

## Appendix B: Definition, statistical methodology, analysis criteria

### *Definitions of analysis quarters*

Quarter	Dates
Quarter 1	1 January – 31 March
Quarter 2	1 April – 30 June
Quarter 3	1 July – 30 September
Quarter 4	1 October – 31 December

The quarterly biochemistry data are extracted from renal unit systems as the last data item stored for that quarter. If the patient treatment modality is haemodialysis, the software will try to select a pre-dialysis value.

### *Renal Registry modality definitions*

#### *Home haemodialysis*

A home haemodialysis patient ceases to be classed as such, if they need greater than 2 weeks of hospital dialysis when not an inpatient.

#### *Satellite dialysis unit*

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

#### *Treatment modality at 90 days*

This is used by the USRDS and is the modality that the patient is on at day 90 regardless of any changes from the start. It is a general indicator of initial dialysis, but could miss failed CAPD. This would also miss patients intended for home haemodialysis, who will not be home yet. This is modality is calculated by the Registry, which allows the definition to be changed.

#### *Start of end stage renal failure*

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

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

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

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

## ***Analysis criteria***

### ***Definition of the Take-On population (Incidence)***

The take-on population in a year included patients who later recovered from ESRF after 90 days from the start of treatment. Patients newly transferred into a centre who are already on renal replacement therapy (RRT) are **excluded** in the take on population for that centre. Patients restarting dialysis after a failed transplant are also excluded (unless they started RRT in that current year).

Since patients who restarted RRT after recovering from ESRF, are included in the take-on population the following scenarios can occur:- A patient may start RRT in 1999, recover and then restart RRT in 1999. These patients are counted twice in the analysis providing they have been receiving RRT for greater than 90 days on each occasion.

Patients who started treatment at a centre and then transferred out soon after receiving treatment are counted at the original centre for all analyses of treatment on the 90<sup>th</sup> day.

### ***Definition of the Prevalent population***

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

### ***Death rate calculation***

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

### ***Odds Ratio***

Odds of dying :-

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

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

### ***Hazard Function***

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

### **Hazard ratio**

Probability of dying in the next interval for a phosphate of 1.71-2.10 mmol/L  
probability of dying in the next interval for a phosphate in the ref range

### **Survival analyses of prevalent cohort**

These analyses exclude the current years incident cohort

### **Criteria for analysis by treatment modality in a quarter**

The following quarterly entries were included and excluded: -

Patients on haemodialysis with a treatment centre of 'elsewhere' were **removed**. It should be noted that there were some patients on transplant with a treatment centre of 'Elsewhere'. These patients were **included**.

Entries for which the hospital centre was not the primary treatment centre were removed from the analysis of data for that centre.

Patients who had been on RRT for less than 90 days were removed. (by definition of ESRF)  
There were a few exceptions to these rules:-

1. If a patient's initial entry on the treatment time line contained a '**transferred in**' code, then the patient was assumed to have been on RRT for longer than 90 days, since the patient must have started RRT earlier than this elsewhere. Therefore, patients with an initial entry on the treatment timeline with a '**transferred in**' code were included for all quarters. For example, a patient with an initial treatment modality of '**transferred in**' on the 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.

Patients who transferred out of their initial treatment centre, were censored on the day they transferred out if there was no further information in the timeline.

### ***Analysis of one year survival of 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.

