Chapter 2: Introduction to the 2003 Report

Summary

In 2002, 42 renal units from England and Wales sent data to the Renal Registry, including seven new units that had not previously submitted data and all the renal units in Wales. In 2003 two further units joined the Registry, and 10 more units are actively in the process of joining during 2004. Some data from Scotland are submitted by the Scottish Renal Registry, and a summary of data from Northern Ireland has been received. It is hoped that during 2004 full data from Northern Ireland will be transmitted. By the end of 2004 the Registry should be receiving data covering at least 90% of patients in the UK receiving renal replacement therapy.

This has been a remarkably significant twelve months for renal patients and Renal Medicine in several ways.

The publication of the Renal National Service Framework (NSF) for England also promises to be a watershed for the Registry. This document firmly recommends that all renal units should participate in national comparative audit through the Renal Registry. The Registry is likely to be an active agent in monitoring implementation of the NSF, and is working closely with the Centre for Health Audit and Inspection (CHAI), and the National Health Service Information Agency (NHSIA), in developing this role.

One potential barrier to the development of the Registry was the need to reconcile the identification of patients as they moved between units with recent legislation designed to protect personal information held on computer databases. A most important step for the Registry has been the success of its application to the Patient Information Advisory Group for temporary exemption under section 60 of the Health and Social Care Act 2001 from some provisions of the Data Protection Act, which will allow the Registry to continue to collect some patient identifiable data whilst procedures are put in place to facilitate the accurate collection of anonymised data. Full details of this are included in this chapter.

The Registry has worked closely with the Department of Health in carrying out a further National Review of Renal Services throughout the UK. There was 100% response and, in addition to some of the information routinely collected by the Registry, details of staff and facilities available for the treatment of renal disease were collected. A summary of the findings will be found in Chapter 3; the full report will be published by the Department of Health.

As the Registry develops the role of monitoring the implementation of the NSF, it is essential that it works efficiently and accurately. This, and the growth of the work of the Registry, has necessitated an increase in staff. A part-time general manager has been recruited; there are now three statisticians, and two Registry Specialist Registrars participating in the work of the Registry, audit and research. To allow this enhanced capability there has been an increase in the annual capitation fee charged to renal units, which puts the Registry on a firm financial footing.

This is the largest and most ambitious report published by the Registry, and contains several new analyses. Of particular interest is the work on equity of access to Renal Replacement Therapy in Chapter 4. The calculation of acceptance ratios for patients in different local authorities, using the national census data to allow correction for population structure, is the first work of its kind. There is also new information concerning ethnic minority groups.

New work is presented on the survival of patients with established Renal Failure and on the influence of both initial co-morbidity and subsequent quality of care on eventual

clinical outcome (Chapter 15). Contrary to reports from the International Dialysis Outcomes and Practice Patterns Study (iDOPPS), survival of patients in the UK compares favourably with Europe and the USA. The reasons for this are discussed further in Chapter 21, where several international comparisons are reported. In essence, the iDOPPS study is a study of haemodialysis practice. The UK has a high proportion of patients with renal transplants or receiving peritoneal dialysis, and the haemodialysis patients are a selected group of above average risk patients. They should not be compared with cohorts of haemodialysis patients from countries where other modalities are much less utilised.

There is new work on serum calcium/phosphate product (Chapter 9), hypertension (Chapter 11), date of first referral and timing of initiation of RRT (Chapter 16), and on social deprivation and ERF (Chapter 17). This report also contains new data and analyses concerning diabetics with ERF, and the control of their diabetes (Chapter 19). The influence of ethnicity is considered in Chapter 20 and the incidence of co-morbidity in patients starting renal replacement therapy is considered in Chapter 21.

It may be worth repeating that the UK Renal Registry is firmly part of the Renal Association, and remains independent of the Department of Health, and of Government. It provides an independent source for auditing the care provided for renal patients throughout the UK, and for monitoring the implementation of the Renal NSF in England.

Areas covered by the UK Renal Registry

The areas covered by the UK Renal Registry, and the completeness of such cover, are illustrated in Figure 2.1.

Centres in the 2003 Registry report

All the renal units in England & Wales (listed in Table 2.1) run the CCL Proton software, except :-
Ipswich and Bangor (Baxter system), Hammersmith (own system), Newcastle (CCL clinical vision), Kings (Own system - Renalware) and Stevenage (Lister's own system Renalplus).

Exclusion of data from the report

Derby and St Mary’s London renal units have not been included in this report (Table 2.2). Due to inaccuracies in the units’ patient treatment history timelines it was not possible accurately to calculate the number of incident and prevalent patients for these units.

The Scottish Registry was unable to submit the detailed data in time to be included in this analysis, although summary numbers for incidence and prevalence in Scotland were provided. Summary data from Northern Ireland on incidence and prevalence were also obtained.

The participating centres are shown in Table 2.1 and the areas represented in Figure 2.1.

Centres who have recently joined the Registry

The renal units shown in Table 2.3 have joined the Registry since the database was closed for this report. At least one file has been successfully loaded onto the Registry database from each site. Data from these units will be included in the next Report.

Centres in the process of joining the Registry

Work is in progress to connect the centres listed in Table 2.4 to the Registry. Some, if not all, will be included in the next Report.

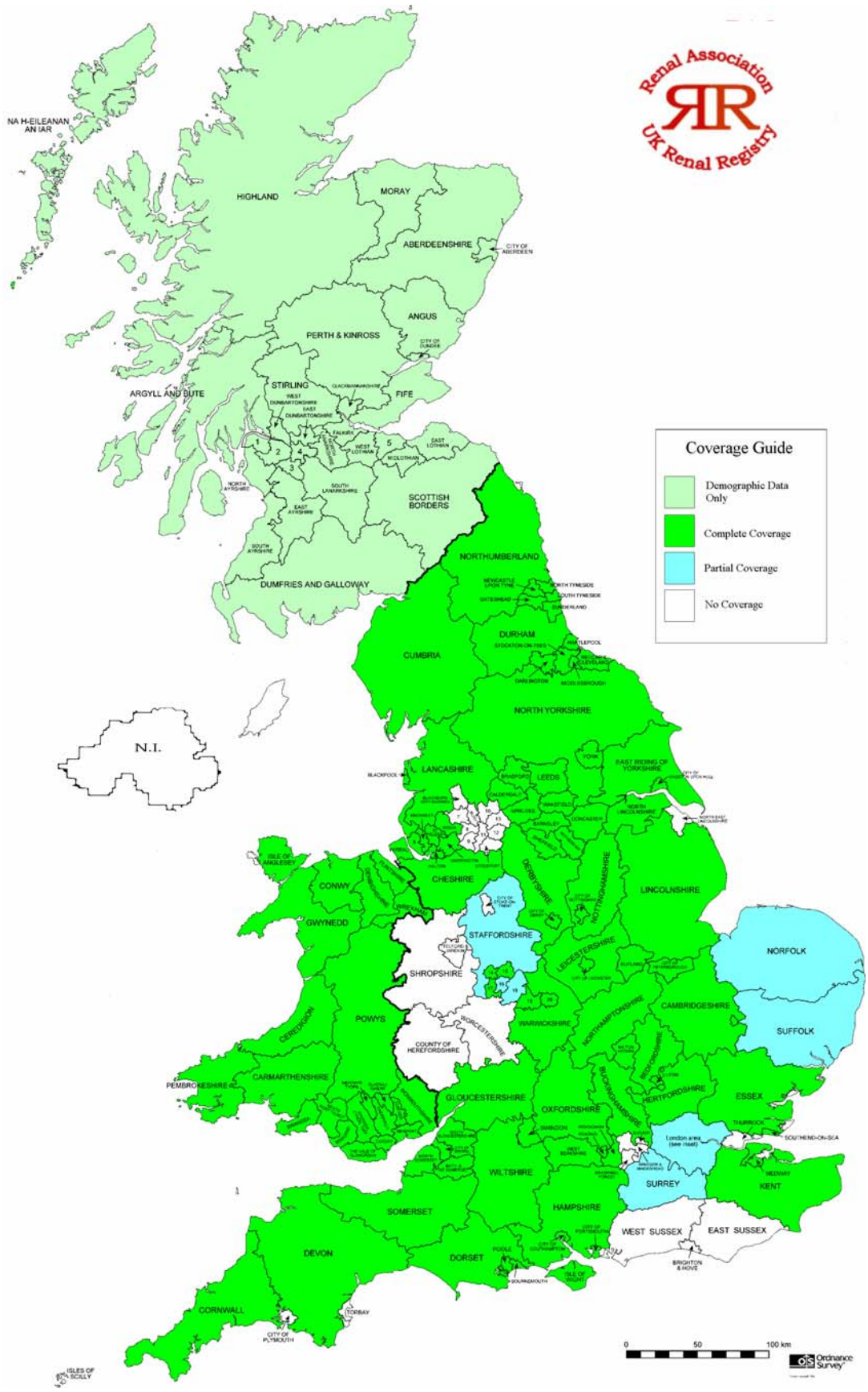

Figure 2.1. Areas covered by the Renal Registry

Table 2.1. Centres in the 2003 Registry Report

England & Wales		**Estimated population (millions)**
*Bangor	Ysbyty Gwynedd	0.18
Birmingham	Heartlands Hospital	0.60
Bradford	St Luke's Hospital	0.60
Bristol	Southmead Hospital	1.50
Cambridge	Addenbrookes Hospital	1.42
Cardiff	University of Wales Hospital	1.30
Carlisle	Cumberland Infirmary	0.36
Carshalton	St Helier Hospital	1.80
Coventry	Walsgrave Hospital	0.85
Exeter	Royal Devon and Exeter Hospital	0.75
Gloucester	Gloucester Royal Hospital	0.55
Hull	Hull Royal Infirmary	1.04
*Ipswich	Ipswich Hospital	0.33
Leeds	Leeds General Infirmary	0.90
Leeds	St James's Hospital	1.30
Leicester	Leicester General Hospital	1.80
Liverpool	Royal Infirmary	1.35
London	Guys and St Thomas' Hospital	1.70
*London	Hammersmith + Charing Cross	1.30
*London	Kings College Hospital	1.01
Middlesborough	James Cook University Hospital	1.00
*Newcastle	Freeman Hospital	1.31
Nottingham	Nottingham City Hospital	1.16
Oxford	Churchill Hospital	1.80
Plymouth	Derriford Hospital	0.55
Portsmouth	Queen Alexandra Hospital	2.00
Preston	Royal Preston Hospital	1.48
Reading	Royal Berkshire Hospital	0.60
*Rhyl	Ysbyty Clwyd	0.15
Sheffield	Northern General Hospital	1.75
Stevenage	Lister	1.25
Southend	Southend Hospital	0.35
Sunderland	Sunderland Royal Hospital	0.34
Swansea	Morriston Hospital	0.70
Truro	Royal Cornwall Hospital	0.36
*Wirral	Arrowe Park Hospital	0.53
Wolverhampton	Newcross Hospital	0.49
Wordsley	Stourbridge Hospital	0.42
Wrexham	Maelor General Hospital	0.42
York	York District Hospital	0.39
Total		37.69

*These units are included in the report for the first time.

Table 2.2. Excluded centres

		Est pop (mil)
Derby	Derby City Hospital	0.48
London	St Mary's Paddington	0.81

Table 2.3. Centres who have recently joined the Registry

	(Indicates IT system used by hospital)	Estimated population (millions)
Norwich	James Paget Hospital (Mediqal system)	0.84
Birmingham	Queen Elizabeth Hospital (own system)	1.82

Table 2.4. IT systems being implemented

	(Indicates IT system used by hospital)	Estimated population (millions)
Basildon	(Mediqal)	
Brighton	Royal Sussex County Hospital– CCL windows	0.98
Canterbury	Kent & Canterbury (Velos system)	1.20
Dorset	Dorchester Hospital (Mediqal)	0.60
London	Royal Free (King's system)	0.67
Manchester	Hope Hospital (EPR hospital system)	0.94
Northern Ireland	Belfast + four renal units (Mediqal system)	
Stoke	North Staffs (Cybernius Canadian system)	0.70

Centres in discussion with the Registry

All the remaining renal units in England have made contact with the Registry and are considering the steps needed to join. These are listed below in Table 2.5. The factor preventing these remaining units joining the Registry is that they do not yet have satisfactory computerised patient information systems. For some of these units, there has been a lack of available finance to purchase suitable systems.

Future coverage by the Registry

From the data presented here, it can be seen that the report on the 2002 data covers up to 80% of the UK for some items, and that by the end of 2003 some 90% or more of the UK will be covered by the Registry. With the recommendation in the Renal National Service Framework (NSF) that all units should par-

Table 2.5. Centres without Registry-compatible IT

	(Indicates IT system used by hospital)	Estimated population (millions)
Chelmsford	Broomfield Hospital (buying Mediqal)	-
Manchester	Royal Infirmary (buying system – undecided)	2.51
Shrewsbury	(Buying Lister system)	0.40
London	Middlesex / UCLH (buying system - undecided)	0.75

ticipate in audit through the Registry, complete coverage of the UK should be accelerated. The Commission for Healthcare Audit and Inspection (CHAI) wishes to use the Registry as one vehicle for monitoring implementation of the NSF. Commissioners of renal services will thus be encouraged to enable the provision of adequate data systems for all units to join the Registry.

Software and links to the Registry

From the above information, it is evident that there are now 13 systems available for purchase and use in renal units. The Registry is working with the relevant companies to help them to provide appropriate software links to the Registry.

In addition, the Lister renal unit in Stevenage has developed an in-house system that has a working Registry interface. The software has been offered free by the Trust to the NHS Information Agency (NHSIA), and there has been an agreement with the NHSIA to support the system. There is an annual support charge levied by the NHSIA for this system.

Paediatric Renal Registry links

In the UK there are an estimated 750 patients under 18 years old who are on renal replacement therapy. As most of the 13 UK paediatric renal units are small, the British Association of Paediatric Nephrology (BAPN) was able to set up its own database to collect data. As in previous years, this report includes a chapter of analyses from these data.

In order to integrate these data with the adult Registry, and also provide funded resources for data management, the BAPN has asked the adult Registry to develop ways of collecting these paediatric data. The plans for these sites are listed in Table 2.6. All of the adult renal IT systems require some modifications to collect the extra data specifically required in the paediatric dataset. This process of integration of paediatric data is now well under way.

Links with other organisations

The UK Renal Registry has been active in supporting the Renal Association Standards Sub-committee in the production of the new standards document. Support has been given to the Department of Health in gaining the basic data necessary for the future planning of renal services. The Registry has also participated in providing data to help formulate the advice for ministers for the renal NSF, and is working with the National Health Service Information Authority (NHSIA) on the information strategy to support the renal NSF. The Registry is part of the Kidney Alliance. Discussions are taking place on forging closer links with the Commission for Healthcare Inspection and Audit.

The Registry has been working with the UK Transplant Authority to produce analy-

Table 2.6. Paediatric renal unit plans

Sites	Comments
Belfast	Plan to join the adult system
Birmingham	Linked directly to Registry
Bristol	Sent with adult data
Cardiff	Sent with adult data
Dublin	Plan to join adult system
Leeds	Sent with adult data
Liverpool	Joining Bristol's system
London Gt Ormond St	Joining Bristol's system until local EPR developed
London Guy's	Joined Guy's adult system
Manchester	Joined Bristol's system
Newcastle	Sent with adult data
Nottingham	Sent with adult data
Southampton	Joining Bristol's system
Glasgow	Sent via Scottish Registry

ses utilising the strengths of both databases. The UK Registry sends fully anonymised data to the European Renal Association Registry. There has been contact with the International Federation of Renal Registries, but patient data are not sent to this organisation.

New arrangements for commissioning renal services

In April 2002, the 95 existing health authorities in England were reformed as 28 strategic health authorities (StHAs). Established renal failure has been designated by the government as a service for specialist commissioning. In the Renal NSF the Strategic Health Authorities have been given a clear role in monitoring the performance of the specialised commissioning consortia. The Registry will try to assist specialised commissioning consortia with appropriate data and analyses. The Registry has also received requests for data from some individual PCTs that are involved in commissioning.

The Registry and clinical governance

There has been considerable debate within the Renal Association Trustee and Executive Committees, and the Registry Sub-committee, about the Registry's responsibilities under the principles of clinical governance, particularly if an individual renal unit appears to be under-performing in some areas of activity. Where outcome data appear to show cause for concern, the Registry will first discuss them further with the renal unit to establish the validity of the data. If, after such investigation, the problems persist, the Registry will recommend that the renal unit seek an external peer review, and may need to consider informing the local commissioners.

The Registry Report is also sent to the Chief Executive of all Trusts in which a renal unit is situated, since the responsibility for clinical governance within the Trust lies with the Chief Executive. For the anonymised parts of the report, the Chief Executive is informed of the code of the relevant unit.

Anonymity and confidentiality

There has been pressure for the Renal Registry to cease the anonymous reporting of results and analyses, and to identify the individual renal centres. The removal of anonymity would not only aid the development of comparative audit and assist learning from best practice, but also assure public accountability. This has been discussed in the Renal Registry Committee and at the Renal Association Executive Committee, and both have recommended the introduction of a timescale for the removal of anonymity. After consultation with the participating renal units, a phased programme towards the removal of anonymity was agreed.

In 2001, the incidence and prevalence data were identified by named renal unit, which has generated increased feedback from sites and improved the accuracy of the data transmitted to the Registry. In 2002, anonymity was removed from all the adult data except for the survival figures in individual renal units.

A meaningful comparison between renal units of survival requires the ability to correct for case mix, which needs robust initial co-morbidity data: these are not yet available from many units. In some of the analyses in this report, it has been possible to study the influence of initial co-morbidity. However, as is evident in Chapter 20, reporting of initial co-morbidity is still very poor in many units, and is not sufficient for meaningful adjustments to outcome data. For this reason, survival data are still reported anonymously. The renal NSF encourages reporting of such data, and it is hoped this will encourage more renal units to collect these data so that accurate comparative results may be achieved.

Where anonymity has been retained in the report, neither the Chairman of the Registry nor the Sub-committee members are aware of the identity of the centres within the analysis; only the Renal Registry director, data manager and statisticians are able to identify the centres. This identification is necessary so that the Registry can discuss with the relevant centre any issues raised or discrepancies in the analysis.

The Data Protection Act and the 'Health and Social Care Act 2001': section 60 exemption

Summary

The Registry has been granted section 60 exemption from compliance with the 1998 Data Protection Act with regard to collecting patient identifiable data.

Section 60 exemption is only granted on a temporary basis until full compliance with the Data Protection Act can be achieved. For full compliance data must be anonymous, or collected with permission of the individual patient. Progress towards this is reviewed annually by the Patient Information Advisory Group (PIAG).

The steps required by the Registry and renal units to gain compliance with the Data Protection Act are detailed below.

Introduction

Under the 1998 Data Protection Act it is only legal to transmit patient identifiable data to a third party with the permission of the patient, and for agreed purposes. This has created problems for several medical registries, including the Renal Registry.

The key patient identifiers collected by the Renal Registry are name, date of birth, and postcode. Even without a name, date of birth and full postcode enable patient identification. The Registry currently requires these patient identifiable data for both data validation, and analysis, as follows:

(a) Validation:

1. To avoid duplication of patients in the database, particularly when they transfer between centres, often for transplantation. Matching of these items, together with a unique identifier allocated by the Registry, when available, is currently important in avoiding this.
2. To validate postcodes with the address fields, using a postcoding package.
3. To use the above items to trace missing NHS numbers using the national tracing service.

(b) Analysis (this is an indicative list):

1. To analyse areas where age is a factor
2. To assess geographical equality of access to treatment, e.g. by local authority wards
3. To assess the influence of social deprivation by calculating deprivation scores from the validated postcode.

One option for full compliance would be to attempt to obtain permission for data transmission from each patient. This would have to be done by the renal units and would be a large workload. More importantly, it would lead to incomplete data collection as some patients would refuse permission, and it is likely that this would not be a representative group of patients. Centres would also default in obtaining permission, or delay 3–6 months from obtaining permission in some patients. This would render many of the analyses invalid.

The alternative is for the Registry to develop processes to anonymise the data whilst retaining enough information for purposes of validation and analysis. The committee has decided to take this course. Whilst this is being developed, in order to continue to obtain identifiable patient data, the Registry needs temporary exemption from compliance with the 1998 Data Protection Act under the Health and Social Care Act 2001, section 60 (England & Wales).

For England & Wales, this can be granted by the Patient Information Advisory Group (PIAG). Section 60 exemption is only granted on a temporary basis until full compliance with the Data Protection Act can be achieved. Progress towards this is reviewed annually by the PIAG.

In common with the experience of UK Transplant and most other medical registries, an initial application to PIAG in 2001 from the Renal Registry was turned down. The Registry was invited to re-submit its application. After consultation with, and support from, the National Kidney Patients Federation, the Department of Health, CHAI, the NHS Information Authority, and PIAG, this has been done. This was considered at the March 2004 meeting of PIAG, and the Registry has been granted temporary exemption under section 60.

Path towards compliance

In the application to PIAG the Registry set out a four-stage path towards full compliance with the Data Protection Act:

> It is government policy in England & Wales, that patient's NHS numbers will be used for all hospital episodes. The ultimate aim of the Registry is to use an encrypted NHS number as a patient marker. This will not allow identification of the patient. In parallel with this approach, a system will be developed to allocate the necessary characteristics to patients with regards to age, social deprivation, geographical area of residence such as local authority or health authority. It will then not be necessary to store the full post code in the database.

Stage 1

1.1. *Posters & Patient Information leaflets*
In the interim period before anonymisation is achieved, formal consent for data transfer will not be necessary. However, patients must be fully informed about what is happening. With the support of the National Kidney Federation (of patients associations), the Registry will produce posters and information leaflets for use in renal units. These communications will describe the extent of the information that is stored regarding patients with established renal failure, and the fact that patient identifiers are only accessible to a small number of skilled and trusted staff. It will also explain how that information is used, and that all outputs are anonymous. Through these communications, patients will be offered the opportunity to contact their local renal unit to withhold consent from sharing their patient identifiable record with the Registry if they wish to do so. Software will be installed on all renal unit clinical databases to enable this opting out to be recorded.

1.2. *Move towards NHS numbers and deletion of patient names in the Registry database*

1.2.1. The Registry will develop a software application that holds patient identifiable data received from renal units in a temporary database.

1.2.2. Where necessary data is incomplete, the Registry will use an existing 'postcode lookup application' to obtain a valid full postcode and then use the NHS Strategic Tracing Service to obtain the NHS Number. It will then advise the renal unit to update the patient demographic data to include the missing data and ask them to use the unique UK Renal Registry Number allocated by the Registry for further communications with the Registry.

1.2.3. The Registry will characterise the patient and check for duplicate records with the records

held in the analysis database containing anonymised patient data.

1.2.4. The Registry will then delete the patient identifiable data from the temporary database at the time of the next submission of data (next calendar quarter) with the proviso that the renal unit is submitting data with a complete set of patient demographic data including the NHS Number and the UK Renal Registry Number.

1.2.5. The Registry will also apply this methodology to the records of deceased patients held in the database.

Stage 2

2.1. The National Programme for Information Technology (NPfIT) National Care Records Service (NCRS) is allocating an NHS Number to every patient. When this becomes available from all renal systems, the Registry will modify the software application that handles pre-analysis characterisation of the patient and checking for duplicate records so that all other patient identifiable data is deleted once this pre-analysis activity has been completed

Stage 3

3.1 The National Programme for IT (NPfIT) National Care Records Service (NCRS) is working on software for a secure encryption system for the NHS Number. This encryption is consistent for the NHS nationally so that record linkage can still be made even if the patient moves between Trusts/Strategic Health Authority areas. The Registry will modify its software to handle the encrypted NHS Number format. The renal software providers will have to modify software to link with the encryption software.

Stage 4

4.1. With the implementation of the electronic Integrated Care Records System (ICRS) the Local Service Providers (LSPs) will take responsibility for making the UK Renal Registry data available in the national set (spine) as a secondary use service (SUS). The UK Renal Registry will then become a user and not a custodian of anonymised patient data.

4.2 In partnership with the NHSIA Datasets Development Programme, the Registry is currently seeking Information Standards Board approval for the National Renal Dataset, which will include data needed by the Registry, for completion by March 2005.

4.3 Through the NHSIA NSF Information Strategy Programme, the Registry will work with Local Service Providers to implement the Renal NSF Core Service that includes the requirement for Local Service Providers to provide the functionality for renal units to send data for the National Renal Dataset to the SPINE, and for the National Application Service Provider to make this available in the National Care Records Service Secondary Users Service. The data held will then be compliant with existing legislation and standards.

After publication of this report, the Registry will be contacting renal units to discuss the implementation of these plans. It is acknowledged by PIAG that some of the timescales may not be achieved due to unresolved technical issues / lack of progress with the NHS IT infrastructure. All these issues will be reviewed annually by PIAG.

Interpretation of the data within the report

It is important to re-emphasise that for the reasons outlined below, great caution must be used in interpretation of any apparent differences between centres.

As in previous reports, the 95% confidence interval is shown for compliance with a Standard. The calculation of this confidence interval (based on the Poisson distribution), and the width of the confidence interval, depends on the number of patients within the Standard and the number of patients with data.

To assess whether there is an overall significant difference in the percentage reaching the Standard between centres, a chi-squared test has been used. Caution should be used when interpreting 'no overlap' of 95% confidence intervals between centres in these presentations. When comparing data between many centres, it is not necessarily correct to conclude that two centres are significantly different if their 95% confidence intervals do not overlap. In this process, the eye compares centre X with the other 41 centres and then centre Y with the other 40 centres. Thus, 81 comparisons have been made, and in any comparison at least four are likely to be 'statistically significant' by chance at the commonly accepted 1 in 20 level. If 41 centres were compared with each other, 860 individual comparisons would be made, and one would expect to find 42 'statistically significant' differences. Thus, if the units with the highest and lowest achievement of a standard are selected and compared, it is probable that a 'statistically significant result' will be obtained. Such comparisons of units selected after reviewing the data are invalid in statistical terms. The Registry has therefore not tested for 'significant difference' between the highest achiever of a standard and the lowest achiever, as these centres were not identifiable in advance of looking at the data.

The most appropriate way of testing for significance between individual centres to see where the differences lie is not clear. The commonly used Bonferroni test is not applicable to this kind of data as the individual comparisons are not independent. The Registry is investigating the most appropriate methods of performing such comparisons.

With the presentation of these Registry data to the renal community, the challenge to nephrologists is to find effective and creative ways of using the data to improve clinical practice. As yet, not all the necessary formal structures are in place to allow full value to be derived from the opportunities presented by the Registry data. The Renal Association is currently considering structures to use the Registry data to facilitate closing the audit loop.

Future potential

Support for Renal Specialist Registrars undertaking a non-clinical secondment

Dr Catherine Byrne has just completed a fruitful two-year post, seconded to the Renal Registry. This was time taken out from an SpR training programme for research and audit experience and training. Dr Alison Armitage, working within the Registry in similar circumstances, was awarded her MD in 2003. Dr Az Ahmad has taken research and audit time from his SpR training and is currently working for an MD in the Registry. Through links with the Universities of Southampton and Bristol some training is available in epidemiology and in statistics. It is hoped that this will encourage other Registrars, who are also interested in undertaking epidemiological work, to consider working with the Registry.

New data collection and analysis

There is considerable interest in collecting data on cohorts of pre-end-stage renal failure patients: many renal units already hold

these data in their systems. It is also clearly important to collect and analyse data on access for dialysis. The members of the Renal Association will be consulted on these and other possible future projects.

A move towards explanation

The analysis and presentation of these data is still being developed, and more work is planned in the assessment of significance and explanation of differences and investigation of good practice. This requires more involvement with renal units to improve the quality and breadth of data capture. In this way, the Registry will be in an excellent position to support the improvement in clinical care and outcomes that is its intended purpose.

Distribution of the Registry Report

The report will also be distributed to Strategic Health Authorities and all PCTs in England and Commissioners throughout the UK.

Further copies of the report will be sent to individuals or organisations on request: a donation towards the £12 cost of printing and postage would be appreciated.

The full report will also appear on the Registry website – *www.renalreg.com*