Chapter 3 Patients starting Renal Replacement Therapy in 1996 and 1997

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

For 1996 data is only available from four pilot units (Bristol, Leeds, Leicester, Sheffield) covering an estimated catchment population of 6.0 million. For 1997 full data was available from nine units in England covering an estimated catchment population of 9.2 million.

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

3:1 Patient characteristics

The median age and gender distribution of patients starting renal replacement therapy in 1996 and 1997 are shown in table 3.1.

Centre	1995 Median Age	1996 Median Age	1997 Median Age	1995 M:F Ratio	1996 M:F Ratio	1997 M:F Ratio
A			65.5			1.5
B			63.5			1.2
C			63			1.3
D		65	59		2.0	1.9
E		57	56		1.3	1.8
F		65	64		1.4	1.5
G			61			1.6
H		58	60		1.3	1.4
I			72			3.3
All	61	62	61	1.6	1.5	1.6
No.		460	822		460	818

Table 3.1 Median age of patients starting renal replacement therapy

Four hundred and sixty patients are recorded in 1996 and 822 for 1997. For 1997 this gives an approximate combined take on rate from the 9 units of 89 per million population per year. This is a very crude figure as we have not been able to make any allowance for cross-boundary flow of patients, and the estimated catchment populations are not precise.

The age distribution of patients starting renal replacement therapy is illustrated in Fig 3.1. Of these new patients 43% were aged 65 or more, and 15% were aged 75 or more.

For comparison figures from the English national survey of renal units in England in 1995 are included. The age group divisions are comparable except that in the English review the youngest age group was 16 to 24 not 18 to 24.

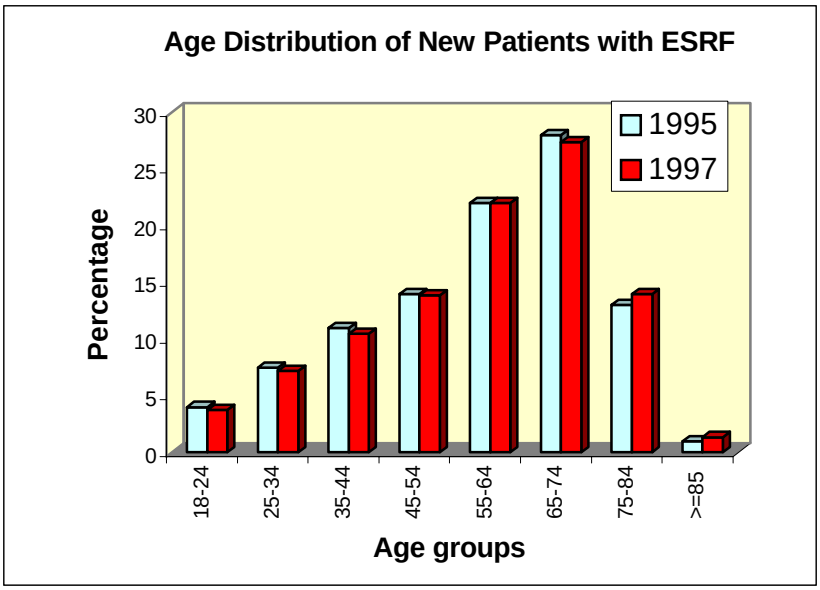

Figure 3.1 Age distribution of patients starting renal replacement therapy

The distribution of aetiology of renal failure for new patients is given in table 3.2. Diagnoses categories were aggregated from EDTA codes for diagnosis.

Diagnosis	1995*	1996 (4 units)			1997 (9 units)				
	ALL	% men	% women	M:F ratio	% men	% women	M:F Ratio	<65	≥ 65
Aetiology uncertain	17.0	52.0	48.0	1.1	58.0	42.0	1.4	17.8	27.9
Glomer. not proven		62.5	37.5	1.7	71.4	28.6	2.5	0.8	2.8
Glomerulonephritis	12.4	63.0	37.0	1.7	70.7	29.3	2.4	15.1	6.0
Pyelonephritis	9.1	57.9	42.1	1.4	64.3	35.7	1.8	7.9	9.7
Diabetes	13.8	62.0	38.0	1.6	66.9	33.1	2.0	21.0	11.7
Reno-vascular dis.	5.5	77.8	22.2	3.5	56.3	43.8	1.3	3.0	14.5
Hypertension	7.8	68.0	32.0	2.1	80.0	20.0	4.0	5.1	4.6
Polycystic Kidney	5.9	45.7	54.3	0.8	57.8	42.2	1.4	11.0	3.4
Not sent	15.7	80.0	20.0	4.0	62.5	37.5	1.7	4.5	5.4
Other	12.6	65.7	34.3	1.9	50.0	50.0	1.0	13.8	14.0
Total numbers		279	181	460	505	313	818	471	351

- figures from the English national survey

Table 3.2 Diagnoses of patients starting renal replacement therapy

The differences in the diagnosis of patients starting treatment in 1997 in different units are shown in table 3.3

Diagnosis	**Centre A**	**Centre B**	**Centre C**	**Centre D**	**Centre E**
Aetiology uncertain	23.2	35.0	18.7	26.5	17.7
Glomer. not proven	3.7	0.0	0.0	0.8	1.8
Glomerulonephritis	7.3	15.0	15.4	5.3	18.6
Pyelonephritis	12.2	12.5	5.5	5.3	9.7
Diabetes	17.1	15.0	23.1	13.6	15.0
Reno Vascular disease	8.5	12.5	7.7	9.1	4.4
Hypertension	6.1	0.0	9.9	1.5	4.4
Polycystic Kidney	4.9	5.0	8.8	9.8	8.0
Not sent	1.2	0.0	2.2	8.3	0.0
Other	15.9	5	8.8	19.7	20.4
Diagnosis	**Centre F**	**Centre G**	**Centre H**	**Centre I**	**All**
Aetiology uncertain	26.9	18.6	18.8	19.6	22.1
Glomer. not proven	1.9	0.0	0.0	13.0	1.7
Glomerulonephritis	14.4	9.7	7.9	8.7	11.2
Pyelonephritis	10.6	6.2	7.9	15.2	8.6
Diabetes	15.4	29.2	8.9	13.0	17.0
Renal Vascular disease	5.8	5.3	11.9	10.9	7.9
Hypertension	4.8	7.1	5.9	0.0	4.9
Polycystic Kidney	8.7	8.0	6.9	6.5	7.8
Not sent	0.0	1.8	21.8	4.3	4.9
Other	11.5	14.2	9.9	8.7	13.9

Table 3.3 Diagnoses of patients starting renal replacement therapy in the 9 units

The median age of new patients (table 3.1) was 61 years, but there was a large variation between centres from 56 to 72. The median age of new patients differed significantly between the centres (Kruskal Wallis test, X^2=40.1,df=8, p<0.001). Centre I, which is the most outlying centre is small, with small numbers of patients accepted. As the Registry matures, and more sequential data are collected, it will be possible to compare over a two or three year running average the characteristics of new patients accepted for dialysis. Centre differences, if present, may become more apparent, and will clearly have an effect on comparison of patient survival between centres (see section 3.3).

The age distribution of new patients in registry units in 1997 is illustrated in Fig 3.1. 43% are 65 or over, compared with 41% in England in 1995 and 37% in 1993. 29% of new patients are 70 or over. Although the catchment populations for these figures differ, there appears to be a trend for accepting older patients.

The overall male to female ratio of new patients was 1.6:1, similar to the stock (1.6:1). Centre I was again the outlier, with a high male to female ratio of 3.3:1. However this centre has the oldest group of patients starting renal replacement therapy, and from the figures on stock of patients (vide infra) it does appear that there is a considerable excess of men on treatment in the older age groups. The English review data also confirm that there is a marked male preponderance amongst older patients starting treatment. There

was no significant difference in the proportion of males and females at the different centres (X^2=8.0, d.f=8, p=0.430).

The age distribution and gender ratio of patients on the Registry in 1997, with the exception of the over 75's, is similar to that of the English figures for 1995 and suggests that the units currently returning to the Registry may be reasonably representative of England as a whole.

Considering the aetiology of renal failure, there is very little missing data, and this was mostly from one centre, I (tables 3.2,3.3). When applying the chi squared tests to figures for the underlying diagnosis, patients with diagnosis "not sent" were removed from the analysis. Hence the corrected percentages quoted below differ slightly from table 3.3. The number of patients recorded is currently too small to analyse data by ethnicity.

It would be expected that some diagnoses are more apparent in younger and some in older patients and some of the differences shown between those above and below 65 are therefore not surprising.. When comparing the proportion of patients with "uncertain aetiology" above and below the age of 65, the chi-squared test indicates that the proportion of patients aged under 65 with the a diagnosis "aetiology uncertain", at 19%, is significantly different from 30% found in those over 65. (X^2 = 12.6, d.f = 1, p<0.001)

Of all patients, 17% had diabetic nephropathy compared with 14% nationally in 1995. The percentage with diabetes in the younger group, is twice that in the older group, a pattern somewhat different from that in the English review (15.7% and 11.1% respectively) and the United States (42.7% vs 33.9%.). The similar distribution of pyelonephritis across the ages may appear surprising, as this commonly thought to be largely due to reflux nephropathy. However the EDTA diagnosis codes on which this is analysis is based are very poor in this area, and include obstructive uropathy in the pyelonephritis category. Elderly men with prostatic obstruction to bladder outflow are thus included.

There does appear to be a wide variation in the diagnostic distribution of patients starting treatment in different renal units (Table 3.3). The proportion of those with diabetes varies from 9% to 30%, and is not highest in the units with high ethnic minority populations. The proportion of diabetic patients in the different units differed significantly (X^2 = 17.4, d.f = 8, p = 0.026). Unknown diagnosis varies from 19% to 35%, glomerulonephritis from 5% to 18%, and hypertension from 0% to 10%.

A chi squared test was used to determine whether the percentage of males and females starting renal replacement therapy (table 3.2) varies by diagnosis. The few patients with no diagnosis sent are excluded from this analysis. There is a significant variation in the diagnostic categories between the two sexes (X^2 = 20.0, D.F = 8, p = 0.010).

The similar incidence in the sexes of autosomal dominant adult polycystic kidney disease is expected. There is no evidence for a male predominance of reno-vascular disease. There is a high male to female ratio for the diagnosis of hypertensive renal disease

3:2. First elective modality of renal replacement therapy.

The Registry defines the first elective modality of renal replacement therapy as transplantation if it is immediate, peritoneal dialysis if it is started within 90 days of initiation of renal replacement therapy, and haemodialysis if this continues uninterrupted for 90 days. If patients die in the first 90 days they can be difficult to classify as they may have been on haemodialysis but with the intention of starting peritoneal dialysis. Such patients were classified as starting electively on haemodialysis.

The first elective modality was calculated and compared with the treatment which patients were receiving at 90 days. As some patients died in that time the populations are slightly different. The results are compared in table 3.4. The differences are small. As the established modality at 90 days is a more clearly defined figure which is easier to derive this has been used in subsequent analysis of elective modality of treatment.

Unit	**Elective treatment**			**Established treatment at 90days**		
	HD	**PD**	**Transplant**	**HD**	**PD**	**Transplant**
A	81	19	0	75	25	0
B	56	44	0	58	40	3
C	81	19	0	73	24	3
D	38	59	3	38	57	5
E	70	30	0	71	29	0
F	53	44	3	52	45	3
G	62	37	1	61	39	0
H	69	25	5	68	25	3
I	63	37	0	62	38	0
TOTAL	**62**	**36**	**2**	**60**	**37**	**3**
No. of pats	**477**	**275**	**13**	**407**	**252**	**17**

Table 3.4 Chosen treatment modality and that established at 90 days

In order to study the established modality of treatment at 90 days during 1997, it is necessary to consider the 765 new patients who started renal replacement therapy from 1st October 1996 until 1st October 1997. Fig 3.2 shows the distribution of treatment modalities established at 90 days after initiation of renal replacement therapy.

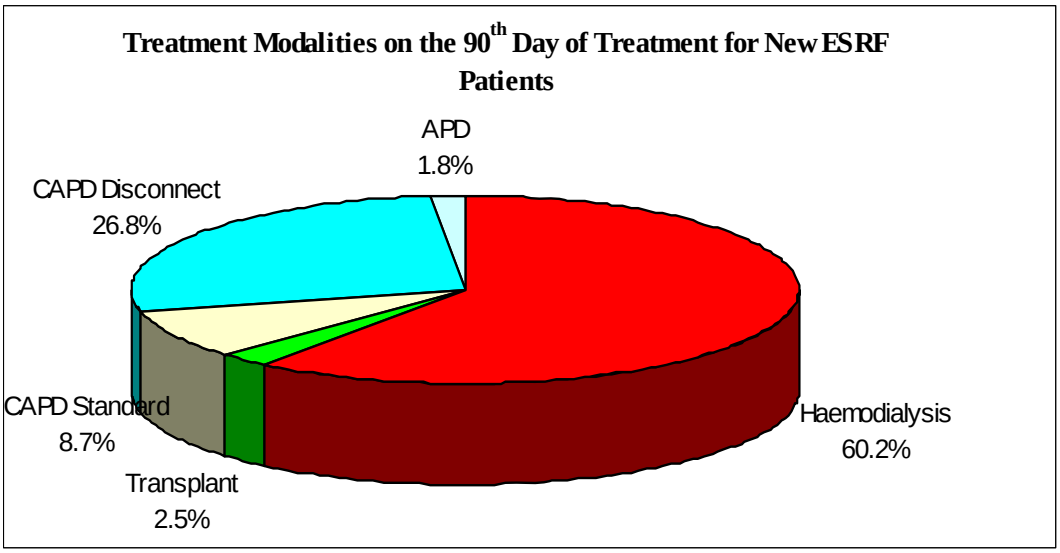

Figure 3.2 Treatment modalities at 90 days of renal replacement therapy.

As only 2% of patients started with pre-emptive transplantation, the subsequent figures indicate the proportions of dialysis patients receiving haemodialysis or peritoneal dialysis. Figure 3.3 shows the unit variation in the percentage of new dialysis patients established on haemodialysis as opposed to all forms of peritoneal dialysis, with a variation from 40% to 75%. A chi-squared test showed that this variation is significant ($X^{2=}42.9$, d.f=8, $p<0.001$)

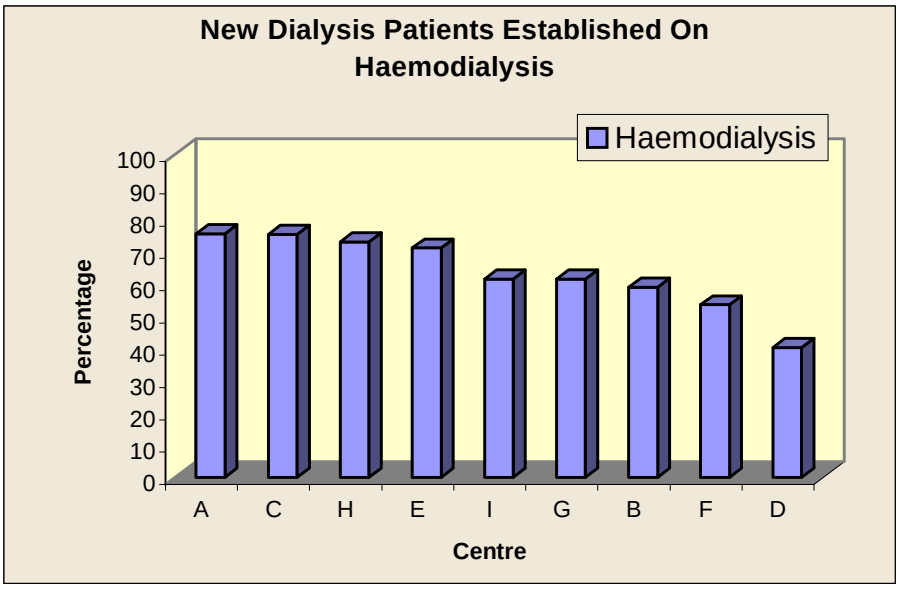

Figure 3.3 Percentage of new patients established on haemodialysis at 90 days.

Figure 3.4 shows the proportions of patients on haemodialysis as opposed to peritoneal dialysis with regard to age above and below 65.

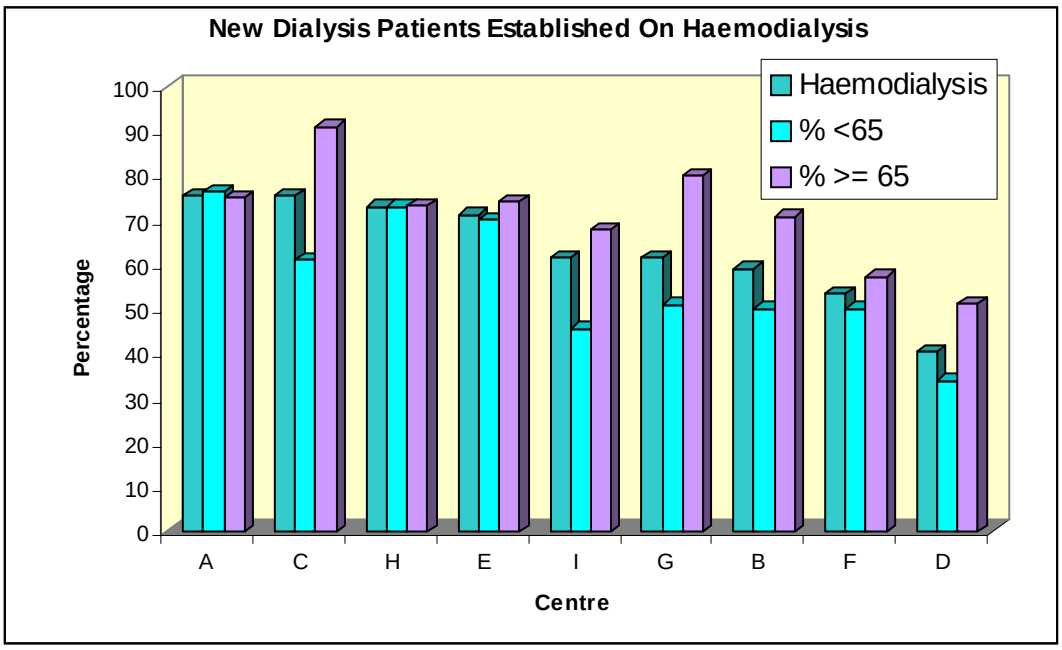

Figure 3.4 Percentage of old and young new patients established on haemodialysis at 90 days.

Overall 56% of dialysis patients under 65 were established on haemodialysis compared with 70% over 65. There was again wide unit variation. Centres A E and H showed no difference in proportion of patients first established on haemodialysis with regard to age whereas all the other units showed a distinct preference to start older patients on haemodialysis. In no unit was there a preference for starting older patients on peritoneal dialysis.

Fig 3.5 shows the distribution of dialysis modality with regard to gender.

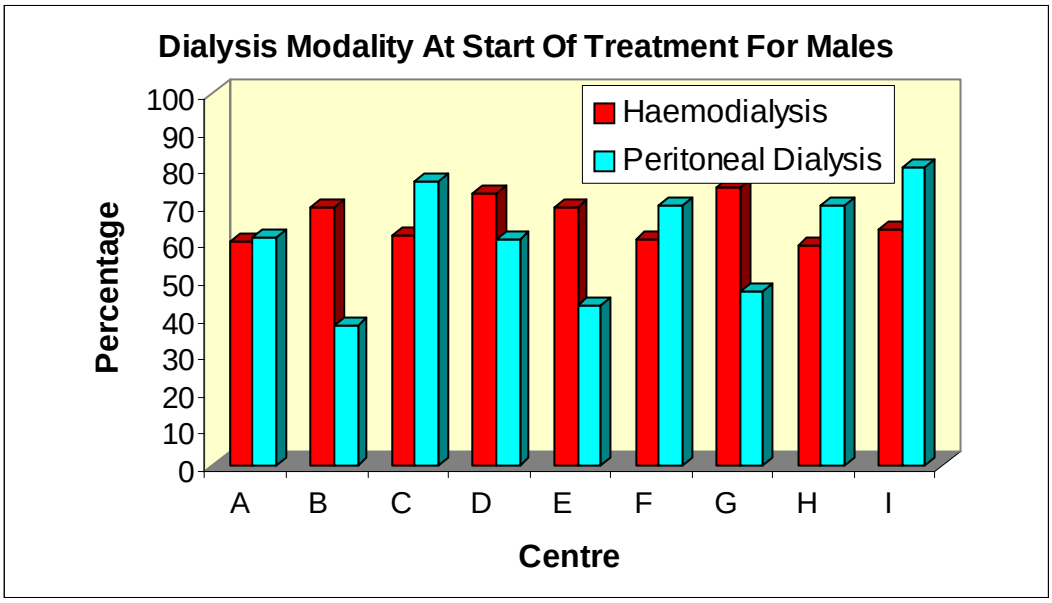

Figure 3.5 Dialysis modality by gender

The overall male to female of ratio for this sample is 1.8:1, but there appears to be a preference to put men on haemodialysis, with a male to female ratio of 2:1, compared with a ratio of 1.5:1 for peritoneal dialysis. There appeared to be a wide variation in unit practice, but a chi-squared test comparing the percentage of haemodialysis patients who were male showed no significant difference between units (X^2=5.9,d.f=8, p=0.66). This will need further investigation when larger numbers and cumulative figures become available to see whether each individual unit's performance remains consistent.

As it is widely believed that peritoneal dialysis may be the treatment of choice for diabetics we compared the treatment modalities on 90th day for diabetics and non-diabetics. There was no significant difference using the Chi-squared test (X^2 = 0.0, d.f = 1, p = 0.992).

3:2.2. The first change of treatment modality within the first year

This analysis considers the 490 patients from 4 centres who started renal replacement therapy between 1.10.95 and 31.9.96, and follows patients for the first 12 months after their first 90 days of treatment.
Changes in treatment modality within that year were analysed. The following rules were applied:

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

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

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

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

The results are shown in table 3.5.and illustrated in figure 3.6

Haemodialysis ***Modality***	**% all patients**	**no. of patients**
Remains on HD	67.8	156
Changed to PD	4.8	11
Transplanted	9.1	21
Transferred out elsewhere	0.4	1
Died	17.8	41

Table 3.5a Haemodialysis patients: change in modality

Peritoneal Dialysis ***Modality***	**% all patients**	**no. of patients**
Remains on PD	66.3	136
Change to HD	10.2	21
Transplanted	11.2	23
Transferred out elsewhere	0.5	1
Recovered	1	2
Died	10.7	22

Table 3.5b Peritoneal Dialysis change in modality

As there were small numbers of patients to study, we have not attempted to interpret these findings. In subsequent reports there will be large enough numbers of new patients returned to the Registry for a statistical analysis to be undertaken. It is possible that some of the changes from haemodialysis to peritoneal dialysis were elective, some patients not having stabilised by 90 days. In subsequent reports it may be possible to study this data with reference to time between referral to the renal unit and renal replacement therapy.

3:3 One year patient survival

This was studied in the 458 hundred patients from the four units who sent returns for 1996. The two patients who recovered renal function were not included. The figures quoted are from the day of first renal replacement therapy.

The probability of surviving one year was calculated using the Kaplan-Meier estimate.

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

Results are shown in table 3.6

	Death Rate **Per 100 Patient Years**	Deaths **No of Patients**	**KM Survival Analysis**	**K-M 95% Confidence Interval**
< 65	9.7	22/260	0.91	0.88 - 0.95
≥ 65	39	62/198	0.68	0.62 - 0.75
All	21	84/458	0.81	0.78 - 0.85

Table 3.6 One year survival of new patients, by age at start of therapy

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

Eighteen percent of those starting on haemodialysis died within the first year, compared with 10.7% of those starting on peritoneal dialysis. This is probably a reflection of the clinical setting as the median age of patients starting haemodialysis was older (61 compared with 59) and initial review suggests that those starting on haemodialysis had greater co-morbidity.

The 90 day survival is shown in table 3.7. The probability of a new patient surviving the first 90 days is 92%, with a death rate of 8.6 per 100 patient '3 months'.

	Death Rate	Deaths No of Patients	KM Survival Analysis	K-M 95% Confidence Interval
All	8.6%	38/458	0.92	0.89 - 0.94

Table 3.7 Ninety day survival of new patients

The figures produced here are not comparable with those reported by the USRDS which excludes patients dying within the first 90 days of renal replacement therapy. The USRDS is unable to collect data with regard to the first 90 days of treatment as much of their data is collected by billing systems, and patients are not eligible for Medicare payment until 90 days of therapy have passed. The Australian registry does not produce a separate figure for deaths of new patients and stock.