Appendix A: The Renal Registry Rationale

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 sequential 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 (RRDSS) as the basis of data transfer and retention.

1.5 Data will be collected quarterly to maintain unit level quality assurance, with an annual report

1.6 Activity is funded by the capitation of renal patients from commissioning agencies.

1.7 The Registry is likely, with the express agreement of participants, to become responsible for providing data to Trusts, commissioning authorities and Regional Offices, and the new European Renal Association–European Dialysis and Transplant Association (ERA–EDTA) Registry.

1.8 The development of the Registry will be open to influence from all interested parties, including clinicians, Trusts, commissioning authorities and patient groups.

1.9 The Registry has charitable status through the Renal Association.

A:2 Introduction

2.1 Registry based National Specialty Comparative Audit is one of the cornerstones of NHS development. The Renal *National Service Framework* (NSF), published in 2004, recommended the participation of all renal units in comparative audit through the Renal Registry.[1] Chief Executives are now responsible for clinical governance, and comparative audit at national level will be an essential part of this agenda.[2] The UK Renal Registry will facilitate such audit. This audit demands the regular transmission of large volumes of data which has become possible with developments in electronic data handling.

2.2 The need for careful comparative audit has been confirmed through the development of government agencies such as the National Institute for Clinical Excellence (NICE) and the Healthcare Commission. The final relationship of the Registry to these organisations as they develop has yet to be defined.

2.3 Demographic information on patients receiving renal replacement therapy (RRT) throughout Europe was collected from 1965 in the Registry of the ERA-EDTA. This voluntary exercise was conducted on paper and by post, demanded considerable effort and time from participating units and eventually proved impossible for many UK renal units. In recent years, the incompleteness of UK data returns to ERA-EDTA has meant that it has not been possible to build a picture of activity of RRT in the UK for planning and policy purposes, although four ad hoc national data collections from England & Wales were solicited from renal centres in 1992, 1996, 1999 and 2002. The Registry will meet this need for demographic and economic data necessary for effective planning.

2.4 Together with the need to know the demographic and economic elements, the NHS has developed a need to underpin clinical activity more rigorously through the scientific evidence base (for example, the Cochrane Initiative) and by quality assurance 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 the ERA-EDTA.

2.5 The Registry is recognised as one of the few high-quality clinical databases available for general use.[3]

2.6 The aspiration for renal services to be provided within the National Service Framework is underpinned by the development of the Renal Registry.[4]

2.7 Similar cultural pressures have more recently affected all clinical disciplines, so that Registries are implemented in cardiac surgery, intensive care, diabetes, etc.

2.8 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. A common data registration provides the simplest device for such comparative audit.

2.9 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 an RRT database could be invaluable to a wide range of research studies.

2.10 It can be seen that the need for a Registry of RRT has developed for a variety of reasons: international comparisons, national planning, local Trust, PCT and health authority management, standard setting, audit and research. The opportunity for data gathering arises partly from improvements in information technology. Although 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 RRT management.

A:3 Statement of intent

3.1 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 RRDSS by automatic downloading from renal centre databases. There will be a core dataset, with optional elements of special interest that may be entered by agreement for defined periods. A report will be published annually to allow a comparative audit of facilities, patient demographics, quality of care and outcome measures. Participation is mandated through the recommendation in the Renal NSF. 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 Relationships of the Renal Registry

4.1 The Registry is a registered charity through the Renal Association (No. 800733). It was established by a committee of the Renal Association, with additional representation from the British Transplantation Society, the British Association for Paediatric Nephrology, and the Scottish Renal Registry. There is cross-representation with the Renal Association Standards and Clinical Trials Committee and Clinical Affairs Board. The Registry has a Chairman and Secretary nominated by the Renal Association. The Registry has an observer from the Department of Health and participants from the National Federation of Kidney Patients' Associations and Health Care Commissioners.

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

4.3 The Scottish Renal Registry sends data to the Renal Registry for joint reporting and comparison.

4.4 It is anticipated that the return of English, Welsh and Northern Ireland data to the ERA Registry will be through the Renal Registry. The Scottish Renal Registry already sends data to ERA Registry.

4.5 A paediatric database has been developed in collaboration with the Renal Registry, and the two databases are compatible. These two databases are in the process of being integrated which will allow long-term studies of renal cohorts over a wide range of age.

4.6 The basis of participation for renal units nationally will be an Agreement to accept the RRDSS for the transmission and retention of data. This will consist of a core dataset 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 will specify the conditions of participation. 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:5 The role of the Renal Registry for nephrologists

5.1 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.

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

5.3 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 Cochrane Collaboration has recently resourced reviews of renal topics, which will support the conversion from clinical anecdote.

5.4 The Registry data will be available to allow the comparative review of many elements of renal unit practice. Centre data will be presented to allow a contrast of individual unit activity and results against national aggregated data.

5.5 Reports of demographic and treatment variables will be available to the participating centres for distribution to Trusts, PCTs, health authorities and Regional Offices as required and agreed with the unit. Reports should facilitate discussion between clinicians, Trust officers and commissioners.

5.6 Customised data reports can be made available by agreement with the Registry committee. A donation to cover any costs incurred will be requested.

5.7 The Registry Committee will welcome suggestions for topics of national audit or research that colleagues feel are of sufficient widespread interest for the Registry to undertake.

5.8 The database has been designed to provide research database facilities for future participation in national and international trials.

Members of the Renal Association and other interested parties are welcome to apply to the Registry committee to conduct local or national audit and research using the database. All such projects will need the agreement of the Registry committee and any costs involved must be met by the applicants.

5.9 These facilities will be sustainable only through co-operation between nephrologists and the Registry. There is a need for high quality and comprehensive data entry at source. Attention will be necessary to the conditions listed in formal Agreements with the Registry.

A:6 The role of the Renal Registry for Trust managers

6.1 As the basis of the clinical governance initiative, the gathering and registration of data relating to patient management is regarded as an essential part of routine patient management in the health service.

6.2 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.

6.3 Renal services data entered on local systems by staff directly engaged with patients are likely to be of the highest quality, and it is these that the Registry intends to capture.

6.4 The Registry will provide a cost-effective source of detailed information on renal services.

6.5 The regular reports of the Registry will supply 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 or commissioner administrative activity. These data should be particularly valuable to contracts managers and those responsible for clinical governance.

6.6 Data will be available on unit case mix, infrastructure and facilities.

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

6.8 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 Registry activity expands.

A:7 The role of the Renal Registry for commissioners of health care

7.1 The commissioners of health care are taken to include Regional Specialty Commissioning Groups and those supporting them, and the Primary Care Trusts.

7.2 The use of information sources such as the Registry is advised in the National Renal Review[5] in order to promote benchmarking and quality assurance on renal programmes. The comprehensive tracking of relatively small but costly renal cohorts should be regarded as a routine part of case management.

7.3 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.

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

7.5 The incidence of RRT treated locally will be apparent from new patient registrations. Mortality and renal transplant rates should also be of interest. The geographical origin of established renal failure 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 future Registry database should give information on nephrology and pre-dialysis patients, which will allow a prediction of the need for RRT facilities.

7.6 Registry data will be used to track patient acceptance and prevalence rates over time which will allow the modelling of future demand and the validation of predictions.

7.7 Information on the clinical diagnosis of new and existing RRT patients will point to areas where possible preventive measures will have maximal impact.

7.8 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.

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

7.10 The Registry offers independent expertise in the analysis of renal services data and their interpretation, a resource that is widely required but difficult to obtain.

7.11 The cost of supporting the Registry is £15 per registered patient per annum, which is less than 0.05% of the typical cost of a dialysis patient per annum. It is expected that the costs will need to be made explicit in renal services contracts in order to ensure the continuation of the Registry on a sound basis.

7.12 The Registry Sub-committee now includes a representative of health care commissioners, which allows an influence on the development of the Registry and the topics of interest in data collection and analysis.

A:8 The role of the Renal Registry for national quality assurance agencies

8.1 The role of the Registry in national quality assurance as developed through NICE and the Healthcare Commission will depend on decisions as to the roles of those agencies.[6]

8.2 The demographic, diagnostic and outcomes data could support the investigation of clinical effectiveness in a variety of ways, depending on the focus of interest.

8.3 There is pressure from some quarters to publish reports in which survival data from renal units are clearly identified. The maintenance of unit anonymity on survival data is likely to be important to some and it may significantly compromise co-operation if abrogated without agreement. It is ultimately possible that a decision could be forced on the Registry from outside, although it is hoped that this situation will not arise. Consideration of this issue in particular would be welcome in nephrological circles, with correspondence to the Registry committee.

A:9 The role of the Renal Registry for patients

9.1 The ultimate aim of the Registry is to improve care for patients with renal disease. The appropriate use of Registry information should improve equity of access to care, adequacy of facilities, availability of important but high-cost therapies such as erythropoietin, and the appropriate and efficient use of resources. The continuing comparative audit of the quality of care should facilitate the improvement of care and outcomes of care. It is intended to identify and publish examples of good practice. In such ways, patients will be the ultimate beneficiaries of the exercise.

A:10 Abbreviations

BAPN	British Association of Paediatric Nephrology
BTS	British Transplantation Society
ERA–EDTA	European Renal Association–European Dialysis and Transplant Association
ERF	Established Renal Failure
NFKPA	National Federation of Kidney Patients' Associations
NHS	National Health Service
NICE	National Institute of Clinical Excellence
PCT	Primary Care Trust
RRDSS	Renal Registry Data Set Specification
RRT	Renal Replacement Therapy

A:11 References

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