and outcome measures, such as growth. Over the next few years, with ongoing data collection, longitudinal studies will become possible. Standards mentioned in this report are provisional. New standards for paediatric patients are being reviewed currently and are due to be published shortly with the new adult standards. Data from this and future reports will help guide the provision and audit of these and future standards.

**Population studied.**

Data was collected from all 14 centres (13 in the UK and 1 in Eire) that participate in the registry. Data was collected from a single time point between September 1999 and May 2000. Only patients below the age of 18 years of age at the time of data collection were used in the analysis. Analysable treatment data was available on 621 patients, 82% of the estimated total population of 755. Figure 15.1. shows the age distribution of the population studied. As with the data in the 1999 report the fall off in numbers after the age of 15 years reflects the variable age of transfer to adult units and the variable referral of new patients between 16 and 18 years to adult or paediatric units.

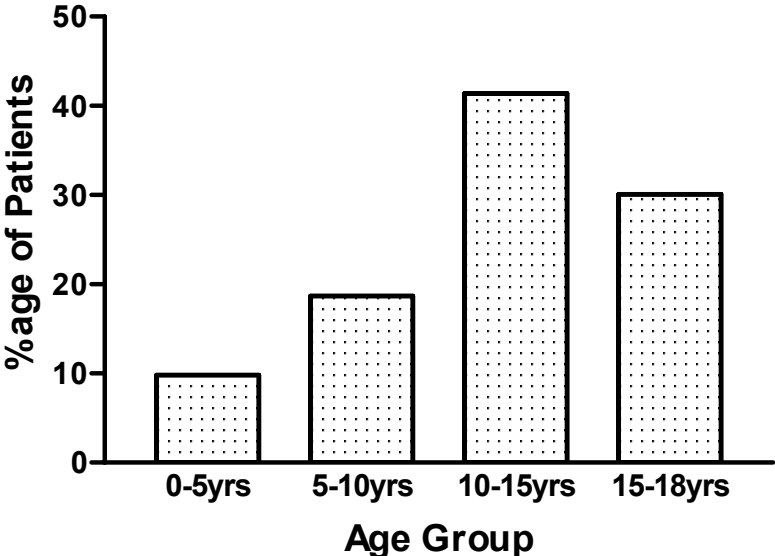


Figure 15.1 Age distribution of population.

The majority of patients looked after in paediatric units present at a young age, as demonstrated in Figure 15.2. This is secondary to the high prevalence of congenital rather than acquired disease as the cause of ESRF in childhood (renal dysplasia 27%, posterior urethral valves 16%). The prevalence of ESRF in childhood remains unchanged at 12.2 per million of the population, as does the annual take on rate at 1.7 per million of the population. The age distribution of the patients presenting in the past year is shown in Figure 15.3. the difference between this and Figure 15.2. is due to the prolonged duration of care the younger patients receive in the paediatric unit compared with the older patients.

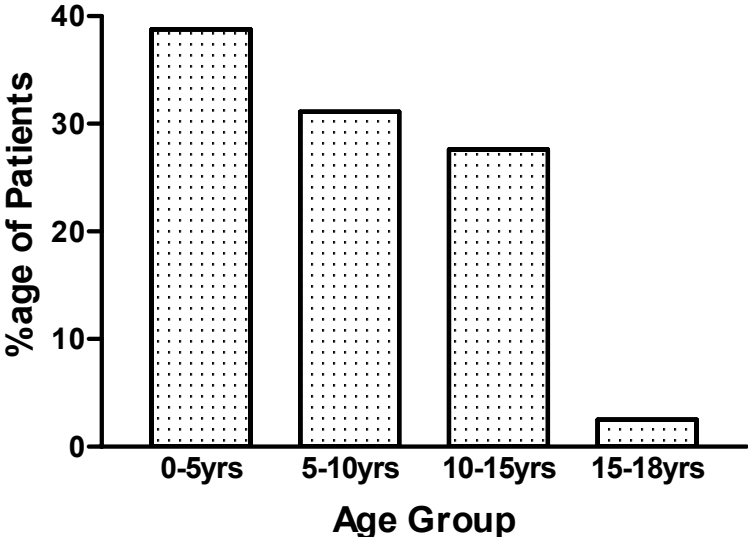


Figure 15.2 Age distribution of the patients at presentation with ESRF.

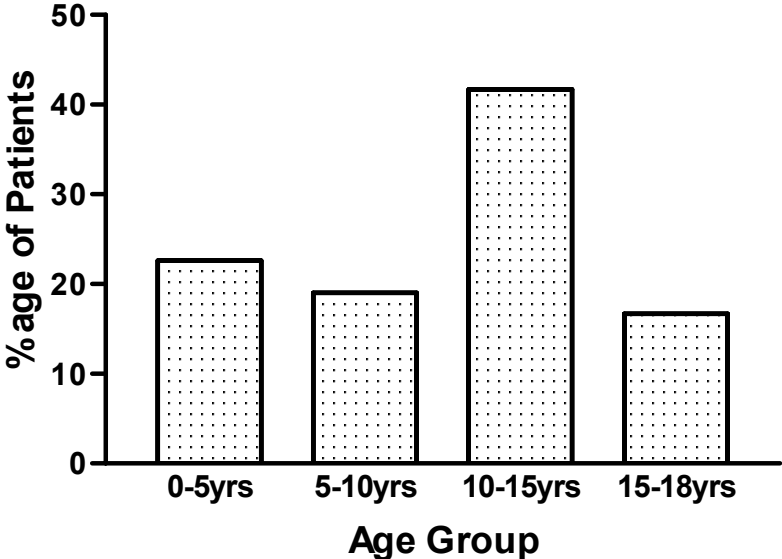


Figure 15.3 Age distribution of patients presenting with ESRF in the previous year.

The under 15 year old population ought to represent a complete cohort of paediatric patients as few will be treated in adult units under this age. Table 1. shows a comparison of the total number of under 15 year olds in the year 2000 compared with 1992. This has been broken down according to treatment modality. There has been an overall increase in the cohort of

23% as reported last year. There has also been a significant change in the distribution of patients between treatment modalities (Chi-squared = 15.77, p=0.0004). This change is composed of two swings. First there is a significant increase in the proportion of the total population with a functioning allograft (p=0.0053, Fisher's exact test) and second there has been a significant swing towards haemodialysis in those without functioning allografts (p=0.0078, Fisher's exact test). The reasons behind the second trend are explored further below.

Year	Total	HD	PD	Transplant
1992	429	38	108	283
2000	528	56	79	393

Table 15.1 Comparison of patient stock and treatments between 1992 and 2000.

**Treatment modality.**

Transplantation is clearly the treatment of choice for paediatric patients and on cross sectional analysis 76% of patients had a functioning renal allograft. The age distribution of the patients broken down according to whether they are on dialysis or have a functioning renal allograft is shown in Figure 15.4. The distributions of patients are significantly different from each other (Chi-square = 38.24, p<0.0001) with that of the transplanted patients mirroring that of the total population whereas the distribution of dialysis patients is fairly flat. Under the age of 5 years there are more dialysis patients than transplant patients, beyond this age there is an approximately 4:1 ratio of transplanted to dialysis patients. Thus even with growth of the total numbers it will be some time before the total number of dialysis patients across the UK exceeds 200. This, together with the knowledge that even fewer patients are on long-term dialysis and they are split between peritoneal and haemodialysis, emphasises the need for national or even international studies of treatments to provide analysable outcome data.

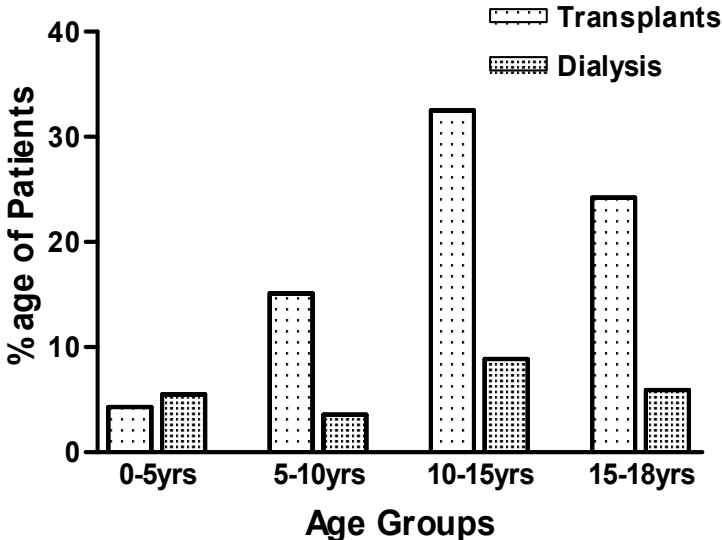


Figure 15.4 Age distribution of the patients according to treatment.



## **Transplant origins and immunosuppressive regimes.**

Data on transplant origin was available for 467 grafts, 98.7% of the total. The vast majority, 405 (86.7%) were cadaveric with just 62 (13.3%) from living related donors. These figures represent point prevalence rather than incidence and, as the overall outcome and longevity of graft survival is longer with living related allografts the incidence of LRD transplantation will be less than the 2:13 ratio demonstrated here.

The emphasis on transplantation being the treatment modality of choice for paediatric patients is also shown by the prevalence of pre-emptive transplantation in anticipation of the need for dialysis. 103 patients with functioning grafts had received that graft pre-emptively (Figure 15.5.)

Transplantation is a major activity area within paediatric nephrology and 83 of the 467 grafts (17.8%) had been performed over the previous 12 months. The breakdown of these according to whether they were cadaveric or from living related donors and the numbers of pre-emptive transplants are shown in Figure 15.6. It can be seen that the proportion of pre-emptive transplants remains unchanged at a little over 20%. The proportion of transplants from living related donors is significantly higher however at 30% of those transplanted over the previous 12 months compared with 10% of those transplanted before this ( $p < 0.0001$ , Fisher's exact test). This could be due to an overall increase in the rate of transplantation or an increased awareness and usage of living related donor kidneys due to the overall shortage of available grafts. The latter is more likely and future reviews of the data will be able to confirm this and demonstrate the size of the trend.

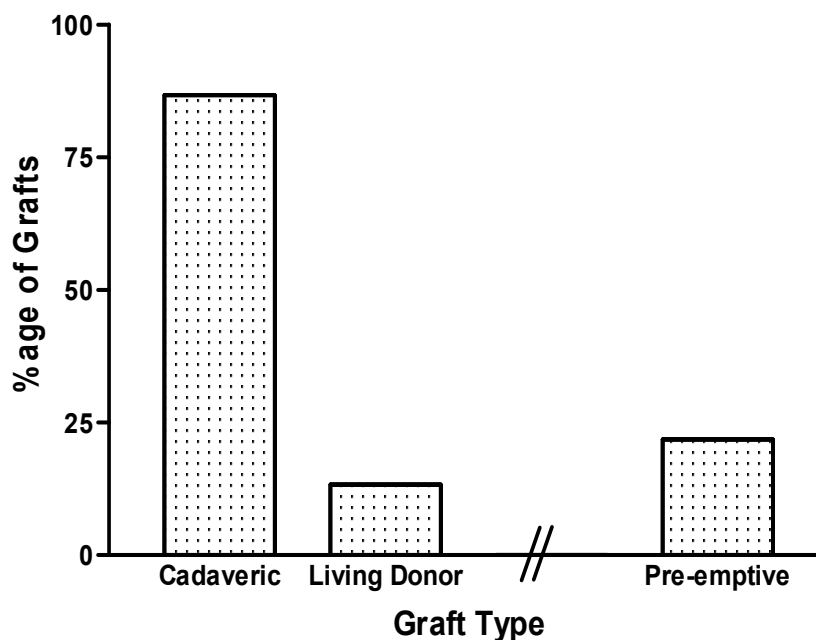
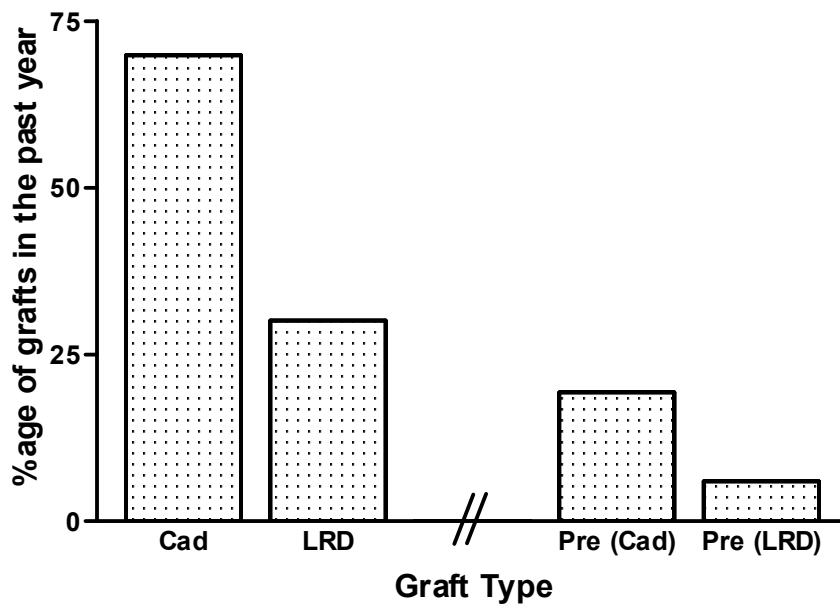


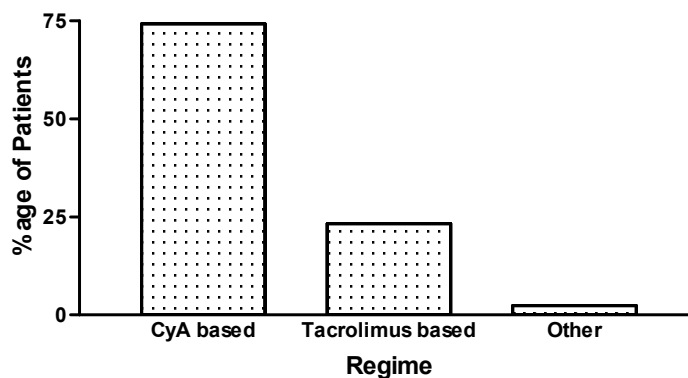
Figure 15.5 Types of graft used.



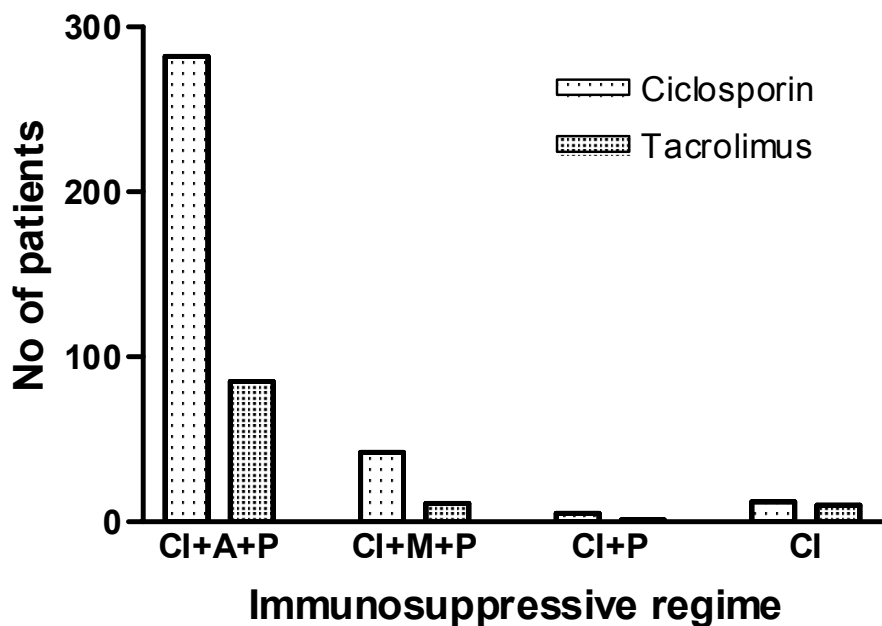
(cad = cadaveric, LRD = Living related donor, Pre = pre-emptive).

**Figure 15.6** Types of graft used over the past year

Details of maintenance immunosuppressive regimes were available for 459 patients (97% of the cohort). Regimens were fairly uniform across the country. The vast majority of patients, 84.7%, were receiving triple therapy with a calcineurin inhibitor, steroids and either azathioprine or mycophenolate. 11.6% were receiving dual therapy with a calcineurin inhibitor and steroids, whilst 1.3% were on monotherapy with a calcineurin inhibitor. The remaining 2.4% were on varied regimes without a calcineurin inhibitor. Despite only recently being the subject of a randomised controlled study, and perhaps because of its side-effect profile, Tacrolimus based regimes have become rapidly popular with almost 1 in 4 patients receiving a calcineurin inhibitor being on Tacrolimus rather than Cyclosporin A (Figure 15.7.). There was no significant difference in the breakdown of regimes used comparing those on Cyclosporin with those on Tacrolimus (Figure 15.8.). Although virtually all patients were receiving steroids as a single alternate day dosage only 1.3% of patients were receiving no steroid. This may be an important factor with regard to growth and weight gain.



**Figure 15.7** Basic immunosuppression regimens.



. (A = azathioprine, M = mycophenolate, P = prednisolone)

**Figure 15.8 Breakdown of immunosuppressive regimes split according to the calcineurin inhibitor (CI) used**

### ***Renal function in patients with transplants.***

Clearance in patients with functioning renal allografts has not been formally measured on a regular basis. Some units measure GFR formally on an annual basis and obtaining a formal GFR measurement on all transplant patients annually is worth consideration. The best estimate of glomerular filtration rate (GFR) available is that calculated using the Schwartz formula ( $40 \times \text{height} / \text{creatinine}$ ). This predicted GFR (pGFR) is a better estimate than the creatinine alone as it takes account of the different normal ranges of creatinine expected for patients of different sizes.

Both a serum creatinine and a height measurement on the same day were available for 443 patients and 4 patients had a measured GFR result available, giving data in 94.5% of those with functioning allografts. Renal function was divided into bands of 20mls/min/1.73sq.m. Those with a pGFR <20mls/min/1.73sq.m were deemed as having poor function whereas those with a pGFR >60mls/min/1.73sq.m were deemed as having excellent function (normal range 80-120mls/min/1.73sq.m). Figure 15.9. Shows the breakdown of patients according to these bands. It is pleasing to see that 43% of patients have excellent function and over 85% have very good function with only 1.6% being in a situation where function is poor and either dialysis or re-transplantation is going to be required soon.

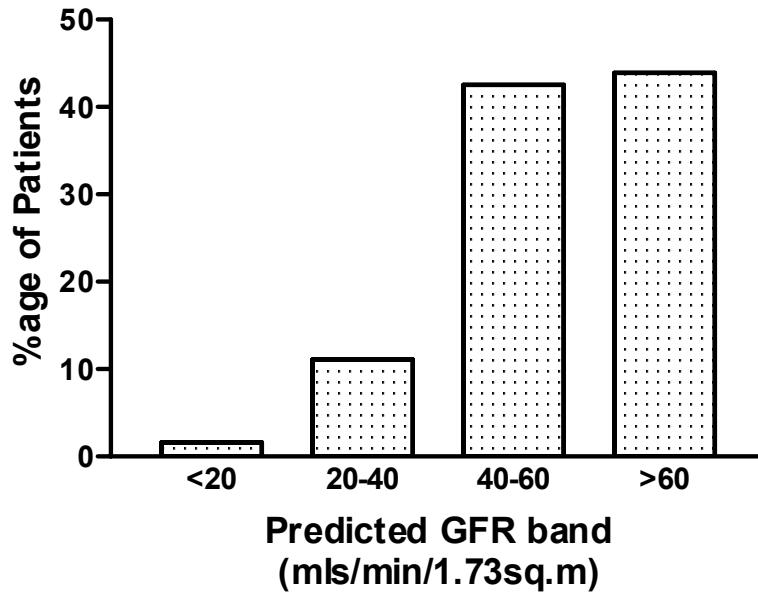


Figure 15.9 Predicted GFR in patients with functioning allografts.

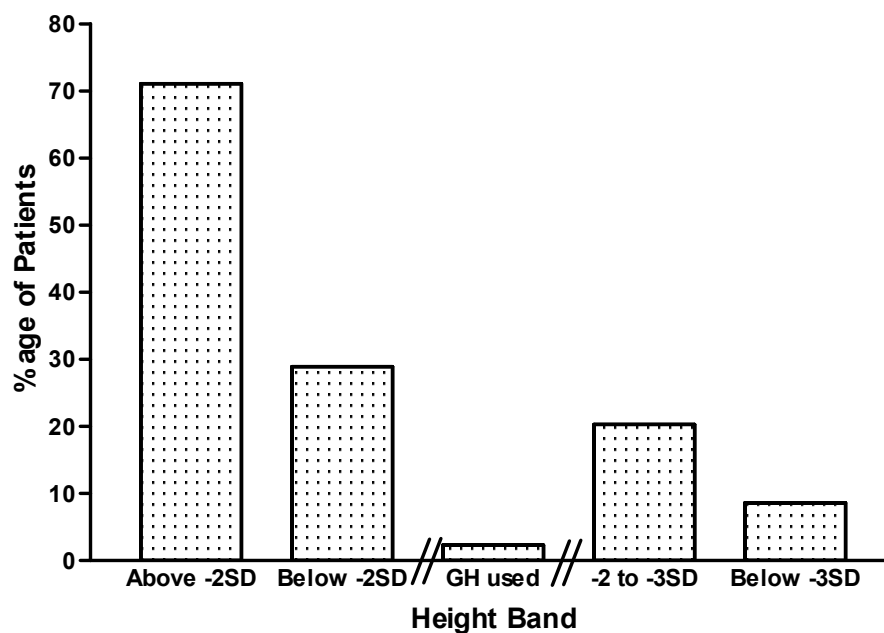
***Growth and nutrition in patients with transplants.***

The normalisation of growth, nutritional status and development are three of the major goals of paediatric nephrologists. Difficulty in achieving these goals on dialysis is one of the reasons for the high incidence of pre-emptive transplantation. Audit of how often these goals are met after transplantation is therefore essential.

Due to changes in the normal ranges for height, weight and body mass index with age, all values have been converted to standard deviation (SD) scores from the mean for age. Thus an average value would be 0 and the accepted normal range between -2 and +2 SDs from the mean. Growth can be judged by height on the whole, though with variability in the age of puberty and its associated growth spurt correction for bone age could be justified. Bone age is not a part of the current data set and so no correction has been made in the analysis of this data. Consideration needs to be given to the inclusion of bone age in future data collections. Weight alone can be a misleading measurement of nutritional status. Ideally estimates of skinfold thickness and lean body mass would be obtained. On a practical basis the best estimate of nutritional status is given by body mass index (BMI) (weight / (height)<sup>2</sup>). This measurement has been validated across the normal population and automatically takes account of low weight secondary to short stature rather than under-nutrition.

Data on height was available in 443 patients, 93.7% of those with functioning allografts. Figure 15.10. shows a breakdown of heights according to standard deviation score. The two columns to the left divide the population into those who were above -2 SDs from the mean (i.e. within the normal range) and those whose height lay below -2 SDs from the mean. A total of 128 patients, 29% of those with functioning allografts, were below -2SD's from the mean. The two columns on the right break this 29% down further into those who were between -2 and -3 SDs from the mean and those who were very small at below -3 SDs from the mean. There were 38 patients, 8.6% of the group who fell into this category. Some conditions causing renal failure in childhood (such as cystinosis) are associated with extreme short stature. However, these conditions account for fewer than 5% of those with renal failure in childhood and, therefore, is not an explanation for the high proportion of small children in

this cohort. Growth hormone has been used to help growth both before and after transplantation in children. The central column in Figure 15.10. shows the proportion of children receiving growth hormone at the time of data collection. Though there are some concerns about side effects of growth hormone after transplantation it was surprising to find that with 29% of the population being below the normal range for height only 11 patients (2.3%) were documented to be receiving growth hormone at the time of data collection. The low rate of usage of growth hormone in transplant patients reflects concern about both the safety and efficacy of this agent in this group of patients. The development of guidelines by the BAPN followed by audit of outcome would be beneficial.



**Figure 15.10 Growth in patients with a functioning allograft.**

Poor nutrition (BMI more the -2SD's from the mean) was not a problem in patients with a functioning allograft but obesity was. A total of 102 patients, 23%, were significantly overweight with a body mass index of more than 2 SDs above the mean. Of these 21, 4.7%, were very obese at more than 3 SDs above the mean (Figure 15.11.). Although the general population trend in children is towards increasing weight and relative obesity, these results are very concerning. Cardiovascular disease is a major cause of death and co-morbidity in adults with renal failure and the combination of obesity with immunosuppressive drug induced hyperlipidaemia and hypertension form a potentially lethal triad for future years when these patients are young adults. More work looking at longitudinal profiles is required to trace the origins of obesity. Immunosuppressive regimens may need review in the light of this data. The BAPN is considering extending its data set to include data on lipids, so that multi-factorial analysis looking at the three parameters detailed above can be performed.

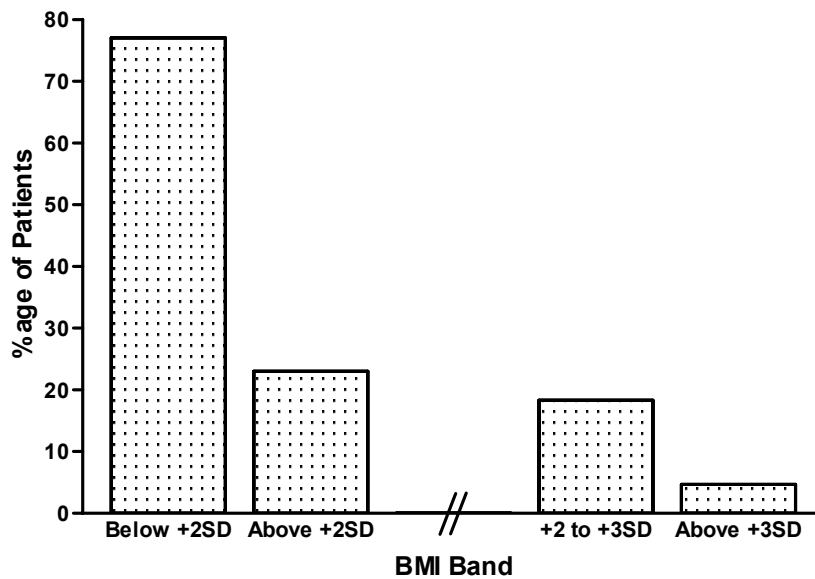


Figure 15.11 Body mass index in patients with functioning renal allografts.

**Dialysis modality and access.**

For patients on dialysis, peritoneal dialysis (PD) has always been the preferred mode of treatment within paediatrics. Of the 148 patients on dialysis in this cohort 94 (63.5%) were on PD. Figure 15.12. shows a breakdown of the modality of dialysis used according to age. It can be seen that although the proportion of patients on peritoneal dialysis is higher in most age groups, there are more patients on haemodialysis (HD) in the 10-15 year old band.

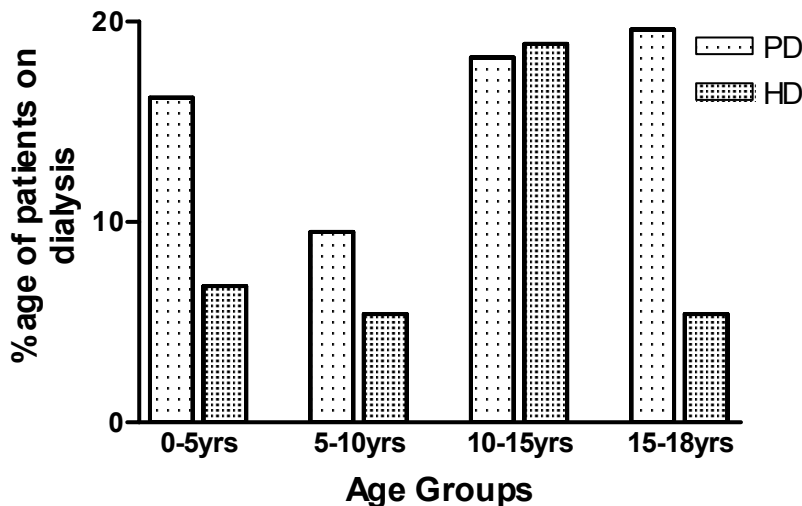


Figure 15.12 Distribution of patients between PD and HD currently.

Moreover, comparing the distribution of dialysis treatments at presentation (Figure 15.13.) to the current distribution it is clear that as the number of older patients increases (i.e. the number who have had a long history of ESRF increases) the number on haemodialysis increases. This would suggest that, either through choice or necessity, (e.g. loss of peritoneal access or function) patients with more longstanding ESRF are being treated with haemodialysis. This needs further investigation with longitudinal rather than cross-sectional

studies as it has major implications for the planning of the provision of dialysis services. More importantly, if this trend turns out to be secondary to loss of peritoneal function, this will have major implication for adult services inheriting these patients. This is particularly the case as most haemodialysis access is through central venous lines, which can jeopardise long-term vascular access.

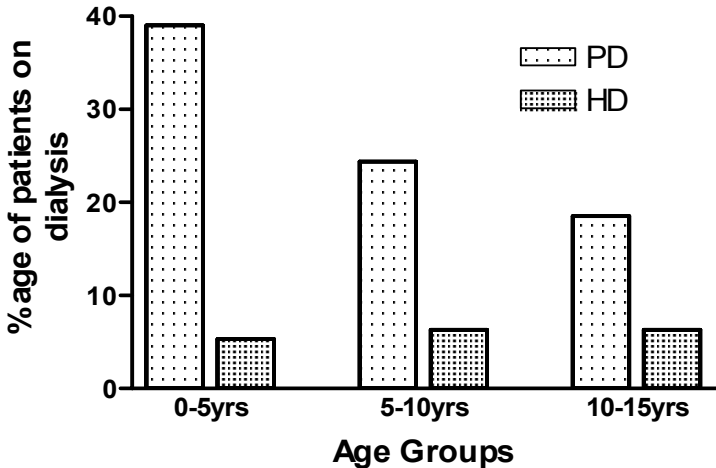


Figure 15.13 Distribution of patients between PD and HD at Day 90 of ESRF.

Details on haemodialysis access were available for 50 of the 54 patients on HD (92.6%). Access was broken down according to whether the patient was being dialysed through a central line (CL), an arterio-venous fistula (AVF) or some form of arterio-venous graft (AVG), be this synthetic or using one of the patient’s veins. The distribution of types of vascular access is shown in Figure 15.14 below. It is noticeable that no children below the age of 10 were on regular haemodialysis through an arterio-venous fistula and even in the older 10-15 year old age-band, two thirds of the children had central lines for dialysis. In the light of the well-recognised published complications of central venous access for dialysis, an audit of dialysis access sites no longer available in young adults transferred to adult dialysis facilities would be well worthwhile. Further thought needs to be given to the difficulties of establishing vascular access in small children.

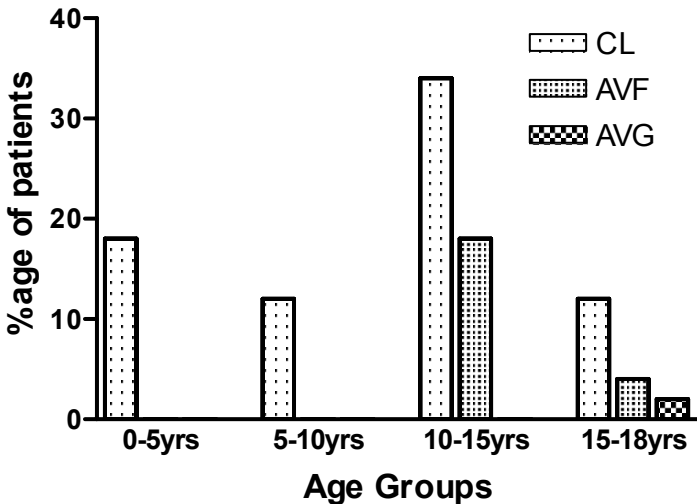


Figure 15.14 Vascular access for dialysis in different age-groups.

For those patients on peritoneal dialysis, automated cycling dialysis is clearly preferred over CAPD. Figure 15.15 shows a breakdown of the type of peritoneal dialysis used according to age-group. In this particular cross-sectional analysis, there were no children under the age of 5 on CAPD. After the age of 5 the proportion on CAPD steadily rises but the overall number of children on CAPD is only 11.6% and even in the 15-18 year old group, the proportion on CAPD rather than automated PD is still less than one third.

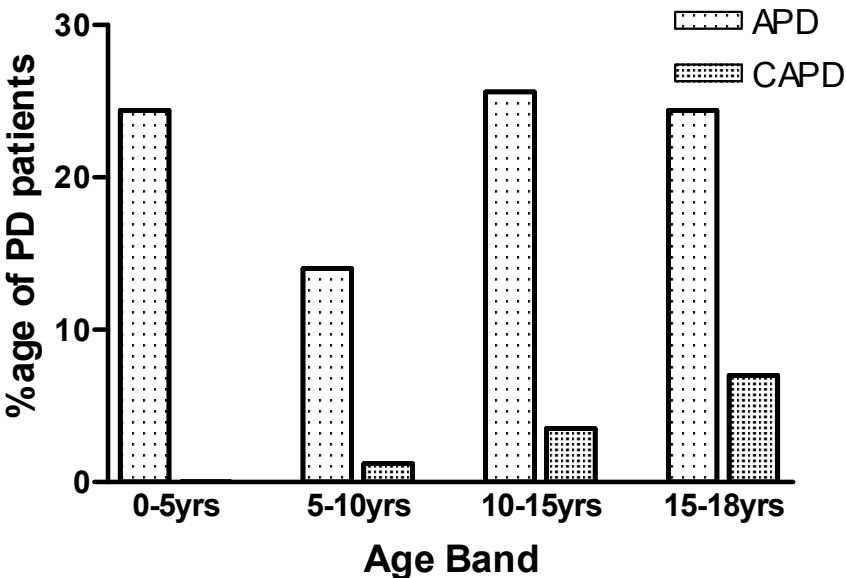


Figure 15.15 Division of PD patients between automated PD (APD) and CAPD.

**Dialysis efficiency.**

The original data set defined for the Paediatric Registry did not contain any specific measures of dialysis efficiency. Although the vast majority of paediatric patients with ESRF are transplanted and those on dialysis are only treated in this way for short periods of time, it is clear that more specific measures of dialysis efficiency are going to be required for the assessment of dialysis effectiveness in the small number that require long term dialysis. These will also be of value in the assessment of growth and nutrition in children. Measures of dialysis efficiency are being included in the new specification for the Paediatric Registry and data from this will become available over the next 12-24 months.

On a day-to-day basis judgements about dialysis efficiency are made on the patient’s biochemistry and particularly the serum creatinine and calculated pGFR as detailed in the section on transplant renal function. These will clearly both take account of the patient’s native renal function as well as the clearance provided by dialysis but they will not allow separation of these two factors. Although GFR is usually expressed in mls/min/1.73sq.m it is more usual to look at dialysis clearance in terms of litres/week. Table 2. below converts the mls/min values as calculated into litres/week.

GFR in mls/min/1.73sq.m	Clearance in litres/week/1.73sq.m
5	50.5
7.5	75.6
10	100.8

Table 15.2 Comparison of standardised GFR with clearance in litres/week.



Figure 15.16. gives a breakdown of the clearances obtained in both PD and HD patients. In the PD patients the samples will have been obtained whilst in a steady state. In HD patients the samples were obtained before dialysis. It can be seen that the majority of patients have an apparently good clearance when combining their dialysis component with native renal function. Until more data is collected on residual native renal function and dialysis efficiency, it is not going to be possible to correlate these figures with other measures of outcome.

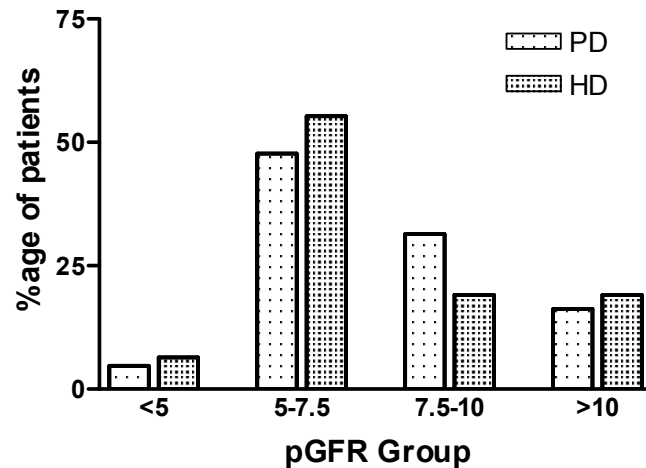
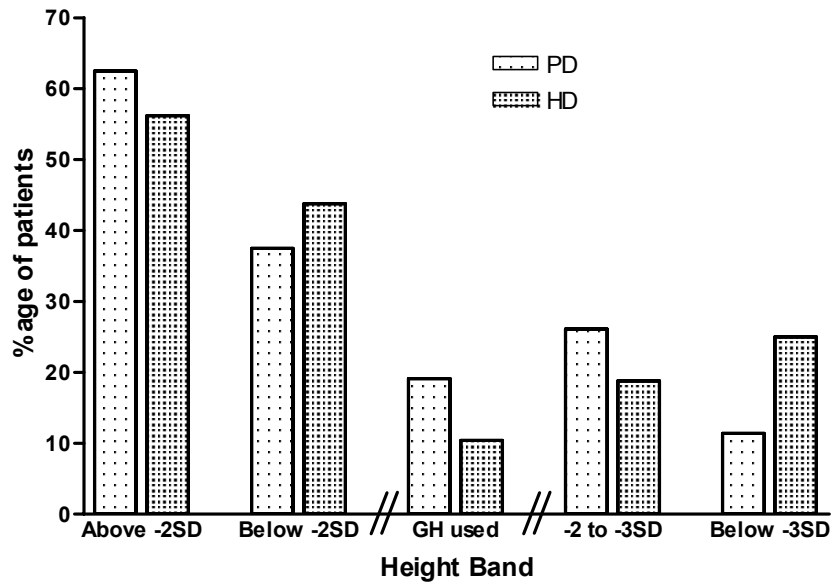


Figure 15.16 Dialysis efficiency as measured by pGFR in HD and PD patients.

### ***Growth and Nutrition in Dialysis Patients.***

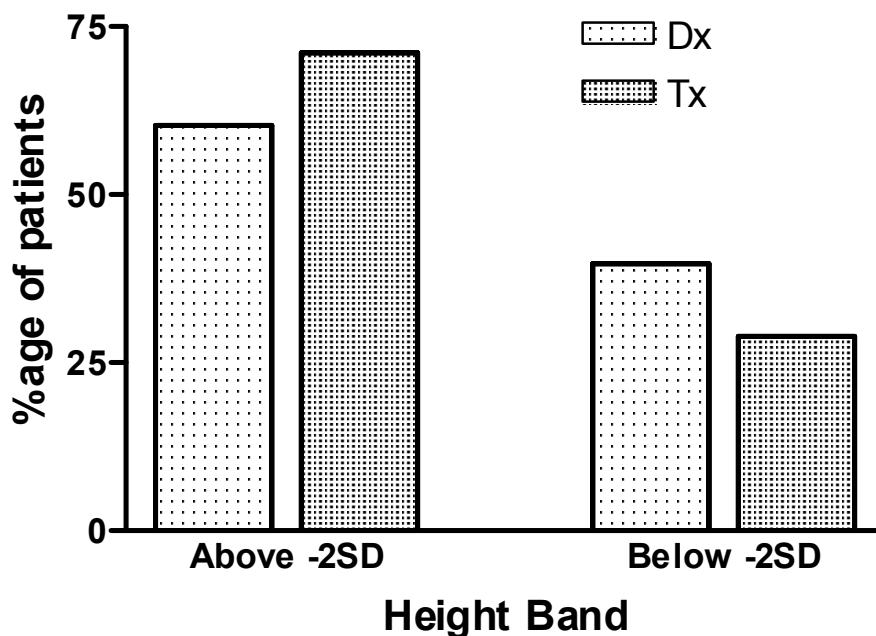
Data with regard to height, weight and body mass index were available in 48 of the 54 patients on haemodialysis (88.9%) and in 88 of the 94 patients on peritoneal dialysis (93.6%). As with the section on growth in transplant patients the data has been broken down into those who had heights more than 2 SDs below the mean for their age and those who were less than 2 SDs below the mean for their age. Those who were more than 2 SDs below the mean were then subcategorised into those who were small and those who were very small at more than 3 SDs below the mean for their age. As before, data on bone age was not available and therefore no corrections for this or pubertal status have been made.

The four columns to the left-hand side of Figure 15.17. show the patients divided according to their dialysis modality and also according to whether they were more than 2 SDs below the mean for height or above this level. It can be seen that 37.5% of PD patients and 43.8% of HD patients were small for their age. The four columns to the far right of Figure 15.17. show the further breakdown of the short stature group. A total of 22 patients were more than 3 SDs below the mean for height for their age, this being 16% of the cohort. The central columns show the numbers of patients being treated with growth hormone. It is clear that with 28 patients (20.6%) of the group receiving growth hormone therapy, concern about short stature is much greater in the dialysis population than in the transplant population.



**Figure 15.17** Height achievement in dialysis patients.

Figure 15.18. shows a comparison of height achieved in dialysis patients compared with height achieved in transplant patients. Overall, as detailed above, many children with transplants remain small, despite this height achievement in dialysis patients was significantly worse ( $p = 0.02$ , Fisher's exact test). On the basis that very few transplanted patients are receiving growth hormone, this is presumably an effect of transplantation itself. Further studies sub-dividing patients according to their primary diagnosis, duration of renal failure and time spent on dialysis will be required to clarify this further.



**Figure 15.18** A comparison of height achieved in dialysis (Dx) vs transplant (Tx) patients.

The achievement of adequate nutrition is a major hurdle in paediatric nephrology. The use of supplementary feeds either through a naso-gastric tube or via a gastrostomy have become commonplace. Inadequate nutrition is closely related to increased co-morbid complications

and was previously felt to be a major element of the growth failure suffered by so many patients with ESRF. Figure 15.19. below shows that, with the close attention currently given to nutrition, the vast majority of patients have a normal body mass index.

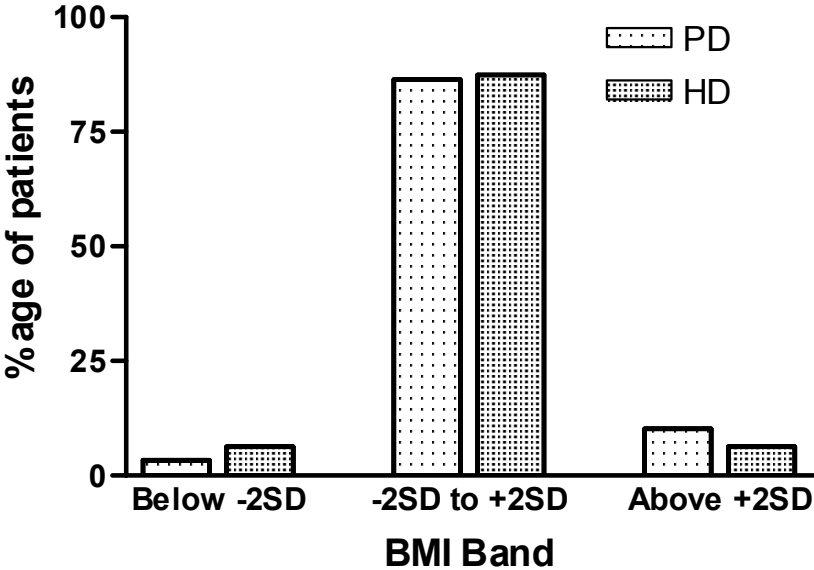


Figure 15.19 Body mass index in patients on dialysis.

Only 6 patients (4.4%) had a BMI more than 2 SDs below the mean for their age. Twelve patients (8.8%) actually had a high BMI at over 2 SDs above the mean for their age and were therefore overweight. No dialysis patient was more than 3 SDs above the mean for their age and comparing BMI in dialysis patients with transplant patients it is clear that obesity is significantly more common in this latter group (p=0.0002, Fisher’s exact test)

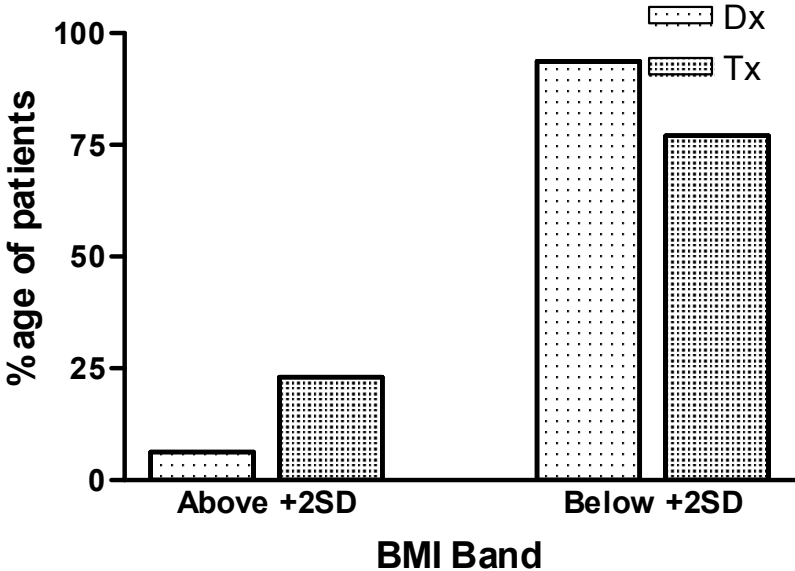
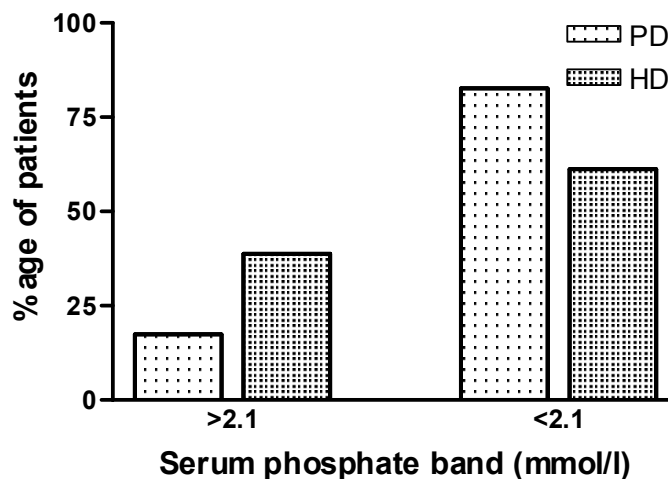


Figure 15.20 A comparison of BMI in dialysis (Dx) vs transplant (Tx) patients.

## **Bone disease, PTH and phosphate.**

Although control of renal osteodystrophy and maintaining a normal serum calcium and phosphate would be considered an essential part of the management of dialysis patients (particularly where striving to achieve adequate growth), these factors were amongst the most incomplete data items submitted. Serum phosphate was available in 91.2% of dialysis patients but PTH was only documented in 49.3%

Serum phosphate is naturally higher in infancy than in children and adults. Although the Renal Association standards suggest that phosphate is kept within the normal range for age this is difficult to achieve in practice and data from the Renal Registry report in 1999 suggested that co-morbid complications in adults increased significantly once the serum phosphate was above 2.1mmol/l. Figure 15.21. Shows the percentage of dialysis patients with a serum phosphate above and the percentage with a serum phosphate below 2.1mmol/l. The groups are split according to dialysis modality. No infant actually had a serum phosphate above 2.1mmol/l so the figures were not skewed for the worse because of the different normal range in this group. It can be seen that overall 25% of patients had a serum phosphate above 2.1mmol/l. Phosphate control in haemodialysis patients was significantly worse than that in peritoneal dialysis patients ( $p=0.0077$ , Fisher's exact test). Although this could be in part due to the fact that blood sampling in PD patients was performed whilst they were in a steady state whereas blood sampling in HD patients was pre dialysis, this effect has not been noted before. It may well be that phosphate is better removed in PD patients, alternatively this group might be more adherent to their dietary restrictions. Whichever, phosphate control as a whole needs improvement in the paediatric dialysis population. Much of the difficulty lies with the difficulties in administering phosphate binders to children and trials of new agents are urgently required.



**Figure 15.21 Serum phosphate in dialysis patients split according to dialysis modality.**

Within adult practice the norm is to try to maintain PTH above the normal range to avoid adynamic bone disease but below three times the upper limit of normal to prevent renal osteodystrophy. There is no information as to whether adynamic bone disease is a problem in children or not. Therefore setting a lower limit for PTH is not possible. Renal osteodystrophy and hyperparathyroidism are definite problems in children with renal failure. Formal standards for PTH will be issued in the forthcoming standards document. Figure 15.22. shows the percentage of patients with a PTH above and the percentage of patients with a PTH below 3 times the upper limit of normal, split according to dialysis modality. It can be seen that

overall 29% of patients had poor control of bone disease with a PTH over 3 times the upper limit of normal. With regard to this parameter HD patients fared significantly better than PD patients ( $p=0.036$ , Fisher's exact test). However, with less than 50% of the data being returned this statistic needs to be interpreted with caution.

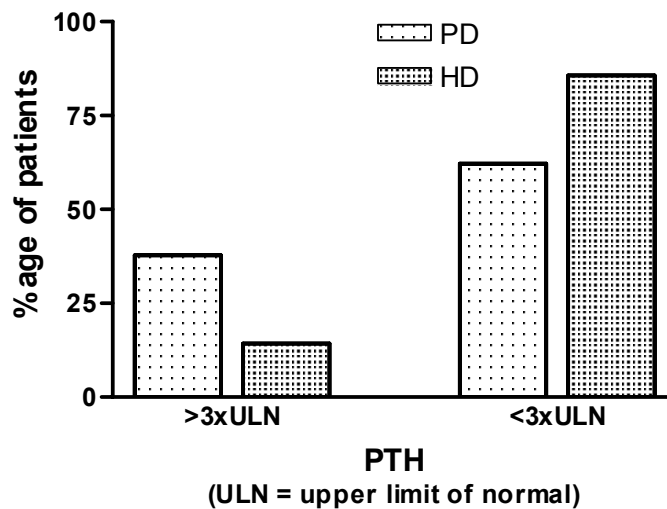


Figure 15.22 Serum PTH in dialysis patients split according to dialysis modality.

### ***Haemoglobin and erythropoietin usage in dialysis patients.***

Data on haemoglobin and the usage of erythropoietin was available in 138 patients, 93.2% of the dialysis patients. Erythropoietin was documented as being used in 119 of these (80.4%). Other patients may well have received erythropoietin but were not doing so at the time of the completion of the record because of a high haemoglobin or some other factor. The distribution of haemoglobins is shown in Figure 15.23. There was a trend towards higher haemoglobins in peritoneal dialysis compared with haemodialysis patients but this was not statistically significant. Again standards for haemoglobin will be appearing in the new standards document. These will vary according to age as normal haemoglobin levels vary with age. All the standards are likely to be at or above 10g/dl. Overall 67% of patients had a haemoglobin over 10g/dl whilst just 5% had a haemoglobin under 8g/dl. Information on the usage of intravenous iron supplementation was not available for this data collection but will be recorded in future collections.

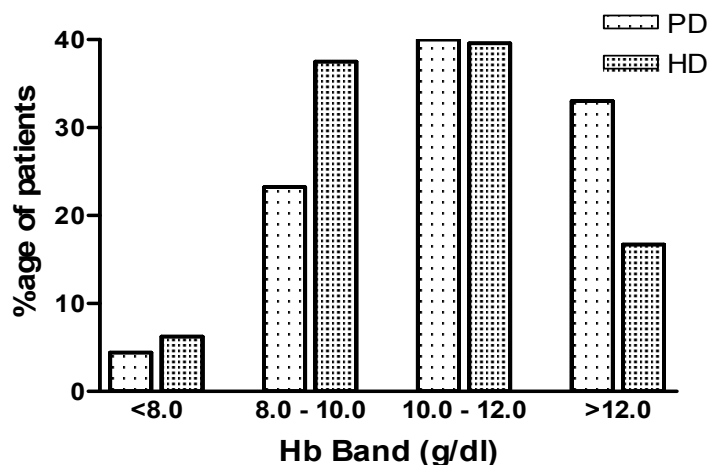


Figure 15.23 Haemoglobin in dialysis patients split according to dialysis modality.

## **Conclusion.**

These data presented above clearly demonstrates the potential value of a paediatric renal registry. Data collected from any one individual unit cannot provide a view of trends and achievements as small numbers and individual patient circumstances prevent the formation of a global overview. There are some potential negative points within this report such as height achievement, obesity in transplant patients and haemoglobin levels in dialysis patients. There are, however, many positive points and these are outlined in the message box below. Improvement in the paediatric service can be achieved through the use of this data, the setting of appropriate standards for children based on our current knowledge and the creation of an audit cycle through further data collections by the registry. Paediatric Standards are currently being set and will be published as a part of the new Adult Standards document. Next year we will be able to gauge performance against these standards.

### **Positive aspects of the year 2000 analysis.**

- 76% of children with ESRF have a functioning renal allograft.
- 86% of transplant patients have a pGFR >40mls/min/1.73sq.m.
- 71% of transplant patients are achieving heights within the normal range.
- 95% of dialysis patients are achieving a pGFR >5mls/min/1.73sq.m.
- 87% of dialysis patients are optimally nourished.

This report was reviewed and revised by the BAPN registry subcommittee. It is presented by that committee on behalf of the BAPN.

The subcommittee consists of :-

Dr Jane Tizard, Bristol

Dr William van't Hoff, London

Prof Adrian Woolf, London

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Dr Malcolm Lewis Manchester

Mrs Jo Shaw has been responsible for much data collection and collation and helped with construction of the manuscript.

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We would like to thank Roche for their financial support of the Registry.

## Chapter 16: Survival of patients on Dialysis

### ***Introduction***

The database of patients available in the 'Renal Registry' enables analysis of the influence of different factors on patient survival. These factors either reflect patient case mix [e.g. age, gender, ethnicity, underlying diagnosis & other co-morbidity] or are dependent on treatment [e.g. haemoglobin, mode of dialysis, phosphate level]. 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 dialysis of incident and prevalent patients. Patients are censored at transplantation or 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. The analysis shows that 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 :

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

Patients were 'censored' from the relevant date if one of the following occurred:

1. He / she was 'transferred out' to a renal unit that did not contribute to the 'Renal Registry'.
2. He / she was transplanted.

If a patient died on the day of transplantation, the death was not included.

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 whilst on dialysis of the incident 1997 and 1998 cohorts***

### ***Introduction***

It has been widely recognised that the mortality rate of a cohort of patients during the first 90 days after starting renal replacement therapy exceeds the mortality rate during any subsequent 90-day period. In part this may be due to the inclusion in the analysis of patients whose death is inevitable from advanced an acute or chronic multi-system disease which is contributing to renal failure. There is also difficulty in classification of patients, and some patients who die with acute renal failure may be included by some centres.

This analysis examines the influence of age on the survival on dialysis of incident patients, and then compares the survival on dialysis, adjusted for age, of patients starting renal replacement therapy during one year.

### ***Patient Cohort***

Patients were included in the analysis if they had started renal replacement therapy with dialysis in one of 'Renal Registry' sites during 1997. the same analysis was repeated for 1998

### ***Statistical methods***

Adjusted survival probabilities were calculated using a 'Stratified Proportional Hazards Model (Cox)' adjusting for age and stratifying by centre. However this methodology cannot be applied to analyse death throughout the first 12 months of therapy because the risk of death is not constant when the first 90 days are included in the analysis. For this reason an analysis has been undertaken of survival during:

- a. The first 90 days of treatment.
- b. The 12 months after the first 90 days of treatment

The mean patient age of the cohort starting RRT in 1997 was 59.2 years and the survival probabilities estimated from the model for each centre were adjusted for a population of mean



age 59.2 years for both 1997 and 1998 cohort (which had a median age of 60.3). Patients were classified according to the centre where they died, or where they were receiving treatment at the beginning of the follow up period.

### *Analysis adjustment*

In the adjusted analysis most centres show an increased survival after adjustment to a median age of 59.2 years. Intuitively it seems wrong that an adjustment towards the mean population results in an improvement for the majority of centres. However this adjustment is correct. This is because the older patients die at a higher rate than the younger patients, leaving a younger cohort as the patient cohort progresses through the one year. In 1998 the cohort had a slightly older median age, but all centres have been adjusted to 59.2 at 90 days and 58.3 in the 1 year after 90 days, to directly compare the 1997 and 1998 incident survival.

### **The stratification method used in this adjusted analysis precludes any testing for statistical significance of the difference in survival between renal units**

## **Results**

### *The influence of age*

In the units contributing to the UK Renal Registry 11.2% of patients die within the first 90 days of treatment in the 1997 cohort and 11.5% in the 1998 cohort. . Of those who survive the first 90 days of treatment, a further 13.3% die during the next 9 months and 17.6% within 12 months. The increase in hazard of death for every increase of 10 years in patient age differs considerably when comparing these 3 time periods (table 16.1)

<b>Death during</b>	<b>Increase in hazard for every increase of 10 years in patient age (% [95% CI %])</b>
First 90 days	75 [47-108]
90 days - 15 months	38 [21 - 58]

**Table 16.1 Relationship of age and hazard of death in 1997 cohort**

These results support the clinical impression that it is mainly elderly patients that die during the first 90 days of treatment. From the data it was possible to make adjustments for age in subsequent analyses.

### *Survival on dialysis during the first 90 days of treatment.*

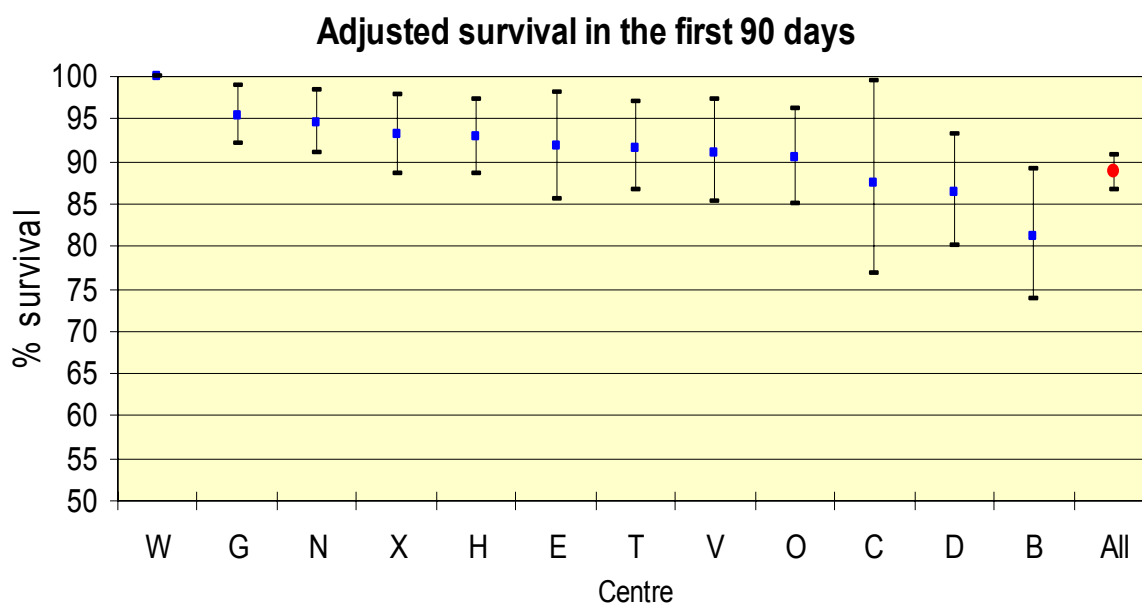
There was wide variation between centres in the unadjusted survival of patients during the first 90 days of treatment (table 16.2, figure 16.1). At one extreme in one small centre in 1997 cohort no patients died during the first 90 days of treatment, whilst at the other extreme only 77% of patients survived the first 90 days in another centre.

<i>Centre</i>	<b>Unadjusted 90 Day Survival 1998</b>		<b>Adjusted 90 Day Survival 1998</b>		<b>Adjusted 1997 KM</b>
	<b>95% CI</b>				
	<i>KM</i>		<i>KM</i>	<i>95% CI</i>	
A	86.8	75.7 – 97.9	90.3	82.7 – 98.6	

Centre	Unadjusted 90 Day Survival 1998		Adjusted 90 Day Survival 1998		Adjusted 1997 KM
	95% CI		95% CI		
	KM		KM		
B	74.5	67.5 – 81.5	81.5	75.3 – 88.3	81.1
C	94.5	87.0 – 100	95.6	89.8 – 100	87.3
D	87.1	79.1 – 95.1	91.3	86.1 – 97.0	86.4
E	84.6	75.6 – 93.6	90.7	85.4 – 96.5	91.7
F	88.9	82.9 – 94.9	92.2	87.9 – 96.6	
G	91.7	87.7 – 95.7	93.6	90.4 – 96.9	95.4
H	86.1	79.8 – 92.4	88.6	83.6 – 93.9	92.9
K	92.7	84.7 – 100	94.7	89.1 – 100	
L	90.6	85.4 – 95.8	93.2	89.5 – 97.0	
M	88.8	81.3 – 96.1	92.7	87.3 – 98.5	
N	91.3	85.8 – 96.8	93.9	90.3 – 97.7	94.6
P	88.5	83.1 – 93.9	92.4	88.7 – 96.2	90.4
Q	93.8	89.7 – 97.9	95.3	92.2 – 98.6	
R	85.0	77.0 – 93.0	86.9	80.4 – 94.1	
S	85.3	76.3 – 94.3	89.2	86.7 – 91.8	
T	89.6	84.2 – 95.0	89.4	84.1 – 95.0	91.6
V	89.8	82.5 – 97.1	92.1	86.6 – 97.9	91.0
W	93.8	86.8 – 100	96.7	93.0 – 100	100
X	88.8	81.3 – 96.1	91.8	86.5 – 97.4	93.1
E&W	88.1	88.0 – 88.2			88.7

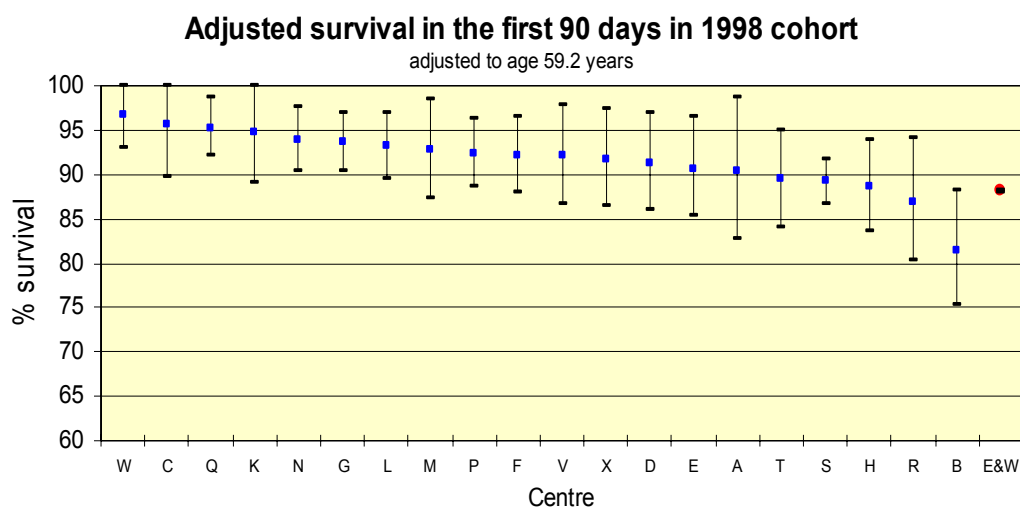
(Adjusted on basis of the mean age 59.2 years)

**Table 16.2 Survival during the first 90 days on dialysis 1998 cohort**



Adjustment has been made on the basis of the mean patient age (59.2 years)

**Figure 16.1a Adjusted survival during the first 90 days, 1997 cohort**



**Figure 16.1b Adjusted survival during the first 90 days, 1998 cohort**

From figure 16.1a and b, it can be seen that whilst the overall survival at 90 days was constant from 1997 to 1998 at about 89%, there was considerable volatility for some individual centres. This demonstrates the danger of drawing conclusions from survival figures derived from small numbers over short periods of time. As more data accumulates with time, it will be possible to analyse for consistent trends.

*Survival during the year after the first 90 days of treatment*

The results are shown in table 16.3 and figure 16.2.

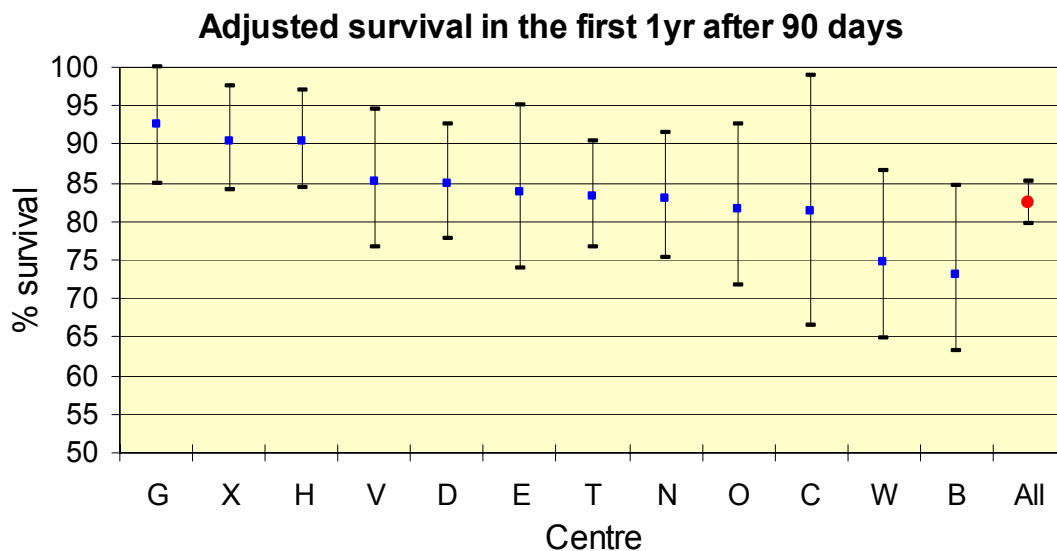
Centre	Unadjusted Survival		Adjusted 1 Year Survival (after the first 90 days) 1998		Adjusted 1997
	KM	95% CI	KM	95% CI	
		(after the first 90 days) 1998		(after the first 90 days) 1998	
A	80.2	65.7 – 94.7	83.8	72.8 – 96.3	
B	74.7	64.3 – 85.1	78.8	70.5 – 88.1	74.7
C	78.9	63.5 – 94.3	81.2	69.0 – 95.6	84.1
D	79.6	69.9 – 89.3	83.4	75.8 – 91.7	75.8
E	66.7	52.0 – 81.4	74.8	64.0 – 87.3	82.2
F	94.3	89.7 – 98.9	95.5	92.1 – 99.1	
G	84.3	78.1 – 90.5	86.5	81.3 – 92.0	83.2
H	85.6	78.7 – 92.5	87.7	82.1 – 93.8	90.9
K	81.8	70.2 – 93.4	85.2	76.3 – 95.2	
L	77.0	68.5 – 85.5	81.9	75.3 – 89.0	
M	89.7	82.3 – 97.1	84.7	77.4 – 92.7	
N	84.2	76.9 – 91.5	88.5	83.2 – 94.0	84.9
P	84.4	78.0 – 90.8	88.7	84.0 – 93.6	82.1
Q	85.2	77.9 – 92.6	87.2	81.1 – 93.8	
R	88.0	80.0 – 96.0	90.2	84.0 – 96.9	
S	79.5	75.7 – 84.3	82.9	79.6 – 86.4	

Centre	Unadjusted Survival (after the first 90 days) 1998	1 Year	Adjusted 1 Year Survival (after the first 90 days) 1998	Adjusted 1997
T	89.4	83.6 – 95.2	88.9	83.2 – 95.0
V	82.4	72.7 – 92.1	83.1	74.6 – 92.7
W	71.3	56.6 – 86.0	81.5	72.1 – 92.2
X	89.7	82.3 – 97.1	91.5	85.7 – 97.7
E&W	82.7	81.0 – 84.4		82.4

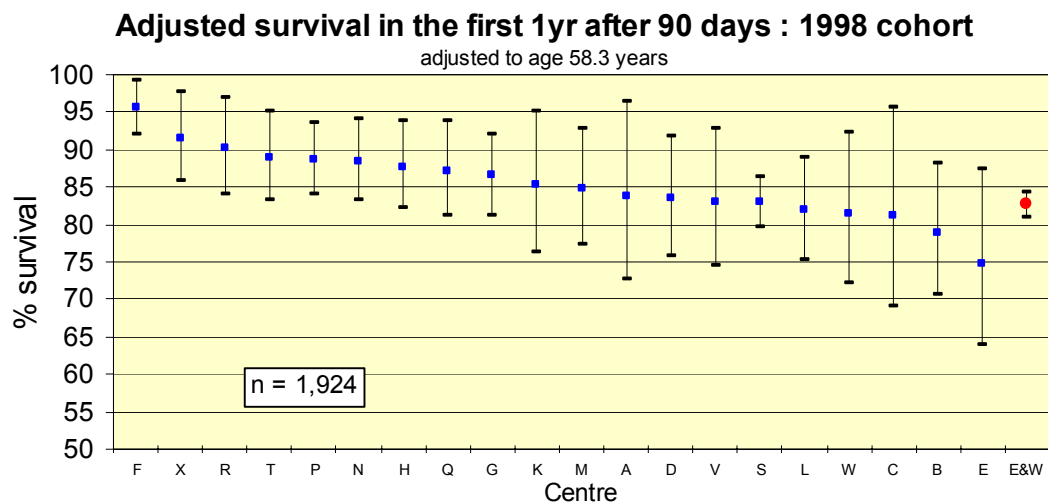
Table 16.3 survival of patients over 1 year after first 90 days in 1998 and 1997 cohort.

Centre	Adjusted survival (after the first 90 days)	
	KM	95% CI
A	83.2	71.9 – 96.2
B	77.6	68.9 – 87.2
C	81.4	69.1 – 95.8
D	83.3	75.6 – 91.7
E	71.7	60.0 – 85.5
F	95.2	91.6 – 99.0
G	85.6	80.1 – 91.4
H	87.3	81.5 – 93.5
K	85.4	76.5 – 95.2
L	81.2	74.5 – 88.6
M	84.2	76.7 – 92.5
N	87.8	82.3 – 93.7
P	87.6	82.6 – 92.9
Q	87.0	80.7 – 93.6
R	90.0	83.6 – 96.8
S	82.4	79.0 – 86.0
T	88.3	82.4 – 94.7
V	83.1	74.5 – 92.6
W	79.1	68.9 – 91.0
X	90.9	84.7 – 97.5

Table 16.4 Survival probabilities during the year after the first 90 days, adjusted by quartiles.



Adjustment has been made on the basis of the mean patient age of 58.3 years  
**Figure 16.2a Survival during the year after the first 90 days, 1997**



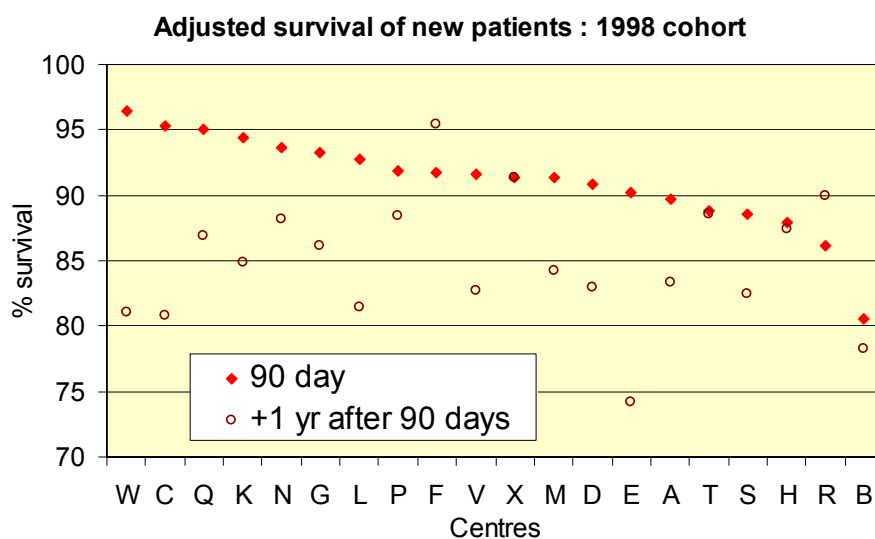
**Figure 16.2b Survival during the year after the first 90 days, 1998 cohort**

As with the 90 day survival the overall subsequent one-year survival is constant at about 83%, but there is volatility from year to year for some individual centres.

There was evidence in the analysis to suggest that the relationship between risk of death and patient age was not completely linear. For this reason the adjusted analysis was repeated by categorising the age of patients into quartiles of  $\leq 47$ , 48 – 62, 63 – 71 and  $\geq 72$  years (table 16.4).

*Comparison of survival on dialysis at 90 days and during the subsequent year*

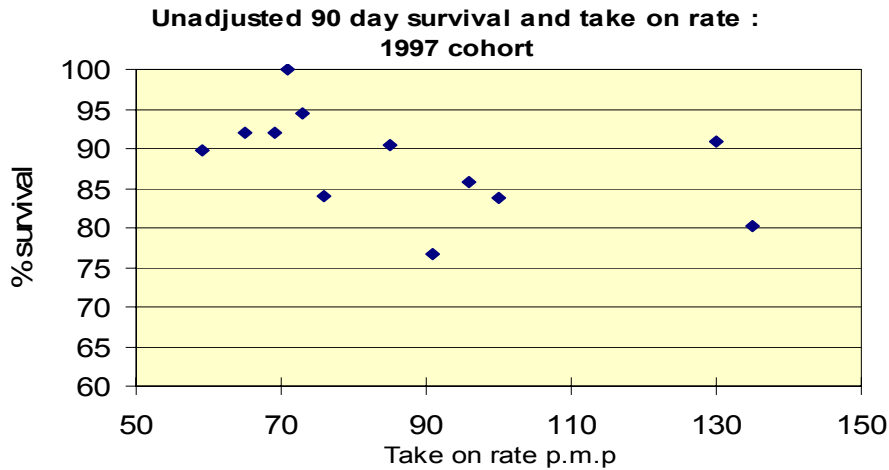
Variations between centres in survival during the first 90 days may partly be due to misclassification of some acute renal failure patients dying in this period. If this were the case the effect would, by definition, be lost after 90 days, and the variation in survival would be smoothed. To examine this hypothesis survival at the two time periods was compared (figure 16.3). There is no obvious smoothing. Centres with the best survival at 90 days do not necessarily have the best survival at one year.



**Figure 16.3 Comparison of the 90 day and 1 year survival on dialysis**

### Relationship between acceptance rate and survival on dialysis

Centres with a high acceptance rate for dialysis might accept more elderly and other patients with many co-morbid conditions, and might be expected to have a higher early death rate. On the other hand centres with large ethnic minorities may have larger numbers of young patients starting dialysis. In figure 16.4 survival is compared with acceptance rate. There is no obvious relationship.



**Figure 16.4 Relationship between acceptance rate and survival on dialysis**

### Discussion

The 1997 patient cohort UK Renal Registry unadjusted 1 year death rate for new patients on dialysis after the first 90 days of treatment is 19.3 per 100 patient years

The one-year survival is 82.4%. This compares with the 1997 United States Renal Data Systems (USRDS) 1-year survival of new patients on dialysis (again after the first 90 days of treatment) of 80.1%. However it is important to recognise that the case mix of the two incident populations differs in several potentially important respects (table 16.5)

	<b>UK Renal Registry 1998</b>	<b>USRDS 1997</b>
<b>1 year survival from day 90</b>	82.4%	80.1%
<b>Mean Age (years)</b>	58.3	60.9
<b>Diabetes (%)</b>	16	44.5
<b>Black patients (%)</b>	3	28
<b>Male to female ratio</b>	1.64	1.12

**Table 16.5 UK and USA new patient characteristics**

These differences in case mix have to be taken into account when interpreting the differences in survival.

The first 90 days of renal replacement therapy is an intense period of treatment with a high mortality. Information about this period is important. In the USA, the USRDS does not report data relating to the first 90 days of treatment. This approach reduces the discrepancy

that can arise consequent on inconsistency in classification of acute and chronic renal failure but misses helpful information. If sufficient detail regarding comorbidity were available accurate information could be gained from analysis of survival during the first 90 days of treatment. The UK Renal Registry will be attempting to improve data quality to enable meaningful analysis of this period.

## ***Survival of patients established on dialysis – the prevalent cohort***

### ***The effects of age, gender and diabetes.***

This analysis examines the survival of a clearly defined '*prevalent cohort*' of dialysed (peritoneal dialysis and haemodialysis-) patients in which all had been treated with renal replacement therapy for at least a year. Those who had only recently started treatment are excluded because of the increased mortality that occurs during the first few months of treatment. The following analyses were undertaken:

The effect of 'Length of Time on Renal Replacement Therapy' on 1-year survival.

The effect of 'Age', 'Gender' and 'Diabetes (when the cause of Renal Failure)' on 1-year survival.

The variation between dialysis centres in 1-year survival.

The variation between dialysis centres in 2-year survival.

### ***Patient Cohort***

Patients were included in the analysis of **1-year survival (1998)** only if they satisfied each of the following criteria:

1. They were being treated with dialysis on 1/1/1998 at one of the Renal Registry sites.
2. They had started renal replacement therapy on or before 1/1/1997.
3. They had been treated with dialysis for at least 6 months on 1/1/1998 if they had had a failed renal transplant.

There were 3,332 patients included.

In a separate, but similar analysis, the **2-year survival (1997 - 1998)** of those patients who had been treated with renal replacement therapy for at least a year and were on dialysis on 1/1/1997 was undertaken. There were 2,105 patients. A proportion but not all these patients were included in the 1-year survival analysis.

## ***The effect of Age, on the survival of Established Dialysis Patients***

### ***Statistical Methods***

A Cox Proportional Hazards Model was used to analyse the relationship between age, and risk of death over the one year follow up period and the analysis was adjusted for centre effect. Survival estimates were calculated using the Kaplan-Meier method.

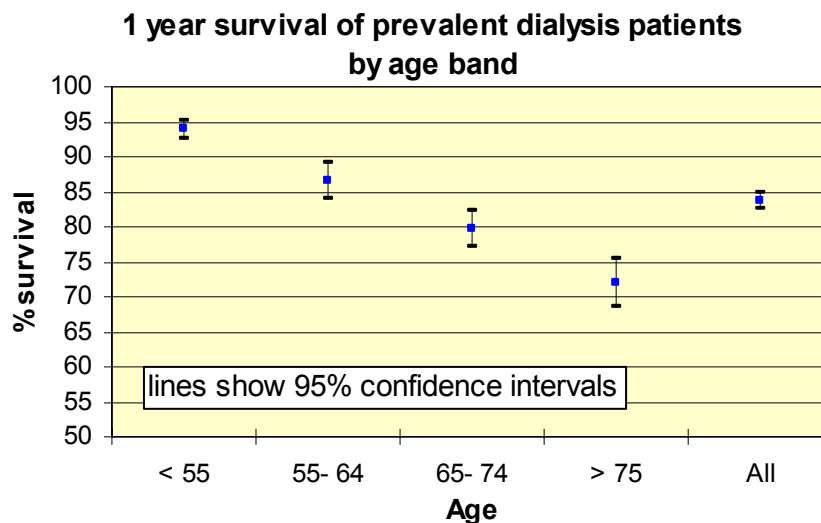


## Results

The unadjusted 1-year survival (1998) of patients in age (years) groups 18 – 34, 35 – 44, 45 – 54, 55 – 64, 65 – 74,  $\geq 75$  were as shown in Table 16.6.

Age (yrs)	No. of patients	No. of deaths	1 year survival	
			KM	95% CI
18 – 34	390	17	95.3	92.5 – 97.0
35 – 44	457	31	92.5	89.5 – 94.7
45 – 54	590	58	89.6	86.7 – 91.8
55 – 64	710	106	84.4	81.5 – 87.0
65 – 74	867	185	78.2	75.2 – 80.8
$\geq 75$	541	156	71.1	67.1 – 74.7

**Table 16.6** Age and 1 year survival of dialysis patients on RRT for at least a year.



**Figure 16.5** 1 year survival of prevalent dialysis patients by age band

An increase in one year of age was associated with an increase in hazard of death of 1.039 [95% CI: 1.032 – 1.046]. An increase in age by 10 years was associated with an increase in hazard of death of 1.47 [95% CI: 1.38 – 1.57].

### ***The effect of 'Length of Time on RRT' on Survival of Established Dialysis Patients.***

Data from this Registry and elsewhere have demonstrated that there is increased mortality of patients during the first 90 days of renal replacement therapy. This suggests that the use of 'prevalent cohorts' that include patients who have recently started renal replacement therapy would not allow meaningful comparison between different units. Thus when using a 'prevalent cohort' to compare the one year survival of prevalent patients from different centres it is important to establish whether subsequent length of time that individuals have previously

been on renal replacement therapy affects the 1 year survival of that cohort. This could be important if one centre has more than 50% of patients dialysed for between 1 and 3 years, and another has only 25% of patients dialysed for between 1 and 3 years. One of the aims of this analysis is to establish whether the use of 'prevalent cohorts' which exclude patients who have been on renal replacement therapy for less than a year allows meaningful comparison between units.

### *Patient Cohort*

As described in Introduction for 1 year survival (1998).

### *Statistical Methods*

A Cox Proportional Hazard model including the variables age and length of time on renal replacement therapy, stratified by treatment centre, was used. To determine whether the relationship between length of time on RRT and risk of death varied for patients of different ages, an interaction between length of time on RRT and age was fitted into the model.

Patient age was included as a continuous variable. The length of time on RRT was calculated in years, and was then categorised into quintiles [1 year, 2 years, 3 – 4 years, 5 – 8 years and  $\geq$  9 years]. Patients with an unknown length of time on RRT were excluded from the analysis, reducing the sample to 3,445 patients.

### *Results.*

After adjusting for age, the risk of death was not found to differ significantly for increasing length of time on RRT ( $p = 0.0946$ ). This means that for a patient of any given the risk of death during 1998 did not increase with increasing time on renal replacement therapy. The results from this analysis are shown in table 16.7 below.

<b>Length of time on RRT</b>	<b>Hazard Ratio [95% CI]</b>
1 year	REF
2 years	1.36 [1.04 – 1.76]
3 – 4 years	1.35 [1.06 – 1.73]
5 – 8 years	1.30 [0.99 – 1.72]
$\geq$ 9 years	1.16 [0.85 – 1.58]
p-value	0.0946

**Table 16.7 Time on RRT and risk of death (Hazard ratio) for dialysis patients on RRT for at least a year.**

### *Summary*

For a cohort of dialysed patients who have all been on renal replacement therapy for more than a year, the one-year survival is not affected by the duration of renal replacement therapy of the individuals.

## ***The effect of Gender and Diabetes on the Survival of Established Dialysis Patients.***

The previous analysis was repeated investigating the effect of gender and diabetes on the one-year survival of dialysis patients who had been on renal replacement therapy for at least one year.

### ***Patient Cohort***

As described in Introduction for 1-year survival (1998), but because of incomplete data the number in the analysis was reduced from 3,332 to 3,328 in the analysis of the effects of gender and to 3,304 in the analysis of the effect of diabetes.

For the purposes of this analysis patients were classified as having diabetes only if the diagnosis was registered as the primary cause of renal failure (and not as concurrent co-morbidity).

### ***Statistical Methods***

A Cox Proportional Hazards Model was used to analyse the relationship between age, gender, diabetes and risk of death over the one year follow up period and the analysis was stratified by treatment centre.

### ***Effect of Gender***

A significant association was found between gender and risk of death ( $p = 0.0074$ ,  $n = 3,328$ ) such that the hazard of death for males was 1.28 [95% CI: 1.07 – 1.53] times that for females. Since the median age of males was 60 years compared with 58 years for females, the analysis was repeated adjusting for age. When this was done, the association between gender and risk of death remained statistically significant ( $p = 0.0397$ ,  $n = 3,328$ ) such that the hazard of death for males was 1.21 [95% CI: 1.01 – 1.45] times that for females. There was no significant interaction between gender and patient age fitted as a continuous variable, indicating that the risk of death for males compared with females did not vary for patients of different ages.

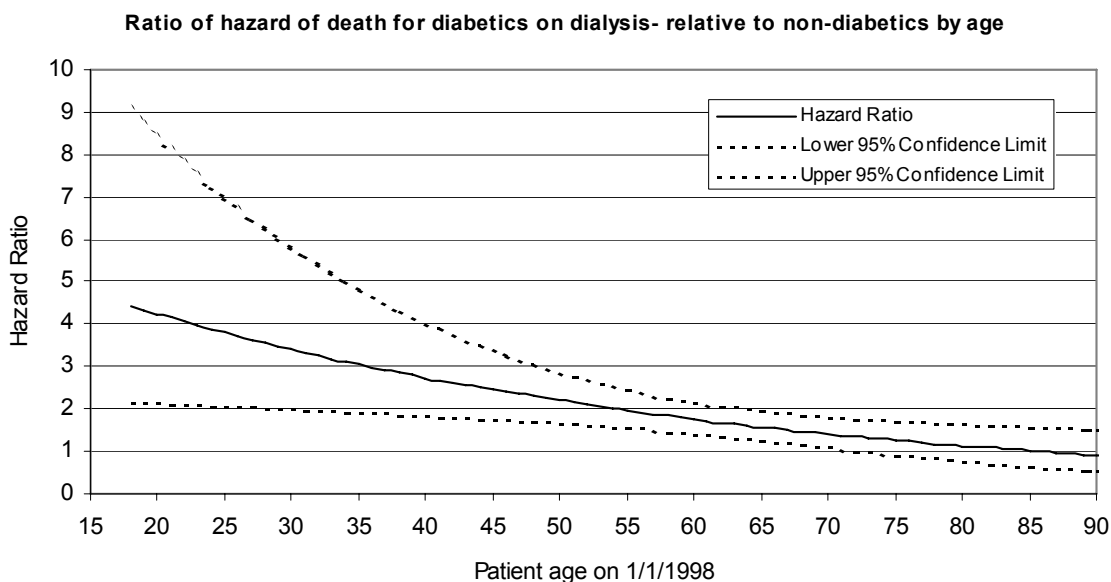
### ***Effect of Diabetes***

The relationship between the risk of death for diabetics of different ages compared with non-diabetics is shown in figure 16.6. A significant interaction for risk of death was found between a diagnosis of diabetes and patient age ( $p = 0.0372$ ,  $n = 3,304$ ) indicating that the relationship between diabetes and risk of death is dependent upon the patients age. The increased hazard for young diabetics compared with others on RRT is much more than for older diabetics. Thus a 25 year old diabetic has an increase in the hazard of death of HHH compared with a non-diabetic patient of the same age; a 57 year old diabetic patient, has an increase in the hazard of death of only 1.92 [95% CI: 1.50 – 2.46] compared with a non-diabetic patient of the same age. This is probably due to the high incidence of cardiovascular disease in young diabetics compared with others on RRT. In the general older patients this increases towards the diabetic incidence.

The relationship between the risk of death and age differs in diabetic and non-diabetic patients. Diabetics have an increase in hazard of death of 1.023 [95% CI: 1.005 – 1.040] for a one year increase in age. In contrast non-diabetics have an increase in hazard of death of 1.043 [95% CI: 1.035 – 1.050] with a one year increase in age.

Some caution is required in the interpretation of these findings because of the potential inclusion of a degree of bias in the calculation of survival probabilities of diabetic dialysis patients compared with non-diabetic patients. This arises because of the policy that all patients are censored at the time of transplantation. In the under 55 age group, a larger proportion of diabetic patients (with greater co-morbidity) may be deemed unsuitable for transplantation than non-diabetic patients of the same age.

When gender was added in the Cox Model (adjusting for age and diabetes), the hazard ratios for males changed marginally from 1.20 to 1.21 [95% CI: 1.01 – 1.45] times that of females ( $p = 0.0437$ ,  $n = 3,300$ ).



**Figure 16.6 The 1 year survival of diabetic and non-diabetic dialysis patients of different ages on RRT for  $\geq 1$  year.**

Waugh et al when comparing the relative hazard of death in diabetic and non-diabetic patients in the general population showed a similar reduction of the increased relative risk of death of diabetics with advancing age. In the patient population studied by Waugh, the diabetic relative risks for mortality from all causes were 5.5, 2.3, 1.7, 1.3 for age ranges 15-44, 45-64, 65-74, and 75 and over, respectively.

### Summary

1-year survival of dialysed patients deteriorates with increasing age. Males of all ages have an increased risk of death. Diabetes increases the risk of death considerably especially in younger patients. The relative increased hazard of death for a diabetic in renal failure compared with non diabetic patients on RRT is similar to that of diabetic not in renal failure comparing with the general population.

## **Variation between centres of 1 year survival (1998) of established dialysis patients**

### **Patient Cohort**

As described in Introduction for 1 year survival (1998).

Data relating to 3,332 patients from 19 renal units in England & Wales were available for analysis.

### **Statistical Method**

The Kaplan Meier Method was used to calculate the unadjusted one-year survival probabilities (with 95% confidence intervals) for each centre. The survival probabilities can be interpreted as the probability of a patient surviving more than a year or as the proportion of patients surviving more than a year.

The adjustment process used in this section gives estimates of the survival and death rates that would have arisen for the cohorts, had they all had the same age, sex, diabetes as a cause of ESRF, and duration of renal replacement therapy as the overall registry prevalent population. As the adjusted survival curves are all adjusted to the same reference population, any remaining differences between them is due to factors other than age, sex, diabetes and duration of ESRD.

A Cox Stratified Proportional Hazards Model was used to estimate the survival probabilities at each centre, adjusting for age and stratifying by centre. Age was entered into the model as a continuous variable. Stratifying by centre enables a separate underlying hazard to be estimated at each centre although it assumes that the effect of age on the hazard is the same at each centre.

For the 1998 sample (n=3,332), the mean patient age was 57.0 years and the one-year survival probabilities at each centre were estimated from the model, for a population with a mean age of 57.0 years.

### **Results**

The unadjusted patient survival for 1998 was 83.7%, which equates with a death rate of 17.8 per 100 patient years. The equivalent figures for 1997 had been 82.3% and 19.5 per 100 patient years. The similarity between the survival figures for the 1997 and 1998 is noteworthy as different centres were included in the compilation of this analysis.

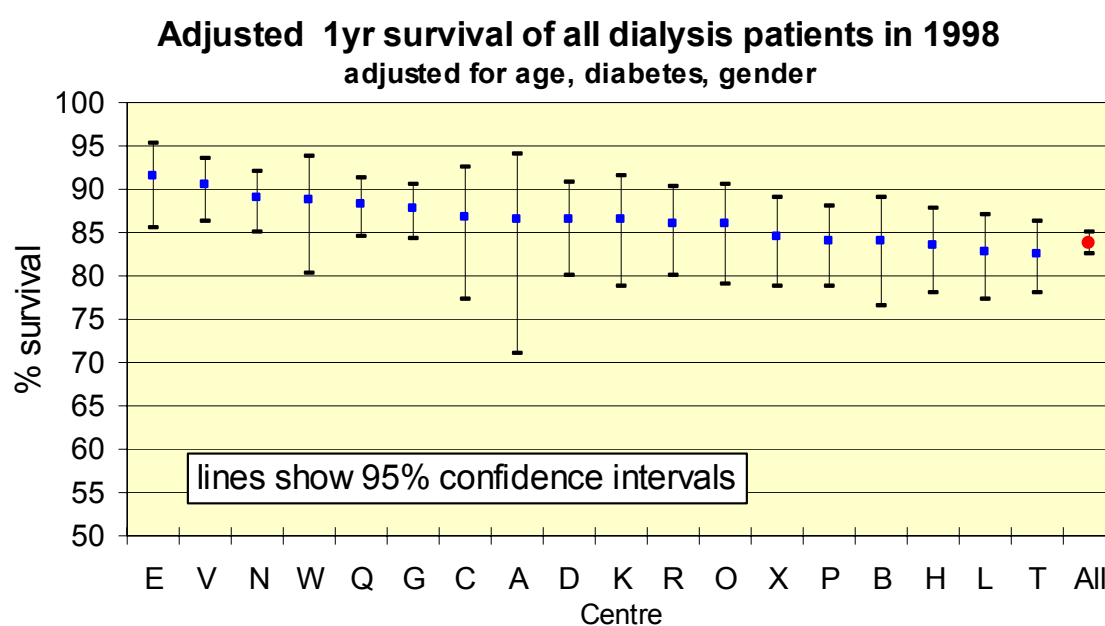
The results for individual centres are shown in table 16.8

Centre	Unadjusted One Year Survival 1998		Adjusted One Year Survival 1998		Adjusted One Year Survival 1997
	KM	95% CI	KM	95% CI	
A	84.2	66.0 – 93.1	86.5	70.9 – 94.0	
B	80.4	71.7 – 86.6	83.9	76.4 – 89.1	88.9 [82.1 – 93.2]
C	83.9	72.8 – 90.8	86.7	77.2 – 92.4	74.8 [62.9 – 83.3]
D	85.0	78.1 – 89.9	86.4	80.1 – 90.8	82.1 [75.6 – 87.0]
E	87.9	79.7 – 93.0	91.6	85.6 – 95.2	

<b>F</b>	85.4	79.9 – 89.5			
<b>G</b>	84.9	80.7 – 88.2	87.8	84.2 – 90.6	85.8 [82.0 – 88.9]
<b>H</b>	81.0	74.9 – 85.7	83.5	78.0 – 87.7	87.0 [82.2 – 90.6]
<b>K</b>	84.1	75.4 – 90.0	86.4	78.7 – 91.4	
<b>L</b>	79.6	73.5 – 84.4	82.7	77.2 – 86.9	
<b>N</b>	86.5	81.8 – 90.0	88.9	84.9 – 91.9	88.0 [83.9 – 91.1]
<b>O</b>	82.1	73.8 – 87.9	85.9	79.1 – 90.6	87.3 [80.9 – 91.6]
<b>P</b>	78.1	71.5 – 83.3	83.9	78.7 – 88.0	
<b>Q</b>	85.4	81.0 – 88.9	88.3	84.6 – 91.2	
<b>R</b>	85.4	79.3 – 89.8	86.0	80.1 – 90.3	
<b>T</b>	81.5	76.6 – 85.4	82.6	77.9 – 86.3	84.2 [79.7 – 87.7]
<b>V</b>	88.8	84.1 – 92.2	90.4	86.2 – 93.4	85.9 [81.3 – 89.3]
<b>W</b>	83.6	71.7 – 90.9	88.8	80.2 – 93.8	81.4 [71.2 – 88.2]
<b>X</b>	81.0	74.4 – 86.0	84.6	78.7 – 89.0	89.9 [84.2 – 93.6]
<b>All</b>	83.7	82.4 – 84.9			

**Table 16.8 One Year Survival Rates for all patients in 1998**

Age, diabetes and gender have been included in the adjusted analysis while differences between centres of ethnicity and other co-morbidity have not been accounted for.



**Figure 16.7 Adjusted 1-year survival of all dialysis patients in 1998**

\* centre H is missing from the adjusted analysis as many of the dead patients had a missing diagnosis, and no adjustment was possible.

### Summary

There is variation in 1-year patient survival between units when adjustment is made on the basis of age, gender and diabetes. However no account was taken of ethnicity or comorbidity in this analysis both of which could potentially have a significant impact.

### **Variation between centres in 2-year survival (1997-98) of established dialysis patients.**

### *Patient Cohort*

As described in the Introduction.

Data relating to 2105 patients from 11 renal units in England were included in the analysis.

### *Statistical Method*

As for 1 year survival.

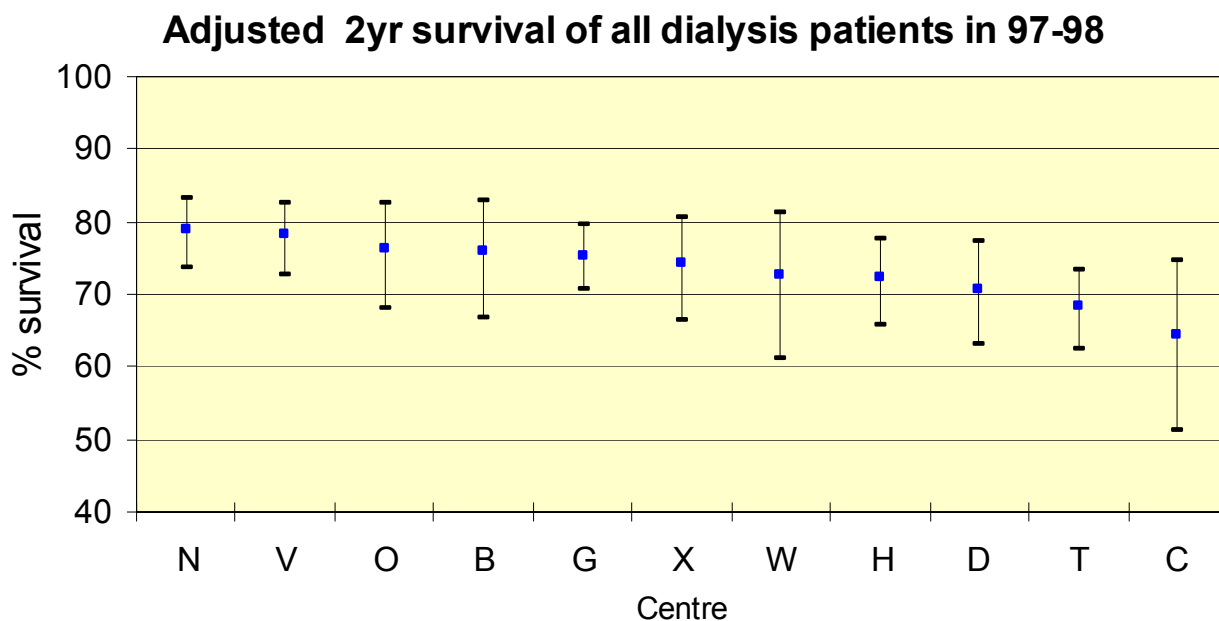
In the 2-year survival analysis the mean patient age was 56.3 years. The two-year survival probabilities at each centre were estimated from the model, for a population of age 56.3 years.

### *Results*

The results are shown in table 16.9, and illustrated in figure 16.8. The unadjusted two-year survival for 1997-98 was 68.8%, compared with the one-year survival of 82.3% for the same cohort.

<i>Centre</i>	<b>Unadjusted Two Year Survival 1997 - 1998</b>		<b>Adjusted Two Year Survival 1997 - 1998</b>	
	<i>KM</i>	<b>95% CI</b>	<i>KM</i>	<b>95% CI</b>
<b>B</b>	68.9	60.7 - 77.2	74.3	67.5 - 81.8
<b>C</b>	60.9	49.8 - 72.1	66.8	57.6 - 77.6
<b>D</b>	68.	61.7 - 75.3	70.7	64.4 - 77.5
<b>G</b>	68.9	64.4 - 73.4	73.2	69.2 - 77.4
<b>H</b>	65.5	59.5 - 71.6	69.6 []	64.2 - 75.5
<b>N</b>	72.6	67.7 - 77.5	77.0 [	72.8 - 81.5
<b>O</b>	66.8	58.9 - 74.7	73.2	66.6 - 80.3
<b>T</b>	67.5	62.5 - 72.5	68.2	63.4 - 73.3
<b>V</b>	73.5	68.3 - 78.6	76.7	72.2 - 81.6
<b>W</b>	61.7	50.5 - 73.0	73.0	64.8 - 82.3
<b>X</b>	68.4	61.8 - 74.9	71.8]	66.0 - 78.2
<b>All</b>	68.8	66.9 - 70.6		

**Table 16.9**Two-year survival rates 1997-1998



**Figure 16.8 Adjusted 2-year survival of all dialysis patients in 1997-1998**

**Summary**

As for 1-year survival there are demonstrable differences in 2-year patient survival between units when adjusted for age, gender and diabetes. However these differences may be due to ethnicity or comorbidity.

**Discussion**

The unadjusted UK Renal Registry 1 year mortality rate for dialysed patients established on renal replacement therapy for at least a year was 19.4 per 100 patient years in 1997 (n = 2,103) and 17.8 per 100 patient years in 1998 (n = 3,332). The USRDS database, which includes information relating to the majority of dialysed patients in the USA (n = 240,022), gives a higher 1-year mortality rate during 1998 of 27.9 per 100 patient years. It is important to recognise that there are differences in methodology and case mix between the two datasets.

In the USRDS report patients are included in the 'prevalent cohort' analysis of 1-year survival after 90 days of renal replacement therapy whereas in this UK report patients have been included in the analysis only if they have been on renal replacement therapy for at least a year. This may have a slight impact on the comparison between mortality rates.

Probably of greater importance are the differences in case mix of the patients included in the two registries. In the units submitting to the UK Renal Registry in 1998 11% of patients starting renal replacement therapy were of non-white ethnic origin (3% black) and 16% had diabetes as the primary cause of renal failure. In the USA (1995) 38% of patients starting renal replacement therapy were of non-white ethnic origin (31% black) and 41% of patients were diabetic.



The life expectancy of black dialysis patients in the USA exceeds that of whites of the same sex at every age. In an unadjusted analysis of dialysed patients (aged 45 - 64 years) whites have an annual mortality rate of 20.7 per 100 patient years whereas blacks have a rate of 14.7 per 100 patient years. Survival in different between ethnic groups in the UK has not yet been evaluated.

The potential impact of the differences in proportion of diabetic patients starting renal replacement therapy in the two countries on patient survival is emphasised by the USRDS report. Non-diabetic haemodialysis patients (aged 45 - 64 years) have a mortality rate of 14.1 per 100 patient years while diabetic haemodialysis patients have a rate of 20.5 deaths per 100 patient years. For peritoneal dialysis the respective figures are 14.6 and 28.2 per 100 patient years.

These differences emphasise the need to consider case-mix when comparing dialysis patient survival between countries and from one unit to another.

The Registry will in time be able to further explore the factors that influence patient survival and allow comparison of performance year to year as well as between different centres and countries.

Adjusting for confounders in survival analyses using the proportional hazards model relies on the underlying assumptions of this model being valid. These assumptions were tested and valid in all cases for the prevalent cohort. It is noteworthy that Johnson et al commented in a recent meta-regression analysis of papers referring to the effect of age, diabetes and comorbidity on patient survival that only 4 of the 23 studies using proportional hazards tested the assumption of proportionality.

Age and diabetes were shown to be major determinants of survival as predicted. The increase in hazard for every increase of 10 years in patient age was similar for the one and two year survival. This was 50% [95% CI 42-59%] in 1998, and 51% [95% CI 43-60%], in 1997 - 98. These data compare closely with the findings of Johnson et al. whose analysis when undertaken using prevalence cohorts of established dialysis patients, produced a pooled risk increase of 48% per 10-year increase in age (relative risk 1.040 per year).

The relative risk associated with diabetes was 1.91 (95% CI 1.67 - 2.17) from the meta-analysis and 1.92 (95% CI 1.50 - 2.46) from the Renal Registry, but varied with age.

As more information relating to other aspects of patient comorbidity becomes available for analysis by the Renal Registry the factors that influence the success of dialysis treatment will become apparent. This will in turn enable the development of more informed guidelines for optimal standards of care.

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## **Chapter 17: Survival on renal replacement therapy: associations with albumin, urea reduction ratio and phosphate**

### ***Background***

The development of the Renal Registry provides the opportunity for UK nephrologists to examine the outcomes for patients with ESRF. Previous studies from the USA (Lowrie 1990, Owen 1993, Collins 1994) have shown that survival on renal replacement therapy is associated with certain biochemical variables.

A number of studies have reported that hypo-albuminaemia is powerful predictor of subsequent mortality in ESRF patients (Lowrie 1990, Owen 1993). The precise role of comorbidity, inflammatory/infective conditions and poor nutrition in the hypo-albuminaemia and the increased mortality rate is uncertain (Kaysen 1995). There are no prospective studies demonstrating a reduction in mortality following interventions which raise serum albumin.

Retrospective (Lowrie 1990) and uncontrolled (Hakim 1994, Parker 1994) prospective studies have shown that higher urea reduction ratios (URR) are associated with improved patient survival in haemodialysis. The current HEMO study in the USA is examining in a prospective fashion the effect of differing doses of dialysis based on urea removal (Eknoyan 1996).

In the 1998 report the relationship between serum phosphate and mortality was explored. It was found that lowest mortality risk was associated with phosphate concentrations of 1.71-2.11mmol/l. Over 2.11mmol/l the risk of death increased in accordance with the findings of Block et al (Block 1998). Further analysis of this data has been performed including adjusting phosphate for serum creatinine. The purpose of this was to try to account for low muscle mass to determine whether phosphate had a direct effect on mortality or whether this was mediated through nutritional considerations.

### ***Patient Selection and Statistical Methods***

The sample consisted of patients who were on dialysis at the start of the 1/1/1998 who were:-

1. receiving treatment at one of the 11 centres on the Renal Registry database
2. were known definitely to have been on dialysis for >1 year
3. had quarterly data for 1997.

Not every centre had a complete set of data for each parameter therefore it was not possible to use a uniform sample for each analysis. The details of the excluded patients, reasons for exclusions and the final sample size are given for each variable. For albumin, the HD and PD patients are considered separately because of the difference in albumin ranges between the two forms of therapy.

A Cox Proportional Hazards Model was used to analyse the relationship between each variable and risk of death over the one year period, adjusting for age, length of time on RRT, whether the patient had a primary diagnosis of diabetes and treatment centre. Age and length of time on RRT were entered into the model as continuous variables. The length of time on

RRT was measured in days on the 1/1/1998 and its log transform was used in the model. Patients with a primary diagnosis of 'Not sent' were excluded from the adjusted analysis, as were patients who had been on RRT for an unknown duration. Patients were categorised at the centre where they were receiving treatment on the 1.1.1998 even if they transferred out to a different Renal Registry Centre during the year.

Patients were censored if they transferred out from a Renal Registry Site to a non Renal Registry Site or if they had a transplant in 1998. The 'number of days at risk' was calculated according to the methods described on page 39 of the 1999 Report. Note that if a patient died on the day of transplant, then the death has not been counted. If a patient transferred out and had a transplant, then the patient was censored on the date of the first event. Note that all patients who were still under follow up on the 31/12/1998 were censored on this date.

The results from the Cox Proportional Hazards Model can be interpreted using hazard ratios. The hazard ratio is the ratio of the estimated hazards, 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 between 2 groups remains constant throughout the follow up period under consideration.

## ***Serum Albumin***

### ***Sample size***

Patients receiving treatment at Centres E and N were excluded from the analysis due to the lack of albumin data from these centres. Patients receiving treatment at Centre H were excluded from the analysis, as this centre measures their albumin using the BCP method. This resulted in a sample of 1,684 PD and 1768 HD patients. Note that patients receiving treatment at Centre G were included in the analysis, although in this centre some HD patients at satellite units had albumin measured by the BCP method.

Patients were included in the analysis, regardless of their previous treatment and transplant history. The analysis only considered patients who had been on PD/HD throughout the last quarter of 1997. This reduced the sample size to 512 PD patients, of which 454 patients had albumin data and 1172 HD patients of whom 1063 had albumin data.

### ***Methods***

Albumin from the last quarter of 1997 was considered in the analysis. The albumin was not laboratory harmonised. The analysis was first carried out categorising albumin as < 35g/L and ≥ 35g/L. This categorisation was chosen since it coincides with the cut-off used in the Renal Registry Report. The analysis was repeated categorising the albumin into quintiles which were defined by albumin concentration (g/L) as:-

	PD	HD
1 <sup>st</sup> quintile	<31	<36
2 <sup>nd</sup> quintile	32-34	37-38
3 <sup>rd</sup> quintile	35-37	39-40

4 <sup>th</sup> quintile	38-39	41-42
5 <sup>th</sup> quintile	>40	>42

The adjusted and unadjusted survival analysis was stratified by centre. Stratifying by centre enables a separate underlying hazard to be estimated at each centre although assumes that the effect of albumin and confounding variables on the hazard to be the same at each centre. In the adjusted model, an interaction was fitted between survival time and whether the patient had a primary diagnosis of diabetes. This was because the assumption of proportional hazards did not seem reasonable for this factor.

## Results

### PD patients

Categorising albumin as < 35g/L and ≥ 35g/L.

Albumin	Unadjusted Analysis (n = 454) Hazard Ratio [95% CI]	Adjusted Analysis (n = 432) Hazard Ratio [95% CI]
< 35g/L	3.09 [1.92 – 4.98]	2.95 [1.75 – 4.97]
≥ 35g/L	REF	REF
X <sup>2</sup>	23.2	17.9
p-value	<0.0001	<0.0001

NB: Although the term ‘Unadjusted Analysis’ has been used, the analysis was stratified by centre.

Categorising albumin into quintiles.

Albumin	Unadjusted Analysis (n = 454) Hazard Ratio [95% CI]	Adjusted Analysis (n = 432) Hazard Ratio [95% CI]
≤ 31g/L	8.72 [3.37 – 22.58]	6.85 [2.31 – 20.26]
32 – 34g/L	2.68 [0.92 – 7.79]	2.38 [0.73 – 7.75]
35 – 37g/L	2.69 [0.99 – 7.30]	1.97 [0.64 – 6.04]
38 – 39g/L	1.24 [0.33 – 4.65]	1.30 [0.32 – 5.32]
≥ 40g/L	REF	REF
X <sup>2</sup>	43.5	31.3
p-value	<0.0001	<0.0001

In the unadjusted analysis, the association between albumin and risk of death could be explained by a linear relationship ( $X^2 = 39.2$ , d.f = 1,  $p < 0.0001$ ), such that moving up one albumin category was associated with a decrease in hazard of 0.56 [95% CI: 0.46 – 0.68].

In the adjusted analysis, the association between albumin and risk of death could also be explained by a linear relationship ( $X^2 = 28.2$ , d.f. = 1,  $p < 0.0001$ ), such that moving up one albumin category was associated with a decrease in hazard of 0.57 [95% CI: 0.46 – 0.71].

#### Fitting Albumin into the Model as a Continuous Variable.

Since some evidence for a linear relationship was found, when albumin was categorised into quintiles, it was decided to fit albumin into the model as a continuous variable. This has the advantage over fitting the categorised albumin as an ordinal variable, in that the results and hence their interpretation are not dependent upon the scores given to the categories.

In the unadjusted analysis, a statistically significant association with albumin was found ( $X^2 = 46.6$ , d.f. = 1,  $p < 0.0001$ ), such that an increase in 1g/L of albumin was associated with decrease in the hazard of death of 0.86 [95% CI: 0.83 – 0.90].

In the adjusted analysis, a statistically significant association with albumin was found ( $X^2 = 37.3$ , d.f. = 1,  $p < 0.0001$ ), such that an increase in 1g/L of albumin was associated with decrease in the hazard of death of 0.86 [95% CI: 0.83 – 0.90].

#### *HD patients*

Categorising albumin as  $< 35\text{g/L}$  and  $\geq 35\text{g/L}$ .

Albumin	Unadjusted Analysis (n = 1063) Hazard Ratio [95% CI]	Adjusted Analysis (n = 1028) Hazard Ratio [95% CI]
$< 35\text{g/L}$	1.74 [1.15 – 2.63]	1.27 [0.82 – 1.96]
$\geq 35\text{g/L}$	REF	REF
$X^2$	6.2	1.1
p-value	0.0128	0.3039

Categorising albumin into quintiles.

Albumin	Unadjusted Analysis (n = 1063) Hazard Ratio [95% CI]	Adjusted Analysis (n = 1028) Hazard Ratio [95% CI]
$\leq 36$	4.09 [2.18 – 7.71]	2.56 [1.33 – 4.93]
37 – 38	4.48 [2.37 – 8.47]	3.16 [1.65 – 6.07]
39 – 40	2.09 [1.06 – 4.13]	1.81 [0.91 – 3.59]
41 – 42	1.10 [0.50 – 2.47]	0.87 [0.38 – 1.99]
$\geq 43$	REF	REF
$X^2$	48.7	26.7
p-value	$< 0.0001$	$< 0.0001$

In the unadjusted analysis, the association between albumin and risk of death could be explained by a linear relationship ( $X^2 = 41.7$ , d.f = 1,  $p < 0.0001$ ), such that moving up one albumin category was associated with a decrease in hazard of 0.68 [95% CI: 0.60 – 0.77].

In the adjusted analysis, the association between albumin and risk of death could not be completely explained by a linear relationship, since although a statistically significant linear trend was found ( $X^2 = 18.7$ , d.f = 1,  $p < 0.0001$ ), there was also a statistically significant departure from trend ( $X^2 = 8.0$ , d.f = 3,  $p = 0.0467$ ).

#### Fitting Albumin into the Model as a Continuous Variable.

Since some evidence for a linear relationship was found, when albumin was categorised into quintiles, it was decided to fit albumin into the model as a continuous variable. This has the advantage over fitting the categorised albumin as an ordinal variable, in that the results and hence their interpretation are not dependent upon the scores given to the categories.

In both the unadjusted and adjusted analysis, a statistically significant quadratic effect was found. Whether this effect is an anomaly due to a few outlying observations, or whether it is valid for these data has not been investigated further at this stage.

## ***Urea Reduction Ratio***

### ***Sample size***

Patients known to be dialysing once, twice, or four times a week in the last quarter of 1997 were excluded from the analysis, although patients dialysing at an unknown frequency were included in the analysis. Patients on home HD were included in the analysis (unlike the analysis of URR data in the 1999 Report). This resulted in a sample of 1,352 patients of which 845 patients had URR data. Patients receiving treatment at Centres E, T V W and V were excluded from the analysis since less than 75% of patients had URR data from these centres. This resulted in a sample of 872 patients, of which 754 patients had URR data.

### ***Statistical Methods***

The URR from the last quarter of 1997 were included in the analysis. The analysis was first carried out categorising the URR as  $<65\%$  and  $\geq 65\%$  to coincide with the Renal Association Standard and was repeated categorising the URR into quintiles. For this sample, the quintiles were defined as follows:  $\leq 60$ , 61-64, 65-68, 69-72 and  $\geq 73\%$ .

## Results

*Categorising URR as < 65% and ≥ 65%.*

URR	Unadjusted Analysis (n = 754) Hazard Ratio [95% CI]	Adjusted Analysis (n = 713) Hazard Ratio [95% CI]
< 65	1.79 [1.26 – 2.55]	1.56 [1.07 – 2.27]
≥ 65	REF	REF
X <sup>2</sup>	10.6	5.4
p-value	0.0011	0.0199

4.3.2. Categorising URR into quintiles.

URR(%)	Unadjusted Analysis (n = 754) Hazard Ratio [95% CI]	Adjusted Analysis (n = 713) Hazard Ratio [95% CI]
≤ 60	2.30 [1.31 – 4.05]	1.90 [1.04 - 3.45]
61 – 64	0.93 [0.49 – 1.76]	0.75 [0.38 – 1.48]
65 – 68	0.99 [0.53 – 1.85]	0.86 [0.45 – 1.66]
69 – 72	0.65 [0.32 – 1.32]	0.64 [0.31 – 1.32]
≥ 73	REF	REF
X <sup>2</sup>	25.5	18.8
p-value	<0.0001	0.0008

The association between URR and risk of death was non-linear in the unadjusted and adjusted analysis.

## **Serum Phosphate**

### **Sample size.**

The same sample as previously used was considered for the analysis published in the 1998 report.

### **Method**

A logistic regression analysis was used to analyse the association between phosphate from the first quarter in 1997 and risk of death in 1998 (adjusting for age, length of time on RRT, whether the patient had a primary diagnosis of diabetes, treatment centre on the 1/1/1998 and serum creatinine. The patient's creatinine from the first quarter of 1997 was used in the



analysis regardless of the treatment modality at that time. The creatinine was included in the model as a continuous variable with no transform applied to it.

The analysis was carried out categorising the phosphate as  $\leq 1.70$ ,  $1.71 - 2.10$  and  $\geq 2.11$  mmol/L, and was repeated categorising the phosphate into quintiles.

The predicted probabilities from the adjusted analysis have been calculated for someone with average patient characteristics (according to those factors considered in the model). Note that these values will vary for patients with different characteristics, i.e. they will depend upon the age of the patient, length of time on RRT, whether the patient has diabetes and treatment centre. The main reason for giving odds ratios rather than predicted probabilities is that odds ratios are not dependent upon the patient characteristics.

## Results

### Unadjusted Analysis.

Phosphate (mmol/l)	N	No. died in 1998	Proportion of patients who died
$\leq 1.7$	584	105	0.180 [95% CI: 0.150 – 0.212]
$1.71 - 2.10$	353	43	0.122 [95% CI: 0.090 – 0.159]
$\geq 2.11$	391	67	0.171 [95% CI: 0.136 – 0.211]

### Adjusted Analysis.

Phosphate (mmol/l)	Predicted probability of dying in 1998 (estimated from logistic regression model)	Odds ratio
$\leq 1.7$	0.145 [95% CI: 0.117 – 0.178]	ref
$1.71 - 2.10$	0.105 [95% CI: 0.078 – 0.142]	0.72
$\geq 2.11$	0.169 [95% CI: 0.134 – 0.212]	1.17

### Odds ratio for unadjusted and adjusted analysis and for creatinine correction

Phosphate(mmol/l) from First Quarter of 1997	Unadjusted Analysis (n = 1328) O.R. [95% CI]	Adjusted Analysis (n = 1299) O.R. [95% CI]	Adjusted Analysis + creatinine (n = 1291) OR [95% CI]
$\leq 1.70$	REF	REF	REF
$1.71 - 2.10$	0.63 [0.43 – 0.92]	0.70 [0.46 – 1.03]	0.78 [0.52 – 1.17]
$\geq 2.11$	0.94 [0.67 – 1.32]	1.20 [0.84 – 1.72]	1.42 [0.97 – 2.09]
p-value	0.0475	0.0367	0.0227

#### 5.3.4. Odds ratio for adjusted analysis by quintile

Phosphate from First Quarter of 1997	Adjusted Analysis (n = 1291) OR [95% CI]
≤ 1.47mmol/L	1.18 [0.74 – 1.88]
1.48 – 1.73mmol/L	REF
1.74 – 1.96mmol/L	0.76 [0.43 – 1.36]
1.97 – 2.23mmol/L	1.37 [0.80 – 2.33]
≥ 2.24mmol/L	1.48 [0.90 – 2.45]
X <sup>2</sup>	7.2
p-value	0.1276

## Discussion

In PD patients, albumin is a powerful predictor of subsequent mortality even after adjustment for age, diabetes mellitus, length of time on RRT and treatment centre. There was a statistically significant continuous inverse relationship between serum albumin and re risk of death such that rise in albumin of 1g/L was associated with a decrease in risk of death of 0.86(95% CI 0.83-0.90). For HD patients, the relationship was less consistent. After adjustment for cofactors there was no difference in outcome between those with serum albumin above or below 35g/L. There was an increased risk with an albumin in the lower two quintiles but no continuous relationship was identified.

There was an increased risk of death in those patients with URR < 65%. This difference was explained by an increased risk of death in those patients with URR < 60% with no apparent improvement in survival with URR above this level. Although similar observations have been made before (Parker 1994), it would be unwise to draw firm conclusions about the optimal URR from this data. The data is retrospective, blood sampling techniques for post-dialysis urea varied and methods for determining dialysis prescription also varied among different centres. For instance, some units had a minimum dialysis time of 4 hours leading to higher average URR. Smaller patients prescribed a standard dialysis time will have a high URR but if malnourished or ill through co-morbid conditions may have limited survival. The importance of body weight as a marker of survival and the complex interaction between body weight, dialysis prescription and achieved urea clearance (URR or calculated Kt/V) has recently been the subject of much debate (Chertow 1999, Lowrie 1999). The HEMO study (Eknoyan 1996) in the USA is likely to provide important data on the optimal dialysis dose in terms of urea clearance.

Phosphate showed an association with mortality which appeared to follow a J shaped distribution. When categorised into 3 groups the lowest mortality was associated with the middle range of phosphate 1.71-2.10mmol/l and was statistically more significant after adjusting for other risk factors and serum creatinine. When categorised by quintiles there was a trend to increasing mortality in the higher quintiles. The precise mechanism whereby hyperphosphataemia may increase mortality is unclear. Block et al suggested the adverse effects could be mediated by hyperparathyroidism or by vascular/cardiac ectopic calcification (Block 1998).

The incomplete data from some centres has made it difficult at present to perform a multiple regression analysis of survival taking into account a range of biochemical, haematological and physiological parameters (e.g. blood pressure, weight). However, as the registry database expands and data completeness and accuracy improves, it will be possible to perform such analyses. These can be used to generate hypothesis to be tested in prospective interventional studies. The continued high mortality of patients on dialysis highlights the need for further improvements in the treatment of this group of patients.

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## **Chapter 18: Survival in dialysis patients: associations with haemoglobin achieved and blood pressure control.**

### ***Haemoglobin achieved***

#### ***Subjects***

The study sample consisted of patients on dialysis on 1/1/1998 at 8 centres on the Renal Registry database who had been receiving renal replacement therapy for at least one year, from whom quarterly data for 1997 had been received. Patients from three other centres were not included because of concerns about completeness and accuracy of data. Patients were included in the analysis regardless of their previous treatment and transplant history. For inclusion at least 2 or more haemoglobin values for 1997 had to be received. The final sample size was 1,916 patients.

#### ***Methods***

A Cox Proportional Hazards Model was used to analyse the relationship between haemoglobin and risk of death over the one year period from January 1<sup>st</sup> to December 31<sup>st</sup> 1998. Patients were censored, and analysed as being alive, at the time of transfer to a non Renal Registry treatment centre, and at transplantation.

The mean haemoglobin was computed for 1997 in each patient. Two analyses were performed. Firstly, outcomes in patients with haemoglobin  $\geq 10$ g/dl were compared with outcomes in patients with  $< 10$ g/dl. This was chosen to test the current Renal Association Standards recommendation, which states that ‘a target haemoglobin concentration of not less than 10 g/dl (approximately equal to a haematocrit  $>31\%$ ) should be achieved in  $>85\%$  of patients after 3 months on renal replacement therapy. Analysis using quintiles of mean haemoglobin was also performed :the quintiles were  $\leq 8.9$ g/dl, 9.0 – 9.9g/dl, 10.0 – 10.9g/dl, 11.0 – 11.9g/dl and  $\geq 12.0$ g/dl. This approach was chosen to mirror recent large-scale analyses, mostly from the United States, which demonstrated that relationships between haemoglobin and mortality, while monotonic, are semi-linear.

Three models are presented:-

**Model I:** haemoglobin and mortality rates are analysed without adjustment for putative confounders or modifiers.

**Model II:** adjustment is made for age, log-transformed length of time on ESRF treatment, a primary diagnosis of diabetes, and treatment centre on January 1<sup>st</sup> 1998.

**Model III** is similar to Model II, with mean albumin levels as an additional adjustment factor. For this analyses were performed using the mean harmonised serum albumin from 1997, obtained from patients with 2 or more albumin readings in 1997. Patients from one centre were excluded from this last analysis, as the BCP method was used to measure albumin. This analysis was performed to try to eliminate the effects of other intercurrent illnesses which frequently reduce both haemoglobin

and serum albumin in a non-specific way. Any association between low haemoglobin and increased mortality in this model is more likely to be causal.

## Results

The results are shown in table 18.1

Mean Haemoglobin	<b>MODEL I</b> Unadjusted Analysis (n = 1,828) Hazard Ratio [95% CI] <sup>a</sup>	<b>MODEL II</b> Adjusted <sup>b</sup> Analysis (n = 1,763) Hazard Ratio [95% CI] <sup>a</sup>	<b>MODEL III</b> Adjusted <sup>b</sup> Analysis + Mean Albumin (n = 1,516) Hazard Ratio [95% CI] <sup>a</sup>
<b>&lt; 10 g/dl</b>	1.25 [0.98-1.59]	1.33 [1.03-1.71]	1.41 [1.07-1.86]
<b>≥ 10 g/dl</b>	1.00 (Reference)	1.00 (Reference)	1.00 (Reference)
<b>P-value</b>	p = 0.08	p = 0.03	p = 0.02
<b>&lt; 8.9 g/dl</b>	1.62 [1.11-2.35]	1.81 [1.22-2.67]	2.15 [1.41-3.29]
<b>9.0 – 9.9 g/dl</b>	1.08 [0.77-1.50]	1.22 [0.87-1.71]	1.23 [0.84-1.79]
<b>10.0 – 10.9 g/dl</b>	1.00 (Reference)	1.00 (Reference)	1.00 (Reference)
<b>11.0 – 11.9 g/dl</b>	1.00 [0.77-1.50]	1.07 [0.76-1.51]	1.10 [0.76-1.61]
<b>≥ 12 g/dl</b>	0.99 [0.67-1.46]	1.12 [0.76-1.66]	1.11 [0.72-1.72]
<b>Overall p-value</b>	p = 0.13	p = 0.07	p = 0.02
<b>P-value for linear trend</b>	p = 0.05 0.91	p = 0.06 0.90	p = 0.03 0.88
<b>Pooled hazards ratio assuming linearity assumption valid<sup>c</sup></b>	[0.82-1.00]	[0.81-1.00]	[0.78-0.98]

**Table 18.1. Relationship between haemoglobin and one year hazard of death**

- CI denotes 'confidence interval'. Confidence intervals that do not include 1 imply a statistically significant ( $p < 0.05$ ) difference in mortality rates from the reference category. A hazard ratio above 1 implies a greater death risk, while a hazards ratio under 1 implies a lower death risk.
- Adjusted for age, log-transformed duration of ESRF, presence or absence of diabetes as primary renal diagnosis and treatment centre.
- Estimate of the average change in hazards ratio associated with going up 1 haemoglobin category.

## **Discussion**

### ***Mortality of Patients with Haemoglobin < 10g/dl and Haemoglobin ≥ 10g/dl.***

Achievement of the recommendation of the Standards document of a haemoglobin of at least 10 g/dl was associated with lower mortality in adjusted analyses, with and without inclusion of mean serum albumin levels. The associated increments in mortality with haemoglobin levels below 10 g/dl were estimated at 33% and 41% respectively. In the unadjusted analysis, the association between haemoglobin values below 10 g/dl and mortality failed to reach statistical significance, with a p value of 0.08.

### ***Mortality With Mean Haemoglobin Categorised by 1g/dl***

Haemoglobin levels below 9 g/dl were associated with higher mortality in all 3 Models. Compared to haemoglobin levels of 10 to 10.9 g/dl, the associated mortality increments were 62% in Model I, 81% in Model II, and 115% in Model III. Tests for a linear relationship between haemoglobin band and mortality did not quite reach statistical significance in Model I (p for trend 0.05) and Model II (p for trend 0.06). The corresponding p-value was statistically significant at 0.03 in Model III. In this model, moving up 1 haemoglobin band was associated with an average mortality reduction of 12% (95% CI 2% to 22%), a figure quantitatively similar to those observed in Model I and Model II.

## **Conclusion**

This analysis supports the evidence that low haemoglobin over a period of time is associated with increased mortality in dialysis patients. Whilst the relationship between haemoglobin and mortality is not entirely linear, there may be some additional gain from increasing the haemoglobin above 10 g/dl.

## ***The Association Between Blood Pressure and Risk of Death***

This section examines the association between observed blood pressure and short term prognosis over one year of patients established on dialysis.

## **Sample**

The sample consisted of patients who were established on dialysis on 1/1/1998, who were receiving treatment at one of the 11 centres on the Renal Registry database with quarterly data for 1997. The sample only included patients who started ESRF treatment before 1/10/1997. The sample totalled 2,699 patients.

The last blood pressure from the last quarter of 1997 was used in the analysis.

In four Centres, less than 75% of patients had blood pressure readings available. Patients from these centres were excluded from the analysis. This resulted in a sample of 1,638 patients, of which 1,451 patients had appropriate blood pressure data available.

## Methods

The analysis was carried out with the systolic blood pressure and diastolic blood pressure separately. Blood pressure was divided into quintiles.

For systolic blood pressure the quintiles were:  $\leq 117$ , 118 – 131, 132 – 146, 147 – 161 and  $\geq 162$ .

For diastolic blood pressure the quintiles were:  $\leq 65$ , 66 – 74, 75 – 80, 81 – 90 and  $\geq 91$ .

The analysis was carried out for the mean arterial blood pressure and pulse pressure. For mean arterial pressure the quintiles were  $\leq 83$ , 84 - 93, 94 - 103, 104 - 112 and  $\geq 113$ .

The pulse pressure was defined as the difference between the systolic blood pressure and the diastolic blood pressure. The analysis was carried out dividing the pulse blood pressure into quintiles, which were defined as:  $\leq 45$ , 46 - 55, 56 - 66, 67 - 80 and  $\geq 81$ .

The outcome was death during 1998. A Cox Proportional Hazards Model was used to analyse the relationship between blood pressure and risk of death over the one year period in 1998, adjusting for age, length of time on RRT, whether the patient had a primary diagnosis of diabetes and treatment centre on 1.1.1998. Age and length of time on RRT were entered into the model as continuous variables. The length of time on RRT was measured in days on the 1/1/1998 and its log transform was used in the model. Patients without a primary diagnosis were excluded from the adjusted analysis, as were patients who had been on RRT for an unknown duration.

The adjusted and unadjusted survival analysis was stratified by centre. Stratifying by centre enables a separate underlying hazard to be estimated at each centre but assumes that the effect of blood pressure and confounding variables on the hazard to be the same at each centre.

Patients were censored if they transferred out from a Renal Registry Site to a non Renal Registry Site or if they had a transplant. Note that if a patient died on the day of transplant, then the death has not been counted.

### Systolic Blood Pressure

The results (table 18.2) show a weak but significant association between systolic blood pressure and survival in the adjusted analysis, such that higher pressures are associated with lower hazard

Systolic Blood Pressure	Unadjusted Analysis (n = 1451) Hazard Ratio [95% CI]	Adjusted Analysis (n = 1391) Hazard Ratio [95% CI]
$\leq 117$	0.92 [0.62 – 1.35]	0.78 [0.52 – 1.17]
118 – 131	REF	REF
132 – 146	0.65 [0.42 – 1.00]	0.55 [0.35 – 0.85]
147 – 161	0.79 [0.53 – 1.18]	0.64 [0.42 – 0.97]
$\geq 162$	0.67 [0.44 – 1.02]	0.55 [0.36 – 0.85]
$\chi^2$	6.2	10.6
p-value	0.1828	0.0320

Table 18.2. Systolic pressure and hazard of death



### Diastolic Blood Pressure

The results (table 18.3) show a highly significant association between diastolic blood pressure and survival in the unadjusted and adjusted analyses, such that higher pressures are associated with lower hazard

Diastolic Blood Pressure	Unadjusted Analysis (n = 1451) Hazard Ratio [95% CI]	Adjusted Analysis (n = 1391) Hazard Ratio [95% CI]
≤ 65	1.59 [1.09 – 2.32]	1.37 [0.93 – 2.02]
66 – 74	1.31 [0.88 – 1.94]	1.14 [0.76 – 1.71]
75 – 80	0.69 [0.44 – 1.08]	0.61 [0.38 – 0.98]
81 – 90	REF	REF
≥ 91	0.51 [0.30 – 0.87]	0.58 [0.34 – 1.00]
<b>X<sup>2</sup></b>	31.7	20.6
<b>p-value</b>	< 0.0001	0.0004

**Table 18.3. Diastolic pressure and hazard of death**

The unadjusted association could not be completely explained by a linear trend, since although there was a statistically significant linear trend ( $X^2 = 23.7$ , d.f = 1,  $p < 0.0001$ ), there was also a statistically significant departure from trend ( $X^2 = 8.0$ , d.f = 3,  $p = 0.0461$ ).

This was also the case with the adjusted analysis, since there was a statistically significant linear trend ( $X^2 = 11.9$ , d.f = 1,  $p = 0.0005$ ) and a statistically significant departure from trend ( $X^2 = 8.7$ , d.f = 3,  $p = 0.0341$ ).

### Mean Arterial Blood Pressure

The results (table 18.4) show a weakly significant association between mean arterial pressure and survival in the unadjusted analysis which is not present in the adjusted analysis.

Mean Arterial Blood Pressure	Unadjusted Analysis (n = 1451) Hazard Ratio [95% CI]	Adjusted Analysis (n = 1391) Hazard Ratio [95% CI]
≤ 83	1.57 [1.07 – 2.30]	1.58 [1.06 – 2.36]
84 - 93	1.29 [0.86 – 1.93]	1.44 [0.95 – 2.17]
94 - 103	REF	REF
104 - 112	1.00 [0.64 – 1.58]	1.06 [0.66 – 1.70]
≥ 113	0.83 [0.53 – 1.29]	0.96 [0.61 – 1.51]
<b>X<sup>2</sup></b>	11.1	8.8
<b>p-value</b>	0.0253	0.0662

**Table 18.4. Mean arterial pressure and hazard of death**

The weak statistically significant association found in the unadjusted analysis conformed to a linear association ( $X^2 = 10.4$ , d.f = 1,  $p = 0.0012$ ), such that moving up one mean arterial

blood pressure quintile was associated with a decrease in hazard of 0.85 [95% CI: 0.77 – 0.94]. This association was abolished by adjustment.

### **Pulse Pressure**

Results are shown in table 18.5. No association was found between pulse pressure and hazard of death.

<b>Pulse Blood Pressure</b>	<b>Unadjusted Analysis (n = 1451) Hazard Ratio [95% CI]</b>	<b>Adjusted Analysis (n = 1391) Hazard Ratio [95% CI]</b>
≤ 45	REF	REF
46 – 55	0.93 [0.61 – 1.42]	0.79 [0.51 – 1.23]
56 – 66	0.98 [0.63 – 1.51]	0.78 [0.50 – 1.22]
67 – 80	0.98 [0.66 – 1.47]	0.73 [0.48 – 1.12]
≥ 81	1.23 [0.81 – 1.88]	0.84 [0.54 – 1.30]
<b>X<sup>2</sup></b>	<b>2.1</b>	<b>2.3</b>
<b>p-value</b>	<b>0.7243</b>	<b>0.6784</b>

**Table 18.5. The association between pulse pressure and hazard of death**

### **Comment**

This study is short term and uses a relatively small sample. The pitfalls of such analysis are considerable and are discussed in chapter 10. The lack of the expected relationship between hypertension and poor outcome in several studies in renal replacement therapy has already been considered in chapter 10. Similar results are found from this Registry data, with hypertension appearing to be a marker for good prognosis. No relationship was found between pulse pressure and short term prognosis. As discussed, the measured blood pressure reflects many things including myocardial function, arterial rigidity and resistance, salt and water balance, and hypotensive treatment given. It is probable, given current dialysis practice, that those with good myocardial function develop hypertension, and that lower blood pressure is may often be a marker of poor myocardial function and thus poor prognosis.

It **must not** be deduced from these analyses that better blood pressure control, whether by means of better dialysis, salt, water control, or use of drugs, would not improve long term survival of dialysis patients.

## **Chapter 19: The influence of socio-economic deprivation on survival of prevalent dialysis patients.**

### ***Summary***

These data show that, using the Townsend index, no significant influence of socio-economic deprivation on survival of the cohort of prevalent dialysis patients on the Registry in 1998 could be demonstrated. This was true for the unadjusted analysis and the analysis adjusted for age, gender, diabetes, and length of time on renal replacement therapy. Some potential confounders of this analysis are discussed.

### ***Aim***

To analyse the relationship between socio-economic deprivation (as measured by the Townsend Score) and one-year survival of prevalent patients on dialysis.

### ***Background***

There are socio-economic differences in both incidence and mortality in a range of chronic conditions. Survival from common cancers has also been shown to be poorer in patients from more deprived areas<sup>1</sup>. Possible reasons include delayed referral/presentation, host factors (e.g. comorbidity, compliance, diet) and quality of care.

There is some evidence of socio-economic differences in the incidence of CRF. Mortality from CRF is higher in lower social classes<sup>2</sup>. Modelling of geographic variation in acceptance from the 1991-2 Renal Review for England showed acceptance rates onto renal replacement therapy programmes were higher in deprived areas, after adjustment for access and ethnicity<sup>3</sup>. A population based cross sectional study in the South West of England showed higher levels of chronic renal failure, as judged by serum creatinine, in deprived areas<sup>4</sup>. In contrast, a prospective study of patients starting renal replacement therapy in Scotland during 1998 did not show a difference in the acceptance rate with social deprivation, although the numbers were small and this may have been a type 2 error<sup>5</sup>. However there are no data on the outcome of renal replacement therapy and socio-economic status in the UK.

### ***Methods***

#### ***Inclusion***

Patients on dialysis at the start of the 1/1/1998 who had been receiving renal replacement therapy for over one year were included.

#### ***Exclusion criteria***

If the duration of renal replacement therapy could not be determined  
Patients who had a transplant between the 1/7/1997 and the 31/12/1997

Transplant patients who transferred in during this period, with an unknown date of transplant.

Patients receiving treatment at Centre G as there were a large number of patients with no Townsend Score at this Centre (27%).

The sample was 3,300 patients. In the analysis adjusting for diabetes, patients at Centre H were also excluded, since most patients who died at this centre had no diagnosis data. This reduced the sample to 3,107 patients.

### ***Deprivation measure***

The patient's Townsend index was derived from the postcode. This is a composite measure of deprivation based on total unemployment rate, no car households, overcrowded households and not owner occupier households based on the electoral ward as at the 1991 Census (6). A comparison of the current methods of scoring deprivation in the UK is listed at the end of this chapter.

Note that the Registry only stores the patient's most recent postcode on the database, so that the postcode may occasionally differ from the patient's postcode at the start of the analysis. This will only affect a small number of patients, some of whom will in any case have probably moved to similar social areas.

There was a Townsend score for 96% (3,209) of the 3,330 patients. The score was categorised into quintiles defined from this sample of  $\leq -3.01$ ,  $-3.00$  to  $-1.29$ ,  $-1.28$  to  $0.64$ ,  $0.65$  to  $3.07$  and  $\geq 3.08$ . Lower Townsend Scores (negative scores) correspond to relatively more affluent areas, and higher Townsend Scores (positive scores) indicate greater need, corresponding to relatively more deprived areas.

### ***Censoring***

Patients were censored if they transferred out to a non Renal Registry site or if they were transplanted in 1998. Patients were classified as having diabetes from their primary renal diagnosis: this excluded those diabetic patients with another cause of end stage renal failure. Patient's age on 1/1/1998 was used.

A Cox Proportional Hazard Model was used to analyse the relationship between Townsend Score and risk of death over the one-year follow up period and was stratified by treatment centre. The analysis was repeated adjusting for age, gender, diabetes and length of time on renal replacement therapy. The logarithm of the length of time on renal replacement therapy was used in the analysis as this normalised the skewed distribution.

## ***Results***

### ***1. Unadjusted Analysis: n = 3,209.***

There was no significant association between deprivation score and risk of death ( $p = 0.4002$ ). There was also no significant linear trend between deprivation score and risk of death ( $p = 0.7620$ ).

Deprivation Score	Hazard Ratio [95% CI]
≤ -3.01	REF
-3.00 to -1.29	1.18 [0.89 – 1.58]
-1.28 to 0.64	1.30 [0.98 – 1.72]
0.65 to 3.07	1.16 [0.87 – 1.54]
≥ 3.08	1.06 [0.79 – 1.43]
P-value	0.4002

**Table 19.1 Unadjusted analysis**

**2. Unadjusted Analysis (centre H also excluded): n = 2,999.**

The analysis was repeated also excluding centre H. This was performed as it is necessary to exclude Centre H from any analysis adjusting for diabetes. Repeating the analysis excluding Centre H will ensure that any differences in results between the unadjusted and adjusted analyses are not due to differences in the centres included.

Deprivation Score	Hazard Ratio [95% CI]
≤ -3.01	REF
-3.00 to -1.29	1.18 [0.88 – 1.59]
-1.28 to 0.64	1.34 [1.00 – 1.79]
0.65 to 3.07	1.13 [0.84 – 1.53]
≥ 3.08	1.07 [0.79 – 1.45]
P-value	0.3566

**Table 19.2 Unadjusted analysis excluding H**

There was no significant association between deprivation score and risk of death ( $p = 0.3566$ ). There was also no significant linear trend between deprivation score and risk of death ( $p = 0.7841$ ).

**3. Adjusted Analysis (for sample excluding Centres G & H): n = 2,874.**

Deprivation Score	Hazard Ratio [95% CI]
≤ -3.01	REF
-3.00 to -1.29	1.16 [0.85 – 1.57]
-1.28 to 0.64	1.40 [1.04 – 1.88]
0.65 to 3.07	1.18 [0.86 – 1.60]
≥ 3.08	1.21 [0.88 – 1.66]
P-value	0.2814

**Table 19.3 Adjusted deprivation analysis**

In the adjusted analysis there was no significant association between deprivation score and risk of death ( $p = 0.2814$ ). There was also no significant linear trend between deprivation score and risk of death ( $p = 0.2464$ ).

## **Discussion**

These data did not demonstrate any significant socio-economic influence on survival of prevalent dialysis patients on the Registry in 1998. The hypothesis that patients from lower social groups had poorer survival because of factors such as comorbidity, other host factors such as diet, and quality of care, was not supported. It seems unlikely that quality of care will vary for different socio-economic groups when once they are receiving regular dialysis.

There are several potential confounders in this analysis:-

The analysis of a prevalent cohort assumes that a large number of patients in one subgroup had not died early on in the renal replacement therapy programme leaving a biased subset of survivors in different deprivation groups.

The analysis assumes equity of access to a renal replacement programme for all social groups. Although the analysis of the 1992 Review data shows a higher incidence of patients in deprived areas starting renal replacement therapy (after adjusting for ethnicity), this was not adjusted for co-morbidity. Furthermore there is no data on the incidence, as opposed to the treatment rate, of end stage renal failure in different socio-economic groups in the UK. If patients from lower socio-economic groups with higher co-morbidity scores were less likely to gain access to a renal replacement therapy programme (or had died prior to starting renal replacement therapy) the analysis would be invalid.

The assignment of socio-economic status by area of residence can lead to misclassification and a reduced chance of findings relationships (i.e. not all people living in deprived areas are deprived and vice versa).

All postcodes in the Renal Registry database are verified and corrected using the patient's address and a postcode software package. The package is updated quarterly for new postcodes issued by the post office. Allocation of a Townsend Index was via the Manchester University database (MIMAS), which is not updated with the recent postcode changes. The 4% of postcodes without a Townsend Index allocated are all related to the recent boundary changes and this may have caused a slight bias.

When sufficient time has elapsed to allow for adequate follow-up, this analysis will be repeated with the much larger 1999 cohort of 6260 prevalent dialysis patients, and with the combined 1998 and 1999 incident cohort of 2990 patients.

## **Conclusion**

With the number of patients available for this analysis it was not possible to demonstrate any effect on socio-economic deprivation on the survival of prevalent dialysis patients in the UK. Further analyses will be carried out when larger numbers of patients are available and will also be repeated using the Carstairs Index

## Comparison of UK Deprivation Scores

Indicator	DoE (1983)	Townsend	Jarman	Carstairs	LWT	DoE, ILC (1994)
Census data						
Total unemployment rate	*	*	*		*	All levels
Male unemployment rate				*		
Overcrowded households	*	*	*	*		All levels
Households lacking amenities	*					All levels
Not owner occupier households		*			*	
No car households		*		*	*	All levels
Low social class (4&5 or SEG 11)			*	*	*	
Lone parent households	*		*		*	
Lone pensioner households	*		*			
Under 5s			*			
Children in unsuitable accom.						All levels
Children in low earning h/h						All levels
Moving with previous year			*			
Limiting long term illness					*	
Born New Commonwealth	*		*			
17 yr olds not in full time ed.						ward/district
Non-census data						
Standard mortality ratio						district
Long term unemployment						district
Income support recipients						district
House contents insurance						district
Low GCSE attainment						district
Derelict land						district

**Table 19.4** Comparative UK deprivation scores

## References

1. Coleman MP, Babb PO, Damiacki P et al. Cancer survival trends in England and Wales. 1971-1995. Deprivation and NHS Region. London: The Stationary Office, 1999.
2. Occupational health decennial supplement. No10. 1995. London:ONS,1995.

3. Roderick P, Clements S, Stone N, Martin D, Diamond I. What determines the geographical variation in rates of acceptance onto renal replacement therapy in England? *J Health Service Res Policy*. 1999;4:139-146.
4. Drey N. PhD. thesis. The epidemiology of diagnosed chronic renal failure in Southampton and South West Hampshire Health Authority. University of Southampton 2000.
5. Metcalfe W, MacLeod AM, Bennett D, Simpson K, Khan IH. Related Articles Equity of renal replacement therapy utilization: a prospective population-based study. *QJM*. 1999 Nov;92(11):637-42.
6. Townsend P, Phillimore P, & Beattie A,. Health and deprivation: Inequalities in the North. London: Croom Helm, 1988



## **Chapter 20: Transplantation and Waiting lists**

This chapter was written in collaboration with UK Transplant and the British Transplantation Society. Data on some aspects have been analysed only for those centres on both the Renal and Transplant databases; for these patients it is possible to analyse the whole RRT history in a longitudinal manner. This approach will be developed in coming years.

### **Summary**

Between 1988 and 1998, there was a decrease in both the percentage and absolute number of grafts in the age range 18-24. By contrast, both the number and percentage of grafts in the age range 35-44 increased, probably because more Type I diabetic patients were transplanted. Despite an increase in the number of patients over 65 years old on RRT (46% of all patients starting dialysis in 1998) only a few patients of this age are transplanted.

In 1998, 48% of kidneys were retained locally, in contrast to over 60% in 1988 and 1993. This is the result of regional arrangements from 1996 to exchange beneficially matched kidneys.

Between 1993 and 1998, the UK transplant waiting list increased from 3,800 to 4,400 with an increase in the percentage of patients in the 35 – 54 age group. In the over 55 age group where there has been the greatest increase in the dialysis population, figures have remained relatively static in terms of percentage and absolute number.

Between 1993 and 1998, there was an overall drop in the percentage of patients on the waiting list who received a graft. This reflects a combination of an increased waiting list and reducing donor numbers. This change was most notable in the drop in transplantation in 18-24 year olds associated with a relative increase in transplantation in the 35-44 age group.

In 1993, 16% of the total number of UK patients on the waiting list were suspended and this had risen to 19% on the 1<sup>st</sup> January 1999. As expected the proportion of suspended patients rises with age.

28% of the 6838 dialysis patients on the Renal Registry in 1998 were on the active waiting list; there remains a large variation (16-38%) in the percentage of dialysis patients on the transplant active waiting list from centre to centre in the Registry. A confounding factor, not analysed this year, may be differences in the age profile from centre to centre, since in the Renal Registry dialysis population, there is a trend for a higher percentage of younger patients to be on the waiting list.

Between 1983 and 1998 there was a marked increase in the incidence of diabetics transplanted. However, the 1983 data may be distorted; no diagnosis is available for 49% of patients in that year whereas this figure is 39% in 1998. The rise in diabetics was mainly noted in the 35-64 age group

For Renal Registry centres only 22% of dialysing diabetics aged under 65 were on the active waiting list compared with 44% of non-diabetics

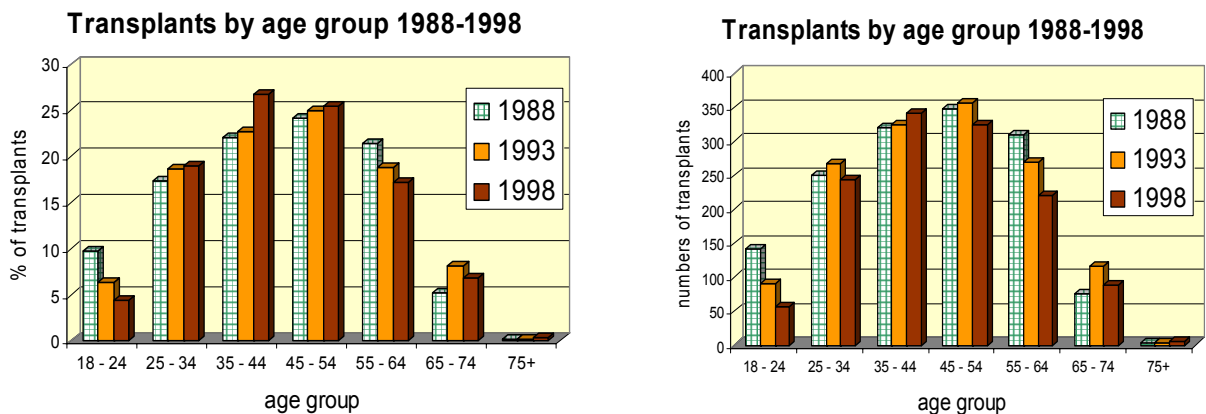
## Introduction

This section inaugurates the first collaboration between the Renal Registry and UK Transplant. It is anticipated that the integration of information from two complementary databases will lead to a more complete, accurate and comprehensive analysis of transplantation trends in the UK.

UK Transplant holds the waiting list, recipient tissue typing data and donor information. Linking this data with the pre-transplant history, post transplant failure data and quarterly biochemistry and blood pressure data collected by the Renal Registry will provide unique insights.

This supplement is a starting point to illustrate the potential of integration. With more centres joining the Registry it is anticipated that this will develop into a substantially more detailed and comprehensive analysis in the future and bear fruit in joint publications.

## 10 year changes in age at transplantation



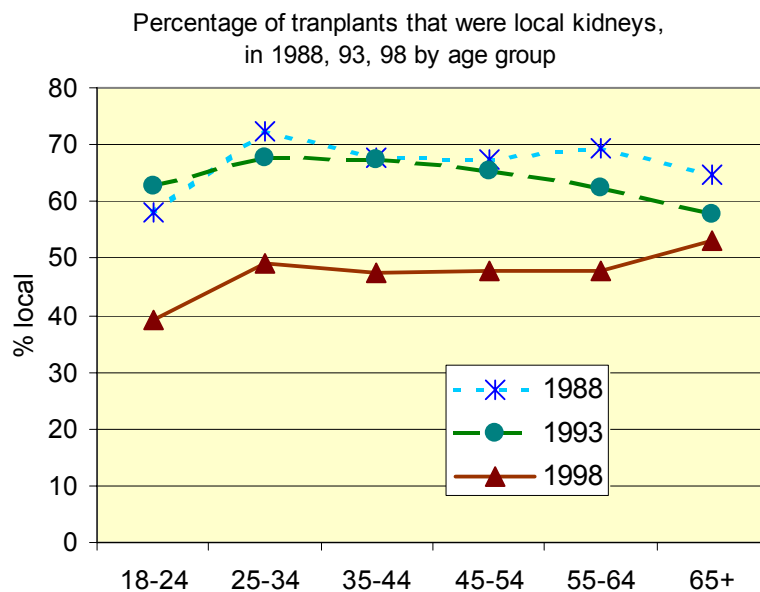
**Figure 20.1a&b Transplantation by age groups 1988 -98**

The figure above of new transplants by age group for the years 1988, 1993, 1998 indicate a trend to increased percentage of transplants in the 25-54 range, a drop in those between 55-64 and an increase in those greater than 65. When analysed using the numbers transplanted there is an increase in the 35-44 age group with a marked reduction in the 18-24 group. The reasons for the increase are probably related to a rise in transplantation rates of Type I diabetic patients.

Only a small percentage of patients over 65 years were transplanted although in 1998 26% of all renal replacement therapy patients were over 65 and 46% of all patients starting dialysis were over 65.

It was uncommon to transplant patients over 75 years although there were a few patients in this category.

## 10 year changes in use of local and exchanged kidneys

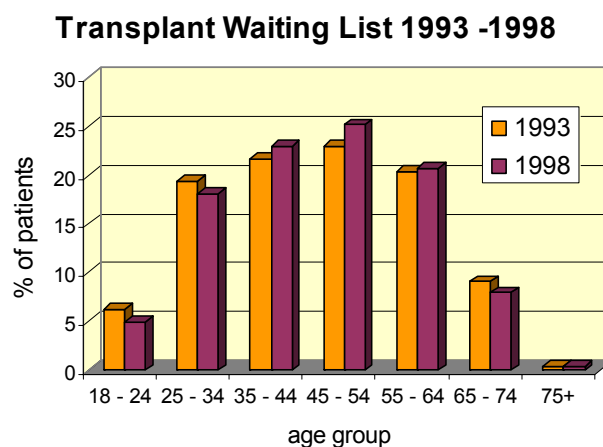


**Figure 20.2 Transplanted local kidneys 1988 - 98**

In 1988 and 1993 over 60% of kidneys were transplanted locally. This was generally true across all age bands and there was no bias to transplant younger people with an available local kidney. Within this period UK Transplant ran a beneficial matching scheme for exchanging kidneys.

In 1996 various transplant centres started to group together to exchange beneficially matched kidneys. As expected this has caused a reduction to 48% of kidneys that are retained locally and there was no age bias.

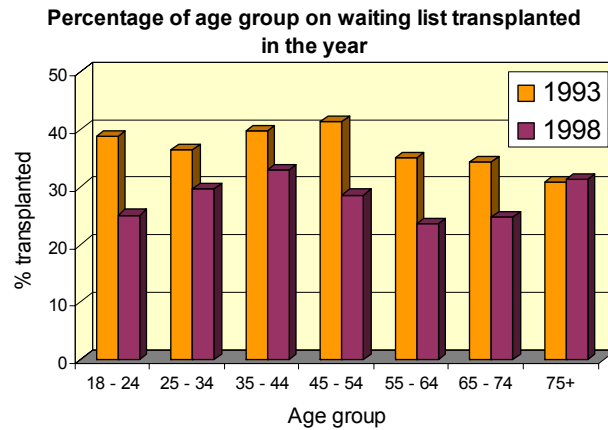
## Five year changes in the transplant active waiting list by age



**Figure 20.3 Transplant waiting lists 1993-98.**

Over 5 years the total number of patients on the UKTSSA active waiting list has risen from 3,800 to 4,400 with an increase in the percentage of patients in the 35 – 54 age group waiting

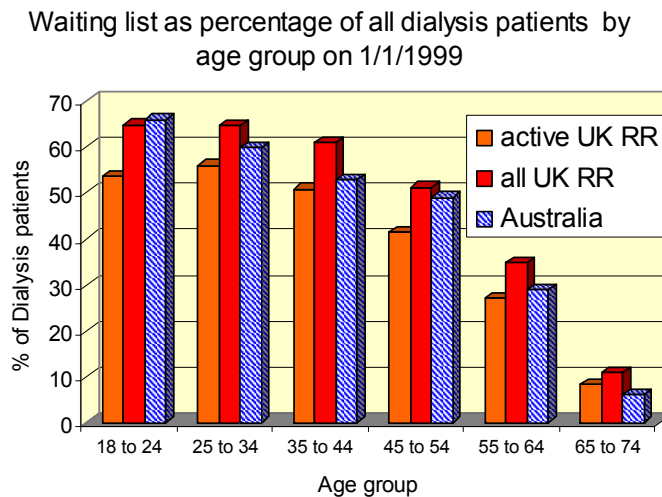
for a transplant. Surprisingly in the over 55 age group where there has been the greatest increase in the dialysis population, these numbers have remained relatively static.



**Figure 20.4 Transplants by age 1993-98.**

Between 1993 and 1998, there is an overall drop in the percentage of patients on the waiting list who received a graft. This reflects a combination of an increased waiting list and reducing donor numbers. This change was most notable in the drop in transplantation of the 18-24 year olds associated with a relative increase in transplantation in the 35-44 age group.

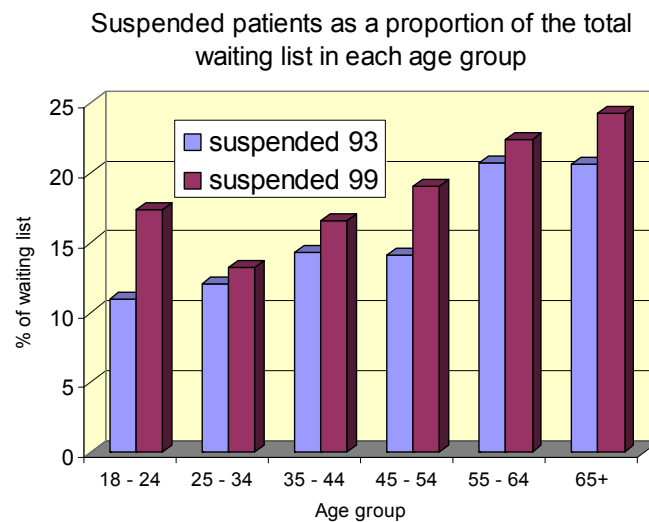
### ***Listing for transplantation***



**Figure 20.5 Waiting lists as a percentage of all dialysis patients**

The above figure only includes data from centres on the UK Renal Registry and is therefore an approximation for the UK. In the UK only 50% of dialysis patients in the 18 – 44 age group were active on the waiting list. The total waiting list including the suspended patients is also shown. The Australian data, taken from the ANZDATA report excludes suspended patients (personal communication).

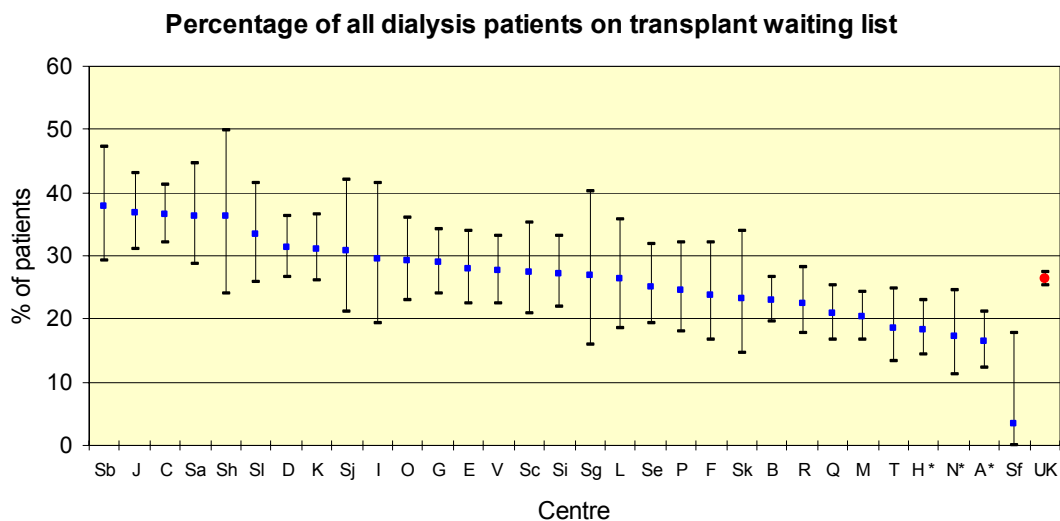
Pre-dialysis patients who have been listed pre-emptively have been excluded from the above UK analysis.



**Figure 20.6 Suspended patients as a proportion of the waiting list**

In 1993, 16% of the total number of UK patients on the waiting list were suspended and this had risen to 19% on the 1<sup>st</sup> January 1999. As expected the proportion of suspended patients rises with age. The reason for the rise in suspension of the 18-24 year olds is unknown.

### ***Access to transplantation***



\* indicates 3 centres with a probable inaccurate count of the dialysis population

**Figure 20.7 Percentage of all dialysis patients on waiting list by centre**

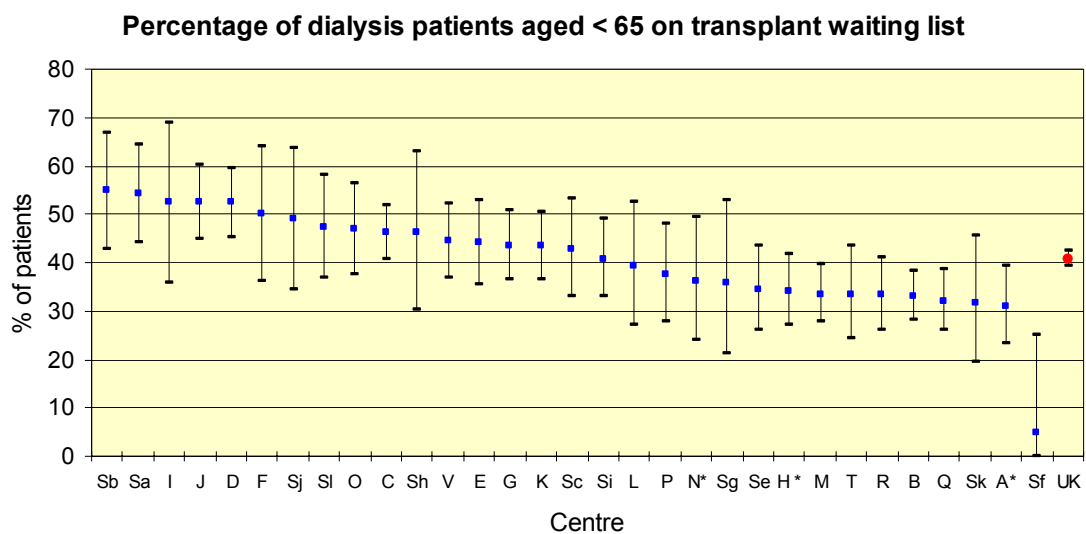
Pre-dialysis and suspended waiting list patients were excluded from this analysis

Figures 20.7-9 show the percentage of dialysis patients for each of the centres on the Registry who were on the transplant active waiting list on 31<sup>st</sup> December 1998. The data is arranged in

descending order and hence each centre position may vary between graphs. The lines indicate the 95% Confidence interval.

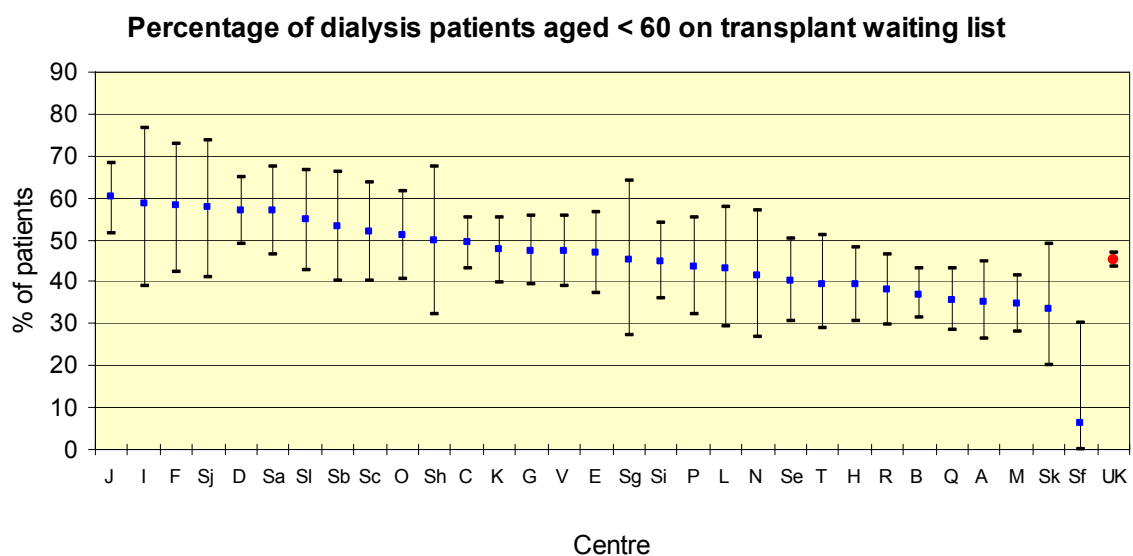
28% of the 6838 dialysis patients on the Registry in 1998 were on the active waiting list. This varied between centres from 16-38% (with one of the small centres <10%).

Figures 20.7-9 show a trend where a higher percentage of younger patients are on the waiting list. This trend may be related to the assumed increase in co-morbid conditions in the elderly. Additionally, these differences between centres may be related to an inter-centre variable proportion of patients in these age bands.



\* indicates 3 centres with a probable inaccurate count of the dialysis population

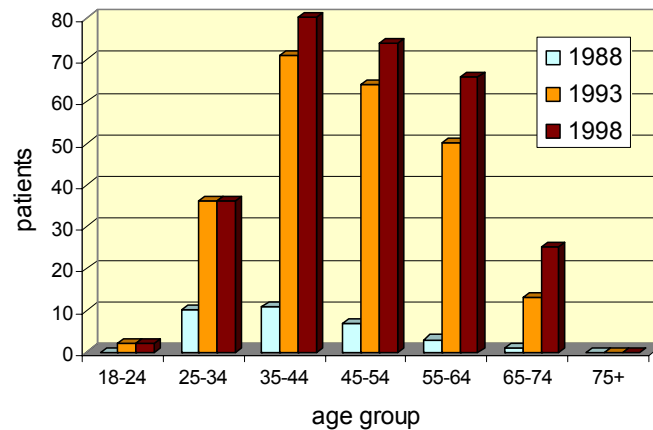
**Figure 20.8 Percentage of dialysis patients aged <65 on waiting list by centre**



**Figure 20.9 Percentage of dialysis patients aged <60 on waiting list by centre**

## Diabetes, transplantation and waiting lists

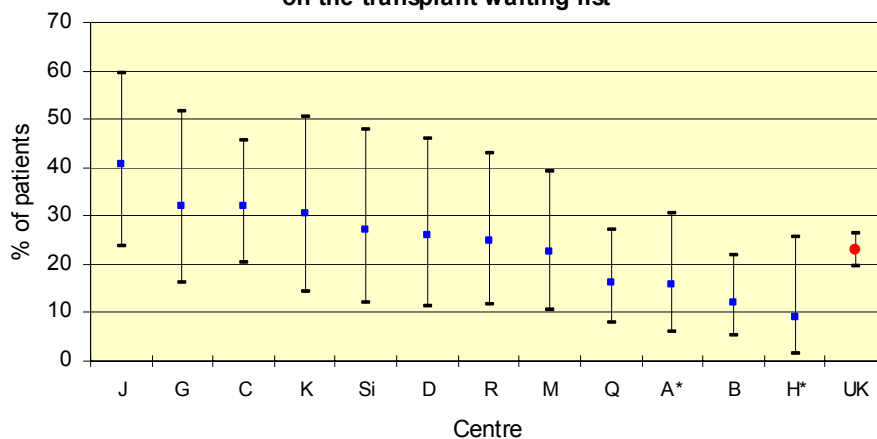
### Numbers of diabetics transplanted



**Figure 20.10** Number of diabetics transplanted

Between 1983 and 1998 there was a marked increase in the incidence of diabetics transplanted. However, the 1983 data may be distorted; no diagnosis is available for 49% of patients in that year whereas this figure is 39% in 1998 (Fig 20.10). The rise in diabetics was mainly noted in the 35-64 age group. This may just be a reflection of the increased percentage of diabetics entering the renal replacement therapy programme or it might additionally be a change in attitude to transplanting diabetic patients.

### Percentage of dialysed diabetics aged < 65 on the transplant waiting list



\* indicates 2 centres with a probable inaccurate count of the dialysis population

**Figure 20.11** Diabetics on the waiting list by centre

The variation in the percentage of dialysing diabetics aged under 65 year who were on the active transplant list by centre is shown in figure 20.11. Centres with less than 20 diabetic patients in this category were excluded from the analysis, but have been included in the UK total. These numbers are small and the 95% confidence intervals are wide. Only 22% [95%CI 19-26%] of dialysing diabetics aged under 65 are on the active waiting list compared with 44% [95%CI 42 -45%] of non-diabetics.





## **Chapter 21: NHS Purchasing & Supply Agency - equipment supplied for RRT in England**

Information supplied from NHS Supply Agency by Karen Guth

This information relates to England alone, as this agency of the NHS works only in England. There are separate organisations for each of Northern Ireland, Scotland, and Wales.

### ***An overview of the Agency***

The management and strategic development of purchasing and supply for the NHS in England is the responsibility of the NHS Purchasing and Supply Agency – an executive agency of the Department of Health, funded by the Department of Health, and formed as a result of recommendations in the Cabinet Office *NHS procurement review*. The Agency comprises several specialist teams that focus on supply issues in different markets. These teams offer a variety of services to the NHS, including negotiation of national call-off contracts, provision of purchasing advice and guidance, and management of the supplier base to ensure the market remains competitive.

### ***The Renal expertise of the Agency***

There are medical and surgical purchasing teams, which concentrate on a number of high-expenditure cores, market areas, including renal replacement therapy, cardiology, pressure area care, continence care and orthopaedic implants. For Renal services the team have one senior buyer and two buyers who concentrate specifically on purchasing renal replacement therapy machines, haemodialysis and peritoneal dialysis consumables. This renal market in England alone is estimated to be worth around £107 million per annum, inclusive of money spent through the commercially run satellite dialysis units (Scotland, Wales and Northern Ireland manage their own procurement).

A primary aim of the renal purchasing team is to enable renal units to obtain the best value for money when purchasing renal equipment and supplies. This will be only achieved by collaborative working between the Department of Health, NHS trusts, suppliers and the Agency. Success in this will free resources to help facilitate the desired increase in acceptance rates for Renal Replacement Therapy and to better achieve the national treatment standards for renal replacement therapy.

The purchasing team's four key objectives are:

- to become the centre of expertise and knowledge relating to the supply of equipment and consumables renal replacement therapy (RRT)
- to enable the NHS to obtain the maximum possible benefit from its supply expenditure relating to RRT
- to obtain the commitment of NHS trusts and suppliers to co-ordination of the market strategy for supply matters relating to RRT
- to provide purchasing & supply guidance to the Department of Health, the NHS Executive, tertiary, secondary and primary care organisations.

## Current market situation

There are currently only a few discrete suppliers in the renal market, and it is important for the NHS Purchasing and Supply Agency to maintain and manage this market to ensure healthy commercial competition is promoted. There are obvious positive benefits to this approach in order that price competition and, potentially, research and development are not stifled.

The cost of a low flux dialyser in England is currently one of the lowest in the world at £6.50 - £7.00 + VAT. All UK consumption is currently imported, largely from Europe or Japan, as there is no UK production. With the move to larger surface areas and medium to high flux dialysers the renal purchasing team is keen to see the continuation of low UK prices, allowing for a maximum number of suppliers in the market place to exist.

Through its ongoing work with trusts, the team has identified huge cost variations in, for example, therapy costing for Peritoneal Dialysis which ranges from as low as £6,000 per patient per year (for a consortium deal) to £19,000 per patient per year. The lower prices have been achieved through recent market testing exercises, and a clinical consensus to rationalise and standardise on consumables used. Enabling Trusts to obtain prices towards the lower end of this range is an important part of the agency's work.

## Current Market Shares

Figure 21.1 shows the current market shares for haemodialysers. This information was compiled primarily by one of the main dialyser companies as a result of annual audit, and includes information relating to renal units, NHS run satellites, and privately run satellites where companies often use their own dialysers.

### Dialysers supplied to the UK Market during 1999

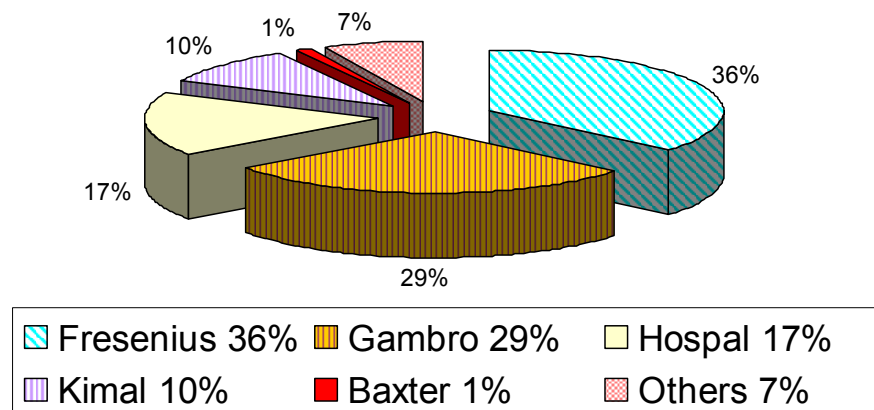
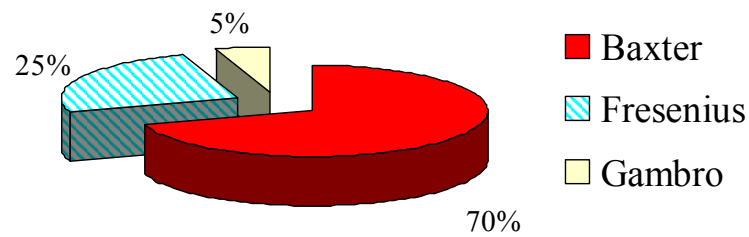


Figure 21.1 UK dialyser market share

Figures 21.2 and 21.3 were compiled by the NHS Purchasing and Supply Agency. The percentages are derived from the 54% of the current market of which the agency has detailed

## Market share for peritoneal dialysis



knowledge. The companies concerned broadly agreed the provisional figures. The figures relate to England only.

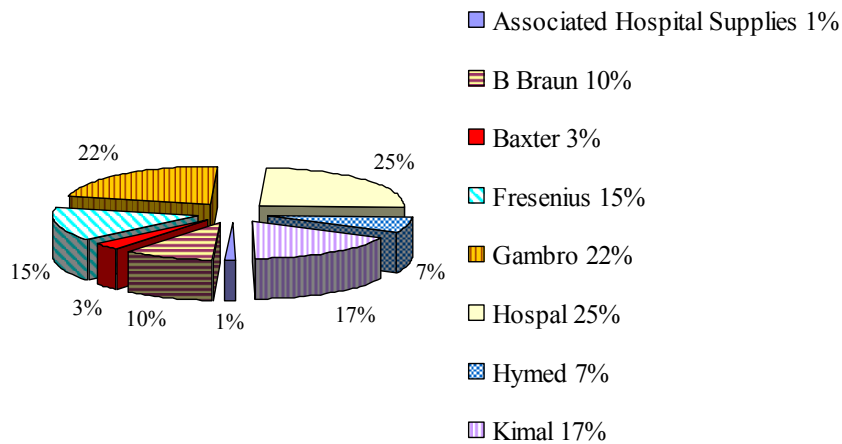
**Figure 21.2 Market shares of haemodialysis equipment, inclusive of machines, but excluding dialysers.**

**Figure 21.3 Market shares of PD supplies, inclusive of all CAPD, APD and IPD.**

## Help available for trusts

The renal purchasing team can provide support and assistance to any renal unit in England

### Market share for haemodialysis equipment and consumables



seeking to tender capital, revenue or special allocation funding on a variety of services or equipment including:

- haemodialysis equipment and consumables
- Peritoneal Dialysis therapy costing
- distribution contracts
- home or in-centre units
- home conversions for patients transferring out of the unit
- water softening plants
- new satellite units.

The team can help trusts in their individual procurement exercises, which usually includes placing an advertisement in the Official Journal of European Communities (OJEC) - this is a

requirement under EU procurement law when an individual contract is worth more than £93,000. The team can also help trusts with benchmarking and commercial information, contract terms and conditions and advice on detailed specifications.

This support is provided to help clinicians and renal service managers in their decision-making, against the background of a national overview, and in consideration of best practice options.

### ***Further information***

For further information on how the renal purchasing team can help your trust, contact Karen Guth, senior buyer, on telephone 01452 414506 or email [karen.guth@doh.gsi.gov.uk](mailto:karen.guth@doh.gsi.gov.uk)

## **Chapter 22: Diabetes, measurement of glycated haemoglobin and data from the Diabetic Registry**

Diabetic nephropathy is the single most common cause of renal failure in patients starting renal replacement therapy in the UK, where even so the incidence is lower than in most of the developed world. It is clearly important for the Registry to try to obtain more information on this condition. The UK Renal Registry and the United Kingdom Diabetic Analysis and Audit Service (UKDIABS) are exploring means of working together. This chapter contains the first results of such work. It comprises a joint analysis of data from the Diabetic Registry. In previous reports the Renal Registry has considered in some detail the problems of variations between clinical chemistry laboratories and the problems of harmonisation of data for comparison between units. This chapter includes a synopsis on methods of measurement of glycated haemoglobin in addition to current and future strategies on harmonisation of these results between hospitals. Some data from non-endstage patients from the UK diabetic registry is also included.

### **Summary**

#### **Summary on HbA1c standardisation**

- HbA1c measurements are an important outcome measure for both type I and type II diabetes mellitus, but techniques of measurement differ, and give varying results. Two very large clinical trials (DCCT and UKPDS) have shown that there is a powerful direct association between HbA1c levels and the risk of diabetic complications. HbA1c measurement systems have been 'standardised' through a process of 'alignment' of numerical results with the original DCCT method. This has been undertaken largely by the US National Glycohemoglobin Standardisation Program (NGSP) using a network of primary and secondary reference laboratories and a process of certification by means of a rigorous accuracy and precision protocol. In the UK, an expert panel published a consensus statement in 2000 that supported progress towards DCCT alignment of all methods used by UK laboratories, but indicated that a more rigorous scientific standardisation should be undertaken. About three quarters of UK laboratories have adopted DCCT aligned methods at the time of writing, many of whom were not-DCCT aligned prior to the Consensus Statement.
- Over the last five years, the International Federation of Clinical Chemistry (IFCC) Working Group on HbA1c Standardisation has created a true reference measurement system for HbA1c based on a re-definition of the chemical entity involved and a reference method. Comparison work has been undertaken with NGSP and the Swedish and Japanese standardisation programmes so that instrument and reagent manufacturers should be ready by the end of 2001 to release IFCC calibrants. It is anticipated that most currently non-DCCT aligned laboratories will adopt IFCC calibration, but those that are currently DCCT-aligned will have a difficult decision to make, as DCCT and IFCC numerical values are different. IFCC values are lower than DCCT below 8.5% HbA1c and greater than IFCC above this level. This change will require modification of the treatment outcome 'cut-off' levels based on DCCT and UKPDS, which clinicians are currently familiar with. The educational effort involved will be considerable. The National Service Framework for Diabetes development groups are aware of this situation.

## **Summary of UKDIABS data**

The UK Registry does not currently collect data on patients who are not receiving renal replacement therapy. The Renal Registry has liaised with the Diabetic Registry to analyse data from 47 district diabetic Registers included in the Diabetic Registry. Serum creatinine was measured at annual review in 56% of diabetic patients (range between centres 20 – 98%). From these measurements, 2.4% and 2.3% of Type 1 and Type 2 diabetics respectively had a serum creatinine > 200  $\mu\text{mol/L}$ . The proportion of patients in different centres with a serum creatinine > 200  $\mu\text{mol/l}$  varied from <1% to 9%.

The Cockcroft and Gault formula was used to calculate creatinine clearance. There is a strong relationship between the calculated creatinine clearance and both age of patient and length of time since diagnosed as diabetic. The relationship between blood pressure and renal impairment in Type 1 and Type 2 diabetics was examined. The only apparent association is between raised systolic blood pressure and renal failure in type I diabetics.

## **HbA1c Standardisation**

Jonathan Middle, UK NEQAS (Birmingham)

### **Detailed description of the background to the current situation**

HbA1c - the major fraction of glycated haemoglobin (glycohaemoglobin in the US) that has glucose bound to the N-terminal valine of the  $\beta$ -chain - may be estimated by a number of different measurement principles: ion exchange chromatography, affinity chromatography and immunoassay. None of these method principles is truly specific for HbA1c; other glycated moieties co-elute or cross-react to some degree.

Until very recently (see below) scientifically correct standardisation of these measuring systems in terms of HbA1c was not possible, as neither a primary standard (pure HbA1c in a bottle) nor a reference method that could measure it without bias, existed.

Since the early 80's, pragmatic 'harmonisation' of results has been undertaken using the Goldstein ion exchange method (as a 'designated comparison method') that underpinned the 'HbA1c' measurements used in the 9 year Diabetes Control and Complications Trial (DCCT) of type I diabetics published in 1993. This showed that the risk for development and progression of the chronic complications of diabetes is closely related to the degree of glycaemic control, and it provided a large body of data relating 'HbA1c' values to mean blood glucose. These results set the stage for establishing specific diabetes treatment goals using 'HbA1c' as an index of mean blood glucose.

Because of the enormous impact of this trial, the American Diabetic Association set up a National Glycohaemoglobin Standardisation Programme (NGSP) to ensure that all measurement systems produced similar results. A core group of primary reference laboratories was established that maintained HbA1c results within strict limits of agreement with the 'original' DCCT ion-exchange method. To these was added a global network of secondary reference laboratories that use a variety of methods, but which are calibrated to agree within tight limits with the primary reference laboratories. Manufacturers may apply to an NGSP reference laboratory for NGSP certification of their methods, through successful completion of a strict accuracy and imprecision protocol.

Outside of the US other 'pragmatic harmonisation' systems have been developed in Sweden and Japan. In the UK, the recently published UK PDS Study confirmed the relationships between 'HbA1c' level and risk of complications for type II diabetics using methodology that was closely 'harmonised' with the 'DCCT method'. In the UK in 2000, an expert group published a consensus statement that supported the importance of DCCT harmonisation of HbA1c measurements, but which also indicated the need for a more rigorous scientific standardisation.

As stated in the first paragraph, NGSP 'harmonisation' can never be true standardisation, as no primary standards are involved in the process. (The 'original' 'DCCT method' was 'adjusted' by varying the temperature of the ion exchange column, for example.) Because the different 'HbA1c' measurement principles do not and cannot measure the same defined chemical entity, harmonisation is only achievable through the application of statistical regression 'factors' which 'align' the numerical results.

In the mid-90's, the International Federation of Clinical Chemistry (IFCC) set up an HbA1c Standardisation Working Group to establish a more scientifically based standardisation. They established a primary standard based on glycosylated and non-glycosylated hexapeptides cleaved from the  $\beta$ -chain (thus re-defining what HbA1c is), and a reference method procedure based on HPLC and either mass spectrometry or capillary electrophoresis. Comparison studies with the three main international systems (NGSP, Sweden & Japan) have been undertaken to establish the relationships between numerical values. During the coming year (2001), the information gained from these comparisons will be applied by manufacturers to develop calibrators for their assay systems that will enable HbA1c results to be expressed in terms of the new IFCC standards.

Although IFCC standardisation is scientifically correct, its application will mean that numerical values for HbA1c measurements will change. The regression slope of DCCT vs IFCC is about 0.76 with an intercept of about 2% HbA1c. This means that below about 8.5% HbA1c (normal to fairly well controlled levels), IFCC results will be lower than DCCT, and above 8.5% (increasingly poor control) IFCC results will be higher. Clinicians who use DCCT/UKPDS treatment outcome levels will have to adjust their decision points accordingly. Because of the weight of the medical evidence base, the educational effort involved will be enormous (it would be impossibly expensive to repeat the two trials using IFCC standardised methods). The committees of the UK National Service Framework (NSF) for diabetes are currently considering the impact of this situation. Because the US has invested huge resources in promoting and maintaining DCCT harmonisation through NGSP, they may not accept IFCC standardisation directly and might attempt to re-calculate IFCC results in terms of DCCT. This will place considerable pressure on US based manufacturers who may have to offer different regional calibrators.

In summary, then, we have a fierce '*true scientific*' vs a '*pragmatic clinical approach*' debate in progress.

Do we change medical decision limits that are supported by a huge evidence base because the numerical values produced by the original and NGSP harmonised methods are wrong and have to be re-evaluated using a true accuracy base?

The UK NEQAS service for HbA1c is helping laboratories understand this situation and come to a decision about how their service should be standardised, by providing individual method

and calibration strategy means and both DCCT and IFCC reference method target values for all materials distributed.

#### **Sources / further information**

- DCCT & NGSP : <http://web.missouri.edu/~diabetes/ngsp/index.html>
- UKPDS : <http://www.dtu.ox.ac.uk/index.html?maindoc=/ukpds/>
- UK Consensus statement : Marshall SM and Barth JH. Standardization of HbA1c measurements: a consensus statement. *Ann Clin Biochem* 2000;37:45-46
- IFCC :<http://www.ifcc.org> and <http://web.missouri.edu/~diabetes/ngsp/IFCCWG.html>

## ***UK Diabetic Registry***

### ***Overview of the UK Diabetic Registry***

In September 1996 the UKDIABS project was initiated at the British Diabetic Association, with the aim of providing an audit and benchmarking service to districts and clinicians who had local databases of clinical information about people with diabetes. The main objective of the project was to enable quality improvement of diabetes services through better monitoring of clinical care.

The project collects data from districts, either through a standardised download (available as part of the standard software on the great majority of Diabetes Information Systems), or through working with local systems to obtain a usable data set for audit.

These data are, as far as possible, standardised on the UK recommended diabetes dataset. They can display variations in diabetes incidence and outcomes, as well as provide some information about local variations in care provision. Results are fed back to local districts in a benchmarking exercise, to inform local care providers about their services, and to assist local quality development. For 1997 and 1998 respectively there are about 102,000 and 155,000 patient records contained within UKDIABS. For 1998 this translates into data on 22% of all UK diabetics who had a medical contact in that year.

### ***Diabetic dataset***

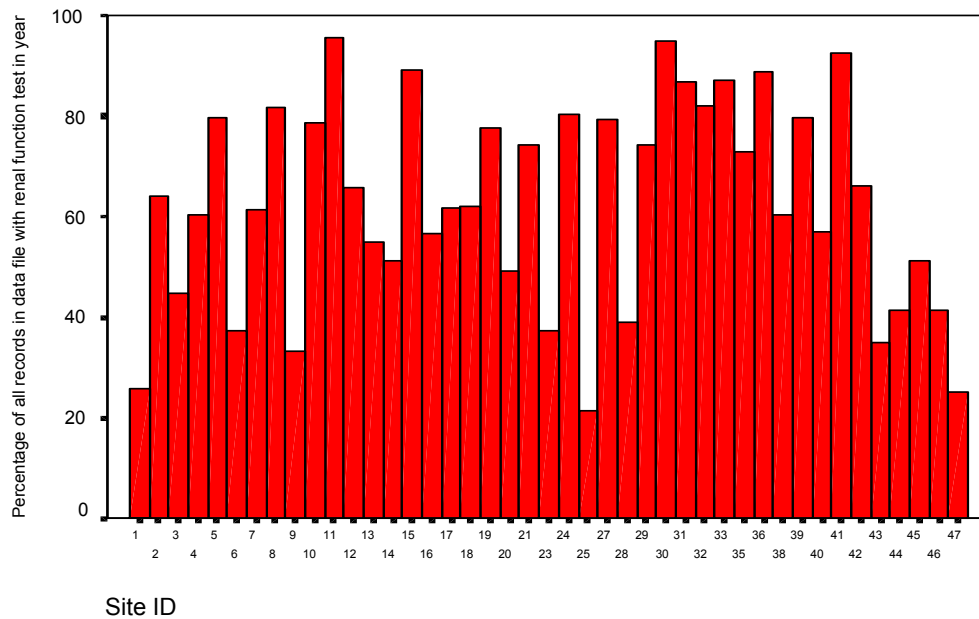
- 8 demographic fields
- 27 true outcome measures
- 27 indicators of adverse outcomes
- 8 risk factors for adverse outcome
- 6 metabolic outcomes
- 4 health satisfaction fields
- 3 local use fields



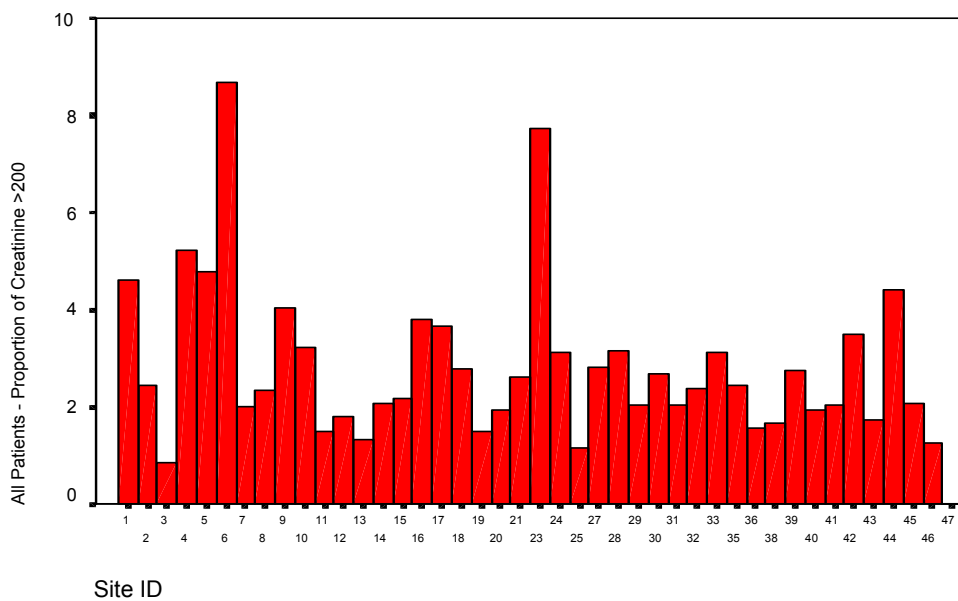
## Results

Using data amalgamated from 47 district diabetic Registers, 56% (range 20 –98%) had a creatinine measured at annual review. Of those patients, 2.4% and 2.3% of Type 1 and Type 2 diabetics respectively had a creatinine > 200  $\mu\text{mol/L}$ .

Figures 22.1 and 22.2 indicate by Centre the percentage of patients in whom serum creatinine was measured at annual review, and the proportion of patients in whom the creatinine was >200 $\mu\text{mol/l}$ . The low rate on creatinine monitoring is disappointing.



**Figure 22.1** The proportion of patients with a creatinine measured at annual review

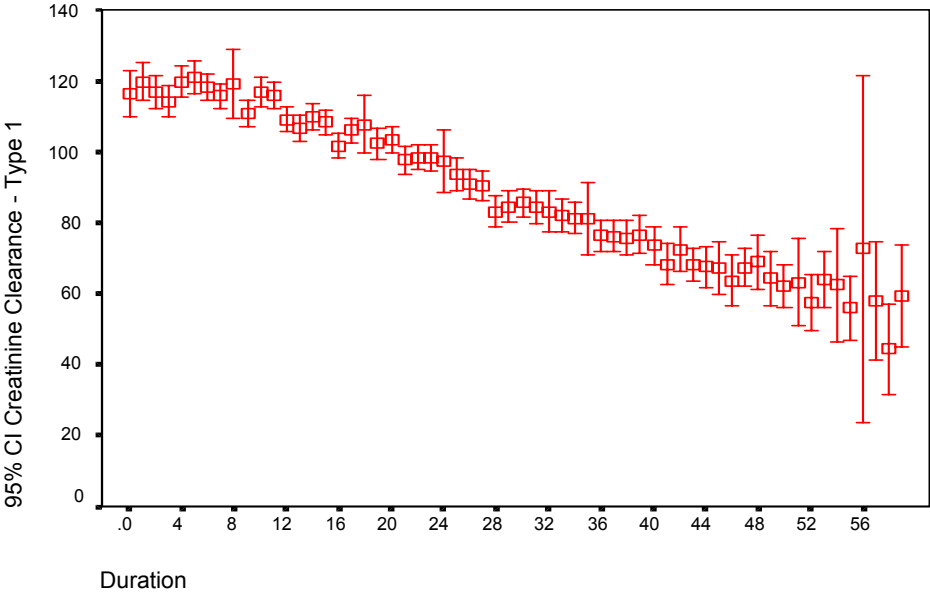


**Figure 22.2** The percentage serum creatinine measurements > 200 $\mu\text{mol/l}$

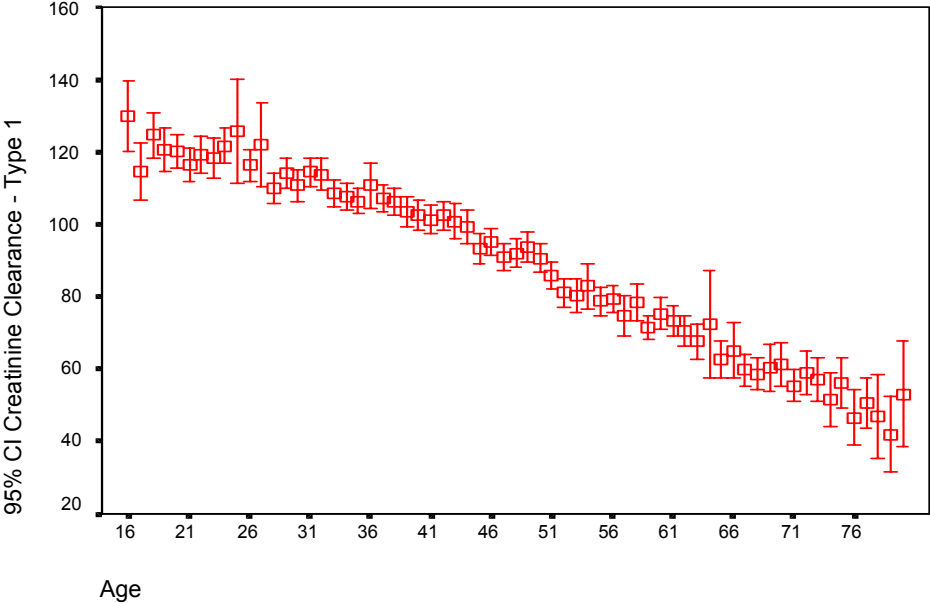
Centres 25 and 47, with two of the lowest rates of measurement of renal function (20%) also have the lowest percentage of tested patients with a creatinine > 200 umol/L. This contrasts with centre 6 where only 36% of patients have a creatinine measured but almost 9% of these results are above 200 umol/L.

**Creatinine clearance**

Figures 22.3 to 22.6 show renal function in relation to duration of diabetes and age. Creatinine clearance has been calculated using the Cockcroft and Gault method. The lines indicated the 95% confidence intervals.

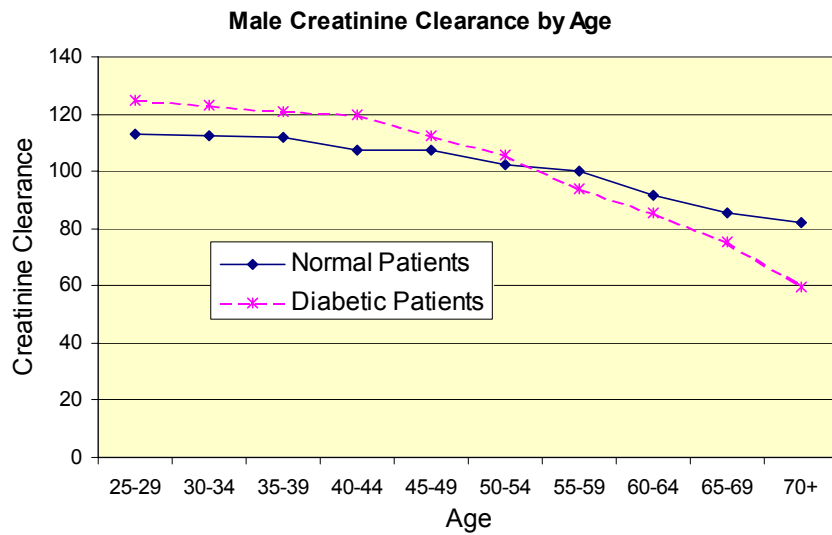


**Figure 22.3** Calculated creatinine clearance and duration of diabetes – type I diabetics.

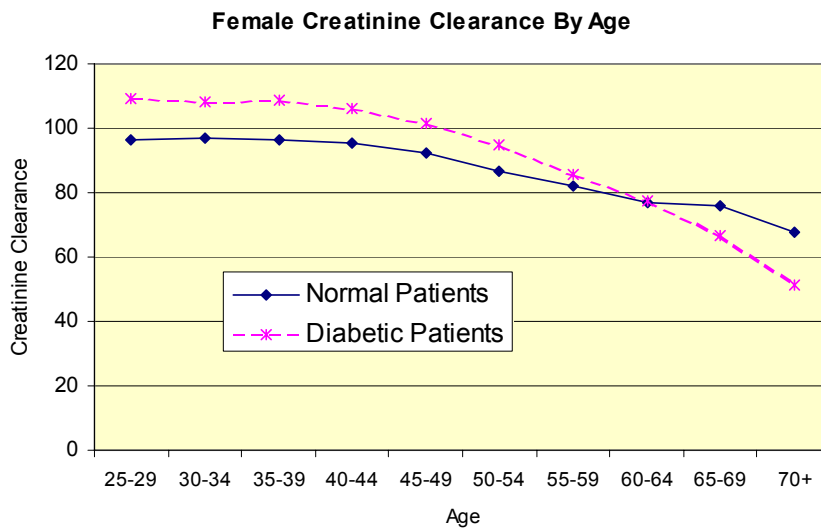


**Figure 22.4** Calculated creatinine clearance and age – type I diabetics.

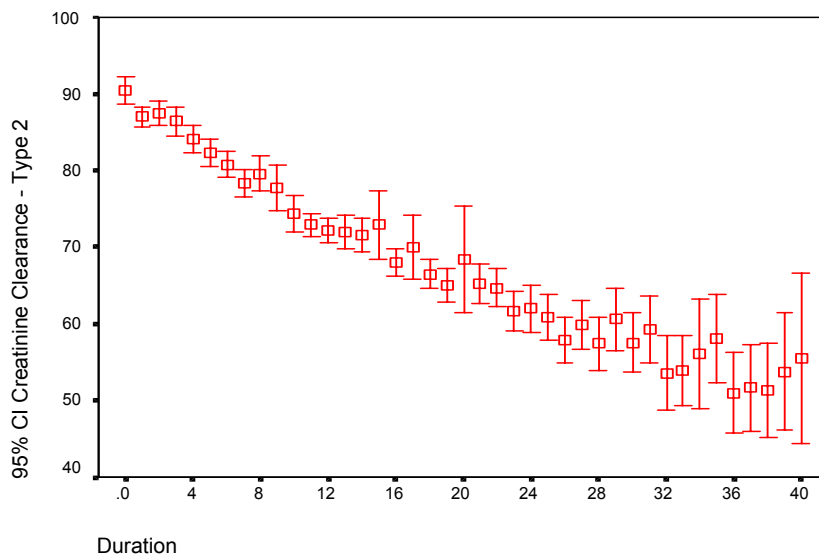
These data are very similar to the normal population and this is shown in the figures 22.5-6



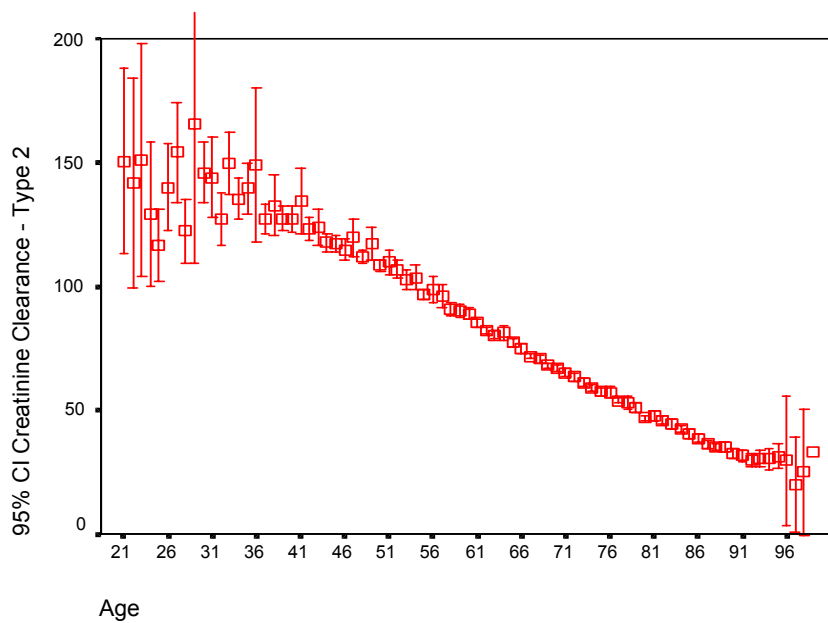
**Fig 22.5 Decline in creatinine clearance in diabetics v non-diabetic males**



**Fig22.6 Decline in creatinine clearance in diabetics v non-diabetic females**



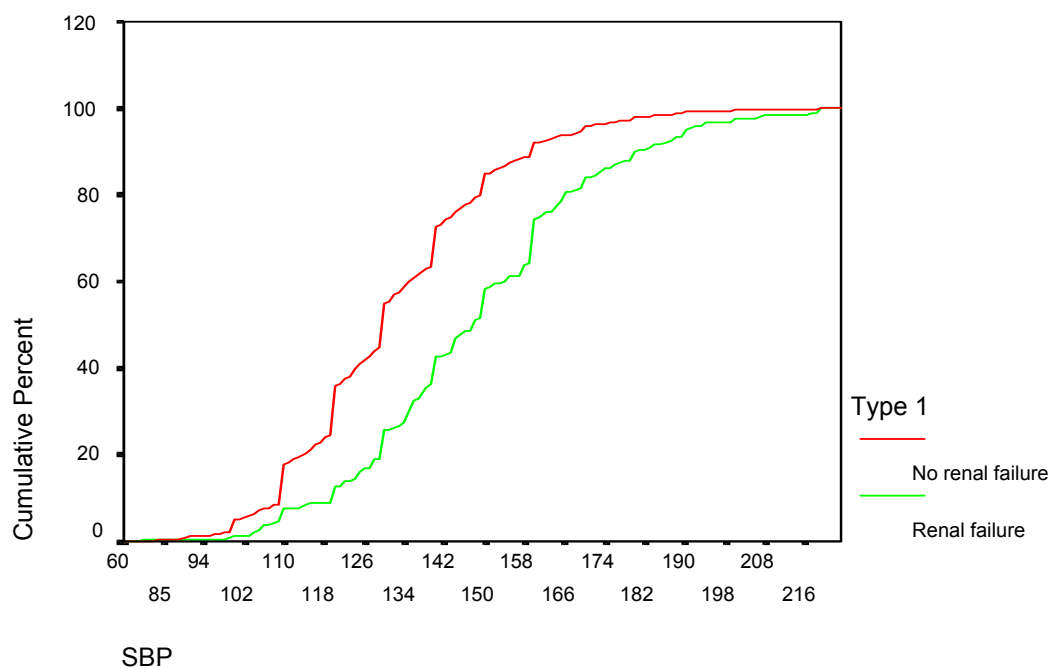
**Figure 22.7 Calculated creatinine clearance and duration of diabetes – type II diabetics.**



**Figure 22.8** Calculated creatinine clearance and age – type II diabetics.

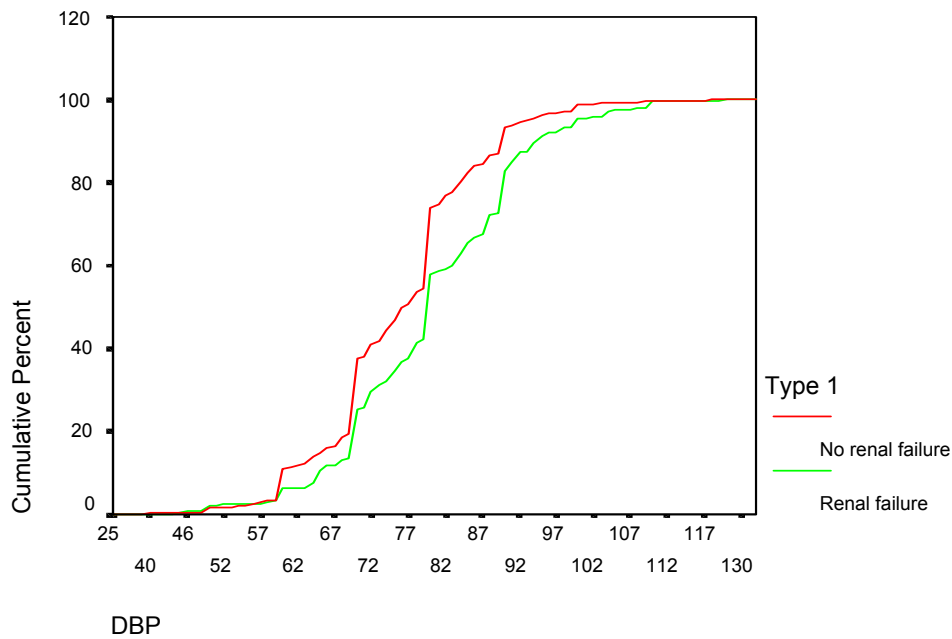
The wide confidence limits at the ends of the spectrum are attributable to the small number of observations at these points.

*Renal impairment and blood pressure in Type 1 diabetics*



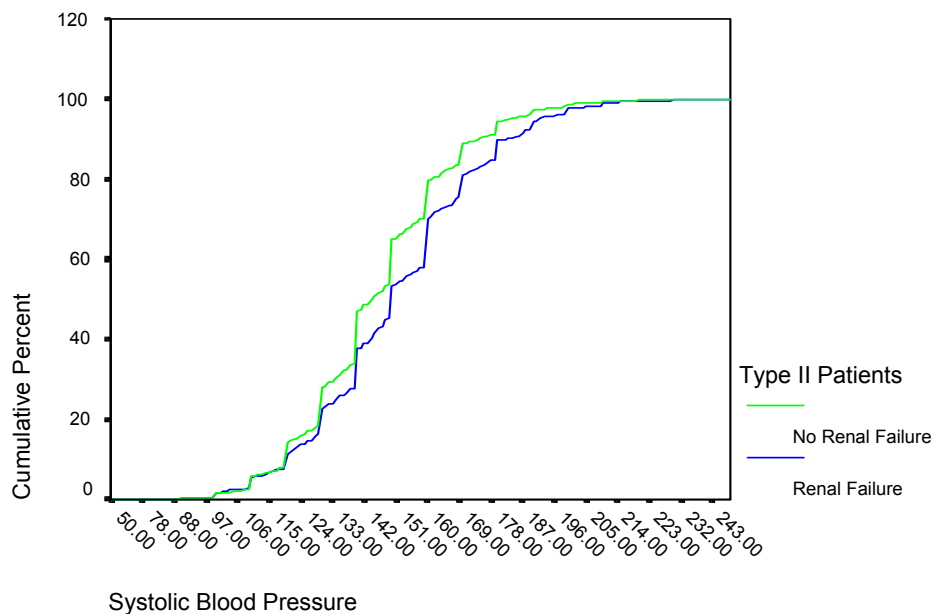
n = 11,088 -no renal impairment,  
n = 241 renal impairment

**Figure 22.9** Systolic blood pressure and renal impairment in Type1 diabetics



**Figure 22.10 Association between diastolic BP and renal impairment in type I diabetics.**

In Type 1 diabetics, the relationship between the incidence of renal impairment and elevated blood pressure was strong for the systolic pressure but weak for the diastolic pressure.



Type 2 diabetics  
 n= 63,750 – no renal failure  
 n= 1,100 – renal failure

**Figure 22.11 The relationship between renal impairment and systolic blood pressure in type II diabetics.**

The data presented here are cross-sectional and do not relate sequentially to individual patients. It is intended to develop a close working relationship between the two registries to create a complete longitudinal dataset for diabetic patients with renal impairment, with which it will be possible to monitor the progress of individuals and track changes which may eventually lead to renal failure.



## **Chapter 23: The Next Steps**

### ***Introduction***

Throughout this year the Renal Registry has been helping the Department of Health with the data to support a 5 year plan for renal services and has also completed the national renal review. The Registry has also had liaison with the Kidney Alliance supporting the shadow national service framework. Other activities include links with the UK Diabetic Registry, UK National Quality Assurance Scheme, and the NHS Information Authority. In the UK there are now 4 research registrars working in conjunction with the Renal Registry. These registrars have been funded locally and it is hoped that more renal units will take advantage of the data held by the Registry.

The three annual reports of the Renal Registry have confirmed the feasibility of the exercise of regular sequential large volume data collection from renal units. A database is developing with detailed information on the day-to-day treatment of patients with renal failure. The consistency of the data as the Registry grows in size suggests the data is reasonably robust and representative of the UK as a whole. Valuable data for planning the future has been obtained, useful comparative audit has been presented, and the data is beginning to raise questions and give new insights on clinical practice. However the Registry is still in early stages of its development. It must continue to develop in the following areas.

### ***Increased participation.***

The Registry is continuing to expand. The ultimate aim is to include all patients in the UK on Renal Replacement Therapy. The Registry remains voluntary. In this way, with the funding by individual renal units, it can remain an organisation under the umbrella of the Renal Association independent of the Department of Health and industry. Nevertheless, the Registry's activities are strongly supported by the Department of Health, which encourages participation. Many commissioners are including participation in the Registry as part of their contract with renal units. It is important that as many units as possible join the registry. This will improve the usefulness of the data. It will also enable it to continue with the present structure managed by the renal community in liaison with patients and other groups, and not be forced into becoming a mandatory exercise outside the control of nephrologists.

### ***Improve data quality***

Some important elements of data return are poor. The most critical items for the usefulness of the data are co-morbidity at start of renal replacement therapy, serum creatinine at start of therapy, patient weight at start of therapy, and ethnic origin. Without these items survival data, and analysis of factors influencing outcomes are greatly reduced in value. Efforts will be made during this year to help units to improve return of these items. The Registry is also exploring the possibility of a validation exercise within renal units to check the data accuracy.

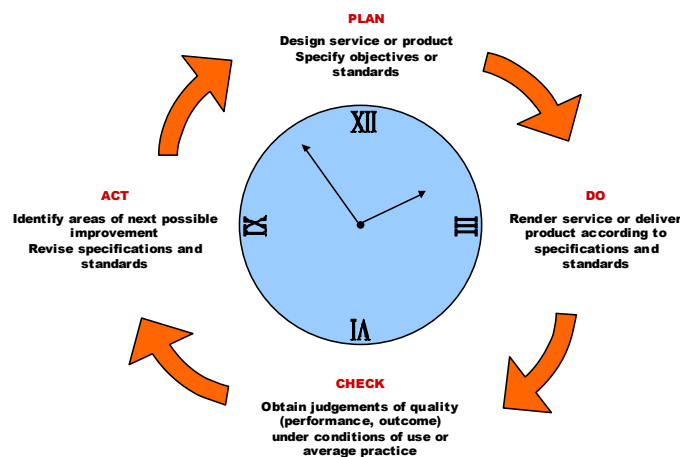
## **Expand the database**

The database has been created to include data in addition to that on renal replacement therapy. The possibilities of beginning to collect other data, perhaps on diabetes in liaison with the diabetic registry, will be explored.

## **Complete the audit cycle**

The greatest challenge to the Registry and the renal community is to use the data presented here to complete the audit cycle and improve patient care. Units are under pressure to improve their performance not only in clinical efficacy but also in cost effectiveness.

The audit cycle is well known (figure 23.1)<sup>(1)</sup>. Services are planned, partly using the Renal Association standards, the renal units do their best, and the Registry sits at 6 o'clock in checking performance. The difficulty is in acting on the information to bring about change.



**Figure 23.1 The audit cycle**

The comparison of performance of different renal units is important in preparing the ground for improvement. However the simple observation of differences in performance does not necessarily bring about change, or point the way to achieve it.

The declaration of Standards or Guidelines (at 12 o'clock) by professional official bodies such as the Renal Association, or DOQI, has been an important stimulus to the examination of clinical management. The philosophy of continuous improvement is behind this approach. Recommendations are based on the available literature, which is stronger on efficacy ('can it work?'), than effectiveness ('does it work?'). The costs and safety of complying with these 'official' recommendations are often not considered. The result is that the guidelines thus set are often unrealistic in everyday practice. By an iterative process involving the Registry, Standards/Guideline statements can be validated through the demonstration of current best practice out-turns and distributions.

When the results are inadequate, how is improvement obtained? The usual assumption is that more efficient application of current methods will produce benefit, but that assumes that units



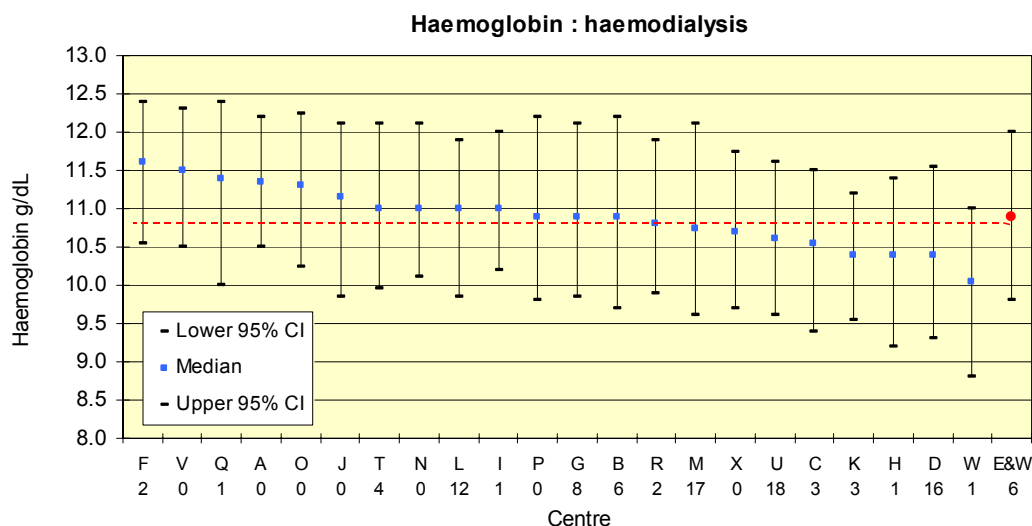
are not trying very hard already. Additional effort without defined changes in procedure may not be effective or sustainable.

### ***Insights from Registry activity, and its limitations***

The outcomes of any Renal Unit must be presented as distributions, whether a range over time for an individual, or as the sum of individual measurements. These are the basis for compliance with guideline statements. These distributions are generally stable unless a major effort has been made to influence clinical outcomes. The data are able to confirm improvement or deterioration against a backdrop of random variation. They illustrate the gaps between desirable and achieved outcomes, but do not necessarily indicate the likely cost and effort of bridging them.

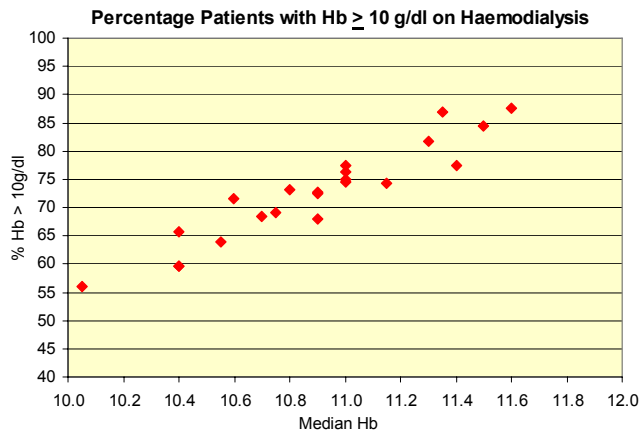
In some settings it will be necessary to innovate to improve outcomes. It may not be adequate to rely on individual renal unit ingenuity to achieve this. It will be necessary to devise structures for the implementation of change and exploration of alternatives. The UK Renal Registry runs an annual user’s meeting to discuss the data in the annual report. This meeting has pointed up variation in post-haemodialysis blood urea sampling in two separate years, but this has not led to a concerted initiative to standardise the methodology in the absence of an official implementation arm in the audit cycle. The cycle has turned twice without effect. It is well recognised elsewhere that it is necessary to organise specific attempts to improve Unit practice in order to make the most of the QA opportunity offered by registry activity <sup>(2,3)</sup>.

Renal Registry reports have shown that haemoglobin measurements within renal units show gaussian distributions of very similar dispersion (Standard Deviation) (figure 23.2).



**Figure 23.2 Haemoglobin distributions for UK centres**

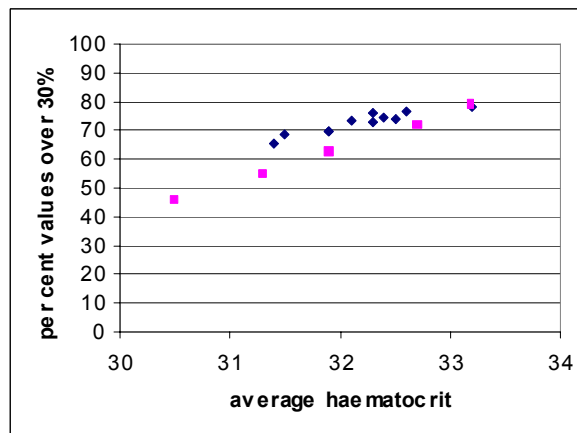
There is linear relationship between the median value of the Unit and the percentage above any given minimum value, as illustrated for a minimum of 10,5g/dl in figure 23.3.



**Figure 23.3 Median Hb against the Percentage  $\geq 10$ g/dl**

Figure 23.3 indicates that with current methods of clinical intervention, to achieve compliance at the RA Standard performance of 85%  $>10$ g/dl, a unit will have a median haemoglobin of 11.5g/dl. This degree of ‘over-treatment’ must be appreciated if the minimum is to be achieved and will need to be justified to funding authorities. Data from the Healthcare Finance Administration (HCFA), derived from completely different populations in the USA show similar behaviour<sup>(4,5)</sup> (figure 23.4). In October 1998 the average haemoglobin in the USA was 11.1g/dl with 78% of patients achieving a haemoglobin  $> 10$ g/dl. This is in keeping with the prediction from the UK data in figure 23.3.

### Combined HCT data (HCFA/DeOreo)



**Figure 23.4 Average population haematocrit plotted against %haematocrit  $>30$  in 2 US studies**

Were it possible to narrow the ranges of data distributions then the curves would differ, but as yet there are no predictable methods of doing so. Adoption of the higher European Standard value for Haemoglobin (11 g/dl)<sup>(6)</sup> will thus mean a large number of patients will have a very high haemoglobin. This approach is important in consideration of the safety and cost of guideline/standard recommendations, since it can indicate likely desirable/achievable outcome

distributions under current clinical conditions, and the implications of them, in advance of attempting them.

## **Conclusion**

The Registry must fit permanently into the Audit Spiral. To be effective it must retain the permanent interest of clinicians, patients and commissioners. To complete the audit cycle, however, more action is needed. The comparative audit from the Registry is simply the indicator for need to change, but of itself will not bring about change. Implementation of change will be most effective if there is a formalised organisation for implementation developed out of the UK Renal Registry, the users group, Renal Association Standards initiatives, and the Kidney Alliance. Formation of such an organisation should be a very strong platform for improvement in the medium term future of Nephrology in the UK

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- 2 McClellan WM, Krisher JO. Collecting and using patient and treatment center data to improve care: Adequacy of hemodialysis and end-stage renal disease surveillance. *Kidney Intl* 2000;57 Suppl. 74:S7-S13.
- 3 Reports from the ESRD Networks. Ed. Jay B. Wish. *Adv Renal Replacement Ther* 2000;7(4) Suppl 1:S1-S104
- 4 DeOreo PB, Eschbach JW. Implementation of the Anemia Guidelines. *Adv Renal Replace Ther* 1999;6:18-27.
- 5 Health Care Financing Administration 1999 Annual Report, *End Stage Renal Disease Clinical Performance Measures Project*. Department of Health and Human Services, Health Care Financing Administration, Office of Clinical Standards and Quality, Baltimore, Maryland, December 1999 or at [www.hcfa.gov/quality/qlty-3.htm](http://www.hcfa.gov/quality/qlty-3.htm).
- 6 European Best Practice Guidelines for the management of Anaemia in Patients with Chronic Renal Failure. *Nephrol Dial Transplant* 1999;14[Suppl 5].



## **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
- 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

## **A:11 References**

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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 satellite unit is a centre which is distinct from the parent hospital where the consultant nephrologist is based.

#### ***Treatment modality at 90 days***

This is used by the USRDS and is the modality that the patient is on at day 90 regardless of any changes from the start. It is a general indicator of initial dialysis, but could miss failed CAPD. This would also miss patients intended for home haemodialysis, who will not be home yet. This is modality is calculated by the Registry, which allows the definition to be changed.

#### ***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 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.

## ***Analysis criteria***

### ***Take-On population***

The take-on population in a year included patients who later recovered from ESRF after 90 days from the start of treatment. Patients newly transferred into a centre who are already in ESRF are not included in the take on population for that centre.

Since patients who restarted 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 90<sup>th</sup> day.

### ***Criteria for analysis by treatment modality in a quarter***

The following quarterly entries were included and excluded: -

Patients on haemodialysis with a treatment centre of 'elsewhere' were **removed**. It should be noted that there were some patients on transplant with a treatment centre of 'Elsewhere'. These patients were **included**.

Entries for which the hospital centre was not the primary treatment centre were removed from the analysis of data for that centre.

Patients who had been on 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 1<sup>st</sup> 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 1<sup>st</sup> March 1999, who recovered on the 1<sup>st</sup> June 1999 and then resumed RRT again on the 1<sup>st</sup> November 1999, the number of days on RRT would be calculated from the 1<sup>st</sup> November 1999. The patient would be excluded from the analysis for quarter 4/99, since on the 31<sup>st</sup> 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 1<sup>st</sup> 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: 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 blood 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.

- |                                  |  |
|----------------------------------|--|
| <b>Co-morbidity</b>              | 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 consequences 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] |
| <b>Renal replacement therapy</b> | 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.  |
| <b>Renal dialysis</b>            | 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.  |
| <b>Haemodialysis</b>             | 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              | Appendix D. 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.  |
| <b>Renal transplantation</b>     | 10. Renal transplantation replaces all the kidney's functions, so erythropoietin and vitamin D supplementation are unnecessary. A single kidney is placed, usually in the pelvis close to the bladder, to which the ureter is connected. The kidney is attached to a nearby artery and vein. The immediate problem is the body's acute rejection of the foreign graft, which   |



has largely been overcome during the first months using drugs such as steroids and cyclosporin. These drugs, and others that can be used for that purpose, have many undesirable side effects, including the acceleration of vascular disease, so myocardial infarcts and strokes are commoner in transplant patients than in age-matched controls. During subsequent years there is a steady loss of transplanted kidneys owing to a process of chronic rejection; treatment of this is quite unsatisfactory at the moment, so many patients require a second or even a third graft over several decades, with further periods of dialysis in between.



## Appendix D: Data Tables

### 1. Patients starting renal replacement in 1999

<b>Take-on figures for new patients on dialysis</b>				
<b>Centre</b>	<b>aged &lt; 65</b>		<b>aged &gt;65</b>	
	<b>% on HD</b>	<b>% on PD</b>	<b>% on HD</b>	<b>% on PD</b>
A	50	50	43	57
B	78	22	86	14
C	86	14	95	5
D	63	38	84	16
E	48	52	62	38
F	58	42	76	24
G	35	65	41	59
H	56	44	81	19
I	79	21	94	6
J	63	37	48	52
K	22	78	50	50
L	48	52	82	18
M	37	63	61	39
N	64	36	70	30
O	52	48	68	33
P	52	48	51	49
Q	40	60	66	34
R	34	66	59	41
Sa	74	26	80	20
Sb	73	27	69	31
Sc	45	55	73	27
Sd	53	47	67	33
Se	77	23	82	18
Sf	47	53	85	15
Sg	38	62	83	17
Sh	55	45	91	9
Si	40	60	88	13
Sj	43	57	80	20
Sk	63	37	68	32
T	66	34	54	46
U	62	38	89	11
V	59	41	70	30
W	35	65	78	22
X	42	58	68	32
Sct	59	41	76	24
E&W	52	48	68	32
<b>UK</b>	<b>53</b>	<b>47</b>	<b>70</b>	<b>30</b>

Table D.1.1 Take-on of new dialysis patients

<b>Take-on figures for new patients on dialysis</b>				
	<b>aged &lt;65</b>		<b>aged &gt;65</b>	
	<b>No. on HD</b>	<b>No. on PD</b>	<b>No. on HD</b>	<b>No. on PD</b>
Sct	137	97	167	54
E&W	509	473	522	248
<b>UK</b>	<b>646</b>	<b>570</b>	<b>689</b>	<b>302</b>

Table D.1.2 Take-on totals of new dialysis patients

Treatment modalities at 90 days						
Centre	% on HD	% on PD	% on transplant	% transferred out	% stopped treatment	% died
A	36	39				25
B	62	14	3			21
C	74	8			2	16
D	64	23				12
E	51	40	1			8
F	57	29	2			12
G	34	56	4			5
H	59	30	1			11
I	82	13		3		3
J	48	38				14
K	33	58		3		8
L	52	31	4	1		11
M	43	50	2			5
N	55	28	6	1	1	10
O	54	35				11
P	48	45	2	1		4
Q	43	43	9	1		4
R	37	49	3		1	9
Sa	66	20	3	1		10
Sb	54	23				23
Sc	57	39				4
Sd	46	31	7	1		15
Se	72	19		2		7
Sf	59	34				6
Sg	54	36				11
Sh	62	23				15
Si	52	33				14
Sj	53	38				9
Sk	56	29	4			10
T	53	32	1			14
U	69	25				6
V	51	29	4			16
W	58	34	2	2		5
X	46	40		5		9
Sct	57	28	2	1		13
E&W	51	36	3	1	0.1	10
UK	52	34	2	1	0.1	10

Table D.1.3 Treatment modalities at 90 days

Treatment modalities at 90 days						
	No. on HD	No. on PD	No. on transplant	No. transferred out	No. stopped treatment	No. died
Sct	304	151	11	3		68
E&W	1031	721	52	11	3	199
UK	1335	872	63	14	3	267

Table D. 1.4 Number of patients per treatment modality at 90 days

First treatment modality			
Centre	% on HD	% on PD	% on transplant
A	50	50	
B	82	18	
C	84	16	
D	75	25	
E	51	48	1
F	64	36	
G	37	59	4
H	66	33	1
I	85	15	
J	56	44	
K	43	58	
L	62	35	4
M	44	56	
N	63	32	5
O	60		
P	51	48	1
Q	44	49	7
R	48	50	2
Sa	74	23	4
Sb	76	24	
Sc	61	39	
Sd	61	33	7
Se	79	21	
Sf	66	34	
Sg	61	39	
Sh	77	23	
Si	67	33	
Sj	58	42	
Sk	63	38	
T	66	33	1
U	75	25	
V	64	31	5
W	63	37	
X	58	42	
Sct	68	31	2
E&W	59	40	2
UK	60	38	2

Table D.1.5 First treatment modality

<b>First treatment modality – patient numbers</b>			
	<b>No. on HD</b>	<b>No. on PD</b>	<b>No. on transplant</b>
Sct	363	164	10
E&W	1182	797	38
UK	1545	961	48

**Table D.1.6 First treatment modality - patient numbers**

<b>Treatment by gender</b>						
<b>Centre</b>	<b>Haemodialysis</b>			<b>Peritoneal Dialysis</b>		
	<b>% Male</b>	<b>% Female</b>	<b>M:F ratio</b>	<b>% Male</b>	<b>% Female</b>	<b>M:F ratio</b>
A	70	30	2.3	36	64	0.6
B	63	37	1.7	79	21	3.7
C	57	43	1.3	75	25	3.0
D	66	34	1.9	59	41	1.4
E	59	41	1.5	52	48	1.1
F	71	29	2.5	56	44	1.3
G	75	25	3.0	58	42	1.4
H	60	40	1.5	41	59	0.7
I	69	31	2.2	60	40	1.5
J	65	35	1.8	71	29	2.4
K	69	31	2.3	74	26	2.8
L	59	41	1.5	59	41	1.4
M	52	48	1.1	63	37	1.7
N	52	48	1.1	45	55	0.8
O	70	30	2.3	64	36	1.8
P	52	46	1.1	69	31	2.2
Q	59	41	1.5	46	54	0.8
R	75	25	3.0	57	43	1.3
Sa	55	45	1.2	56	44	1.3
Sb	53	47	1.2	67	33	2.0
Sc	77	23	3.3	78	22	3.5
Sd	54	46	1.2	53	47	1.1
Se	61	39	1.6	75	25	3.0
Sf	68	32	2.2	64	36	1.8
Sg	60	40	1.5	60	40	1.5
Sh	69	31	2.2	33	67	0.5
Si	55	45	1.2	86	14	6.0
Sj	54	46	1.2	70	30	2.3
Sk	52	48	1.1	50	50	1.0
T	83	17	4.8	69	31	2.2
U	66	34	1.9	54	46	1.2
V	73	27	2.7	57	43	1.3
W	69	31	2.3	67	33	2.0
X	47	53	0.9	73	27	2.7
Sct	58	42	1.4	62	38	1.6
E&W	64	36	1.8	59	41	1.4
UK	63	37	1.7	59	41	1.5

**Table D.1.7 Treatment modalities by gender**

<b>Treatment by gender</b>						
	<b>Haemodialysis</b>			<b>Peritoneal Dialysis</b>		
	<b>No. males</b>	<b>No. females</b>	<b>No. unknown</b>	<b>No. males</b>	<b>No. females</b>	<b>No. unknown</b>
Sct	175	129		93	58	
E&W	661	369	1	424	297	
UK	836	498	1	517	355	

**Table D.1.8 Treatment modality numbers by gender**

## 2. Current patients 1999

Centre	Treatment Modalities by centre							
	for patients aged < 65				for patients aged > 65			
	% on HD	% on PD	% on Transplant	HD:PD	% on HD	% on PD	% on Transplant	HD:PD
A	15	15	70	1.0	63	17	20	3.6
B	27	10	63	2.7	65	11	24	5.8
C	29	10	61	2.8	75	4	20	17.3
D	41	11	48	3.6	75	11	14	6.7
E	17	13	70	1.3	47	19	34	2.5
F	43	17	39	2.5	72	21	8	3.5
G	26	24	50	1.1	40	40	19	1.0
H	27	18	54	1.5	59	25	16	2.4
I	56	29	15	2.0	86	7	7	12.8
J	53	16	31	3.3	71	24	6	3.0
K	32	27	42	1.2	41	42	17	1.0
L	13	15	72	0.9	49	15	36	3.2
M	39	28	32	1.4	60	28	13	2.2
N	25	8	67	3.2	61	17	22	3.6
O	22	19	59	1.1	51	28	22	1.8
P	22	18	60	1.2	37	47	16	0.8
Q	16	13	72	1.3	46	18	36	2.5
R	25	21	54	1.2	48	26	26	1.8
Sa	25	8	68	3.2	62	12	26	5.2
Sb	34	15	51	2.3	66	17	17	3.9
Sc	26	21	53	1.3	45	36	18	1.3
Sd	13	8	80	1.7	43	17	40	2.5
Se	82	18		4.6	77	23		3.3
Sf	63	37		1.7	83	17		4.8
Sg	38	34	27	1.1	63	32	5	2.0
Sh	72	28		2.5	72	28		2.6
Si	64	22	14	2.9	81	14	5	5.7
Sj	73	27		2.7	87	13		6.6
Sk	28	9	63	3.3	54	17	30	3.2
T	40	14	46	2.8	53	22	25	2.4
U	25	24	51	1.1	66	24	11	2.8
V	23	8	69	2.9	58	9	34	6.6
W	21	27	52	0.8	73	20	7	3.7
X	34	21	44	1.6	66	18	15	3.6
Sct	30	13	57	2.3	61	18	21	3.3
E&W	27	16	57	1.7	56	22	22	2.5
UK	27	15	57	1.8	57	22	21	2.6

Table D.2.1 Treatment modalities for patients aged under 65 and over 65

	Treatment Modality numbers					
	for patients aged < 65			for patients aged > 65		
	No. on HD	No. on PD	No. on transplant	No. on HD	No. on PD	No. on transplant
Sct	633	271	1209	465	139	158
E&W	2271	1375	4901	1865	749	718
UK	2904	1646	6110	2330	888	876

Table D.2.2 Numbers of patients under and over 65 per treatment modality

Haemodialysis Modalities with gender ratios									
Centre		Haemodialysis		Home Haemodialysis		Hospital Haemodialysis		Satellite Haemodialysis	
Code	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio
A	1.6	29	2.3	0	n/a	46	1.2	18	1.9
B	1.6	37	1.3	1	0.0	58	0.9	20	1.3
C	1.8	42	2.0	1	0.0	82	1.0	0	n/a
D	1.8	53	1.9	9	1.7	65	1.0	8	0.9
E	1.6	26	1.3	1	0.7	62	0.9	0	n/a
F	2.0	54	2.1	0	n/a	5	1.1	70	1.1
G	1.6	30	1.8	5	3.0	32	1.1	14	1.1
H	1.4	35	1.4	1	1.6	49	1.2	14	1.1
I	1.4	69	1.6	0	n/a	78	1.1	0	n/a
J	1.5	58	1.5	0	n/a	41	0.7	35	1.7
K	1.9	35	2.4	3	1.4	50	1.2	0	n/a
L	1.5	22	1.4	0	n/a	26	1.0	33	0.9
M	1.7	46	1.6	2	1.3	31	1.0	29	1.0
N	1.5	35	1.6	15	2.8	20	1.0	43	0.9
O	1.9	31	2.3	0.4	0.0	29	0.9	30	1.2
P	1.7	26	1.4	2	0.0	39	0.8	10	0.9
Q	1.4	24	1.5	6	1.2	57	1.2	0	n/a
R	1.7	31	2.2	4	4.6	55	1.0	0	n/a
Sa	1.7	33	1.3	2	0.0	77	0.9	0	n/a
Sb	1.4	46	1.4	2	0.4	73	1.0	0	n/a
Sc	1.6	32	1.3	0	n/a	56	0.8	0	n/a
Sd	1.3	19	1.3	0	n/a	66	1.0	0	n/a
Se	1.4	80	1.6	20	1.7	61	1.0	0	n/a
Sf	1.5	70	1.6	0	n/a	70	1.0	0	n/a
Sg	1.3	46	1.6	3	1.4	55	1.1	0	n/a
Sh	1.9	72	2.4	1	n/a	71	1.2	0	n/a
Si	1.5	70	1.5	2	0.0	76	1.1	0	n/a
Sj	1.2	79	1.1	0	n/a	79	1.0	0	n/a
Sk	1.2	36	1.1	5	2.2	72	0.9	0	n/a
T	1.7	43	2.1	9	1.0	34	1.3	30	0.9
U	1.4	38	1.4	0	n/a	62	1.0	0	n/a
V	1.5	30	1.8	2	3.1	34	1.0	43	1.2
W	1.3	45	1.6	0	n/a	66	1.0	0	n/a
X	2.0	44	1.3	6	0.9	44	0.7	19	0.9
Sct	1.4	38	1.4	4	1.7	69	1.0	0	n/a
E&W	1.6	35	1.7	4	1.8	42	1.0	21	1.1
UK	1.6	35	1.6	4	1.8	47	1.0	17	1.1

Table D.2.3 Haemodialysis modalities and gender ratios

Peritoneal Dialysis Modalities with gender ratios													
Centre		Peritoneal Dialysis		Standard PD		Disconnect PD		Cycling PD >= 6 nights		Cycling PD < 6 nights		Unknown type PD	
Centre	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio	%	M:F ratio
A	1.6	16	1.1	1	0.0	28	0.6	6	1.7	0	n/a	0	n/a
B	1.6	10	1.7	0	n/a	22	1.2	0	0.0	0	n/a	0	n/a
C	1.8	9	2.3	0	n/a	10	0.7	7	3.4	0	n/a	0	n/a
D	1.8	11	1.3	0	n/a	15	0.6	3	1.4	0	n/a	0	n/a
E	1.6	15	1.5	0	n/a	36	1.1	0	n/a	0	n/a	0	n/a
F	2.0	18	1.3	0	n/a	26	0.7	0	n/a	0	n/a	0	n/a
G	1.6	29	1.2	0.2	0.0	43	0.8	6	1.0	0	n/a	0	n/a
H	1.4	20	0.9	0	n/a	33	0.7	3	0.8	0	n/a	0	n/a
I	1.4	20	0.9	0	n/a	22	0.6	0	n/a	0	n/a	0	n/a
J	1.5	18	1.4	0	n/a	24	0.9	0	n/a	0	n/a	0	n/a
K	1.9	32	1.8	0	n/a	48	0.9	0	n/a	0	n/a	0	n/a
L	1.5	15	1.5	0	n/a	41	1.1	0	n/a	0	n/a	0	n/a
M	1.7	28	1.6	0.3	0.0	30	1.0	5	0.9	3	1.0	0	n/a
N	1.5	10	1.1	7	0.8	14	0.8	2	0.5	0	n/a	0	n/a
O	1.9	22	2.1	0	n/a	39	1.1	1	0.2	1	0.0	0	n/a
P	1.7	26	2.1	0	n/a	40	1.2	10	1.3	0	n/a	0	n/a
Q	1.4	14	0.9	0	n/a	31	0.7	6	0.9	0.4	0.0	0	n/a
R	1.7	22	1.7	0	n/a	41	0.9	0	n/a	0	n/a	0	n/a
Sa	1.7	9	1.6	0	n/a	16	1.1	4	1.7	0	n/a	0	n/a
Sb	1.4	16	1.5	0	n/a	15	1.5	10	0.6	0	n/a	0	n/a
Sc	1.6	25	2.4	0	n/a	25	1.2	20	1.8	0	n/a	0	n/a
Sd	1.3	10	1.2	0	n/a	30	0.9	4	1.4	0	n/a	0	n/a
Se	1.4	20	0.8	0	n/a	19	0.6	1	0.0	0	n/a	0	n/a
Sf	1.5	30	1.4	0	n/a	21	0.7	8	2.0	0	n/a	0	n/a
Sg	1.3	33	1.3	0	n/a	30	1.0	12	0.7	0	n/a	0	n/a
Sh	1.9	28	1.1	0	n/a	4	1.1	24	0.5	0	n/a	0	n/a
Si	1.5	19	1.2	0	n/a	6	0.3	12	0.7	4	0.0	0	n/a
Sj	1.2	21	1.4	0	n/a	19	1.3	2	0.4	0	n/a	0	n/a
Sk	1.2	11	1.3	0	n/a	20	1.0	3	2.6	0	n/a	0	n/a
T	1.7	16	1.6	0	n/a	27	0.8	0.4	0.5	0	n/a	0	n/a
U	1.4	24	1.4	0	n/a	3	0.7	35	1.0	0	n/a	0	n/a
V	1.5	8	1.1	18	0.7	0	0.0	3	0.6	0	n/a	0	n/a
W	1.3	24	1.4	3	1.0	27	1.0	4	0.7	0	n/a	0	n/a
X	2.0	20	2.9	0	n/a	24	2.0	8	1.2	0	n/a	0	n/a
Sct	1.4	14	1.3	0	n/a	20	0.9	7	1.0	0.1	0.0	0	n/a
E&W	1.6	18	1.4	1	0.7	29	0.9	3	1.0	1	0.9	0	n/a
UK	1.6	17	1.4	1	0.7	27	0.9	4	1.0	1	1.0	0	n/a

Table D.2.4 Peritoneal dialysis modalities and gender ratios

<b>Median ages and dialysis modalities by centre</b>					
<b>Centre</b>	<b>Median age on Dialysis</b>	<b>Median age on HD</b>	<b>Median age on PD</b>	<b>Median age on transplant</b>	<b>Median age for all</b>
A	65	68	54	50	55
B	62	64	54	52	56
C	62	65	54	50	55
D	63	63	60	50	57
E	63	68	60	52	55
F	64	64	62	48	60
G	60	59	61	48	56
H	59	61	57	47	53
I	63	65	58	55	61
J	60	59	60	48	56
K	61	58	63	50	57
L	61	66	53	48	52
M	60	60	58	49	56
N	64	64	63	49	55
O	64	65	62	48	56
P	63	58	65	49	55
Q	61	65	55	51	54
R	59	60	57	49	54
Sa	60	61	54	48	52
Sb	65	65	53	52	57
Sc	63	63	63	46	54
Sd	62	62	59	46	49
Se	57	57	57		57
Sf	61	63	55		61
Sg	58	61	53	43	53
Sh	60	61	58		60
Si	60	60	60	45	59
Sj	61	62	60		61
Sk	59	59	59	48	52
T	55	55	56	47	52
U	64	67	56	46	56
V	58	60	48	46	49
W	69	72	61	50	62
X	60	62	56	46	54
Sct	60	61	57	47	52
E&W	61	62	59	49	54
UK	61	62	59	48	54

**Table D.2.5 Treatment modality median ages by centre**

<b>Dialysis Modalities for patients aged under 65</b>								
<b>Centre</b>	<b>% on Home HD</b>	<b>% on Hosp HD</b>	<b>% on Satellite HD</b>	<b>% on standard PD</b>	<b>% on disconnect PD</b>	<b>% on cycling PD &gt;=6 nights</b>	<b>% on cycling PD &lt; 6 nights</b>	<b>% on unknown type PD</b>
A	0	35	15	3	35	12	0	0
B	1	55	17	0	27	0	0	0
C	2	72	0	0	17	9	0	0
D	16	57	5	0	20	2	0	0
E	2	54	0	0	44	0	0	0
F	0	5	66	0	28	0	0	0
G	8	34	10	0.3	40	7	0	0
H	1	46	13	0	35	5	0	0
I	0	66	0	0	34	0	0	0
J	0	41	36	0	23	0	0	0
K	4	50	0	0	46	0	0	0
L	0	22	24	0	54	0	0	0
M	3	31	24	1	31	8	3	0
N	26	20	30	3	18	3	0	0
O	1	29	23	0	43	2	2	0
P	3	44	9	0	34	10	0	0
Q	9	47	0	0	36	8	0.4	0
R	6	49	0	0	45	0	0	0
Sa	4	72	0	0	18	6	0	0
Sb	2	67	0	0	17	13	0	0
Sc	0	56	0	0	24	21	0	0
Sd	0	63	0	0	31	6	0	0
Se	26	56	0	0	17	1	0	0
Sf	0	63	0	0	24	13	0	0
Sg	5	48	0	0	32	15	0	0
Sh	2	70	0	0	2	26	0	0
Si	3	71	0	0	6	16	3	0
Sj	0	73	0	0	23	3	0	0
Sk	9	68	0	0	21	3	0	0
T	12	34	28	0	26	0	0	0
U	0	51	0	0	4	45	0	0
V	3	35	37	21	0	4	0	0
W	0	44	0	4	42	11	0	0
X	8	37	16	0	28	10	0	0



Sct	6	64	0	0	21	9	0.1	0
E&W	6	39	18	1	31	4	1	0
UK	6	44	14	1	29	5	1	0

**Table D.2.6 Dialysis modalities for patients aged under 65**

Dialysis Modalities for patients aged 65 and over								
Centre	% on Home HD	% on Hosp HD	% on Satellite HD	% on standard PD	% on disconnect PD	% on cycling PD >=6 nights	% on cycling PD < 6 nights	% on unknown type PD
A	0	57	22	0	22	0	0	0
B	0	63	23	0	15	0	0	0
C	0	95	0	0	2	4	0	0
D	2	73	12	0	9	3	0	0
E	0	71	0	0	29	0	0	0
F	0	4	74	0	22	0	0	0
G	0.5	29	21	0	46	4	0	0
H	1	55	15	0	30	0	0	0
I	0	93	0	0	7	0	0	0
J	0	40	35	0	25	0	0	0
K	0	49	0	0	51	0	0	0
L	0	32	44	0	24	0	0	0
M	1	32	36	0	27	0	5	0
N	3	19	56	11	11	1	0	0
O	0	28	36	0	35	1	0	0
P	1	33	11	0	47	9	0	0
Q	2	69	0	0	25	3	0.5	0
R	0	65	0	0	35	0	0	0
Sa	0	84	0	0	14	2	0	0
Sb	1	78	0	0	13	7	0	0
Sc	0	56	0	0	26	19	0	0
Sd	0	71	0	0	28	1	0	0
Se	4	73	0	0	23	0	0	0
Sf	0	83	0	0	17	0	0	0
Sg	0	67	0	0	28	6	0	0
Sh	0	72	0	0	7	21	0	0
Si	0	85	0	0	5	5	5	0
Sj	0	87	0	0	13	0	0	0
Sk	0	76	0	0	20	3	0	0
T	1	34	35	0	28	1	0	0
U	0	74	0	0	1	25	0	0
V	0	31	56	13	0	0	0	0
W	0	79	0	3	18	0	0	0
X	1	55	23	0	18	4	0	0
Sct	0.5	76	0	0	19	4	0.2	0
E&W	1	46	25	1	25	2	1	0
UK	1	52	20	1	24	2	1	0

**Table D.2.7 Dialysis modalities for patients aged over 65**

Patients Age Ranges by Centre								
Centre	% 18-24	% 25-34	% 35-44	% 45-54	% 55-64	% 65-74	% 75-84	% 85+
A	1	9	16	21	23	23	6	
B	3	11	16	18	24	18	9	0
C	3	9	18	19	21	23	7	
D	4	11	14	17	21	24	10	1
E	3	8	20	17	22	15	13	1
F	1	10	12	17	23	23	12	1
G	2	10	17	18	25	19	8	1
H	3	11	19	21	22	18	6	0.1
I	1	5	10	14	29	24	15	3
J	3	13	12	19	23	20	10	0.4
K	2	7	12	23	24	23	9	
L	3	12	19	23	18	16	7	0.1
M	4	10	15	18	21	20	11	0.2
N	4	9	16	20	23	17	10	1
O	3	11	14	19	20	21	11	
P	2	15	15	19	22	17	10	2
Q	2	9	18	22	22	17	8	1
R	2	13	17	18	23	18	7	1
Sa	1	12	20	23	22	14	7	1
Sb	1	12	12	19	18	23	13	1
Sc	4	10	19	19	17	25	4	3
Sd	3	15	24	20	19	14	5	0
Se	1	9	14	22	22	21	9	1
Sf	6	9	10	12	27	23	11	1
Sg	1	16	21	14	19	16	12	1
Sh	1	9	19	12	20	25	13	
Si	7	7	12	16	21	28	9	
Sj	1	7	10	20	20	28	12	1
Sk	4	12	17	23	16	19	9	1
T	2	11	18	23	23	17	6	
U	2	12	15	19	20	20	12	1
V	6	15	19	19	21	13	7	1
W	2	6	13	13	20	23	19	4
X	3	12	15	21	20	20	9	1
Sct	2	13	19	20	20	18	8	1

E&W	3	11	16	20	22	18	9	1
UK	3	11	17	20	21	18	9	1

**Table D.2.8 Age ranges by centre**

<b>Treatment Modalities with gender ratios</b>										
	No. of males	No. of females	No. unknown	M:F ratio	No. on HD	M:F ratio	No. on PD	M:F ratio	No. on transplant	M:F ratio
Sct	1687	1188		1.4	1098	1.4	410	1.3	1367	1.5
E&W	7288	4585	6	1.6	4136	1.7	2124	1.4	5619	1.6
UK	8975	5773	6	1.6	5234	1.6	2534	1.4	6986	1.6

**Table D.2.9 Numbers of patients by treatment modality with gender ratios**

<b>Non-diabetic dialysis modalities (all patients)</b>											
Centre	% on HD	% on Home HD	% on Hospital HD	% on Satellite HD	% on PD	% on CAPD Standard	% on CAPD Disconnect	% on Cycling PD $\geq$ 6 nights/wk	% on Cycling PD<6 nights/wk	% on PD Type Unknown	% on Transplant
A	26	0	43	18	17	2	31	7	0	0	57
B	33	1	57	19	10	0	23	0	0	0	57
C	40	1	84	0	7	0	9	6	0	0	53
D	51	11	63	9	11	0	15	2	0	0	38
E	25	2	62	0	14	0	37	0	0	0	61
F	56	0	4	71	18	0	24	0	0	0	27
G	29	6	33	13	26	0.2	42	6	0	0	45
H	32	1	47	15	19	0	34	3	0	0	49
I	75	0	84	0	14	0	16	0	0	0	11
J	57	0	41	36	18	0	24	0	0	0	26
K	35	3	53	0	28	0	44	0	0	0	37
L	17	0	24	31	14	0	46	0	0	0	69
M	47	2	33	30	25	0.4	28	5	2	0	28
N	33	17	18	43	10	7	14	1	0	0	57
O	26	1	34	28	16	0	35	2	1	0	58
P	22	3	40	10	20	0	37	10	0	0	58
Q	22	7	57	0	12	0	29	6	0.3	0	66
R	31	5	58	0	19	0	38	0	0	0	50
Sa	33	2	77	0	8	0	16	4	0	0	59
Sb	45	2	72	0	15	0	15	11	0	0	40
Sc	26	0	49	0	27	0	28	23	0	0	47
Sd	18	0	68	0	9	0	28	4	0	0	73
Se	81	20	61	0	19	0	19	0	0	0	
Sf	73	0	73	0	27	0	20	7	0	0	
Sg	49	3	57	0	31	0	28	11	0	0	20
Sh	73	2	72	0	27	0	3	23	0	0	
Si	71	3	78	0	18	0	8	13	0	0	11
Sj	78	0	78	0	22	0	21	2	0	0	
Sk	35	6	72	0	10	0	20	3	0	0	56
T	42	10	34	30	14	0	25	0	0	0	43
U	26	0	59	0	18	0	2	39	0	0	57
V	30	2	34	44	7	17	0	3	0	0	63
W	44	0	63	0	25	4	28	5	0	0	31
X	43	7	43	18	20	0	24	8	0	0	37
Sct	37	4	70	0	13	0	20	7	0	0	50
E&W	33	5	42	21	16	1	27	3	1	0	51
UK	34	5	47	17	15	1	26	4	0.5	0	51

**Table D.2.10 Treatment modalities for non-diabetic patients**

<b>Non-diabetic dialysis modalities (all patients)</b>			
	No. on HD	No. on PD	No. on Transplant
E&W	906	325	1242
Scotland	3336	1606	5168
UK	4242	1931	6410

**Table D.2.11 Numbers of non-diabetic patients by treatment modality**

Non-diabetic treatment modalities for patients aged under 65											
Centre	% on HD	% on Home HD	% on Hospital HD	% on Satellite HD	% on PD	% on CAPD Standard	% on CAPD Disconnect	% on Cycling PD ≥ 6 nights/wk	% on Cycling PD < 6 nights/wk	% on PD Type Unknown	% on Transplant
A	14	0	30	17	16	3	37	13	0	0	71
B	23	1	53	18	9	0	28	0	0	0	68
C	26	2	73	0	9	0	15	10	0	0	65
D	40	18	55	6	10	0	19	2	0	0	50
E	17	3	55	0	12	0	42	0	0	0	71
F	44	0	6	68	16	0	26	0	0	0	40
G	25	10	34	10	21	0.4	40	6	0	0	54
H	24	1	44	14	17	0	36	6	0	0	58
I	62	0	73	0	23	0	27	0	0	0	15
J	52	0	42	36	14	0	22	0	0	0	34
K	32	5	52	0	23	0	43	0	0	0	45
L	10	0	20	23	14	0	57	0	0	0	76
M	40	3	33	24	26	1	30	8	1	0	34
N	24	30	18	31	6	3	16	2	0	0	69
O	20	1	37	21	14	0	37	2	1	0	66
P	20	4	48	10	12	0	29	9	0	0	68
Q	16	11	50	0	10	0	31	7	0	0	75
R	25	8	52	0	17	0	40	0	0	0	58
Sa	24	4	73	0	7	0	18	5	0	0	69
Sb	31	3	65	0	15	0	17	15	0	0	54
Sc	25	0	55	0	20	0	24	21	0	0	55
Sd	13	0	65	0	7	0	29	6	0	0	80
Se	82	27	55	0	18	0	18	0	0	0	
Sf	70	0	70	0	30	0	20	10	0	0	
Sg	42	5	52	0	32	0	27	16	0	0	26
Sh	74	3	71	0	26	0	3	24	0	0	
Si	64	4	71	0	21	0	8	17	0	0	14
Sj	73	0	73	0	27	0	24	3	0	0	
Sk	28	11	69	0	7	0	18	2	0	0	65
T	39	14	34	28	12	0	24	0	0	0	49
U	13	0	45	0	16	0	3	52	0	0	71
V	23	4	35	38	7	19	0	4	0	0	70
W	18	0	37	0	30	4	46	13	0	0	53
X	32	10	36	14	21	0	28	12	0	0	47
Sct	29	6	65	0	11	0	20	8	0	0	60
E&W	25	7	39	18	14	1	30	4	1	0	61
UK	26	7	44	15	13	1	28	5	0.5	0	61

Table D 2.12 Treatment modalities for non-diabetic patients aged under 65

Non-diabetic dialysis modalities for patients aged < 65			
	No. on HD	No. on PD	No. on Transplant
Sct	522	207	1094
E&W	1852	1023	4488
UK	2374	1230	5582

Table D.2.13 Numbers of non-diabetic patients aged under 65 by treatment modality

Non-diabetic treatment modalities for patients aged 65 and over											
Centre	% on HD	% on Home HD	% on Hospital HD	% on Satellite HD	% on PD	% on CAPD Standard	% on CAPD Disconnect	% on Cycling PD ≥ 6 nights/wk	% on Cycling PD < 6 nights/wk	% on PD Type Unknown	% on Transplant
A	58	0	55	19	20	0	26	0	0	0	23
B	61	0	63	21	12	0	16	0	0	0	27
C	74	0	96	0	3	0	2	2	0	0	23
D	74	2	73	13	11	0	10	3	0	0	16
E	43	0	70	0	19	0	30	0	0	0	38
F	74	0	3	75	21	0	22	0	0	0	6
G	40	1	31	19	39	0	45	5	0	0	21
H	58	1	53	16	25	0	30	0	0	0	17
I	92	0	98	0	2	0	2	0	0	0	6
J	68	0	38	35	25	0	26	0	0	0	7
K	43	0	53	0	38	0	47	0	0	0	19
L	41	0	30	42	16	0	28	0	0	0	43
M	62	1	32	40	23	0	25	0	2	0	15
N	57	3	17	56	18	11	12	1	0	0	26
O	44	0	29	38	22	0	32	2	0	0	34
P	30	1	31	9	44	0	47	12	0	0	25
Q	41	3	66	0	18	0	26	4	1	0	41
R	47	0	67	0	23	0	33	0	0	0	29
Sa	61	0	83	0	12	0	14	2	0	0	27
Sb	68	1	79	0	17	0	13	7	0	0	15
Sc	29	0	39	0	46	0	33	28	0	0	25
Sd	42	0	72	0	16	0	27	1	0	0	42
Se	79	2	76	0	21	0	21	0	0	0	
Sf	80	0	80	0	20	0	20	0	0	0	
Sg	64	0	68	0	30	0	29	3	0	0	6
Sh	73	0	73	0	27	0	4	23	0	0	
Si	82	0	88	0	12	0	6	6	0	0	6
Sj	84	0	84	0	16	0	16	0	0	0	
Sk	51	0	75	0	17	0	21	4	0	0	32
T	53	2	35	35	21	0	27	2	0	0	25
U	59	0	73	0	22	0	0	27	0	0	19
V	57	0	31	55	9	13	0	0	0	0	34
W	72	0	78	0	21	4	19	0	0	0	8
X	66	1	53	24	18	0	18	3	0	0	16
Sct	59	0.4	76	0	18	0	19	5	0	0	23
E&W	54	1	46	25	21	2	24	2	1	0	25
UK	55	1	52	20	21	1	23	2	0.4	0	24

Table D.2.14 Treatment modalities for non-diabetic patients aged over 65

Non-diabetic dialysis modalities for patients aged 65 and over			
	No. on HD	No. on PD	No. on Transplant
Sct	384	118	148
E&W	1484	583	680
UK	1868	701	828

Table D.2.15 Numbers of non-diabetic patients aged over 65 by treatment modality

<b>Diabetic Patient Dialysis Modalities</b>											
<i>Centre</i>	% on HD	% on Home HD	% on Hospital HD	% on Satellite HD	% on PD	% on CAPD Standard	% on CAPD Disconnect	% on Cycling PD >=6 nights/wk	% on Cycling PD <6 nights/wk	% on PD Type Unknown	% on Transplant
A	56	0	70	20	6	0	10	0	0	0	38
B	58	0	67	19	10	0	14	0	0	0	32
C	60	0	75	0	20	0	19	6	0	0	20
D	65	0	74	3	19	0	16	6	0	0	16
E	27	0	55	0	22	0	45	0	0	0	51
F	50	0	3	63	27	0	35	0	0	0	23
G	42	0	38	14	38	0	39	8	0	0	20
H	51	0	54	12	26	0	33	1	0	0	23
I	57	0	63	0	33	0	37	0	0	0	10
J	66	0	41	34	22	0	25	0	0	0	12
K	32	0	33	0	64	0	67	0	0	0	4
L	41	0	37	44	10	0	20	0	0	0	49
M	44	0	24	26	44	0	40	2	7	0	13
N	47	4	19	47	20	8	17	6	0	0	33
O	47	0	27	41	22	0	32	0	0	0	31
P	22	0	29	6	42	0	53	12	0	0	36
Q	27	2	44	0	32	0	46	6	2	0	41
R	33	0	42	0	47	0	58	0	0	0	20
Sa	35	0	73	0	13	0	18	9	0	0	52
Sb	53	0	75	0	18	0	18	7	0	0	30
Sc	33	0	50	0	33	0	33	17	0	0	33
Sd	27	0	53	0	24	0	45	3	0	0	49
Se	84	5	79	0	16	0	11	5	0	0	
Sf	43	0	43	0	57	0	29	29	0	0	
Sg	32	0	40	0	47	0	47	13	0	0	21
Sh	64	0	64	0	36	0	9	27	0	0	
Si	80	0	80	0	20	0	0	10	10	0	
Sj	85	0	85	0	15	0	12	4	0	0	
Sk	44	0	70	0	19	0	25	5	0	0	38
T	46	0	37	25	28	0	38	0	0	0	26
U	45	0	59	0	31	0	9	0	32	0	24
V	38	0	32	35	18	32	0	0	0	0	44
W	44	0	78	0	13	0	22	0	0	0	44
X	53	0	45	24	23	0	24	6	0	0	23
Sct	46	0.5	67	0	22	0	24	8	0	0	31
E&W	44	0.4	41	20	28	2	33	3	1	0	29
UK	44	0.4	46	16	27	1	31	4	1	0	29

**Table D.2.16 Treatment modalities for diabetic patients**

<b>Diabetic Patient Dialysis Modalities</b>			
	No. on HD	No. on PD	No. on Transplant
Sct	136	66	92
E&W	520	334	341
UK	656	400	433

**Table D.2.17 Numbers of diabetic patients by treatment modality**

<b>Diabetics</b>						
<b>Centre</b>	<b>Median age on 31.12.99</b>	<b>Median age at start of treat</b>	<b>% with age known at start of treat</b>	<b>M:F ratio</b>	<b>Median time on ESRF treatment</b>	
					<b>in days</b>	<b>in years</b>
A	55	56	88	2.2	707	1.9
B	56	54	95	2.4	868	2.4
C	51	47	90	2.3	488	1.3
D	61	58	93	1.6	679	1.9
E	52	47	85	0.8	1361	3.7
F	58	56	95	1.3	1009	2.8
G	57	54	97	2.1	853	2.3
H	55	52	99	1.3	745	2.0
I	58	55	99	1.1	645	1.8
J	54	52	94	1.5	660	1.8
K	65	63	99	1.8	643	1.8
L	57	53	94	1.9	1075	2.9
M	60	57	90	2.2	341	0.9
N	55	51	99	0.9	815	2.2
O	57	58	97	1.3	1079	3.0
P	53	49	96	1.5	966	2.6
Q	51	46	96	1.1	1237	3.4
R	54	52	96	2.5	699	1.9
Sa	50	46	99	1.4	1682	4.6
Sb	62	58	100	1.9	658	1.8
Sc	63	62	99	2.0	1212	3.3
Sd	49	42	100	1.3	1299	3.6
Se	63	63	100	1.7	494	1.4
Sf	45	42	100	2.5	1106	3.0
Sg	51	47	100	0.7	879	2.4
Sh	62	60	100	2.7	533	1.5
Si	53	51	100	2.3	464	1.3
Sj	61	58	100	0.9	515	1.4
Sk	53	48	100	0.9	919	2.5
T	52	48	98	3.1	865	2.4
U	57	55	99	1.2	919	2.5
V	52	51	96	1.9	1387	3.8
W	47	43	98	0.8	1259	3.4
X	55	53	97	1.9	912	2.5
Sct	53	50	100	1.4	882	2.4
E&W	55	52	96	1.6	871	2.4
UK	55	52	96	1.5	877	2.4

**Table D.2.18 Diabetics**

<b>Transplant rates with gender ratios</b>			
<b>Centre</b>	<b>Overall M:F</b>	<b>% on transplant</b>	<b>M:F</b>
A	1.6	55	1.5
B	1.6	52	1.8
C	1.8	49	1.5
D	1.8	36	1.8
E	1.6	59	1.7
F	2.0	28	2.3
G	1.6	41	1.8
H	1.4	45	1.7
I	1.4	12	1.8
J	1.5	23	1.5
K	1.9	34	1.7
L	1.5	64	1.5
M	1.7	26	2.3
N	1.5	54	1.5
O	1.9	47	1.5
P	1.7	48	1.7
Q	1.4	62	1.5
R	1.7	47	1.5
Sa	1.7	59	2.1
Sb	1.4	38	1.3
Sc	1.6	42	1.5
Sd	1.3	72	1.4
Se	1.4		unknown
Sf	1.5		unknown
Sg	1.3	21	0.8
Sh	1.9		unknown
Si	1.5	11	2.0
Sj	1.2		unknown
Sk	1.2	54	1.3
T	1.7	41	1.4
U	1.4	38	1.4
V	1.5	62	1.4
W	1.3	32	1.0
X	2.0	36	2.8
Sct	1.4	48	1.5
E&W	1.6	47	1.6
UK	1.6	47	1.6

**Table D.2.19 Transplant gender ratios**



