Appendix B: Definition, statistical methodology, analysis criteria

Definitions of analysis quarters

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>1 January – 31 March</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>1 April – 30 June</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>1 July – 30 September</td>
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<tr>
<td>Quarter 4</td>
<td>1 October – 31 December</td>
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</tbody>
</table>

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

Renal Registry modality definitions

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

Satellite dialysis unit
A satellite unit is a centre which is distinct from the parent hospital where the consultant nephrologist is based.

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

Analysis criteria

Take-On population
The take-on population in a year included patients who later recovered from ESRF after 90 days from the start of treatment. Patients newly transferred into a centre who are already in ESRF are not included in the take on population for that centre.

Since patients who restarted ESRF treatment after recovering from ESRF, are included in the take-on population the following scenarios can occur:- a patient may start ESRF treatment in 1996, recover and then restart ESRF treatment in 1996. These patients are counted twice in the analysis providing they have been receiving ESRF treatment for greater than 90 days on each occasion.
Patients who started treatment at a centre and then transferred out soon after receiving treatment are counted at the original centre for all analyses of treatment on the 90th day.

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

The following quarterly entries were included and excluded:

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

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

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

1. If a patient's initial entry on the treatment timeline contained a 'transferred in' code, then the patient was assumed to have been on ESRF for longer than 90 days, since the patient must have started ESRF treatment earlier than this elsewhere. Therefore, patients with an initial entry on the treatment timeline with a 'transferred in' code were included for all quarters. For example, a patient with an initial treatment modality of 'transferred in' on the 1st March 1996, would be included for quarter 1/97, even though the number of days on ESRF treatment would be calculated as 30 days.

2. For patients who recovered renal function, for a period of time, then went into ESRF, the length of time on ESRF treatment was calculated from the day the patient restarted ESRF treatment. For example, for a patient with an initial treatment start date of the 1st March 1996, who recovered on the 1st June 1996 and then resumed ESRF treatment again on the 1st November 1996, the number of days on ESRF treatment would be calculated from the 1st November 1996. The patient would be excluded from the analysis for quarter 4/96, since on the 31st December 1996, they only would have been on ESRF treatment for 60 days. The patient would be included in the analysis from quarter 1/97 onwards.

Patients who had transferred out or stopped treatment without recovery of function before the end of the quarter, were excluded.

**Criteria for analysis of biochemistry in a quarter**

The analysis used information from the quarterly treatment table. In addition to the treatment modality criteria listed above, patients with the following quarterly entries were also excluded:

1. Patients who had 'transferred in' to the centre in that particular quarter were excluded. For example, if a patient transferred in on the 1st March 96, then the patient was excluded from that biochemistry analysis of the centre they transferred to in that quarter.

2. Patients who had changed treatment modality in that particular quarter were excluded.
**Treatment modality on day 90 of starting ESRF treatment**
This is obtained from the treatment modality of the take-on population after 90 days of being on ESRF. For this reason patients who started treatment between 1/10/96 and 31/9/97 were used in this analysis.

The sample used was that defined by the take-on population.

Patients are counted at their take-on hospital centre rather than at their hospital centre on day 90. This is important since some patients had transferred out of their initial hospital centre by day 90.

Patients who died before they reached 90 days are excluded.

**One year survival of the take-on population**
The sample used was the same as that defined for the take-on population except for recovered renal function patients, who were excluded.

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

**Analysis of one year survival of stock**
The death rate within year was calculated separately for the patients established on dialysis and with a functioning transplant on 1st January 1997. As there is an increased death rate in the first six months following transplantation, patients were only included in the analysis if they had not received a transplant between 1st July 1996 and 31st December 1996. For the same reason patients who received a transplant within the year were censored at the time of transplantation.

The sample criteria thus became:

1. Patients who had been receiving renal replacement therapy for more than 90 days on 1/1/97.
2. Patients who had a transplant between 1/7/96 and 31/12/96 were excluded
3. Patients who transferred into a Registry centre were excluded if information was not available to confirm that they had not received a transplant between 1/7/96 and 31/12/96.
4. The few patients who recovered renal function in 1997 were excluded.
5. Patients who transferred out of a Registry centre to a non-Registry centre were censored at that date
6. A transplant patient whose transplant failed was censored at the time of restarting dialysis, and dialysis patients who received a transplant were censored at the time of transplant.
7. Patients who died, received a transplant, or transferred out on 1/1/97 were included and were counted as being at risk for one day.

Patients who died on the day of the transplant were censored on this day, rather than counted as a dialysis death.