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An evaluation of the costs, effectiveness and quality of renal replacement therapy provision in renal satellite units in England and Wales

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Abstract

An evaluation of the costs, effectiveness and quality of renal replacement therapy provision in renal satellite units in England and Wales

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Objectives: To survey of the structure, processes and organisation of renal satellite units (RSUs) in England and Wales (Phase 1), and to compare the effectiveness, acceptability, accessibility and economic impact of chronic haemodialysis performed in RSUs compared to main renal units (MRUs) (Phase 2).
Data sources: Phase 1: all renal satellite units in England and Wales. Phase 2: haemodialysis patients in a representative sample (based on geography, site, private–public ownership, medical input) of 12 RSUs and their MRUs.
Review methods: Phase 1 consisted of a questionnaire survey. Semi-structured interviews were held in a representative sample of 24 RSUs with the senior clinician, senior nurse and manager. Phase 2 consisted of a cross-sectional comparison of patients in these RSUs and patients in the parent MRUs deemed suitable for satellite care by senior staff. Clinical information was obtained from medical notes and unit computer systems. Generic and disease specific health-related quality of life (HRQoL) measures were used. Co-morbidity was assessed by the Wright/Khan Index, the Lister/Chandna score, the Modified Charlson Index, and the Karnofsky Performance Score. Statistical analyses compared RSU versus MRU patients and took account of the paired and clustered nature of the data.
Results: In Phase 1, responses were received from 74/80 (93%) of RSUs; 2600 patients were being treated in these RSUs. The interviews were generally positive about the impact of RSUs in terms of improved accessibility and a better environment for chronic haemodialysis (HD) patients, and in expanding renal replacement therapy patients (RRT) capacity. In Phase 2, some 82% of eligible patients took part, 394 patients in the 12 RSUs and 342 in the parent MRUs. The response rate was similar in both groups. There were no significant differences in clinical processes of care. Most clinical outcomes were similar, especially after pooled analysis, although a few parameters were statistically significantly different – notably the proportion achieving Renal Association Standards for adequacy of dialysis as measured by the urea reduction ratio (URR) was higher in the RSU patients. Patient-specific quality of life did not differ except on the patient satisfaction questions from the KDQOL^{TM}, which were scored higher by the RSU sample. Strength of preference for health status on and off dialysis was very similar between the groups, as were EQ-5D utilities. Major adverse events were not common in the RSU patients, although there were many hypotensive episodes on HD, a proportion of which affected the duration of the HD session. Of the costs measured, the only difference that was statistically significant was for District Nurse visits. Of particular note was that despite the MRU group having a higher proportion of patients hospitalised, this did not translate into a statistically significant budgetary impact in terms of the total cost per patient of hospitalisations or mean cost per patient per hospitalisation.
Conclusions: This study has shown that RSUs are an effective alternative to MRU HD for a wide spectrum

of patients. They improve geographic access for more dispersed areas and reduce patients' travel time, and are generally more acceptable to patients on several criteria. There does not seem to be an adverse impact of care in the RSUs although comparative long-term prospective data are lacking. The evidence suggests that satellite development could be successfully expanded; not all MRUs have any satellites and many have only a few. No single RSU model can be recommended but key factors would include local geography, the likely catchment population and the type of patients to be treated. There is a need for more basic budgetary information linking activity and expenditure to be available and more transparent, to perform at least an insightful top-down costing of the two care settings. Other areas suggested for further research include: a comparison of adverse events occurring in MRUs and RSUs with longer duration and larger numbers to identify more severe events, along with the more research into the scope for preventing such events, and a study into the patients deemed ineligible for satellite care. International comparisons of satellite care would also be useful.

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Contents

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List of abbreviations

AVF	arterio-venous fistula
BCG	Bromocresol Green
BCP	Bromocresol Purple
BMI	body mass index
CAPD	continuous ambulatory peritoneal dialysis
CI	confidence interval
CRS	constant returns to scale
DEA	data envelopment analysis
DGH	district general hospital
DHA	district health authority
DOPPS	Dialysis Outcomes and Practice Patterns Study
ED	Enumeration District
EDTA	European Dialysis and Transplant Association
EPO	erythropoietin
EQ-5D	EuroQol 5D Instrument
EQ VAS	EQ-5D visual analogue scale
ESRD	end-stage renal disease
ESRF	end-stage renal failure
HbA1c	glycosylated haemoglobin
HCA	healthcare assistant
HD	haemodialysis
HDF	haemodiafiltration
HIV	human immunodeficiency virus
HRQoL	health-related quality of life
IQR	interquartile range
iPTH	intact parathyroid hormone
KDQOL™	Kidney Disease Quality of Life
KPS	Karnofsky Performance Score
LREC	Local Research Ethical Committee
MCS	mental component score
MIMAS	Manchester Information and Associated Services
MREC	Multi-research Ethical Committee
MRSA	methicillin-resistant *Staphylococcus aureus*
MRU	main renal unit
NEQAS	National External Quality Assessment Services
OR	odds ratio
PCS	physical component score
PD	peritoneal dialysis
pmp	per million population
PRD	primary renal disease
PTH	parathyroid hormone
QALY	quality-adjusted life-year
QoL	quality of life
RRT	renal replacement therapy
RSU	renal satellite unit
SD	standard deviation
SE	standard error
SF-36	Short Form with 36 items
UKRR	United Kingdom Renal Registry
URR	urea reduction ratio
VRS	variable returns to scale
WTE	whole time equivalent

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Background

The prevalence and annual acceptance rates for renal replacement therapy (RRT) have increased significantly over the past decades and continue to rise. Over 30,000 patients were being treated with RRT in England by 2000, at a cost of about £600 million. The patients now being treated are older with more co-morbidity. Given the continued shortage of kidneys for transplantation, the expansion of RRT in the last decade has largely been in dialysis. Peritoneal dialysis, although popular in the 1980s, has not grown in recent years; most expansion has been in hospital haemodialysis (HD), increasingly delivered in renal satellite units (RSUs). In general these are nurse-run renal units which provide only chronic HD. They are linked to main renal units (MRUs) at which nephrologists, inpatient services and interventional facilities are based. They are more geographically accessible for patients. Previous national surveys have shown them to be of variable size, location (e.g. some are on non-hospital sites) and organisational arrangements (e.g. some are private). However, there are few data on the effectiveness and costs of RSUs or of patients' experience. This report presents data first from an updated survey of the structure, processes and organisation of RSUs in England and Wales (Phase 1), and then a detailed comparison of the effectiveness, acceptability, accessibility and economic impact of chronic haemodialysis performed in RSUs compared with MRUs (Phase 2).

Methods

Phase 1

Questionnaire survey to all renal units in England and Wales in 1999. The content was similar to previous surveys, including the structure, processes and organisation of care in the RSUs. Semi-structured interviews were held in a representative sample of 24 RSUs with the senior clinician, senior nurse and manager.

Phase 2

Effectiveness, acceptability and accessibility

Cross-sectional comparison of patients from a representative sample (based on geography, site, private-public ownership, medical input) of 12 RSUs from throughout England and Wales and MRU HD patients deemed by senior staff to be suitable for satellite care, and where possible matched by groups on age and sex. Clinical information was obtained from medical notes and unit computer systems. This included processes of care such as vascular access, medication, biochemical and other indices of the impact of HD and healthcare contacts. Generic and disease-specific health-related quality of life (HRQoL) measures – Short Form with 36 items (SF-36), Kidney Disease Quality of Life (KDQOL^{TM}) and the EuroQol 5D Instrument (EQ-5D) and also a specially constructed patient satisfaction questionnaire were used.

Co-morbidity was assessed by the Wright/Khan Index, the Lister/Chandna Score, the Modified Charlson Index and the Karnofsky Performance Score. Adverse events on dialysis were recorded for 6 weeks in RSU patients only.

Statistical analyses compared RSU with MRU patients and took account of the paired and clustered nature of the data.

Accessibility was assessed for RSU and MRU patients using unit and patient postcodes and the Autoroute program to generate road time and distance to the RSU and MRU for RSU patients.

Costs

Identification of resources for costing was based on the key health and personal cost items expected to differ, or where it was unclear whether differences would be expected. Unit level resources were measured using information extracted from Trust personnel during site visits, telephone interviews or completion of specially constructed forms. Patient level resources were collected from a patient questionnaire and medical notes review. Unit cost data were from national cost and salary sources and manufacturer's list prices and costed in 2000 prices.

Results

Phase 1

Responses were received from 74/80 (93%) of RSUs; 2600 patients were being treated in these RSUs, of whom 42% were over 65 and 12% diabetic. Although most RSUs were on acute hospital sites, one-third were on other hospital sites and one in eight were not on a hospital site. Unit size varied substantially with a median of eight HD stations (range 3–31). One-quarter were privately owned; these were larger and more often on non-hospital sites. Most RSUs had no daily medical input but they accepted patients with temporary necklines once they were stabilised. One-quarter did accept some patients starting HD for the first time.

The interviews were generally positive about the impact of RSUs in terms of improved accessibility and a better environment for chronic HD patients, and in expanding RRT capacity. There was some concern about the level of medical cover, siting on non-acute hospital sites and the potential isolation of nurses in RSUs from the main renal unit.

Phase 2

Some 82% of those eligible units took part, 394 patients in the 12 RSUs and 342 in the parent MRUs. The response rate was similar in both groups, with participants being younger than non-participants in both. The mean age of the RSU group was 63 years; 18% of RSU patients were diabetic, 33% scored 'high risk' on the Wright/Khan Index and 34% were dependent or required assistance (assessed by Karnofsky Performance Score). The MRU group had similar co-morbidity scores and dependency but a lower mean age (57 years) and a higher proportion from ethnic minorities.

There were no significant differences in clinical processes of care (e.g. haemodialysis methods such as fluid used, medication). Most clinical outcomes were similar, especially after pooled analysis, although a few parameters were statistically significantly different – notably the proportion achieving Renal Association Standards for adequacy of dialysis as measured by the urea reduction ratio (URR) was higher in the RSU patients. The proportion of patients previously hospitalised was less in the RSU patients although the number of hospitalisations per patient, total length of stay and patient's mean length of stay were comparable between the groups.

Patient-specific quality of life (KDQOL^{TM}, SF-36, EQ-5D) did not differ except on the patient satisfaction questions from the KDQOL^{TM}, which were scored higher by the RSU sample. The specially constructed patient satisfaction instrument also showed higher satisfaction in RSUs on the themes of communication with staff and the environment and atmosphere of the unit. Strength of preference for health status on and off dialysis was very similar between the groups, as were EQ-5D utilities.

Major adverse events were not common in the RSU patients, although there were many hypotensive episodes on HD, a proportion of which affected the duration of the HD session. No comparative data were available from MRUs.

Patients travelling to RSUs saved a potential mean of 17 km or 19 minutes of travel three times a week, although this saving could be partially offset if there were multiple patients to collect using NHS transport.

Of the costs measured, the only difference that was statistically significant was for District Nurse visits. Of particular note was that despite the MRU group having a higher proportion of patients hospitalised, this did not translate into a statistically significant budgetary impact in terms of the total cost per patient of hospitalisations or mean cost per patient per hospitalisation. Limitations of the study, however, meant that costing was incomplete and the full cost consequences of RSU/MRU care remain uncertain. Patients in RSUs experienced statistically significant less amounts of time associated with dialysis; out-of-pocket expenses were marginal in both groups.

Conclusion

This study has shown that RSUs are an effective alternative to MRU HD for a wide spectrum of patients. They improve geographic access for more dispersed areas and reduce patients' travel time, and are generally more acceptable to patients on several criteria. There does not seem to be an adverse impact of care in the RSUs although comparative long-term prospective data are lacking.

The cost-effectiveness of RSUs compared with MRUs remains uncertain. Effectiveness may be better in RSUs and there is greater satisfaction and in many areas improved accessibility. Drawing conclusions about the relative cost advantage of RSUs, however, is difficult. No reliable data were obtained in many key economic components such as capital/overheads, medical staff, transport and non-scheduled visits to the MRU, nor was the most straightforward of expenditure information easy to access. The findings and experience have shed important light on how to design a long-term study of cost-effectiveness that could not have been appreciated without having first conducted this study.

From a clinical point of view, the evidence suggests that satellite development could be successfully expanded; not all MRUs have any satellites and many have only a few. Models of future demand for RRT predict a continued increase in the prevalence of RRT, rising to nearly 50,000 in England by 2010, with the growth being differentially higher in older patients and those on HD, particularly if kidney transplant supply does not increase. No single RSU model can be recommended but key factors would include local geography, the likely catchment population and the type of patients to be treated. In planning the development of RSUs, allowance needed to be made in opening a new RSU for future growth in staff and HD stations in order to treat more patients and the knock-on impact of RSU patients on medical workload in the MRU. It is important that there are appropriate policies in place in the RSUs to deal with emergencies and for transfer of patients, protocols for management on common clinical problems and good communication links with the MRU. Staff rotation would help overcome the professional and social isolation felt by some staff in RSUs.

Finally, although this study's findings of comparable outcomes in RSUs and MRUs are reassuring, the appropriateness of further expansion of dialysis provision by RSUs at the expense of the MRU base, which remains uniquely small compared with other countries, is an open question.

Chapter 1

Introduction

Renal replacement therapy (RRT) is a life-saving treatment for patients with end-stage renal failure (ESRF). The two main treatment modalities are transplantation and dialysis [haemodialysis (HD) or peritoneal dialysis (PD)]. Dialysis can be undertaken by filtering the blood directly using a semi-permeable membrane in a dialysis machine (HD) or using fluid exchange in the peritoneal cavity [usually termed continuous ambulatory peritoneal dialysis (CAPD)]. HD now takes place predominantly in hospital, with most patients requiring thrice-weekly dialysis for about 4 hours at a time.

During the 1960s and 1970s, RRT in the UK was provided by a small number of renal units in teaching hospitals. As a result, patients often had to travel long distances for their dialysis. RRT was almost exclusively HD and restricted to younger, fitter patients. This was in contrast to other European countries, Japan and the USA, which had a greater number of renal units and dialysis stations, thereby providing a more accessible centre HD service.

In the 1980s renal services expanded in the UK, prompted by a national target set in 1984,[1] and the advent of PD, which allowed increased numbers of patients without the need for additional HD facilities. However, a major congestion has since occurred in hospital HD facilities in UK renal units. This is due to a decrease in the use of home HD programmes, the limited life-span of PD as a treatment and the increasing acceptance of elderly patients with other co-morbid illnesses who are unable to manage PD.

In 1993, the English Department of Health commissioned a survey of all renal units in England. It showed an annual acceptance rate of new patients starting RRT in 1991–92 of 67 per million population (pmp), well below the minimum estimated need of 80 pmp for those under the age of 80 years.[2–4] Moreover, there was considerable geographic variation between areas in both the supply of services and in acceptance rates. Although this was in part due to different population age and ethnic minority profiles, distance from renal units was inversely related to the acceptance rate, particularly in non-metropolitan areas, suggesting that access to services was a barrier to referral.[5] National Renal Purchasing Guidelines, which were distributed to health authorities as a guide to commissioning effective renal care, recommended that the development of renal satellite units (RSUs) be expanded to improve geographical accessibility.[6] These units are attached to main renal units (MRUs) at which nephrologists, inpatient beds and interventional facilities are based. RSUs, in contrast, provide a chronic maintenance HD service, largely run by nurses, and often in populations at some distance from the main unit. They first started in the USA in the 1960s, with the first one opening in the UK in the mid-1970s. RSUs are distinct from minimal care units as treatment is administered by skilled nurses rather than as self-care. These guidelines hastened the development of RSUs and the decentralising of renal services. During the 1990s, annual acceptance rates for RRT in England have increased significantly from 67 pmp in 1991–92[6] to 82 pmp in 1995[7] and 92 pmp in 1998.[8] As shown in *Figure 1*, the greatest growth has been in satellite HD.

Table 1 shows that whereas the number of HD stations (i.e. available dialysis machines) within main units increased by 37% over this period, there was a 300% increase in the number of HD stations within RSUs.[8,9] There was no commensurate increase in MRUs.

The trend in the growth of prevalent patients is set to continue for the next few decades until an equilibrium position is reached.[10] The ageing of the population, especially of ethnic minorities, the rise in Type 2 diabetes and the current unmet need of RRT for patients with ESRF are all pressures which will increase acceptance rates on to RRT. Shortages of kidneys for transplantation and improvements in survival on dialysis will contribute to increase the pool of patients on HD.

Data from the 1996 National Renal Review in England provided some limited information on satellite units. Sixty units had been opened by the end of 1995, with 37 planned. Over 1400 patients were dialysing in satellites, a median of 24 per unit. The units were heterogeneous in terms of medical input, size, setting, management and patient mix. Although some units had permanent day-to-day medical input on-site, most were nurse run.

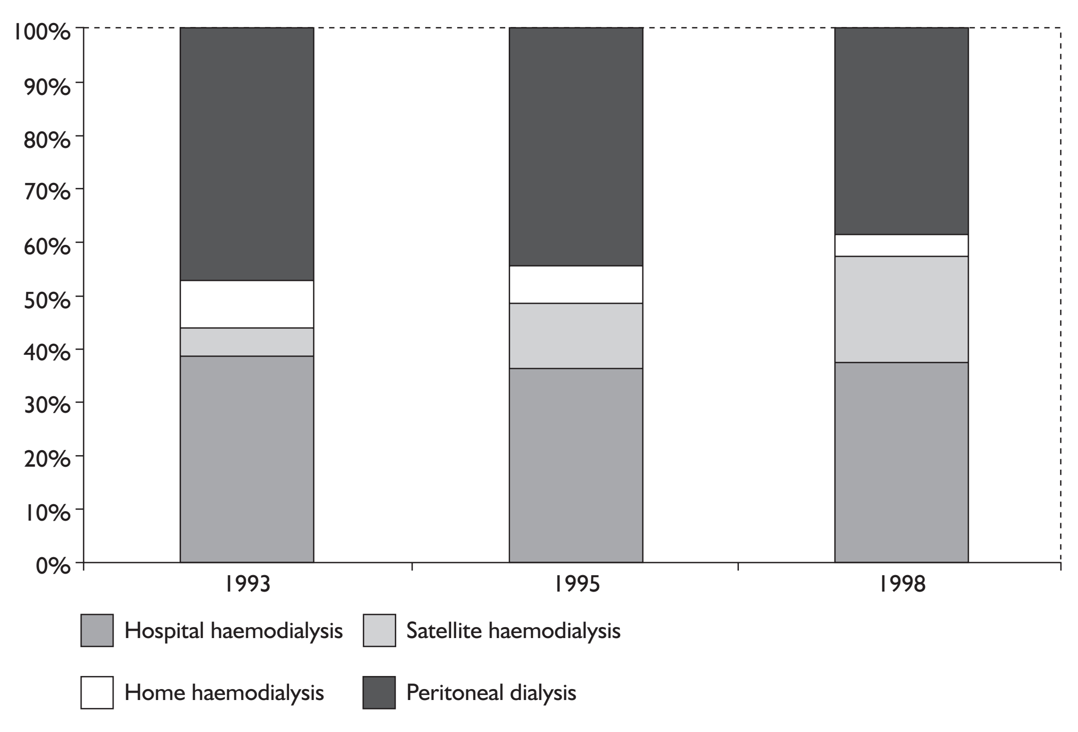


FIGURE 1 *Changes in dialysis modality in England 1993–98*

TABLE 1 *Changes in renal units in England, 1993–98*

	1993	1995	1998	Increase 1993–98 (%)
Main renal units	52	51	52	0
Main unit HD stations	743	832	1021	37
Satellite units	36	60	73	103
Satellite unit HD stations	189	472	761	303

As satellite units are taking on an increasing elderly population with associated co-morbidity, evaluation of their performance is timely. There are very few published evaluations of RSUs, particularly with the type of case mix of patients now on HD. Moreover, there are problems of generalisability of results from other countries because there is no standard definition of an RSU and because of different healthcare systems. There are standards for HD produced by the Renal Association which apply to both main and satellite units.[11,12] Satellite units should make renal dialysis more accessible to patients and reduce the travel burden for patients and their carers and for NHS transport services. This has not been formally assessed. The cost of HD provision in satellite and main units and in the different models of satellite provision is not known.

This research was therefore aimed at evaluating the effectiveness, costs, acceptability and accessibility of renal satellite units.

The study is divided into two phases:

Phase 1 objectives

1. To survey all satellite units in England and Wales to determine their structure, processes and organisation of care.
2. To identify a sample frame for Phase 2.

Phase 2 objectives

In a representative sample of RSUs:

1. To compare the effectiveness [including health-related quality of life (HRQoL)], safety and acceptability of care for dialysis patients in an RSU with a similar group of patients in the parent MRU.
2. To determine the improvement in geographical accessibility from dialysing in an RSU.
3. To identify, measure and compare the cost of health service and patient resources associated with RSU and MRU care.

We present Phase 1 and Phase 2 separately.

Chapter 2

Phase 1: a national survey of renal satellite units

Phase 1 objectives

1. To survey all satellite units in England and Wales to determine their structure, processes and organisation of care.
2. To identify a sample frame for Phase 2.

Methods

All MRUs in England and Wales and their corresponding RSUs were identified from the UK Renal Registry (UKRR) and previous national renal surveys. The Directors of each of the units with an RSU were contacted to confirm the number and name of each RSU. RSUs were defined as those renal units which were linked to an MRU and not autonomous for medical decisions, and which provided a chronic outpatient maintenance HD service, but with no acute or in-patient nephrology beds.

A questionnaire seeking information on the structure, organisation and processes of care of RSUs, policies on accepting patients for their first dialysis, high-risk patients and those with temporary vascular access and the arrangements for medical input both elective and emergency was sent to all Directors with an RSU. Demographic data on the proportions of patients who were over 65 years of age or with diabetes were collected. The questionnaire was piloted in two RSUs. Questionnaires were sent out at the beginning of 1999 requesting data relating to the 31 March of that year.

Data were entered directly into an SPSS[83] database using 'automated forms scanning'. Standard summary statistics were used to describe the baseline data. Comparisons between different categories of RSU were made by using either Pearson's chi-squared test or, for paired summary data, the two-sample t test and non-parametric methods such as the Mann–Whitney *U*-test where appropriate.

A representative sample of 24 renal satellite units was chosen for in-depth telephone interviews out of the total of Renal Satellite Units in England and Wales in 1999. The interviews were with the consultant nephrologists responsible for the RSU, the RSU senior nurse and the manager responsible. They were designed to capture detailed information about the origins, development, current policies and future plans for the RSU. The interviews were semi-structured but allowed for a free expression of opinion from the interviewee; such information was analysed thematically to saturation. Interview times varied from 15 minutes to almost 2 hours. The sample of 24 was chosen to be representative of the different kinds of RSU in terms of district general hospital (DGH) versus non-DGH site, public versus private ownership and permanent medical cover or not. A total of 23 out of 24 RSUs responded.

Results

Of the 57 MRUs identified, 38 (67%) had a total of 80 RSUs. Questionnaires were received on 74 (93%). Two MRUs did not respond (with six RSUs). *Figure 2* shows that five MRUs had four or more RSUs, nine had three RSUs, nine had two RSUs and 15 MRUs only had one RSU. Nineteen (33%) did not have an RSU. In a few cases an RSU served more than one MRU.

Of the 2599 patients treated in the RSUs responding, 1518 (58%) were male, 1101 (42%) were over 65 years [unit median 50%, interquartile range (IQR) 35–58%, range 0–88%) and 311 (12%) were diabetic (unit median 14%, IQR 10–18%, range 0–42%).

Units were sited mainly on acute hospitals (57%), with 31% in other hospital sites and 12% on non-hospital sites (*Table 2*). Ownership was predominantly by the NHS, although 26% were

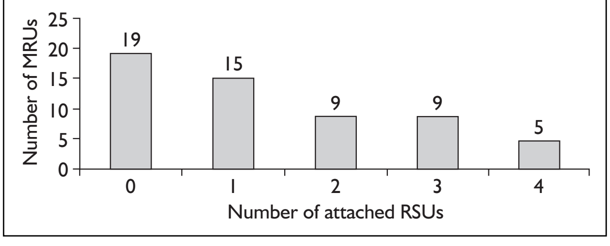


FIGURE 2 *Main renal units and attached renal satellite units*

TABLE 2 *Organisational characteristics of RSUs in England and Wales (1999)*

	Number/denominator (%)[a]
Location	
Acute hospital	42/74 (57%)
Other hospital	23/74 (31%)
Non-hospital	9/74 (12%)
Unit management	NHS 55 (74%), private 19 (26%)
Median number of HD stations (range)	8 (3–31)
Median number of patients (range)	34 (8–120)
Support services	
CAPD support	6/69 (9%)
Home HD support	6/69 (9%)
Automated peritoneal dialysis support	4/69 (6%)
Integral outpatient clinic	18/66 (27%)
Permanent medical cover	9/74 (12%)
Consultant	5/9 (56%)
Associate specialist	1/9 (11%)
Staff grade	3/9 (33%)
Specialist Registrar (SPR)	3/9 (33%)
Non-permanent medical cover	65/74 (88%)
Methods of receiving medical care	
Telephone call to MRU	57/65 (88%)
GP visits	4/65 (6%)
Ambulance 999 call	25/65 (38%)
On-site emergency cover from local hospital	29/65 (45%) (81% for those based on acute hospital site)
Call out of MRU staff	7/65 (11%)
Other	16/65 (25%)
Patient: nurse ratio	5.6
Patient: all staff ratio[b]	4.0

[a] Denominator varies owing to missing data.
[b] Includes health care assistants.

privately run, mainly by two companies. The size of the RSUs varied considerably, with a median of eight HD stations per unit (range 3–31) and 34 patients (range 8–120). Few RSUs provided support for patients on other modes of RRT. However, 27% did offer an integral outpatient clinic, thereby avoiding the need for the satellite patients to travel to the main renal unit for regular follow-up.

Only nine (12%) RSUs had permanent daytime medical cover (defined as a doctor regularly on-site during the daytime most days of the week). This was mainly at consultant level (5/9), with lower grades of doctor providing cover in the other hospitals. In the other 65 (88%) RSUs without permanent daytime medical cover, medical care was sought by a variety of means, principally by telephone advice from the MRU. A few RSUs (6%) also relied on cover by a local primary care physician. For more serious situations, 45% reported that they relied on support from the local acute hospital (rising to 81% of those units on an acute hospital site), 38% relied upon emergency ambulance calls and 11% would call out a doctor from the MRU.

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

Eighteen (28%) RSUs accepted patients for their first dialysis without stabilising them first in the MRU, and 63 (85%) accepted patients with a temporary neckline: all bar one RSU would accept patients with a permanent tunnelled neckline (*Table 3*). Only 36 (49%) RSUs would accept patients who were hepatitis B positive, 54 (73%) accepted hepatitis C-positive patients and 45 (61%) accepted HIV-positive patients.

Forty-one (55%) RSUs dialysed some patients less than three times per week (a median of 3% of

TABLE 3 *Treatment acceptance policies of renal satellite units*

Accept for first dialysis	18/65[a] (28%)
Temporary neckline	63/74 (85%)
Hepatitis B positive patient	36/74 (49%)
Hepatitis C positive patient	54/74 (73%)
HIV positive patient	45/74 (61%)

[a] Missing data.

patients per RSU). The most common factors influencing this decision were residual renal function (28 RSUs) and patient choice (20 RSUs). Only four (5%) RSUs reported lack of staff or HD station time as a reason for less frequent dialysis. Only four (5%) RSUs reported re-use of dialysers. Patients arrived for dialysis mainly by hospital car (median 70% of patients per RSU), 20% drove themselves and 5% relied upon ambulance transport.

Table 4 compares NHS and private RSUs. NHS RSUs were more likely to be on acute (60 versus 47%) or other hospital (36 versus 16%) sites, and less likely to be on a non-hospital site (4 versus 37%). There was also a significant difference in unit size; private RSUs had a greater number of HD stations and patients, but did not differ in the patient-to-staff ratio or in the proportions of patients over 65 years or diabetic.

Treatment acceptance policies generally did not differ significantly, except that private RSUs were less likely to accept patients with temporary necklines or who were hepatitis B positive. Patients seemed more likely to drive themselves to private RSUs than to NHS RSUs, although this was not statistically significant.

The location of the RSU appeared to have little impact on the organisation or processes of care. The only differences were that RSUs on acute hospital sites tended to have slightly more nurses but fewer overall staff per patient than non-acute site RSUs (patient:nurse ratio, acute 5.4 and non-acute 5.9; patient:all staff ratio, acute 4.1 and non-acute 3.8), although these differences were not statistically significant. Integral outpatient clinics were more common in RSUs based on acute hospital sites than in other locations.

Permanent medical staffing only appeared to make a few differences to the organisation and processes of care. This may have been a function of the small number of medically staffed units [nine (12%)]. Medically staffed units were more likely to accept patients for their first dialysis (62 versus 23% of non-medically staffed units, $p = 0.019$), and to provide an integrated outpatient clinic (86 versus 20% of non-medically staffed units, $p = <0.001$). Permanently staffed units appeared to have slightly more staff than non-medically staffed units (patient:staff ratio 3.60 and 4.04, respectively), but this difference was not significant.

Results of interviews

There was general agreement between the Clinical Directors, nurses and managers. Where one group identified a new theme, we have mentioned it specifically.

TABLE 4 *Comparison of NHS and private renal satellite units*

RSU characteristic	NHS (55)	Private (19)	*p*
Location			
Acute hospital	33 (60%)	9 (47%)	
Other hospital	20 (36%)	3 (16%)	0.001
Non-hospital	2 (4%)	7 (37%)	
Median number of HD stations (range)	8 (3–16)	12 (6–31)	0.000
Median number of patients (range)	28 (8–96)	44 (22–120)	0.014
Unit treatment acceptance policies			
Accept for first dialysis	10/47 (21%)	8/18 (44%)	0.062
Temporary neckline	50/55 (91%)	13/18 (72%)	0.045
Hepatitis B positive patient	34/55 (62%)	4/19 (21%)	0.002
Hepatitis C positive patient	17/55 (31%)	3/19 (16%)	0.201
HIV positive patient	25/55 (45%)	4/19 (21%)	0.060
Patient: staffing ratios			
Patient: nurse	5.5	5.8	
Patient: all staff	3.7	5.5	

Establishing the RSU

The key factor in prompting the setting up of RSUs was the need for a convenient geographical location to avoid long patient travel times and patient demand for such a service:

> "RSUs work very well in areas of geographical isolation, providing patients with a good continuity of care."

However, transport arrangements were still an issue, in terms of the reliance on volunteer transport and the fact that patients were often picked up in batches, especially in inaccessible areas, resulting in long journey times:

> "Transport is not very cost-effective and often has to go round the houses to pick up and drop off all the patients."

In some cases RSUs were established opportunistically owing for example, to a site becoming available. In general, there was a desire to site RSUs in or very close to DGHs.

In almost all cases the MRU was the key organisation involved in the process of setting up a new RSU; the host NHS trust and DHA were involved to a lesser extent.

The necessary capital to build or convert a building for RSU use was by and large not problematic. Most MRUs had adopted a formal tendering process. The source of funding was very diverse and ranged over such bodies as private finance, charity funds and various NHS bodies. Some felt that contracting could have been more explicit to avoid conflicts between the RSU/MRU, local trust or DHA. Although contracting with the private sector was perceived by some to be good (e.g. due to staff management, provision of new equipment), this view was not universal:

> "There is a worry that big companies will want to run MRUs. Initially there is a honeymoon, then the NHS won't be able to step back, a *fait accompli*."

There were some delays in opening RSUs because of building problems or staffing issues, but these were in the minority.

RSU development

Most of the RSUs increased the number of dialysis stations and number of patients dialysed over time, although there was little or no development in expanding the kinds of services offered by the RSUs beyond chronic HD. The principal result of the RSU was to ease pressure in terms of the number of patients in the MRU, although this had less impact over time owing to increasing numbers of patients needing dialysis.

Some consultants felt that there was a danger that the development of RSUs in some locations had had a deleterious effect on DGH nephrology service development, in that district health authorities (DHAs) and trusts felt that an RSU took the pressure off them to develop other services:

> "The RSU has inhibited the local DHA from developing renal services."

Some RSUs felt that there were services that they would like to offer but could not, notably dietician and CAPD services.

About one-sixth of the units surveyed felt that they had had to increase MRU capacity, staffing and consultant time in response to opening an RSU in order to cope with patients returning to the MRU when ill or unstable on satellite dialysis, although no MRU had more than five RSU patients dialysing in the MRU at any one time.

Most units planned to develop their RSU(s) in the future, in terms of patient numbers, staff, HD stations and shifts, and in offering outpatient services.

RSU policies

Most satellite units operated few medical constraints on who was accepted for dialysis; the most common were poor vascular access and cardiac instability. Most units accepted patients for dialysis using necklines; nurses raised this as being more problematic than did clinicians. Few would accept a person for their first dialysis. Most units reviewed patients on a case by case basis rather than setting rules. One-third of the units could not offer beds for dialysis so the patient had to be capable of using a dialysis chair.

Local patients were given preference for dialysis in RSUs, and by and large these were felt to meet local HD needs, although some took overspill from the MRU. There was little spare capacity in the units. Mostly there were no constraints on the duration of dialysis but a few units were too short of staff to operate at maximum capacity.

Audit of dialysis was almost a universal feature in RSUs mainly to Renal Association standards and a substantial number were involved with the UKRR. Monthly reviews of results were also universal.

Some felt that "in audit RSUs were as good as, if not better than, MRUs". No patients were seen by their consultant less frequently than 6-monthly and most were seen monthly. Most units had computerised record systems often linked to the MRU. A couple, however, still had to rely on telephone, letter and fax.

General perceptions

RSUs were unanimously thought to be successful; this view was particularly strong amongst nurses. The principal advantages stated were accessibility for patients and, with less acutely ill cases than in the MRU, they provided a more calm and pleasant environment with nurses able to spend more time with patients. On the downside, the lack of medical input was felt by some to be problematic and that nurses and doctors based in RSUs got no experience of other aspects of renal medicine apart from chronic maintenance dialysis:

> "For an RSU to be successful there needs to be an outstanding senior nurse on-site, good support from the MRU and appropriate medical cover."

Potential for litigation over lack of medical cover was felt to be an issue by some.

Not all were satisfied with the RSU infrastructure. Some raised issues of lack of space, poor buildings, inappropriate access and inadequate parking.

Nurses thought they had more autonomy and responsibility and that they were able to spend more time with individual patients:

> "It is very nurse led and provides more patient-focused holistic care."

However, a downside was a sense of geographical, social and professional isolation from the main unit and from other NHS facilities. Some felt a sense of alienation from the MRU:

> "There is a perception that RSUs are cushy, and this leads to a 'them and us' situation. Main renal unit staff don't see the responsibility that we have to take."

Nurses and managers identified the need for rotation of staff amongst the RSU and MRU to overcome such problems.

Nursing recruitment varied, with some units able to recruit and others, particularly in large cities, finding it difficult. Many recruited non-renal nurses and trained them on the job.

Managers felt that there were problems in running the RSUs when ownership varied and as they were on distant sites from the MRU. For example, maintenance of the building fabric was more difficult when the RSU was hosted by another trust.

When asked if they would have done anything differently regarding RSU development, with hindsight many said that they would have gone for bigger units to allow for expansion on-site and would have sited them at a DGH for emergency medical cover.

If more money were available for renal service development, few felt that they would spend more on individual RSUs, although some wanted to open more RSUs. They felt that dialysis provision needed to be expanded and up-to-date machines installed. Some would pay nurses more to ease recruitment and investment in vascular services was also prioritised. In terms of the MRU specifically, more capacity was desired, including more machines and staff.

Discussion of Phase I

Since the 1990s, there has been a significant increase in both the number of RSUs in England and Wales and the number of patients dialysing within them.[7,8] The results from this survey show that service provision by RSUs is heterogeneous in size, location, finance and the services they provide. The size of the RSUs varies considerably, with a few being larger than some main renal units in the UK. There are no guidelines as to where RSUs should be sited. Whilst a large proportion of RSUs are within the grounds of hospitals that provide an acute medical service, some are sited on non-hospital sites such as industrial estates and shopping centres that are some distance from the acute hospital environment. RSUs are accepting older co-morbid patients; the proportions of patients on HD over 65 years (42%) or diabetic (12%) are similar to those found by the UKRR in participating renal units in 1999 (43% over 65 years old and 14% diabetic).[9]

Most RSUs do not have permanent medical cover. This is of particular concern to those satellites sited away from any form of acute medical service. Senior nursing staff in charge of these RSUs bear a responsibility for both the day-to-day running of the unit and the management of acute emergencies. The mechanisms for dealing with an adverse event on dialysis need to be examined further. Somewhat surprising is the number of RSUs who are willing to accept patients for their first dialysis, contradicting the assumption that RSUs only provide an HD service for patients who have been stabilised on HD in the main renal unit first.

The link between the private sector and provision of renal services is well established and the choice to utilise a private company to provide RSUs is becoming increasingly common. The 1996 Renal Review[7] found that 19% of RSUs in England and Wales had private sector involvement, rising to 26% by 1999. We have shown many similarities in the services provided by private and NHS units. This is not surprising, as although the ownership of the units differs, the medical management remains the responsibility of an NHS consultant nephrologist. However, there are differences, in terms of size. Private RSUs are significantly larger in numbers of HD stations and patients. Acceptance of patients with hepatitis B is less likely in a private unit, although the reason for this is not clear. It may be related to the need for an isolation cubicle and a dedicated machine for each patient with hepatitis B (as outlined by the UK Renal Association Standards document[11]).

The interviews in general supported the role of RSUs as providing accessible high-quality care in a better environment for chronic HD patients. The main drawbacks related to the feelings of isolation by nursing staff, the lack of medical cover, particularly for emergencies, and the difficulties in managing some RSUs due, for example, to their siting on different Trusts.

The growth in satellite HD care in response to the increasing numbers of patients being accepted on to RRT is a trend that is predicted to continue. The development of RSUs for chronic HD has allowed expansion of patient numbers and a reduction in travelling times to and from dialysis sessions. This type of HD facility is not unique to the UK. The increasing demand for RRT and resultant expansion in HD services has occurred in many other countries.[13,14] However, most other developed countries have had a higher proportion and absolute number of patients on hospital HD than the UK, and more doctors and renal centres to treat them. Renal satellite care is described in the international literature although there is no universal definition for an RSU. In some countries minimal care facilities (whereby the patients carry out their own dialysis in a centre with no medical supervision and often without a trained nurse on-site) are included in the number of patients on satellite dialysis. This makes comparison across countries problematic. Nevertheless data from national registries suggest there has been a major growth in RSUs in other countries.[14,15]

Although the model of an RSU requires flexibility with respect to the size of the population served, several questions are raised by the findings of this survey. The optimal size for an RSU is far from clear, as shown by the considerable variation in those currently operating, which in part reflects the geographical distribution of the catchment population of the MRU. As a significant proportion of patients dialysing in these units are elderly and or diabetic, with co-existing co-morbidity, the safety of RSUs sited far from an acute medical facility needs to be investigated as most RSUs do not have permanent medical cover. It is also important to evaluate patients' views of dialysis away from the main unit, and the impact of care in an RSU on the quality of life (QoL) of patients. As RSUs are becoming a significant part of the provision of RRT in the UK, their cost-effectiveness and how this varies by type of RSU need to be evaluated. As demand for RRT continues to grow, more RSUs are likely to open, with the main units treating largely the most difficult HD patients. However, eventually it is probable that some RSUs, particularly those on an acute hospital site and with a large local catchment population, will evolve into medically staffed autonomous renal units which can provide not only a chronic HD service for all HD patients in their catchment area, but also a full nephrology service. This would be closer to the model of services in other developed countries.

It was also possible to extend the use of the survey data in a judicious way that allowed the illustration of how relative performance can be assessed. From an economics perspective, it is considered important to understand relative efficiency of units. This helps managers to examine overall and individual performances and compare a unit with appropriate 'peers'. However, to assess such performances requires linking data on inputs (e.g. medical/nursing time) and outputs of RSU care (e.g. patients treated, including some measure of the quality of care) and typically such data are not readily available. Indeed this is a general problem for the NHS. The survey data presented a unique opportunity to apply data envelopment analysis (DEA) to a renal service in the UK for the first time.

DEA is a technique used by economists to quantify the concept of efficiency and is suited to analysis of services readily disaggregated into distinctive productive units with similar input and output orientations. It is a data-driven technique (for technical details, see Hollingsworth and Parkin[16]). The concept of efficiency used is measured by transforming observed data on inputs and outputs into a single efficiency score for each productive unit that can be compared with a set of appropriate peers. Appendix 1 presents an example, followed by the findings of comparative efficiency of RSUs using DEA.

In summary, this survey has identified a diverse range of models of service provision for the RSUs in England and Wales. Phase 2 was designed to evaluate clinical and patient-based outcomes and resource use and costs of care for patients treated in a representative sample of RSUs, and to compare these parameters with those of similar patients treated in the parent MRUs.

Chapter 3

Methods for Phase 2: recruitment of sample, measures of effectiveness, acceptability and accessibility

Phase 2 objectives

In a representative sample of RSUs:

1. To compare the effectiveness [including health-related quality of life (HRQoL)], safety and acceptability of care for dialysis patients in an RSU with a similar group of patients in the parent MRU.
2. To determine the improvement in geographical accessibility from dialysing in an RSU.

Design of study

There are several methodological issues that need to be considered in interpreting this study. Ideally a comparison of the effectiveness of these two modes of HD would be based on randomised comparison of patients treated in an RSU or the parent MRU. Randomisation should balance known and unknown confounders between the groups, any imbalance occurring by chance. However, randomisation is not feasible largely because spare HD capacity is not available, but also treatment in an RSU is dependent on a patient's place of residence and their preference. Therefore, an observational design must be used which raises the issue of a comparable control group. Although we have shown in Phase 1 that RSUs are increasingly accepting elderly co-morbid patients, for some patients an RSU will not be an appropriate setting for their HD. Such patients are likely to have physical or psychological problems. Therefore, we tried to identify a patient group in each parent MRU which is comparable to those patients treated in the RSU under study.

The next issue is the clustered nature of the data; this is discussed in more detail under statistical methods. We cannot assume independence of patients; they are treated in clusters – MRU or RSU – and we have recruited from pairs of linked MRU–RSUs representing different parts of the country.

Attributing the resource use and costs is complex because the MRU will treat many other types of patient for HD (acute renal failure, temporary PD patients and patients unsuitable for RSU). These problems are outlined in detail in Chapter 4.

The chosen design was a cross-sectional prevalence study of patients in 12 RSUs and a comparable group of patients in their parent MRUs. The main unit patients were group matched on suitability for RSU care and, where possible, age and gender. Some data were collected retrospectively, for example, hospitalisation. Time constraints of the study did not permit a prospective design; for example the detailed fieldwork required three researchers and site visits took 3–4 days each and were carried out over a 1-year period. We have, however, collected limited survival and mode transition data over the ensuing 1 year.

Unit selection

A stratified random sample of 10 RSUs was initially selected using random number tables. Stratification was necessary in order to reflect the proportion of different models of RSU currently existing in England and Wales. Private versus NHS and location of RSU (i.e. hospital site versus non-hospital site) were the key factors taken into account for stratification. An attempt was made to ensure that units with and without medical cover were represented and, in addition, at least one private unit from each of the main providers [Baxter Healthcare Ltd and Fresenius Medical Care (UK) Ltd].

Two MRUs that failed to return data in Phase 1 were excluded from the sample for Phase 2 on the assumption that they were unlikely to agree to participate. These units were purposively replaced by Bristol and Lister Hospital MRUs. Whereas the RSUs of these units (Bath and St Albans) were chosen randomly according to the stratification outlined above, the choice of main units was pragmatic on the grounds that as their Clinical

Directors, Professor Feest and Dr Greenwood, were members of the study Steering Group, we had an immediate agreement to include their RSUs. In doing so, we were able to pilot the feasibility of the study visits and address any problems with the study Steering Group, prior to commencing data collection in other units. Any further substitutions required were conducted in a random fashion.

A broad geographical range of units was also felt to be important. There were no London units in an initial sample of 10 satellite units, so a further two RSUs from London were added to the study sample, giving a total of 12 satellite and 12 main units for the study.

Seventy-four RSUs responded to Phase 1; 55 were NHS units and 19 were private; 42 were on DGH sites and 32 not (of which nine were not on any NHS site) (*Figure 3*). Nine had permanent medical cover. Our sample of 12 had 9/55 NHS units and 3/19 private, 7/42 DGH and 5/32 non-DGH and 3/9 medical cover. *Table 5* shows the geographical distribution of RSUs in the final sample for Phase 2.

Once the 12 units had been selected, the Clinical Director of the corresponding MRU was approached by one of the consultant nephrologists on the Steering Group, supported by correspondence giving details of the study. From the original sample of 12, all units agreed to participate. One satellite unit (Lincoln) was undergoing significant building work and it would not have been possible to make a visit within the timescale of the study. It was replaced by an RSU attached to the same MRU (Leicester) and with similar characteristics, namely an NHS unit of comparable patient size, within the grounds of a DGH, which had regular consultant on-site supervision. Another of the units attached to Guy's Hospital in London agreed to participate; however, it was subsequently found to have no patients in the MRU judged to be 'suitable for satellite care' for use as a control group. In view of this, another pair of units in London (Barnet RSU and Royal Free MRU) was selected randomly from the original Phase 2 sample as a replacement. *Table 6* shows the units who participated.

Sample size

In view of the fact this study was not driven by one hypothesis, a single power calculation was not performed. The aim was to collect data on ~ 400 patients from 12 RSUs and a similar number in the corresponding MRU. This number of patients was thought to be both pragmatic and feasible. Given the distributions found, we would have had

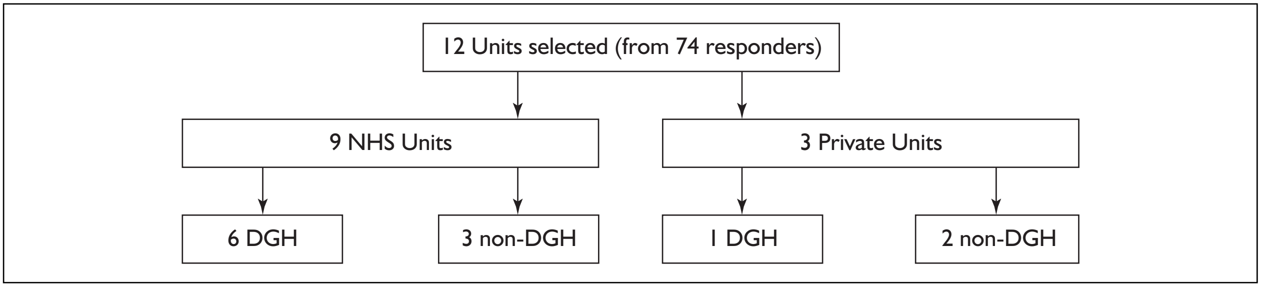


FIGURE 3 *Selection of RSU for Phase 2 national renal satellite evaluation study*

TABLE 5 *Geographical distribution of RSUs in final sample for Phase 2*

Region	Number of RSUs in final sample for phase 2
Northern and Yorkshire	2
North West	1
Trent	1
West Midlands	1
Eastern	1
London	2
South East	1
South West	2
Wales	1
Total	12

TABLE 6 *Units participating in Phase 2 of the National Renal Satellite Unit Evaluation Study*

Site of RSU	Site of linked MRU
Accrington	Preston (Preston Royal Infirmary)
Barnet	London (Royal Free Hospital)
Bath	Bristol (Southmead Hospital)
Bradford	Bradford (St Luke's Hospital)
Huddersfield	Leeds (St James' Hospital)
Kettering	Leicester (Leicester General Hospital)
Lichfield	Birmingham (Heartlands)
Newport	Cardiff (University Hospital of Wales)
Penzance	Truro (Royal Cornwall Hospital)
St Albans	Stevenage (Lister Hospital)
Woking	Carshalton (St Helier Hospital)
Worthing	Brighton (Royal Sussex County Hospital)

TABLE 7 *Study's power to detect key variables*

Outcome[a]	RSU/main mean	Difference to detect	Pooled SD	Power (%)
Predialysis systolic BP	150	5	23.7	76
Predialysis diastolic BP	80	5	13.2	99
Hb	11	0.5	1.6	97
SF-36 MCS	46	5	11.6	99

[a] BP, blood pressure; Hb, haemoglobin; MCS, mental component score.

the following power to detect the outcomes below on individual analysis. We are unable to calculate these for pooled analysis, which would be more conservative, but it suggests that we would have had sufficient power for some of these key variables (*Table* 7).

Ethical approval

Multi-research Ethical Committee (MREC) approval was applied for and granted by the South and West MREC. Subsequently Local Research Ethical Committee (LREC) approval for each individual satellite and main unit was sought and, once granted, enabled us to set up a unit visit.

Patient selection

Once ethical approval had been obtained, the senior nurses in charge of the RSU and corresponding MRU were telephoned by the research team in order to explain the study. A list of all RSU patients was obtained and, in the MRU, a list of all patients who were judged to be suitable for dialysis in the study RSU regardless of where the patient lived, their own personal preference or the availability of spaces in the RSU.

The rationale for suitability was explored with senior nurses. Although some had formal criteria for selection of patients suitable for satellite dialysis, many relied solely on their judgement. Furthermore, those who did have written-down criteria admitted that these were not always adhered to, mainly owing to the fluctuating pressure on dialysis places in the MRU caused by an increasing number of new and unstable patients being accepted on to the ESRF programmes. In these situations it may be that certain patients who initially are judged borderline for satellite care (or perhaps even unsuitable) are sent to RSUs to make space for new patients.

Those patients dialysing on a twilight shift (i.e. a dialysis shift which starts later in the day/early evening, e.g. around 6 p.m.) were included in the 'suitable for satellite' group, provided that they fulfilled the criteria above, and even if there was no twilight shift in the study RSU. Patients who were blind, cognitively impaired or could not read English were managed as described below under 'Minimising non-response'.

Once patient details had been obtained, a letter signed by the MRU consultant (Appendix 2) and a study information sheet/consent form (Appendix 3) was sent to each patient in the week prior to the planned study visit.

Group matching

Prior to each unit visit, a list of all RSU patients and suitable MRU patients was received. For the first two pairs of units visited (Bristol/Bath and Lister/St Albans), all suitable MRU patients were approached for consent as the members eligible in the MRU were less than in the RSU. For subsequent units, where the number of MRU patients exceeded the number in the RSU, the MRU patients were group matched for age (<65/>65 years) and gender. Where there were more MRU patients in an age/gender group than RSU patients, random selection was made using a random numbers table. This was used to reduce the collection of additional data, which would not be utilised in the final analysis.

Minimising non-response

Most patient-related data were collected during field visits by a team of two researchers. It became apparent that certain groups of patients would be unable to participate fully in the study. Total exclusion of these individuals might have introduced bias to the eventual results and the study population would not have been an accurate representation of the RSU patient population. A standard procedure was therefore applied with the aim of capturing at least some information on each of these groups of patients.

1. Patients who were blind or had severely impaired vision and so were unable to read the information sheets and fill out the patient questionnaires. These patients were approached at the study visit, given an oral explanation of the study and asked whether or not they would consent to the completion of all parts of the study except the patient questionnaire.
2. Non-English-speaking patients. Patient information sheets were translated into Urdu and Hindi as these were the most commonly spoken languages after English in the potential study population. It was not possible to translate the patient questionnaires as the QoL measures have not been validated in these languages. However, as with the group above, they were asked to consent to the other parts of the study in order to characterise in some detail these important patient subgroups. Patients understanding languages other than those mentioned above were excluded from the study, unless an interpreter was available during the study visit.
3. Those patients who were in-patients in the MRU at the time of the study visit. This was an important group which we were unable to include.
4. Patients who felt too unwell on the day of the visit to complete the questionnaire were approached with the agreement of the nurse in charge and asked to consent to all parts of the study, with the exception of the patient questionnaire.
5. Those patients who were cognitively impaired to the extent they were unable to complete the patient questionnaire were included in the study if their relatives were present on the day and were happy to give consent for all parts of the study, again with the exception of the patient questionnaire.

Patients were asked to complete the patient questionnaire whilst on dialysis. In a significant number this was not possible as their vascular access was in their dominant arm. In these cases we asked them to complete the questionnaire at home without assistance and return it by post. These patients were followed up with written reminders if their questionnaire was subsequently not received.

Ineligibility for RSU

By selecting a group of patients in the MRU who were suitable to dialyse in the study RSU, a further group of patients who were ineligible for RSU care was created. Some of these patients would have been temporarily unsuitable for satellite dialysis at the time of preparation for the study visit, and a two-way movement of patients will always occur between an RSU and its linked MRU. However, there will always be a permanent ‘pool’ of patients in the MRU who will never be able to move away and make use of a satellite facility.

The number of patients judged to be ineligible for the selected study RSU was documented. This was calculated simply from the number judged by the senior nurse as ‘suitable for satellite care’ (thus acting as a possible control for the RSU patients) and the total number of patients being dialysed in the MRU at the time of the visit. For three of the units (Leicester, St Helier and Bristol) a specific reason was given for each ineligible patient. For the remaining nine units a retrospective telephone survey was conducted to elicit general reasons for ineligibility for satellite care. These telephone conversations were relatively brief and were not pre-arranged and therefore the list given for each unit is not exhaustive. It should be noted that ineligibility did not include geographical proximity to the MRU. For those patients where more than one reason for ineligibility was given, the first/predominant reason was recorded.

Unit visits and data collection

Figure 4 summarises the data collected for individual patients. Fieldwork was conducted over a period of 13 months between June 2000 and July 2001. Prior to these visits, each patient was written to with an explanatory letter and information sheet. During these visits eligible patients were approached by our researchers for consent. With the exception of those patients mentioned previously, each participant was given a patient questionnaire, and a clinical questionnaire was completed using a combination of patient notes, dialysis charts and computer records. At each visit nursing staff were asked to complete the Karnofsky Performance Scores (KPSs) on each patient and the Major Adverse Events form was left for each of the patients agreeing to participate in the study (only in RSU patients) (see Appendices 4–7 for the questionnaires, KPS and Adverse Event forms).

Baseline characteristics

The following information was collected by the patient self-completed questionnaire and by the researcher-completed clinical questionnaire.

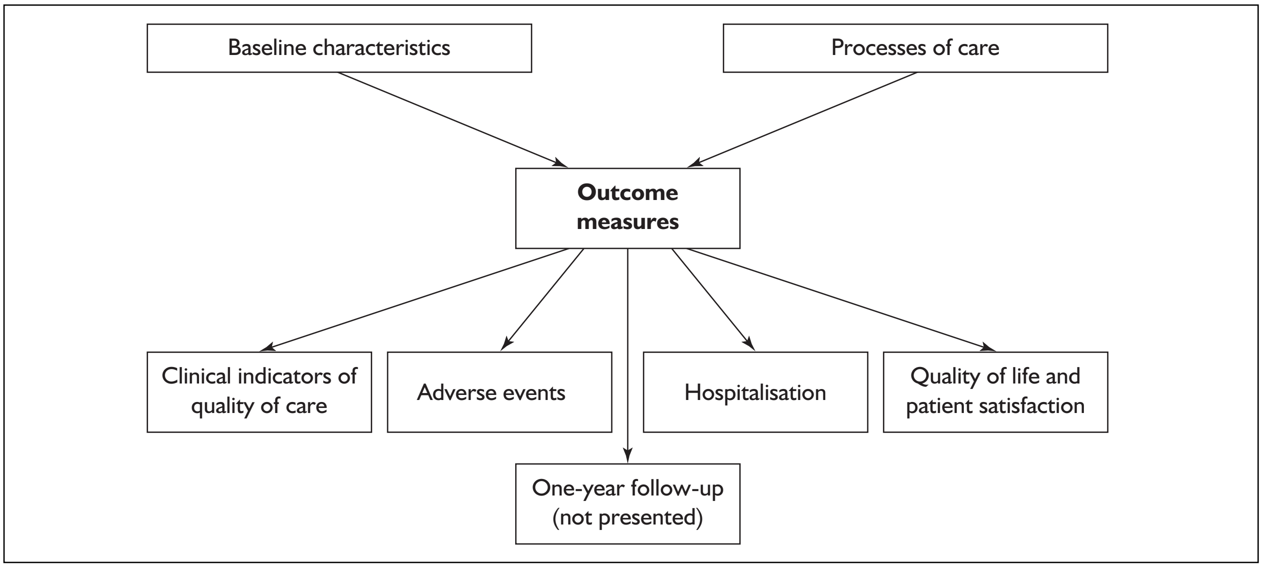


FIGURE 4 *Summary of data collected for individual patients*

Patient questionnaire

Socio-demographic data
Quality of life – Kidney Disease Quality of Life (KDQOL™), Short Form with 36 items (SF-36), patient satisfaction, EuroQol 5D Instrument (EQ-5D).

Clinical questionnaire

Cause of end-stage renal disease (ESRD)
Co-morbidity
Processes of care – timelines of modes of care, current dialysis methods, medication
Clinical outcomes – biochemistry, dialysis adequacy, haemoglobin
Hospitalisation, out-patient attendance

Some of these parameters are discussed in more detail below.

Cause of ESRD (clinical questionnaire)

This was taken from the patients' hospital records and coded according to the European Dialysis and Transplant Association (EDTA) classification,[17] which consists of 65 different codes (assigned between 0 and 99). The individual classifications were grouped in order to simplify the presentation of data. Each group either was caused by a similar disease process or conveyed a similar prognosis (see Appendix 8 for grouping).

Current vascular access (clinical questionnaire)

The preferred long-term vascular access in a patient on HD is a native arterio-venous fistula (AVF), which produces the highest blood flows, minimises sepsis and has the greatest longevity.[18] Unfortunately, many patients' veins have been damaged by venepuncture or cannulation. This, in combination with the increasing number of patients entering RRT programmes with poor arterial vessels due to diabetes and widespread vascular disease, has resulted in fewer patients having successful AVFs. The alternatives are either synthetic grafts, which carry an increased risk of sepsis and have a shorter lifespan[19,20] or 'permanent' tunnelled cannulae, also complicated by sepsis,[19,21] reduced longevity, poor blood flows and the risk of subclavian vein stenosis, which causes obstruction and venous hypertension.

The Dialysis Outcomes and Practice Patterns Study (DOPPS)[22] has recently shown that in the units studied, 67% of chronic HD patients in the UK have functioning AVFs. Corresponding figures for France, Italy, Germany and Spain were 77, 84, 90 and 82%, respectively.[23] There is now widespread agreement amongst nephrologists in the UK of the need to improve vascular access services and these are addressed in the Renal Association Standards document.[11]

The additional complications caused by access other than an AVF result in an increased number of hospital admissions and increased morbidity.[24] These data were collected for the study in order to compare the frequency of access type in RSU and MRU patients and to assess any impact that type of access may have on outcomes, such as number of hospitalisation episodes.

First referral, length of time on dialysis and modality switches (clinical questionnaire)

Both late referral (variably defined in studies as starting dialysis within 1 month or 3–4 months from first referral to a dialysing nephrologist) and length of time on RRT are potential confounding factors when interpreting results relating to QoL and clinical indicators of the quality of dialysis care. It was important, therefore, to collect such data where possible, in order to account for them in the final analysis. However, it was impossible to collect late referral data in many patients because the date of referral was not specifically mentioned in the medical notes.

Information was collected on previous modalities, in particular transplantation, since these may well affect a patient's perspective on their QoL.

Length of time on RRT can be associated with more co-morbidity and complications, resulting in more hospitalisations, poorer physical health and a poor QoL. This can act in two ways. First, those newly established on HD take time to stabilise, particularly as they include patients starting as an emergency and/or after late referral. We adjusted for this in the analyses (see below). Conversely, those on RRT for a long period may accumulate co-morbidity and dialysis-related complications.

Co-morbid disease and disability (clinical questionnaire)

Given the observational design of the study, it was important to characterise the co-morbidity and disability of patients as these are major contributing factors to patient survival and QoL. Amongst others, Wright,[25] Khan,[26] Charlson[27] and more recently Chandna (Lister Score)[28] have devised risk categories for patients according to their co-morbidity. Acceptance studies on populations of renal patients commencing RRT have shown a significant correlation between survival and burden of co-morbid disease.[25,26,28,29] It is interesting that these scales differ considerably in content.

We chose to collect sufficient baseline data to enable us to allocate a co-morbidity score to each patient on the Wright/Khan, Lister and Modified Charlson co-morbidity scales. All co-morbid data including symptom scores on the Lister scale were collected retrospectively from the patients' hospital notes during each visit.

Wright/Khan Index (clinical questionnaire)

The risk stratification index as described by Khan and colleagues[26] combines co-morbid disease with age at onset of RRT, separating patients into one of 3 groups; low, medium and high risk (see Appendix 9).

Lister Score (clinical questionnaire)

Each co-morbid condition is graded according to a symptom score. For cardiac disease the scores are based on the New York Heart Association functional classification. Other diseases are graded in a similar way from mild to severe disease. For each patient the scores are combined to form a co-morbidity severity score: None, 0; mild/moderate, 1–4; severe, 5–8 (see Appendix 10).

Modified Charlson Index (clinical questionnaire) (see Appendix 11)

The Charlson Index was originally developed in a cohort of medical patients and validated in patients with primary breast cancer,[27] but has been subsequently used in the ESRF population.[29] It assigns a weighted score for each individual's co-morbidity and includes a weighting for age.

Beddhu and colleagues[29] modified the original Charlson scoring system by replacing 'myocardial infarction' with all forms of 'coronary artery disease' as these were not included, and were felt to convey an equally poor outcome in dialysis patients. Those patients with ESRF secondary to diabetes received a score of at least four (two for ESRF and two for diabetes with end organ damage). All patients with ESRF patients have a Charlson score of two or above.

Diabetes (not separated by type) is included in both Wright/Khan and Charlson co-morbidity scores. Owing to the problems of accurately distinguishing type of diabetes (type 1/type 2, insulin-dependent versus non-insulin-dependent) in an individual, this distinction was not made in this study.

The early Wright/Khan and Charlson scales were devised as tools to stratify patients on dialysis programmes in order to make comparison of outcomes between different programmes easier.[30] More recently, these scales have been applied to populations of patients starting on RRT to try to predict those patients who will die early and so question the reasons for accepting them for treatment in the first place. These studies also compared different scoring systems on the same group of patients and have found significant discrepancies. In the UK, the Wright/Khan Index has been widely used and more recently Chandna and colleagues published an alternative scoring system,[28] which includes a weighting for the severity of an individual co-morbid condition. They also used the Wright/Khan Index on the same group of patients. Although both co-morbidity scales were significantly related to 1-year survival,[28] Chandna and colleagues concluded that their scoring system was more predictive of patient survival. In addition to survival alone, Beddhu and colleagues recently concluded that scores on the modified Charlson Index were strongly associated with adverse outcomes such as hospitalisation episodes and costs in dialysis patients.[29] Chandna and colleagues also showed that co-morbidity group was associated with hospitalisation episodes.[28]

Pitfalls encountered using the co-morbidity scoring systems

Section 2 of the clinical questionnaire was designed around the Lister and Wright/Khan scales with supplementary questions on disability and other major illnesses. By this design, extra elements included in the Charlson Index were recorded and also any conditions of uncertain relevance. These were reviewed and certain issues arose. First were the differences in the content of the three co-morbidity scales, all of which aim to predict survival. Second, it was unclear for certain conditions whether or not to include them within the scoring system. Where possible we contacted the authors of the co-morbidity scores for clarification. The following list highlights the conditions that we chose to exclude.

Cardiovascular conditions

1. valve disease (in the absence of documented evidence of ischaemic heart disease)
2. atrial arrhythmias such as atrial flutter/atrial fibrillation (in the absence of documented evidence of ischaemic heart disease).

Respiratory conditions

1. asthma (without evidence from the hospital notes of chronic, severe lung damage)
2. pulmonary tuberculosis
3. pulmonary emboli.

Other conditions

1. deep vein thrombosis
2. Barrett's oesophagus
3. myelodysplasia.

Four malignancies were recorded that did not appear in the Lister grid and therefore had not been assigned a score: lymphoma, renal cell carcinoma, testicular tumour and Kaposi's sarcoma. A suitable weighted score was agreed with the authors of the original paper according to published evidence predicting prognosis related to each particular malignancy. Where time since diagnosis or stage of tumour was not known, a modal score was assigned.

The handling of missing data for the co-morbidity scores is described below. Although the retrospective nature of the data collection may lead to under-reporting of the amount of co-morbid disease present in the study population, great efforts were made to locate hospital notes and use other data sources such as dialysis charts and computer records in order to obtain as much information as possible.

Karnofsky Performance Score (KPS) (see Appendix 6)

The stratification of patients into risk groups based on co-morbid disease, in order to grade overall disease severity and predict outcome, is a complex task. Another approach to predicting outcome has been to use the KPS.[31] This scoring system measures functional activity in an individual patient and has been shown to be an independent predictor of survival in renal patients beginning dialysis.[32,33] Chandna and colleagues showed that the KPS score at the time of commencing RRT, 3 months before, and the change in between, were useful in predicting survival.[28] Carlson and colleagues also showed an improvement of 11% in the KPS scores of survivors during their first 2 years on dialysis.[34] Whether the KPS score in combination with a measure of co-morbidity would be a more accurate predictor of survival has not been tested and is outside the scope of this study.

Pitfalls have been noted in the original KPS[35] and a modified KPS has subsequently been developed[36] and used more recently in the ESRF population.[37] This has an increased number of activity steps from 10 (original KPS) to 14, narrowing the range at each level to minimise observer variation.[37]

Despite this, the original score is still widely used and remains a useful tool when completed by dialysis staff who are well acquainted with the patient. It was felt to be both simple and quick to complete, which was an important factor when dealing with dialysis staff pressurised for time on a busy unit. Each patient enrolled in the study was given a KPS score during the unit visit, by either the senior nurse or the patient's individual named nurse, depending on the time constraints of the staff at each individual unit.

Processes of care

Membrane use (clinical questionnaire)

Although there is no definitive evidence to support the use of synthetic (biocompatible), high-flux membranes rather than the non-synthetic, cellulose type,[38] there may be benefits due to reduced progression of β2M-related dialysis amyloidosis,[39] improved systolic cardiac function,[40] prevention of the development of lipoprotein abnormalities[41] and reduction in intra-dialytic symptoms.[42] Synthetic membranes are expensive and financial constraints play a significant role in dictating the type used. Some units reserve the synthetic membranes for use on certain patients, e.g. those who have symptoms on dialysis or those who are underdialysed. The main types of membrane used at each unit were collected primarily for costing. It also informed us of any differences between MRUs and RSUs, which would be important owing to the influence that membrane type may have on clinical outcome.

Frequency of dialysis (clinical questionnaire)

Frequency of dialysis is a major factor contributing to dialysis adequacy. The Renal Standards document[11] recommends "the adoption of thrice weekly dialysis sessions as a minimum in the majority of patients with the exception of those patients with significant residual renal function". In reality, patient preference and factors such as geographical constraints are also reasons to give dialysis twice weekly. At present it is not clear how many of the UK units fulfil the recommendations. There is evidence to suggest that although many have a small proportion of patients on twice-weekly dialysis, some units have disproportionately large numbers of patients who dialyse only twice a week and this is largely due to limited facilities and financial restraints.[43] Phase 1 of the National Renal Satellite Unit Evaluation Study showed that more than half (55%) of RSUs dialysed some patients less than thrice weekly. However, only 5% of these RSUs reported lack of staff or HD station time as a reason for less frequent dialysis. It was important to document the number of patients in the study who were on less than thrice-weekly dialysis as this subgroup of patients might confound the results.

Type and quantity of dialysis and monitoring techniques (clinical questionnaire)

In addition to frequency of dialysis sessions, the amount of time on HD per session also contributes to dialysis adequacy. Most nephrologists aim to dialyse a patient for 4 hours per session, although this figure may need to be lower or higher depending on the individual. Lack of space and financial constraints may also be limiting factors of this variable.

A variety of dialysis monitoring techniques, such as sodium profiling, which graduates the removal of fluid over a dialysis session and may reduce intra-dialytic symptoms, are now incorporated into newer dialysis machines. Their use in individual dialysis units is variable and was surveyed in the study population.

Any process that influences the adequacy of a patient's dialysis may affect not only their clinical outcomes but also their QoL. For example, if they are well dialysed, one assumes they will feel physically better. However, this must be contrasted with the social benefits of attending dialysis sessions only twice, as opposed to thrice, weekly. The aim of collecting these data in individual satellite and main unit patients is not to control for each of these factors individually when comparing RSU with MRU patients, but to describe any differences there may be between the two groups as they are potential confounders to the main outcome measures in the study.

Most renal units in the UK use conventional HD. However, there are some that use haemodiafiltration (HDF) widely and others that are beginning to utilise it for certain problematic patients. The pros and cons of these two methods will not be discussed. However, the type of dialysis used for study patients was documented as lengths of dialysis sessions are significantly shorter in those undergoing HDF and therefore where necessary separate analyses were conducted.

Medication (clinical questionnaire)

Limited data on type but not dose [with the exception of erythropoietin (EPO)] of each patient's medication were collected from a combination of hospital notes, recent prescriptions and computer records. In general these were drugs directly related to the indicators of the quality of dialysis care, such as phosphate binders, alfacalcidol, EPO and iron supplements. The number and class of antihypertensive agents were also documented. Any differences in prescribing practices observed in the two patient groups may be a reflection of the level of on-site medical supervision. It should be noted that prescribing practices do differ between renal units, including differences between an MRU and its own RSU. Some renal units prescribe all drugs to their dialysis patients whereas others ask GPs to do so, and some even split the prescribing into 'renal' versus 'non-renal' drugs. Where possible this has been documented.

Routine outpatient visits (clinical questionnaire)

The number of routine outpatient visits for each study patient was recorded from the hospital notes. Some units did not hold outpatient clinics for HD patients and this was recorded. Outpatient review is a mechanism by which patients on dialysis undergo a review of their overall care and physical health. For the RSU patients, in particular those dialysing in a unit without medical cover, this is an important measure to document.

Outcome measures

Clinical indicators of quality of dialysis care (clinical questionnaire)

In 1997, the UK Renal Association together with the Royal College of Physicians of London produced guidelines for the management and treatment of adult patients with renal failure.[11] They recommended standards and audit measures for many aspects of the care of dialysis and transplant patients. There is increasing pressure in all areas of medicine to aim for and to achieve a national level of acceptability in standards of care. Renal medicine is no exception and these standards allow audit at the level of both an individual renal unit and nationally via the data collected by the UKRR.

We collected a number of clinical measures in the study, some of which are used as indicators of the quality of dialysis care. At the time of the study, the 1997 second edition of the standards was in clinical use[11] and we compared RSU and MRU performance against a selected number of these, which are summarised in *Table 8*. The document has recently been updated and changes in this third edition[12] to the measures we used are shown in *Table 8*.

Dialysis adequacy

The Renal Standards document gives recommended targets for two different measures: Kt/V and urea reduction ratio (URR).[11] There is evidence from the USA that patient survival improves to a threshold with an increase in URR and Kt/V.[44,45] For this study we set out to collect both measures. However, although most units calculated URR for individual patients, far fewer had Kt/V results available. Both sets of results are presented later in the report, but more emphasis has been placed on the findings of adequacy as judged by URR simply owing to the greater number of patients with data.

The calculation of URR is not without its pitfalls. Like all methods of calculating HD adequacy, the URR requires a precise and reproducible method of predialysis and, more important, postdialysis blood sampling. The standardisation of postdialysis blood sampling is critical to limit the overestimation of urea removal that is inevitable if no account is taken of the postdialysis rebound that occurs after each dialysis session. Early rebound of urea (which ceases within minutes of stopping HD) is due to access recirculation (for patients with AVFs) and cardiopulmonary recirculation. Late rebound (which ceases 30–45 minutes after HD) is due to intercompartmental urea disequilibrium.[9]

It is not practical to expect patients to wait for 30 minutes or more after their dialysis session to have blood taken. Methods have been described to calculate the URR that make estimates of late rebound and negate the effects of early rebound. One example of this is the 'slow flow method'[46] of postdialysis blood sampling and this is the method currently recommended by the Renal Association. However, even this method involves several steps where timing is crucial and where accuracy may not be possible on a busy renal unit.

The UKRR undertook an informal survey, using participating renal units, of methods of postdialysis blood sampling. This found that a wide range of sampling techniques were in use, many not following the recommended method. This information is acknowledged in the interpretation of our results.

Biochemical and haematological parameters

The laboratory indices of particular interest in the study were serum phosphate and calcium, bicarbonate, albumin, intact parathyroid hormone (iPTH), cholesterol, haemoglobin and ferritin in all patients. HbA1c [glycosylated haemoglobin (HbA1)] was also noted in diabetic patients. These results represent clinical indicators of the quality of care received by the patients in the units, which will allow the exploration of any differences there may be between RSUs and MRUs. For the study, the most recent available result was taken, which for most measurements was within 1 month, except for the iPTH and cholesterol results where a 6-month window was felt to be a reasonable representation of a patient's current state.

Patients who had been on HD for <3 months were not included in these analyses to allow for stabilisation after starting dialysis. Expert advice on the analysis and interpretation of the

TABLE 8 *The Renal Association recommended standards and audit measures for HD patients, second edition, 1997*[11]

Clinical indicator of quality of dialysis care	Recommended minimum standard second edition[11]	Changes for third edition[12]
Dialysis adequacy	Every patient on thrice-weekly haemodialysis should show either URR > 65% or *Kt*/*V* > 1.2. *Kt*/*V* method of calculation should be noted	Same
Correction of anaemia (haemoglobin)	A target Hb concentration of not less than 10 g/dl should be achieved in the great majority (>85%) of patients after 3 months on HD	Same but 6 months after
Correction of acidosis (serum bicarbonate)	A target predialysis serum bicarbonate within the normal range quoted by the local pathology laboratory should be the aim in all patients after 3 months on HD	Predialysis level 20–26 mmol/l
Albumin (included in the nutritional indices category)	A target serum albumin within the normal range quoted by the local pathology laboratory in all patients should be the target after 6 months on regular HD	No audit standards until progress in standardisation of laboratory measures and understanding causes and treatment of low albumin
Blood pressure	Target predialysis blood pressures should be: Age <60: ≤ 140/90 mmHg Age >60: ≤ 160/90 mmHg	Predialysis: <140 systolic and <90 diastolic, no age difference
Phosphate	Predialysis phosphate: 1.2–1.7 mmol/l	Predialysis phosphate: <1.8 mmol/l
Calcium	Predialysis calcium within the normal range quoted by the local pathology laboratory, corrected for serum albumin concentration, or normal ionised calcium where available	Predialysis calcium corrected for albumin: 2.2–2.6 mmol/l
Hyperparathyroidism (PTH)	iPTH (intact parathyroid hormone assay) should be maintained at between 2 and 3 times the local normal range	<4 times

biochemical data was given by the late Dr David Newman, Consultant in Clinical Biochemistry at St Helier Hospital, Carshalton. Laboratory methods of analysis for some biochemical parameters are complex and vary from centre to centre, thus leading to interlaboratory variation in results. In some cases the RSU and its linked MRU used different laboratories, each with their own local reference ranges and assays. Some laboratories in the UK are part of the UK National External Quality Assessment Services (NEQAS) scheme, which has produced a number of harmonisation factors that can be used to minimise the effect of differing analytical factors, thereby allowing comparative audit. Harmonisation factors were available for albumin, uncorrected calcium, cholesterol and phosphate. Eight pairs of study units were members of NEQAS and for those pairs separate analyses were performed to exclude any bias due to non-harmonised data.

The methodology by which serum albumin is measured and the way in which calcium corrected to albumin is subsequently calculated are particularly problematic when attempting to compare results between different laboratories. These two indices require further explanation.

Albumin

Serum albumin is measured by one of two methods, both of which utilise a colour change induced by a dye binding to albumin, namely Bromocresol Green (BCG), the most commonly used method, and Bromocresol Purple (BCP). BCG binds to other proteins in addition to albumin and as a result there may be significant overestimation of the albumin concentration in patients with low albumin levels. BCP predominantly binds to albumin and gives a more accurate reading in particular at albumin concentrations of <30g/l.[9] The difference in performance of these two methods is thought to hold true even in uraemic serum.[47] Following a comparison of both methods using sera of patients on HD, the UKRR concluded that the BCP method would be the preferred albumin assay in the monitoring of renal patients. A survey of the biochemistry laboratories used by our study units revealed that all but one pair of units (Brighton and Worthing) used the BCG method. This pair of units was excluded from any comparison of albumin and corrected calcium (see below) results.

Calcium

Calcium results are corrected for serum albumin using a variety of equations that differ between laboratories. Both difficulties with method of albumin measurement and choice of equations used for correction impact on corrected calcium values and make direct comparison between different units problematic.

For all units, we attempted to collect both uncorrected and corrected calcium values. Where uncorrected values were not readily available at the study visit, the correction equation for the particular laboratory was obtained and patients' values were 'uncorrected' for future comparison. In order to overcome this, we chose to follow the UKRR method of standardising each uncorrected calcium measurement according to the following equation;

$$\text{corrected calcium} = \text{uncorrected calcium} + [(40\text{–albumin}) \times 0.02)]$$

The target range for corrected calcium was set at 2.25–2.65 mmol/l.

For corrected calcium results, the Brighton and Worthing pair was excluded in view of the fact that their albumin assay was different to those of all other laboratories in the study. Without further adjustment to the results, the remainder of the units' data were compared and then a subgroup of unit pairs that shared the same laboratory (and so the same correction equation) was identified and the results were analysed.

For data on haemoglobin and phosphate, we calculated the number of patients whose results fell within the Renal Association Standards (second edition) recommendations (see *Table 8*). Many of the recommendations made by the Renal Association document are based on parameters falling within the local laboratory reference range. Owing to the relatively small number of patients within each unit/attached to a particular laboratory, the comparison with Renal Association standards was not made.

Acidosis and serum bicarbonate

The Renal Association Standards recommend that the predialysis serum bicarbonate level is maintained within the local laboratory reference range after 3 months on dialysis. An association has been shown between predialysis acidosis and survival.[48] This association is likely to be a result of associated inadequate dialysis. In addition, acidosis is commonly thought to be associated with an increase in protein breakdown,[49] although how significant this is in terms of impact on the nutritional status of a patient is unclear.[50] Nevertheless, it is generally accepted that persistent and significant acidosis is not beneficial to a patient and the past few years have seen a change in practice for those on HD, moving from lactate dialysate to a bicarbonate-containing fluid.

Phosphate and intact parathyroid hormone

Serum phosphate, calcium and iPTH are all markers for renal bone disease and poor control over time leads to significant morbidity in patients. The consequences of hyperphosphataemia include the development and progression of secondary hyperparathyroidism and a predisposition to metastatic calcification if the serum calcium/phosphate product is raised.[51] There is some controversy over recommended targets for both phosphate and PTH levels. The Renal Association Standards document[11] states that predialysis phosphate levels for HD patients should be between 1.2 and 1.7 mmol/l. Some nephrologists feel that this is not achievable or evidenced based. Although very low phosphate levels are associated with malnutrition and under-dialysis, and therefore poor survival, it is unclear what the upper limit of the given range should be. Two studies in the USA and analysis carried out by the UK Registry on HD patients found a higher risk of death to be associated with a serum phosphate of 2.1 mmol/l.[9,48,51]

Hyperparathyroidism is also associated with increased morbidity in renal patients including renal osteodystrophy and as a risk factor for cardiovascular disease. The Renal Association Standards[11] recommend that PTH should be maintained between two and three times the local normal reference range.

Different assays are used by laboratories for the measurement of iPTH. Harmonisation factors for these are not available. In addition, results are given in one of two units: nanograms per litre (ng/l) or picomoles per litre (pmol/l). The conversion factor of ng/l = pmol/l × 9.5 was used to allow comparison of results between units.

Cholesterol

The level of cholesterol data available (including the number of patients on lipid-lowering agents) is of interest. There is convincing evidence in the non-renal population that lowering cholesterol is effective and safe and leads to a reduction in the risk of cardiovascular disease.[52] To date there is little published evidence to echo these findings in the renal population as this particular group has historically been excluded in the major cholesterol-lowering trials. Many nephrologists believe their patients should be on lipid-lowering therapy in view of the increased incidence of vascular disease in the dialysis population over and above the normal population. A pilot study has been completed in the UK and an international multicentre study commenced to determine whether the cholesterol-lowering agent simvastatin and/or aspirin reduces cardiovascular mortality in chronic renal failure.

Blood pressure

The Renal Association Standards document[11] recommended predialysis target values for haemodialysis patients:

- Age <60 years: <140/90 mmHg
- Age >60 years: <160/90 mmHg

However, there is little evidence supporting either the difference in these target values by age or indeed the actual values themselves. In general, persistent predialysis hypotension after correct assessment of dry weight and antihypertensive therapy is a poor prognostic sign as it is likely to represent poor left ventricular function. In contrast, the significance of high (i.e. above the recommended levels) predialysis blood pressures is uncertain. Port and colleagues[53] showed an elevated mortality risk with low predialysis systolic blood pressure but failed to show a similar correlation with predialysis systolic hypertension (except for an increase in cerebrovascular deaths). Foley and colleagues[54] concurred with these findings for low blood pressure and mortality. However, they also showed a mean arterial blood pressure of >60 mmHg to be associated with an increase in LV mass and the development of *de novo* ischaemic heart disease.

Three consecutive measurements for pre- and postdialysis blood pressure were taken for each patient in the study (three readings were taken in order to obtain a single average reading and reduce the margin of error). The results are compared with both the recommended Standards and the UKRR data.

Nutritional indices

Numerous studies have shown the relationship between malnutrition in HD patients and an increase in morbidity and mortality rates.[55,56] The assessment of malnutrition in dialysis patients varies between units depending on individual diatetic preference and available resources. A variety of biochemical measurements such as predialysis urea and phosphate can be useful in combination with anthropometric measurements, e.g. triceps thickness and measures of body size such as body mass index (BMI). Serum albumin is commonly used as a marker for malnutrition. However, albumin levels are influenced greatly by co-existing illness such as sepsis, which is common amongst patients on dialysis, and therefore its reliability as a marker for malnutrition alone is variable. For this study it was not feasible to carry out anthropometric measurements on each patient and so albumin levels and measurements to calculate BMI were collected.

BMI is widely used to define nutritional status. It is derived from the following simple formula of weight in kilograms divided by the square of the height in metres. The accepted 'normal range' for the general population is 20–25. Obesity is taken to start at a BMI of 30 and undernutrition is graded in severity starting at a BMI of <20 with severe undernutrition defined as a measurement of <16. Wolfe and colleagues found several measures of body size, including a low BMI, to be independent predictors of mortality in a population of chronic HD patients.[57] Preliminary data from the DOPPS[22] found that in a group of 9000 black and white HD patients in the USA and Europe, the mortality risk was highest for those with a low BMI (<20) and did not increase significantly for high BMI (>30).[58]

Due to the importance of nutritional status in the HD population it was important to include a measure of this in the clinical questionnaire. In addition to a recent set of biochemical parameters, the height and dry weight (an average of three measurements of post-dialysis weight) of the study patients were documented in order to calculate their BMI. Whereas the weight of the patients was taken from their dialysis charts and therefore measured on calibrated scales, the heights documented were rarely recorded at the unit.

They were obtained by direct questioning of the patients and not by measurements taken by the researchers, introducing an opportunity for error.

Hospitalisation episodes (clinical questionnaire)

These were documented retrospectively. The 'reason for hospital admission' was coded using a modification of a system developed for a previous study on dialysis patients[59] that was felt to be a suitable system reflecting causes for admission commonly seen in clinical practice. Like the EDTA codes discussed above, these admission codes were subsequently grouped further for the purposes of presentation (see Appendix 8). The aim of this part of the data collection was to assess the impact and interaction between RSU and MRU and to note any differences that there may be between RSU and MRU patients. The hypothesis was that any complication arising with a patient in an RSU would more likely result in the patient being admitted to the MRU, whereas an MRU patient may be managed as an outpatient in some circumstances as they have the opportunity to be reviewed on dialysis by a member of the medical staff.

This analysis was complicated by the different lengths of time patients had been on dialysis. We only collected hospitalisation data for up to 1 year of dialysis or from the start of uninterrupted haemodialysis if they had been on HD for <1 year. In the analysis we first compared hospitalisation of all patients and second restricted the comparison to those who had been in the RSU or MRU for a full year.

Quality of life and patient satisfaction (patient questionnaire)

Health-related quality of life (patient questionnaire)

We included both generic (or global assessment) and disease-specific instruments. Generic measures are designed to be applicable to a wide variety of populations, and therefore allow for comparison between groups. They may not, however, detect small, clinically important changes in specific chronic disease populations such as ESRF patients. Disease-specific instruments are potentially more sensitive to the characteristics of specific populations and responsive to change over time, but are only applicable to the specific populations.

Several instruments, including both generic and disease-specific instruments have been used to assess HRQoL in ESRF.[60] The KDQOL,[61] which includes the Medical Outcomes Study 36-item Short-form Health Survey (SF-36)[62] was used in the study. A brief description of each instrument and their suitability for the study is outlined below. In addition, the EQ-5D,[63] a measure of HRQoL that has primarily been used for economic evaluation, was included and is also described below.

Medical Outcomes Study 36-item Short-form Health Survey (SF-36) (patient questionnaire)

The SF-36 is a global assessment instrument. It includes eight multi-item scales: physical functioning, role limitation due to physical problems, pain, general health perceptions, mental health, role limitation due to emotional problems, social functioning and energy/vitality. Each scale is scored on a 0–100 possible range, with higher scores representing better health. These can be combined into two weighted scores: the physical and mental component scores (PCS and MCS), which are reported here; high scores indicate good QoL.[64,65] The SF-36 has proven to be both reliable and valid in the assessment of HRQoL.[66–69]

The SF-36 has been used alone to assess HRQoL in ESRF patients[59,70,71] and as part of the KDQOL instrument.[61] Meyer and colleagues[70] assessed the reliability of the SF-36 in a dialysis population. Reliability estimates for five of the eight SF-36 scales were lower in dialysis patients than in the general US population. However, for the physical functioning, social functioning and role-emotional scales, reliability estimates were the same or slightly higher in the dialysis population. Reliability coefficients ranged from 0.77 to 0.94. Wight and colleagues found the SF-36 to be a practical and consistent measure of HRQoL in a group of patients in the UK with ESRF.[72] Practical advantages to the SF-36 include the fact that it is relatively short, takes little time to complete and can be self-administered.

Kidney disease quality of life instrument (KDQOL) (patient questionnaire)

The KDQOL[61] is a disease-specific instrument that was developed specifically for patients undergoing dialysis. It includes the SF-36 as a generic core and is supplemented with multi-item scales targeted at particular concerns of ESRF patients. The dialysis-related issues were identified by a review of the literature on HRQoL and patient and staff focus groups. The scale includes items on symptoms commonly experienced in kidney disease, the effects of kidney disease on daily life, burden of kidney disease, cognitive function, work status, sexual function, quality of social interaction and sleep. Also included are multi-item measures of social support, dialysis staff encouragement, patient satisfaction and a single-item overall rating of health.[60] A five-point response scale is used to assess the impact of symptoms and the effects of kidney disease on daily life. Some parts of the scale are taken from other HRQoL instruments. For example, the cognitive function items are derived from the Sickness Impact Profile[73] and the sexual function scale from the Medical Outcomes Study.[74] The six items relating to dialysis staff encouragement were written *de novo*.[60]

Hays and colleagues[61] investigated the reliability and validity of the KDQOL in a study of 165 patients on dialysis. Internal consistency reliability estimates for 19 multi-item scales exceeded 0.75 for every measure except one. The mean scores for the SF-36 component were lower in the mental health, general health perception and physical functioning domains. There was a significant correlation between a number of the scales with the number of days spent in hospital and number of medications taken. Carmichael and colleagues[75] studied the KDQOL in 190 chronic dialysis patients. Compared with the general population, the HRQoL of the patients was impaired for all SF-36 subscales. Use of the disease-specific components of the KDQOL found 'satisfactory sleep', 'dialysis-related symptoms', 'effect of kidney disease on lifestyle' and 'burden of kidney disease' to be the most important determinants of HRQoL in the study population.[75] Like the SF-36, the KDQOL can be self-administered and takes ~30 minutes to complete.[60]

EQ-5D

Although it was premature to consider the long-term impact of care settings on HRQoL, it was pertinent in our study to describe and evaluate HRQoL across care settings and 'on' and 'off' dialysis, using an economic outcome measure, EQ-5D. Such a measure provides essential information on the value patients place on current health status and changes to it. The rationale for considering HRQoL both 'on' and 'off' dialysis was to test the hypothesis that HRQoL would be lower during dialysis sessions as the patient is physically (if not psychologically) further limited. Thus any saving in dialysis time might be valued for its gain in HRQoL. This could be relevant to the care settings in this study, other modalities or indeed to new technological advances being made in dialysis care.

EQ-5D[63] is a standardised instrument to measure health outcome designed to complement other QoL measures such as the SF-36 and disease-specific measures such as KDQOL. It has been designed for self-completion by patients and takes only a few minutes to complete. It has two components:

1. A descriptive profile that covers five dimensions: mobility, self care, usual activities, pain/discomfort and anxiety/depression. Respondents are asked to note which of three possible levels ('no problem, some/moderate problems, extreme/unable to') for each dimension best describes their health state today. The resulting one-digit numbers expressing the level selected for each dimension can be combined in a five-digit number describing the respondent's health state, for which 243 are possible. In addition, the descriptive profile can be converted into a single summary index value (utility) for health status by applying scores from a standard set of values derived from general population samples.[76] These indices (utility weights) were compared with published QoL weights for the UK age-adjusted population norm. Weighted health state index scores, henceforth referred to as EQ-5D utilities, are of particular interest to economists since they can be used to determine quality-adjusted life-years (QALYs). However, QALY derivation was not undertaken in this study as data were collected at only one time point.
2. An EQ-5D visual analogue scale (EQ VAS) which generates a self-rating of HRQoL to be used with the five-digit health state classification for a composite picture of the respondent's health status. The respondent rates his/her health state between 0 and 100 by drawing a line from the box marked 'your health state today' to the appropriate point on the EQ VAS.

The EQ-5D has been widely used in many European countries and for different disease states. Studies have found the EQ-5D to be both a valid and a reliable measure.[69,77]

Patients were on dialysis when they completed the EQ-5D. They were asked to rate their health state directly on the EQ VAS (on dialysis) and additionally to complete the descriptive profile and EQ VAS for a typical day when not dialysing. The derived EQ-5D utilities were examined to see whether factors such as setting (MRU/RSU) appeared to be influencing the data. *Table 9* summarises the key HRQoL measurements undertaken.

TABLE 9 *Health-related quality of life measurements*

Category	Resource item	Measurement unit
Health-related quality of life	In general (i.e. off dialysis)	Mean and median EQ-5D utility Mean and median EQ VAS
	On dialysis	Mean and median EQ VAS
	Difference between off and on dialysis	Mean difference EQ VAS

Patient satisfaction (patient questionnaire)

There is increasing pressure on providers of healthcare to monitor patient satisfaction as a measure of the quality of care given. There are many well-recognised pitfalls in the design of patient satisfaction questionnaires and their interpretation; for example, results of such surveys are often highly skewed with most patients giving high satisfaction ratings.[78] However, they remain a useful tool in evaluating the effectiveness of a service in ways other than clinical indicators. There is evidence to suggest that patients' criteria for satisfaction may be specific to their disease process and medical setting.[79] Following a review of the literature, we did not feel that there was a suitable instrument for use in the study. The questionnaire needed to be adaptable to renal patients within the unique setting of a UK RSU.

Our initial plan had been to construct a questionnaire specifically for the purpose of this study. Interviews were conducted with 30 patients in two RSUs and 20 patients in the corresponding MRU asking general, open-ended questions on issues related to dialysing in their unit (e.g. What are the good things about dialysing in this unit? Do you have any worries or concerns about dialysing in this unit? What changes/improvements would you make?).

Several themes raised by the patients emerged:

- travelling times to and from the unit and transport issues
- time taken to get on and off the dialysis machine
- relationships between other patients, dialysis staff and consultants
- organisation of delivery of medicines
- the atmosphere within the unit
- the structure of the unit (e.g. layout, privacy)
- safety within the unit, including the issue of medical cover
- dialysing within an acute versus a non-acute environment
- access to a nephrologist.

These were then ordered by importance (assessed by most frequently raised theme and rank of importance by individual patient), and translated into a series of Yes/No questions. The series of questions is shown in the patient questionnaire (Appendix 4)

Travel burden (patient questionnaire)

The importance of both time taken to travel to and from a dialysis session and time spent waiting to get on and off the dialysis machine was apparent in the interviews above. This is in agreement with previous studies.[80]

Patient safety

We took this to mean potentially avoidable acute events arising on dialysis or their consequences because of the lack of or reduced access to medical cover within RSUs.

The interaction between an RSU and its linked MRU over life-threatening situations or events which interfere with a patient's dialysis is important and there exists no published literature investigating the problem. Rather than rely on historical information from each unit, a form prospectively documenting major adverse events was devised with advice from the nephrologists on the study Steering Group (see Appendix 7).

This was piloted at an RSU that was not to be involved in the main study, for a period of 4 weeks. Staff were asked to comment on any problems with both the layout of the form and any difficulties they encountered during the trial period. These were taken into account before the final version of the form was completed.

For the main study, following each RSU visit, the nursing staff were asked to complete a form for each study patient for a period of 6 weeks. A method of negative reporting was employed whereby the nurses were asked to complete the form after each dialysis (as opposed to only times when the patient suffered an adverse event). This was in an attempt to improve the completeness of the data. A period of 6 weeks was chosen as this was felt to be a reasonable length of time to capture a representative number of adverse events for the unit as a whole and for individual patients, whilst also respecting the fact that the RSU staff were busy with many demands on their time. Negative reporting was not initially employed by one unit (Bath) and the 6-week period was therefore repeated at a later date, by which time some patients from the original sample were not dialysing in that particular unit.

A more general but related issue is how an MRU deals with those patients dialysing in RSUs who have a problem that cannot be resolved without attending the main centre. The way to resolve this may be via an unscheduled outpatient visit, a visit to the MRU to be seen on the ward by the medical team or a hospital admission. Details of these events were collected from hospital notes for the RSU patients where possible.

Additional emergency visits to MRU (clinical questionnaire) (RSU patients only)

Any unscheduled (i.e. non-emergency) outpatient appointments made or emergency visits to the MRU were collected retrospectively from hospital notes.

Methodology for measuring patient to renal unit access

Each patient's postcode was used to calculate the time and distance between their home and their RSU and MRU. Full unit postcodes were provided for each patient and for their MRU and RSU. These postcodes were run through the pc2ed facility on the Manchester Information and Associated Services (MIMAS) service at the University of Manchester, which returned extracts from the 1998 postcode to Enumeration District (ED) directory containing an Ordnance Survey 100-m grid references for each matched postcode. These grid references were then assigned to all the matching records in the renal survey dataset. All non-matching postcodes were examined to ascertain the reasons for failure. Some were simply not valid postcodes and could not be corrected or inferred (e.g. 'HERTS'), so these records were dropped from the analysis. Apparently valid postcodes which were not found in the postcode to ED directory were then validated against the royalmail.co.uk and multimap.co.uk websites, the latter providing grid references for some additional postcodes. Remaining unmatched codes were assigned the grid reference of the closest postcode in the postcode to ED directory (for example, the grid reference for SO17 1BJ being used where no matching record could be found for SO17 1BK), providing a match could be found with the same district code (e.g. SO17).

Once grid references had been assigned to all records remaining in the dataset, crow-fly distances were calculated as simple Pythagorean distances between the two locations using a Visual Basic application which also supplied each pair of locations to Autoroute Plus software[81] in order to obtain a road journey time and distance (using settings which chose the fastest route in the slowest car). Some pairs of locations were too close for a route to be computed (i.e. some patients' postcodes are very close to renal services in urban areas and it is not necessary to take any major road in order to reach them), hence Autoroute is unable to give a journey distance and time based on its principal roads database. These pairs were checked against the crow-fly distances, and generally found to be less than 1 km apart.

Thus, for each patient, the output data consist of crow-fly road distances and road travel times to the corresponding renal centre and satellite, using postcode locations derived primarily from the 1998 postcode to ED directory. In addition to this postcode analysis of travel times, patients also reported their own typical journey times as described in Chapter 4.

Data entry and validation of results

Data entry

All information collected for the study was entered into a central database held at the Health Care Research Unit based at Southampton General Hospital. The patient questionnaires were scanned (using Teleform Elite) in the department and the clinical questionnaires sent to a punching agency.

Data validation

This included range checks for each variable in order to exclude any errors there may have been in data entry, and subsequent hand searching of the questionnaires in which variables were found to be outside the identified ranges. Consistency checks were performed such as sequence of dates.

Once the co-morbidity data had been validated, algorithms were derived to generate a score on each of the three scales for individual patients. A significant amount of work was required to translate the raw co-morbidity data into each of the three scores we chose to use in the study. An algorithm for each score was written in SAS by A Armitage and R Mehta. The questionnaires for all patients for whom a score was not calculated were hand searched to exclude punching errors that may have accounted for failure to generate a score. Those patients with missing data were allocated modal scores or excluded from the analysis as described earlier in the chapter. Illnesses not coded for in the co-morbidity section of the clinical questionnaire were assigned codes and scores and included in the algorithms.

The ranges set for the laboratory data and blood pressure values were based on those used by the UKRR and for any values falling outside these the questionnaires were checked by Drs Roderick or Armitage and a decision made to include or exclude the data based on clinical experience.

Missing data

This section refers to missing data for the Phase 2 data only.

Missing data – clinical questionnaire

Of the 736 patients entering the study, only three refused consent for the clinical questionnaire and four additional questionnaires were completely blank. The remaining 729 contained full or part information and the response rate for each individual analysis is documented in the individual results tables.

The co-morbidity section included a number of variables contributing to the Lister Scale.[28] It includes a severity rating of a particular disease state. In view of the fact that the data collection was from hospital notes, computer records, etc., it was not always possible to allocate a degree of severity. For example, it may have been documented that a patient suffered from cardiac disease but the severity of the condition was not apparent from reading the notes, and was therefore coded as ‘not known’. Initial review of the data revealed a distinct group of patients who had complete co-morbidity information with the exception of a disease severity score for one disease state. In these cases the modal value for each patient who had that particular disease state and had been given a severity score was calculated and this was allocated to those with missing values. Those patients who had more than one disease state with a severity score of ‘not known’ were excluded from the final analysis.

For the other two co-morbidity scores generated (Wright/Khan and Modified Charlson Indices) a patient was not allocated a score unless all relevant variables were completed. In the final analysis, 50/736 (7%) of patients were found to have insufficient data to calculate any of the three co-morbidity scores.

Missing data – patient questionnaire

The SF-36, KDQOL and EQ-5D formed a significant part of the patient questionnaire. These are published scales that have been widely used and validated. Published guidelines for the handling of missing data were available for SF-36[65] and these were followed. This allowed scale scores to be calculated where a respondent had answered at least half the items with missing items replaced by the individual’s mean across the remaining items. KDQOL scoring ignores missing data,[82] that is, the scale scores are averages across all items answered. In contrast, EQ-5D utilities were not derived unless the patient had answered all questions.

In terms of cost outcomes, at both the unit and patient levels, no missing data were imputed. The pairing of units was potentially important for the unit-level analyses. Therefore, we re-did some key analyses excluding unit pairs where data were missing for one of the units. We present these results only where they appear to differ from the analyses including all data.

Statistical methods

Standard statistical methods were used for comparing two groups. For categorical data the chi-squared test was used to test the null hypothesis of no association between categorical variables. When the sample size was not sufficiently large, Fisher’s exact test was applied. For continuous data which were normally distributed, the two-sample t-test was used; if not, the non-parametric method Mann–Whitney U-test was used. Two-tailed p values are quoted. All analyses were performed using SPSS,[83] Stata,[84] or SAS.[85]

A key feature of this study was that individuals were recruited from each renal unit and that each RSU was pair-matched to its MRU. Hence the data were clustered with a pair-matched structure. Since the response of an individual within a cluster cannot be regarded as statistically independent, there is likely to be between-cluster heterogeneity in addition to the usual between-individual variability. The statistical issues where clusters of individuals (within renal units) rather than individuals are recruited are not fully appreciated.[86] These authors suggest that meta-analysis techniques may be considered for analysis of cluster pairs and can be usefully presented as such.

Hence, in an attempt to take account of the paired cluster structure of the data, pooled (combined) estimates of effect, comparing MRUs with RSUs, were estimated using meta-analysis within Stata.[84] An odds ratio (OR) and standard error (SE) (for binary outcome measures) and mean difference and associated SE (for continuous outcomes) were computed for each RSU unit versus MRU pair. Woolf's method for estimating the pooled ORs were used for binary outcomes. When calculating Woolf estimates, 0.5 was added to entries in all 2 × 2 tables if any of the cells was zero, as recommended by Breslow and Day.[87] A weighted mean difference was the calculated pooled estimate for continuous variables and the OR for categorical variables. Analyses for continuous data required complete information (i.e. the analyses excluded cells with zero and hence the unit pair). However, this affected <25% of unit pairs that were typically the smaller units anyway.

Further methods of accounting for the cluster variability as described by Thompson and colleagues[88] and Donner and Klar[86] were also implemented for comparison, but are not reported here since the conclusions about the comparisons invariably remained unchanged although the methods produced more conservative estimates.

The pooled estimates represent a weighted average of the stratum-specific (unit-pair) estimates (OR or mean difference). Both fixed and random pooled effects were estimated. For fixed-effects pooled estimates, the stratum-specific weight is the reciprocal of the within-stratum variance (e.g. variance for the OR or mean difference for each pair). The stratum-specific weight for random effects pooled estimates is the reciprocal of the total variance, total variance being the sum of the within- and between-stratum variance. A test of heterogeneity was used to determine if there was evidence that the unit-pair comparisons varied across strata (between unit-pairs). Evidence of significant heterogeneity indicated that the random effects estimate should be reported.

Forest plots have been presented for some comparisons, as a graphical representation of the comparison between the stratum (unit-pairs), along with the pooled combined effect. Such a graphical presentation has advantages which include indicating how the pooled estimates were computed from the results of each unit-pair. It also allows the possible heterogeneity of results between unit-pairs to be examined with reference to the plot. The estimate of effect between each unit-pair is represented by the box within the 95% confidence interval (CI). The area of the box is proportional to the weight (inverse of the variance) of the paired comparison. The 95% CI of the pooled estimate is represented by the diamond at the bottom of each plot. The solid vertical line represents no difference within strata (OR = 1 or mean difference = 0) and the dashed vertical line corresponds to the pooled estimate.

Logistic and multiple linear regression techniques were used to calculate estimates of outcome, adjusted for possible confounders (age, ethnicity). The p values for comparison of outcomes of RSU with MRUs were calculated using likelihood ratio tests. Adjustment at the patient level was reported to take account of differences between main and satellite units in age and ethnicity. We were unable to adjust for these possible confounders in calculating the pooled estimates. It is difficult to predict exactly what effect such adjustments would make, but it is unlikely to be great given the overall balance in co-morbidity measures.

Additional analyses were performed on the EQ-5D utilities and EQ VAS (self-rated health status). The mean EQ-5D utilities and EQ VAS were compared with age-adjusted population norms by two-sample t-test for each age group and plotted using Microsoft Excel.[89] EQ-5D utilities were examined to see whether factors such as age appeared to be influencing the data. Since the EQ-5D utilities were skewed, the non-parametric Mann–Whitney U-test (two group comparisons) or Kruskall–Wallis test (more than two group comparisons) were used to compare EQ-5D utilities between groups. Where data were continuous, EQ-5D utilities were plotted against the possible explanatory variable and correlation coefficients computed (the Spearman rank correlation for non-parametric variables). Where data were discrete EQ-5D utilities, they were plotted using a boxplot.

Since there were only 12 unit pairs, unit-level cost data were simply analysed by examining means and significance testing was not undertaken. In addition, as explained in Chapter 4, a total cost was not derived for each setting and therefore no adjustment was made to cost categories for possible confounding (due to age or ethnicity), since this could have been misleading.

The results tables show the summary values and variation in the two groups (in some cases with the group difference and CIs) and the p-value using the individual level data ignoring clustering. We present the analysis taking account of the paired-clusters as 'pooled estimates' to demarcate them from individual level analyses. We comment in the text about adjustment for confounders using regression methods on the individual level data.

Chapter 4

Costing methods

Objective

To identify, measure and compare the cost of health service and patient resources associated with RSU and MRU care.

Introduction

The original proposal was for a cost-effectiveness analysis but this had to be moderated for several reasons. First, the assessment of effectiveness is multidimensional and there is no single measure which can adequately represent the clinical outcome. If we had been able to collect HRQoL measured using EQ-5D over a period of time, rather than simply a baseline measure without change, it would have been possible to conduct a cost–utility analysis and hence derive a cost per QALY for each setting. Second was our doubts about the sensitivity of EQ-5D. Finally, and most important, even if we had calculated a QALY, pragmatic reasons impeded the extent to which full costing could be conducted across the two settings and prevented derivation of a cost per QALY. These reasons related principally to lack of comparability between units, study design, data collection and accounting practices. The analyses were revised and report key resource use and limited cost analyses. These provide essential information to inform the design of a long-term study of costs and effectiveness of RSUs from the perspective of the health service sector and patient that could not have been appreciated without having conducted this study.

Economic questions addressed

Potential, but as yet unproven, advantages of RSUs in the delivery of care for chronic HD patients include more efficient use of resources particularly through release of medical time and improved patient accessibility and travel time. Two important economic issues were investigated in Phase 2.

The first economic question to be considered reflected the desire to evaluate the difference in health service costs, all else being equal, associated with the delivery of care to HD patients in RSU and MRU settings. In our study we sought to identify and describe components of the main health service resources used under different RSU models and affiliated MRUs, cost the key resource components believed to be major cost drivers and compare resource and cost elements across settings as appropriate.

The second economic question addressed recognised that care of chronic conditions such as ESRF requires the patients themselves routinely to incur substantial time and possibly other costs. Potential changes to the way care is delivered ought to consider the impact on patients' resources also. In our study, for the first time for such a patient group, patient time and other costs for routine dialysis and associated travel were estimated.

Comparability of patient groups and homogeneity of study population

The study faced two further generic issues that influenced the way in which joint resource use and costs could be assessed. The first of these relates to the general nature of renal services. It tends to be the case that both the workload of RSUs but particularly MRUs is multifunctional, that is, the patient group served is heterogeneous. In RSUs, the large majority of patients are chronic HD patients but a small proportion use the RSU for other reasons, usually minor things such as change of dressings or blood tests, and on occasions patients receiving CAPD may need attention. However, at the MRU the mix of patients is more diverse and complex. Some MRUs treat acute renal failure patients by HD, home HD and PD patients with dialysis complications or other medical problems, and a range of other nephrology patients including, in some centres, transplant patients. To ensure 'like-for-like' comparisons, it was important to be able to differentiate between different patient groups using common facilities to attribute resources and costs on an appropriate basis. Many non-study categories of patients treated at MRUs utilise resources more intensely, particularly nursing staff. If these differences cannot be accurately attributable to the severity of the patient, the concern is that comparison of patient groups will not be justified or will be inaccurate, in which case results ought to be interpreted with great care. *Figure 5* diagrammatically presents the problem faced.

The diagram should not be interpreted as exactly depicting the relative scale of the problem in MRUs and RSUs. Patients with ESRF requiring HD form a subgroup of the renal patient population. At the study RSUs, the total amount of work that was not chronic HD was minimal (represented by the small area marked 'other' in relation to the overall area set aside for 'RSU'). MRUs tend to be larger than RSUs and at MRU study sites the other work formed a larger proportion of the workload undertaken and case mix was more complex. Furthermore, the chronic HD workload was not always readily demarcated.

The patient selection criteria applied also complicated matters further (as discussed in Chapter 3) as they gave rise to two groups of chronic HD patients at MRU sites, one eligible for RSU (of interest to this study) and the other not. Some MRUs also added to this complexity by conducting chronic HD outside the area in the main unit dedicated to chronic HD (e.g. on renal wards – these are referred to as outlier patients). Thus, in general, study RSUs comprised a more homogeneous chronic HD workload and the MRUs a more heterogeneous and less clearly demarcated one.

A second issue was the need to recognise that the apportionment of resources across patient groups was on the basis of a 'steady-state' throughput of workload at RSU and MRU and did not account for the fact that the scale of throughput could vary between units. Particular questions about how the RSU and MRU as a whole function need to be addressed to understand the relationship between scale and resources and costs.

Description of process associated with a routine haemodialysis

Figure 6 illustrates the general process associated with a routine HD visit for a typical chronic renal patient and is useful for demarcating relevant resource use categories used for estimation purposes.

In addition to assessing patient outcomes to determine the effectiveness of the different settings (MRU/RSU), the ideal study design would have measured and evaluated full and detailed costs by setting over a lifetime of care. This prospective view would allow for the dynamic nature of treatment for patients with ESRF, detect fluctuating health service use and determine whether this varied by setting. Cost comparisons of lifetime care would comprise routine dialysis, follow-up care (community and hospital based), diagnosis and treatment related to dialysis and other renal complications, changes in treatment

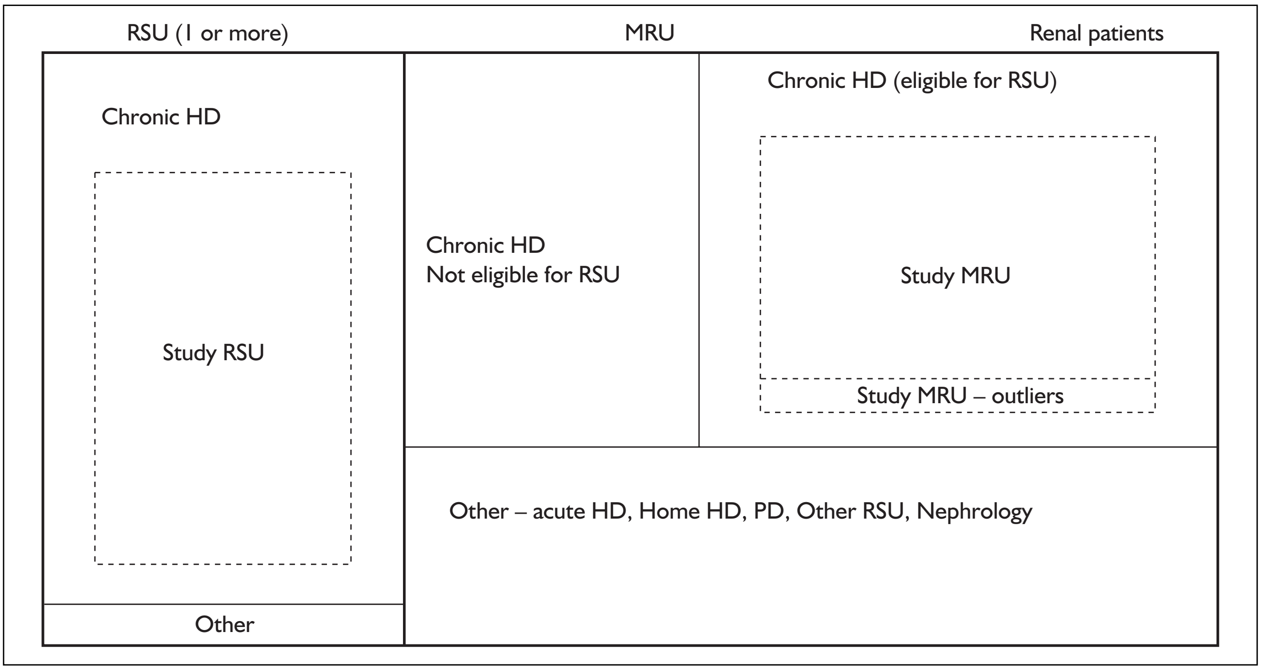


FIGURE 5 *Population for study*

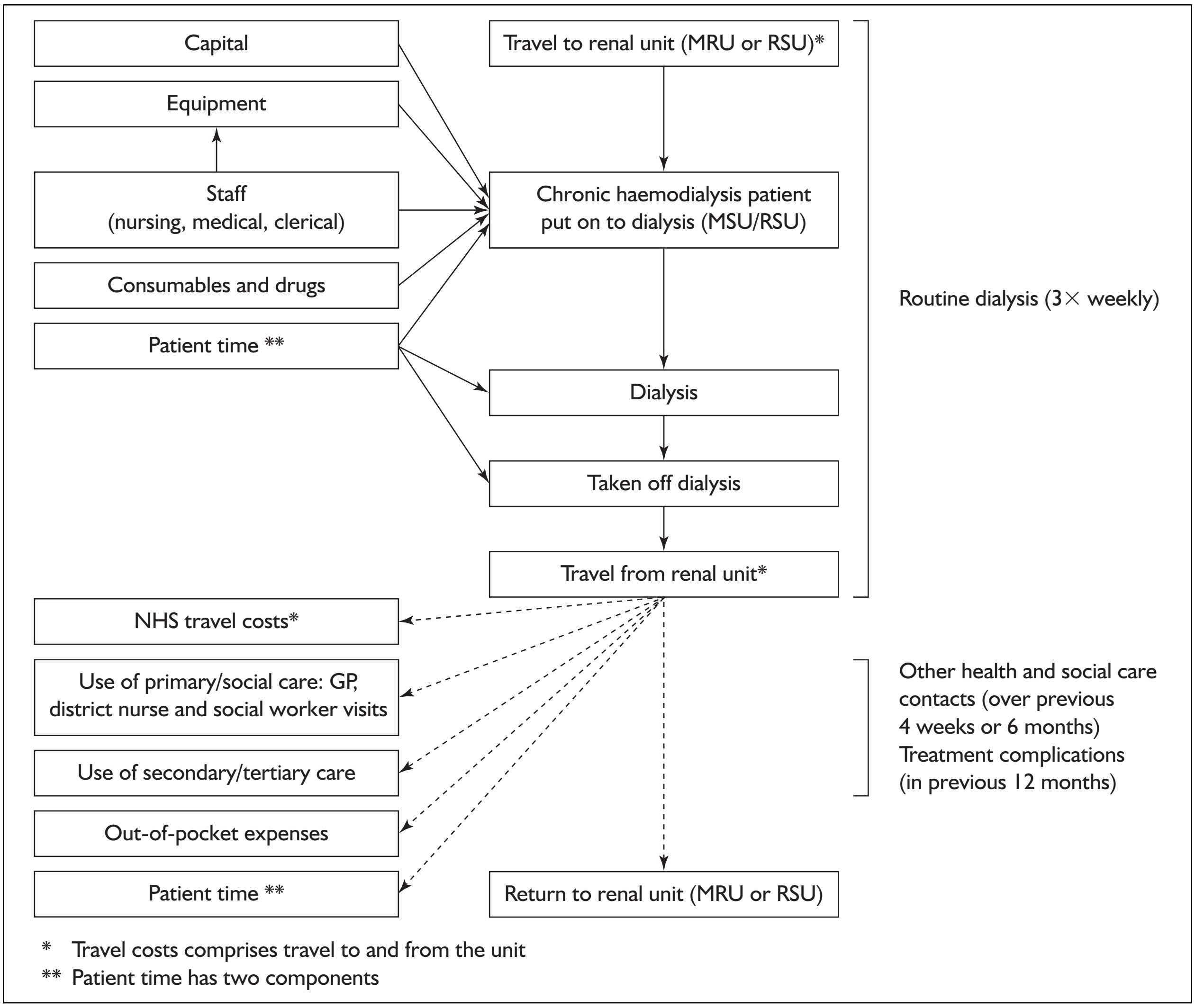


***FIGURE 6** Process of routine haemodialysis for end-stage renal failure patients*

modality and all associated travel and personal expenditure related to diagnosis, procedures and treatment.

The actual study design was naturally more restrictive as it had to be more practical. A marginal analysis approach was undertaken identifying key factors *a priori* where there would be the most important differences between MRUs and RSUs, or where it was unclear whether such differences would exist.

Sample and sample size

The economics study was incorporated alongside the clinical-effectiveness study, thus accessing a similar patient sample and pool of RSU/MRUs as described in Chapter 3. All of the 12 MRU/RSU pairs identified in *Table 6* were eligible for the economics study. However, depending on the method of data collection (researcher- or patient-completed questionnaires), the denominator used (i.e. number of eligible patients) varied from 619 to 729 depending on the analyses (full details are give in Appendix 12).

Overview of costing

Costing was approached from a health service and patient perspective. A top-down (gross) costing approach was planned although later abandoned. This involves generalised apportionment of the total cost to cost centres (e.g. wards, consultants, specialities or procedures), that is, disaggregating total cost to lower levels. The advantage of this approach is that it is simpler, more readily accessible and therefore less time consuming than bottom-up (micro) costing. The latter approach involves calculating the cost of each component (from the resource use multiplied by a unit cost for this) and aggregating them to determine the cost of a procedure, bed-day and so on. However, severe practical limitations to top-down costing were encountered. A pilot investigation at one of the study Hospital Trusts revealed that the renal expenditure budget could not be easily attributed to distinct activities or functions. For example, the skill mix reported in the budget (and hence salaries) differed markedly from levels given by renal unit duty rotas. Financial personnel did not support more detailed exploration of such differences, possibly because it would expose the fact that budgetary information had not been updated from historically established activity levels. The expected unreliability of budgetary information across remaining sites meant a change in focus towards bottom-up costing methods. This approach, in theory, should reflect the opportunity cost of resources. Opportunity cost measures the value of resources by the value of the next best alternative for using these resources.

In practice, the bottom-up approach was applied to the expected key cost drivers of renal care considered important for this study. A further advantage of taking this approach is that it identifies true resources rather than expenditure differences simply due to local price negotiations (e.g. on salary costs, drugs and supplies). For this reason, unit cost data were taken from national cost sources, manufacturers' list prices and mid-points of salary scales, where possible and appropriate (sources are shown in Appendix 13). The base year for resource use and unit costs used was 2000–01. Where required (i.e. dialysis machines), costs were discounted at 6% per annum.[90]

The renal patient population was found to be more heterogeneous at the MRUs than RSUs, as demonstrated in *Figure 5*. Accurately differentiating shared resources (i.e. nursing staff and capital) between study and non-study patients proved unworkable. Instead, for nursing staff, assumptions about how to apportion these were made. It was assumed that non-study patients required the same amount of nursing time as those eligible for RSU care. This may be an erroneous assumption as it could be argued that ineligible patients were more likely to be a sicker population and thus require a greater intensity of nursing input. The issue was investigated further with senior nursing staff (see Appendix 14), but since renal units do not use validated measures to assess patient dependency and nursing requirements, adjustment could not be made. Capital could not be appropriately apportioned and therefore descriptive information was collected from the RSUs since due to contracting arrangements they could usually provide some information.

Scope

Figure 6 shows the process of routine haemodialysis for ESRF patients. The key measurable elements for study were the routine dialysis phase (most patients attended three times per week) and other services in the health and social care sectors required, for example, for renal-related complications. A renal complication would be one, for example, where the access site becomes infected and the patient is hospitalised. However, as this group of patients has much co-morbidity, other treatments or complications could arise for other (i.e. non-renal) reasons. Data were collected on current and past use rather than prospectively.

The resource-use elements captured in the study and differences between RSUs and MRUs were initially identified through discussions with various stakeholders and previously reported studies. Resource items were measured at two levels of aggregation: unit and patient. This can also be seen in *Figure 6*. Unit-level items applied to common resources used for routine dialysis care and that required apportionment across workload (i.e. each unit's use of capital, equipment, staff and non-patient-related consumables were apportioned). Patient-level items were directly attributed to individual patients either through observation, patient recall or extraction of medical notes (i.e. patient-level variation was obtained for patient's own time costs, out-of-pocket expenses, use of relevant drugs, hospitalisations and health service contacts other than for routine HD). Thus resource use was measured either in naturally occurring units (e.g. number of visits, number of days length of stay per hospitalisation) or apportioned in a meaningful way (e.g. per dialysis session). Wherever possible, resource quantities were reported even if it was not possible to cost key drivers. This helped to identify gaps for future costing work.

The patient and clinical questionnaires described earlier were used for patient-level data collection. A health economist (TN) collected the unit-level data using site visits, telephone interviews and postal data collection forms. Stakeholders contacted at each site included unit Business Managers, unit Sisters and Trust Finance Managers responsible for units. Data were collected between June 2000 and January 2002 to correspond with the roll-out of site visits by other team members (see Appendix 15 for a full list of stakeholders).

Time periods

Different time frames were used for data collection to make the research task workable. However, this came at a price, a trade-off between accuracy and coverage. The unit-level data collection periods were affected by staff recall and data accessibility. The patient questionnaire typically collected data to reflect the patients' 'usual' patterns of service contacts over a 4-week period. This was considered a realistic period for patients to recall primary care and community healthcare contacts, for example, visits to the GP, but may not have been long enough to pick up true differential resource use patterns between settings. The clinical questionnaire was used to extract outpatient data over the previous 6 months and inpatient data over the previous year from medical records. These longer time frames were important to reflect the fact that such resource use would be less frequent but more intense and therefore costly.

Unit of analysis

Cost data are presented as means rather than medians. Although cost data are usually skewed, economists report means for their relevance in calculating the budgetary impact of an intervention (a multiplication of the number of patients treated and mean cost). It is not possible to calculate the budgetary impact using median data.

Mean resource use and costs were calculated per patient for routine dialysis, primary care and community healthcare contacts, scheduled outpatient visits and hospitalisations. However, presentation of inpatient resource use and cost data was somewhat problematic. In order to provide comparable units, resource use and costs were aggregated from their unit of measurement (i.e. session, month or 6 months) to the cost per patient per year, assuming patients underwent dialysis three times per week.

Itemised resources and units of measurement

The following sections describe the key healthcare sector resources enumerated and unit of measurement as outlined in *Table 10*. Resources captured excluded changes to treatment modalities, long-term changes in diagnosis and treatment for complications (i.e. longer than the previous 12 months) and long-term changes in follow-up care (i.e. longer than the previous 4 weeks). *Table 11* shows the components of renal care costs that could not be addressed by this study.

Description of unit capacity and workload

Data on the capacity of each RSU and MRU pair were collected in terms of maximum number of dialysis stations available for chronic HD patients and opening hours and days for each unit. These data included chronic HD patients who were cared for in another part of the hospital (usually a renal ward), referred to as 'outlier' patients in this report. They are important to include in the analysis if they are eligible MRU HD patients; their only difference is that they could not be treated in the MRU because it was full.

Workload was assessed in terms of the type of patients treated (case mix), numbers of patients at the time of the study visit and the potential number of patients who can be treated weekly (i.e. patient treatment slots available divided by frequency of weekly dialysis). Measuring the non-chronic HD workload undertaken within each unit's identified chronic HD area was not always possible.

Potential patient capacity was derived by dividing the potential session capacity into three (i.e. assuming patients attended three times per week). The latter was calculated from the sum per week of each day's stations available multiplied by the average number of patients treated per station each day. This assumes that the units work at full capacity. This is usually the case at RSUs since in order to maintain 'spare' capacity at the MRU, MRU patients are often sent temporarily to fill RSU vacancies. If underutilisation of sessions could be reliably quantified, it would be possible to increase the MRU cost per session appropriately. However, although information was available on the types of patients treated, lack of accurate activity data meant that it was not always straightforward to demarcate the capacity or workload attributable to purely chronic HD work. Allocation of staffing resources to the chronic HD patients was similarly affected.

TABLE 10 *Healthcare sector resources included*

Category	Resource item	Measurement unit[a]
Unit capacity and workload		
Capacity	Chronic HD stations, opening hours	Descriptive information, chronic HD capacity
Workload	Unit case mix	Descriptive information
Routine dialysis		
Capital	Type of RSU facility provided:	Descriptive information:
Equipment and maintenance	Dialysis machines	Descriptive information, available dialysis sessions (annual equivalent cost selected models)
	Profiling	Descriptive information
	Machine maintenance	Descriptive information
	Water purification system	Descriptive information
Staff	Medical staff contacts	Descriptive information, average journey time and staff cost
	Visits to RSU	WTEs, skill mix and total nursing cost:
	Nursing staff: trained and HCAs	Per dialysis session Per patient per year
	Other staff (administrative/clerical and technicians)	Descriptive information
Drugs	EPO therapy	Descriptive information, mean total weekly dose and mean cost per patient per year
Transport	Unit budget arrangements/issues and mode of patient travel	Descriptive information
Other health and social care contacts		
Community – primary/social care	GP consultation District nurse visit Social worker visit	Data collected over previous 4 weeks: Mean number of contacts per patient per year Mean total cost per patient per year
Hospital – secondary/tertiary care	Scheduled (routine) renal outpatient visits	Data collected over previous 6 months[b]: Mean number of visits per patient per year Mean total cost per patient per year
	Hospitalisations (treatment for all illness, renal-related complications and procedures and co-morbidities)	Data collected over previous 12 months[b]: Mean total length of stay per patient per year Mean total cost per patient per year Mean cost per hospitalisation (per patient admitted) Two analyses: all patients and those at unit more than 12 months

[a] Descriptive information = no quantitative comparisons.
[b] Or since starting uninterrupted haemodialysis.

Routine dialysis

Capital

It was desirable to evaluate the capital costs of providing dialysis care in RSU and MRU settings but the data were not readily available or were deemed too sensitive. The key problem faced was identification of 'like-for-like' budgetary information about the capital assets both within RSU/MRU pairs and across pairs. First and foremost, it was not meaningful to apportion capital costs in MRUs according to our patient study group. Second, capital budgets were constructed for local purposes and this was reflected in the fact that many elements were not common (for example, the definition of what an overhead was varied). Instead, descriptive information was sought from RSUs only concerning ownership of the site and building, opening date, whether the building was purpose built or adapted, estimates

TABLE 11 *Healthcare sector resources excluded*

Item	Example
Overheads	Heating, lighting, energy, water, sewerage, Trust management costs, employee services, building maintenance, etc.
Equipment	Dialysis chairs and other renal/medical equipment
Staff	Cost of staff – medical, administrative/clerical and renal technicians Additional costs, e.g., for training and nursing management or the renal unit Domestic, porters, medical records
Dialysis-related costs (including consumables and drugs)	Access site (fistula, graft or neckline) Consumables Drugs (except EPO) and pharmacy overheads (i.e. dispensing costs) Pathology and radiology tests
Transport	Cost of NHS transport for routine dialysis
	RSU patient journeys to MRU attributable to the lack of medical cover at the RSU Patient journeys associated with outpatient visits or hospitalisations Staff (except medical) journeys between MRU and RSU
Other health and social care contacts: community – social care sector	Social care (e.g. home care, private domestic help or care, meals-on-wheels, lunch clubs, day centres, voluntary organisation help and residential/nursing home)
Other health and social care contacts: hospital (secondary/tertiary care)	Costs of non-scheduled outpatient and ward visits (e.g. due to dialysis-related adverse events) Non-renal outpatients or Accident and Emergency visits
Miscellaneous	Post, telephones, printing, stationery, laundry, linen, uniforms, etc.

of floor area used by the RSUs and in some instances associated annual rental cost. The last was the cost normally borne by MRU for use of hospital facilities at another site and potentially included capital charges, rates and some overhead items. Five of the RSUs were at non-DGH sites that were defined as hospitals with no acute medical/surgical service available. For example, some were community hospitals with outpatient facilities or long-stay rehabilitation (medical/elderly care) wards. These data provide useful insights into important aspects of the RSUs capital variation.

Equipment and maintenance

The main pieces of equipment of interest were the dialysis machines and associated profiling modules (e.g. sodium or ultrafiltration profiling and relative blood volume or blood pressure monitoring). The hypothesis was that RSUs may require more machines, all else being equal, because of scale inefficiencies. Important factors contributing to this were the units' policies for managing dialysis machine breakdowns (i.e. keeping spare machines) and handling infections. Due to the latter, in some units there might be unused capacity for machines reserved for patients with HIV, hepatitis B or C and methicillin-resistant *Staphylococcus aureus* (MRSA). However, the number of patients with these infections was generally small and there was insufficient information about their impact (i.e. whether room/machine out of use for other patients that day/permanently) to adjust properly. In addition, it was not possible to adjust dialysis machine capacity for RSU or other treatment modality patients dialysing at the MRUs.

Available dialysis sessions per machine were derived by dividing the number of dialysis machines (including spares) attributable to chronic HD by the potential session capacity.

Price information for dialysis machines was sensitive. In addition, there were previously mentioned difficulties in accurately attributing workload to chronic HD and difficulties in obtaining dates of purchase in order to adjust the present value of the machines. For these reasons, equivalent annual costs are presented only as an outline range available, not by unit. The impact of profiling on the cost of the machines was also investigated. The annual costs per patient were calculated using the mean dialysis machine cost and the unit's potential patient capacity. Full details of the methods to calculate these are given in Appendix 16.

It was unfeasible to cost accurately technicians' time allocated to maintaining dialysis machines.

However, additional issues that needed to be taken into consideration were the geographical area covered by the MRU and its RSUs, the number of RSUs or external contracts for other renal units, the number of home HD patients, age of machines, workload attributable to additional other equipment for other modalities or other medical equipment and extent of other duties (e.g. assessing new equipment, teaching staff about equipment or duties within the MRU hospital). In the private units (RSUs), technicians were not based on-site.

Another aspect of dialysis machines, which may have an impact on the running costs of the machines, related to the water purification system used and its maintenance arrangement. It was unclear from the outset whether large cost differences would be expected between MRU/RSU pairs after adjusting for dialysis capacity. However, when looked into, it quickly became clear that this is a complex area owing to the variety of water treatment arrangements in place both with the dialysis units and for outlier patients. For example, water treatment plants varied from individual machines (reverse osmosis machines) to more complex plants, many of which had back-up facilities for emergencies. There were wide variations in frequency of water treatment testing (biochemical, bacterial and endotoxin) from never to weekly, depending on the test. Similarly, disinfection of the water treatment plant (by heat or chemical as appropriate to the components) varied between daily and annually, although in some units components such as the ring main were never disinfected. Accessing information was further complicated, since often staff other than the renal technicians were involved in maintaining this equipment. For example, in three MRUs the Trust's engineers or Estates Department were responsible, and in three units private companies were partly or totally responsible. Therefore, for this study it was not possible to assess what impact water treatment had on overall cost of dialysis.

Staffing and staff cover

Descriptive information was collected about medical staff cover at the RSUs. This comprised on-site renal medical staff cover (hours covered and grade), off-site renal medical cover such as transfer to MRU or telephoning MRU, in addition to other services available from the host hospital or 999 calls. The use of renal outpatients at the RSU hospital site was also investigated (either within the RSU or independently in the host hospital's outpatient department). These do not necessarily include medical input into regular patient review. In addition, information could be passed between all MRUs and their RSUs via computer links. Only three unit pairs did not have such links (and unknown for one pair).

Costing medical staff was not undertaken as attributing such costs was highly complex, especially since they often also work outside the renal units and are funded from a variety of sources, not all of which are NHS (e.g. research fellows). However, journey times (return) and costs for medical staff travelling between the MRU and RSU were estimated (methods are described in Appendix 17).

Nursing staff comprised trained and support staff. The latter were healthcare assistants, technical officers or similar who directly assisted patients with dialysis, collectively referred to as healthcare assistants (HCAs) in this analysis. Data were collected on the WTE in-post and vacancies, skill mix in terms of senior (F grade or above) to junior (E grade or below) trained nurses, and percentage of nursing staff who were trained nurses. These data were for the month of patient data collection and were assumed to reflect annual staffing. In addition, descriptive information was collected on the use of HCAs, methods used to determine the staffing establishment [i.e. funded posts that variably cover leave (annual, study and maternity) and sickness] and administrative/clerical staff and renal technicians.

Mean costs of nursing staff in-post per dialysis session were estimated for basic pay and for basic pay plus unsocial hours (for Saturdays, Sundays, bank holidays and night duty). Annual nursing staff costs per patient were also calculated (including unsocial hours). A full description of the methods is given in Appendix 18; however, difficulties were often experienced in attributing staff to chronic HD work.

Consumables and drugs

Consumables were not costed, for two reasons. First, the techniques and consumables for HD were almost entirely the same for the majority of unit pairs, with only two unit pairs (F and J) known to differ. The most costly item is the dialyser membrane. All units limited the choice, although the minority of patients intolerant of the usual dialysers used more expensive products accordingly to their clinical need. Second, within the study, it was not possible to conduct patient-level data collection for consumables. Thus, we could have investigated the variation between unit pairs, but we would not have been able to detect patient-level variation.

The only other issue that was not pursued in cost terms was the use of sodium bicarbonate as prepacked cartons or powder requiring mixing. These have a different resource use impact, particularly as although it has a cheaper material cost, powder requires greater staffing input and it affected two MRUs and two RSUs (although only one unit pair).

Erythropoietin (Epoetin alfa or beta, henceforth referred to as EPO) use was costed using the patient's dose and British National Formulary list price.[91] This excluded prescribing costs as it could have been dispensed by either a hospital or community pharmacy. Costing other drugs used was not possible as data were not collected on specific drugs (doses, frequency and route) and who prescribed them (GP or hospital doctors).

Transport

Unit-level data were collected on transport issues and problems such as lengthy waiting times for transport, lack of guaranteed arrival times, difficulties getting patients home after dialysis and use of private ambulance and/or taxis that incur additional expense to the Hospital Trust. In addition, information was gathered on budgetary arrangements (namely which unit paid for transport and whether a unit's Trust reimburses patients for their public transport or private travel costs). Patient-level data were collected on patients' mode of transport to determine the percentage of study patients who used NHS transport (hospital car or ambulance). This was in addition to the distances and road travel times measured between the patient's home and renal service (MRU or RSU) as described in Chapter 3.

Other health and social care contacts

Community (use of primary/social care)

Data were collected on important contacts with primary/social care services during the 4 weeks prior to the study visit. These comprised GP consultations and district nurse and social worker visits. The methods used to cost these contacts are described in Appendix 19.

Hospital (use of secondary/tertiary care)

Renal outpatient visits

Data were also collected on scheduled outpatient visits in the previous 6 months, or since starting uninterrupted haemodialysis (if less than 6 months). These were valued using the cost per nephrology outpatient attendance (£95 per visit),[92] inflated from the published 1999–2000 figures to 2000–01 using the pay and prices inflation index.[93] Non-scheduled outpatient or ward attendances were considered unreliable data as many were not documented and medical notes were often kept at multiple sites. These were not costed.

Hospitalisations

Data were collected on number of hospitalisations, reasons and lengths of stay during the last year or during the time at the unit if less than 1 year. These were valued adopting two approaches described below, using a cost per inpatient day[92] inflated from the published 1999–2000 figures to 2000–01 using the pay and prices inflation index.[93] First, the speciality was derived from the admission reason (full details are given in Appendix 20). However, patients are often admitted to the nephrology ward rather than another speciality in order to provide dialysis as required. Therefore, the second approach was to assume that all hospitalisations incurred the nephrology ward cost per inpatient day. The second approach proved more useful since missing data about admission speciality hampered the first approach. Neither approach differentiated between emergency or planned hospitalisations. The following were calculated per patient: total length of stay, mean length of stay per hospitalisation, total cost of hospitalisations and mean cost per hospitalisation.

Patients were analysed in two groups, namely all relevant patients in the study and the subgroup of patients who had been dialysing continuously at the MRU or RSU over the year prior to the study visit. The latter subgroup was a more stable group that was examined for systematic difference in the use of secondary/tertiary care.

Patients' out-of-pocket expenses and time

Table 12 details the key patient out-of-pocket expenses and time associated with routine dialysis that were measured.

Out-of-pocket expenses and impact of dialysis sessions on others (e.g. carer)

Patients were asked about their out-of-pocket expenses (i.e. for which they are not reimbursed). These comprised the costs patients bore for travel to and from dialysis sessions, the impact of their dialysis in terms of whether they were accompanied during dialysis, or needed a minder to look after children or a relative and the

TABLE 12 *Patient out-of-pocket expenses and time valuations*

Category	Resource item	Measurement unit
Patient – routine dialysis	Medications, special foods, etc.	Descriptive information
Out-of-pocket expenses costs per dialysis session	Mode of transportation/distance Carers Out-of-pocket expenses (medications, special foods, etc.)	Descriptive information, travel Use and range of expenditure Range of expenditure
Time	Travel: waiting for transport Travel: journey time Total patient time (waiting and journey) and dialysis time (excludes time getting on/off dialysis)	All: mean duration per dialysis session

associated cost, and costs of over-the-counter medicines (i.e. non-prescription items), special foods and alternative therapies.

Patients' time

Further to the patient travel times from the postcode analysis (see Chapter 3), each patient's time was measured as the time per week waiting for transport to and from sessions, journey times and weekly dialysis duration (excluding the time to get on or off dialysis). The total weekly time for these was also calculated.

Statistical methods for costs

The statistical methods used for cost analyses are described in Chapter 3.

Chapter 5

Results of Phase 2: patient recruitment, measures of effectiveness and acceptability

Summary of study response

Figure 7 is a flow diagram showing all stages of recruitment in the study.

Identification of sample for MRUs

Table 13 shows the number of patients in each participating MRU who were judged by the senior

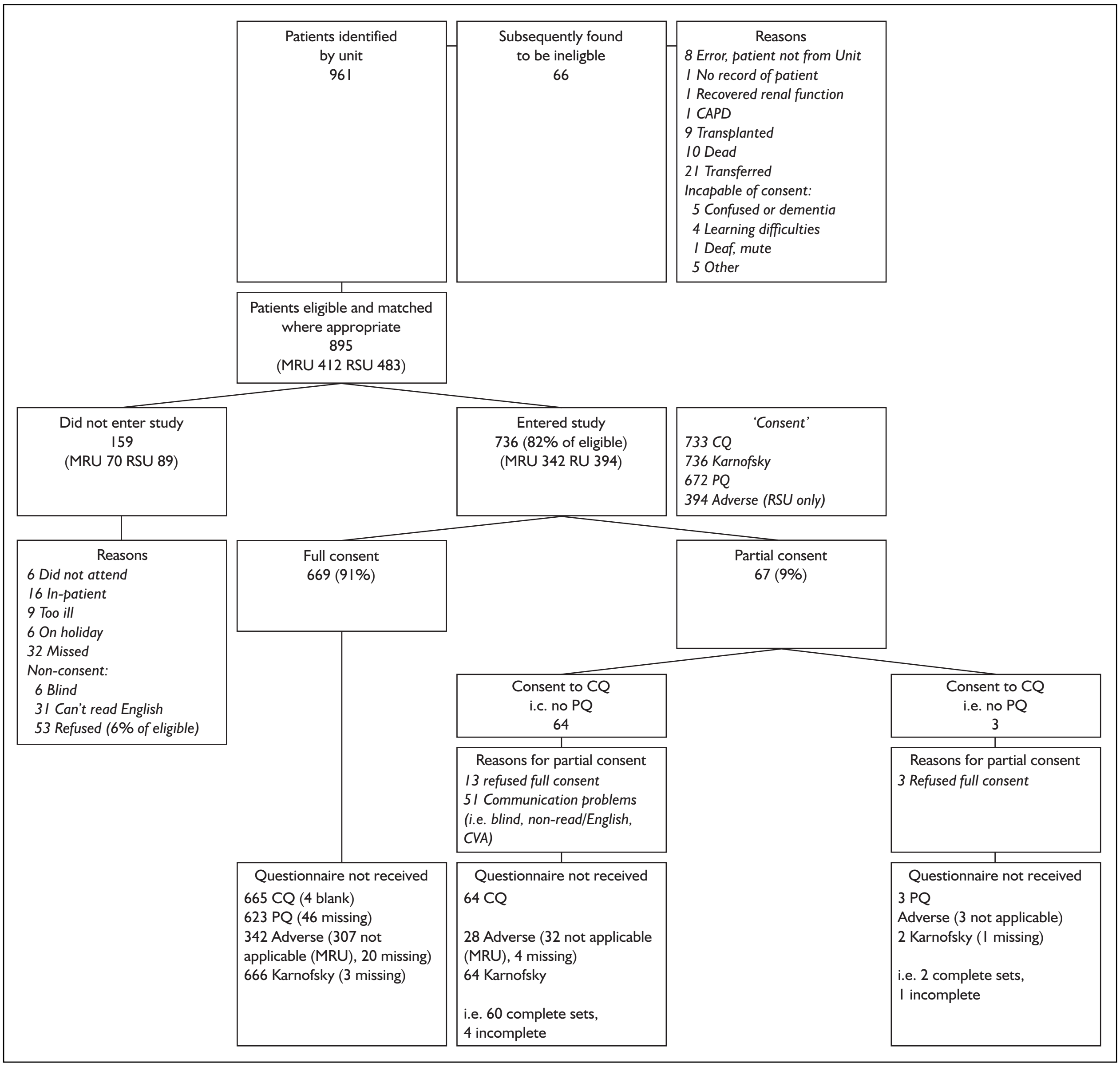


FIGURE 7 *Outlines of patient flow and study response rates (CQ, clinical questionnaire; CVA, cerebrovascular accident; PQ, patient questionnaire)*

TABLE 13 *Percentage of patients ineligible for satellite care in study MRUs*

MRU	No. of RSUs	Total No. of chronic HD patients in MRU	No. of patients ineligible (%)	Reason for ineligibility	
A1	5	64	22 (34%)	Cardiovascular instability	**2**
				Associated medical problems	**13**
				Dementia/confusion	**2**
				Patient preference	**4**
				New on dialysis	**2**
				Vascular access	**2**
				Language barrier	**1**
B1	1	149	62 (42%)	Cardiovascular instability	
C1	1	65	41 (63%)	Cardiovascular instability	
				New on dialysis	
				Need isolation	
				Physical access	
				Vascular access	
D1	1	103	28 (27%)	Cardiovascular instability	**14**
				Associated medical problems	**5**
				Psychological	**3**
				Physical access	**2**
				Learning difficulties	**1**
				Dementia/confusion	**6**
E1	1	69	47(68%)	Cardiovascular instability	
				Associated medical problems	
				Physical access	
				Need isolation	
F1	3	96	72 (75%)	Vascular access	
				Associated medical problems	
				Psychological	
G1	3	146	49 (34%)	Cardiovascular instability	**31**
				Associated medical problems	**10**
				Vascular access	**3**
				Need isolation	**2**
				Non-compliance	**2**
				Patient preference	**1**
H1	3	64	12 (19%)	Vascular access	
				Associated medical problems	
				Cardiovascular instability	
				Need isolation	
				Physical access	
J1	2	96	32 (33%)	Vascular access	
				Associated medical problems	
				Need isolation	
K1	2	110	66 (60%)	Cardiovascular instability	
				Associated medical problems	
				Vascular access	
				Need isolation	
				Patient preference	
L1	2	101	47 (47%)	Physical access	
				Vascular access	
				Cardiovascular instability	
				Associated medical problems	

continued

TABLE 13 *Percentage of patients ineligible for satellite care in study MRUs (cont'd)*

MRU	No. of RSUs	Total No. of chronic HD patients in MRU	No. of patients ineligible (%)	Reason for ineligibility
M1	4	115	65 (57%)	Cardiovascular instability Associated medical problems Dementia/confusion Patient preference Vascular access Aggressive patients
Total		1178	543 (46%)	

nurse to be unsuitable for satellite care. Also presented are the number of RSUs attached to each individual MRU. Six MRUs reported a greater percentage of ineligible patients than the total calculated for all units (46%).

The main reasons were medical, need for isolation, vascular access and cognitive impairment. Three MRUs in the table gave reasons for ineligibility on an individual patient basis. The number of patients with each reason in these units is shown in bold.

Previsit identification of eligible patients

Following initial contact with the units prior to the study visit, 961 patients were identified by the senior nursing sisters of the MRU/RSUs. Subsequently, 66 (6.9%) patients were found to be ineligible, mostly (42/66) because by the time the study visit was made they were not dialysing at the study unit owing to, for example, death or change in modality/unit. Of the remaining ineligible patients, nine patients' names were given in error and 15 were incapable of consent (i.e. were not suitable for the study from the outset).

Eligible patients

Of the 895 patients eligible for the study, 412 were treated in the study MRUs and 483 in the RSUs; 736/895 (82%) consented to the study, which was very similar in both MRU and RSU patients. Limited patient data, namely age and gender, were available on those patients who were eligible but did not consent for the study. The mean age of the non-consenters in the MRU group was 58.1 years, whereas for the RSU group it was 63.5 years. Although there was a significant difference ($p < 0.05$) between the two groups of non-consenting patients in these basic characteristics, they reflected the distributions in the RSU and MRU patients, so there was no age or gender difference between participants and non-participants. *Table 14* shows how this response rate varied by unit.

TABLE 14 *Number of eligible patients entering study by individual unit pairs*

Unit pair[a]	Eligible patients	Patients entered into study
A1	36	30 (83%)
A2	55	38 (69%)
B1	83	64 (77%)
B2	81	57 (70%)
C1	23	20 (87%)
C2	20	20 (100%)
D1	40	35 (88%)
D2	44	32 (73%)
E1	21	18 (86%)
E2	20	17 (85%)
F1	23	22 (96%)
F2	53	44 (83%)
G1	39	31 (79%)
G2	37	35 (95%)
H1	42	39 (93%)
H2	61	46 (75%)
J1	17	15 (88%)
J2	24	22 (92%)
K1	40	26 (65%)
K2	37	33 (89%)
L1	18	15 (83%)
L2	19	18 (95%)
M1	30	27 (90%)
M2	32	32 (100%)

[a] 1 = MRU; 2 = RSU.

The reasons for non-participation in 159 patients are given in *Figure 7*. Of these, 53 (33%)

non-participant patients (6% of all eligible patients) refused consent after receiving written and oral information about the study. On the day of visit, 25 patients (16% of non-participants, 3% of all eligible patients) were too unwell or hospital inpatients; 44 patients (28% of non-participants, 5% of all eligible patients) were missed by the researchers or absent (including six patients on holiday); 31 patients (19% of non-participants, 3% of all eligible patients) were from ethnic minority groups and were unable to read English or understand the translated Patient Information Sheet. The six patients who were unable to consent owing to blindness were from the first two unit pairs visited. Following these visits, all patients who were blind were approached for consent to all parts of the study with the exception of the patient questionnaire.

Table 15 shows the response of participating patients to the study's individual data collection components. Of the 736 patients entered into the study, 669 (91%) gave consent for all parts of the study (i.e. patient questionnaire, clinical questionnaire, KPS and adverse event monitoring). The remaining 67 patients (9%) consented to certain parts of the study. Within this group, the majority (64 patients) did not consent to the patient questionnaire, mainly owing to physical limitations. It included some patients from ethnic minorities who were able to understand the study via oral explanation and give consent, but who were unable to read the patient questionnaire without help. Only three patients refused consent to the clinical questionnaire alone.

Of the 733 patients consenting to the clinical questionnaire, four questionnaires were found to be blank and were therefore subsequently not included in analyses relating to clinical outcomes. From the 672 patients consenting to complete a patient questionnaire, 625 were eventually received for use in the analyses. The major adverse events forms were for consenting RSU patients only ($n = 394$) and 368 were received. All patients agreeing to participate in the study consented to a KPS; of the 736 possible, 732 were received.

The characteristics of non-responders to the patient questionnaire were analysed (*Table 16*). Patients were older with more co-morbidity and, as expected, were more likely to be blind. These patterns were similar in both MRU and RSU

TABLE 15 *Response of participating patients to individual components*

	Eligible patients	Patients participating	Clinical questionnaire	Patient questionnaire	KPS	Adverse events (RSU only)
Total	895	736 (82%)	729 (99%)	625 (85%)	732 (99%)	368 (94%)
MRU	412 (46%)	342 (83%)	335 (98%)	286 (84%)	340 (99%)	n.a.
RSU	483 (54%)	394 (82%)	394 (100%)	339 (86%)	392 (99%)	368 (94%)

TABLE 16 *Non-response to patient questionnaire*

	MRU			RSU		
	Response	Non-response	*p* value[a]	Response	Non-response	*p* value[a]
Age [*N*, mean, (SD)]	286, 56.0 (17.6)	56, 59.5 (17.5)	0.174	340, 61.7 (16.4)	54, 67.3 (13.4)	0.017
Gender [*N* (%)]						
Male	171 (59.8)	37 (66.1)	0.378	221 (65.0)	29 (53.7)	0.109
Female	115 (40.2)	19 (33.9)		119 (35.0)	25 (46.3)	
Wright/Khan [*N* (%)]						
Low	106 (39.6)	10 (19.2)	0.011	101 (32.1)	7 (13.7)	0.020
Medium	87 (32.5)	26 (50.0)		116 (36.8)	21 (41.2)	
High	75 (28.0)	16 (30.8)		98 (31.1)	23 (45.1)	
Blind [*N* yes (%)]	9 (3.3)	10 (18.2)	0.000	8 (2.4)	15 (28.3)	0.000
URR [*N*, Mean, (SD)]	231, 68.6 (7.8)	50, 69.4 (8.6)	0.519	308, 70.0 (7.4)	47, 69.2 (7.3)	0.489

[a] Comparing responders with non-responders.

TABLE 17 *Patients on HD for 3 months or less*

	MRU	RSU	Total
HD >3 months	303 (93.23%)	368 (97.61%)	671
HD ≤3 months	22 (6.77%)	9 (2.39%)	31
Total[a]	325	377	702

[a] 27 missing.

patients. The URR, a measure of the adequacy of dialysis, was also not different between the groups.

Patients on HD for more than 3 months

We present some of the clinical outcomes for patients who we knew were on HD for > 3 months (90 days) to allow for the stabilisation of their clinical situation after starting dialysis. The numbers involved were 303/342 (89%) for the MRU and 368/394 (93%) for the RSU patients, as shown in *Table 17*.

Demography of participants

Table 18 summarises the demographic characteristics of individual patients in the two groups. There was a significant difference in the mean age between the RSU and MRU, with the patients in the RSU group being older {RSU mean 62.5 [standard deviation (SD) 16.1] years, MRU mean 56.6 (SD 17.6) years, $p < 0.001$}. The weighted mean difference in age was 6.02 years (95% CI 2.60 to 9.43, $p = 0.001$). The difference is particularly marked in three unit pairs, all of

TABLE 18 *Demographic characteristics of two participating groups*

	MRU	RSU	*p*
Age [*N*, mean, (SD)]	342, 56.55 (17.56)	394, 62.48 (16.11)	<0.001
Gender [*N* (%)]			
Male	208 (60.8)	250 (63.5)	0.462
Female	134 (39.2)	144 (36.5)	
Education [*N* (%)]			
0–15 years old	104 (39.7)	150 (47.6)	0.055
16–18 years old	102 (38.9)	119 (37.8)	
>18 years old	56 (21.4)	46 (14.6)	
Employment [*N* (%)]			
Employed full-time	31 (11.4)	23 (7.4)	0.019
Employed part-time	13 (4.8)	12 (3.9)	
Self-employed	11 (4.1)	12 (3.9)	
Unemployed	24 (8.8)	23 (7.4)	
Retired	107 (39.3)	157 (50.6)	
Full-time student	7 (2.6)		
Looking after home/family	16 (5.9)	9 (2.9)	
Permanently sick or disabled	57 (21.0)	66 (21.3)	
Other (specified in text)	6 (2.2)	8 (2.6)	
Ethnicity [*N* (%)]			
White	221 (79.5)	289 (90.3)	<0.001
Mixed	5 (1.8)	3 (0.9)	
Asian or Asian British	23 (8.3)	23 (7.2)	
Black or Black British	24 (8.6)	5 (1.6)	
Chinese or other ethnic group	5 (1.8)		
Car Owner [*N* (%)]			
No car	61 (22.3)	99 (30.8)	0.029
1 car	146 (53.3)	164 (51.1)	
2 or more cars	67 (24.5)	58 (18.1)	
Live alone [*N* (%)]			
Alone	61 (21.9)	83 (26.0)	0.246
With others	217 (78.1)	236 (74.0)	

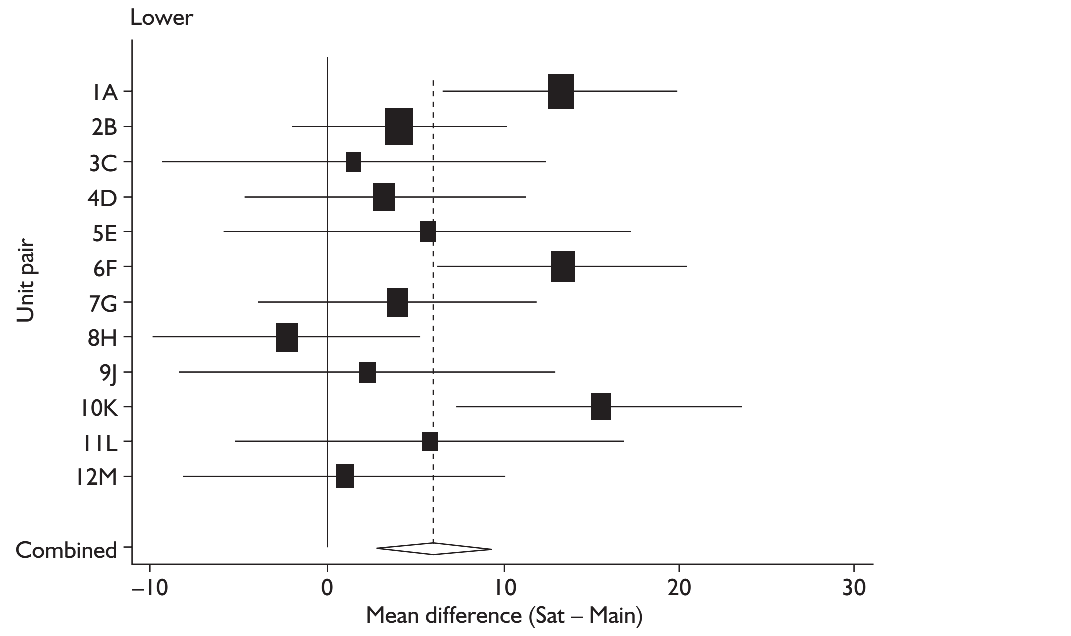


FIGURE 8 *Age of patients (years) at interview: RSU versus MRU*

which had a twilight shift in the MRU but not the RSU (*Figure 8*). However, this situation also occurred in several other unit pairs, but the age difference was less apparent.

A significant difference was also found with respect to ethnicity, with a smaller proportion of ethnic minority patients in the RSUs (individual level analysis $p < 0.001$, pooled analysis OR 0.56 (95% CI 0.33 to 0.94, $p = 0.027$). *Figure 9* shows the Forest plot. The difference is largely confined to four pairs of units where the MRUs were inner city units.

Fewer patients in the RSU owned a car [individual patient level analysis $p = 0.029$, pooled OR for no car 1.48 (95% CI 1.01 to 2.18) for RSU].

Full-time employment was more common in the MRU group. Nevertheless, only 20% of MRU patients were employed at all, compared with 15% in the RSU group. There was also some indication that a greater proportion of RSU patients had left full-time education at 15 years, although this was not statistically significant ($p = 0.055$).

Gender and living alone were not associated with the type of unit.

Figure 8 shows the patients' age (years) at interview for RSUs compared with MRUs. 'Lower' means the age was lower in RSUs compared with the paired MRUs. Overall, RSU patients were significantly older than MRU patients. The pooled (combined) estimate of the mean age difference was 6.02 years (95% CI 2.60 to 9.43, $p = 0.001$).

Figure 9 shows ethnicity (Asian/black patients) across the units. 'Reduction' represents the reduction in Asian/black patients in RSUs compared with the paired MRUs. Overall, the odds of an Asian/black patient were significantly lower in RSUs than MRUs and the pooled (combined) estimate OR was 0.56 (95% CI 0.33 to 0.94, $p = 0.027$).

Baseline clinical characteristics

Table 19 compares clinical baseline characteristics of the two groups of patients. There were no significant differences in the cause of renal disease or in the proportions diabetic, with viral infection or disabled. The level of co-morbidity, as measured by three scales, did not differ. Approximately one-third of patients in both groups scored high on the Wright/Khan Index. Half of the patients in both groups had no or low co-morbidity as judged by the Lister/Chandna and Modified Charlson scales, respectively. Despite this reasonably high level of co-morbidity, a large proportion of the patients in both groups were judged by their dialysis staff as being independent/having normal activity on the KPS (RSU 66% versus MRU 71%, $p = 0.181$). There was no difference in the KPS between the two groups after adjusting for age and ethnicity.

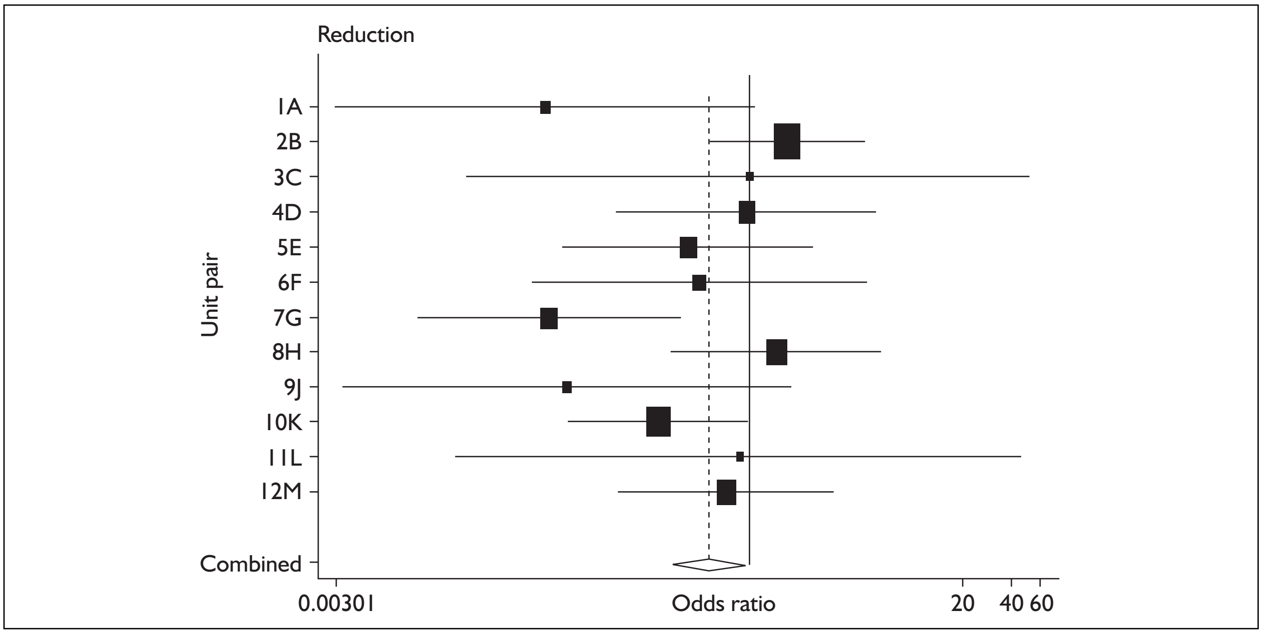


***FIGURE 9** Ethnicity (Asian/black patients)*

***TABLE 19** Baseline clinical characteristics*

	MRU	RSU	*p*
Primary renal disease (PRD) [*N* (%)]			
Other	204 (60.9)	242 (61.4)	0.885
PRD	131 (39.1)	152 (38.6)	
Diabetic ESRD			
Diabetic nephropathy [*N* (%)]	32 (9.6)	42 (10.7)	0.622
Diabetes [*N* yes (%)]	59 (18.0)	67 (17.8)	0.939
Co-morbidity index: Wright/Khan [*N* (%)]			
Low	116 (36.3)	108 (29.5)	0.152
Medium	113 (35.3)	137 (37.4)	
High	91 (28.4)	121 (33.1)	
Co-morbidity score: Lister [*N* (%)]			
None	167 (52.2)	177 (48.4)	0.124
Mild/moderate	125 (39.1)	139 (38.0)	
Severe	28 (8.8)	50 (13.7)	
Co-morbidity score: Modified Charlson [*N* (%)]			
Low	199 (62.2)	213 (58.2)	0.285
Moderate	79 (24.7)	87 (23.8)	
High	24 (7.5)	43 (11.7)	
Very high	18 (5.6)	23 (6.3)	
Binary KPS [*N* (%)]			
Normal activity (80+)	237 (71.0)	260 (66.3)	0.181
Require assistance/dependent	97 (29.0)	132 (33.7)	
Viral infection [*N* yes (%)]			
Hepatitis B	5 (1.6)	5 (1.4)	0.879
Hepatitis C	6 (1.9)	5 (1.4)	0.483
HIV	0	0	

continued

TABLE 19 Baseline clinical characteristics (cont'd)

	MRU	RSU	*p*
Disability [*N* yes (%)]			
Blindness	19 (6.1)	23 (6.4)	0.913
Wheelchair use	27 (8.8)	40 (11.1)	0.315
Other disability	45 (14.7)	60 (16.7)	0.479
Blind and wheelchair use	6 (1.9)	4 (1.1)	0.380
Time on RRT [median (25th and 75th centile)]	2.74 (1.06, 7.07)	2.84 (1.41, 6.32)	0.595
Duration (years) of current HD [median (25th and 75th centile)]	1.43 (0.63, 3.05)	1.43 (0.07, 2.71)	0.737

TABLE 20 Processes of care

	MRU	RSU	*p*
Patients access type [*N* (%)]			
Fistula or graft	241 (76.5)	310 (82.4)	0.053
Catheter	74 (23.5)	66 (17.6)	
Patients access type – patients on HD >3/12 months [*N* (%)]			
Fistula or graft	230 (80.1)	297 (83.9)	0.216
Catheter	57 (19.9)	57 (16.1)	
Dialysis type (Lister/St Albans only) [*N* (%)]			
Conventional dialysis	11 (25.0)	13 (32.5)	0.447
Haemodiafiltration	33 (75.0)	27 (67.5)	
Dialysis type (others) [*N* (%)]			
Conventional dialysis	259 (97.0)	328 (99.4)	0.048
Haemodiafiltration	8 (3.0)	2 (0.6)	
Frequency of dialysis – times per week for patients on HD >3/12 months [*N* (%)]			
2	16 (5.6)	3 (0.9)	0.001
3	268 (94.4)	346 (99.1)	
Duration excluding Lister St Albans [*N*, mean hours, (SD)]	246, 3.88 (0.37)	310, 3.89 (0.44)	0.796
Monitoring [*N* yes (0%)]			
Sodium profiling	28 (10.0)	86 (23.4)	< 0.001
Blood volume	–	–	–
Ultra filtration	31 (11.1)	30 (8.5)	0.259
Blood pressure	2 (0.7)	11 (3.0)	0.038
Membrane used [*N* (%)]			
Modified cellulose	120 (38.5)	127 (34.1)	0.241
Synthetic	192 (61.5)	245 (65.9)	

There was no difference in the time spent on RRT ($p = 0.60$) or on haemodialysis ($p = 0.74$).

Processes of care

Table 20 describes the processes of care for the two groups of patients. There were more patients with permanent forms of access (fistula or graft) in the RSU group compared with those with temporary access (catheters), although this was not statistically significant on pooled analysis (OR for temporary access 0.83, 95% CI 0.55 to 1.25, $p = 0.37$).

A similar analysis was undertaken on the frequency of dialysis sessions per week. The number of patients on twice-weekly dialysis was small, although there were more in the MRU group [RSU 0.9% ($n = 3$) versus MRU 5.6% ($n = 16$), $p < 0.001$].

TABLE 21 *Modalities*

Modalities	**MRU [N (%)]**	**RSU [N (%)]**
1 or 2	223 (68.4)	234 (61.9)
3	51 (15.6)	60 (15.9)
4	27 (8.3)	38 (10.1)
5	11 (3.4)	19 (5.0)
6	2 (0.6)	11 (2.9)
7	6 (1.8)	7 (1.9)
8	1 (0.3)	4 (1.1)
9	4 (1.2)	4 (1.1)
11	1 (0.3)	–
13	–	1 (0.3)
Previous transplant	68 (20.3)	60 (15.2)

One of the unit pairs (Lister/St Albans) used HDF for a large number of their patients in both settings. In the others this method was rarely used (10/597). For this reason, the Lister/St Albans pair was analysed separately for the variables 'type of dialysis' and 'duration of dialysis'. Those on HDF require a shorter time to dialyse in order to achieve similar adequacy and this was found to influence the mean values for dialysis times.

The mean duration of dialysis was just under 4 hours in both groups.

There was significantly more use of sodium monitoring in the RSU group (23.4 versus 10%, $p < 0.001$), which remained on pooled analysis (OR 2.72, 95% CI 1.21 to 6.14, $p = 0.016$). In both groups approximately two-thirds of the patients were treated using synthetic as opposed to modified cellulose membranes.

Modalities

Table 21 shows the number of modalities that each patient had received since commencing RRT. The majority in both groups had been on only one or two modes of RRT. RSU and MRU dialysis were counted each as a separate modality and the majority of RSU patients who had two modality switches had been dialysed initially in the MRU before moving out to the satellite, that is, they had been on hospital HD from the start. Conversely, most of the MRU patients had only one modality

TABLE 22 *Medication prescribed to patients on HD over 3 months*

	MRU (*n* = 303)	**RSU (*n* = 368)**	***p***
Number of antihypertensive drugs [*N* (%)]			
0	111 (37.9)	147 (43.2)	0.139
1	89 (30.4)	105 (30.9)	
2	62 (21.2)	70 (20.6)	
3	26 (8.9)	15 (4.4)	
4	3 (1.0)	3 (0.9)	
5	2 (0.7)		
Antihypertensive drug [*N* (%)]	111 (37.9)	147 (43.2)	0.172
Vitamin D [*N* yes (%)]	174 (58.6)	203 (60.4)	0.640
Phosphate [*N* yes (%)]	254 (85.8)	306 (89.5)	0.159
EPO [*N* yes (%)]	269 (91.2)	309 (90.1)	0.635
EPO total weekly dose per patient prescribed [*N*, mean IU (SD)]	262, 7368 (4251)	297, 7472 (3915)	0.765
Iron [*N* yes (%)]	176 (60.9)	232 (68.4)	0.048
Statin [*N* yes (%)]	45 (15.3)	65 (19.5)	0.160
Aspirin [*N* yes (%)]	101 (34.1)	125 (36.9)	0.470
Other antithrombotics [*N* yes (%)]	45 (15.8)	54 (16.8)	0.758
Who prescribes medication [*N* (%)]			
GP	74 (30.3)	122 (39.9)	0.011
Renal unit	101 (41.4)	91 (29.7)	
Both	69 (28.3)	93 (30.4)	

recorded as they had started in the MRU and not moved elsewhere since that time. The number of patients who had received a transplant previously was not significantly different in the two groups ($p = 0.15$).

Medication

Table 22 outlines the data on prescribing practices of medication for the study patients on HD over 3 months. Most patients in both groups were on two or less drugs to control their blood pressure. The proportion of patients who were prescribed an antihypertensive agent was lower in the RSU group but this was not statistically significant on individual or pooled analysis (pooled OR 0.81, 95% CI 0.56 to 1.16, $p = 0.25$). There was no difference in the other types of medication.

Prescribing of medication (excluding EPO) differed, with the RSU group being more likely to obtain their drugs from their GP as opposed to the renal unit, although this did not reach statistical significance (pooled analysis OR 1.32, 95% CI 0.91 to 1.93, $p = 0.144$). In both groups there was a sizeable number of patients receiving drugs from either the renal unit, GP or both, reflecting a variety of prescribing practices.

TABLE 23 *Clinical outcomes (patients on HD > 3 months)*

	MRU	**RSU**	***p***	**Pooled estimate RSU–MRU (95% CI)**
URR [*N*, mean (SD)]	285, 68.65 (7.50)	361, 69.95 (7.37)	0.028	1.17 (–0.42 to 2.76)
URR [*N* (%)]				
≤65	78 (27.4)	65 (18.0)	0.004	1.66 (1.08 to 2.54)
>65	207 (72.6)	296 (82.0)		
Kt/V [*N*, mean (SD)]	105, 1.37 (0.22)	162, 1.42 (0.24)	0.087	0.04 (0.01 to 0.07)
Kt/V [*N* (%)]				
≤1.2	35 (33.3)	41 (25.3)	0.156	
>1.2	70 (66.7)	121 (74.7)		
Weight gain [*N*, mean (kg), (SD)]				
Patient's mean predialysis weight	297, 69.26 (15.82)	362, 72.33 (15.64)	0.013	3.24 (0.90 to 5.58)
Patient's mean postdialysis weight	296, 67.41 (15.54)	362, 70.44 (15.31)	0.012	3.20 (0.90 to 5.50)
Patient's mean dialysis weight loss	296, 1.88 (0.92)	362, 1.89 (0.923)	0.882	
Blood pressure [*N*, mean (SD)]				
Mean predialysis systolic BP	297, 150.41 (22.35)	349, 148.61 (24.78)	0.334	
Mean predialysis diastolic BP	297, 80.38 (12.84)	349, 78.14 (13.49)	0.032	−1.83 (–5.33 to 1.67) (*p* = 0.28)
Blood pressure meets RA standards [*N* yes (%)]				
Predialysis systolic BP	145 (48.8)	202 (57.9)	0.021	1.38 (0.93 to 2.05)
Predialysis diastolic BP	232 (78.1)	294 (84.2)	0.046	0.70 (0.47 to 1.04)
BMI [*N*, mean (SD)]	266, 23.61 (4.98)	340, 24.60 (4.97)	0.016	0.96 (0.20 to 1.71) *p* = 0.013
BMI [*N* (%)]				
≥20	215 (80.8)	291 (85.6)	0.117	
<20	51 (19.2)	49 (14.4)		
Hb [*N*, mean (SD)]	301, 11.24, 1.57	367, 11.46, 1.69	0.087	
Hb [*N* (%)]				
≤10	64 (21.3)	70 (19.1)	0.482	
>10	237 (78.7)	297 (80.9)		
Ferritin [*N*, mean (SD)]	287, 436.95 (316.66)	359, 439.36 (363.64)	0.929	
Cholesterol [*N*, mean (SD)]	207, 4.64 (1.12)	254, 4.65 (1.19)	0.943	
HBA1c [*N*, mean (SD)]	35, 6.96 (1.56)	41, 7.26 (1.79)	0.448	

Clinical outcomes

Table 23 shows the clinical outcomes for those patients on HD for >3 months.

There was a small significant difference in measures of dialysis adequacy (URR, *Kt/V*) in favour of the RSU group; this was not significant on pooled analysis.The proportion achieving the Renal Association Standard was significantly greater in the RSUs; pooled analysis showed an OR of 1.64 (95% CI 1.21 to 2.45, $p = 0.016$) in favour of RSUs. This effect remained after adjusting for age and ethnicity (OR 1.64, 95% CI 1.08 to 2.42, $p = 0.02$). *Figure 10* shows the Forest plot of URR differences for the unit pairs.

Figure 10 shows patients with a URR >65% (and on HD >3 months) across the unit pairs. 'Reduction' means reduction in RSUs compared with the paired MRUs. Overall, the odds of URR >65% were significantly greater for patients in RSUs than MRUs and the pooled (combined) estimate OR was 1.64 (95% CI 1.10 to 2.45, $p = 0.016$).

There were more missing data for *Kt/V*, but in the 267 patients with data there was a small but statistically significant increase of 0.04 (95% CI 0.01 to 0.07) in RSUs on pooled analysis, but this was non-significant after adjusting for age and ethnicity.

There was no difference in weight loss on dialysis, although RSU patients were heavier predialysis.

There was no significant difference in predialysis systolic or diastolic blood pressure readings on pooled analysis or after adjusting for age. RSU patients were more likely to achieve the Renal Association Standards for blood pressure measures (160/90 >65 years, 140/90 <65 years), although this was not significant on pooled analysis (OR 1.40, 95% CI 0.93 to 2.10, $p = 0.109$) or after adjusting for age and ethnicity.

RSU patients had a higher BMI, which was significant on pooled analysis and remained significant after adjusting for age.

Haemoglobin levels were slightly higher in the RSU group (11.24 versus 11.46 g/dl); this difference was not significant. There was no significant difference in the proportion of patients achieving the Renal Association Standard of haemoglobin level of >10 g/dl on individual or pooled analysis, or after adjusting for age and ethnicity (OR 1.3, 95% CI 0.87 to 1.94, $p = 0.198$).

Figure 11 shows the Forest plot of haemoglobin differences (haemoglobin >10 g/dl) for the unit pairs. 'Reduction' represents a reduction in RSUs compared with the paired MRUs. Overall, the odds of haemoglobin >10 g/dl were greater, but not significantly so, in RSUs compared with MRUs. The pooled (combined) estimate OR was 1.45 (95% CI 0.83 to 2.52, $p = 0.188$).

Ferritin levels were the same in both groups.

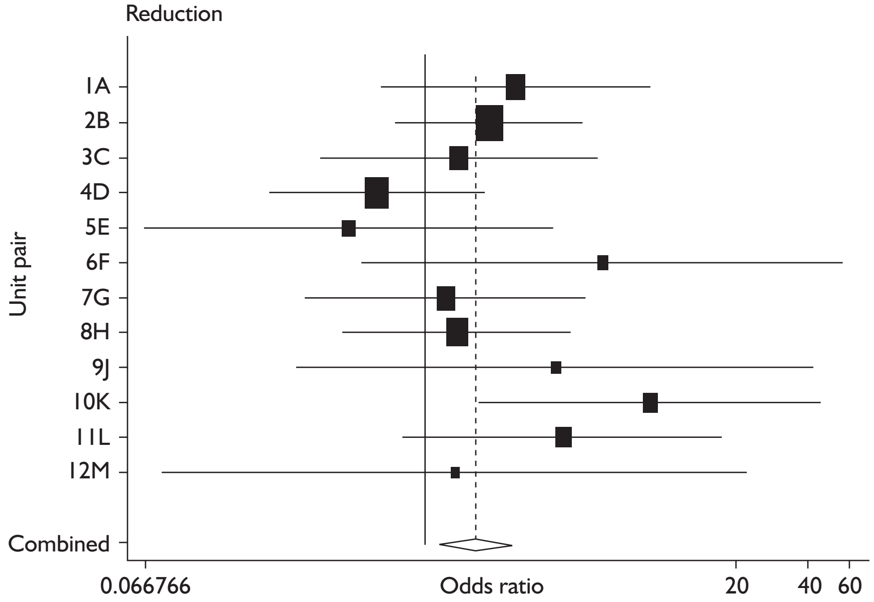


***FIGURE 10** Forest plot of URR differences for the pairs of units*

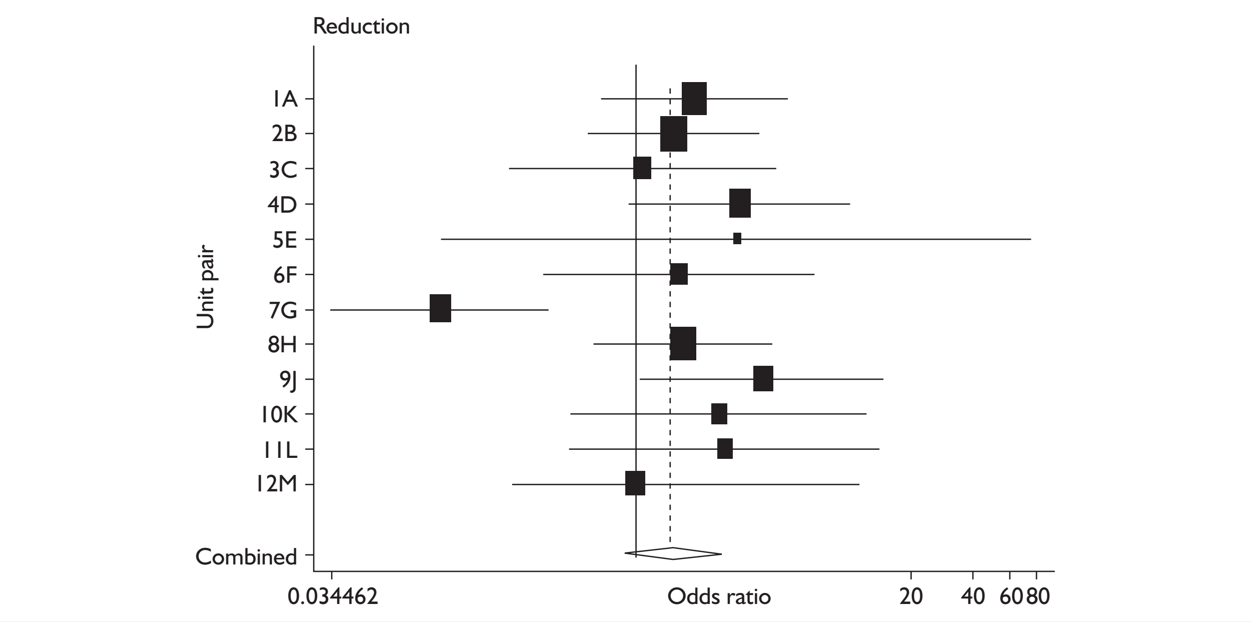


FIGURE 11 *Forest plot of haemoglobin differences for the pairs of units*

TABLE 24 *Biochemical parameters in patients on HD >3 months*

	MRU	RSU	*p*
Albumin (g/l) [*N*, mean (SD)]	286, 38.12 (4.25)	350, 38.19 (4.14)	0.828
Unit analysis 7 pairs albumin[a] [*N*, mean (SD) – harmonised]	209, 37.43 (4.08)	251, 38.00 (4.35)	0.145
Phosphate (mmol/l) [*N*, mean (SD)]	300, 1.80 (0.58)	365, 1.65 (0.53)	0.000
8 paired units – harmonised			
Phosphate [*N*, mean (SD)]	222, 1.77 (0.58)	268, 1.62 (0.52)	0.003
Phosphate (1.2–1.7 mmol/l) [*N*, %]	88 (29.3)	127 (34.7)	0.13
Corrected calcium (mmol/l) [*N*, mean (SD)]	198, 2.44 (0.24)	288, 2.45 (0.21)	0.623
Unit pair analysis with same laboratory (5) [*N*, mean (SD)]	114, 2.42 (0.21)	133, 2.43 (0.22)	0.667
Uncorrected calcium [*N*, mean (SD)]	289, 2.37 (0.26)	367, 2.40 (0.25)	0.097
Unit analysis 8 pairs [*N*, mean (SD)] – harmonised	222, 2.37 (0.23)	268, 2.40 (0.25)	0.207
iPTH (pmol/l) [*N*, mean (SD)]	243, 47.39 (67.62)	298, 31.84 (42.22)	0.001
Ln [iPTH (pmol/l)] [*N*, mean (SD)]	243, 3.17 (1.27)	294, 2.83 (1.24)	0.002
Bicarbonate (mmol/l) [*N*, mean (SD)]	266, 23.04 (3.72)	310, 23.75 (3.73)	0.024

[a] The table excludes Brighton/Worthing from the analysis because they use BCP methods.

No differences were found in serum cholesterol or HbA1c levels (diabetic patients only).

Analysis of biochemistry variables is summarised in *Table 24*, excluding those patients who had been on HD for < 3 months.

One pair of units was excluded from all analysis of albumin results as the laboratories serving them used a different method of albumin assay and therefore comparison was not valid. On an individual patient level using crude albumin data, there was no significant difference between the two groups.

There was no difference when comparing the seven pairs of units which used the same laboratory and after harmonisation using NEQAS factors.

Serum phosphate levels were found to be significantly lower in the RSU group on an individual patient level. Phosphate results were lower in the RSUs, but again became non-significant on clustered analysis (in eight pairs the difference was –0.17, 95% CI –0.35 to 0.019, $p = 0.78$).

The pitfalls of analysis of the corrected calcium measurements are outlined in Chapter 3. There was no significant difference in unadjusted corrected or uncorrected calcium levels on an individual patient level, including after harmonisation and when comparing only units sharing the same laboratory.

The RSU patients appeared to have lower parathyroid hormone (PTH) levels, although there was a large amount of variability in the data. Pooled analysis showed a difference of 8.5 pmol/l (95% CI 0.47 to 16.5, $p = 0.038$). Bicarbonate levels were higher in the RSU patients, but this was not significant on pooled analysis or after adjusting for age.

NHS resource use

Hospitalisation data are presented here because of their clinical relevance; other aspects of NHS care are presented in Chapter 6.

Table 25 shows the hospitalisations, number of hospitalisations, length of stay and hospitalisation reasons for all relevant patients in the study and for the subgroup of patients who had been dialysing continuously at the MRU or RSU over the year prior to the study visit.

TABLE 25 *Hospitalisations in the previous year*

	MRU	**RSU**	***p***
All patients:			
Hospitalisation: patients hospitalised [*N* (%)]	153 (48)	141 (38)	0.006
Missing [*N* (% of total patients)]	16 (5)	19 (5)	
Hospitalisation reasons [*N* (%)]			
Access related	61 (26)	62 (29)	
Access formation	42 (18)	40 (19)	
Renal (investigations, other)	14 (6)	29 (13)	
Cardiac or vascular	23 (10)	14 (7)	
GI/liver	25 (11)	12 (6)	
Infection (not access related)	30 (13)	19 (9)	
Other	31 (16)	40 (19)	
Length of stay (days)			
Total per patient [N, mean (SD)]	316, 4.7 (11.9)	369, 3.6, (8.3)	0.142
Median (IQR)	0 (4.0)	0 (2.0)	0.010
Mean per hospitalisation [*N* mean (SD)]	150, 5.5 (7.3)	135, 6.1 (7.2)	0.452
For those who were hospitalised:			
Number of hospitalisations [*N* (%)]			
1	85 (56)	87 (62)	0.487
2	47 (31)	32 (23)	
3	11 (7)	11 (8)	
4–8	10 (7)	11 (8)	
Patients with 1 year at MRU/RSU:			
Hospitalisation: patients hospitalised [*N* (%)]	93 (50)	85 (38)	0.020
Hospitalisation reasons [*N* (%)]			
Access related	39 (27)	45 (32)	
Access formation	20 (14)	19 (13)	
Renal (investigations, other)	7 (5)	21 (15)	
Cardiac or vascular	14 (10)	10 (7)	
GI/liver	21 (14)	6 (4)	
Infection (not access related)	19 (13)	10 (7)	
Other	26 (18)	31 (22)	

continued

TABLE 25 *Hospitalisations in the previous year (cont'd)*

	MRU	RSU	*p*
Length of stay (days)			
Total per patient [*N*, mean (SD)]	187, 4.6 (10.6)	219, 4.5, 9.8	0.889
Median (IQR)	0 (4.0)	0 (2.0)	0.065
Mean per hospitalisation [*N*, mean (SD)]	93, 5.5 (7.3)	82, 7.1 (8.1)	0.164
For those who were hospitalised:			
Number of hospitalisations [*N* (%)]			
1	52 (56%)	48 (57%)	0.394
2	29 (31%)	23 (27%)	
3	7 (8%)	4 (5%)	
4–8	5 (5%)	10 (12%)	

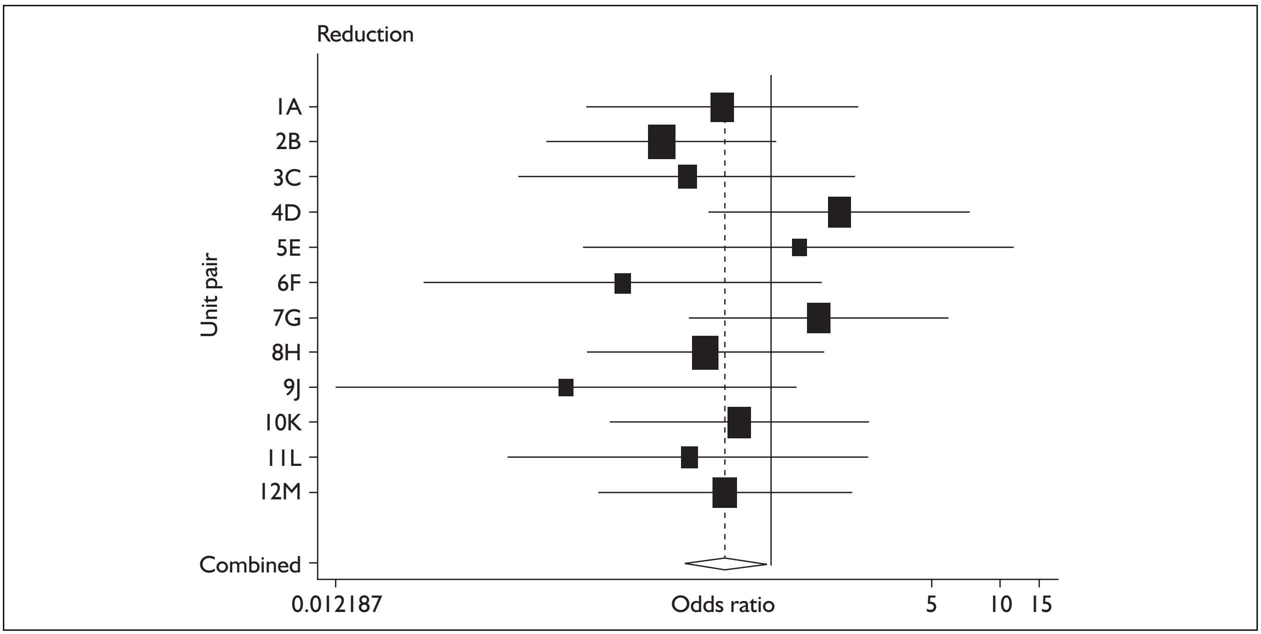


FIGURE 12 *Forest plot of whether hospitalised for patients in the units for over 1 year*

Overall a lower proportion of patients in the RSU than MRU group were hospitalised. This remained significant after calculating the pooled estimate (OR 0.67, 95% CI 0.49 to 0.91, $p = 0.011$). *Figure 12* shows a Forest plot for patients in the units for over 1 year. The number of hospitalisations per patient, total length of stay and patients' mean length of stay were comparable between the RSU and MRU groups.

The majority of hospitalisations (46%) were related to access (infection, access failure/formation, etc.). A further 9% of hospitalisations were for renal-related reasons. There were no obvious differences between the RSU and MRU groups. The findings were similar when analysis was restricted to patients who had attended the unit for at least 1 year.

Some 37% of all patients dialysed for <1 year and there was no significant difference between the MRU and RSU groups in this proportion. These patients were comparable across the MRU and RSU groups in terms of time attending the unit (mean 6.2 versus 6.7 months respectively, $p = 0.134$) and duration on renal replacement therapy (mean 2.7 versus 3.2 years, $p = 0.374$).

Figure 12 shows the Forest plot of whether or not patients were hospitalised for those with 1 year at MRU/RSU. 'Reduction' represents the reduction in hospitalisations in RSUs compared with the paired MRUs. Overall, the odds of hospitalisation were significantly lower in RSUs than MRUs. The estimated pooled (combined) OR was 0.63 (95% CI 0.41 to 0.96, $p = 0.032$).

Patients with long total length of stay (>40 days)

The data for people with a long total length of stay (over an arbitrary threshold of 40 days) were investigated to see whether there were any obvious patterns. There were only nine cases, five from MRUs and four from RSUs. Four patients had non-renal reasons for admission and the remaining five patients had a mixture of renal complications (including the need for new access formation) and other admissions, although two of these patients were hospitalised predominantly for renal-related reasons.

Patients with multiple admissions (≥4 per year)

The data for people with multiple admissions (over an arbitrary threshold of four or more per year) were investigated to see whether there were any obvious patterns. There were 21 cases, 10 from MRUs and 11 from RSUs. In five cases the patients had both multiple admissions and long total lengths of stay. Seven patients had all-renal-related admission reasons, including access-related (five from RSUs and two from MRUs). Six patients were hospitalised predominantly for renal-related reasons (four from RSUs and two from MRUs). Five patients had a mixture of non-renal-related admissions and renal complications (two from RSUs and three from MRUs). In three MRU patients, no admission reasons were available.

Quality of life

KDQOL and SF-36 data are shown in *Tables 26* and *27*. There were no significant differences between the two groups on any dimension of the KDQOL except 'patient satisfaction', 'dialysis staff encouragement' and 'sexual function' scales. The first two remained significant on pooled analysis.

Some patients had insufficiently complete data to calculate the SF-36 component scores. There was no significant difference in the PCS or MCS scales between RSU and MRU patients with age, gender or any measure of co-morbidity. Similarly, there were no differences between the groups in either the SF-36 physical or mental component summary scores. All these findings held even when account was taken of the unit clustering (pooled estimate), restricting analysis to patients on HD for >3 months, and after adjusting for age.

Figure 13 shows a Forest plot of the KDQOL 'patient satisfaction' item. 'Lower' represents a = lower mean score in RSUs compared with the paired MRUs unit. Overall, patients in RSUs were significantly more satisfied than MRU patients; the pooled (combined) estimate of mean satisfaction score difference was 7.50 (95% CI 1.33 to 13.67, $p = 0.017$).

EQ-5D

Table 28 shows the patients' HRQoL measured using EQ-5D utilities off dialysis, EQ VAS scores on and off dialysis and the difference between the

TABLE 26 *KDQOL results [N, mean (SD)]*

	MRU	RSU	*p*
Burden of kidney disease	281, 34.48 (27.83)	330, 37.26 (28.35)	0.223
Quality of social interaction	281, 75.59 (18.72)	329, 76.65 (18.50)	0.484
Cognitive function	275, 79.12 (18.24)	326, 77.63 (20.74)	0.355
Symptom/problem list	279, 71.97 (17.98)	332, 72.05 (18.88)	0.96
Effects of kidney disease	278, 59.79 (22.70)	334, 62.88 (24.33)	0.107
Sexual function	80, 77.81 (27.34)	70, 68.21 (30.22)	0.043
Sleep	279, 56.91 (21.43)	332, 57.69 (18.92)	0.634
Social support	277, 72.02 (27.74)	329, 75.12 (26.71)	0.162
Work status	276, 27.72 (37.44)	322, 24.84 (33.55)	0.323
Patient satisfaction	280, 70.36 (23.66)	330, 78.33 (21.46)	0.000
Dialysis staff encouragement	279, 82.08 (23.26)	328, 87.46 (17.31)	0.001

TABLE 27 *SF-36 results – physical and mental component summary scores [N, mean (SD)]*

	MRU	RSU	*p*
SF-36 physical score	204, 34.10 (11.27)	231, 34.12 (11.31)	0.989
SF-36 mental score	204, 46.37 (11.76)	231, 47.98 (11.52)	0.152

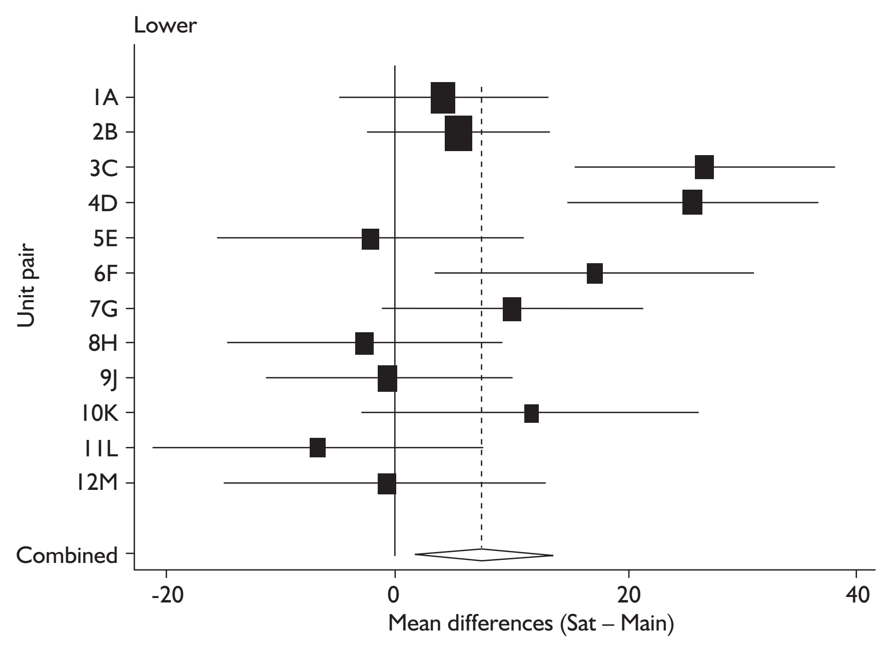


FIGURE 13 *Forest plot of the KDQOL 'patient satisfaction' item*

TABLE 28 *Health-related quality of life (EQ-5D)*

	MRU	**RSU**	***p***	**Pooled estimate RSU – MRU (95% CI)**
EQ-5D utilities off dialysis				
N, mean (SD)	269, 0.60 (0.28)	314, 0.60 (0.31)	0.979	0.01 (–0.04 to 0.06)
Median (IQR)	0.69 (0.32)	0.69 (0.28)	0.821	
EQ VAS on dialysis				
N, mean (SD)	269, 58.93 (19.76)	313, 59.33 (19.06)	0.804	0.19 (–2.96 to 3.33)
Median (IQR)	60 (20)	60 (26)	0.820	
EQ VAS off dialysis				
N, mean (SD)	269, 59.83 (18.18)	314, 58.79 (19.58	0.509	–1.10 (–4.14 to 1.94)
Median (IQR)	60 (20)	60 (26)	0.679	
Difference between off and on dialysis (EQ VAS) [*N*, mean (SD)]	266, 0.82 (14.02)	311, –0.27 (10.36)	0.286	–0.62 (–2.57 to 1.3)

latter. Patients' HRQoL was not significantly different between the MRU and RSU groups for any of these outcomes.

Table 29 shows the comparisons of the renal and UK population norms[76] for EQ-5D utilities and EQ VAS scores. *Figures 14* and *15* present these data by age group.

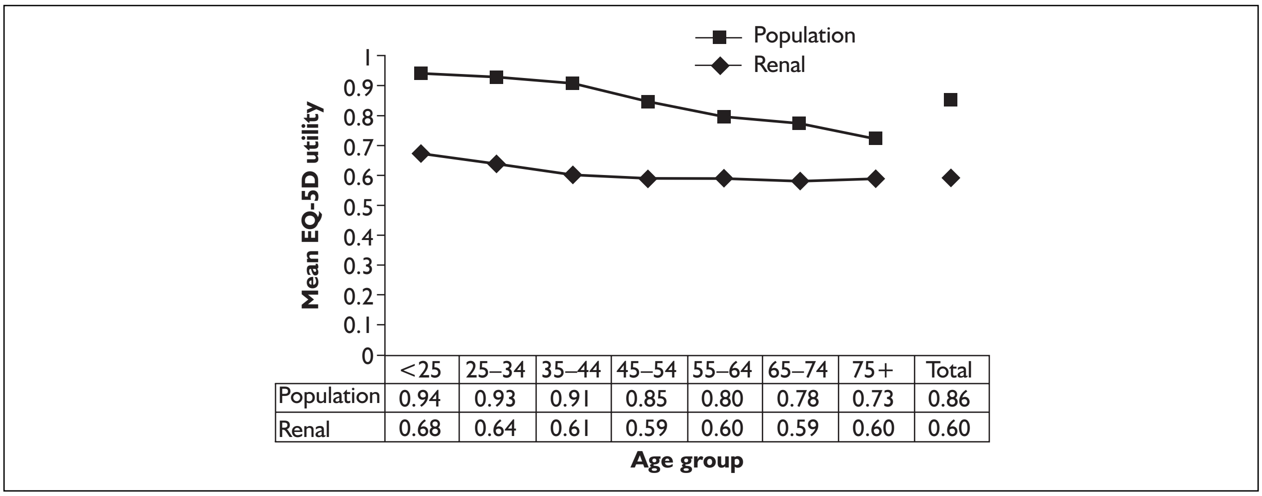
From *Table 29*, it can be seen that the renal dialysis patients had significantly lower EQ-5D utilities and EQ VAS scores than the UK population norms. This was also the case for each age group, as shown in *Figures 14* and *15* ($p < 0.001$ at every age group). EQ-5D utilities and EQ VAS scores for the UK population decreased with age. However, for renal dialysis patients the EQ-5D utilities only decreased in the younger age groups (up to 45 years) and then were stable, and EQ VAS scores were stable across age groups.

The EQ-5D utilities were examined to see whether factors (e.g. age) appeared to be influencing the data. As expected, the EQ-5D utilities (off dialysis) were not normally distributed, but negatively skewed as good health equated to a score of 1.0 [mean (SD) 0.60 (0.29), median (IQR) 0.69 (0.28); see *Figure 16*].

The following factors were poorly correlated (coefficient <0.2) with EQ-5D utilities: age, total weekly dialysis time, URR (as an indicator of the quality of dialysis) and duration on RRT.

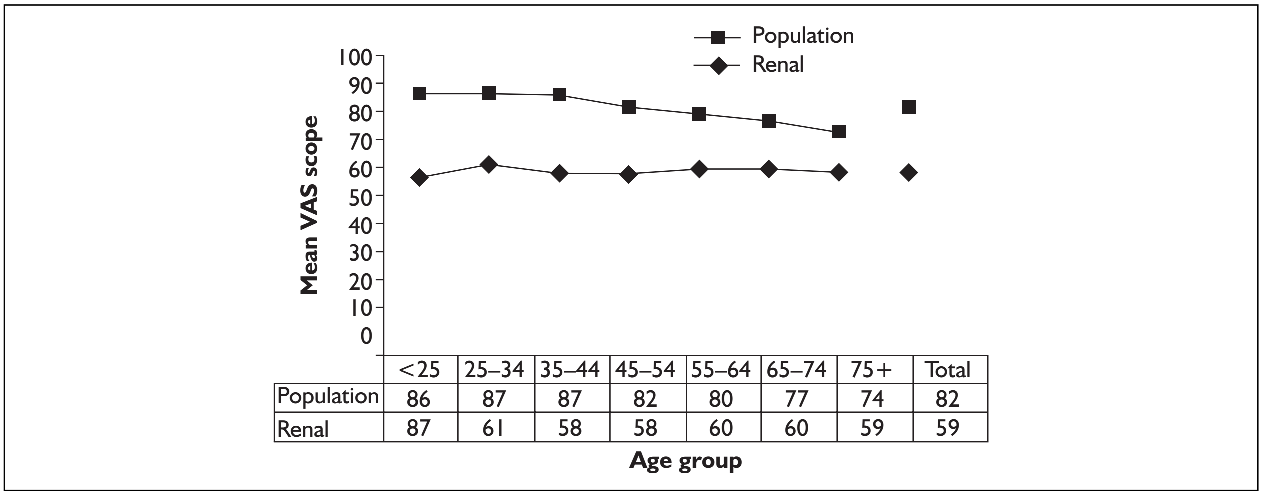
TABLE 29 *Comparison of EQ-5D data for renal dialysis patients and UK population norms [*N*, mean (SD)]*

	Renal patients	**Population norms**	**Mean difference (patient – population) (95% CI)**	***p***
EQ-5D utilities off dialysis	583, 0.60 (0.29)	3392, 0.86 (0.23)	–0.26 (–0.28 to –0.24)	<0.001
EQ VAS scores off dialysis	583, 59 (19)	3378, 82 (17)	–23 (–25 to –22)	<0.001



	<25	25–34	35–44	45–54	55–64	65–74	75+	Total
Population	0.94	0.93	0.91	0.85	0.80	0.78	0.73	0.86
Renal	0.68	0.64	0.61	0.59	0.60	0.59	0.60	0.60

FIGURE 14 *EQ-5D utilities for renal dialysis patients and UK population norms by age*



	<25	25–34	35–44	45–54	55–64	65–74	75+	Total
Population	86	87	87	82	80	77	74	82
Renal	87	61	58	58	60	60	59	59

FIGURE 15 *EQ-5D VAS scores for renal dialysis patients and UK population norms by age*

There were no significant differences between EQ-5D utilities and the groups defined by gender, ethnicity (Caucasian compared with other), living arrangements (i.e. alone or with others), dialysis frequency, blindness (although this only affected a small number of patients, $n = 17$) and dialysis type (i.e. HD or HDF).

EQ-5D utilities were significantly higher for those who left education at 16–18 years old compared with those who left before 16 years old [median (IQR) 0.69 (0.30) and 0.62 (0.41), respectively, $p = 0.009$]. EQ-5D utilities were significantly higher for those who owned at least one car compared with those who did not own a car [median (IQR) 0.69 (0.30) and 0.66 (0.45), respectively, $p = 0.037$]. Unsurprisingly, EQ-5D utilities were significantly lower for patients who were assessed as dependent (required assistance) compared with those who had 'normal' activity as assessed by the KPS [median (IQR) 0.59 (0.46) and 0.69 (0.30), respectively, for KPS >80 and <80, respectively, $p < 0.001$). As expected, wheelchair users reported lower EQ-5D utilities than non-users [median (IQR) 0.37 (0.40) and 0.69 (0.28), respectively, $p < 0.001$].

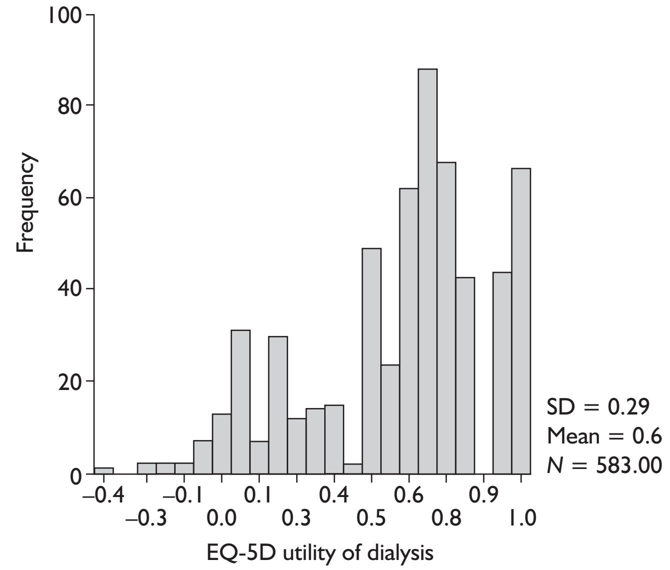


FIGURE 16 *Distribution of EQ-5D utilities (off dialysis)*

TABLE 30 *EQ-5D utilities by co-morbidity scores*

	N	**EQ-5D utilities: median (IQR)**
Wright/Khan Index		
Low risk	201	0.69 (0.22)
Medium risk	184	0.65 (0.28)
High risk	161	0.64 (0.47)
Lister/Chandna Score		
None	280	0.69 (0.30)
Mild/moderate	201	0.66 (0.25)
Severe	65	0.62 (0.49)
Modified Charlson Co-morbidity Index		
Low (≤ 3)	343	0.69 (0.30)
Moderate (4–5)	125	0.62 (0.47)
High (6–7)	49	0.62 (0.50)
Very high (≥ 8)	29	0.69 (0.46)

In terms of co-morbidity, *Table 30* shows the EQ-5D utilities by the three scoring systems. EQ-5D utilities were significantly higher for patients at low compared with high risk on the Wright/Khan Index ($p = 0.005$); and for patients with no compared with severe co-morbidity on the Lister/Chandna Score ($p = 0.003$). Patients scoring low compared with moderate or high scores on the Modified Charlson Co-morbidity Index also had higher EQ-5D utilities ($p = 0.018$ and 0.034, respectively).

Patient satisfaction

Table 31 shows the percentage response of individual patients in the MRU and RSU for questions on satisfaction with the care they receive in their dialysing unit. Those questions found to show statistically significant differences between RSU and MRU patients are highlighted in bold. There are significant differences in favour of the RSU in time to discuss problems, communication about the treatment, the design and atmosphere of the units and the continuity of patients dialysing together.

Major adverse events in RSUs

Table 32 summarises the data received from a 6-week prospective study of major adverse events occurring on dialysis undertaken in the RSU patient group. Adverse events records were

TABLE 31 *Patient satisfaction questionnaire*

	MRU		**RSU**		
Question	**Yes**	**%**	**Yes**	**%**	***p***
I have a good relationship with my consultant	244	90.4	288	89.7	0.793
I have a good relationship with the dialysis nurses	272	97.1	322	98.8	0.151
I feel safe dialysing in this unit	269	97.1	316	97.8	0.573
I am confident in the nurses' ability to deal with emergencies	265	96.4	316	97.2	0.546
There is usually enough time to discuss my problems with the nurses	**229**	**83.9**	**302**	**93.8**	**<0.001**
It is easy to arrange to see a doctor who knows me well at short notice	187	69.8	237	76.0	0.094
There are enough opportunities to discuss my problems with my consultant	185	69.3	221	72.2	0.441
Dialysis staff tell me as much as I want to know about my kidney failure/dialysis treatment	**238**	**86.2**	**309**	**96.0**	**<0.001**
Renal staff tell me as much as I want to know about my medical condition and treatment	**236**	**85.5**	**306**	**95.0**	**<0.001**
My regular medications are delivered without a problem	251	93.0	282	92.5	0.817
Delivery of an extra/emergency supplies of medication is easily arranged at short notice	228	89.1	272	90.4	0.613
It is easy to arrange to see a social worker at my request	176	75.9	178	71.5	0.277
It is easy to arrange to see a dietician at my request	233	87.9	275	89.9	0.459
Dialysis limits my social life outside the dialysis unit	220	80.3	253	78.1	0.509
Dialysis limits social life of my partner/carer	141	62.7	153	57.3	0.227
Unit has friendly atmosphere	270	97.5	320	98.2	0.563
Unit atmosphere is calm and relaxing	**224**	**82.4**	**311**	**96.0**	**<0.001**
Unit is well designed	**201**	**75.3**	**269**	**85.7**	**0.002**
I would prefer more privacy when I dialyse	47	17.8	43	13.9	0.202
I dialyse with the same group of patients at each session	**235**	**87.0**	**319**	**98.5**	**<0.001**
I enjoy meeting other patients when I come for dialysis	249	90.9	306	94.2	0.126

TABLE 32 *Adverse events in RSU patients only (*n *= 394)*

	n		
Number of adverse events per patient [*N* (%)]	368	0:	138 (37.5)
		1:	93 (25.3)
		2:	62 (16.8)
		3:	33 (9.0)
		4:	16 (4.4)
		5:	8 (2.2)
		6:	9 (2.4)
		7:	3 (0.8)
		8:	3 (0.8)
		9:	1 (0.3)
		10:	0
		11:	1 (0.3)
		12:	1 (0.3)
Type of Adverse Event [*N* (%)]	551 events	Hypotensive episode	269 (48.8)
		Chest pain	7 (1.3)
		Cardiac dysrhythmia	3 (0.5)

continued

***TABLE 32** Adverse events in RSU patients only (n = 394) (cont'd)*

	n		
		Cardiac arrest call	1 (0.2)
		IV iron reaction	1 (0.2)
		Dialyser reaction	0
		Blood transfusion reaction	0
		Access problems interfering with dialysis	84 (15.3)
		Breathlessness	9 (1.6)
		Other	177 (32.1)
Impact on dialysis [*N* (%)]	538	None	419 (77.9)
		Stopped dialysis early	110 (20.5)
		Dialysis not started at RSU	9 (1.7)
Action taken [*N* (%)]	544	No action taken	502 (92.3)
		MRU contacted by telephone	18 (3.3)
		Patient sent to MRU	11 (2.0)
		Patient sent to other hospital	12 (2.2)
		999 called	1 (0.2)

***TABLE 33** Details of events requiring transfer from RSU to MRU*

Subject ID	**Type of adverse event**	**Frequency**	**Age (years)**	**Wright/Khan Index**
19	Hypotensive episode	1	52	Low
22	Chest pain	3	32	Medium
116	Other	1	62	–
165	Cardiac arrest call	1	35	Low
170	Cardiac dysrhythmia	1	75	–
	Breathlessness	1		
355	Access problems interfering with dialysis	1	45	Medium
674	Other	1	69	Medium
771	Access problems interfering with dialysis	1	49	Low
775	Other	1	65	Low
791	Other	1	40	Low
955	Other	1	28	Low
962	Other	4	40	Low
964	Access problems interfering with dialysis	4	22	Medium
1079	Other	1	35	Low

completed satisfactorily for 368 (93%) of the possible 394 patients. A total of 551 events were recorded. Of the 368 patients, 37.5% did not have a major adverse event on dialysis during the 6-week period. A further 40% had only one or two events in the given period. The maximum number of adverse events was 12, with one patient experiencing this number. Looking at the type of event, hypotensive episodes (defined for the purposes of the study as a drop in blood pressure requiring fluid resuscitation) accounted for 50% of those recorded. One-third of the events were classed as 'other' and there is no further information on the nature of these. Access problems interfering with dialysis accounted for 15% of adverse events. In over 20% of the events the dialysis had to be stopped early or was not started; this was about 1.8% of all dialysis sessions in this period in all the RSU patients. In 23 episodes the patient had to be transferred to the MRU; there was no consistent pattern of age, co-morbidity or reason for these episodes (see *Table 33*).

Analysis of satellite characteristics

We compared the following types of satellite unit on various baseline and outcome measures: private versus NHS; DGH versus non-DGH site; and medical input versus no medical input on a weekly basis.

Table 34 shows that NHS units were more likely to have a higher degree of dependence, better

TABLE 34 *Comparison of satellite units – NHS versus private*

	NHS (n = 9 units)	Private (n = 3 units)	p
Age (years) [*N*, mean (SD)]	272, 62.36 (15.7)	122, 62.76 (16.8)	0.819
Wright/Khan Index [*N* (%)]			
Low	78 (30.4)	30 (27.5)	0.738
Medium	93 (36.2)	44 (40.4)	
High	86 (33.5)	35 (32.1)	
KPS [*N*, mean (SD)]	270, 77.04 (14.40)	122, 80.82 (14.23)	0.016
Normal activity [*N* (%)]	172 (63.7)	88 (72.1)	0.102
Require assistance [*N* (%)]	98 (36.3)	34 (27.9)	
URR [*N*, mean (SD)]	266, 70.16 (7.21)	118, 69.05 (7.91)	0.178
≤65 [*N* (%)]	48 (18.0)	24 (20.3)	0.595
>65 [*N* (%)]	218 (82.0)	94 (79.7)	
Pre-systolic (mmHg) [*N*, mean (SD)]	251, 146.09 (24.52)	122, 154.50 (23.30)	0.002
Pre-diastolic (mmHg) [*N*, mean (SD)]	251, 75.72 (12.97)	122, 83.07 (12.90)	< 0.001
Post-systolic (mmHg) [*N*, mean (SD)]	250, 132.48 (23.84)	122, 145.09 (23.03)	< 0.001
Post-diastolic (mmHg) [*N*, mean (SD)]	250, 72.92 (11.95)	122, 79.27 (12.55)	< 0.001
SF-36 mental score [*N*, mean (SD)]	167, 47.77 (11.60)	64, 48.52 (11.39)	0.660
SF-36 physical score [*N*, mean (SD)]	167, 34.22 (10.90)	64, 33.85 (12.40)	0.825
Hospitalisation			
Admitted [*N* (%)]	101 (39)	40 (35)	0.404
Total length of stay (days):			
[*N*, mean (SD)]	254, 3.8 (8.4)	115, 3.2 (8.0)	0.521
Median (IQR)	0 (3)	0 (2)	0.442
Hepatitis B [*N* yes (%)]	5 (1.9)	–	0.033
Hepatitis C [*N* yes (%)]	3 (1.2)	2 (1.8)	0.637
Haemoglobin (g/dl) [*N*, mean (SD)]	271, 11.39 (1.74)	121, 11.48 (1.48)	0.632

TABLE 35 *Comparison of satellite unit location: DGH versus non-DGH*

	DGH (n = 7)	Non-DGH (n = 5)	p
Age (years) [*N*, mean (SD)]	205, 64.91 (14.8)	189, 59.85 (17.0)	0.002
Wright/Khan Index [*N* (%)]			
Low	41 (22.2)	67 (37.0)	0.008
Medium	76 (41.1)	61 (33.7)	
High	68 (36.8)	53 (29.3)	
KPS [*N*, mean (SD)]	203, 77.14 (15.43)	189, 79.37 (13.23)	0.128
Normal activity [*N* (%)]	121 (59.6)	139 (73.5)	0.004
Require assistance [*N* (%)]	82 (40.4)	50 (26.5)	
URR [*N*, mean (SD)]	198, 69.63 (7.04)	186, 70.02 (7.87)	0.614
≤65 [*N* (%)]	36 (18.2)	36 (19.4)	0.769
>65 [*N* (%)]	162 (81.8)	150 (80.6)	
Pre-systolic (mmHg) [*N*, mean (SD)]	202, 147.46 (23.79)	171, 150.47 (25.10)	0.236
Pre-diastolic (mmHg) [*N*, mean (SD)]	202, 75.47 (13.61)	171, 81.27 (12.44)	0.000
Post-systolic (mmHg) [*N*, mean (SD)]	201, 133.98 (24.59)	171, 139.72 (23.62)	0.023
Post-diastolic (mmHg) [*N*, mean (SD)]	201, 71.95 (12.17)	171, 78.59 (11.94)	0.000

continued

TABLE 35 *Comparison of satellite unit location: DGH versus non-DGH (cont'd)*

	DGH (n = 7)	**Non-DGH (n = 5)**	***p***
SF-36 mental score [*N*, mean (SD)]	114, 48.06 (11.32)	117, 47.90 (11.76)	0.915
SF-36 physical score [*N*, mean (SD)]	114, 33.17 (10.32)	117, 35.04 (12.17)	0.211
Hospitalisation			
Admitted [*N* (%)]	68 (35)	73 (40)	0.330
Total length of stay (days):			
N, mean (SD)	190, 3.2 (7.0)	179, 4.0 (9.5)	0.343
Median (IQR)	0 (2)	0 (2)	0.413
Hepatitis B [*N* yes (%)]	4 (2.2)	1 (0.5)	0.143
Hepatitis C [*N* yes (%)]	4 (2.2)	1 (0.5)	0.215
HIV	0	0	
Haemoglobin (g/dl) [*N*, mean (SD)]	203, 11.30 (1.64)	189, 11.54 (1.69)	0.151

TABLE 36 *Comparison of satellite units – medical input or not*

	No input (n = 6)	**Some input (n = 6)**	***p* (weighted)**
Age (years) [*N*, mean (SD)]	165, 60.19 (17.2)	196, 64.28 (15.1)	0.017
Wright/Khan Index [*N* (%)]			
Low	50 (32.1)	53 (29.6)	0.762
Medium	55 (35.3)	70 (39.1)	
High	51 (32.7)	56 (31.3)	
KPS [*N*, mean (SD)]	164, 75.30 (14.24)	196, 79.85 (14.72)	0.003
Normal activity [*N* (%)]	98 (59.8)	136 (69.4)	0.056
Require assistance [*N* (%)]	66 (40.2)	60 (30.6)	
URR [*N*, mean (SD)]	164, 69.07 (7.55)	189, 70.02 (7.03)	0.223
$\leq$65 [*N* (%)]	35 (21.3)	35 (18.5)	0.507
$>$65 [*N* (%)]	129 (78.7)	154 (81.5)	
Pre-systolic (mmHg) [*N*, mean (SD)]	165, 145.13 (22.36)	176, 152.21 (25.70)	0.007
Pre-diastolic (mmHg) [*N*, mean (SD)]	165, 78.05 (13.36)	176, 78.39 (13.22)	0.815
Post-systolic (mmHg) [*N*, mean (SD)]	165, 136.38 (22.73)	175, 139.25 (25.46)	0.274
Post-diastolic (mmHg) [*N*, mean (SD)]	165, 76.39 (13.10)	175, 74.68 (12.12)	0.212
SF-36 mental score [*N*, mean (SD)]	98, 48.25 (11.56)	112, 47.60 (11.72)	0.685
SF-36 physical score [*N*, mean (SD)]	98, 33.20 (11.43)	112, 35.15 (11.35)	0.216
Hospitalisation			
Admitted [*N* (%)]	64 (41)	69 (36)	0.308
Total length of stay (days):			
N, mean (SD	154, 3.5 (7.6)	188, 3.5 (8.3)	0.960
Median (IQR)	0 (2)	0 (2)	0.329
Hepatitis B [*N* yes (%)]		1 (0.6)	0.263
Hepatitis C [*N* yes (%)]	1 (0.6)	3 (1.7)	0.626
HIV	0	0	
Haemoglobin (g/dl) [*N*, mean (SD)]	165, 11.40 (1.56)	195, 11.25 (1.72)	0.399

TABLE 37 *Patient travel road network times and distances to RSU and MRU*

	MRU patients		RSU patients	
Travel to usual dialysis unit	***N***	**Median (25–75th quartiles)**	***N***	**Median (25–75th quartiles)**
Distance (km)	333	14.0 (7–27)	389	14.6 (9–23)
Journey time (min)	333	22 (12–36)	389	22 (14–32)
Saving for RSU patients over journey to MRU				
Distance (km)		n.a.	389	18 (7–28)
Journey time (min)		n.a.	389	16 (7–29)

n.a., not applicable.

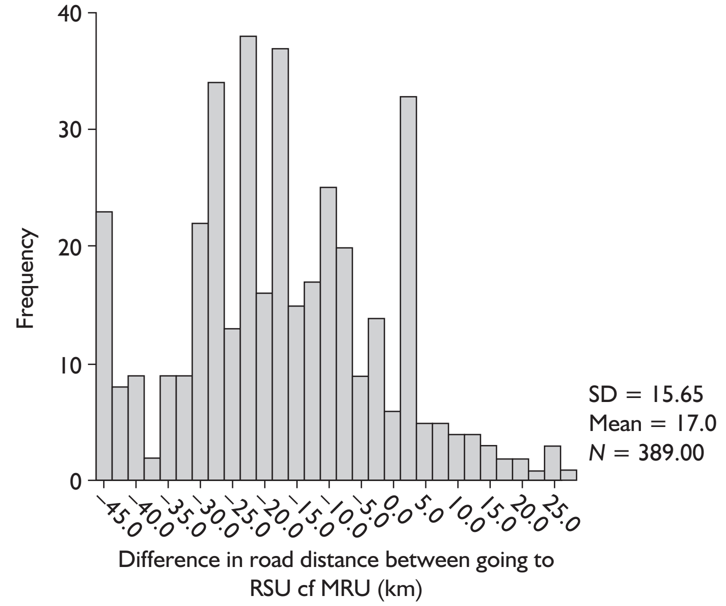


FIGURE 17 *Distribution of road travel distance potentially saved for RSU patients*

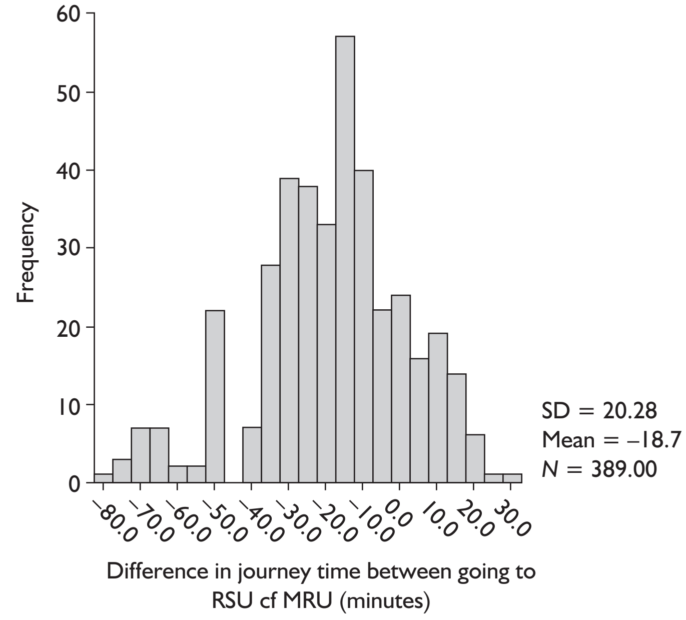


FIGURE 18 *Distribution of road travel time potentially saved for RSU patients*

control of blood pressure and some excess of hepatitis B patients (although numbers were small). There were no differences in dialysis adequacy or QoL.

Table 35 shows that patients in DGH units tended to be older and to have greater co-morbidity and dependence. There were no outcome differences except lower blood pressure in the DGH units.

Table 36 shows that the only difference on comparing medical versus no medical input was the older age of the patients in the RSUs with some medical input.

Patient travel times and distance

Table 37 shows the patients' distance and travel time to their usual dialysis unit. RSU patients had a median journey of 14.6 km or 22 minutes to reach their RSU. This was a mean saving of 17 km or 19 minutes over travel to the MRU (*Figures 17* and *18*; note effects are negative, indicating a saving for RSU patients).

The sample of MRU patients had a similar distance and time to travel for HD (see *Figures 19* and *20*), reflecting the fact that most lived in urban areas near the MRU, and in effect used the MRU as their local satellite unit.

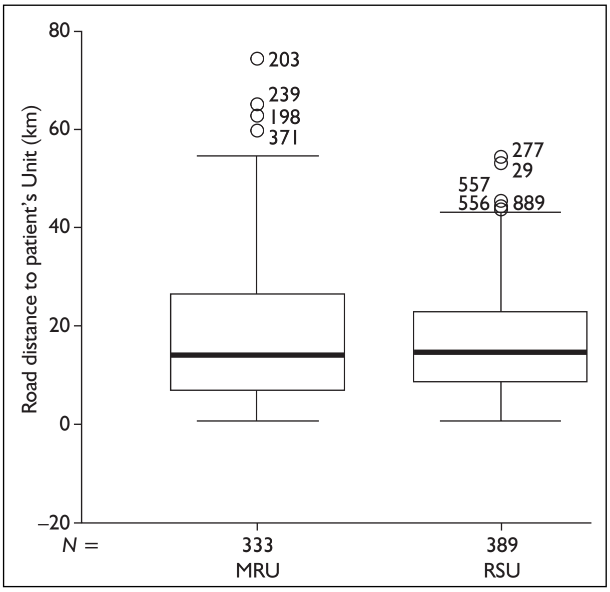


FIGURE 19 *Comparison of road distances to regular HD unit for RSU and MRU patients*

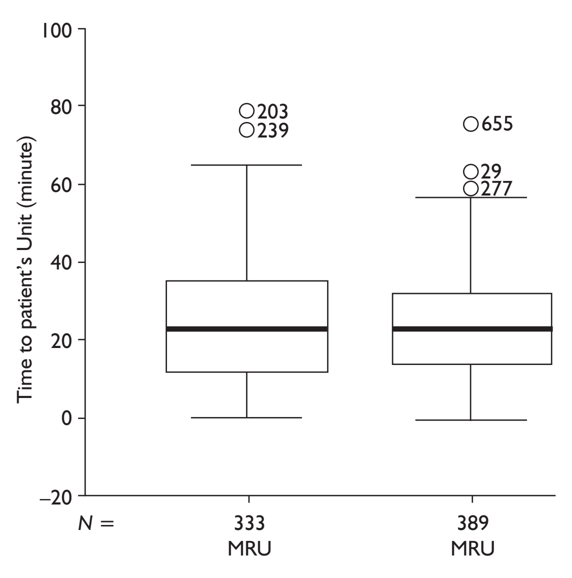


FIGURE 20 *Comparison of road time to regular HD unit for RSU and MRU patients*

Chapter 6

Cost results

Appendix 12 sets out the relevant denominators associated with each of the cost measures presented in this section. In some cases, these vary from the denominators presented earlier in the report as here we have used all available patient data rather than selected patient subgroups. For example, the earlier presentation of EPO doses was only for patients who had been on HD for at least 3 months.

Healthcare sector resources

Description of unit capacity and workload

Tables 38 and *39* describe capacity and workload of each RSU and MRU pair in relation to a number of aspects: maximum number of dialysis stations available for HD patients; mean hours each unit opens per day; provision of evening dialysis; type of patients treated (case mix); patient workload at the time of the study visit; and the potential number of patients who can be treated weekly. As described in Chapter 4, outlier chronic HD patients were also included.

The number of dialysis stations available within units varied from a minimum of five to a maximum of 26. In all but one case (unit A2), the RSU had a smaller number of stations than its MRU counterpart and eight RSUs (units C2, D2, E2, G2, H2, J2, L2 and M2) had half, or less than half, of the number of stations of their MRU counterpart. In addition to dialysis stations within the unit, four of the 12 MRUs (units A1, B1, C1 and F1) accommodated 'outlier' patients, although staffing for these was by renal ward staff in two cases (units A1 and H1). Further analyses include outlier patients staffed by the chronic HD unit as part of the total.

The mean number of hours units opened ranged considerably. The MRUs tended to be open for longer hours. All the MRUs were open for an average of at least 13 hours per day (e.g. 7 a.m. to 8 p.m.). In contrast, only six of the RSUs (units A2,

TABLE 38 *Unit capacity*

Unit code: MRU/RSU	Maximum No. of dialysis stations available		MRU outlier patients (staff)	Mean hours open per day		No. of days unit provides evening dialysis[a]	
	MRU	RSU	MRU	MRU	RSU	MRU	RSU
A1/A2	13	15	Yes (ward)	19.0	13.0	Most	None
B1/B2	20	16	Yes (unit)	15.5	14.5	Most	Most
C1/C2	11	5	Yes (unit)	16.0	10.0	Most	None
D1/D2	22	11	No	15.7	15.0	Some	Some
E1/E2	12	5	No	15.3	11.0	Most	None
F1/F2	20	15	Yes (ward)	16.0	12.0	Most	None
G1/G2	22	8	No	15.4[b,c]	13.3	Most	Some
H1/H2	26[b]	12	Yes (n.a.)	13.1[b,c]	14.5	Some[d]	Some
J1/J2	16	8	No	18.0	14.0	Most	Some
K1/K2	n.a.	n.a.	No	n.a.	n.a.	n.a.	n.a.
L1/L2	20	10	No	14.0	7.4	Most	None
M1/M2	25	10	No	24.0[b,c]	11.8	Most	None
Min.	11	5	–	13.1	7.4	–	–
Max.	26	16	–	24.0	15.0	–	–

n.a., not available.

[a] Most = 5–7 days open per week; some = typically 3 days per week; none = no evening sessions.

[b] Includes acute HD patients.

[c] Open 7 days per week (as opposed to 6 days per week).

[d] Had evening dialysis, but only two people dialysed per day.

TABLE 39 *Unit workload*

Unit code: MRU/RSU	Case mix[a]		No. of patients at end of month of study visit		Typical No. of potential patients (including outliers, %) per week	
	MRU	RSU	MRU	RSU	MRU	RSU
A1/A2	0	0	70	60	63	60
B1/B2	1	0	149	96	167 (28)	95
C1/C2	1, 2	0	65	20	74 (12)	20
D1/D2	1, 2	1	n.a.	45	59	52
E1/E2	2	0	69	20	72	20
F1/F2	1	0	89	60	96	60
G1/G2	1	1	n.a.	40	147	40
H1/H2	1, 2	1	85	n.a.	71	60
J1/J2	2	0	85	39	98	39
K1/K2	2	0	n.a.	n.a.	n.a.	n.a.
L1/L2	2	0	108	25	114	25
M1/M2	2	0	n.a.	n.a.	131	40
Min.	–	–	65	20	59	20
Max.	–	–	149	96	167	95
Mean	–	–	90	45	99	46
Median	–	–	85	40	96	40

n.a., not available.

[a] Case mix codes: 0 = only chronic HD patients treated; 1 = chronic HD patients and others requiring minor supervision (e.g. home HD training); 2 = chronic HD patients and others requiring major supervision (e.g. acute HD).

B2, D2, G2, H2 and J2) were open similar hours and the minimum was approximately seven hours per day (unit L2). Three MRUs (G1, H1, M1) were open 7 days per week (M1 was open 24 hours), whereas all the other units opened 6 days per week. Two MRUs (units D2 and H2) opened for evening dialysis for 3 days per week, whereas the remaining MRUs were open most evenings (i.e. 5–7 days per week). By comparison, six RSUs (units A2, C2, E2, F2, L2 and M2) did not provide evening dialysis sessions, four RSUs (units D2, G2, H2 and J2) provided evening sessions about thrice weekly and one RSU (unit B2) was open most evenings.

Chapter 4 described some of the challenges of measuring capacity and workload. All the RSUs and four MRUs (units A1, B1, F1 and G1) reported a case mix that was either caring only for patients on chronic HD or, if there were other patients, these were both small in number and required minimal supervision. Typically, such additional patients attended the RSU for home HD training or respite care, plasma exchange or HD breaks from peritoneal dialysis. Often such patients only attended for short periods (e.g. a couple of weeks). This meant that they could be assumed low marginal resource users and would not distort the average cost of caring for chronic HD patients. In the other eight MRUs (units C1, D1, E1, H1, J1, K1, L1 and M1), the case mix of units was more complex as care was also given to a more acutely ill group of patients as part of the typical workload. At any one time, the number of acute HD patients treated in these units could vary from between one and 12 patients per month. These additional patients were likely to be high marginal resource users, but it was not possible to decompose different resource use patterns for the two groups of patients.

Additional care is usually required for patients with infections, particularly hepatitis (B or C), HIV and MRSA. Hence another factor that affected comparability between units was the way infection control issues were managed. For example, where data were available for the month of the study visit (16 units), the majority of units had no patients with hepatitis B, but the maximum number was three patients. Similarly, most units did not have any patients with hepatitis C, although the maximum number managed at one time was four patients. Patients with HIV were uncommon, but patients with MRSA could be expected in most units (typically ranging from one to five patients, although one unit had 12 patients at the time of the study).

Units operated different acceptance policies for patients with infections. MRUs were much more likely than RSUs to treat people with infections such as hepatitis B or C or MRSA. Two MRUs and seven RSUs would not accept patients with Hepatitis B (units E1, H1, A2, C2, D2, E2, G2, H2 and M2); no MRUs but six RSUs would not accept patients with hepatitis C (units C2, D2, E2, G2, H2 and M2). Two MRUs (units E1 and H1) and nine RSUs (units A2, C2, D2, E2, F2, G2, H2, L2 and M2) would not accept patients with HIV. Patients with MRSA were accepted by all units except two RSUs (D2 and M2).

Within these acceptance policies, there were huge variations in the way in which such patients were nursed. In some units, patients were isolated from the remaining patients and dialysis machines could be restricted for use by individual patients. Overall, the number of patients with these infections was generally small. Clearly, such policies affected the way in which resources were used and hence available dialysis capacity required some adjustment, but measurement was not possible.

An important way of comparing workload was to examine the number of patients treated at a point in time. The number of patients treated at the end of the month of the study visit ranged from a minimum of 20 patients (unit C2) to a maximum of 149 patients (unit B1). In every case, the MRU treated more patients than its corresponding RSU and the mean number of patients treated at RSUs was approximately half that of MRUs. Data were unavailable for six units for a variety of reasons. Two units (D1 and G1) experienced difficulty in separating MRU workload and four units (K1, K2, M1 and M2) did not produce data within the study timescale.

Another way to compare the capacity of units considers the typical number of patients per week who can be accommodated with the stations and sessions available. In order to calculate this measure, we used the information on typical patients per station per day and stations available each day. The potential number of patients who could be treated weekly varied. Within RSUs, the weekly capacity for treating patients ranged from 20 to 95 patients and within MRUs from 59 to 167 patients. Comparison between RSU/MRU pairs showed that RSU capacity ranged from 22 to 95% of that of the MRUs. Where outlier patients were cared for by the unit staff (units B1 and C1), these comprised 42 (28%) and eight (12%) patients, respectively. The numbers of outlier patients cared for by renal wards staff at units F1 and A1 were 16 and variable (unknown), respectively.

By comparing actual patients treated and potential capacity within units, it appeared that all RSUs were working at or close to capacity. Only D2 had substantial spare capacity. The reason why most appeared stretched could be that if RSU patients dialyse elsewhere for prolonged periods, many RSUs temporarily take a replacement from the MRU. The capacity of MRUs was more varied: two were over-capacity (A1 and H1) and six operated within 13% of full capacity (B1, C1, E1, F1, J1 and L1). However, whereas it might be expected that units C1, E1, J1 and L1 would operate at lower capacity to allow some slack for the unpredictability of acute dialysis, unit H1's over-capacity did not follow this pattern.

Routine dialysis

RSU capital

Table 40 presents descriptive information on RSU capital (i.e. the site allocated for RSU activity).

TABLE 40 *Description of RSU capital*

RSU unit code	Ownership of RSU service	Site/type of RSU building	Approx. floor area (m^2)	Estimated annual rental cost (2000–01) (£)	Date opened
A2	NHS	DGH[a]	340	25308	1995
B2	NHS	Not DGH[b]	357	45000	1992
C2	NHS	DGH[a]	300	19400	1996
D2	Private	Not DGH[a]	120	33020	1996
E2	NHS	DGH[a]	225	16364	1989
F2	Private	DGH[a]	473	n.a.	1998
G2	NHS	DGH[a]	375	50874	1997
H2	Private	Not DGH[a]	525	n.a.	1990
J2	NHS	Not DGH[a]	277	n.a.	1979
K2	NHS	DGH (n.a.)	n.a.	n.a.	n.a.
L2	NHS	DGH[a]	230	n.a.	1998
M2	NHS	Not DGH[a]	n.a.	n.a.	~ 1991

n.a., not available.
[a] Adapted existing building
[b] Purpose-built building.

It can be seen that all the RSUs except one (unit B2) were built from existing buildings and four RSUs were located away from DGH sites (units B2, D2, H2 and J2). The services provide by three RSUs were privately managed (units D2, F2 and H2), but in all cases NHS Trusts owned the capital. The designation as a DGH or non-DGH site related to whether acute medical/surgical services were available (see Chapter 4). The size of units varied (approximate floor area ranged from 120 to 525 m^2) and a number were well established, five units having been open for at least a decade (units B2, E2, H2, J2 and M2).

Rental cost information supplied by Trust Finance Departments was incomplete and the quality of available information poor. This was partly due to local accounting practices varying markedly and the fact that data could not be deconstructed into the relevant components (i.e. capital charges, rates and overheads) to make consistent comparisons. Hence, although rental cost per square metre of floor space varied considerably, it is not possible to attribute reasons for this.

Equipment – dialysis machines

In *Table 41*, descriptive information pertains to a central piece of renal dialysis equipment, the dialysis machine.

It can be seen that where information was available, the stock of dialysis machines varied greatly across units. The age of the oldest machine (as assessed in April 2002) ranged from 2 to 13 years. There seemed to be no particular pattern as to whether MRUs or RSUs had a stock of predominantly newer machines. For example, units E1 and E2 both had machines that were ≤ 8 years old and the oldest machines for units B1 and B2 were 12 and 13 years, respectively. Typically the machines were expected to last 5–10 years, so it appeared that the majority of units held a substantial stock of 'out-of-date' machines, particularly at units B1, B2, C1, J1 and J2.

The total number of dialysis machines available at MRUs and RSUs varied from 19 (unit E1) to 59 (unit M1) and from seven (unit E2) to 22 (unit F2), respectively. The number of dialysis machines per station indicates an aspect of the relative efficiency of machine use in different units. This varied from 0.8 to 2.4 across MRUs, but had a slightly smaller range across RSUs (0.9 to 1.6). The majority of MRUs (eight) had greater numbers of machines per station than their RSU. On the one hand, we might have expected RSUs to hold greater numbers of machines given that technicians were

TABLE 41 *Dialysis machines*

Unit code: MRU/RSU	Age of oldest machine (at April 2002) (years)		Total number of dialysis machines		Dialysis machines per station		Profiling[a] used on dialysis	
	MRU	RSU	MRU	RSU	MRU	RSU	MRU	RSU
A1/A2	9	6	24	18	1.8	1.2	All	All
B1/B2	12	13	30	18	1.5	1.1	Majority	Majority
C1/C2	10	6	20	8	1.8	1.6	Majority	None
D1/D2	7	n.a.	37[b]	10	1.7	0.9	Majority	All
E1/E2	8	8	19	7	1.6	1.4	All	All
F1/F2	2	n.a.	21	22	1.1	1.5	All	Minority
G1/G2	n.a.	n.a.	37	11	1.7	1.4	n.a.	n.a.
H1/H2	n.a.	n.a.	22	14	0.8	1.2	All	All
J1/J2	13	11	38	9	2.4	1.1	Majority	n.a.
K1/K2	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
L1/L2	n.a.	n.a.	61[c]		2.0[c]		2.0	2.0
M1/M2	n.a.	n.a.	59	12	2.4	1.2	n.a.	n.a.
Min.	2	6	19	7	0.8	0.9	–	–
Max.	13	13	59	22	2.4	1.6	–	–
Mean	–	–	31	13	1.7	1.3	–	–
Median	–	–	27	12	1.7	1.2	–	–

n.a., not available.

[a] Majority ≥ 50%; minority < 50%.

[b] Includes all acute HD, but relative workload unknown.

[c] Machines shared between MRU and RSU – average across both units as not possible to attribute to either accurately (excluded from calculations of minimum, maximum, mean and median)

not on-site to maintain machines. This was true of two (of the three) privately run RSUs (F2 and H2). On the other, one might expect that the technicians would keep a large pool of machines at the MRU to substitute across any of the sites if problems arose. This appeared to be more likely for NHS run units. The figure for unit pair L represents an average of the dialysis machines across all the stations since the machines were shared across the two units. However, the data were excluded from the ranges as the assumption of equal use may not have been true and would have markedly affected the RSU figures.

In addition, as described in Chapter 4, it was not possible to measure how dialysis capacity should be adjusted to reflect differing infection control policies and workload. Although in many instances it was difficult to attribute the relative workload between chronic and acute dialysis, the data suggest that some units could make better use of dialysis machines.

The majority of the MRU dialysis machines were suitably sophisticated to have some profiling capability (usually sodium profiling and/or ultrafiltration were available on at least 50% of a unit's machines). Two of the RSUs (units C2 and F2) had no such facility or had less than half the stock of machines equipped for profiling. Information on profiling capability of machines was not available for nine units, leaving the picture somewhat incomplete. *Table 42* shows a range of costs of dialysis machines available in the units and the impact that profiling modules had within these costs. Due to the sensitivity of pricing information, this has been anonymised and averaged across the three manufacturers (namely Baxter/Althin, Fresenius and Gambro/Cobe). The sensitivity analysis was based on a best/worst estimate of a dialysis machine cost. From the table it can be seen that equivalent annual costs might range from just over £1000 to nearly £6000. The narrower cost range for the renal unit data is slightly misleading as it was based on only 13 machines from the many available. The annual dialysis machine cost per patient was broadly comparable across the two settings. It should be noted that the exclusion of unit pairs with missing data led to figures that were more similar (£684 and £667 for MRUs and RSUs, respectively).

Staffing and staff cover

Table 43 reports the arrangements made for medical cover at RSUs along with some important contextual information.

Although it was expected that medical cover at RSUs would be minimal, in practice medical cover arrangements, although intermittent, could also be substantial. Five RSUs had no routine renal medical staff cover (units A2, D2, E2, H2 and M2) and two had regular visits from a variety of medical grades once or twice per week (units C2 and J2). The remaining four RSUs had medical cover for most weekdays. The nature of the medical workload was also variable, depending, for example, on whether the same staff provided renal outpatient services at the RSU site. Half of the RSUs reported renal outpatient clinics at the host hospital site (units B2, C2, D2, G2, J2 and L2). Five of these units had medical cover (i.e. unit F2 had medical cover but no outpatients clinics at the RSU). A sixth RSU (unit D2) had renal outpatients but no medical cover within the unit.

TABLE 42 *Unit costs of dialysis machines (2000/2001) and annual costs per patient*

		Purchase cost (£)		Equivalent annual cost (£)		Maximum additional cost for profiling on	
Dialysis machine	**Useful life (years)**	**Min.**	**Max.**	**Min.**	**Max.**	**Purchase cost (£)**	**Equivalent annual cost (£)**
Renal units	7	10000	14350	2034	2918	2850	580
Sensitivity analysis	5	7000	20000	2020	5772	–	–
	7	7000	20000	1424	4067	–	–
	10	7000	20000	1029	2940	–	–
Cost per patient	**No. of units**	**Mean**	**Min.**	**Max.**			
MRU	10	715 (684)[a]	408	1023			
RSU	10	644 (667)[a]	430	908			

[a] Values in parentheses = excluding unit pairs with missing data.

TABLE 43 On-site renal medical staff cover arrangements for RSUs

RSU unit code	Non-DGH	Average medical staff hours provided on-site	Off-site renal medical staff cover	Renal outpatients at RSU	Journey between MRU/RSU	
					Minutes one way	Medical staff time cost (2000–01) (return journey) (£)[a]
A2		None	GP RSU's host A&E Department and resuscitation team	No	60	–
B2	Yes	19 h/week Associate specialist	Call-out staff from MRU	Yes	25	11.30 (Associate specialist)
C2		5.3 h/week[b] Associate specialist or junior doctor[b]	RSU's host on-site medical cover (emergencies)	Yes	30–40	8.28 –18.08 (SHO – Associate specialist)
D2	Yes	None	Call-out staff from MRU	Yes	45–60	–
E2		None	Call-out staff from MRU	No	10	–
F2		14 h/week Staff grade	None	No	30	10.19 (Staff grade)
G2		32 h/week Consultant[c]	Call-out staff from MRU RSU's host resuscitation team	Yes	45	27.53 (Consultant)
H2	Yes	None	None	No	30–40	–
J2	Yes	5 h/week[b] Consultant	GP	Yes	35–40	21.41–24.47 (Specialist Registrar – Consultant)
K2		n.a.	n.a.	No	n.a.	–
L2		Daily (hours n.a.) Consultant and Specialist Registrar	None	Yes	45	14.14 –27.53 (Specialist Registrar – Consultant)
M2	Yes	None	RSU's host A&E Department	No	30	–
						Min: 16.56 Max: 55.06 Mean: 36.20

n.a., not available.

[a] Excludes actual travel cost (e.g. petrol allowance as this varies by NHS Trust and car capacity).

[b] Only 1–2 days per week.

[c] Medical cover includes outpatient clinics.

Should the nursing staff at RSUs need to call on medical support at times when cover was not directly available, they could do so using a number of alternative arrangements. All units had the options of calling the 999 emergency service if needed, making arrangements for the patient to be transferred to the MRU or speaking with a medical colleague at the MRU to discuss the patient's condition and follow-up actions. Additional on-site medical cover was also provided in some units using a variety of other services, although five RSUs were non-DGH sites (see Chapter 4) and therefore had no acute medical/surgical service available. Three RSUs had no additional arrangements (units F2, H2 and L2). However, in an emergency, four RSUs could also call out the MRU medical staff (units B2, D2, E2 and G2) and two (units A2 and J2) could call out the patient's GP. Two of these previous units (A2 and G2) also had the option to use either their host hospital's resuscitation team or Accident and Emergency Department. A further two RSUs (units M2 and C2) used their host hospital's Accident and Emergency Department or duty medical team.

For any face-to-face medical contact at RSUs, whether routinely arranged or unplanned, additional journeys were incurred by staff. Journey times between the RSU and its respective MRU provided an indication of one aspect of the additional time cost and varied from around 10 to 60 minutes with a majority of journeys being around 30–45 minutes one way. There was no apparent association between journey times and provision of on-site medical care. The estimated cost of medical staff travel time varied from £16.56 to £55.06 per return journey. However, since several patients can be seen at each visit, this additional expenditure may reflect a more efficient use of resources than paying for NHS transport to take individual patients to the MRU.

The following two tables focus on nursing staff. *Table 44* reports nursing staff WTE numbers and skill mix. These data comprise both trained nurses and support staff (HCAs or similar). Trained nurses are subdivided as senior (i.e. nurse grade F or above) or junior (i.e. below nurse grade F) staff.

The table differentiates between WTEs for staff in-post at the time of the study visit and the WTE establishment numbers (i.e. places funded). The first half of the table presents data on WTE numbers in-post. The number of WTE nursing staff can be expected to vary across units owing to different workload capacities. As expected given their typically lower capacity, the RSUs had fewer staff than MRUs (mean 12.1 and 26.1 WTEs for RSU and MRU, respectively, range 4.8–31.0 and 12.2–47.0 WTE, respectively). *Table 45* standardises data for unit size by presenting nursing staff cost per available dialysis session.

TABLE 44 *Nursing staff (trained and HCAs)*

	In-post									
	Total WTE nursing staff[a]		**Percentage senior:junior trained nurses**[b]		**Percentage trained nurses**		**Percentage vacancies WTE trained nurses**		**Percentage vacancies WTE HCAs**	
Unit code: MRU/RSU	**MRU**	**RSU**	**MRU**	**RSU**	**MRU**	**RSU**	**MRU**	**RSU**	**MRU**	**RSU**
A1/A2	14.7	13.5	27	25	76	66	18	5	32	12
B1/B2	47.0	31.0	62	47	37	39	6	0	0	14
C1/C2	12.2	4.8	11	5	92	66	12	0	0	0
D1/D2	22.2	10.4	31	n.a.	52	68	18	26	0	0
E1/E2	19.8	4.8	16	21	65	100	0	0	0	0
F1/F2	17.6	15.0	82	27	32	73	20	0	8	0
G1/G2	29.3	11.5	44	23	63	77	29	20	23	16
H1/H2	20.8	12.5	19	22	74	74	0	6	0	0
J1/J2	38.0	9.7	19	21	80	92	0	0	0	0
K1/K2	19.0	n.a.	38	n.a.	68	n.a.	13	n.a.	0	n.a.
L1/L2	32.0	11.4	21	23	59	75	17	0	19	0
M1/M2	40.3	8.5	18	29	67	81	7	0	18	33
Min.	12.2	4.8	11	5	32	39	6	5	8	12
Max.	47.0	31.0	82	47	92	100	29	26	32	33
Mean	26.1	12.1	32	24	64	74	16	14	20	19
Median	21.5	11.4	24	23	66	74	17	13	19	15
Grand mean	19.4		29		69		15		19	
Grand median	15.0		23		68		17		18	

n.a., not available.

[a] Includes trained nurses and HCAs.

[b] Senior = Grade F or above; junior = Grade E or below.

It can be seen from *Table 44* that the proportion of senior to junior trained nurses ranged from 11 to 82% at MRUs and from 5 to 47% at RSUs. The most common pattern of skill mix used was observed in 14 units where ~20–30% of nurses were senior grades but other skill mixes were observed. Three units (C1, C2 and E1) used between 5 and 16% of senior nurses and five units (B1, B2, F1, G1 and K1) used a more senior structure (more than ~40% of nurses of senior grades).

The proportion of senior staff in-post was also examined to see whether it was within 10% of the establishment. Sixteen units were within this limit, but four units (A2, D1, K1 and M1) had senior level vacancies of > 10%. Vacancies at junior level increased the proportion of senior nurses by > 10% in two units (F1 and G2). After considering this, the maximum proportion in the MRU group was reduced from 82% in-post to 66% for establishment. The wider variation in senior staff at the MRUs compared with the RSUs may be due to a number of factors. For example, it may reflect historical staffing patterns, higher grading to retain staff or a different patient case mix.

The percentage of trained nurses of the nursing total also varied widely from 32 to 100%. The trained staffing percentage was slightly higher at the RSUs than the MRUs (means 74 and 64%, respectively). None of the units' corresponding establishment figures differed by more than ~10% from their in-post equivalent staffing, implying that the impact of vacancies was less for HCAs than trained nursing staff.

It is particularly difficult to comment on differences in skill mix across units and within RSUs and MRUs. One reason is that no common set of job descriptions was in place for HCAs and their role varied considerably across and within units. So, for example, in some units these staff, at particular grades, could connect patients to dialysis machines or insert and remove needles. At other units or grades this was not permitted. Obviously, the way in which such staff are used has an impact on the demand for trained nurses. Furthermore, at one unit pair, HCAs assisted the renal technicians and had additional responsibility for cleaning dialysers for re-use (although the latter practice is now being abandoned).

The staffing issue is complex. There did not appear to be a relationship between units' staffing (overall, by senior/junior or by trained/HCAs) and in terms of their broad case mix. However, for the reasons discussed in Chapter 4, it was not possible to adjust for this quantitatively.

The last four columns in *Table 44* present the proportion of vacant WTE funded posts. In-post staffing could vary considerably from the intended establishment; for example, vacancies ranged between 5 and 29% for trained staff and between 8 and 33% for HCAs. There appeared to be differences between the MRUs and RSUs in terms of the trained staff vacancies; nine MRUs (units A1, B1, C1, D1, F1, G1 K1, L1 and M1) had vacancies compared with four RSUs (units A2, D2, G2 and H2). For these units, the majority of MRUs (80%, $n = 7$) but only half of the RSUs ($n = 2$) had more than 10% WTE vacant. For seven units (five MRUs, A1, F1, G1, L1 and M1, and two RSUs, A2 and G2), there were both trained staff and HCA vacancies. However, although some units were operating at a lower nursing level than desired, it was not clear whether this simply reflected difficulties in recruiting nursing staff.

The way in which units calculated their establishment staffing was investigated. This was important because units may be staffed in a number of ways, for example by using bank or agency nurses instead of regular staff to cover leave. As these may have an impact on different budgets, simply using the salary scales may not be comparable in all cases. It was found that establishment staffing levels at all units covered annual leave, the majority covered study leave and sickness, few covered maternity leave, but the allowances differed. Typically, staffing WTE were increased by 18–23% above the minimum shift requirements, but varied as to whether they were allocated by grade or across the total staff. In some cases the allowance was lower (6–12% extra) and in other cases the time to cover leave was calculated directly as WTE. Only one unit pair simply increased the staff budget (by 20%). Hence the previous routine staffing comparisons are partly a reflection of how the units set their establishment. Where leave is not covered by the establishment, additional payments may be incurred for overtime (via bank, agency or additional payments to the unit's staff).

Two other categories of staff were typically found in all the MRUs: administrative and clerical staff, and technicians responsible for maintaining dialysis equipment (see Chapter 4). Six of the RSUs (units A2, B2, D2, G2, H2 and J2) were able to identify dedicated administrative and clerical staff time. Whereas the NHS RSUs received technician cover from their parent MRU, the three private RSUs (units D2, F2 and H2) had separate arrangements with the private company that managed the unit.

Table 45 reports total nursing staff costs per dialysis session and per year. This shows the mean cost of nursing staff per dialysis session presented as basic pay and with unsocial hours payments (i.e. for night-time hours, Saturdays, Sundays and Bank holidays). For basic pay, it can be seen that the mean cost per dialysis session varied from ~£18 to ~£52, with no systematic pattern emerging for MRUs or RSUs. For five unit pairs (A, B, C, E and H), the RSU basic cost per dialysis session was within ~20% of the MRU cost. However, for three pairs (F, G and L), the MRU cost was approximately two-thirds that of its paired RSU. Conversely, two MRUs (units J1 and M1) had costs that were 30–50% more than their RSU counterpart. In one RSU (D2), a private unit, it was not possible to perform costing because the nursing grades were kept as confidential information. The reasons why costs appeared to vary by more than threefold could not be investigated further, but is partly a function of the complex staff issue as mentioned earlier.

Unsocial hours payments were important to investigate since units' opening hours vary and hence could impact differently across each unit's staffing costs. The payment rates for unsocial hours were typically 30% extra for nights and Saturdays and 60% extra for Sundays and Bank holidays, or within 10% more than this. There was only slight variation in terms of the period during which night rates were incurred. The majority of hospitals paid unsocial hours to a maximum F grade rate. In practice, unsocial hours payments did not appear to impact significantly on the mean cost per dialysis session, adding only

TABLE 45 *Mean cost of nursing staff (trained and HCAs) in-post per dialysis session and annually per patient*

	Nursing staff cost per dialysis session (2000–01)				**Unsocial hours pay as a percentage of basic pay (%)**	
	Basic pay (£)		**Basic pay plus unsocial hours (£)**			
Unit code: MRU/RSU	**MRU**	**RSU**	**MRU**	**RSU**	**MRU**	**RSU**
A1/A2	26.89	24.55	30.54	25.90	14	5
B1/B2	30.09	35.26	31.54	37.16	5	5
C1/C2	19.91	24.90	21.83	26.52	10	6
D1/D2	39.24	n.a.	42.22	n.a.	8	n.a.
E1/E2	28.80	29.49	31.48	32.00	9	8
F1/F2	17.62	28.45	19.32	29.54	10	4
G1/G2	22.93	34.63	25.64	n.a.	12	n.a.
H1/H2	28.67	23.74	n.a.	25.55	n.a.	8
J1/J2	44.27	30.45	47.06	32.93	6	8
K1/K2	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
L1/L2	30.41	51.64	31.80	52.95	5	3
M1/M2	33.41	25.30	36.76	27.33	10	8
Min.	17.62	23.74	19.32	25.55	5	3
Max.	44.27	51.64	47.06	52.95	14	8
Mean	29.29	30.84	31.82	32.21	9	6
Median	28.80	28.97	31.51	29.54	9	6
Grand mean	30		32		8	
Grand median	29		31		8	

	Nursing staff cost per patient per year[a]			
	No. of units	**Mean (£)**	**Min. (£)**	**Max. (£)**
MRU	10	4916 (4881)[b]	2538 (3014)[b]	7341
RSU	9	4831 (5154)[b]	3395 (4040)[b]	8260

n.a., not available.

[a] Including unsocial hours.

[b] Values in parentheses = excluding unit pair with missing data (if value different from using all data).

£1.09–3.65 per dialysis session. One explanation would be that staffing is reduced at night. In relative terms, the proportion of salary costs attributable to unsocial hours ranged from 3 to 14%, but was generally lower in the RSUs, probably owing to their more restricted opening times.

Overall, the mean nursing staff cost (including unsocial hours) per patient per year was comparable between the two settings. However, in this instance, whereas the cost was slightly greater for MRUs than RSUs when using all available data, this was reversed and the difference widened when only unit pairs with complete data were used (£4916 versus £4831 and £4881versus £5154 MRUs and RSUs in the respective analyses).

Drugs

EPO use was common and prescribed in similar quantities at the MRUs and RSUs (as shown in Chapter 5). *Table 46* shows the cost of EPO for the MRU and RSU patients. Similarly to the dosage data, cost data for EPO were skewed owing to a small number of people on high doses. The unit cost of EPO was £8.38 per 1000 IU.[91] However, the cost per patient was not significantly different between the MRU and RSU groups (mean difference £–2.45, 95% CI £–7.95 to £3.05, $p = 0.382$).

Transport arrangements

From *Table 47*, it can be seen that only two RSUs paid the transport costs for their dialysis patients (units H2 and J2). For the other RSUs these costs were paid by the MRU. The proportion of the study patients who used NHS transport varied from 24 to 76%. Overall, NHS transport was used significantly more by RSU than MRU patients [58 versus 48%, OR 1.46, 95% CI 1.06 to 2.01, $p = 0.021$; pooled estimate (fixed effect) 1.45, 95% CI 1.04 to 2.02, $p = 0.030$]. These findings may reflect easier access by MRU patients to public transport, patient preference in terms of convenience of driving for MRU patients or the fact that on average the RSU patients were slightly older. The distances and road travel times measured between the patient's home and renal service (MRU or RSU) are shown in Chapter 5.

One MRU (C1) and four RSUs (A2, C2, D2 and J2) never used private ambulances or taxis to transport patients to or from their dialysis sessions. However, for some of the remaining units, this transport incurred considerable expenditure over and above the hospital's block contract arrangement. Only five units (D1, D2, E1, E2 and J2) did not appear to experience problems with patient transportation. For the other units such problems were frequent. The main problems were difficulty in getting enough hospital car drivers, patients arriving late for their allocated slot and long waiting times for transport home. In one case, patients requiring ambulance transport could not be sent to the RSU. Another unit had problems because their catchment area was covered by several ambulance services.

It appears that dialysis patients do not pay a contribution towards NHS transport. However, from the data available (two-thirds of the units), there were discrepancies between units' reimbursement policies for patients' out-of-pocket transport costs. This could affect demand for NHS transport. Only two units (B1 and B2) reimbursed public transport costs for all patients. A further 11 units only reimbursed patients who were in receipt of state benefits (e.g. income support) and three units did not reimburse patients at all. In terms of private car costs, one unit did not reimburse patients. A further 15 units did reimburse these expenses (e.g. at £0.09–0.15 per mile), although of these units eight only did so for patients on state benefits. Patients were not required to pay parking

TABLE 46 *Mean dose and cost of EPO*

	MRU	RSU	*p* value
EPO prescribed [N *(%)*]			
Yes	296 (88)	328 (83)	0.665
No	29 (9)	36 (9)	
Missing	10 (3)	30 (8)	
Per patient [N, *mean (SD)*]			
Mean total weekly dose (IU)	317, 6595 (4525)	351, 6777 (4429)	0.600
Cost per year (£)	317, 2879.18 (1973.19)	351, 2958.45 (1929.25)	0.600
Missing data[a]	18 (5)	43 (11)	

[a] Overall, for patients prescribed EPO ($N = 624$) dose and /or frequency missing for 21 (3%) patients.

TABLE 47 *Transport arrangements*

Unit code: MRU/RSU	**MRU pays RSU transport costs**	**NHS transport (% of study patients)**		**Use of private ambulance or taxi**		**Problems with transport[a]**	
		MRU	**RSU**	**MRU**	**RSU**	**MRU**	**RSU**
A1/A2	Yes	44	48	Yes	No	Yes	Yes
B1/B2	Yes	35	75	Yes	Yes	Yes	Yes
C1/C2	Yes	58	47	No	No	Yes	Yes
D1/D2	Yes	46	61	Yes	No	No	No
E1/E2	Yes	54	41	Yes	Yes	No	No
F1/F2	Yes	47	62	Yes	Yes	Yes	Yes
G1/G2	Yes	68	76	Yes	Yes	Yes	Yes
H1/H2	No	57	64	n.a.	n.a.	Yes	Yes
J1/J2	No	60	57	Yes	No	Yes	No
K1/K2	Yes	24	50	Yes	Yes	Yes	Yes
L1/L2	n.a.	50	35	Yes	Yes	Yes	Yes
M1/M2	Yes	58	64	n.a.	Yes	Yes	Yes

n.a., not available.

[a] e.g. lengthy waiting time for transport, lack of guaranteed arrival times, difficulties getting patients home after dialysis and use of private ambulance and/or taxis, etc.

TABLE 48 *Use of primary/social care*

	MRU	**RSU**	**Difference: MRU – RSU (95% CI)**	***p***
Seen by following staff in the last 4 weeks [*N* (%)]				
GP	79 (28)	110 (32)	1.25 (0.89 to1.77)[c]	0.199
District nurse	11 (4)	36 (11)	2.96 (1.48 to 5.93)[c]	0.002
Social worker	24 (8)	21 (6)	0.72 (0.39 to 1.32)[c]	0.287
Number of visits per patient in 1 year [*N*, mean (SD)]				
GP[a]	285, 4.5 (8.3)	340, 6.0 (12.2)	–1.4 (–3.0 to 0.2)[d]	0.087
District nurse[b]	285, 1.9 (14.0)	340, 4.7 (19.7)	–2.8 (–5.4 to –0.1)[d]	0.042
Social worker	286, 1.9 (7.3)	340, 1.1 (5.6)	0.8 (–0.2 to 1.8)[d]	0.131
Total cost of contacts per patient per year (£) [*N*, mean (SD)]				
GP[a]	285, 26.74 (49.02)	340, 35.07 (72.00)	–8.33 (–17.89 to 1.22)[d]	0.087
District nurse[b]	285, 11.80 (85.04)	340, 28.59 (119.93)	–16.79 (–32.95 to –0.64)[d]	0.042
Social worker	286, 80.77 (285.20)	340, 51.44 (221.51)	29.33 (–11.35 to 70.00)[d]	0.157

[a] Excluding one outlier (MRU patient) with 20 GP visits in previous 4 weeks as this seemed likely to have been a mistake in patient completion of the questionnaire.

[b] Excluding one outlier (MRU patient) with 28 district nurse visits in previous 4 weeks (i.e. daily). If correct, this was deemed unlikely to be due to renal reasons as the patient used a wheelchair and had other co-morbidity).

[c] Odds ratio.

[d] Mean difference.

charges at any of the units. This issue requires further investigation to determine whether reimbursement of all patients' out-of-pocket travel costs would be able to alleviate some of the transport problems encountered.

Other health and social care contacts

Community – use of primary/social care

Table 48 shows the percentage of patients who had at least one visit in the 4 weeks prior to the study visit from a GP, district nurse or social worker and the number and cost per year per patient for such visits.

Data on primary or social care visits were almost complete as virtually none of the patients had been at the MRU or RSU for < 1 month (0.6 and 0.3%, respectively). Significantly more people in the RSU group reported at least one district nurse visit in the previous 4 weeks and this remained significant for the pooled estimate (OR 1.94, 95% CI 1.05 to 3.59, $p = 0.034$). In contrast, a GP or social worker visit was equally likely in both settings.

Visits by a district nurse and their cost per year were both significantly higher for RSU than MRU patients. However, the more conservative pooled estimates were not statistically significant: the mean additional visits per patient per year was 1.38 (95% CI –0.10 to 2.87, $p = 0.068$) and the mean additional cost per patient per year was £8.43 (95% CI £–0.61 to £17.48, $p = 0.068$). These analyses excluded one outlier (an MRU patient) with 28 district nurse visits in the previous 4 weeks (i.e. daily). If correct, this resource use was deemed unlikely to be due to renal reasons as the patient used a wheelchair and had other co-morbidity. The number of GP or social worker visits and associated costs were similar between the two settings.

It should be noted that these contacts (particularly district nurse and social worker visits) were only applicable to a small number of the study patients and there was some concern about the sensitivity of the 4-week time frame to detect real contact differences. In addition, differences between any professional groups require cautious interpretation as they may simply reflect substitution of roles that need to be considered as a whole. RSUs appear to result in some shift of workload and costs from acute to secondary care. If resources do not follow this shift then this may have consequences out of all proportion to the cost identified.

Hospital – Use of secondary/tertiary care

Scheduled renal outpatient visits

In terms of renal outpatient visits there were two patient groups within each MRU/RSU setting, namely those at the time of the study who had attended the MRU or RSU for at least 6 months and those who attended for a shorter period. About 20 and 15% at the MRU and RSU, respectively, had not attended the unit for at least 6 months. However, results are presented here for all patients regardless of duration at the MRU or RSU.

Table 49 shows the number of patients who had more than three scheduled renal outpatient visits in the previous 6 months and total cost of scheduled renal outpatient visits per patient.

Less than one-fifth of patients had three or more scheduled renal outpatient visits in the previous 6 months. There were no significant differences between the MRU and RSU groups in the latter or cost of the scheduled renal outpatient visits. However, there were differences between some hospital pairs, for example the MRU M1 did not have specific outpatients clinics for its renal patients whereas its RSU did. Units E1 and E2 saw dialysis patients when they attended for dialysis session, not in outpatients.

However, scheduled renal outpatient visits are only a small part of the potential medical input for patients. As mentioned in Chapter 4, non-scheduled outpatients or emergency ward visits were not adequately captured as they were often not reported in the medical notes.

Hospitalisations

Table 50 shows the total cost of all hospitalisations and mean cost per hospitalisation for all relevant patients in the study and for a subgroup of patients who had been dialysing continuously at the MRU or RSU over the year prior to the study visit.

Results are presented separately for the two scenarios, that is, using the unit cost per inpatient day for specialities derived from the hospitalisation reason or assuming that all

TABLE 49 *Use of scheduled renal outpatient and associated costs*[a]

	MRU	RSU	Difference: MRU – RSU (95% CI)	*p*
Scheduled renal outpatient visits in previous 6 months [*N* (%)]				
Three or more	52 (19)	54 (16)	0.85 (0.56 to 1.30)[b]	0.459
Scheduled renal outpatient visits per patient per year				
N mean (SD)	278, 3.5, 2.2	329, 3.4, 2.2	0.1 (–0.3 to 0.4)[c]	0.659
Missing [*N*, (%)]	12 (4)	16 (5)		
Total cost (£) [*N*, mean (SD)]	278, 331.47 (208.28)	329, 323.98 (208.35)	7.49 (–25.84 to 40.82)[c]	0.659

[a] Note two unit pairs (E and M) were excluded from analysis as they did not hold outpatient clinics.
[b] Odds ratio.
[c] Mean difference.

TABLE 50 *Hospitalisation costs per patient (over previous year or since starting dialysis)*[a]

	MRU	RSU	Difference MRU – RSU[b] (95% CI)	*p* value
All patients				
Total cost of all hospitalisations (£)				
Scenario 1[c]				
N, mean (SD)	304, 1289 (3252)	359, 1026 (2423)	263 (–171 to 697)	0.234
Missing [*N* (%)]	31 (9)	35 (9)		
Scenario 2[c]				
N, mean (SD)	316, 1400 (3508)	369, 1065 (2446)	336 (–113 to 785)	0.142
Missing [*N* (%)]	19 (6)	25 (6)		
Scenario 1				
Mean cost per hospitalisation (per patient admitted) (£) [*N*, mean (SD)]	138, 1651 (2196)	125, 1823 (2110)	–171 (–695 to 353)	0.521
Patients with 1 year at MRU/RSU				
Total cost of all hospitalisations (£)				
Scenario 1				
N, mean (SD)	181, 1289 (2872)	215, 1280 (2840)	9 (–557 to 575)	0.975
Missing [*N* (%)]	12 (6)	15 (7)		
Scenario 2				
N, mean (SD)	187, 1369 (3126)	219, 1327 (2876)	42 (–544 to 628)	0.889
Missing [*N* (%)]	6(3)	11 (5)		
Scenario 1				
Mean cost per hospitalisation (per patient admitted) (£) [*N*, mean (SD)]	87, 1643 (2122)	78, 2124 (2399)	–481 (–1176 to 214)	0.174

[a] Effectiveness data (i.e. resource use) for length of stay, etc., shown in *Table 25*.
[b] Mean difference (95% CI).
[c] Scenario 1: using cost per inpatient days for specialities, derived from hospitalisation reason. Scenario 2: using cost per inpatient day on nephrology ward for all hospitalisations.

TABLE 51 *Patient time each dialysis session*

Time per patient	MRU	RSU	*p*	Pooled estimate RSU – MRU (95%CI)
Time waiting for transport to and from unit (minutes)				
N, mean (SD)	286, 39 (54)	340, 25 (31)	< 0.001	–13 (–25 to –0.6)[a]
Median (IQR)	15 (60)	13 (40)	0.045	
Journey time one way (minutes)[b]				
N, mean (SD)	277, 30 (18)	324, 25 (15)	0.001	–4 (–8 to –0.6)[a]
Median (IQR)	25 (25)	25 (15)	0.007	
Time per dialysis session (return journey, waiting and dialysis time) (hours)				
N, mean (SD)	251, 5.22 (1.13)	300, 5.03 (0.57)	0.001	–23 (–37 to –9)[c] minutes
Median (IQR)	5.10 (1.35)	4.59 (1.17)	0.004	

[a] Mean weighted difference (95% CI).
[b] Excluding people with any missing data (*N* = 68).
[c] Journey times are patient reported and therefore differ from those derived from the postcode analysis in *Table 37*.

hospitalisations were to a nephrology ward. The associated resource use was shown in Chapter 5.

There was no significant difference between the MRU and RSU groups in the total cost per patient of hospitalisations or mean cost per patient per hospitalisation. This applied to all patients or those at the unit for at least 1 year. As expected, the cost data were positively skewed with smaller median than mean costs.

TABLE 52 Summary of main cost results

Category	Main result (where relevant min. and max. estimates provided)[a]
Unit capacity and workload	
Capacity: Chronic HD stations, opening hours	Various arrangements in place
Workload: Unit casemix	Problems disaggregating chronic HD workload
Routine dialysis	
Capital: type and age of RSU facility provided	Mostly converted buildings. Approximately half of the units had been open > 10 years
Equipment and maintenance	
Dialysis machines	Equivalent annual cost £2034–2918 (plus up to an additional £580 per year for profiling) Mean dialysis machine cost per patient per year: MRU £684; RSU £667
Machine maintenance and water purification	Technicians' workload highly complex making attribution to chronic HD impractical. Wide variety of water purification systems and maintenance regimes in place
Staff	
Medical staff cover at RSUs	Various cover arrangements in place. Cost of medical staff time for return journey between MRU/RSU: £16.56–55.06
Nursing staff: trained and HCAs	Mean nursing staff cost per patient per year (basic pay plus unsocial hours): MRU £4881; RSU £5154
Drugs: EPO therapy (1 year)	Mean difference[b]: £–2.45 (£–7.95 to £3.05)
Transport: unit budget arrangements/issues and mode of patient travel	NHS transport used by approximately half of the patients (although more at RSU than MRU). Most units experience problems with NHS transport (e.g. late arrival)
Patient out-of-pocket expenses and time	
Patient out-of-pocket expenses	Reported by small numbers of patients (n = 75, 12%), most of whom incurred small expenses. Costs to patients for return journey: £1–15
Time waiting for transport to and from unit	Mean difference: –13 (–25 to –0.6) minutes
Journey time one way	Mean difference: –4 (–8 to –0.6) minutes
Time per dialysis session (return journey, waiting and dialysis time)	Mean difference: –23 (–37 to –9) minutes
Other health and social care contacts	
Community – Primary/Social care (1 year)	
GP consultation	Mean difference[b]: £–8.33 (£–17.89 to £1.22)
District nurse visit	Mean difference[b]: £–16.79 (£–32.95 to £–0.64)
Social worker	Mean difference[b]: £29.33 (£–11.35 to £70.00)
Hospital – secondary/tertiary care (1 year)	
Scheduled (routine) renal outpatients	Mean difference: £7.49 (£–25.84 to £40.82)
Hospitalisations (treatment for all illness, renal-related complications and procedures and co-morbidities)	Scenario 1[c] Mean difference[b]: £263 (£–171 to £697) Scenario 2[d] Mean difference[b]: £336 (£–113 to £785)

[a] Base year for resource use and unit costs: 2000/01.
[b] Mean difference = Mean difference (95% CI) between MRU and RSU (i.e. negative = 'saving' for MRU patients).
[c] Scenario 1: all patients, using cost per inpatient days for specialities, derived from hospitalisation reason.
[d] Scenario 2: all patients, using cost per inpatient day on nephrology ward for all hospitalisations.

Despite the fact that the proportion of patients hospitalised was greater in the MRU than the RSU group (48 versus 38%), this did not translate into a statistically significant budgetary impact.

Patients' out-of-pocket expenses and time

The number of people who reported they incurred out-of-pocket expenses because of their dialysis was small (n = 75, 12%) and there was no significant difference between the MRU and RSU groups. The cost to patients ($n = 36$) for a return journey (including parking but not petrol) ranged from £1 to £15, with a mean of £4.72. For 72% patients, the cost was ≤ £5.

Only 15 people (3%) said that a friend or relative accompanied them during dialysis. Conversely, whilst on dialysis, 38 people (6%) required a carer for their children, partner or a relative and, of these, 10 people (26%) paid the carer. For the majority of people (70%) this cost was < £10; the range per session was £1–£40, with a mean of £13.30.

For the people ($n = 31$) who recorded the costs they incurred for over-the-counter medicines due to dialysis, the majority (87%) paid ≤ £10 per week, but the costs ranged from £1 to £50, with a mean of £7.61. Other costs per week (e.g. food, alternative therapies) for 46 people ranged from £1 to £72 (mean £16.37). For this group, 50% paid ≤ £10 and 76% paid ≤ £20 per week.

Although only a small proportion of patients incurred costs, in some cases these were a considerable expense on a weekly basis.

Patient's time
Table 51 shows the patients' waiting times for transport to and from sessions, journey time and total patient time per dialysis.

Both the time waiting for transport to and from unit and journey times appeared to be less at RSUs than MRUs. Dialysis times per patient were shown in Chapter 5. The total duration of a patient's day in terms of time was examined by combining times that were transport-related (i.e. journey and waiting) and dialysis-related. The total patient time per dialysis session was longer by 23 minutes at MRUs than RSUs (95% CI: MRU time longer by 9 to 37 minutes).

Summary of main cost results

Table 52 summarises the main cost results from the study. These are for the cost categories that could be disaggregated or were potentially measurable, although they were measured over differing time frames. Other items were excluded for the reasons discussed in Chapter 4 (and shown in *Table 11*).

Chapter 7

Discussion

This study is the first major evaluation of the effectiveness and costs of renal satellite units compared with main renal units. It has provided evidence of similar effectiveness, if not better, for RSUs, and greater patient satisfaction and accessibility in RSUs. However, it is not a full cost-effectiveness analysis, for two main reasons. First, the assessment of effectiveness used was multidimensional and there was no single measure which could adequately represent the outcome of care. Second, there were pragmatic reasons which limited the extent to which full costing could be conducted. These reasons related principally to lack of comparability between units, study design and difficulties with data collection from units and variable accounting practices. It was necessary to revise the analyses and report key resource use, limited cost analyses and economic outcomes (EQ-5D). Nevertheless these data provide essential information to inform the design of a long-term study of cost-effectiveness of RSUs from the perspective of the health service sector and patients that could not have been appreciated without having conducted this study.

The major findings are summarised and the methodological strengths and weaknesses of the study are outlined. Finally, the implications for policy and research are presented.

Main findings

Renal unit and patient sample

The Phase 1 survey identified the considerable diversity in the organisation of RSUs throughout England and Wales. The sample in Phase 2 was representative in terms of location (both geographical and hospital site), private–public split and medical input. The response rate of eligible patients to joining the study and completing questionnaires was generally high, although non-responders had factors that might be associated with poorer outcome such as greater age and co-morbidity. Whereas these factors were similar between RSU and MRU samples, absolute values of QoL and clinical outcomes found in the study are more favourable than would occur for the whole dialysis patient population.

Organisation of RSUs and MRUs in Phase 2 study

Considerable variations were found in the organisation of and resources available to MRUs and RSUs. For example, none of the RSUs were purpose built. Most units opened 6 days per week, but RSUs had fewer dialysis stations available, treated fewer patients, were open for shorter periods of time and were less likely to provide evening sessions. Three-quarters of MRUs reported a complex mix of dialysis patients whereas most RSUs only cared for chronic HD patients. Units operated a range of acceptance policies for patients with infections such as hepatitis B. Overall, MRUs were more likely to have patients with viral infection.

Whereas RSUs appeared to operate closer to full capacity, this was somewhat artificial as MRUs' workload was more varied and had to allow for emergency workload including RSU patients. Dialysis machine utilisation varied, but not systematically by type of unit. Much of the dialysis machine stock was working beyond the recommended life, although it was sophisticated enough for patient profiling.

Renal medical staff cover provided at RSUs could be substantial but it was highly variable and raises questions of what level is appropriate. Those staff based at the MRU and visiting the RSU could expect an additional journey time of ~30–45 minutes one way. Whereas standard emergency medical arrangements existed for all RSUs (i.e. 999 service, MRU staff contact or transfer to MRU), additional options were tailored to suit local circumstances.

The WTE numbers of nurses and HCAs differed between types of unit owing to different capacities. The RSUs had fewer staff but differences in skill mix (i.e. grades and proportion of trained nurses) were difficult to interpret because job descriptions and roles were highly variable. Staff vacancies appeared to differ in part by MRU/RSU with a higher probability of nursing staff vacancies associated with MRUs.

With the exception of the private RSUs, which had separate arrangements, technicians were based at

MRUs. It proved too complicated to disentangle their workload across the settings. Their work across varying numbers of units, types of equipment and modalities impeded closer examination of technician activity.

Patients treated in RSUs and MRUs

RSUs deal with a diverse range of patients that includes a substantial proportion who are elderly and with co-morbidity and/or dependency (e.g. one-third had a high Wright/Khan Index, one-third were dependent as judged by the KPS and one in nine required a wheelchair). The mean age of RSU patients in the study was 62 years; this is the same as for UKRR prevalent patients on HD in 1999.[10] The proportion with diabetic ESRD in RSUs was 10% compared with the UKRR figure of 13%, probably reflecting the selectivity of RSUs in relation to co-morbidity and to different ethnic minority proportions.

RSUs then are clearly distinct from minimal care units at which patients dialyse themselves. Nevertheless, there is a group being treated at the MRUs who have particular problems, particularly cardiovascular instability on dialysis, which was deemed by senior nursing staff to preclude their treatment in RSUs. This proportion varied considerably between MRUs. This might reflect different interpretations of the concept of ‘suitability’, space pressures on the MRU and perceived capacity of the RSU in question to cope with more difficult patients. The number of such patients is set to increase as acceptance rates on to RRT rise to meet population need. If main units expand their satellite programme, the proportion of such difficult patients in MRUs will increase, raising issues of how services should be organised to cope with such patients and to what extent satellites can treat them.

Comparison of two groups

To evaluate the effectiveness and costs, we tried to recruit a comparable MRU patient group in the main unit. Despite attempts to match on age and gender, the MRU patients were younger, with a higher proportion from ethnic minorities, and were better educated than the RSU group. The age difference probably reflects the use of twilight shifts in the MRUs, which allow those in work to attend, and the higher proportions from ethnic minorities reflect the fact that MRUs are found in urban areas, which tend to have a higher concentration of ethnic minorities. Where possible we attempted to adjust for confounding by age and ethnicity in analyses. However, there was no difference in the level of co-morbidity or dependency between the groups and these are the major factors affecting clinical and patients’ self-reported outcomes.

Processes of care

The methods of dialysis and medication used were very similar between the two groups. This is perhaps not surprising given that clinical oversight of the RSUs was the responsibility of nephrologists in the linked MRUs. Apart from one pair of units, conventional HD was the most common form of HD.

Use of permanent vascular access was equal in both types and at 80% higher than that for UK units in the DOPPS study, although that study included both prevalent and incident patient.[22] The main aspect of relevance was the greater use of sodium profiling in RSUs. Although there is little direct evidence to support its use, it does allow for a tailored prescription of dialysis and gentler removal of solute, which may in turn reduce adverse events on HD. Such profiling was conducted largely under nurse supervision in the RSUs. There may have been more time to focus on patients’ intradialytic symptoms and to deal with them. The number of antihypertensive agents prescribed per patient may be indicative of the degree of fluid removal on HD and adequacy of dialysis; over 40% did not require such agents in the RSUs, although there was no significant difference compared with the MRUs.

Management of anaemia was similar in the two groups and the level was comparable with units on the UKRR. Drug costs for EPO were not differently distributed between MRUs and RSUs.

The use of GPs for prescribing was greater in the RSUs. Patients attending an MRU can have certain drugs sent from the hospital pharmacy; although this is possible in some RSUs, there is clearly more reliance on local primary care. For patients this means more visits to collect prescriptions; for the NHS there is a degree of cost shifting between renal services and primary care.

Clinical outcomes

To allow for early stabilisation of clinical parameters after starting HD, we presented data on patients on HD for > 90 days. There was a slightly higher percentage of patients who had newly started RRT in MRUs (i.e. < 90 days), reflecting the fact that patients were generally not transferred to an RSU until they had been stabilised.

TABLE 53 *Proportion of patients achieving the Renal Association Standards in RSUs and in UKRR units*

Clinical indicator of quality of dialysis care	**RSU (% achieving)**	**UKRR 1999 HD patients (% achieving)**
Dialysis adequacy		
Every patient for thrice-weekly HD should show URR >65%	82	England and Wales 65 Scotland 73
Correction of anaemia (haemoglobin)		
A target Hb concentration of not less than 10 g/dl should be achieved in the great majority (>85%) of patients after 3 months on HD	81	England and Wales 73
EPO use	90	85
Blood pressure		
Target pre-dialysis blood pressures should be:		
Age <60: ≤140/90 mmHg	57.9 systolic	Age <60 = 41
Age >60: ≤160/90 mmHg	84.2 diastolic	Age >60 = 60
Phosphate (predialysis)		
% 1.2–1.7 mmol/l	34.8	England and Wales 32

Generally, clinical outcomes in the RSUs compared with levels found in participating units in the UKRR. *Table 53* shows the proportions achieving the Renal Association Standards in RSUs and in UKRR units. It is important to recognise that RSU non-responders to the study would be likely to have more adverse results and that the UKRR includes the full range of HD patients including those deemed ineligible for RSU care, so we would expect the study RSU measures to be at least as good as if not better than those of all UKRR units.

There was no evidence that RSU patients fared worse than MRU patients; on the contrary, for some parameters there was a suggestion that outcomes were better. However, parameters that were significantly different between the groups at the individual level did not remain with the more appropriate pooled analysis. This partly reflects more conservative estimates from pooled analysis. Only URR, BMI and PTH remained significantly greater in the RSUs after adjustment for age or pooled analysis.

The mean value of URR in the RSUs was 70%, with 82% achieving the Renal Association Standard, indicating a relatively well-dialysed population despite only intermittent nephrologist review. There was a small but probably not clinically significant difference in URR in favour of the satellite unit. There was no difference in anaemia management; this might be due to the use of clinical protocols and regular monitoring of results.

BMI was significantly higher in the RSU patients after adjusting for age. Although this might indicate better nutrition, nevertheless one in seven had BMI < 20 kg/m^2, indicating a degree of malnutrition. Good dietetics advice is one factor that can improve nutrition along with better dialysis, highlighting the importance of dietetics input into the RSUs. PTH measures are complex to interpret; they depend on many factors, including length of time on HD and previous parathyroidectomy. It is usually measured only intermittently and can be easily assessed by nephrologists for patients in both settings.

We used the 1997 second edition of the Renal Association Standards;[11] although there were changes in the definition of some of the standards for the 2002 edition, these are not likely to affect our conclusions.

Patient safety in RSUs

Phase 1 interviews had identified some concern about the level of medical cover in RSUs, especially for emergencies.

RSUs dialyse a fairly elderly, co-morbid group of patients. Most had adverse events on dialysis, mainly hypotensive episodes for which no specific action was taken. There was no evidence that these were clustered in the most high-risk patients. Nevertheless, in a minority there was a significant impact with termination of dialysis or occasionally transfer of the patient to the MRU, although we had too short a follow-up by which to accrue sufficient information on these rarer outcomes. We had no comparable data on event frequency from the MRU. There is a lack of published data on adverse events for comparison and our definition of major adverse events was developed specifically for this study. It does raise the issue of the safety of RSUs situated away from major acute hospital sites. Moreover, there need to be clear policies from MRUs about how they aim to cope with any emergencies. The scale of this problem is likely to grow as more elderly patients with co-morbidity are moved to RSUs.

Another proxy measure for safety is hospitalisation. Over 60% of prevalent RSU patients who had been on HD for > 1 year had had no hospitalisation in the last year, which is a high figure considering the nature of the patients. Moreover, of those requiring admission over half were admitted on only one occasion. A few patients had multiple admissions and there may be scope to review the suitability of such patients for RSU care. The cross-sectional nature of the study, of course, may introduce a survivor effect by excluding those who had died or changed from RSU to MRU.

The commonest reason for hospital admission in both RSU and MRU was related to vascular access. Overall, demand for such surgery is increasing and current provision is insufficient, as evidenced by rising waiting lists. A major driver to such demand is the increasing acceptance rate on to RRT. However, this study highlights the contribution of prevalent patients to hospital demand and surgical workload. The provision of access surgery is a major concern of the forthcoming Renal Services National Service Framework. Availability of vascular access surgery and support must be a major component of the planning of any new RSU. Reducing admission for access problems in both RSU and MRU patients would reduce healthcare and patient costs. In addition, MRUs need to have the spare capacity to cope with the varying demand for emergency admissions from their RSUs.

Patient quality of life

On all elements of the KDQOL and SF-36, no difference was found between RSU and MRU patients on any dimensions except the KDQOL patient satisfaction and staff encouragement. This was supported by our satisfaction questionnaire, where RSUs fared significantly better on dimensions of the unit's atmosphere and environment and communication with staff. Such findings are probably to be expected. Although few RSUs were new build, most were only designed to cope with chronic HD patients. HD sessions can be planned in a more systematic way in RSUs so that individual patients can keep the same times, and they usually have the same group of patients dialysing with them (assuming no intercurrent events). As nursing staff are not dealing with acute renal failure or more difficult chronic HD patients, they may have more time to spend with patients and the unit's atmosphere may appear more relaxed. Certainly this was borne out by the patients' responses and the observations of our research staff. Of interest was the finding that RSU patients felt that access to a doctor they knew was at least as easily arranged as in the MRU. This may reflect the fact that RSUs receive regular visits from consultant nephrologists whereas in MRUs patients are more likely to see various junior staff.

Dialysis places a major limitation on a patient's social life. About 80% in both MRUs and RSUs felt that their life was affected, with 60% reporting the burden on their carers. Time and resources precluded any detailed study of carers' views or assessment of their QoL; more research is needed into the impact of different types of HD on carers.

The valuations obtained for HRQoL using EQ-5D showed, as expected, utilities that were lower than full health and consistently lower than age-related population norms, but no systematic difference between MRUs and RSUs was observed. Contrary to expectations that patients would have lower HRQoL during dialysis, patients' self-rated valuation of health status (EQ VAS) was comparable on and off dialysis and did not differ between MRUs and RSUs. However, these results require cautious interpretation since patients were not asked to rate their current health status, but rather their status when off dialysis, and this could have led to measurement error. However, the patients EQ-5D utilities and EQ VAS scores, mean (SD), of 0.60 (0.29) and 59 (19), respectively, were comparable to those in a small group ($n = 46$) of similar HD patients found by other researchers[94] [EQ-5D utilities and EQ VAS scores, mean (SD), of 0.66 (0.29) and 58 (19), respectively].

Other healthcare contacts

RSU patients had a greater chance of a district nurse visit in the last 4 weeks, but not GP or social worker visits. There were no significant differences between type of unit in the mean number or cost per patient per year of GP, social worker or scheduled renal outpatient visits. The mean cost difference per patient per year for district nurse visits was an additional £16.79 for those at RSUs (95% CI £32.95 to £0.64), which although statistically significant would not be economically significant alone.

Accessibility, transport and waiting times

From the postcode analysis, it appeared that the RSUs were closer to patients' homes and there was a mean potential saving of nearly 19 minutes or 17 km distance per journey compared with going to the MRU. Of course, this may not be realised, for example, if NHS transport collects more than one patient per trip. Nevertheless, patients' self-reports also showed savings for RSU patients. The saving varies by pair depending on the relative locations of the MRU and RSU.

MRU patients reported fewer NHS ambulance and hospital cars used than did RSU patients. Most units used private ambulance or taxis to resolve transport problems. Total patient time in terms of waiting for transport, journeys and dialysis (excluding getting on and off dialysis) was ~5 hours, and on average 23 minutes longer per session for MRU patients owing to slightly longer transport-related times. Patients undergoing HDF saved about 2 hours per week of dialysis time.

Patients' out-of-pocket expenses

Patients' out-of-pocket expenses were reported by only a small number of patients and there was no systematic difference between the MRU and RSU groups. Of these patients, 72% paid ≤ £5 for their return journey to a dialysis session.

Inter-RSU comparison

This was very difficult to assess for reasons outlined below. The limited analyses performed suggested that the case mix might be different depending on the unit's location and ownership, with DGH- and NHS-run units more likely to have more dependent patients. This may reflect the proximity of medical cover and the selectivity of private units. No differences were seen in some key clinical and QoL outcomes.

Integrating costs and effectiveness

The cost-effectiveness of RSUs compared with MRUs remains uncertain. As described above, effectiveness may be equal or possibly better for RSUs compared with MRUs and patient satisfaction and possibly staff stability (from the smaller proportion of trained nurse vacancies) greater. Costs would then be a crucial factor in any policy decision to expand the role of RSUs. However, drawing conclusions about the relative cost advantage of MRUs or RSUs is difficult. From investigation of some of the major cost drivers, it appears that there was no significant difference between MRUs and RSUs in terms of the mean cost per patient of EPO, GP or scheduled renal outpatient visits, hospitalisations or patients' out-of-pocket expenses. RSUs could offer some advantages over MRUs in terms of slightly shorter total patient times per session and fewer hospitalised patients, but the latter did not produce a statistically significant budgetary impact. Conversely, more RSU patients were visited by a district nurse and this had a statistically significant cost impact. Importantly, some aspects of RSU workload represent potential cost shifting from secondary to primary care. If resources do not follow this shift then the consequences may be well in excess of the cost identified. However, the economic importance of net cost differences has to be judged by the relevant decision-makers.

It would be premature to judge the net costs of RSUs as it was not possible to value and compare costs over periods of time sufficient to capture all important 'downstream' costs (importantly, outpatient contacts were limited to 1 or 6 months and hospitalisations to 12 months) or to include the costs of capital/overheads, medical staff and technicians, patient and staff transport, healthcare in terms of unscheduled outpatient, ward or Accident and Emergency Department visits and a comprehensive range of services in the social care sector. However, based on the experience of this study, we now have a better understanding of those aspects of service delivery that would require detailed data collection in any further study where patients are comparable, but the setting varies.

Generalisability

The findings are generalisable within the countries of the UK as UK nephrologists have a similar understanding of the concept of RSUs, and the units operate within the same healthcare system. Moreover, we selected a representative sample in terms of RSU geography and organisation. However, it is difficult to compare the organisation of renal care across other countries. A review of Registry reports found no standard definitions of renal unit types. However, an email survey of experts in seven countries did indicate that there were similar RSU type units in some countries, notably Australia, Canada, Finland, Malaysia and France, so that the findings here may be generalisable in part to other countries.

Strengths and limitations of the study

The study included a representative sample of RSUs and an MRU control group, it had high response rates and it used validated measures (i.e. co-morbidity, SF-36, KDQOL, EQ-5D). Statistical analysis took account of the clustered and paired nature of the data. However, there were some limitations:

- The allocation of eligibility of patients being treated in the main renal units was made by the senior nurse. This was a pragmatic strategy as in practice this is generally how decisions about transfer to a satellite unit are made. The proportion deemed eligible varied significantly between renal units. This may reflect different unit policies, the particular characteristics of the satellite unit under study or variations in how senior nurses judged eligibility. By comparing outcomes within main-satellite unit pairs, we should partly control for these influences.
- It was cross-sectional with retrospective collection of some key data such as hospitalisation and other healthcare use. It is more difficult to attribute association in cross-sectional compared with prospective study designs. Differences in QoL, for example, may reflect prior care rather than the specific impact of RSU or MRU care. Prospective follow-up of patients starting RRT in the MRU or RSU would overcome this. We did try and make some allowance for different patterns of care between the two groups by, for example, looking at day 90 onwards and for hospitalisation we took account of different duration on RRT.
- Retrospective data have to rely on routinely available data sources and there are problems of incomplete and inaccurate data. Collecting data, for example, on the interface between RSU and MRU was difficult. Much of this may be regarded as informal, such as telephone calls and unscheduled attendances, which are not recorded routinely in medical records. A prospective study could have instituted *ad hoc* procedures, although of course the feasibility of such an approach across the renal clinical team would need to be established.
- We had limited data on the medical input to each of our RSU sites. This was mainly obtained from interviews with RSU nurses. In retrospect, it would have been helpful to have more detail and their views on the advantages and disadvantages of RSU care.
- The groups were imbalanced on potential confounders such as age. Although we were able to adjust for this on regression analysis, this used individual level rather than unit level data.
- Adverse event data were collected only in the RSUs and for only a relatively short time period of 6 weeks.
- We were unable to look in detail at the benefits of particular models of RSU. This was due to the pragmatic limits to the size of the study with only 12 pairs, the heterogeneity of types of RSU with multiple combinations of the different dimensions and the small numbers of patients treated in each satellite.
- Our patient satisfaction questionnaire was not previously validated or tested for reliability. However, it was based on themes elicited from patients and proved easy to complete. We have evidence of construct validity in that the findings agree with those from the two domains on satisfaction on the KDQOL.
- Time and resource constraints meant that we were unable to collect data on the perspectives of carers. We had limited data on nurse perceptions from the interviews.
- This study was unable to undertake comprehensive costing to compare the different settings owing to the factors previously described and the poor quality of budgetary and cost information encountered in both the NHS and private sectors. Particularly important issues are the effect of case mix and patient dependency on costs. Given our difficulty extracting basic activity and financial information from a large number of providers of renal services, it is our contention that many of the published costings in this area are probably less reliable than initially apparent unless the authors specifically describe their methods for adjusting for comparability.

Policy implications for health professionals and commissioners

This study has shown that RSUs are as effective as MRUs for the management of most patients considered for chronic HD. RSUs are generally more acceptable to patients and reduce patient travel time and burden. From a clinical point of view, the evidence suggests that satellite development could be successfully expanded; not all MRUs have any satellites and many have only a few. Models of future demand for RRT predict a continued increase in the prevalence of RRT, rising to nearly 50,000 in England by 2010, with the growth being differentially higher in older patients and those on HD, particularly if kidney transplant supply does not increase. However, it is important to recognise that, from an economic point of view, the question of cost-effectiveness has yet to be answered.

The question of what type to propose is also difficult to answer. Key factors would include:

- Local geography and the likely catchment population and hence the current and future pool of chronic HD patients should determine the size and type of the unit. An area with a sizeable urban catchment population might even sustain a consultant-led service including not only chronic HD patients but also acute renal failure, general nephrology and local support for home or PD patients.
- Types of patient to be treated. In the future, MRUs may need to place older patients with co-morbidity into RSUs. If so, it might be preferable to site RSUs on a DGH rather than non-DGH site so that local medical cover would be available. This would also affect whether the site could be developed into a consultant-led nephrology service.
- The availability of vascular access surgery and support should be a major component of the planning of any new RSU.
- RSUs are a useful model for chronic HD in urban areas; they may even be sited alongside an MRU as they offer such patients a more relaxed setting to dialyse than the MRU.

It is important that there are appropriate policies in place in the RSUs to deal with emergencies and for transfer of patients, and also protocols for management on common clinical problems and good communication links with the MRU. Staff rotation would help overcome the professional and social isolation felt by some staff in RSUs.

In planning the development of RSUs, Phase 1 had demonstrated that allowance needed to be made in opening a new RSU for future growth in staff and stations in order to treat more patients. We did not systematically capture the impact of RSU patients on medical staff workload in the MRU. Not only are there intermittent visits by senior staff but also a regular review of results and dealing with telephone queries, unscheduled visits and inpatient stays of RSU patients.

Implications for patients and carers

RSUs offer an alternative form of hospital HD to the MRU. They are largely nurse-run units just offering chronic HD and so often usually have a more relaxed atmosphere, which patients in our study appreciated. For most patients they will be easier to travel to, except for those patients living near the main unit, and possibly easier to park at as they are not all on busy, large, acute hospital sites. The medical aspects are coordinated from the main unit so the standards of dialysis and other medical and nursing care do not differ from those at the main unit. There is no evidence that they are less safe than dialysing in the main unit. Similar procedures are used for dialysis. It is easier for drug prescriptions to be accessed from GPs and the renal unit. Patients seem to prefer dialysing in the RSU rather than the MRU. There has been no research on the effect on carers, but the reduced travel burden and general atmosphere of the units would suggest that RSUs have an advantage.

Research implications

There are several research issues that arise from this study, which we have listed in order of priority as follow:

1. **Cost-effectiveness.** This ought to be addressed if rational policy decisions about the expansion of RSUs are to be taken, given that the study has provided evidence of similar effectiveness (if not better for RSUs). In addition, the study found greater patient satisfaction, accessibility and possibly staff stability in RSUs (from the point of view of fewer trained nurse vacancies). These findings raise the question of what additional costs are incurred.

   In order to answer this question, there is an urgent need to make basic budgetary information linking activity and expenditure available and more transparent, to perform at least an insightful top-down costing of the two care settings. Given the major contribution of staffing costs to units' budgets, the relationship between patient factors (e.g. dependency, co-morbidity) and staffing requirements needs more research. Although there remain gaps in knowledge that would need to be addressed by primary research, the cost-effectiveness issues may be enhanced by additional modelling.
2. **Patient safety**. A comparison of adverse events occurring in MRUs and RSUs with longer duration and larger numbers to identify more severe events would be helpful, along with the more research into the scope for preventing such events.
3. Any desire to increase the number or size of RSUs needs to be informed about which RSU models are the most efficient (including the ideal unit size for a given population). One approach to this could be building on the preliminary DEA work undertaken. This has shown that DEA is potentially a valuable tool in modelling the efficiency of RSUs, but it is

dependent on the quality and completeness of key data. To move this forward, further studies are required to ascertain whether altering the characterisation of RSUs and improved data are associated with changes in the pattern of efficiency scores, and thus confirm the value of this technique as a measure of efficiency for RSUs.

4. **Patients deemed ineligible for satellite care.** More research is needed into the characteristics and size of the HD population judged to be unsuitable for RRT between units and over time in order to inform the needs for MRU care, as this may be the only option for such patients.
5. **Carer perspectives.** The burden of RRT on carers was highlighted by many patients. Whether there are differences from different models needs to be explored.
6. **Nursing perspectives.** The attitudes of nursing staff should be investigated further, given the increased responsibility and autonomy of senior staff in RSUs, evidence of greater stability of staff in RSUs, but also feelings of isolation.
7. **Integrated approach to dialysis.** An integrated approach to the analysis of a full dialysis service is required. Minimal care units and home HD are currently the other alternatives to an MRU or RSU. Their cost-effectiveness and efficiency also need investigating, given the concerns about the reliability of previous costing exercises and the associated impact of patient factors.
8. **International comparisons.** On an international perspective, there is a need for Registries to agree common definitions of different types of unit and for more comparative research on the impact of the organisation of units on the quality of care provided.

Conclusion

RSUs in the UK have arisen in response to the increasing demand to provide chronic HD for patients with ESRF. This study has shown that RSUs in the UK are as effective as MRUs for the management of most patients considered for chronic HD. RSUs are generally more acceptable to patients and provide more geographically accessible care. The cost-effectiveness of RSUs has yet to be established and further work into the safety of these units is required. There will always be patients treated at the MRUs who are deemed unsuitable for RSU care; the number of such patients may increase as acceptance rates rise to meet population need. Finally, although this study's finding of comparable outcomes in RSUs and MRUs is reassuring, the appropriateness of further expansion of dialysis provision by RSUs at the expense of the MRU base, that remains uniquely small compared with other countries, is an open question.

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Appendix 1

Data envelopment analysis to examine the comparative efficiency of RSUs

Example of DEA

Consider four RSUs (A, B, C, D). The main inputs influencing the number of chronic HD patients treated weekly are the numbers of trained nurses and dialysis machines. *Table 54* highlights the steps in assessing relative performance. Each unit uses different combinations of inputs to treat a level of patients per week; the ratio of output to each input depicts the intensity to which each unit uses that input; a higher ratio is more efficient. In the example, B makes most efficient use of nurses and D most efficient use of machines. They lie on the frontier of best practice (in a two-input, one-output world the frontier can be drawn as a line between the graphical coordinates for each unit's output/input ratios, that is, 'ratio of patients treated per trained nurse' and 'ratio of patients treated per machine'). The less efficient units, A and C, are measured as the ratio of the distance from the point of origin to each unit's respective coordinates divided by the distance from the point of origin to the intersection with the frontier (i.e. the proportional distance each unit is from the frontier, in this example unit A is 88% efficient and C is 93% efficient).

Aim

DEA was judiciously applied to enquire about its potential to assess the relative efficiency of RSUs in England and Wales.

Methods

DEA is a technique used to quantify the concept of efficiency and is suited to the analysis of services readily disaggregated into distinctive productive units with similar input and output orientations. It is based on a deterministic, non-parametric frontier approach using linear programming techniques (technical details can be found elsewhere[16,95,96]). The technique requires a suitable characterisation of the production process in question and suitable variables that represent the inputs and outputs of interest.

Characterising a suitable RSU production process required balancing clinical meaning, data availability and degrees of freedom needed to estimate the model. In practice, this meant using clinical experts to help extract suitable variables from the Phase 1 data.

The output variable was 'total weekly HD treatments produced per RSU' (i.e. combining the number of people on HD and frequency of treatment). This was felt to reflect the primary purpose of RSUs, but could not be adjusted for case-mix differences for a number of reasons. Patient-level information on age and co-morbidities were beyond the scope of the survey. Absence of agreement on measuring patient dependency meant that it could not be classified in advance of data collection, and infection status in terms of the proportion of patients with HIV,

TABLE 54 *Example of relative efficiency using an illustrative characterisation of RSUs*

	Unit			
	A	**B**	**C**	**D**
Output: patients treated per week	30	90	60	90
Input 1: WTE trained nurses	2	4	5	7
Input 2: Dialysis machines	12	35	20	28
Output/input 1: patients treated per nurse	15	22.5	12	12.8
Output/input 2: patients treated per machine	2.5	2.5	3	3.2
Efficiency of trained nurses relative to most efficient unit (%)	66	100	53	56
Efficiency of dialysis machines relative to most efficient unit (%)	78	78	93	100
Relative efficiency score, weighted sum of output to inputs (%)	88	100	93	100

hepatitis B or hepatitis C was requested but incomplete. Similarly, owing to a lack of patient-level outcomes data, a more desirable output was unavailable. This would have captured the ability to 'maintain the level of renal functioning, allowing the patient to survive and carry out usual activities of daily living with acceptable QoL'.

Input variables selected related to the essential health service resources needed to provide maintenance HD, nursing staff, HCAs (healthcare assistants or equivalent) and available dialysis sessions per week. Data available included total WTE numbers for all nurses and HCAs, but not separated by grade. Available dialysis sessions per week reflected capacity. This was the total weekly sum of dialysis stations multiplied by sessions available per station each day. This assumed static conditions and that no dialysis stations are spare or restricted, for example, for high-risk patients. The inputs were selected on the basis of quality of data available for potential variables, dropping ones with excessive missing data and those strongly correlated with another variable. Whilst the survey identified few units with some form of permanent on-site nephrology cover, unfortunately data were unavailable on grade and frequency, making it impossible to construct a suitable indicator for the analysis. DEA software cannot run with missing data; so of 80 satellites returning surveys, eight had too much missing data to be confident of imputing anything meaningful. Of the remaining 72 units, there was one missing value for one variable and eight missing values for another. Hence, there were minimal missing data and the imputation followed standard practice for DEA, namely the mean for available cases approach.

The optimisation objective was to maximise the total weekly number of HD treatments within existing resources available at RSUs. The base case model assumed a 'variable returns to scale' (VRS) relationship between the inputs and output, that is, that units may operate at under-, over- or full capacity. This seemed realistic as it allowed for the possibility of economies of scale.

Sensitivity analysis assessed the impact of uncertainty in three of the assumptions. First, the number of staff currently employed was substituted by the number of funded posts (establishment). This estimated the uncertainty associated with these two data sources as nursing staff vacancy rates can be high and therefore the base case might underestimate resource inputs. Second, the VRS assumption was substituted by constant returns to scale (CRS), where output levels change directly in proportion to input levels. This helped ascertain the extent to which VRS assumptions discriminated between units. Third, minimum weights of 20% (based on common practice) were placed on two of the input variables: nurse (WTE or establishment) and maximum sessions. This guaranteed that RSUs delivered care with at least a minimum level of nursing and equipment (approximated by sessions) and helped check if outlier values impacted results unduly. Assessment of sensitivity was judged by comparing the efficiency scores obtained under each new model variant with scores from the original model.

The DEA software Frontier Analyst produced the efficiency scores and score rankings and identified best-practice peers.[97]

Results

Of the 82 RSUs surveyed for Phase 1,74 (90%) completed the survey and, of these, 70 questionnaires were complete enough for DEA purposes. This meant that 85% of all the RSUs were represented in the DEA exercise. Of those excluded, two were not operational at the time of study and two returned data that were difficult to interpret.

Table 55 presents observed outputs and inputs used to characterise the production of HD under base-case assumptions. The difference in maximum sessions available and total treatments revealed an average of 16 spare sessions per week.

The efficiency scores obtained are given in *Table 56*. The data show that, on average, if all RSUs had followed the 24 best-practice RSUs identified, all else being equal, current levels of mean inputs could have produced nearly 10% more output. Instead, 46 RSUs can be identified as under-performing to some extent when compared with best-practice peers, with 12 RSUs scoring less than 80% efficiency. The least efficient RSU had a score of 38%. Sensitivity analyses did not significantly change scores for the base case.

DEA allows the systematic and transparent investigation of efficiency improvements for individual RSUs and setting of targets in relation to best-practice peers. The analysis identified some RSUs that appeared to have unused dialysis sessions and others that appeared to be under-performing with respect to staffing. All else being equal, one low-performing RSU (44%

TABLE 55 *Model variables (base case), observed mean values*

Variable	Mean	SD
Input		
Nurse WTE (all grades)	6.75	2.73
HCA WTE (all grades)	2.54	2.96
Maximum number of dialysis sessions available per week	124.07	72.13
Output		
Total weekly number of HD treatments (adjusted for frequency)	108.01	61.06

TABLE 56 *Efficiency scores produced for RSUs in England and Wales using three inputs (WTE nurses, WTE HCAs, dialysis sessions) and a single output (weekly HD treatments)*

	Mean (SD)	Median (IQR)	Minima	Ranking
All RSUs (*N* = 70)	90.4% (14.0)	97.4% (86.2–100)	37.5%	100% 24 (34%) 90–99% 21 (30%) 80–89% 13 (19%) 60–79% 9 (13%) 40–59% 2 (3%) < 40% 1 (1%)

efficient) used 0.5 WTE more nurses and 0.9 WTE more HCAs, but produced 81 fewer weekly treatments than one of its peers. Before concluding that these were true inefficiencies or that an individual RSU's output could improve to match its peer, local managers would need to examine the results in conjunction with important contextual information. For example, apparent inefficiency might result for 'legitimate' reasons such as covering the risk of machine breakdown, staff shortages or staff spending more time talking to patients/carers or providing 'higher quality' care.

Discussion

The sample studied represented 85% of RSUs in England and Wales operating by 31 March 1999. The findings suggest that there is scope for improvements in efficiency in the delivery of HD at RSUs. Overall performance for the sample studied identified about one-third of RSUs as output maximising with respect to available inputs and a further 50% that operated close to the frontier of best practice. The remaining 15% of RSUs were identified as poorer performers, the worst performing one-third as well as its closest peer. On average, if production practices in all RSUs had followed the best practice of the 24 efficient RSUs identified, all else being equal, current levels of mean inputs could have produced about 10% more output.

The identification of poorer performers provides managers of RSUs with specific information with which to question performance and discuss improvement. Interpretation of the efficiency improvement targets illustrated ought to be handled carefully, as what is theoretically possible may not be realistically plausible or even desirable without modification. Despite this, one advantage of DEA is the identification of peers within the same sample operating with similar input:output orientations.

The sample indicated that ~16 dialysis sessions per week per RSU were unused (equating to ~3–5 patients not treated in this setting). Such information could be helpful in planning for expansion of HD places, but to do so would require an understanding of why sessions were unused. It may be that some RSUs can be candidates for expansion given additional resources or improvements in working practices. Alternatively, unused sessions may arise from barriers such as labour market shortages. [The estimate for unused sessions is, however, a biased estimate because the measure was insufficiently sensitive to take account of a number of other relevant factors that determine the use of sessions. Such factors include whether RSUs operate a policy of keeping spare or underutilised dialysis sessions for emergencies, 'high-risk' patients (e.g. those with blood borne viruses), recent deaths/transfers or awaiting new patients from the MRU.]

The study had a number of limitations. DEA is highly sensitive to the variables included and quality of the data used. This study piggy-backed on to a survey designed for other purposes, yet despite a high response it was not possible to validate the data so that any inaccuracies in, say, the staffing complement or patient numbers could have an impact on efficiency scores. Therefore, although the best set of data is available, it may still fall short of providing valid DEA results. Future research should pay attention to validating this model.

The measurement of comparative efficiency rests on the premise that efficient units are genuinely efficient. What was not possible to show from these data was whether efficient units were operating at too high a stress level for staff to cope with (i.e. staff 'burn out'), leaving them no time for attention to more caring aspects or perhaps appropriate clinical assessment. In that case, it would be inappropriate for the less efficient units to emulate so-called 'good practice'. More research is needed to relate apparent technical efficiency to quality of care in the production of renal satellite services.

The output measure used was restricted to a simple count aggregating dialysis sessions per patient. This omits measuring differences in the quality of care given and assumes that all patients achieve homogeneous, adequate dialysis regardless of the severity of their condition, associated co-morbidities or the duration and techniques of the dialysis. Although it is unlikely that routine measurement of QoL and patient well-being will become more accepted practice, it is hoped that routine reporting will allow for better output measures to become available in future.[18] For example, adequacy of dialysis is being collected by the UKRR on an individual patient basis and so could, in time, be used to adjust for quality.

The input variables used were by necessity highly aggregated and potentially incomplete. The data that were available did not permit examination of different skill mix and potential for staff substitutions across RSUs. In particular, there may be important differences in the mix of nursing and HCAs used that were masked and different types of medical input unaccounted for. Part of the production process potentially missing in this model specification relates to the transportation of patients to and from RSUs. Anecdotal evidence suggests that transportation arrangements can delay start and finish times of sessions and impact on patient throughput. Future research should try to assess this.

In summary, this study was a judicious one to demonstrate the potential of DEA in raising questions about the comparative efficiency of RSUs. Addressing inefficiencies might improve the throughput of chronic HD patients and thereby capacity to deal with the growing demand for HD delivered in RSUs. This premise needs to be established by further research. Clearly, further studies are required to ascertain whether altering the characterisation of RSUs and improved data are associated with changes in the pattern of efficiency scores, and thus confirm the value of this technique as a measure of efficiency for RSUs.

Appendix 2

Patient letter (RSU)

«Title» «Forename1» «Surname»
«Address1»
«Address2»
«Town»
«Postcode»

«Unit_Name»
«Unit_ad1»
«Unit_ad2»
«Unit_ad3»
«Unit_ad4»

Monday 23rd April 2001

Dear «Title» «Surname»

Our renal unit, «Unit_Name», is one of 12 units selected, as a representative sample, to take part in a national study, funded by the NHS Research & Development Programme, comparing the benefits and costs of dialysis in satellite units with dialysis in main renal units.

You are invited to take part in this study. All patients in our satellite unit have been asked to take part. Before you decide to take part or not it is important for you to understand why the research is being done and what it will involve.

Please take time to read the enclosed information carefully and discuss it with friends, relatives, your nurse or myself if you wish. Take time to decide whether or not you wish to take part.

If you agree to take part in this study it will only involve answering some questions about your health and your experience of dialysis, together with a review of your medical history from your notes.

This study will not affect your care in any way and you are completely free to not take part in the study or to withdraw from the study at any time without giving any reason.

The researchers will be visiting our unit during the week commencing «Visit_date» and they would be grateful if you could bring your reading glasses with you, if you need them.

Yours sincerely

Dr AN Other
Consultant Nephrologist

Appendix 3

Patient information sheet and consent form

National Renal Satellite Evaluation Study

Background to the Study

- The number of people who have haemodialysis for kidney failure is steadily increasing.
- In order to meet the need for haemodialysis, kidney units have had to expand so that they can take greater numbers of patients. Some units have expanded the main kidney unit, while others have set up new smaller satellite units. However it is not known how effective or costly the new satellite units are in comparison with main units.
- We have set up a national research project to see if there are any differences between the main kidney units and the smaller satellite kidney units in terms of treatment, quality of care and how patients feel about dialysing in these different kinds of unit.

If you do decide to take part you will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

If you take part in the study, you will be asked to fill in a questionnaire which asks you some questions about your health and well being and the impact of dialysis on your life so that we can compare patients in the satellite unit to patients in the main kidney unit. Your medical notes will also be examined, by a qualified researcher, to record more information about your condition and the treatments you have received.

All information collected about you during the course of the research will be kept strictly confidential.

Any information about you which leaves the renal satellite/main renal unit will have your name and address removed so that you cannot be recognised from it.

The results of this study will be available sometime in 2002. Your unit will be sent a copy of the report which you are free to inspect. No individuals will be identifiable in any of the published research.

The National Renal Satellite Evaluation Study Group, who will be responsible for the research, is a group of health care researchers and renal physicians:

Dr Paul Roderick, Study Co-ordinator, Senior Lecturer in Public Health Medicine, Health Care Research Group, University of Southampton.

Prof Terry Feest, Professor of Clinical Nephrology, University of Bristol and Director of the Richard Bright Renal Unit, Bristol.

Dr Roger Greenwood, Lead Clinician, Renal Services, Lister Hospital, Stevenage and President of the British Renal Symposium.

Dr Donna Lamping, Head & Senior Lecturer, Health Services Research Unit, London School of Hygiene & Tropical Medicine.

Prof Joy Townsend, Director, Centre for Research in Primary and Community Care, University of Hertfordshire.

Mr Mark Mullee, Senior Research Fellow in Medical Statistics, Department of Medical Statistics, University of Southampton.

Ms Karen Gerard, Senior Lecturer in Health Economics, Health Care Research Group, University of Southampton.

Dr Nicholas Drey, Senior Research Fellow in Public Health Medicine, Health Care Research Group, University of Southampton.

Dr Alison Armitage, Specialist Registrar in Renal Medicine, Richard Bright Renal Unit, Southmead Hospital, Bristol.

Ms Tricia Nicholson, Research Fellow in Health Economics, Health Care Research Group, University of Southampton.

National Renal Satellite Unit Evaluation Study

Consent Form

Study Number: ☐

	Please cross out as necessary
Have you read the Patient Information and General Information sheets?	**Yes/No**
Have you had an opportunity to ask questions and discuss this study?	**Yes/No**
Have you received satisfactory answers to all of your questions?	**Yes/No**
Have you received enough information about the study?	**Yes/No**
Who have you spoken to Dr/Mr/Mrs	
Do you understand that you are free to withdraw from the study at any time without giving any reason and without affecting your future medical care?	**Yes/No**
Do you understand that sections of your medical notes may be looked at by responsible researchers where it is relevant to the study? Do you give permission for these individuals to have access to your records?	**Yes/No**
Do you agree to take part in this study?	**Yes/No**

Signed... Date...

Signature of person taking consent:

Signed... Date...

Name of person taking consent:

Appendix 4

Patient questionnaire

Introduction

This questionnaire is part of the National Renal Satellite Evaluation Study, funded by the NHS Research & Development Programme. The aim of the study is to assess the quality of haemodialysis care in different types of dialysis units. Details of the study are available on the patient information sheet, which you should have read already.

This questionnaire will ask you about your health and well being and the impact of dialysis on your life including your travel arrangements.

Confidentiality of information?

Your answers will be combined with those of other participants in reporting the findings of the study. Any information that would permit identification of you will be regarded as strictly confidential. In addition, all information collected will be used only for purposes of the study, and will not be disclosed or released for any other purpose without your prior consent.

Instructions

Can you please complete the questionnaire today, and hand it in, in a sealed envelope after your dialysis session.

Most questions require a cross to be placed in the box ☒ indicating your answer. However, a few questions may require a short written answer. Please read the individual instruction of the question.

Thank you very much for completing these questions

Matching number ☐☐☐

Study number ☐☐ ☐ ☐☐

Section 1.

This section asks you questions about how you get to and from your dialysis session and how long you have to wait

1.1 How do you usually get to your dialysis sessions? Please put a cross ☒ in one box only

☐ Drive yourself
☐ Driven by friend or relative
☐ Hospital car, alone
☐ Hospital car, with other dialysis patients
☐ Ambulance, alone
☐ Ambulance, with other dialysis patients
☐ Bus or train
☐ Other, alone (please specify) ____________________
☐ Other, with other dialysis patients (please specify) ____________________

1.2 These questions ask how long it usually takes you to travel to your dialysis session. Please write the time on the dotted line below

a How long do you usually have to <u>wait</u> for transport to your dialysis session?
.... hours .... minutes Not applicable (e.g. drive yourself) ☐☐ ☐☐

b How long does your <u>journey</u> to dialysis usually take?
.... hours .... minutes ☐☐ ☐☐

c Do you usually arrive early? (i.e. more than 15 minutes before your scheduled time)
☐ No (if no please go to question d, below)
☐ Yes
If yes, how early do you arrive?
.... hours .... minutes ☐☐ ☐☐

d Do you usually arrive late? (i.e. more than 15 minutes after your scheduled time)
☐ No (if no please go to question e, below)
☐ Yes
If yes, how late do you arrive?
.... hours .... minutes ☐☐ ☐☐

e How much does your return journey cost you? You should include your total fares and car parking but <u>NOT</u> petrol. (Please estimate to the nearest £).
£ .... ☐☐

f Does a friend or relative usually accompany you throughout your dialysis?
☐ No
☐ Yes

1.3 These questions ask about the time it takes to start and stop your dialysis

a When you arrive at the dialysis unit, on average how long does it usually take to get <u>on</u> the machine?
.... hours .... minutes ☐☐ ☐☐

b When you finish dialysis, on average how long does it usually take to get <u>off</u> the machine?
.... hours .... minutes ☐☐ ☐☐

c How long do you usually have to <u>wait</u> from the arranged time, for transport to arrive to take you home after your dialysis?
.... hours .... minutes ☐☐ ☐☐

1.4 Do you usually have to get someone to look after your children, partner or relatives so that you can come for dialysis?

☐ No (if no please go to question 1.5, below)
☐ Yes

If yes did you have to pay someone to look after your children or relatives?

☐ No (if no please go to question 1.5, below)
☐ Yes

If yes, you had to pay someone, how much did it cost you today? (to the nearest £)
£ .... ☐☐☐

1.5 Do you usually pay for other costs because of your dialysis treatment? (these might include, e.g. special foods, over the counter medicines or alternative therapies).

☐ No (if no please go to question 1.6, below)
☐ Yes (if yes…)

a How much do you usually spend on over the counter medication per week? (to the nearest £)
£ .... ☐☐☐

b Other costs (e.g. special foods or alternative therapies? (to the nearest £)
£ .... ☐☐☐

1.6 During the last 4 weeks, how many times have you visited (or been visited by) your GP?
.... times ☐☐

1.7 During the last 4 weeks, how many times have you been visited by a district nurse?
.... times ☐☐

1.8 During the last 4 weeks, how many times have you seen a social worker?
.... times ☐☐

1.9 Have there been any other visits connected with your dialysis over the last 4 weeks?

☐ No
☐ Yes If yes, please specify)

Section 2 – Your Health

This section includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues

Please put a cross ☒ in the one box that best describes your answer for each question

1 In general, would you say your health is:

☐ Excellent
☐ Very good
☐ Good
☐ Fair
☐ Poor

2 Compared to one year ago, how would you rate your health in general now?

☐ Much better than one year ago
☐ Somewhat better than one year ago
☐ About the same
☐ Somewhat worse now than one year ago
☐ Much worse now than one year ago

3 The following questions are about activities you might do in a typical day. Does your health limit you in these activities? If so, how much? Please put a cross in one box on each line

		Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b	Moderate activities, such as moving a table, pushing a vacuum, bowling or playing golf	☐	☐	☐
c	Lifting or carrying groceries	☐	☐	☐
d	Climbing several flights of stairs	☐	☐	☐
e	Climbing one flight of stairs	☐	☐	☐
f	Bending, kneeling or stooping	☐	☐	☐
g	Walking more than a mile	☐	☐	☐
h	Walking half a mile	☐	☐	☐
i	Walking 100 yards	☐	☐	☐
j	Bathing and dressing yourself	☐	☐	☐

4 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		Yes	**No**
a	Cut down on the amount of time you spent on work or other activities	☐	☐
b	Accomplished less than you would like	☐	☐
c	Were limited in the kind of work or other activities	☐	☐
d	Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐

5 During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

		Yes	**No**
a	Cut down on the amount of time you spent on work or other activities	☐	☐
b	Accomplished less than you would like	☐	☐
c	Didn't do work or other activities as carefully as usual	☐	☐

6 During the past 4 weeks, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

☐ Not at all
☐ Slightly
☐ Moderately
☐ Quite a bit
☐ Extremely

7 How much bodily pain have you had during the past 4 weeks?

☐ None
☐ Very mild
☐ Mild
☐ Moderate
☐ Severe
☐ Very severe

8 During the past 4 weeks, how much did pain interfere with your normal work (including work both outside the home and housework)?

☐ Not at all
☐ A little bit
☐ Moderately
☐ Quite a bit
☐ Extremely

9 These questions are about how you feel and how things have been with you during the past month. For each question please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

		All of the time	**Most of the time**	**A good bit of the time**	**Some of the time**	**A little of the time**	**None of the time**
a	Did you feel full of life?	☐	☐	☐	☐	☐	☐
b	Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c	Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d	Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e	Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f	Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g	Did you feel worn out?	☐	☐	☐	☐	☐	☐
h	Have you been a happy person?	☐	☐	☐	☐	☐	☐
i	Did you feel tired?	☐	☐	☐	☐	☐	☐

10 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

☐ All of the time
☐ Most of the time
☐ Some of the time
☐ A little of the time
☐ None of the time

11 Please choose the answer that best describes how <u>true</u> or <u>false</u> each of the following statements is for you?

		Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a	I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b	I am as healthy as anybody I know	☐	☐	☐	☐	☐
c	I expect my health to get worse	☐	☐	☐	☐	☐
d	My health is excellent	☐	☐	☐	☐	☐

<u>Your Kidney Disease</u>

12 How true or false is each of the following statements for you?

		Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a	My kidney disease interferes too much with my life	☐	☐	☐	☐	☐
b	Too much of my time is spent dealing with my kidney disease	☐	☐	☐	☐	☐
c	I feel frustrated dealing with my kidney disease	☐	☐	☐	☐	☐
d	I feel like a burden on my family	☐	☐	☐	☐	☐

13 These questions are about how you feel and how things have been going during the <u>past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

		None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
a	Did you isolate yourself from people around you?	☐	☐	☐	☐	☐	☐
b	Did you react slowly to things that were said or done?	☐	☐	☐	☐	☐	☐
c	Did you act irritably toward those around you?	☐	☐	☐	☐	☐	☐
d	Did you have difficulty concentrating or thinking?	☐	☐	☐	☐	☐	☐
e	Did you get along well with other people?	☐	☐	☐	☐	☐	☐
f	Did you become confused?	☐	☐	☐	☐	☐	☐

14 During the past 4 weeks, to what extent were you bothered by each of the following?

		Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremly bothered
a	Soreness in your muscles?	☐	☐	☐	☐	☐
b	Chest pain?	☐	☐	☐	☐	☐
c	Cramps?	☐	☐	☐	☐	☐
d	Itchy skin?	☐	☐	☐	☐	☐
e	Dry skin?	☐	☐	☐	☐	☐
f	Shortness of breath?	☐	☐	☐	☐	☐
g	Faintness or dizziness?	☐	☐	☐	☐	☐
h	Lack of appetite?	☐	☐	☐	☐	☐
i	Washed out or drained?	☐	☐	☐	☐	☐
j	Numbness in hands or feet?	☐	☐	☐	☐	☐
k	Nausea or upset stomach?	☐	☐	☐	☐	☐
l	Problems with your access site?	☐	☐	☐	☐	☐

Effects of Kidney Disease on Your Daily Life

15 Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease bother you in each of the following areas?

		Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremly bothered
a	Fluid restriction?	☐	☐	☐	☐	☐
b	Dietary restriction?	☐	☐	☐	☐	☐
c	Your ability to work around the house?	☐	☐	☐	☐	☐
d	Your ability to travel?	☐	☐	☐	☐	☐
e	Being dependent on doctors and other medical staff?	☐	☐	☐	☐	☐
f	Stress or worries caused by kidney disease?	☐	☐	☐	☐	☐
g	Your sex life?	☐	☐	☐	☐	☐
h	Your personal appearance?	☐	☐	☐	☐	☐

The next three questions are personal and relate to your sexual activity, but your answers are important in understanding how kidney disease impacts on people's lives.

16 Have you had any sexual activity in the past 4 weeks?

☐ No if no, please go to question 17

☐ Yes

How much of a problem was each of the following in the past 4 weeks?

		Not a problem	**A little problem**	**Somewhat a problem**	**Very much a problem**	**Severe problem**
a	Enjoying sex?	☐	☐	☐	☐	☐
b	Becoming sexually aroused?	☐	☐	☐	☐	☐

17 For the following question, please rate your sleep using a scale ranging from 0 representing 'very bad' to 10 representing 'very good'.

If you think your sleep is half-way between 'very bad' and 'very good', please mark the box under the number 5. If you think your sleep is one level better than number 5, mark the box under the number 6. If you think your sleep is one level worse than 5, mark the box under 4 (and so on).

On a scale 0 to 10, how would you rate your sleep overall? Mark a cross in one box.

Very bad									Very good
1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

18 How often during the past 4 weeks did you…

		None of the time	**A little of the time**	**Some of the time**	**A good bit of the time**	**Most of the time**	**All of the time**
a	Wake up during the night and have trouble falling asleep again?	☐	☐	☐	☐	☐	☐
b	Get the amount of sleep you need?	☐	☐	☐	☐	☐	☐
c	Have trouble staying awake during the day?	☐	☐	☐	☐	☐	☐

19 Concerning your family and friends, how satisfied are you with…

		Very dissatisfied	**Somewhat dissatisfied**	**Somewhat satisfied**	**Very satisfied**
a	The amount of time you are able to spend with your family and friends?	☐	☐	☐	☐
b	The support you receive from your family and friends?	☐	☐	☐	☐

20 During the past 4 weeks did you work at a paying job?

☐ No

☐ Yes

21 Does your health keep you from working at a paying job?

☐ No

☐ Yes

22 Overall, how would you rate your health? Mark a cross in one box.

Worst possible (as bad or worse than being dead)				Halfway between worst and best					Best possible
1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Satisfaction With Care

23 Think about the care you receive for kidney dialysis. In terms of your satisfaction, how would you rate the friendliness and interest shown in you as a person?

☐ Very poor
☐ Poor
☐ Fair
☐ Good
☐ Very good
☐ Excellent
☐ The best

24 How true or false is each of the following statements?

		Definitely true	**Mostly true**	**Not sure**	**Mostly false**	**Definitely false**
a	Dialysis staff encourage me to be as independent as possible	☐	☐	☐	☐	☐
b	Dialysis staff support me in coping with my kidney disease	☐	☐	☐	☐	☐

Section 3

The questions in this section ask about your own health state TODAY.

By placing a cross in each box for each question below, please indicate which statement best describes your own typical health state when you are not dialysing.
Please do not cross more than one box in each section.

3.1 Mobility

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

3.2 Self-care

I have no problems with self-care ☐
I have some problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

3.3 Usual activities

I have no problems with performing my usual activities (e.g., work, study, housework, family or leisure activities) ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

3.4 Pain/Discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

3.5 Anxiety/Depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

3.6 Your own health state

We want to know about your own health state TODAY and your own health state in GENERAL.

On the next page we would like you to indicate the state of your own health today and your own health in general.

To help you say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

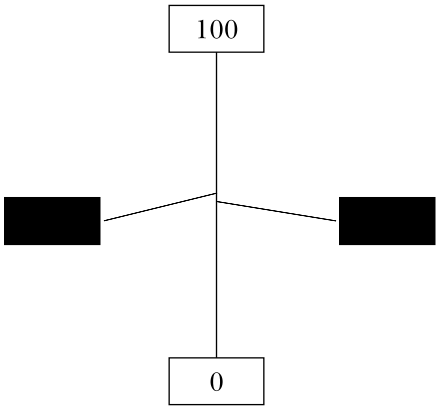
We would like you to indicate in this scale, in your opinion, how good or bad:

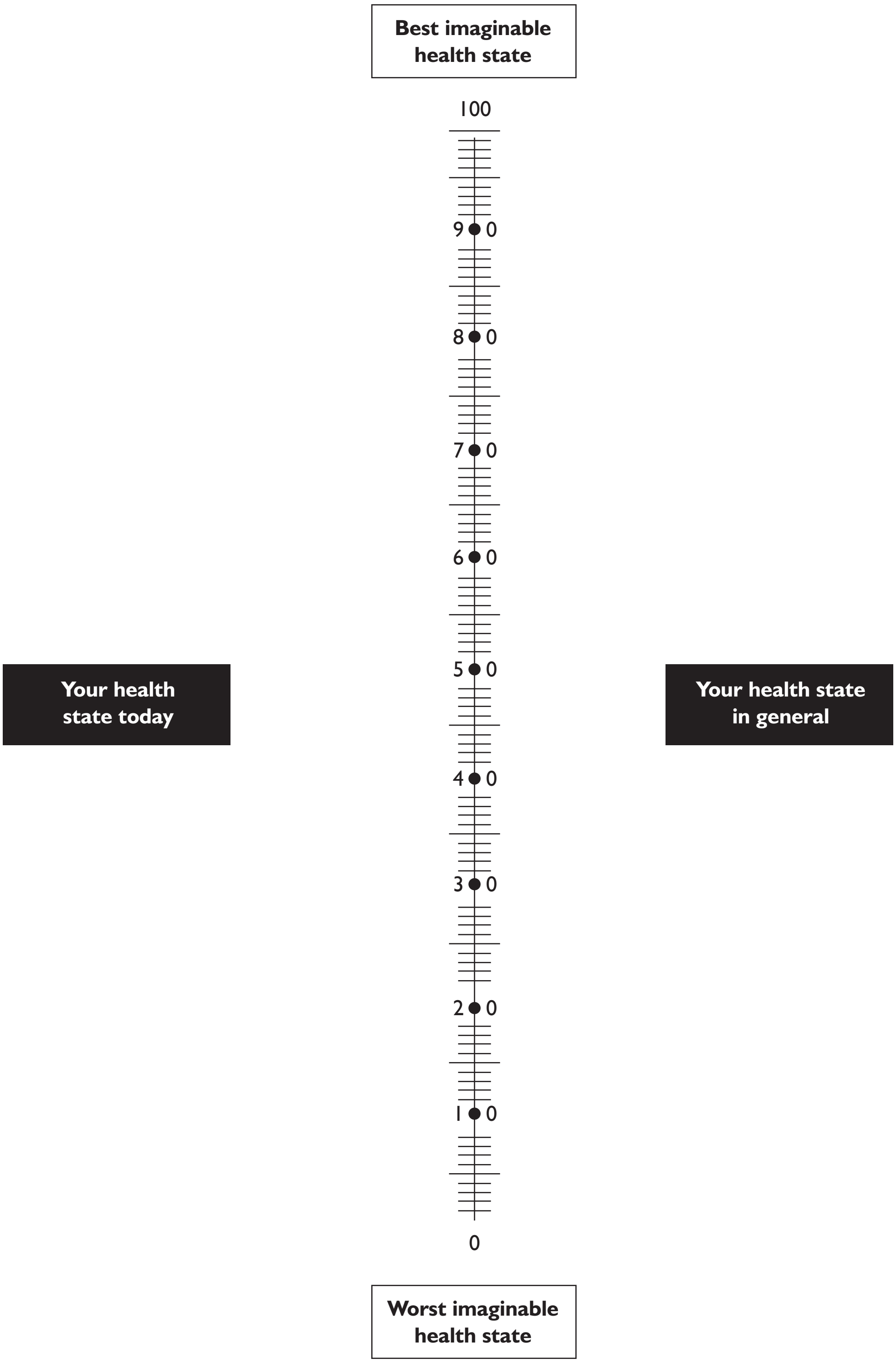
ii) your own health state is <u>today</u> and
ii) your own health state is in <u>general</u>

Please do this by drawing a line from the black boxes to whichever point on the scale indicated how good or had each health state is.

The lines may go anywhere on the scale but please make sure that the end of each line goes right up to the scale so we know exactly where it is.

Example:




Best imaginable health state
100
9●0
8●0
7●0
6●0
5●0
4●0
3●0
2●0
1●0
0
Your health state today
Your health state in general
Worst imaginable health state

Section 4

This section asks a few questions about yourself and where you live.

4.1 What age were you when you left full-time education? Please write your age in the box.

☐☐ years

4.2 During the last 30 days, were you:

☐ Employed full time
☐ Employed part-time
☐ Self employed
☐ Unemployed
☐ Retired
☐ Full-time student
☐ Look after home/family
☐ Permanently sick/disabled
☐ Other (please specify) ________________________

4.3 What is or was (if retired or unemployed) your main occupation?

☐ I do or did not work outside the home (please put a cross in the box if appropriate)

OR

Full job title ________________________

What do (did) you actually do in this job? ________________________

What do (did) your employer make or do? ________________________ ☐

4.4 What is or was (if retired or unemployed) your husband's/wife's/partner's main occupation?

☐ I do or did not work outside the home (please put a cross in the box if appropriate)

OR

Full job title ________________________

What do (did) they actually do in this job? ________________________

What do (did) their employer make or do? ________________________ ☐

4.5 How would you describe the ethnic group to which you belong? Please put a cross in one box only.

White	☐ British ☐ Irish ☐ Any other White background, please specify
Mixed	☐ White and Black Caribbean ☐ White and Black African ☐ White and Asian ☐ Any other Mixed background, please specify
Asian or Asian British	☐ Indian ☐ Pakistani ☐ Bangladeshi ☐ Any other Asian background, please specify
Black or Black British	☐ Caribbean ☐ African ☐ Any other Black background, please specify
Chinese	☐ Chinese
Any ethnic group	☐ Any other, please specify

4.6 Which of the following people live in the same household with you? Please put a cross in one box only.

☐ I live alone
☐ I live with my husband/wife or partner
☐ I live with other relatives
☐ I live with other non-relatives

4.7 How many cars does your household own? Please put a cross in one box only.

☐ No car
☐ 1 car
☐ 2 or more cars

Section 5

This section asks you questions about how you feel dialysing in your unit. (Please put a cross in the appropriate box).

	Yes	No
I have a good relationship with my consultant	☐	☐
I have a good relationship with the nurses who look after me on the dialysis unit	☐	☐
I feel safe dialysing in this unit	☐	☐
I am confident in the nurses' ability to deal with an emergency situation	☐	☐
There is usually enough time to discuss any problems I have with the nurses	☐	☐
It is easy to arrange to see a doctor who knows me well at short notice	☐	☐
There are enough opportunities to discuss my problems with my consultant	☐	☐
The dialysis staff tell me as much as I want to know about my kidney failure/dialysis treatment	☐	☐
The staff in the renal unit tell me as much as I want to know about my medical condition and treatment	☐	☐

Excluding Erythropoietin (EPO) who prescribes your regular medication?

☐ GP
☐ Renal Unit
☐ Both

	Yes	No
My regular medications are delivered without a problem	☐	☐
Delivery of an extra supply of regular medication or emergency medication (e.g. antibiotics) is easily arranged at short notice	☐	☐
It is easy to see a social worker at my request	☐	☐
It is easy to see a dietician at my request	☐	☐

These questions ask you about the impact of dialysis on your daily living

	Yes	No
Dialysis limits my social life outside the dialysis unit	☐	☐
Dialysis limits my partner's/carer's social life	☐	☐

These questions ask you about the general environment where you dialysis

	Yes	No
The unit has a friendly atmosphere	☐	☐
The atmosphere in the unit is calm and relaxing	☐	☐
The unit is well designed	☐	☐
I would prefer more privacy when I dialyse	☐	☐
I dialyse with the same group of patients at each dialysis session	☐	☐
I enjoy meeting other patients when I come for dialysis	☐	☐

Do you have any other comments that you would like to make?

Thank you very much for taking the time to complete this questionnaire

Appendix 5

Clinical questionnaire

Study Number: ☐☐ ☐☐☐ 1–5

☐1 6

Section 1: History of CRF

Date completed: ☐☐ / ☐☐ / ☐☐ 7–12

By: ND | AA | PR 13–15

Name of renal unit: ____________________ ☐☐ 16 17

			Not Known
1.1	When was the patient first referred to a nephrologist?	☐☐ / ☐☐ / ☐☐ 18 19 20 21 22 23	☐ 1 24
1.2	What was the creatinine at referral?	☐☐☐☐ **μmol/l** 25–28	☐ 1 29
1.3	When was the patient first referred to a dialysis centre (if different)	☐☐ / ☐☐ / ☐☐ 30 31 32 33 34 35	☐ 1 36
1.4	What was the creatinine at referral to the dialysis centre (if different from above)	☐☐☐☐ **μmol/l** 37–40	☐ 1 41

1.5 What is the main cause of CRF?

EDTA Code Description:

☐☐☐

42–44

1.6 What has been the history of patient’s renal replacement therapy in terms of dialysis and transplantation?

Start date:..................................

	Code	**Date**	**Comments**
1	☐ **45**	☐☐ / ☐☐ / ☐☐ **46–51**	
2	☐ **52**	☐☐ / ☐☐ / ☐☐ **53–58**	
3	☐ **59**	☐☐ / ☐☐ / ☐☐ **60–65**	
4	☐ **66**	☐☐ / ☐☐ / ☐☐ **67–72**	
5	☐ **73**	☐☐ / ☐☐ / ☐☐ **74–79**	
6	☐ **80**	☐☐ / ☐☐ / ☐☐ **81–86**	
7	☐ **87**	☐☐ / ☐☐ / ☐☐ **88–93**	
8	☐ **94**	☐☐ / ☐☐ / ☐☐ **95–100**	
9	☐ **101**	☐☐ / ☐☐ / ☐☐ **102–107**	
10	☐ **108**	☐☐ / ☐☐ / ☐☐ **109–114**	

Coding: 1 CAPD, 2 APD, 3 HOME HD, 4 HD PARENT MRU, 5 HD THIS SAT, 6 HD OTHER MRU, 7 HD OTHER SAT and 8 TRANSPLANT

1.7 What is the patient’s current access?

A-V Fistula ☐1 Graft ☐2 Temporary Catheter ☐3 Tunnelled Catheter ☐4 **115**/1/2/3/4

If tunnelled catheter used is more permanent access planned?

Yes ☐1 No ☐2 Nk ☐3 **116**/1/2/3

1.8 Site of current access?

Forearm ☐1 Brachial/ Upper arm ☐2 Leg ☐3 Internal Jugular Vein ☐4 Subclavian Vein ☐5 **117**/1/2/3/4/5

1.9 What type of dialysis is used for this patient?

Conventional diffusive dialysis ☐1 Haemodiafiltration ☐2 **118**/1/2

1.10 Monitoring techniques used routinely on this patient?

	Yes	No	Not known	
Sodium profiling	☐1	☐2	☐3	**119**/1/2/3
Relative blood volume monitoring	☐1	☐2	☐3	**120**/1/2/3
Ultra filtration profiling	☐1	☐2	☐3	**121**/1/2/3
BP monitoring	☐1	☐2	☐3	**122**/1/2/3
Other	☐1	☐2	☐3	**123**/1/2/3

1.11 Membrane/Dialyser used:

Membrane	Standard ☐1	Mod cellulose ☐2	Synthetic ☐3	**124**/1/2/3
Flux	High ☐1	Medium ☐2	Low ☐3	**125**/1/2/3

1.12 How often does the patient dialyse? ☐ / Week **126**

1.13 How long does the patient dialyse for? ☐☐.☐☐ Hrs/week **127–130**

1.14 If less than 3 × 4 hrs/week why? ☐☐ **131–132**

1.15 What admissions to hospital either during the last year on HD, or if < 1 year, since starting uninterrupted HD?

Start date:.................................

	Admission Date	Where Code	Discharge Date	Reason	Where Dx
1	☐☐ / ☐☐ / ☐☐ 133–138	☐☐ 139–140	☐☐ / ☐☐ / ☐☐ 141–146	☐☐ 147–148	☐☐ 149–150
2	☐☐ / ☐☐ / ☐☐ 151–156	☐☐ 157–158	☐☐ / ☐☐ / ☐☐ 159–164	☐☐ 165–166	☐☐ 167–168
3	☐☐ / ☐☐ / ☐☐ 169–174	☐☐ 175–176	☐☐ / ☐☐ / ☐☐ 177–182	☐☐ 183–184	☐☐ 185–186
4	☐☐ / ☐☐ / ☐☐ 187–192	☐☐ 193–184	☐☐ / ☐☐ / ☐☐ 195–200	☐☐ 201–202	☐☐ 203–204
5	☐☐ / ☐☐ / ☐☐ 205–210	☐☐ 211–212	☐☐ / ☐☐ / ☐☐ 213–218	☐☐ 219–220	☐☐ 221–222
6	☐☐ / ☐☐ / ☐☐ 223–238	☐☐ 229–230	☐☐ / ☐☐ / ☐☐ 231–236	☐☐ 237–238	☐☐ 239–240
7	☐☐ / ☐☐ / ☐☐ 241–246	☐☐ 247–248	☐☐ / ☐☐ / ☐☐ 249–254	☐☐ 255–256	☐☐ 257–258
8	☐☐ / ☐☐ / ☐☐ 259–264	☐☐ 265–266	☐☐ / ☐☐ / ☐☐ 267–272	☐☐ 273–274	☐☐ 275–276
9	☐☐ / ☐☐ / ☐☐ 277–282	☐☐ 283–284	☐☐ / ☐☐ / ☐☐ 285–290	☐☐ 291–292	☐☐ 293–294
10	☐☐ / ☐☐ / ☐☐ 295–300	☐☐ 301–302	☐☐ / ☐☐ / ☐☐ 303–308	☐☐ 309–310	☐☐ 311–312
11	☐☐ / ☐☐ / ☐☐ 313–318	☐☐ 319–320	☐☐ / ☐☐ / ☐☐ 321–326	☐☐ 327–328	☐☐ 329–330
12	☐☐ / ☐☐ / ☐☐ 331–336	☐☐ 337–338	☐☐ / ☐☐ / ☐☐ 339–344	☐☐ 345–346	☐☐ 347–348
13	☐☐ / ☐☐ / ☐☐ 349–354	☐☐ 355–356	☐☐ / ☐☐ / ☐☐ 357–362	☐☐ 363–364	☐☐ 365–366
14	☐☐ / ☐☐ / ☐☐ 367–372	☐☐ 373–374	☐☐ / ☐☐ / ☐☐ 375–380	☐☐ 381–382	☐☐ 383-384
15	☐☐ / ☐☐ / ☐☐ 385–390	☐☐ 391–392	☐☐ / ☐☐ / ☐☐ 393–398	☐☐ 399–400	☐☐ 401–402

1.16 How many routine planned out patient visits has the patient made in the last 6 months on HD, or if less than 6 months, since starting uninterrupted HD? And where did they take place?

Scheduled OP visits ☐☐ **403–404**

Where? [Tick box]

MRU ☐ 1

RSU ☐ 2

Other (specify) ☐ 3

405/1/2/3

☐ **406**

1.17 In addition to routine, planned out patient visits. How many non scheduled, non emergency out patient visits or ward visits have been made to the MRU in the last 6 months on HD, or if less than 6 months, since starting uninterrupted HD?

Non scheduled OP visits ☐☐ **407–408** Ward visits ☐☐ **409–410** total ☐☐ **411–412**

Definition of non scheduled / non emergency between 24 hours and 2 weeks of contact with MRU

1.18 How many dialysis related events have required an emergency visit to the MRU (either out patients or ward visit) in the last 6 months or if less than 6 months, since starting uninterrupted HD?

Total no of emergency visits ☐☐ **413–414**

Definition of emergency = within 24hrs of contact with the MRU.

Study Number: ☐☐ ☐☐☐ **1–5**

☐2
6

Section 2: Co-morbidity, therapies and baseline data

Co-morbidity Severity Score

2.1 Cardiac Disease

	Yes	**No**	**Nk**		
History of angina?	☐1	☐2	☐3	(include angioplasty or CABG)	**7**/1/2/3

	Yes	**No**	**Nk**	
Previous MI?	☐1	☐2	☐3	**8**/1/2/3

If so when? ☐☐ / ☐☐ / ☐☐ **Not Known** ☐ 1
9 10 11 12 13 14 15

Cardiac disease severity

	Yes	**No**	**Nk**	
None	☐1	☐2	☐3	**16**/1/2/3
Cardiac disease but no symptoms on effort	☐1	☐2	☐3	**17**/1/2/3
Minor limitations of activity by symptoms	☐1	☐2	☐3	**18**/1/2/3
Marked limitations of activity by symptoms	☐1	☐2	☐3	**19**/1/2/3
Symptoms at rest or on minimal exertion	☐1	☐2	☐3	**20**/1/2/3
Previous coronary angioplasty or CABG?	☐1	☐2	☐3	**21**/1/2/3

2.2 Peripheral Vascular Disease

	Yes	**No**	**Nk**	
History of ischaemic / neuropathic ulcers?	☐1	☐2	☐3	**22**/1/2/3

PVD severity

	Yes	**No**	**Nk**	
None	☐1	☐2	☐3	**23**/1/2/3
No symptoms on ordinary effort	☐1	☐2	☐3	**24**/1/2/3
Minor limitations of activity by symptoms (eg. claudication at > 100 yds)	☐1	☐2	☐3	**25**/1/2/3
Marked limitations of activity by symptoms (eg. claudication at < 100 yds)	☐1	☐2	☐3	**26**/1/2/3
Symptoms at rest or on minimal exertion OR previous arterial surgery/angioplasty/amputation	☐1	☐2	☐3	**27**/1/2/3

2.3 CNS severity

	Yes	**No**	**Nk**	
None	☐1	☐2	☐3	**28**/1/2/3
TIA	☐1	☐2	☐3	**29**/1/2/3
Previous stroke with good recovery	☐1	☐2	☐3	**30**/1/2/3
Previous stroke with incomplete recovery	☐1	☐2	☐3	**31**/1/2/3
Previous stroke with significant disability	☐1	☐2	☐3	**32**/1/2/3
Carotid endarterectomy	☐1	☐2	☐3	**33**/1/2/3

2.4 Respiratory Disease

	Yes	**No**	**Nk**	
History of chronic obstructive airways disease?	☐1	☐2	☐3	**34**/1/2/3

	Yes	**No**	**Nk**	
None	☐1	☐2	☐3	**35**/1/2/3
No symptoms on ordinary effort	☐1	☐2	☐3	**36**/1/2/3
Minor limitations of activity by symptoms (e.g. dyspnoea at > 100 yds)	☐1	☐2	☐3	**37**/1/2/3
Marked limitations of activity by symptoms (e.g. dyspnoea at < 100 yds)	☐1	☐2	☐3	**38**/1/2/3
Symptoms at rest or on minimal exertion	☐1	☐2	☐3	**39**/1/2/3

2.5 Liver Disease

	Yes	**No**	**Nk**	
History of liver disease?	☐1	☐2	☐3	**40**/1/2/3

	Yes	No	Nk	
Cirrhosis	☐1	☐2	☐3	**41**/1/2/3

2.6 Malignancy

			ACTIVITY			
	Quiescent [>5 years]	Low [<5years]	Medium [local spread]	High [metastasis]	Activity score Nk	
Skin Breast Bladder Cervix Uterus	☐1	☐2	☐3	☐4	☐5	**42**/1/2/3/4/5
Prostate Rectum Colon	☐1	☐2	☐3	☐4	☐5	**43**/1/2/3/4/5
Ovary Leukaemia	☐1	☐2	☐3	☐4	☐5	**44**/1/2/3/4/5
Stomach Lung Oesophagus Pancreas	☐1	☐2	☐3	☐4	☐5	**45**/1/2/3/4/5

	Yes	**No**	**Nk**	
Myeloma	☐1	☐2	☐3	**46**/1/2/3

2.7 Diabetes

	Yes	**No**	**Nk**	
Diabetes?	☐1	☐2	☐3	**47**/1/2/3
Is diabetes the presumed/biopsy proven cause of renal failure?	☐1	☐2	☐3	**48**/1/2/3

2.8 Viral Illnesses

	Yes	No	Nk	
Hepatitis B (HbsAg +ve)	☐1	☐2	☐3	**49**/1/2/3
Hepatitis C (HCV)	☐1	☐2	☐3	**50**/1/2/3
HIV	☐1	☐2	☐3	**51**/1/2/3

2.9 Other Major Illnesses (specify)

A ☐☐ **52–53**

B ☐☐ **54–55**

C ☐☐ **56–57**

D ☐☐ **58–59**

E ☐☐ **60–61**

2.10 Disability

	Yes	No	Nk	
Blindness	☐1	☐2	☐3	**62**/1/2/3
Wheelchair use	☐1	☐2	☐3	**63**/1/2/3
Other disability	☐1	☐2	☐3	**64**/1/2/3

(specify) ☐ **65**

Section 3: Current Dialysis Care

Current Medication/therapies

3.1 Renal Therapies

	Yes	No	Nk	
Vitamin D (alfacalcidol)	☐1	☐2	☐3	**66**/1/2/3
Phosphate binders	☐1	☐2	☐3	**67**/1/2/3
Sodium Bicarbonate	☐1	☐2	☐3	**68**/1/2/3
Iron supplements / IV iron infusion	☐1	☐2	☐3	**69**/1/2/3

3.2 Lipid Lowering Therapies

	Yes	No	No	
Statin	☐1	☐2	☐3	**70**/1/2/3
Fibrate	☐1	☐2	☐3	**1**/1/2/3
Other	☐1	☐2	☐3	**72**/1/2/3

3.3 Aspirin

	Yes	No	Nk	
Aspirin	☐1	☐2	☐3	**73**/1/2/3
Other anti thrombotic agents	☐1	☐2	☐3	**74**/1/2/3

3.4 EPO

	Yes	No	Nk	
EPO	☐1	☐2	☐3	**75**/1/2/3

Date started ☐☐ / ☐☐ / ☐☐ **Not Known** ☐ 1
76 77 78 79 80 81 82

Dose ☐☐☐☐ **IU**
83–86

Frequency ☐ / Week
87

Route **S/C** ☐1 **IV** ☐2 88/1/2

3.5 Antihypertensive Agents

Class	Yes	No	Nk	
Ace Inhibitors	☐1	☐2	☐3	**89**/1/2/3
AII Receptor Blockers	☐1	☐2	☐3	**90**/1/2/3
Calcium Channel Blockers	☐1	☐2	☐3	**91**/1/2/3
Beta Blockers	☐1	☐2	☐3	**92**/1/2/3
Alpha Blockers	☐1	☐2	☐3	**93**/1/2/3
Centrally Acting Agents	☐1	☐2	☐3	**94**/1/2/3
Other (specify)	☐1	☐2	☐3	**95**/1/2/3

________________________________ ☐ **96**

3.6 Blood Results Baseline Measurements (most recent result)

		Units	Date
Pre dialysis Urea	☐☐·☐ 97–100	mmol/l	☐☐ / ☐☐ / ☐☐ 101–106
Post dialysis Urea	☐☐·☐ 107-110	mmol/l	☐☐ / ☐☐ / ☐☐ 111-116
Haemoglobin	☐☐·☐ 117–120		☐☐ / ☐☐ / ☐☐ 121–126
Ferritin	☐☐☐☐ 127–130	Mcg/l	☐☐ / ☐☐ / ☐☐ 131–136
Uncorrected Calcium	☐·☐☐ 137–140	mmol/l	☐☐ / ☐☐ / ☐☐ 141–146
Corrected Calcium	☐·☐☐ 147–150	mmol/l	☐☐ / ☐☐ / ☐☐ 151–156
Alkaline phosphatase	☐☐☐☐ 157–160	iu	☐☐ / ☐☐ / ☐☐ 161–166
Phosphate	☐·☐☐ 167–170	mmol/l	☐☐ / ☐☐ / ☐☐ 171–176
Bicarbonate	☐☐ 177–178	mmol/l	☐☐ / ☐☐ / ☐☐ 179–184
Albumin	☐☐ 185–186	g	☐☐ / ☐☐ / ☐☐ 187–192
Cholesterol	☐☐·☐ 193–196	mmol/l	☐☐ / ☐☐ / ☐☐ 197–202
HBA1c	☐☐·☐ 203–206	%	☐☐ / ☐☐ / ☐☐ 207–212
iPTH	☐☐·☐ 213–216		☐☐ / ☐☐ / ☐☐ 217–222

Normal Range for centre ☐☐☐☐ : ☐☐☐☐
223–226 227–230

How often measured ☐☐ / Yr
231-232

URR ☐☐ % ☐ Not known
233–234 235

KT/V ☐·☐ ☐ Not known
236–238 239

3.7 BMI

Height: ☐☐☐ cm Weight: ☐☐☐·☐ kg
240–242 243–247

3.8 Blood Pressure (last 3 dialysis sessions)

	Pre Dialysis BP		**Post Dialysis BP**	
	Systolic	**Diastolic**	**Systolic**	**Diastolic**
1	☐☐☐ **248–250**	☐☐☐ **251–253**	☐☐☐ **254–256**	☐☐☐ **257–259**
2	☐☐☐ **260–262**	☐☐☐ **263–265**	☐☐☐ **266–268**	☐☐☐ **269–271**
3	☐☐☐ **272–274**	☐☐☐ **275–277**	☐☐☐ **278–280**	☐☐☐ **281–283**

3.9 Intradialytic weight gain (last 3 dialysis sessions)

	Pre Dialysis weight (kg)	**Post Dialysis weight (kg)**
1	☐☐☐ · ☐ **284–288**	☐☐☐ · ☐ **289–293**
2	☐☐☐ · ☐ **294–298**	☐☐☐ · ☐ **299–303**
3	☐☐☐ · ☐ **304–308**	☐☐☐ · ☐ **309–313**

Appendix 6

Karnofsky Performance Score

Study Number: ☐☐ ☐☐ ☐

Surname: ☐

Forename: ☐

Score %	Functional status
100	The patient has no complaints and is without evidence of disease
90	The patient has minor signs/symptoms, but is able to carry out his or her normal activities
80	The patient demonstrates some signs/symptoms and requires some effort to carry out normal activities
70	The patient is able to care for self, but is unable to do his or her normal activities or active work
60	The patient is able to care for self, but requires occasional assistance
50	The patient requires medical care and much assistance with self care
40	The patient is disabled and requires special care and assistance
30	The patient is severely disabled and hospitalisation is indicated; Death is not imminent
20	The patient is very ill with hospitalisation and active life-support treatment necessary
10	The patient is moribund with fatal process proceeding rapidly
0	Dead

Instructions:

Please circle the most appropriate score for this patient

Please do not write below this line:

....

Karnofsky Performance Score: ☐☐

Appendix 7

Adverse event monitoring

National Renal Satellite Unit Evaluation Study **MAJOR ADVERSE EVENTS**

Study Number: «RefNo»
Patient Name: «Surname» «Forename1»

Dialysis Session		Adverse Event Y or N	Type of event Code^1	Impact on dialysis Code^2	Action taken Code^3	Comment	Initials
	Date						
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							

[1]<u>CODING FOR ADVERSE EVENTS</u>

1. Hypotensive episode [defined as symptomatic drop in BP]
2. Chest pain
3. Cardiac dysrhythmia
4. Cardiac Arrest Call
5. IV Iron reaction
6. Dialyser reaction
7. Blood transfusion reaction
8. Access problems interfering with dialysis
9. Breathlessness
10. Other (specify)

[2]<u>CODING FOR IMPACT ON DIALYSIS</u>

1. None
2. Stopped dialysis early
3. Dialysis not started at satellite unit

[3]<u>CODING FOR ACTION TAKEN</u>

1. No action required
2. Main renal unit contacted by telephone only
3. Patient sent to main renal unit [MRU]
4. Patient sent to hospital other than MRU
5. 999 Called

Appendix 8

Supplementary information on clinical questionnaire coding

NOTES TO ACCOMPANY CLINICAL QUESTIONNAIRE

Section 1: History of chronic renal failure

1.1 Date of referral letter to nephrologist
1.2 Should be in referral letter or on computer
1.3 Date of letter from nephrologist to dialysis centre
1.4 Should be in referral letter or on computer
1.5 EDTA coding (see below) and longhand description from case notes

EDTA Code	**Codes**
Chronic renal failure: aetiology uncertain	0
Unknown/Unavailable	
Glomerulonephritis; histologically NOT examined	10
Focal segmental glomeruloscerosis with nephrotic syndrome in children	11
IgA nephropathy (proven by immunofluorescence, not code 76 and not 85)	12
Dense deposit disease; membrano-proliferative GN; type II (proven by immunofluorescence and/or electron microscopy)	13
Membranous nephropathy	14
Membrano-proliferative GN; type I (proven by immunofluorescence and/or electron microscopy – not code 84 or 89)	15
Crescentic (extracapillary) glomerulonephritis (type I, II, III)	16
Focal segmental glomeruloscerosis with nephrotic syndrome in adults	17
Glomerulonephritis; histologically examined, not given above	19
Pyelonephritis – cause not specified	20
Pyelonephritis associated with neurogenic bladder	21
Pyelonephritis due to congenital obstructive uropathy with/without vesico-ureteric reflux	22
Pyelonephritis due to acquired obstructive uropathy	23
Pyelonephritis due to vesico-ureteric reflux without obstruction	24
Pyelonephritis due to urolithiasis	25
Pyelonephritis due to other cause	29
Interstitial nephritis (not pyelonephritis) due to other cause, or unspecified (not mentioned above)	30
Nephropathy (interstitial) due to analgesic drugs	31
Nephropathy (interstitial) due to cis-platinum	32
Nephropathy (interstitial) due to cyclosporin A	33
Lead induced nephropathy (interstitial)	34
Drug induced nephropathy (interstitial) nor mentioned above	39
Cystic kidney disease – type unspecified	40
Polycystic kidneys; adult type (dominant)	41
Polycystic kidneys; infantile (recessive)	42

Medullary cystic disease; including nephronophthisis	43
Cystic kidney disease – other specified type	49
Hereditary/Familial nephropathy – type unspecified	50
Hereditary nephritis with nerve deafness (Alport's Syndrome)	51
Cystinosis	52
Primary oxalosis	53
Fabry's disease	54
Hereditary nephropathy – other specified type	59
Renal hypoplasia (congenital) – type unspecified	60
Oligomeganephronic hypoplasia	61
Congenital renal dysplasia with or without urinary tract malformation	63
Syndrome of agenesis of abdominal muscles (Prune Belly)	66
Renal vascular disease – type unspecified	70
Renal vascular disease due to malignant hypertension	71
Renal vascular disease due to hypertension	72
Renal vascular disease due to polyarterito	73
Wegener's granulomatosis	74
Ischaemic renal disease/cholesterol embolism	75
Glomerulonephritis related to liver cirrhosis	76
Cryoglobulinaemic glomerulonephritis	78
Renal vascular disease – due to other cause (not given above and not code 84–88)	79
Diabetes glomerulosclerosis or diabetic nephropathy	80
Myelomatosis/light chain deposit disease	82
Amyloid	83
Lupus erythematosus	84
Henoch-Schoenlein purpura	85
Goodpasture's Syndrome	86
Systemic sclerosis (scleroderma)	87
Haemolytic Uraemic Syndrome (including Moschcowitz Syndrome)	88
Multi-system disease – other (not mentioned above)	89
Tubular necrosis (irreversible) or cortical necrosis (different from 88)	90
Tuberculosis	91
Gout nephropathy (urate)	92
Nephrocalcinosis and hypercalcaemic nephropathy	93
Balkan nephropathy	94
Kidney tumour	95
Traumatic or surgical loss of kidney	96
Other identified renal disorders	99

1.6 Definition of date of first dialysis
No standard definition of the point at which an ESRF patient enters the renal replacement programme, particularly if they present as a uraemic emergency.
90 days after first dialysis session. (?Even if initially intermittent)
[1] Planned start of chronic patient should be easy to identify (from case notes or dialysis staff)
[2] Late referral/emergency presentation. For those patients who present 'acutely' and are treated as acute renal failure but are subsequently found to have ESRF. Date of first dialysis should be deemed their first dialysis from admission
[3] For those requiring intermittent dialysis? Renal Association standards document states that for patients who undergo repeated admissions in the first few months of treatment sometimes requiring short periods of dialysis before becoming permanently dependant on OP dialysis. The start of uninterrupted dialysis counts as the initiation date?

Registry definition
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.

Change in mode of dialysis
[1] A home haemodialysis patient ceases to be classed as such if they need greater than 2 weeks of hospital dialysis when not an inpatient.
[2] For patients who come off a mode of treatment temporarily Registry as yet has no definition for length of time needed to be off a particular mode before registering it as change in mode. Probably count change if > 1 month on a different modality.

If in doubt put in 'comments' column for discussion

1.7 Temporary access; a dialysis catheter [tunnelled or not] used for dialysis when the patient has either permanent access in situ [i.e. a graft or fistula] but not yet mature or permanent vascular access is planned.

1.8 Probably best to ask patient or nurse or look in dialysis folder (not always in case notes) wrist – self-explanatory, brachial comes from the elbow.
HD catheter temporary or permanent as above.
Subclavan vs internal jugular need to look in notes or ask.

1.9/1.11/1.12/1.13 Ask nurse or patient or look in dialysis charts

1.14 Case notes or ask nurse

1.15 Dialysis charts/machine or nurse

1.16 CODING

Where admitted
1. Parent MRU hospital
2. Other hospital with MRU
3. Other hospital without MRU
4. Other hospital without MRU + subsequent transfer as in patient to MRU
5. Other (specify)
6. Not known

Where dialysis
1. Parent MRU
2. This RSU
3. Other hospital MRU
4. Other hospital ITU/HDU
5. Other (specify)
6. Not known

Reason for admission

Renal related

1. infection related to access
2. other access problems e.g. stenosis/clotted lines etc. which are treated.
3. access failure
4. formation of new access
5. renal investigations
6. other (specify) e.g. related surgery such as carpal tunnel/transplant nephrectomy

Non renal

7. cardiac
8. vascular
9. cancer
10. gastro-intestinal
11. liver
12. trauma
13. social
14. psychological
15. infection (not access related)
16. emergency surgery (not renal related)
17. elective surgery (not renal related)
18. other
19. unknown

This information will give
Number of bed days
Number of admissions
Are satellite patients admitted more readily than MRU patients?
Will give information for planning and facilities needed in MRU to support RSU.

1.17/1.18 patient or nursing cardex/dialysis notes. Ward visits related to patients being sent up to unit and seen on the ward by a doctor or nurse for a particular problem and then sent home/back to RSU again. For definition of 'emergency' see Q.

Section 2: Co-morbidity, therapies and baseline data

from case notes and patient

2.1 MI = myocardial infarction (heart attack)
CABG = Coronary artery bypass graft ("heart bypass")
Cardiac disease = history of MI, angina, CABG, heart failure (left ventricular failure LVF, right heart failure RHF, congestive cardiac failure CCF)
Need to clarify definitions of minor and marked limitations? as with PVD

2.2 Include any leg ulcer unless definitely says venous ulcers (exclude)
Peripheral vascular disease (PVD) should be documented in notes; patients complain of claudication which is a cramping pain in the back of their calves when walking.
Previous arterial surgery e.g. anything below the waist e.g. fem – pop bypass graft, fem – fem bypass graft, aorto-fem bypass graft.
Angioplasty is a procedure with a balloon to stretch up the narrowed artery.

2.3 TIA is a transient attack or 'mini stroke' is stroke signs which resolve within 24 hours.
If previous history of carotid endarterectomy score as 2.

2.4 Chronic Obstructive Airways Disease = COAD
Chronic Obstructive Pulmonary Disease = COPD
Should be documented in notes

2.5 History of liver disease = previous or current hepatitis B, C, D or if documented as any liver disease in the notes including cirrhosis.

2.7 Diabetes = IDDM/NIDDM/Type 1 or Type 2 DM
If labelled as 'diabetic nephropathy" = cause of renal failure

2.8 Should be in case notes/dialysis notes or known by dialysis staff

Section 3: Current dialysis care

3.1 **Phosphate binders** Calcichew
Alucaps
Calcium 500
Calcium acetate (Phosex/Titrilac)
Iron supplements Ferrous Sulphate
Ferrous Gluconate
(Pregaday/Fersaday/Fersamal/Sytron)

3.2 **Statins** Simvastation (Zocor)
Fluvastatin (Lescol)
Atorvastatin (Lipitor)
Cerevastatin (Lipobay)
Pravastatin (Lipostat)
Fibrates Clofibrate (Atromid-S)
Bezafibrate (Bezalip)
Ciprofibrate (Modalim)
Fenofibrate (Lipantil),
Gemfibrozil (Lopid)
Other Cholestyramine (Questran)
Ispaghula (Fibrozest Orange)
Colestipol (Colestid)

3.3 **Other anti thrombotic/anti platelet agents**
Dipyridamole (Persantin),
Tranexamic Acid (Cyklokapron)
Clopidogrel

3.4 **EPO (erythropoietin)** (NeoRecormen, Eprex)
S/C = sub cutaneous (patients will either self administer or get an injection into the skin on dialysis)
IV = intravenous nurses will give during dialysis quite uncommon

3.5 **Antihypertensive agents.** There are hundreds of these. If in doubt just take down name.
Ace Inhibitors usually end in 'pril'
Captopril (Capoten)
Enalopril (Innovace)
Fosinopril (Staril)
Lisinopril (Carace/Zestril)
Perindopril (Coversyl)
Quinapril (Accupro)
Ramipril (Tritace)
Trandolapril (Gopten)
AII or Angiotensin II receptor blocks usually end in 'sartan'
Losartan (Cozaar)
Valsartan (Diovan)
Candesartan (Amias)
Irbesartan (Aprovel)
Calcium Channel Blockers often end in 'pine' also used as anti anginal agents. Try and distinguish if possible.
Amlodipine (Istin)
Felodipine (Plendil)
Nifedipine (Adalat)
Lacidipine (Motens)
Lercanidipine (Zanidip)

Diltiazem (adizem) tends to be used as an anti anginal but can be used for both

Beta Blocks	again used for both hypertension and angina Atenolol (Tenormin) Bisoprol Metoprolol
Alpha Blocks	also used for prostate Doxazisin (Cardura) Prazosin (Hypovase) Terazosin (Hytrin) Indoramin (Baratol)
Centrally Acting Agents	Moxonidine (Physiotens) Methyldopa (Aldomet)

3.6 From computer most recent result check that units are same as on questionnaire and document units where not mentioned on questionnaire.
URR = Urea reduction ratio dialysis staff should know where this is kept

$100 \times (1 - Ct/Co)$ Ct = *post dialysis urea*
Co = *pre dialysis urea*

Blood sampling is important. Renal Standards doc recommends method by Priester, Coary and Daugirdas (see page 98).
Renal Registry has previously carried out a telephone survey of methods of blood sampling in all units on the registry and there is much variation.

Appendix 9

Wright/Khan Co-morbidity Index

Risk group	**Age (years)**		**Other factors**[a]
Low	< 70	And	No co-morbid Illness
Medium	70-80	Or	Age < 70 with one of: Angina Previous MI Cardiac failure CVA COAD Pulmonary fibrosis Liver diseases (cirrhosis or chronic hepatitis)
		Or	Age < 70 with DM
High	> 80	Or	Any age with 2+ organ dysfunctions and ESRF
		Or	Any age with DM and cardiac/pulmonary disease
		Or	Any age with visceral malignancy

[a] MI, myocardial infarction; CVA, cardiovascular accident; COAD, chronic obstruction airway disease; DM, diabetes mellitus; ESRF, end-stage renal failure.

Appendix 10

Lister co-morbidity scoring system

2.1 Cardiac disease
0 = none
1 = cardiac disease but no symptoms on effort
2 = minor limitations of activity by symptoms
3 = marked limitations of activity by symptoms
4 = symptoms at rest or on minimal exertion
Note that history of angina/previous MI/previous CABG is not part of this scoring system

2.2 Peripheral vascular disease
0 = none
1 = no symptoms on ordinary effort
2 = minor limitations of activity by symptoms (e.g. claudication at > 100 yards)
3 = marked limitations of activity by symptoms (e.g. claudication at < 100 yards)
4 = symptoms at rest or on minimal exertion OR previous arterial surgery/amputation
Note history of ulcers is not part of this scoring system

2.3 Central nervous system
0 = none
1 = transient ischaemic attack
2 = previous stroke with good recovery
3 = previous stroke with incomplete recovery
4 = previous stroke with significant disability
Note carotid endarterectomy is not part of this scoring system

2.4 Respiratory disease
0 = none
1 = no symptoms on ordinary effort
2 = minor limitations of activity by symptoms (e.g. dyspnoea at > 100 yards)
3 = marked limitations of activity by symptoms (e.g. dyspnoea at < 100 yards)
4 = symptoms at rest or on minimal exertion
Note history of chronic obstructive airways disease is not part of this scoring system

2.5 Liver disease

2.6 Malignancy

	Activity			
	Quiescent [> 5 years]	**Low [< 5 years]**	**Medium [local spread] [metastasis]**	**High**
Skin Breast Bladder Cervix/uterus	1	1	2	3
Prostate Rectum/colon	1	2	3	3
Ovary Leukaemia	2	3	3	4
Stomach Lung Oesophagus Pancreas	3	3	4	4

Myeloma = 3

Note different scores assigned to different groups of malignancies
Diabetes/viral illness and other major illnesses are not in this scoring system

Appendix 11

Modified Charlson Co-morbidity Index

Weight (score for each condition)	**Condition**
1	Myocardial infarction Congestive cardiac failure Peripheral vascular disease Cerebrovascular disease Chronic pulmonary disease Connective tissue disease Peptic ulcer disease Mild liver disease Diabetes
2	Hemiplegia Moderate or severe renal disease Diabetes with end organ damage Any tumour (no metastasis within past 5 years Leukaemia (inc acute and chronic polycythemia vera) Lymphoma (inc Hodgkins, Waldenstroms, Myeloma, Lymphosarcoma)
3	Moderate or severe liver disease
6	Metastatic solid tumour AIDS

Note that this is a cumulative/additive scoring system: score the relevant 'weight' for each condition that a patient has to give the overall co-morbidity score.

Age weighting: add appropriate age score to co-morbidity total:

≤ 49 years	+0
50–59	+1
60–69	+2
70–79	+3
>80	+4

Appendix 12

Denominators associated with economic measures presented

Table 57 sets out the relevant denominators associated with each of the economic measures presented.

TABLE 57 *Number of patients analysed for each main cost outcome*

Item	**Denominator**	**Source**[a]
MRU (all possible patients)	335	–
RSU (all possible patients)	394	–
EPO dose and cost	729	CQ
Transport: NHS transport	626	PQ
Other health and social care contacts		
Community (use of primary/social care, i.e. GP, district nurse and social worker visits)	626	PQ
Use of secondary/tertiary care – scheduled renal outpatient visits (drops unit pairs without outpatients)	635	CQ
Hospital (use of secondary/tertiary care, i.e. hospitalisations)	729	CQ
Patient out-of-pocket expenses	626	PQ
Patient times		
Haemodialysis	729	CQ
Travel and waiting times	626	PQ
Total patient time	619	CQ and PQ

[a] CQ = clinical questionnaire – completed by researcher. PQ = patient questionnaire – completed by patient.

Appendix 13

Unit cost sources

The following is a list of items included under the different cost categories and the source of unit cost derivations.

Routine dialysis:

1. **Equipment and maintenance**
   Dialysis machines (including profiling) – manufacturer's list price.
2. **Staff**
   Medical staff time per journey from MRU to RSU and nursing staff (Trained and HCAs) – national pay scales[98] and unit costs of health and social care.[92]
3. **Consumables and drugs**
   EPO therapy – British National Formulary.[91]

Other health and social care contacts:

1. Community – Primary/social care
   GP consultation, district nurse and social worker visit – unit costs of health and social care[92] and national pay scales.[99]
2. Hospital – secondary/tertiary care
   Scheduled renal outpatient visits and hospitalisations – unit costs of health and social care.[92]

Appendix 14

Influence of patient dependency on staff time

As is typically the case, nursing staff time comprises a significant proportion of the total cost of treatment. However, in any one speciality or patient group, average nursing costs per patient (i.e. assuming that all patients use the same nurse time irrespectively) are likely to be a significant overestimate of the true costs for less nurse-dependent patients and an underestimate for more nurse-dependent patients. For this reason, it is usually desirable to consider the breakdown of nursing time for subgroups of patients who have different nursing needs and thus apportion nursing costs on the basis of a nurse dependency classification system. This was recognised as important for this study as the MRU patients were a mixture of chronic and acute HD patients and other renal patients. Furthermore, within the category of chronic HD patients there was a range of co-morbidities and other factors which influenced the amount of nursing care needed. However, the problem encountered was to find a suitable nurse dependency classification system which could be used to apportion nursing time appropriately. One potential candidate was the KPS included within the study. However, on closer inspection it was thought to be inadequate as the scores rated functional activity rather than dialysis-related dependency and did not indicate the staff time required.

One of the economists (TN) explored the possibility of identifying/developing a more suitable nurse dependency measure by eliciting the views of five key senior nurses based at different units. After an open-ended telephone discussion with the nurses to establish the purpose of the study, they were sent a list of patients' characteristics that were thought to identify patients who would take substantially more than the average amount of nurse time available during dialysis. The nurses were asked to rank the importance of these characteristics based on their own experience and, if they could, to supply other characteristics. Two nurses were also asked to give their expert views on the approximate amount of extra time required for trained and untrained nursing staff.

The responses obtained were variable and proved difficult to pool, particularly as the approach did not allow for patients who had several characteristics. There was broad consensus that patients with access issues (i.e. problems, new access sites and use of neckline); potential problems with fluid removal; a 'recent' inpatient stay; 'new' to the unit; requiring additional care such as iron injections, glucose infusions and blood transfusions; required more than average trained nursing time per session. Patients with disability (i.e. in terms of impaired use of arms/legs) often necessitated the use of two nurses or increased transport problems.

It was also agreed that patients who had communication problems (e.g. blindness, deafness, inability to speak and inability to understand English) were not thought to increase staff time requirements greatly unless they were 'new' patients.

Co-morbidity (e.g. diabetes), acute/recent events (e.g. fall at home or infection), treatment of adverse events (e.g. allergy to dialyser), ethnicity and social support produced variable responses from the nurses. Interestingly, factors other than older age or male gender (e.g. poor mobility or social problems) were deemed more likely to require greater nursing time.

The list of characteristics examined was not considered exhaustive; for example, patient adherence to fluid restrictions and tolerance of dialysis *per se* were not discussed. The main conclusion drawn was that no straightforward way was available to classify HD patients in terms of nursing requirements and the main study would have to revert to apportioning nursing costs to reflect average rather than marginal costs of care. Furthermore, since the impact on trained staff and HCAs varied according to the factor, the effect would vary by skill mix within each unit. It would be worthwhile for future cost studies to factor in more research into this issue.

Appendix 15

Key stakeholders approached for health economics data

The following lists the key stakeholders (staff or departments) providing unit-level data for calculation of healthcare costs. In many cases the Senior Nurse was able to collate all the information required.

- Finance Department: Finance Director or person responsible for renal budget
- Salaries: salaries and wages or payroll department
- Estates: for example, Facilities Director
- Hospital Trust: For example, Directorate Manager, Capital Planning
- Renal Services Management: for example, Business/Operations/Renal Services Manager, Renal Unit Administrator or Clinical Nurse Manager
- Nursing: HD Unit Senior Nurse Manager or Sister
- Medical: Clinical Director
- Technicians: Senior Renal Technician or Technical Manager, Maintenance Department
- Stores: person responsible for stock within HD unit or technical supplies.

Appendix 16

Equipment costs – dialysis machines

Equivalent annual costs were estimated using equation (2) for a range of machines available in the units. The impact of profiling on the cost of the machines was also investigated by subtracting the cost of each basic machine from those with profiling modules.

$$E = \frac{K - (S/1 + r)n}{A(n,r)} \qquad (2)$$

where

E = equivalent annual cost (£).

K = capital outlay (i.e. purchase price) (£). These prices were manufacturer's retail (list) price or occasionally tender prices obtained by the NHS Purchasing and Supply Agency (personal communication). Although these prices related to 1999–2001, the figures were not inflated to 2000–01 prices as machine prices have not varied greatly over the last few years, although technology has advanced.

n = useful life of equipment (years) minus 1 (to adjust for equipment being paid for in advance). The expected life of machines was assumed to be 7 years based on information collected from the units (reported to vary between 5 and 10 years).

r = discount (interest) rate (%) – assumed to be 6%.[88]

$A(n,r)$ = annuity factor for n years at discount rate r. This was calculated $A(n,r) = [1 - (1 + r) - n]/r$

S = resale value of the machine at the end of its useful life (£). This was assumed to be zero since most units donated the equipment to third-world countries or occasionally used them for parts.

Sensitivity analysis

Cost data were available for only 13 dialysis machines from three manufacturers (Baxter/Althin, Fresenius and Gambro/Cobe). Therefore, sensitivity analysis was performed using a best/worst estimate for the price of a dialysis machine (i.e. £7000 and £20,000). In addition, the useful life of a machine was varied between 5 and 10 years.

Annual dialysis machine costs per patient

The annual dialysis machine costs per patient used the mean dialysis machine equivalent annual cost divided by the unit's potential patient capacity per year. The latter was derived from the available dialysis sessions per machine per week divided by three (assuming three sessions per week per patient).

Appendix 17

Medical staff journey costs

Journey time and costs

The time costs for medical staff journeys (return) between the MRU and RSU were estimated. A senior nurse at each RSU was asked the typical duration of a one-way journey between the MRU and RSU. This was then doubled and multiplied by the hourly pay rate for the relevant grades of medical staff that provide on-site cover at the RSU. These results could not be aggregated to annual costs as the frequency of these journeys was very variable and the data were incomplete.

Annual salaries including National Insurance and superannuation

The mid-point (or one above if an even number of points) pay scale for each grade[99] was used to calculate the gross annual salary payable by an NHS Trust, including salary on-costs of employer's National Insurance and superannuation contributions. Rates for the latter were obtained from Southampton University Hospitals NHS Trust (personal communication) and are given in *Table 58*.

Hourly pay rates

Basic pay for medical staff was assumed to cover a 40-hour working week and a total of 44 working weeks per year (allowing 30 days of annual leave and 10 days of statutory leave including bank holidays, but excluding any allowance for study or sick leave – from working time for Specialist Registrars and Consultants[92]). This translated into the hourly pay rates shown in *Table 59*.

TABLE 58 *Employer's National Insurance and superannuation contributions (2000–01)*

Salary range (£)	National Insurance (£)	Superannuation (%)
0–4384.99	0	5
4385–27819.99	(9.2% × salary) – £399	5
≥27820	(12.2% × salary) – £1049	5

TABLE 59 *Mid-point and hourly pay rates for hospital medical staff (2000–01)*

Grade	Pay code	Mid-point gross annual salary (£)	Hourly rate (£)
Consultant	MC21 or MCRP	64601	36.70
Associate Specialist	MC01 or MCNP	47724	27.12
Senior Registrar	MN41 or MNTP	36619	20.81
Staff Grade Practitioner	(MH01 or MHNP) or (MH03 or MHNS) i.e. old/new contract averaged	35869	20.38
Specialist Registrar	MN25 or MNRU	33173	18.85
Registrar	MN31 or MNSP	29875	16.97
Senior House Officer	MN21 or MNRP	29145	16.56

Appendix 18

Nursing and HCA staff costs

Nursing and HCA staff costs were estimated per dialysis session and annually per patient.

Basic gross annual salaries

Annual salary scales payable by NHS Trusts were derived from the mid-point (or one above if an even number of points) pay scale for each grade.[99] This included the salary on-costs of employer's National Insurance and superannuation contributions (as described in Appendix 17). The basic gross annual salaries are shown in *Table 60*.

At each staff grade, the basic gross annual salary was multiplied by the WTE number of nurses or HCAs and summed to give the total cost of nursing and HCA staff. Where necessary, equivalent grades were used for staff. For example, the Senior Assistant Technical Officers pay scale was approximately equivalent to an HCA Grade B salary and Assistant Technical Officers and Renal Dialysis Orderlies approximately equivalent to HCA Grade A. The nearest equivalent national salary was also used to impute staff costs from units not using national salary scales. These calculations only applied to staff directly involved in chronic HD as far as it was possible to attribute (e.g. by use of sessions). In one private unit grades/salaries were negotiated individually and were confidential data. In this case salary costs could not be calculated. Pay also excluded London weighting and bonuses to attract staff [although the latter were rare (one unit)].

Additional payments for unsocial hours

It was also necessary to calculate the cost of unsocial hours (i.e. for Saturdays, Sundays, night work and bank holidays) for each unit. These were estimated over 1 year from the unit's 'out-of-hours' opening hours multiplied by the typical number of staff (nurses and HCAs) for the relevant shifts. Where necessary, staffing numbers were averaged across different shift patterns. Bank holiday payments were based on eight per year and used the Monday opening hours where a unit's daily opening hours varied. To avoid double counting, night hours worked during bank holidays were deducted.

Three further assumptions were made, namely that all shifts were full-time, weekend staffing patterns mirrored those of the week (unless informed otherwise) and staffing outlier sessions did not incur unsocial hours payments (i.e. dialysed during usual 'business' hours). Unsocial hours were averaged across grades by shift (i.e. did not take into account actual skill mix) and therefore may have overestimated costs where senior staff worked fewer nights or weekends.

For each unit, an average annual salary (per WTE) was calculated separately for nurses and HCAs, but using the Grade F basic gross annual salary for Grades G and above (in line with common practice for unsocial hours payments). Separate average hourly rates payable for nurses and HCAs

TABLE 60 *Nurses and HCAs: mid-point basic gross annual salaries by grade (2000–01)*

Staff type and grade	Pay code	Mid-point basic gross annual salary (£)
Trained nurses		
I	NP56	30977
H	NP51	28071
G	NP46	25239
F	NP41	22470
E	NP36	19763
D	NP31	17782
HCAs		
C	NP21	14955
B	NP16	12586
A	NP06 (over 18)	10998

were calculated by dividing their respective average annual salaries by annual hours available (1950 or 52 weeks at 37.5 hours per week). Average additional hourly rates payable were derived by multiplying the additional percentage payable by the average hourly rate. This adopted the most commonly used percentages (i.e. 30% for nights and Saturdays and 60% for Sundays and bank holidays).

Unsocial hours payments were calculated by multiplying the unsocial hours by the average additional hourly rates in proportion to the trained/HCA split, and then summing across nurses and HCAs.

Nursing staff cost per dialysis session

The available dialysis sessions per year were calculated by multiplying the number of sessions available per week by 52. This ignored whether or not sessions were attributable to acute or chronic HD dialysis in cases where units had mixed workloads.

The total cost of nursing staff, using basic pay and basic pay plus unsocial hours, was then divided by the sessions per year to give the cost per dialysis session. All the above calculations were performed for both the staff in-post and establishment (i.e. including vacancies).

Nursing staff costs per patient per year

Annual nursing staff costs per patient were also calculated by aggregating to 1 year the nursing staff in-post cost per dialysis session including unsocial hours. This assumed that patients underwent thrice-weekly dialysis, 52 weeks per year.

Appendix 19

Primary care costs

The cost per patient for GP, district nurse and social worker visits during the 4 weeks prior to the study visit were valued by multiplying the number of relevant contacts by a unit cost per contact whose derivation is explained below. These costs were then aggregated to 1 year.

Unit cost per GP contact

Basic pay for a GP in 2000–01 (£59,380) was assumed to cover a 44.7-hour working week and 46.5 weeks per year (including annual leave and an allowance for study and sick leave[92]) or an hourly rate of pay of £28.03. Elsewhere it has been shown that about 58% of GPs' time is spent on direct patient contact and that this varies by type of GP consultation (i.e. surgery, clinic, home and by telephone).[92] Since study data did not record type of GP consultation, the unit cost of GP time was adjusted to account for time in different settings. Weighting factors were derived as shown in *Table 61* and produced an averaged consultation time of 12.6 minutes (allowing for travelling time for home visits) and an hourly rate of £5.88 per GP contact.

Unit cost per district nurse contact

The basic annual salary for a district nurse in 2000–01 (£25,239) was taken as the mid-point G Grade[99] including salary on-costs (as described in Appendix 17). This was assumed to cover a 37.5-hour working week and a total of 45 working weeks per year (allowing 25 days of annual leave and 10 days of statutory leave, but excluding any allowance for study or sick leave (from working time for district nurse[92]). This translated into 1688 working hours per year and was divided into the annual salary to derive the hourly pay rate (£14.96). Using 20 minutes as the typical duration of a home visit and travel cost of £1.10 per visit,[92] the unit cost per district nurse contact was £6.09. It should be noted that the salary oncosts (i.e. Employer's National Insurance and contribution to superannuation) from this source[92] vary slightly from those used above.

TABLE 61 *Derivation of average duration of GP contact*

Consultation type[a]	**Proportion of time (%)**	**Weighting factor (i.e. proportion of direct patient contact time)**	**Consultation time (minutes)**
	a	*b* = *a*/total direct patient contact	*c*
Surgery	36.6	0.63	9.36
Clinic	2.9	0.05	12.6
Telephone	7.7	0.13	10.8
Home visit (including 12 minutes travelling time)	10.5	0.18	25.2
Total (weighted) per consultation (i.e. sum of *b* × *c*)			12.6

[a] Note: total direct patient contact 57.7%.

Unit cost per social worker contact

The costs per social worker contacts were calculated using the face-to-face and client-related hourly rates for a social worker (adult) in 2000–01 (£87 and £23, respectively).[92] These figures included overheads and capital overheads, but excluded travel costs as there was no information on the latter. The following assumptions were made about contact times:

1. First visit (£55):
    (a) 30 minutes face-to-face
    (b) and 30 minutes client-related
2. Subsequent visits (£27.50 per visit):
    (a) 15 minutes face-to-face
    (b) and 15 minutes client-related.

Appendix 20

Hospitalisation costs

Table 62 shows the unit costs per inpatient day corresponding to reasons given for hospitalisations. Total hospitalisation costs per patient were derived by multiplying length of stay data for each hospitalisation by the relevant unit cost (per inpatient day). It was assumed that day cases were half the cost of inpatient days. All unit costs per inpatient day were inflated from the published 1999–2000 figures to 2000–01 using the pay and prices inflation index.[93]

TABLE 62 *Unit costs per inpatient day (2000–01)*

Admitting speciality	Reasons for admissions extracted from medical notes	Unit cost per inpatient day (£)
Nephrology	Infection related to access – renal Other access problems – renal Access failure – renal Formation of new access – renal Renal investigations – renal Other renal reason specified – renal and Fluid overload – renal	295
Cardiology	Cardiac – non-renal	447
Gastroenterology	Gastrointestinal – non-renal Liver – non-renal	259
Generic	Vascular – non-renal Social – non-renal Infection – non-renal not access Other – non-renal Unknown	252
Medical oncology	Cancer – non-renal	374
People with mental health problems	Psychological – non-renal	172
Surgery	Trauma – non-renal Emergency surgery – non-renal And Elective surgery – non-renal	355

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The HTA Programme and the authors would like to know your views about this report.

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We look forward to hearing from you.

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