Appendix A The Renal Registry Rationale

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A:1 Executive summary

1.1 The Renal Registry has been established by the Renal Association to act as a resource in the development of patient care in renal disease.

1.2 The Registry will act as a source of comparative data for Audit/Benchmarking, Planning, Policy and Research. The collection and analysis of biochemical and haematological data will be a unique feature of the Registry.

1.3 Agreements will be made with participating renal centres which ensure a formal relationship with the Registry and safeguard confidentiality

1.4 The essence of the Agreement will be the acceptance of the Renal Registry Data Set Specification as the basis of data transfer and retention.

1.5 Data will be collected quarterly to maintain Unit-level quality assurance, with two reports per annum.

1.6 A pilot study has been successfully completed, with funding from the Department of Health and donations from industry. Subsequent activity will have to be self-funded by capitation of renal patients from commissioning agencies.

1.7 The Registry is likely to become responsible for reporting UK activity in ESRF to the EDTA Registry as well providing data to Trusts, Commissioning Authorities and Regional Offices.

1.8 The development of the Registry will be open to influence from all interested parties, including Clinicians, Trusts, Commissioning Authorities and Patient Groups.

The Registry has charitable status through the Renal Association.

A:2 Introduction

2.1 Few important developments have a single origin and that is true of The Renal Registry. Information on patients receiving Renal Replacement Therapy (RRT) was first collected in the Registry of the European Dialysis and Transplant Association (EDTA) after 1965 and that continues with a base in London and Annual Reports to the membership. This exercise was voluntary for Renal Units throughout Europe and was conducted on paper and by post. As well as the main Centre Questionnaire and individual patient follow up data occasional detailed studies of specific topics were undertaken. Latterly, the completeness of data recording, particularly patient-specific detail, has become a problem, for a number of reasons. The development of single country databases, such as RENINE in the Netherlands, has improved the quality of data and there have been several models of computer-based returns. Registries developed later in the USA (USRDS) and the Antipodes have benefited from the earlier experience. They have been typically better resourced, as well as more conveniently embedded in the administrative infrastructure of renal services. In the United Kingdom the Scottish Renal Registry was established with initial assistance from the Scottish Office and has demonstrated the practicalities of data collection in a UK renal environment.

2.2 In recent years the incompleteness of UK data returns to EDTA has meant that it was not possible to build a picture of RRT activity for planning and policy purposes. The Renal Association steered an investigation of renal demographics in three centres which was published subsequently, but national data for England only became available through two *ad hoc* national data collections solicited from renal centres in 1992 and 1996. The first of these not only led to a report of national demographic and treatment data but also carried a review of the cultural and clinical expectations of RRT activity (The National Renal Review). One of the recommendations of the Review was the participation of renal units in comparative audit. The two data collections were not resourced at unit level and clearly did not provide a robust model for information gathering in the future.

2.3 After the NHS Reforms of 1990 the need for accurate and timely information about clinical services became pressing and that remains the case. The interests of both Trusts and Health Authorities demand knowledge of activity in Renal Services, which is costly to produce and express.

2.4 Together with the need to know the demographic and economic elements of the Health Service has developed a need to underpin clinical activity more rigorously through the scientific evidence base (for example the Cochrane Initiative) and quality

assure that activity through audit. These initiatives require comprehensive information about the 'Structures. Processes and Outcomes' of RRT, which go well beyond the detail previously compiled by EDTA.

2.5 The Renal Association has made a start in the area of Audit by publishing guidelines in 'Renal Standards' documents. It was apparent during the development of the guidelines that many criteria of clinical performance were uncertain or unknown, and that only the accumulated data of practising renal units could provide the evidence for advice on best practice and what might realistically be achieved. The impetus towards comparative audit between renal units, piloted in preliminary exercises by Lister/St.James's and the West Midlands Group, has become irresistible. A common data registration provides the most simple device for comparative audit.

2.6 Similar cultural pressures have affected all clinical disciplines, so that Registries are implemented or planned in cardiac surgery, intensive care, diabetes etc. Where information is held for other purposes there has also been a move to use it for reporting and audit. This has been apparent in the renal field where UKTSSA have published data drawn from information held for the management of organ matching and graft follow-up. These are useful data of course, but UKTSSA is unfortunately not in a position to provide comprehensive data on other modes of renal replacement therapy. The longitudinal consequences of the national renal replacement programme must be derived from additional sources.

Registry-based National Specialty Comparative Audit is likely to be one of the cornerstones of NHS development. More specifically, the aspiration for renal services to be provided within a National Service Framework is underpinned by the development of the Renal Registry (A First Class Service: Quality in the new NHS).

2.7 The recent emphasis on Evidence Based Practice is being supported by the changes in research funding (Culyer Report), which lean towards collaborative projects and include both basic science and 'Health Services Research' components. It is apparent that a RRT database could be invaluable to a wide range of research studies. The Renal Association has recognised the potential for integrated work in renal disease through a Clinical Trials Committee, which is supporting a number of national studies in renal disease.

2.8 It can be seen that the need for a Registry of RRT, at least, has developed for a variety of reasons; international comparisons *2.1*, national planning *2.2/2.6*, local Trust and Health Authority management *2.3*, standard setting / audit *2.4/2.5*, and research *2.7*. The opportunity for data gathering partly arises from improvements in information technology, a field in which renal units have always been strong compared with the clinical community. While it was possible to see the need for a national renal database a decade and a half ago, the circumstances are now ideal for the maintenance of a data repository for all the purposes described above, supported by the clinical users and resourced for national benchmarking as a routine part of orthodox RRT management.

A:3 Statement of intent

The Renal Registry provides a focus for the collection and analysis of standardised data relating to the incidence, clinical management and outcome of renal disease. Data will be accepted quarterly according to the Renal Registry Data Set Specification (RRDSS) by automatic downloading from renal centre databases. There will be a core data set, with optional elements of special interest which may be entered by agreement for defined periods. Reports will be published twice yearly to allow comparative audit of facilities, patient demographics, quality of care and outcome measures. Participation is voluntary but the expectation is that all UK renal and transplant units will take advantage of the database by their involvement ultimately. There will be an early concentration on RRT, including transplantation, with an extension to other nephrological activity at a later date. The Registry will provide an independent source of data and analysis on national activity in renal disease.

A:4 Pilot study

4.1 A two year pilot project was started in April 1995.

4.2 The Renal Registry Data Set Specification was developed by the Clinical Co-ordinator in consultation with a Steering Committee and implemented on the computer system at UKTSSA, Bristol. It consists of approximately 200 core items, with additional data sets which are regarded as optional.

4.3 A limited number of renal sites with well-developed information systems were visited* and their database structures aligned with the RRDSS. Data on ESRF patients were then transferred to the registry database to provide the substrate for the first report to the Renal Association, March 1997.

4.4 The pilot study was funded partly by the Department of Health and partly by donations from industry.

4.5 The pilot study demonstrated the feasibility of data capture from a range of sites and was regarded as successful by the Renal Association and the Registry management committee. The Registry has subsequently been opened for any renal unit to participate. Software to accommodate reporting from centres without a CCL database has been written.

4.6 * Bristol, Gloucester, Leeds (St.James's), Leicester, Plymouth, Sheffield

A:5 Relationships of the renal registry

5.1 The Registry is a registered Charity through the Renal Association (No. 800733). It was established by a sub-committee of the Renal Association, with additional representation from the British Transplantation Society and the British Association for Paediatric Nephrology. There is cross representation with the Renal Association

Standards and Clinical Trials Committees. The Registry has a Chairman and Secretary nominated by the Renal Association. The Registry is pleased to receive an observer from the Department of Health.

5.2 It is anticipated that there will be a need for the development of a number of sub-committees as the database and participation enlarges, particularly for data analysis and interpretation.

5.3 The Registry is grateful to UKTSSA for early assistance with accommodation and supporting services and regrets the constraints which prevented further sharing of resources. It is hoped to continue to work closely with UKTSSA in future for the sharing and validation of data held by the two groups.

5.4 It is anticipated that the return of English, Welsh and at least Northern Irish data to EDTA will be through the Renal Registry. Further discussions are to be undertaken with the Scottish Renal Registry and renal centres in Eire regarding collaborative data reporting and comparison.

5.5 Data from paediatric renal units will be entered on the database, which will allow long-term studies of renal cohorts over a wide range of age.

5.6 The basis of participation for Renal Units nationally will be an Agreement to accept the Renal Registry Data Set Specification for the transmission and retention of data. This will consist of a core data set of some 200 items and further optional elements, which will be returned on a special understanding with the unit for a defined period of reporting. The Agreement specifies the conditions of participation and guarantees confidentiality of the data. The responsibilities of the Unit and Registry are clarified in the clauses of the Agreement, as well as the conditions of publication of data.

A:6 Registry role for nephrologists

6.1 The clinical community have become increasingly aware of the need to define and understand their activities, particularly in relation to national standards and other renal units.

6.2 The Renal Standards documents are designed to give a basis for unit structure and performance, as well as patient-based elements such as case-mix and outcomes. It is anticipated that Standards will become increasingly based on research evidence and the Cochran Collaboration has resourced reviews of renal topics recently which will support the conversion from clinical anecdote.

6.3 The registry data will be available to allow comparative review of many elements of renal unit practice. Data will be anonymised and presented as graphical output in various convenient formats to allow a contrast of individual unit activity and results with national aggregated data.

6.4 Reports of demographic and treatment variables will be available to the participating centres for distribution to Trust, Health Authorities and Regional Offices

as required and agreed with the Unit. EDTA reporting should be transparent for the Unit where complete data have been registered. Common reports should facilitate discussion with Trust officers and Purchasers, particularly for Clinical Directors where appointed.

6.5 Customised data reports will be available after negotiation in regard to feasibility and costs. A charge may be levied if requests are outside Registry objectives for the current round.

6.6 The database has been designed to provide research database facilities for future participation in national and international trials. There will be an opportunity to be involved in the selection of topics for national audit and research according to local and professional interests.

6.7 The Registry is run by a sub-committee of the Renal Association and therefore by colleagues with similar concerns and experience.

6.8 These facilities will only be sustainable through co-operation with the need for high quality and comprehensive data entry at source. Attention is drawn to the conditions listed in the formal Agreement with the Registry.

A:7 Registry role for trust managers

7.1 One of the principles of health service informatics is that the best data are acquired from clinical information recorded at the point of health care delivery.

7.2 The gathering and registration of data relating to patient management should be regarded as an essential part of routine patient management in the health service.

7.3 Renal Services data entered on local systems by staff directly engaged with patients is likely to be of the highest quality, and it is this that the Registry intend to capture through the RRDSS.

7.4 The regular reports of the Registry will supply the details of patient demographics, treatment numbers and changes, treatment quality and outcomes. Data will be compared with national standards and national performance for benchmarking and quality assurance. The assessment of contract activity and service delivery will be possible through the data returns without the need for further, costly Trust administrative activity. These data should be particularly valuable to Contracts Managers and Medical Directors.

7.5 The comparisons with other centres will allow unbiased estimates of Renal Unit performance against costs. Data will be available on Unit infrastructure and facilities.

7.6 The Registry is focused on Renal services and will provide a cost-effective source of detailed information.

7.7 It is anticipated that data on patients with renal disease other than those requiring RRT will become available in time.

7.8 It is anticipated that Trust interests will ultimately be served by the participation of a national trust representative in the management body of the Registry as the database expands.

A:8 Registry role for commissioners of health care

8.1 The use of information sources such as the Registry is advised in the National Renal Review so as to promote benchmarking and quality assurance on renal programmes. The comprehensive tracking of a relatively small but costly renal cohort should be regarded as a routine part of case management.

8.2 The Registry will be able to provide validated, comparative reports of renal unit activity on a regular basis to participating centres. These will allow assessment of unit performance in a wide range of variables relating to 'Structure, Process and Outcome' measures.

8.3 There must be economies of scale in the performance of audit through the Registry, since multiple local audits will no longer be required.

8.4 The incidence of ESRF treated locally will be apparent from new patient registrations. Mortality and renal transplant rates should also be of interest. The geographical origin of ESRF cases will be indicated by postcode data which allows the assessment of referral and treatment patterns. This information will allow the expression of geographical and ethnic variations. These data will indicate unmet need in the population and permit judgements of the equity of service provision. The later Registry database should give information on nephrology and pre-dialysis patients which will allow prediction of the need for ESRF facilities.

8.5 Registry data will be used to track patient acceptance and ‘stock’ rates over time, which will allow the modelling of future demand and validation of predictions.

8.6 Information on the clinical diagnosis of new and existing RRT patients will give a lead to possible preventive measures in regard of hypertension and diabetes in particular. Any clusters of genetic disorders should also be apparent. The origin of ESRF in acute renal failure (ARF) that does not recover will be of interest in assessing the quality of local ARF Services. The results of higher acceptance rates in the elderly and the consequences of increasing demand from ethnic groups bearing a high prevalence of renal, circulatory and diabetic disease will be measurable.

8.7 Comparative data will be available in all categories for national and regional benchmarking.

8.8 The Registry offers independent expertise in the analysis of Renal Services data and their interpretation, a resource which is widely required but difficult to obtain.

8.9 The cost of supporting the Registry is estimated at between £10 and £20 per registered patient per annum, which is less than 0.1% of the typical cost of a dialysis patient per annum. It is expected that the costs will need to be explicit in renal services contracts so as to ensure the continuation of the Registry on a sound basis.

8.10 It is anticipated that the joint Commissioning Authorities will be asked to suggest a representative for the management committee of the Registry as the database expands, which will allow for purchasers to influence the development of the Registry and the topics of interest in data collection and analysis.

A:9 Abbreviations

ARF	Acute Renal Failure
CCL	Clinical Computing Limited
EDTA	European Dialysis and Transplant Association (European Renal Association)
ESRF	End Stage Renal Failure
NHS	National Health Service
RRDSS	Renal Registry Data Set Specification
RRT	Renal Replacement Therapy
UKTSSA	United Kingdom Transplant Support Service Authority
USRDS	United States Renal Data System