



THE UK RENAL REGISTRY

The First 25 Years

1995 - 2020

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Terminology

Favoured terms for describing various clinical states in people with kidney disease have changed over the 25 year period covered by this account. Although not all the changing terms are precisely synonymous with their predecessors, for simplicity the terms in common use at the time of writing (2019) are used.

The terms used are therefore:

- **Acute kidney injury (AKI)** - not acute renal failure (ARF).
- **Chronic kidney disease (CKD)** - not chronic renal failure (CRF) or chronic renal insufficiency.
- **End-stage kidney disease (ESKD)** – not end-stage renal failure (ESRF), end-stage renal disease (ESRD) or established renal failure (ERF).

Introduction

This record of the origins, development, and achievements of the Renal Association United Kingdom Renal Registry (hereafter called ‘the Registry’) was written in 2019, in order to be available to Renal Association (RA) members, to the wider kidney community and beyond in 2020 – the 25th anniversary of the foundation of the Registry (and also the 70th anniversary of the RA itself).

I have tried to describe why, how, where, and when the Registry was established; to show how it has grown to play a key and expanding role in kidney care in the UK; and to show how these developments have made the Registry one of the most effective, comprehensive and well organised renal registries in the world. I have attempted to find a middle course between a brief journalistic résumé and a heavily referenced forensic historical account of events

The story is generally one of continuing growth and success inevitably interspersed with some challenges and vicissitudes, which I hope I have described with sufficient accuracy and honesty to provide a truthful and useful account.

I observed and admired the development of the Registry especially during my time as RA president (2004-2007), and the years before and after that when I was a member of the RA Executive Committee. But I was not directly involved in the early development or leadership of the Registry; giving me I hope a balanced objectivity in describing these events.

The story is of course a continuum, but for convenience I have divided the 25 years of the Registry into five phases.

1	Before 1995	Beginnings
2	1995-1999	Proof of principle
3	2000-2005	Towards complete coverage
4	2006-2011	Strengthening governance and expanding the Registry's scope
5	2012-2020	Unleashing the Registry's potential

Many people over the years have made valuable and distinctive contributions to the Registry. It would have been impossible to name them all, and invidious should I attempt to do so but I will have inadvertently excluded some. So I have preferred to identify by name only those with key leadership positions during these 25 years (these are also tabulated in appendix 1).

The UK's role in the development of renal information technology (IT)

A context for the development of the Registry was the growing importance of 'renal IT' in the UK from the 1980s onwards, which paved the way for the kidney community to become a leader in the application of digital support for the care of patients. The UK is a leader in this arena when compared to renal services in many other countries, and within the NHS the renal community started sooner, and has moved further in the application of IT to improving care than any other specialty.

Therefore please read alongside this history, an account of the broader developments in UK renal IT through the efforts of a group of enthusiasts whose work formalised in the 1980s and 1990s as the British Renal Computing Group¹, and who promoted many innovations, most notably the development of a digital clinical record, which provided the foundation for the success of the Registry.

¹ Perspective on UK Renal Computing 1979-1994 Seminar at the Royal College of Physicians, 19-20 July 2017.
<https://renal.org/wp-content/uploads/2018/12/Clinical-Renal-Computing-Witness-Seminar.pdf>

Was a UK Renal Registry needed and wanted?

Hindsight can bring false wisdom. In retrospect: of course a Renal Registry was needed in the UK, of course it improves care, of course it has an expanding portfolio of support and innovation across both the clinical care and research kidney communities, of course all kidney units would embrace it enthusiastically, of course its core funding should be through capitation fees covered by the resource allocation given to kidney units for clinical service delivery. But in 1992, when the Renal Association established its Renal Registry Working Group, none of those things were certain.

What is a Registry – and what is it for?

A registry is no more or less than a database holding both demographic and sequential clinical data on substantial cohorts of patients.

It is the analyses of the data held in a registry database, their correct interpretation and accessible reporting, and the range of questions and concerns to which the analyses are applied which determine the power and effectiveness of a registry, and thus justify the resources required for data acquisition, validation and analysis.

There is a wide range of potential uses for analysed registry data. The focus of the existing major renal registries worldwide has been to provide information on the incidence and prevalence of end-stage kidney disease (ESKD) and its treatment modalities. Such data has high value in supporting local and national healthcare planning, particularly important given the high cost of renal replacement therapy (RRT). But use of a registry platform for broader data collection and a wider range of analysis could in due course enable a registry to deliver a much greater scope of epidemiology, audit, and research activity.

Though I have given a precise definition of a registry, in common parlance ‘the Registry’ is used flexibly with meanings including not only the database itself, but the offices, a body of opinion, a publisher, a base for research projects, and more. I leave the reader to recognise the meaning I give to ‘the Registry’ with each usage below.

Phase I: Beginnings - before 1995

Innovation and planning before the Registry was established

In the few years before the notion of the Registry was mooted, there was already activity which suggested that some in the UK renal community understood the value of sharing data held in renal unit clinical information systems. For example there was already data sharing between the units at Stevenage and St. James's Leeds, which showed substantial inter-unit differences, and identified problems in choice of statistics and data presentation.

A seminal report on the incidence of RRT in the UK published in 1990² analysed shared data from Manchester, Exeter and Belfast and reported an incidence of ESKD in those aged < 80 years of 78 per million population per year (pmp). Today this figure seems an underestimate compared to the median incidence reported by the Registry from 2010-2019 of 108 pmp. Nevertheless the '78 per million paper' proved powerful in convincing the Department of Health and the NHS of the necessity to expand RRT provision in the UK beyond the 40 pmp per year which based on slim evidence had been the NHS benchmark over the previous twenty years.

Another initiative led by Colin Brown (Sheffield) had demonstrated in 1992 the feasibility of transferring data from a UK unit which used the Clinical Computing Ltd (CCL) Proton³ system (Sheffield) into the National Medical Care (NMC)⁴ database in the United States in a form facilitating outcome analyses of the sort which NMC was already publishing using U.S. data⁵. An extension of this scheme involving data from other CCL units (notably Leeds St. James's) was mooted, but NMC wished to arrange a confidentiality agreement through the RA, which the RA leadership did not support, and the initiative did not progress.

Experience from the European Dialysis & Transplant Association (EDTA) Registry

The Registry of the EDTA had been in existence since 1964, seeking to pool data from across all European countries. From 1976, its physical base was in London, and a number of UK nephrologists played important leadership roles notably Tony Wing (St. Thomas's, London), Netar Mallick

² Feest TG, Mistry CD, Grimes DS, Mallick NP. Brit Med J. Incidence of advanced chronic renal failure and the need for end stage renal replacement treatment. Brit Med J 1990;301:897

³ 'Proton', developed by CCL (Clinical Computing Ltd.) and its further iterations (notably ClinicalVision©) remain in 2019 the clinical information systems in a large number of UK renal units

⁴ NMC – National Medical Care, a for-profit company providing dialysis care at that time for some 30,000 ESKD patients in 350 centres in North America

⁵ For example: Lowrie EG, Lew NL. Death risk in haemodialysis patients: the predictive value of commonly measured variables and an evaluation of death rate differences between facilities. Am J Kidney Dis. 1990 ;15:458-82

(Manchester) and Douglas Briggs (Glasgow). From the 1980s the British Renal Computing Group had coordinated UK returns to the EDTA Registry from up to 24 UK units. For various reasons the EDTA Registry was foundering in the early 1990s. It was struggling to keep pace with the number of dialysis centres in Europe (4,000 by the 1990s) all of which made data returns on paper. Furthermore its systems did not enable sequential data collection on individuals, which prevented longitudinal analyses or cohort studies, and only enabled a series of cross-sectional analyses of incidence and prevalence. Data collection from small countries (for example in Scandinavia) had gone well; retrieving data from larger countries with more complex RRT provision much of it in privately funded facilities (for example Germany and Italy) had proved extremely challenging. In 1981 it found fresh success as the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Registry and from 2000 was based in Amsterdam⁶.

Other international renal registries

The two other major renal registries active in the 1990s (and still today) are the USRDS⁷ and ANZDATA⁸.

The USRDS was able to collect data on all patients receiving RRT in the United States through access to the billing which underpins remuneration for nephrologists and their institutions in the US health care system. The dataset collected on each patient was relatively small, and there were challenges in tracking patients through the complex US healthcare system, but the very large patient numbers gave analytical power. The USRDS was also able to support its work with a level of investment in staff and infrastructure well beyond any resources likely to be available in the UK.

The ANZDATA, founded in 1977, was achieving complete data collection from all units in Australia and New Zealand – despite relying on paper data returns; this being achieved presumably because the population covered and the number of kidney units were relatively small and the coherence of the clinical nephrology community was strong.

Scottish Renal Registry

The Scottish Renal Registry was established in 1991 and funded by NHS Scotland. Led initially by Keith Simpson (Glasgow) its primary goal was to collect data on those treated with RRT in Scotland. When the Scottish Renal Registry began, the small Scottish population was served by a small number of kidney units which allowed a strong focus on complete data collection for each year before

⁶ The reasons for the cyclical fortunes of the ERA-EDTA Registry are well beyond the scope of this account, but the lessons learnt from observing its nadir undoubtedly helped to establish a sound foundation for the UK Renal Registry

⁷ United States Renal Data System

⁸ Australia & New Zealand Dialysis & Transplant Registry

analyses were undertaken and reports were presented. The new UK Renal Registry was always intended to be a UK-wide registry, and Scottish Renal Registry representatives were involved from the beginning in its planning. The Scottish Renal Registry continued to make separate analyses and reports. Once agreement was reached for Scottish data to be transferred to the Registry, the process was straightforward since the Scottish data, having been validated, were all held on one server in Glasgow.

The beginning of the UK Renal Registry

If a single individual is to be credited with stimulating the foundation of the Registry, it should be Netar Mallick (RA president, 1989-92). Mallick had personal experience of the challenges and opportunities of a renal registry from his time as chair of the EDTA Registry. He also saw that the UK had significant advantages in establishing a Registry: the NHS provided a non-competitive arena in which commercial influence should not adversely affect data sharing, the UK was already demonstrably a leader in clinical renal IT, a large number of UK renal units already used digital clinical information systems, and a majority of those used the same commercial system (CCL Proton). The EDTA Registry experience also showed that it was impossible to rely on paper data returns as the number of units and patients relentlessly grew; a successful registry must use exclusively digital data returns.

In 1990, during Mallick's presidency, the RA Executive Committee first discussed the notion of a national database/registry for ESKD with the preliminary suggestion that it might be co-owned by the RA and BTS⁹, and perhaps associated with the EDTA Registry, then based in London. The context of the discussion was the changing role and diminishing value to UK nephrology of the EDTA Registry. It was mooted that the collected data could also be used, with appropriate permission, by the EDTA and UKTSSA¹⁰. If this was to work, it was agreed that data transfer must not duplicate that already being sent to Regional Health Authorities by individual units; and if data collection was to be a unit responsibility, then funding should be provided to units to facilitate data collection.

The NHS Information Management Centre was invited later in 1990 to give advice to the RA Executive Committee on setting up a Registry and how it might be used for audit. They duly attended but their contribution is not documented and it seems added little to the ideas already emerging among RA members.

⁹ British Transplantation Society

¹⁰ UK Transplant Support Service Authority – the name at that time for the Department of Health 'arms length' body overseeing organ transplantation in the UK. Previously known as UK Transplant and subsequently (following amalgamation with the Blood Transfusion Service) as UK Blood & Transplant

In 1991 the Department of Health (DoH) established a committee chaired by Norman Halliday which provisionally agreed to fund a pilot study to look into the feasibility of a ‘national renal registry’, but by the following year there had not been substantial progress. Mallick therefore proposed that the RA should organise a pilot scheme to test the feasibility of establishing a RRT registry with nationwide coverage. To lead this pilot he approached Terry Feest, who had played a major role in the ‘78 per million’ paper, and had been an early adopter of digital clinical information technology in Exeter before his move to Bristol in 1991.

The ‘Harvester’ meeting

Mallick called a small meeting to consider his proposal for a pilot Registry scheme. It was held (for geographical convenience for the participants) in a ‘Harvester’ family eatery just off the M5 near Bristol early in 1991. It was attended by Mallick, Brown, Feest and Neville Selwood (UKTSSA). There is no written record of that meeting, but those present recall unanimity about the importance of trying to establish a UK Renal Registry, that feasibility should be tested in a pilot scheme, and that Terry Feest was the right person to take the lead. Even then some key principles were agreed: data acquisition should be digital, directly from renal units’ systems, a small committed group of nephrologists could lead but professional expertise in computing would be necessary from the beginning, the starting point should be units using the same clinical information system (the units chosen for the pilot scheme all used the CCL Proton system), but the eventual goal must be universal coverage across all UK units.

The Renal Registry Working Party and the RA Registry Subcommittee

Mallick gained the support of the RA Executive Committee which agreed that establishing a Registry was a major RA priority, suggesting that the data might be jointly owned by the RA, British Association for Paediatric Nephrology (BAPN), BTS, and DoH, and that a Registry would need ‘central’ funding.

A RA Registry working party was established to scope the pilot scheme; it held its first meeting in December 1992 and met regularly until rebranded with a smaller membership as the RA Registry Subcommittee in 1994. The working party, and then the subcommittee, were chaired by Feest, with Brown as secretary¹¹.

¹¹ Original membership of the Registry Working Party included representatives of: RA - Terry Feest (Bristol), Colin Brown (Sheffield), Es Will (Leeds, St. James’s), Ciaran Doherty (Belfast); Netar Mallick (Manchester); EDTA Registry - Tony Raine (Barts); Scottish Renal Registry - Keith Simpson (Glasgow); BAPN - Alan Watson (Nottingham); BTS - Douglas Briggs (Glasgow); UKTSSA - Sheila Gore. The RA President and Secretary were *ex officio* members. Paul Roderick (Southampton) joined the Registry Subcommittee in 1994. Once DoH funding had been finalised, DoH was also offered observer status at the Registry Subcommittee

The discussions of the working party, and then the subcommittee soon coalesced around nine issues which needed to be considered, and which have been recurring themes of challenge and discussion ever since as the Registry has grown and adapted; they will be referred to regularly as this story unfolds: funding, governance, staffing, infrastructure, scope of work, data extraction and validation, data analysis and presentation, confidentiality, communications.

In October 1992, Feest attended the RA Executive Committee presenting a paper describing the purpose, funding, administration and challenges of the proposed Registry. With some amendments this paper was also submitted to the DoH in January 1994¹². It provided a detailed description of the Registry's goals, initial scope of work, and potential benefits along with a financial and governance plan for the two year pilot scheme. This description emphasised the benefits of a Registry as both a descriptor of RRT activity and a driver to improve care. It pointed out that simplifying data acquisition through digital returns would facilitate collection of a much richer dataset than presently obtained by UKTSSA for transplant activity or by the EDTA Registry. The responsibility for developing the Registry would sit with the RA, and the Registry would initially be housed at UKTSSA in Bristol. A two year pilot scheme was described establishing data acquisition from nine English centres: Bristol, Belfast, Exeter, Gloucester, Leeds St. James's, Oxford, Plymouth, Sheffield, and Truro), and Scotland (through the Scottish Renal Registry).

Stewart Cameron (Guy's, London) who succeeded Netar Mallick as RA president in 1993 was equally supportive of the Registry development plans, and the next two years were largely occupied by the questions of funding, staffing, and physical infrastructure for the Registry.

Finances

Funding the pilot

How would funding be obtained for the pilot scheme? The Registry working party's estimate was that a two year pilot involving the five renal units would require a minimum of £120,000 per year to provide proof of concept. This budget was intended to cover staff costs, contracts with UKTSSA, secretarial support, travelling to units to engender support for the Registry and to assess the suitability of information systems. The DoH was the most likely source for such funding. From 1992 a series of meetings were held at the DoH in which the RA was represented by Mallick, Brown and Feest; and the DoH mainly by Norman Halliday. A mutual respect between Mallick and Halliday, based on previous work in the renal arena, was the basis for the eventual success of these discussions. Before it was certain that the DoH was committed to funding the Registry, Feest

¹² Link to pdf: Feest letter to DoH Jan 1994

suggested to the RA Executive Committee that the Registry might have to be started with corporate sponsorship if the right terms of engagement for unrestricted grants from companies could be agreed. By October 1993, the DoH did commit £120,000 over two years, sufficient for the pilot if a further £120,000 could also be raised from industry. By October 1994 an additional £110,000 had been obtained from four companies - Baxter, Cilag, and Fresenius each contributing £30,000 and Gambro £20,000. Some other companies offered support conditional upon their access to Registry data, but only those able to offer unconditional donations were accepted.

Thus a total of £230,000 was available for the two year pilot scheme. It was agreed this money would be 'ring-fenced' within the RA budget.

Long term funding

Funding a pilot was one thing, but how would the Registry achieve long term financial security? Funds set aside for audit by the DoH, or by the Royal College of Physicians might be forthcoming, commercial funding might continue, but neither of these would offer the solid consistent funding the Registry would need as it acquired fixed costs including buildings and staff. A long term funding solution might emerge if the Registry became sufficiently powerful and comprehensive enough to report results to NHS purchasers and if so reporting could therefore become compulsory; but this was not an immediate prospect.

Feest proposed that the preferred model to offer future stability was based on an annual levy on each unit submitting data. This could be a capitation fee, whereby each kidney unit would be required to pay an annual amount for each patient registered. This would provide a growing income stream as more units joined, and even when there was universal coverage would provide continuing income growth as there was no evidence to suggest in the short to medium term that the prevalence of RRT in the UK was moving from its current relentless increase towards a steady state. The capitation funding model should become acceptable to kidney units when pilot feasibility had been demonstrated, and was intended to avoid the inequity of a fixed fee per unit which would disadvantage smaller units.

The capitation funding model would also give the Registry independence from the DoH and from industry, in particular ensuring editorial independence in the analysis and presentation of data.

Infrastructure

The DoH commitment to funding carried the proviso that the Registry must collaborate with UKTSSA. Negotiations resulted in an offer of office space within UKTSSA's Bristol base, as well as use of appropriate hardware and software. A contractual agreement between UKTSSA and the RA followed once the scope of work for the Registry had been sufficiently defined.

Staff

As the governance of the Registry began to take shape, the need for an employed coordinator was obvious, and the desired profile was an individual with some nephrology knowledge (although not necessarily clinically qualified) and substantial computing skills. There were a number of applicants for the post, and from them David Ansell was appointed, beginning work as Clinical Coordinator of the Registry in April 1995. Initially only 50% of his salary was available from within the RA pilot budget and the other 50% was provided by UKTSSA; but from 1996 his entire salary was funded by the RA.

Ansell was qualified in medicine, with several years' experience as a junior physician up to registrar level, including some experience in nephrology. He was also very knowledgeable about the rapidly changing digital environment, with high programming competence. Feest and Ansell worked closely together, providing between them the vision, the technical platforms, and the external communications necessary for the success of the pilot.

Ansell's appointment was a watershed moment in the Registry's financial and business gestation; the RA committing to employing him when there was still no guarantee of funding beyond the first two years.

Governance

The DoH requirement that the Registry be established initially alongside UKTSSA seemed sensible. UKTSSA was based in Bristol, was a DoH special health authority, had expertise in data collection from transplant units, and significant infrastructure – physical spaces, computer hardware, and services such as finance and human resources. While the longer term goals of the Registry were expected to require independent structures, a partnership with UKTSSA seemed to offer a sound basis for launching the Registry's work. Contract discussions with UKTSSA continued into 1994. There was need for careful definition of the Registry's goals and intentions with regard to data collection and validation, and a clear understanding of how this would interdigitate with UKTSSA's existing organisation. Importantly, it was specified that the Registry would be 'portable', i.e. was not

dependent on UKTSSA's infrastructure and systems. It could be moved to a different physical venue and different virtual systems at any time, when the relationship with UKTSSA might end.

Neither the burgeoning Registry nor the RA had any human resources function or other support structures for employed staff; at this stage employment contracts were with UKTSSA.

Meanwhile the place of the Registry within the RA's existing organisation was approved. The Registry Subcommittee would work closely with both the Subcommittee for Provision of Renal Failure Services and the Standards Subcommittee in developing its scope, goals, and measures of success.

Scope of work

The early goal of the Registry was to establish the processes needed to provide a reliable, validated database of all those receiving RRT for ESKD in the UK, with the analyses necessary to describe the need for RRT, and the volume and quality of care provision. That would be a sufficient and challenging task for the first phase of the Registry's life, and until it had been achieved, there might be scepticism that the effort required was justifiable.

Nevertheless from the beginning the potential was seen for a future broadening of scope:

- Should the database be restricted to those with ESKD receiving RRT in the UK (an obvious target since all units with digital clinical information systems collected data on such patients), or could it expand to collect data on those with acute kidney injury (AKI), those with chronic kidney disease (CKD) not receiving RRT, or indeed enable more detailed data acquisition on any specified cohorts of kidney patients?
- How could the sequential clinical laboratory values collected by the Registry be used to drive and measure improvements in clinical care, and evaluate the impact of the clinical practice guidelines which began to emerge in nephrology in the 1990s?
- How could the Registry provide a foundation for epidemiological and clinical research as well as healthcare planning and clinical quality improvement processes?
- How could the Registry platform be used to enable more detailed data collection to support interventional clinical trials?

In its 25th year, the Registry has developed all of these functions to varying extents, but this has come only through a gradual and determined expansion of its portfolio, having built a robust and reliable platform to deliver the original primary aims.

Phase 2: Making the Registry viable: 1995-1999

The Registry pilot scheme began in April 1995.

Data extraction, validation and convergence

Data fields were developed which ideally would reconcile with other registries, especially the Scottish Renal Registry to facilitate inclusion of Scottish data within UK Renal Registry reporting. The UK Registry would also share data with the EDTA Registry to save each unit from having to make its own independent report to the EDTA Registry as had previously been the case^{13,14}. A data set was defined with some mandatory and some voluntary elements; 33 data items would be required for a new patient to register.

To facilitate the development of the Registry it had been agreed to work initially only with units using the CCL Proton database. However Proton was customised by each centre, so that even an apparently straightforward field such as the haemoglobin value might be stored differently.

Aluminium values caused particular problems since they were variously reported in mass and molar units. Bespoke extraction software was therefore written for each unit, and had to be revised every time a centre modified its Proton system. This proved a very time-consuming task for David Ansell, and others who were later recruited to support him. By the end of the 1990s about half of units were using Proton; other units used a range of commercial products or ‘in-house’ developments; no fewer than thirteen different systems were in use, each needing its own data extraction routine¹⁵. This inevitably led to a phase in which the Registry stood or fell on the availability and leadership of one individual (Ansell) to develop and trouble shoot all extraction routines. A sustainable solution would in due course need to be found.

Extracted data have no value unless ‘clean’ and can be verified. From the beginning, substantial effort was needed to deal with data points outside agreed parameters, ‘sense check’ apparent anomalies, and communicate with units to obtain corrected data. The amount of staff time at the Registry to provide this step was substantial. Likewise staff time required in each unit to respond to such queries was more than originally expected, and was not identified in job plans, leading to continuing pressure on a range of administrative, informatics and clinical staff; and inevitably some delays in data verification.

¹³ This also provided challenges; for example the EDTA codes for cause of ESKD, developed in the 1970s were already unfit for purpose. Not until 2009 was this resolved when new EDTA codes for cause of ESKD were developed, agreed and implemented

¹⁴ Although the SRR continued to send Scottish data directly to the EDTA Registry

¹⁵ There were also a few renal units which still had no digital clinical information system, and therefore could not be involved in the Registry. All paediatric units were still using paper returns.

As well as variations in the way each unit's information system held data (exemplified by haemoglobin and aluminium), there were more substantial challenges to the goal of presenting data in ways which allowed true comparisons between units. For example there were two assay methods for measuring serum albumin extant in UK laboratories (bromocresol green and bromocresol purple) which had to be reconciled for presentation of both serum albumin and corrected serum calcium. There were also significant clinical variations in sample collection – notably precise timing of the post-dialysis sample used to generate urea reduction ratios.

Confidentiality

From the beginning, the need to respect patient confidentiality was a fundamental principle of the Registry's working processes. Nevertheless complete anonymisation was not possible; sufficient identifiers must be held, for example to avoid duplication and to enable patients to be tracked when their care was transferred between units. A unique Registry number was assigned to each patient (and later the NHS number was also increasingly available). The date of birth, gender, and ethnicity were also held. Use of these data was based on a presumption of consent, i.e. that patients would be content that their data could be used in analyses producing aggregated data at local or national level. The passing into law of the 1998 Data Protection Act however reset attitudes and expectations in this arena, and was to have a major impact on the systems and governance of the Registry which is further discussed in the next phase.

Pilot progress

Once the Registry pilot work began in 1995, the Renal Registry Subcommittee met only twice yearly¹⁶, and a smaller project group¹⁷ based in Bristol drove the practicalities of the project, meeting monthly. Early progress was encouraging and by March 1996 (the end of Year 1 of the pilot) a minimum mandatory dataset and optional additional data items were defined. The database was almost complete, and it was already being estimated that a large proportion of future work would relate to validation routines for data verification. A system had been established for tracking patients when they moved between renal units. The programming focus had been on extraction routines for CCL systems, but a transfer file format had been developed which would allow data from other systems to be loaded onto the Registry database. Even for CCL systems it was being

¹⁶ The Renal Registry Subcommittee lacked agreed terms of reference. In the pilot phase, the continuing membership of the highly committed individuals who had driven the early success made sense. But it was agreed with the RA Executive Committee that from 1997, when the pilot phase was completed, committee members would serve a three year term, and the Chair should also be a fixed term appointment

¹⁷ Original members of the Renal Registry Project Group were Ansell, Feest, and representatives of UKTSSA

estimated it could take up to two weeks per site to install Registry software at a likely cost of £6,000 per unit; it seemed the most cost effective way to do this was to employ an external consultant, Andy Webb¹⁸.

The two year pilot ended in March 1997, by which time the systems were set up, data extraction was achieved in the nine chosen units, and data validation routines were underway, involving substantial interchange between the Registry and individual units.

An important point in the development of the Registry came in March 1997 when analyses of aggregated data from the first six units were made available to the contributing units and the RA Executive Committee. The first annual report of the Registry, available to all RA members and in the public domain was published in September 1998 (based on 1996 and 1997 data collected from nine units)¹⁹. The second report published in 1999 confirmed rapid progress – data for the calendar year 1997 were available from 31 English centres. From then on the Annual Registry report became a well-recognised and valued document throughout the RA, the wider kidney community and beyond (appendices 2 & 3). It was now possible to invite participation from other units, and by 1999 data were being collected from a total of 40 units (including the Scottish units). There were however particular areas in the country - notably Newcastle, Manchester and London - which were as yet providing no data.

So the pilot had shown proof of principle: the Registry was organisationally and technically viable. Now came the challenge of securing the longer term future of the Registry – especially its finances and governance, and also securing its position and recognition in the renal community and beyond.

External communications

In 1997, communications were initiated with commissioners of renal services & health authorities explaining the purpose and value of the Registry and its reports, using wherever possible local nephrologists as mediators and supporters. The Registry also began to reach out to other national specialty registries through the DoH, and through the Royal College of Physicians Audit office, although substantive new partnerships and projects were slow to emerge.

¹⁸ Andy Webb, a former employee of CCL, now ran an independent company and was the person in the UK with the most practical understanding of Proton. He worked for the Registry over many years as an independent contractor visiting renal units and writing extraction routines for the local Proton system.

¹⁹ The 1st Registry Annual Report (1998) and all subsequent reports are available at:

<https://www.renalreg.org/publications-reports/> . The 11th to 17th Reports were also published by Nephron Clinical Practice. From the 18th Report (2015) onwards they were published as a supplement to Nephron

Staff

By July 1997, employed staff now included, as well as Ansell, a data liaison manager, a programmer, and a statistician. Once the Registry moved from UKTSSA in 1997 (see next paragraph), Southmead Hospital provided payroll and HR support. But HR support developed slowly, and although salaries were being paid, contracts were not issued to all staff until 1999.

In 1999, Colin Brown stood down as the Secretary of the Registry Subcommittee subsequent to his move from the NHS to a role in industry, and he was replaced by Es Will.

Infrastructure

Accommodation

The decision that the Registry be housed in the UKTSSA building in Bristol had initially seemed appropriate but proved less than ideal. There were differing perspectives on the extent of the independence which should be afforded to the Registry. UKTSSA was a DoH body, and its leadership thought that it was incumbent on them to provide input into Registry documents, and to review and comment on Registry reports. Feest concluded that the Registry needed more space and greater autonomy, notably editorial independence, and this would be helped by a move out of the UKTSSA premises. In 1997 therefore the nascent Registry moved to Southmead Hospital, Bristol. Initially Feest and Ansell shared Feest's hospital office on the renal unit until three offices were made available the following year at low rent elsewhere on the Southmead site.

IT network

At first, digital communications with units had used ISDN²⁰ lines (as used by UKTSSA) but this was not satisfactory, and the change was made to NHS Net as soon as it became available from late 1997 onwards in Southmead Hospital and all participating units.

Governance - the relationship between the Registry and the Renal Association

The Registry was established as a constituent part of the RA. From the beginning therefore, RA members had a sense of ownership of the Registry's work, and embraced its growing reputation. Nevertheless adjustments were needed as the reach, output, and reputation of the Registry grew. The RA was at that time, and remains, a company limited by guarantee registered with Companies House, and also a registered UK charity. During this phase of the Registry's development, there was

²⁰ ISDN (Integrated Services Digital Network) - a set of communication standards for simultaneous digital transmission of voice, video, data, and other network services over the traditional telephone network

debate and uncertainty about the optimal relationship between the Registry and the RA, and how the liabilities associated with the Registry were assigned. External specialist advice suggested that this might best be achieved by incorporating the Registry as a 'Company Limited by Guarantee with Charitable Purposes covenanted to RA for any surpluses'. To help maintain the links between the Registry and the RA, at least one of the directors of the new limited company should be the president of the Association; and one registry representative (usually the chair) would be a RA trustee.

Finance

There were significant uncertainties surrounding the Registry's financial position in the early years after the completion of the pilot study in 1997 when the fixed term funding from the DoH and corporate donors had expired. This concern widened to the financial and reputational risks carried by the RA, especially in the development phase before capitation funding was in place. The Registry funds were 'ring-fenced' within the RA accounts, but the cash turnover of the Registry represented by far the largest element of the RA annual budget. Delayed receipt of annual payments from renal units (or indeed non-payment) might create cash flow challenges because the Registry had fixed outgoings (for example rent and salaries). 1998 was the year in which these challenges were greatest, and the RA Executive Committee set aside from RA general funds up to £8,000 per quarter if required to balance the Registry's income and expenditure. In the event, this contingency was never called upon. Capitation funding was established, units sometimes delayed in paying the capitation fee, but pay they almost always did, and the growth in the number of participating units meant a steady growth in Registry income, which guaranteed financial security.

The tariff charged by the Registry to each unit was based on the number of RRT patients the unit treated. By the time capitation funding was proposed, the Registry was already proving its worth, the first annual report was published, and there was a rapid increase in the number of units contributing. The capitation was initially set (somewhat arbitrarily) at £10 per patient and this rather small proportion of each unit's budget proved to be acceptable to most clinical directors.

Estimates in this phase were that the Registry would be financially secure with an income of £200,000 - £250,000 per year. To achieve this at least two thirds of the approximately 30,000 RRT patients in the UK needed to be on the Registry, and their units paying the capitation fee.

Phase 3: Towards complete coverage: 2000-2005

Coverage

The success of the pilot and the first published report encouraged other units to participate in the Registry. One important continuing incentive was that the Registry made returns to the EDTA Registry on behalf of each participating unit. By 2000 all renal units in the country had established some contact with the Registry with a view to participation. The National Service Framework (NSF) for Renal Services in England²¹ recommended that all units send data to the Registry. Though falling short of an absolute mandate this was a further stimulus to complete coverage in England, although some units still did not have adequate IT systems to facilitate this. It was hoped that the NSF and the accompanying NHS Renal Information Strategy might strengthen negotiations for local IT resources. There were however still a range of IT issues to resolve as the Registry worked to develop interfaces with an increasing number of different clinical information systems.

There were still substantial hindrances to paediatric units joining the Registry. The units themselves and the BAPN were uniformly supportive, but local IT issues were rate limiting. As small specialist units, paediatric nephrology could not gain the local IT investment needed to provide systems for routine clinical care, let alone to join the Registry. The DoH had given a grant for work with the Paediatric Registry, but despite this, and the committed support of BAPN representatives, coverage lagged. Throughout this phase paediatric data were collected as paper returns by Malcolm Lewis (Manchester) who collated and validated them before presenting a single digital paediatric file to the Registry.

The 8th Registry Annual Report which was published in 2005 included data from 83% of the population of England and Wales, and complete data from Scotland. By the end of 2004, only four units in the UK were not returning data to the Registry. Three in England were still resolving IT systems issues (and the last of these problems was not resolved until 2008). The fourth was Northern Ireland (5 renal units, classed as one unit here, as one combined file came from NI), where sustained negotiation was needed to dissuade the province's information commissioner from using a very cautious interpretation of the Data Protection Act to prevent data reaching the Registry; this issue was finally resolved in 2005.

²¹ National Service Frameworks (NSF) were specialty descriptions of the high quality care which should be the goal of the modern NHS. They became a part of government health policy for England in the early years of the 1997 Labour government. The NSF for renal services was published in two parts in 2004 and 2005.

Data analysis and presentation

The early phases of the Registry's development included some innovative explorations of the best statistical methods to be applied, and discussion about the most useful and accurate ways to present the data in order to provide meaningful inter-unit comparisons. The familiar norm in Registry reports, once centres were identifiable, became the box and whisker plot with 95% confidence intervals, showing centres sequentially along the horizontal axis according to the achieved mean of the parameter. In Registry reports up to 2005, laboratory data were also presented as Rose-Day plots²² showing the rise in median value needed to increase the proportion of patients reaching the agreed RA standard; and emphasising how a plateau might be reached whereby further increases in the median were not matched by gains in numbers reaching the RA standard.

Annual reports

The Registry annual reports were now an established and eagerly anticipated feature of the annual cycle of the UK renal community. There was a stable pattern of chapter topics in the Report (appendix 3).

Tardiness in publication was however a continuing frustration. The goal of publishing within the calendar year following the year end date of the data analysed was never met during this period (the 2003 report for example, an analysis of 2002 data, was finally published in May 2004) and since then has only been met once when the 16th Annual Report was published in December 2013. This was despite intensive efforts within the Registry to streamline all the relevant processes - data collection, data validation, analysis, and writing. As the publication date neared each year, the focus of the Registry staff on the report became almost absolute, there was seven day working by senior staff, and other important Registry business often had to be deferred. A major rate limiting step beyond the Registry's direct control was the slowness of some units both to make initial data returns, and to respond to data validation queries raised by Registry staff. This in turn reflected that most units still did not have sufficient IT support staff to maintain systems for day to day clinical work let alone meet the needs of the Registry.

It was decided to send to clinical directors quarterly returns which it was expected would stimulate responsiveness and help improve quality of data and rapidity of data submission. It was even discussed that rebates on capitation fees might be offered to entice units into providing speedy and accurate data for the Registry, although this was never implemented.

²² Rose G, Day S. The population mean predicts the number of deviant individuals. Brit Med J 1970; 301: 1031-4

There was always the intention that the next Registry report would be published on time, and that the paper publication would be slimmed down, with electronic appendices of additional data. But in practice the same weighty tome was published with delays year on year. The realisation that it cost £15 per copy to produce and distribute the Annual Report provoked discussion about whether there should be a wholesale change to web-based reporting, or whether some combination of digital and paper might be preferable. But the value was recognised of having a physical report to share with purchasers and commissioners, and a paper version continued to be available.

From 2001 an important change was made with a phased plan for removing unit²³ anonymity from the Report; this started with a number of laboratory parameters, such as haemoglobin. But it was agreed that data about patient survival and outcomes from each unit would remain anonymous until the Registry had sufficient confidence in the robustness of the data.

Attention also turned to the accessibility of the Report to non-renal health professionals, and also in due course to patients and carers. This provided considerable communication challenges: on the one hand the need for clarity and simplicity in presentation; on the other hand the need properly to represent the complexity and uncertainty of interpretation which surrounded some analyses. In 2004, one attempt was made to resolve this conundrum with the development of chapter extracts in an attractive card format (known as Registry Dips); the first was on diabetes with target audience of diabetes physicians and specialist nurses²⁴. This initiative was however not sustained²⁵.

Staff

Registry staff

Throughout this phase, there were growing staff numbers including data managers, statisticians, and administrators; by 2005 the Registry employed 11.5 FTE (full time equivalents).

Notable appointments included in 2001 Dirk van Schalkwyk, from Stellenbosch University, South Africa, a highly experienced statistician who also contributed much to the training of other staff; also in 2001 Catherine Byrne, the first Specialist Registrar paid by the Registry (whose remit included

²³ Staff, patients, and hospitals almost always know their local kidney care service as a ‘renal unit’. The Registry has always reported on activity by ‘centre’. As renal services have developed a ‘centre’ reported by the Registry may include the data from several adjacent ‘units’. For simplicity I have used the term ‘unit’ throughout this account, and avoided the term ‘centre’

²⁴ Link to pdf: Registry Dip 2004

²⁵ No funding stream could be identified; perhaps surprising given the expected benefits of communicating with colleagues beyond nephrology

contributing to the preparation of the Annual Report as well as her own research)²⁶; and in 2003 Hilary Doxford, the first general manager of the Registry.

From 2004, changes reflected the development of the Registry from being a ‘start up’ into a more mature ‘small business’. David Ansell was re-designated as Director of the Registry. A service level agreement for human resources support was made with North Bristol NHS Trust, who reviewed new Registry staff contracts. Pension arrangements were established on a sounder footing. Appraisals of senior Registry staff became the responsibility of the chair of the Renal Registry Management Board (RRMB)²⁷.

Renal unit informatics staff

Informatics staff within renal units remained critical to the success of the Registry, let alone their vital local role in developing and maintaining digital clinical information systems. It was a staff group lacking cohesive national leadership, and was not identified as a necessary element of renal unit staffing in the National Renal Workforce Planning document published in 2002. Nor did NHS Agenda for Change²⁸ recognise data managers as a staff group, so they were not developed by trusts²⁹. Informatics staff were however supported by the Registry through regular user meetings which were well attended and focused on technical issues of data management, as well as outcome data and explanation of methods.

Accommodation

Inevitably there was a need for more accommodation as the staff of the Registry grew. In 1999 the space increased using an adjacent area to increase the working space from three to six offices. There were recurrent concerns during this period that the Registry’s offices were identified for demolition as part of the Southmead Hospital rebuilding programme, but it turned out that the Registry did not need to move elsewhere until 2010.

Finance

The financial stability of the Registry, a matter of considerable concern to the RA in the early years, was now much more assured. From 2000 onwards the Registry received no DoH grant support.

²⁶ The first Specialist Registrar involved in the Registry was Alison Armitage from 1999. She completed an MD with funding from the NHS Health Technology Assessment programme, and from a Bristol charitable donation

²⁷ RRMB is discussed further under *Governance*, page 29

²⁸ Agenda for Change, a change in NHS staff categories and salary structure, introduced in the first decade of the 21st century

²⁹ Nor did most trusts have the necessary IT equipment properly identified in asset logs, or integrated into capital replacement planning

Corporate sponsorship was also intentionally diminished, so that the main income was participating unit capitation. Joining units were given a ‘grace period’ being charged in the year in which their data appears in the annual report. There was continuing concern that salaries and other growing costs would outstrip this income, and the pros and cons of an increase in capitation fee were regularly rehearsed. On the one hand more income, on the other hand a possible disincentive to existing and joining units. Capitation income increased as more units joined, but more slowly than might have been expected as among the last units to join were several of the largest in the UK which therefore would have brought proportionally more capitation income. Even when all units had joined, income from capitation fees would continue to rise as the UK’s prevalent RRT population increased. Nevertheless further increases in the capitation fee were unavoidable, to £12 per dialysis patient registered from Sept 2001, and then £15 from 2005. The need for capitation fee increases came from the Registry’s rapidly growing annual expenditure – some £300,000 by 2003, nearing £500,000 by 2005 – predominantly reflecting the increasing staffing necessary to meet the Registry’s goals. The Registry now budgeted for two sessions of consultant time for the chair, increasing statistical capacity was needed, and the Registry continued to employ research SpRs.

Capitation fee increases were accepted without demur by the great majority of clinical directors who were required to find this sum from within their clinical budgets³⁰. This acceptance reflected the growing impact of the Registry’s work, and the increasing value attributed to the Registry annual reports. One financial risk remained, non-payment of capitation fees by hospital trusts, independent of the commitment to the Registry of the renal units themselves. A process of escalating action was agreed, ending with the RA president writing to the Trust chief executive with the final sanction that a hospital’s data would be removed from the annual report, and an explanation printed. Happily these processes only rarely needed to be activated.

With its finances now on a sounder footing, the Registry was also well placed to respond to the requirements of ‘Agenda for Change’, which was thought likely to mandate salary uplifts for many staff; and also provide a contingency sufficient to meet responsibilities to staff such as maternity leave, and long term sickness. A reserves policy was established to maintain sufficient to cover six months of expenditure on salaries and other fixed costs; there would not be further accumulation of reserves when the six months requirement had been reached, and any further excess would be invested in new Registry activity. It was agreed that a Registry business plan must be balanced without commercial income, and also must include more realistic hardware and software replacement and development costs.

³⁰ At < 0.01% of the annual cost of treating a typical RRT patient this was, and remains, widely accepted as ‘good value for money’.

The national landscape

Ownership of data – the National Programme for IT

Financial security, guaranteed by capitation funding had given the Registry valuable independence. The data belonged to the RA and the Registry, and to the renal units which had provided it. This was by contrast with all other national clinical databases and audits which at that time were owned by the DoH or the NHS (for example those in stroke and diabetes). The RA and the Registry took responsibility for data quality, agreed on the analyses to be undertaken, and took responsibility for its presentation and publication. Through most of the Registry's twenty five years, this model has been unchallenged; indeed the DoH and the NHS have valued the quality and precision of the Registry's output and have made use of it in a range of healthcare planning strategies.

In only one period was this model at risk. In the late 1990s the government decided on a major investment to transform health through the deployment of effective IT; and the National Programme for IT (NPfIT) was established with a very large investment of public money. The failure of that programme has been well documented elsewhere³¹. At its most bullish, NPfIT envisaged that clinical data sufficient for all clinical care, and healthcare planning would be obtained directly from hospital IT systems; these data would then be available on request to those (such as the Registry) who were deemed to have an appropriate secondary use. In such a model, the Registry would have no data collecting function, no control over the scope of neither data retrieved nor its quality, and would have only an analytical function. Of real concern was the presumption by those developing this approach that data validation was not a necessary step in primary data collection from the NHS. Such proposals were lost in the ashes of NPfIT's demise before the quality of primary clinical data collected by their systems, and the processes of data release for secondary uses, were ever tested.

National Service Framework

The NSF recommended the participation of all renal units in the Registry (although this fell short of an enforceable mandate), and it provided unequivocal support for the role of Registry data in documenting provision, monitoring NSF recommendations, and driving improvement. The Renal IT Strategy which accompanied the NSF documented the need for informatics staff at unit level and implied the need for a permanent infrastructure for their categorisation and career development.

³¹ One reason for the failure was the conviction of those IT professionals brought in to lead NPfIT that it was unnecessary to take advice from clinicians or heed their warnings that the use of IT in healthcare brought a challenge and complexity unfamiliar to IT professionals from a commercial background. Nor was there recognition of the need for the validation of collected data. Thus was clinical input continually eschewed - a point made by representatives of the renal community and others to the House of Commons Health Committee when it was taking evidence on these issues in 2007.

However these formal recommendations did not, as some hoped, bring more resources to the Registry, nor local resources to support data collection and validation.

Confidentiality & data protection

The 1998 Data Protection Act transformed the consent and approval landscape for the registry; presumed consent could no longer be relied upon, unless specific criteria were met allowing exemption.

The Registry's work fell under Section 8 of Schedule 3 of the Data Protection Act 1998, which allowed access to personal information for necessary medical purposes. Under common law individual consent to collect identifiable data is required, but Section 60 of the Act allowed exemption from the requirement for individual consent provided that there was appropriate anonymization. The key patient identifiers collected by the Registry (name, date of birth and postcode) were necessary both for data validation (e.g. avoiding duplication, for example when transferring to transplant units) and for analysis (e.g. analysing the impact of age, social deprivation and geography on care).

One option for full compliance with the Data Protection Act might have been to obtain consent for data transmission from each patient, which would create an untenable large recurring workload for renal units, and would lead to incomplete data collection, since some patients would refuse permission, rendering many of the Registry analyses invalid. Therefore the Registry developed processes which retained sufficient information for purposes of validation and analysis; processes which needed to be approved by the national Patient Information Advisory group (PIAG)³².

The Registry's compliance goal was pseud-anonymisation using an encrypted Registry or NHS number as a patient marker, while developing a system to allocate the necessary characteristics to patients (e.g. age, social deprivation, geographical area of residence) which made it unnecessary to store the full postcode in the database. During an interim period, before this was achieved, patients were kept informed through posters and information leaflets distributed in renal units with the support of the National Kidney Federation³³, and an opportunity given to withhold consent from sharing their personal identifiable information record with the Registry if they so wished. In the event fewer than 1% did choose to withhold consent.

³² A group at the DoH established 'to advise the Secretary of State directly on use of powers provided by Section 60 of the Health & Social Care Act 2001'

³³ National Kidney Federation (NKF), the umbrella organisation for local kidney patient associations. The patient 'voice' expressed through NKF were in general very enthusiastic about the registry and its role in describing and auditing RRT care, and expected that their personal data would be used in this way

On the basis of this plan, the Registry was granted a section 60 exemption by the Secretary of State under the 1998 Data Protection Act. The exemption allowed the registration of identifiable patient information from renal units without first asking the consent of each individual patient.

This exemption remains temporary and continues to be reviewed annually³⁴.

Clinical Governance

Up to 2005, unit anonymity for survival data was still being maintained. The decision to publish survival data by unit, seemed in principle correct, but raised many issues, including the clinical governance responsibilities of the Registry and the RA towards units which were identified as ‘survival outliers’. A role for the Registry as ‘policeman’ of the renal community was not thought appropriate. So a process was agreed in which the RA president would contact the renal unit clinical director and medical director of the Trust in order to ensure local clinical governance processes took over.

The presentation and discussion of survival data raised other issues which are archetypal of the complexities of Registry work. First, there is the question of the correct statistical definition of an outlier (arbitrarily defined as > 3 standard deviations from the mean). Next, faults in data collection and definition were the commonest cause of discrepant results, and there was a clear responsibility for thorough data verification and subsequent accurate analysis shared by the unit and the Registry. Even then, comorbidity data were not always available to allow appropriate adjustment³⁵.

Nor should survival data become the unwitting vehicle of perverse incentives; for example unjustified criticism of units with a more liberal take-on, or incentivising units to turn down sicker dialysis candidates. While some renal registries only include patients who have survived 90 days from the start of dialysis, it was decided that the Registry would also count those who survived less than 90 days (a period of high mortality). It was very unfortunate that centres varied in their adoption of the agreed rules: some only counting patients from the time they are transferred to a chronic dialysis facility, others including the sicker patients during their initial in-patient stay. Such inconsistencies make fragile the conclusions that can be drawn from survival data, requiring great care in presentation and interpretation. For example, it could be tempting to seek solace that

³⁴ PIAG was disbanded in 2009 and its functions taken over by the National Information Governance Board, to which the Registry makes an annual application for exemption. Exemption is now granted under Section 251 of the Health and Social Care Act 2001, which has superceded the 1998 Data Protection Act

³⁵ At this time the only source of comorbidity data was the returns made by each unit, which were frequently missing or incomplete. Once linkage to HES is achieved (now achieved in 2019), reliable comorbidity data would be available based on coding and causes for hospital admissions

inferior comparative outcomes between units were explicable by such input variation, rather than representing real and important outcome differences requiring further analysis.

Governance

This phase of the Registry's development brought considerable discussion of its organisational structures and governance. Within the RA, the Registry Committee³⁶ came under the aegis of the Clinical Affairs Board when established in 2004, alongside the Standards Committee and Clinical Service Committee.

Despite the many successes of the Registry it was felt that there were opportunities to improve its organisation and function and the RA trustees asked Sue Sutherland (chief executive of UK Transplant) to undertake an independent review of the Registry's governance; her report was received in 2003, and her recommendations were largely accepted by the RA trustees.

Most notable was her identification of weaknesses in project management, in large part to the overcommitment of David Ansell, whose role in development and analysis was being compromised by day-to-day managerial tasks. There were also weaknesses in policies and procedures, and quality control. This lead in 2003 to the appointment of a general manager, Hilary Doxford, to relieve Ansell of the managerial burden.

The RA trustees also needed to assume more effective oversight, acting more explicitly as a management board for the Registry. In 2004, the Renal Registry Management Board (RRMB) was therefore established with the RA immediate past-president as chair, with the remit to ensure adequate governance of the Registry's increasingly complex and substantial structure in terms of contract obligations and finance. Other members of the RRMB were the RA trustees with the director and general manager of the Registry in attendance. The RRMB met four times a year, including one meeting each year at the Registry offices in order to incorporate staff presentations.

The RRMB had ultimate responsibility for the probity of the Registry, ensuring it was run effectively as a business and complied with all rules raised by regulatory bodies. The RRMB would not be responsible for the strategic direction of the work of the Registry, except when it might compromise the effective running of the business or cause conflict with regulatory bodies.

The RA Executive Committee, through the Clinical Affairs Board, was to be responsible for the strategic direction of the Registry. The Registry Committee was to have the responsibility for advising the Clinical Affairs Board on strategy, and for devising the content of the annual report.

³⁶ In 2005, a change in the taxonomy of RA structures re-designated all RA Subcommittees as Committees, without any changes in terms of reference

Changes were also instigated in 2003 to make more explicit the relationship between the Registry and the RA. This was in response to the advice of auditors concerned about the external perception that the Registry was an independent body. A new logo incorporating the Renal Association was developed and the website and letterheads amended to make clearer the Registry was part of the RA.

Research

Now a solid platform was established for the Registry's core business, the research focus of the Registry began to develop more rapidly. Registry work was being submitted regularly in abstract form to national and international academic renal meetings, including the RA Conference, and the congresses of ISN³⁷, ASN³⁸, and EDTA. The first peer-reviewed publication from the Registry was published in 1998 (appendix 4 lists Registry publications).

A productive collaboration began with the Department of Social Medicine, University of Bristol, initially investigating access to RRT and socioeconomic deprivation.

There were many more opportunities to obtain project funding for research and analyses, but the time by senior staff taken in developing applications was significant and had to be balanced against the 'core business'.

The Registry offered access to data for academic investigators with sound project plans. There were notably few such requests at this time. The Registry database was often viewed as developed for audit rather than research. There were few academic centres in the UK at that time with an active interest in the study of kidney disease through large datasets. There was also some caution among senior registry staff that the complexities and nuances of the Registry database might be misconceived by external academic investigators, leading to erroneous conclusions. But it should also be acknowledged that some academic investigators regarded the Registry's data quality as insufficient for some research studies.

Scope of work

One of the Registry's primary goals - to report on the epidemiology of RRT in the UK - was being increasingly fulfilled during this phase. Coverage was close to complete, and there was growing confidence in the accuracy of the data both within and beyond the kidney community.

³⁷ ISN – the International Society of Nephrology

³⁸ ASN – the American Society of Nephrology

The second primary goal, that Registry data should be used to measure quality of care, and to drive improvements in that care was progressing more slowly. The audit cycle had become a familiar element in clinical governance thinking. The RA should have been ideally placed to drive improvements in care nationally through the audit cycle since there were agreed RA Standards (the precursors of current clinical practice guidelines) and now the Registry was collecting the data to show achievement against those Standards, which should in turn be the prelude to implementing clinical strategies which would improve compliance with Standards. Individual units were undoubtedly active, and typically would focus on Standards where local compliance was weakest, and develop innovative strategies to drive improvement. Anaemia management and phosphate control were most commonly targeted, and a number of units began to publish protocol-driven care pathways when they were successful in making measurable improvements in care. Used in this way, Registry data also highlighted the challenges of seeking targets which were unrealistic, for example realising the number of individuals who might need to be ‘overtreated’ in order to achieve the mean target for the whole patient cohort. This was perhaps most strikingly illustrated in erythropoiesis stimulating agent (ESA) dosing patterns necessary to achieve the RA Standard for haemoglobin in dialysis patients. The ESA cost implication of driving up the mean haemoglobin of a unit’s patient cohort was a challenge, still more important were safety concerns when data emerged that higher haemoglobin worsened outcomes in high risk patients³⁹.

Although individual units began to publish their local quality improvement strategies, this lacked national coordination, and there was undoubtedly duplication of effort as each unit sought improvements in measures of quality. The wish to turn such efforts into a national quality improvement programme gained some impetus when Charlie Tomson became Registry chair, and proposed a scheme based on his experience during time spent at the Institute for Healthcare Improvement in the United States. But progress was slow, and resources few⁴⁰.

As the Registry grew in confidence in its ability to deliver its central task of auditing and reporting on RRT in the UK, it began to consider its potential to collect data more widely in people with kidney disease. For example in 2005, a registry of those with non-dialysed CKD⁵ was first mooted, possibly to be funded by an addition to the capitation fee. In an initial step such data were collected from a limited number of units and studied for a PhD by a Registry SpR. But it was not until 2016 that a

³⁹ For example: Singh AK et al. Correction of anemia with epoetin alfa in chronic kidney disease. N Engl J Med. 2006;355:2085-98. Pfeffer MA et al. A trial of darbepoetin alfa in type 2 diabetes and chronic kidney disease. N Engl J Med. 2009;361:2019-32

⁴⁰ It is hoped that KQuIP (Kidney Quality Improvement Partnership) now active in 2019 gives the opportunity for such work to move forward more effectively again

mandate was obtained from commissioners to collect data on CKD4&5 from all centres, and the Registry database adjusted to achieve this⁴¹.

The Registry also sought to expand its scope by forming partnerships beyond the renal community. Typically there was obvious potential and goodwill, but few substantial initiatives followed, at least in part reflecting the intense existing workload of the senior registry staff. For example in 2000, there were discussions with the nascent National Diabetes Register, and in 2002 with the Royal College of Physicians (RCP) Audit Office, which had much experience using RCP regional offices to oversee audit in myocardial infarction and in stroke; neither led to new activity.

Another possible partner was ‘Dr Foster’ (a for-profit organisation focused on the evaluation of healthcare outcomes in the UK). Dr Foster had access to the Hospital Episodes Statistics (HES) dataset, containing (among much else) discharge codes from every hospital admission in England, and information on comorbidity (which was being poorly reported to the Registry by many centres). Linkage to HES therefore offered the opportunity for powerful new analyses of the impact of RRT on health outcomes. There was little progress despite positive discussions with Dr. Foster and a pilot study using Bristol data showing that HES linkage did indeed identify a significant number of RRT patients who had diabetes which had not been reported by their unit to the Registry⁴². HES linkage was eventually achieved in 2009.

⁴¹ Such long drawn out pathways from initial work on a new dataset through to eventual mandate into routine Registry work have been common during the Registry’s history reflecting the many internal and external challenges to be met. This theme recurs elsewhere in this story

⁴² Fotheringham J et al. Variation in centre-specific survival in patients starting renal replacement therapy in England is explained by enhanced comorbidity information from hospitalization data.
Nephrol Dial Transplant. 2014 Feb;29(2):422-30.

Phase 4: Strengthening governance and expanding the Registry's scope – 2006-2011

In 2004, Terry Feest had indicated his wish to stand down as Registry chair in 2006 after fourteen years in Registry leadership. He had received no remuneration, but it was agreed that the Registry should make available two paid sessions of consultant time for his successor. The Registry was embedded in Bristol, and patterns of work might have changed considerably if the appointee came from outside Bristol. But in due course, following an open application process, Charlie Tomson from Bristol was appointed, and succeeded Feest in May 2006. Es Will stood down in 2007 as Secretary of the Registry Committee and was replaced by Andrew Williams (Swansea), who in turn was replaced in 2011 by Afzal Chaudhry.

Coverage

The 2009 Registry Annual Report based on 2008 data provided, for the first time included complete coverage of the United Kingdom – a major landmark in the Registry's growth and development. Delays in getting the final few units to submit data were mostly the result of local technical IT system issues, which were only solved by a major effort by both Registry and local renal unit staff.

Annual reports

It was decided to enhance the visibility of the Registry annual report, by publishing in a PubMed⁴³ listed journal, therefore improving searchability and reference citations. In 2007, it was published as an on-line supplement in NDT⁴⁴ but this did not go entirely smoothly, and from the 11th Annual Report, the Report has been published in Nephron Clinical Practice and latterly in Nephron.

The core chapters of the Report remained unchanged (appendix 3). Notable additional analyses included in various annual reports from 2006 to 2011 included: vascular access (2006, 2010), MRSA bacteraemia (2008), advanced CKD & start of RRT (2009), home therapies (2010), peritoneal dialysis (PD) access (2011) and analysis using linkage to HES⁴⁵ data (2011).

In 2008, a major finding was in a funnel plot analysis of the distribution of patients on the transplant waiting list. It showed that several units were outliers, and three units were ≥ 3 standard deviations below the mean proportion of patients on the UKT active renal transplant waiting list. Pre-emptive

⁴³ PubMed Central® - a free full-text archive of biomedical and life sciences journal literature at the US National Institutes of Health's National Library of Medicine

⁴⁴ NDT – Nephrology Dialysis Transplantation- the journal of the ERA-EDTA

⁴⁵ Hospital Episode Statistics – NHS data reporting on admissions to hospital and their outcomes in England

living donation without UKT listing provided some but not all of the explanation. These findings were the stimulus to the development of the ATTOM project⁴⁶.

Alongside the annual report, additional data analyses began to be presented on the Registry website including interactive maps, centre-specific reports, and Rosling charts depicting trends over time using quarterly data. But these proved time-consuming to produce, and the effort could not at that time be sustained.

Data extraction and validation

Data validation and correction of errors remained a major part of the Registry's work. There were renewed efforts to emphasise the partnership between the Registry and contributing units, and their shared responsibility for data accuracy and completeness. Quarterly timeliness and completeness reports were now being sent to all clinical directors and system managers aiming to identify remedial gaps in data, but this did not seem to have the desired effect of reducing delays in data returns.

New EDTA diagnostic codes became available and were gradually being introduced (the new codes were mapped to old codes to allow combined analysis during the transition, and avoid recoding). The challenge of achieving data returns from paediatric units persisted. Although data were complete, this was still very time-consuming, requiring data from paper returns to be uploaded onto a Proton database by Malcolm Lewis, and thence to the Registry database. By 2011 many paediatric units still did not have electronic databases.

National Renal Dataset

In 2009, NPfIT in England proposed a National Renal Dataset - a mandated set of data to be collected on all patients on RRT. Registry staff had extensive discussions with NPfIT attempting to shape the dataset. Collection and reporting of many of the data items was to be made mandatory for trusts, so it was seen as an opportunity to collect more items than were currently reported to the Registry by renal units. As it became clear that the hospital IT systems being supplied through

⁴⁶ Access to Transplantation and Transplant Outcome Measures (ATTOM) Study. Funded by the National Institute for Health Research (NIHR) (RP-PG-0109-10116). Publications from the ATTOM Study included: Wu DA et al. Barriers to living donor kidney transplantation in the United Kingdom: a national observational study. Nephrol Dial Transplant. 2017;32:890-900

Connecting for Health were not up to the task, a temporary solution was arrived at in which trusts would report data to the Registry which would then share the data with the NHS Information Centre (NHS IC)⁴⁷. There were sensitivities about who would ‘own’ and control interpretation of the data, and significant issues related to the requirement that NHS trusts invest in their IT systems to make them able to collect the entire dataset. In due course the mandating of the collection of data items proved to have no teeth, and Registry business continued as usual using its well-established dataset.

Finance

The capitation fee in 2010 was £18 per patient. Possible variations in capitation fees continued to be discussed. For example offering rebates for units providing prompt and accurate data returns, or charging more when additional Registry time and effort was needed to complete data extraction validation (for example paediatrics). But it was always preferred to keep capitation fees the same for all.

Although the great majority of Registry income continued to come from capitation fees, charitable donations were being received from time to time, and these were most commonly used to enhance staff training.

During this period the Registry was taking on significant new externally funded project work while maintaining its ‘core business’ of retrieving, analysing and reporting data for patients receiving RRT. For example in 2010, including all project work, the annual income, had grown to nearly £900,000. This success provided organisational and budgeting challenges. New staff were needed to deliver project work, but forward planning was difficult when much external funding came from competitive grant income when success could not be predicted in advance. Likewise many staff began to be involved in some project work alongside the ‘core business’ and the correct assignment of staff to each element was not straightforward. This was not helped from 2009 onwards when the NHS endured a period of lean funding.

⁴⁷ The taxonomy of digital data collection in the NHS continually changes. Known in the early 2000s as the NHS Information Centre, it was then subsumed into the Health and Social Care Information Centre (HSCIC), and now in 2019 into NHS Digital. The range and provenance of data held by NHS Digital is substantially expanded compared to that originally held in the NHS IC, and includes a number of disease and organ specific registries. In principle, this could make it easier for the Registry to obtain approval for informative data linkages, since negotiation is required with a single structure. Nevertheless, delays because of bureaucratic requirements and information governance continue to blight the approval process.

Staffing, accommodation & infrastructure

Staff numbers continued to increase, and by 2010 there were sixteen employees.

In 2010 the Registry moved premises to the Learning and Research Building at Southmead Hospital (a building jointly owned by the North Bristol NHS Trust and the University of Bristol). This increased the Registry's rental costs to £40,000 a year. But it was a necessary move away from accommodation which was no longer fit for purpose and for the first time the Registry was housed in purpose built modern office accommodation, providing a much superior work environment.

SWOT analysis & strategic plan

In light of the increasing complexity of the Registry's work, a SWOT analysis was undertaken in 2009.

An important strength was seen to be that the Registry was recognised as one of the leading national specialty-specific audits, professionally led, and trusted by clinicians.

A major weakness was reliance on renal-specific IT systems which were often unsupported by NHS Trust IT departments. They were silo systems that did not share information easily with other healthcare systems. They required bespoke extraction software and many of the problems with validation were due to failures of data extraction. These stand-alone systems were unlikely to be supported in the long-term and would atrophy. This provided both an opportunity and a threat.

Another weakness was that the success of recent years had occurred in spite of a lack of effective project planning, and this was a stimulus in 2010 for the Registry's first five year strategic plan.

A possible threat was any insecurity in the capitation funding model, but this seemed not to be an immediate concern given the view expressed by the DoH that the Registry was giving value for money.

Another possible threat, especially if trusts all began to use similar systems, was that data may flow directly to the NHS IC, and that NHS Connecting for Health⁴⁸ may wish to take on the role of the Registry. It was deemed essential therefore that the Registry be an equal partner in its relationship with the NHS IC, and maintain control over analyses so that these remained professionally led. Even if data in due course went through the NHS IC, the Registry needed to maintain a mandate to perform the audits, since Connecting for Health could not replicate the expertise of the Registry and its advisors.

⁴⁸ NHS Connecting for Health (2005-2013) had the task of developing the NHS national IT infrastructure to deliver the NHS NPfIT. Some of its responsibilities were taken over by the Health and Social Care Information Centre

Intellectual property

In 2009 the Registry became aware that an organisation known as Collaborative Health Informatics (CHI) was extracting registry data (which were in the public domain) and selling them. This was the first significant challenge there had been to the Registry's intellectual property. CHI had submitted a trademark for the name Renal Registry Plus, which was already gaining visibility on internet search engines. CHI also owned RR.co.uk and RR.com. Following a RA challenge, CHI did not renew ownership of those web names that mimic the Renal Registry and re-pointed these websites to the Renal Registry.

Research

The Registry's research portfolio continued to expand.

Authorship & publications

There was increasing concern that publication of a chapter within the annual report may prejudice related future publication in peer reviewed journals, which could be viewed as dual publication. In future proposed authorship of any publications arising from research performed by the Registry would be submitted to the Registry Committee for discussion and approval. Not all Registry output was included in the annual report: new analyses were first published in peer-reviewed journals and if thought valuable may then be included in the annual report.

Academic links

A more formal academic link with the Department of Social Medicine at the University of Bristol remained under discussion. This would bring obvious benefits for the Registry's research and academic efforts. Although concerns were voiced that the Registry might be 'swallowed' by a large academic department, the unique and sustained strengths of the Registry made this a low risk. The potential for honorary academic appointments for Registry staff was seen as one benefit of such a new arrangement.

Research SpRs

The first research SpR worked in the Registry from 1999 with external funding. From 2001 the Registry then began to regularly fund research SpRs, there were usually two in post, employed by NBT, but with salaries paid by the Registry (see appendix 5). However the approach to SpR project supervision had been reactive; unfunded support was being given by the Professor of Social Medicine at Bristol University. It was now agreed that Registry SpRs must register for a PhD having obtained grant funding which included supervision costs, in order not to use capitation funding for

research. Charitable donations (rather than capitation income) would be used to pay PhD fees where necessary. Registry SpRs had been giving significant time to writing the Registry annual report while also pursuing a research project. While this undoubtedly helped them gain additional skills, this pattern of work was not compatible with current PhD regulations. It was also agreed there should be opportunities for allied health professionals to undertake PhD work⁴⁹.

Scope of work

The routines of data extraction, validation, and analysis were well established for RRT, and the Registry provided complete UK coverage. Production of the annual report followed a consistent template, although requiring a very large annual burden of work.

The Registry was therefore able to look more at the external opportunities to build on the platform which it had established. As the Registry's reputation and achievements grew, there was increasing partnership work with external agencies, including statutory bodies (e.g. NHS IC and UK Transplant), as well as other academic organisations (e.g. Kidney Research UK and ERA-EDTA Registry), and approaches from the pharmaceutical industry. Although there were project-specific contracts, care was taken in each case to protect the Registry's charitable status, to conform to VAT rules, and to provide proper data sharing agreements. The challenge became the Registry's capacity to deliver these increasing demands for both internal and external project work alongside core business.

The following are some examples of new external partnerships discussed in this phase, and the progress that was made.

- In 2005, the Healthcare Commission proposed a 'National Renal Audit'. The Registry worked with the RA and other relevant kidney organisations to agree a scope of work published in 2006, and eventually funded in 2007. After prolonged discussion the funding was eventually awarded to the NHS IC in 2009, some funding coming to the Registry. The final result was the production of national audits on vascular access (2009-2011) and on transport for dialysis (2008)⁵⁰.
- A registry of non-dialysed CKD5 patients, and a national CKD4 and 5 audit in partnership with the NHS IC combining data from the Registry and from general practice IT systems. The gestation of these CKD proposals was very long (see below, page 53).

⁴⁹ The first allied health professional Registry PhD student, Katie Fielding, was eventually appointed in 2019

⁵⁰ These reports are available at: <https://digital.nhs.uk/data-and-information/publications/statistical/national-kidney-care-audit-vascular-access> and <https://digital.nhs.uk/data-and-information/publications/statistical/national-kidney-care-audit-patient-transport-survey/national-kidney-care-audit-patient-transport-survey-2008>

- Modelling to allow health authorities to predict the future incidence of CKD5. Although software was developed in partnership with an analyst at the DoH, it was not maintained and the predictive power was never properly tested.
- Record linkage with external NHS datasets. Linkage with HES had been long awaited and finally bore fruit when a large merged dataset (250,000 admissions in 22,000 prevalent dialysis patients) was analysed by Reetha Steenkamp working at the Registry for her PhD thesis, and also by a KRUk funded fellow James Fotheringham⁵¹. There was also a proposal for linkage with the Health Protection Agency's LabBase which would provide bacteraemias in patients on dialysis. A linked dataset was produced, but no outputs were ever agreed and eventually the dataset was destroyed.

These examples demonstrate some of the challenges and frustrations for the Registry of such proposals. Progress was typically very slow, sometimes due to internal Registry technical challenges. But most often sustained persistence was needed by Registry staff to negotiate with external agencies to justify the linkage, agree outputs, secure funding, and resolve the necessary permissions in the context of an increasingly cautious information governance environment⁵².

Another significant change in this phase came from the integration into the RA alongside the Registry of two new digital initiatives from within the renal community - the rare disease registry (RaDaR) and Renal PatientView (PV).

Rare Renal Disease Registry (RaDaR)

In 2008, the Registry in collaboration with the BAPN had acquired MRC funding to pilot a rare renal disease registry (RaDaR). The aim was to develop a model for a generic system for all rare diseases,

⁵¹ Publications from this work include:

Fotheringham J et al. Variation in centre-specific survival in patients starting renal replacement therapy in England is explained by enhanced comorbidity information from hospitalization data. *Nephrol Dial Transplant*. 2014;29:422-30
Fotheringham J et al. The mortality and hospitalization rates associated with the long interdialytic gap in thrice-weekly hemodialysis patients *Kidney Int*. 2015;88:569-75

Fotheringham J et al. The association between longer haemodialysis treatment times and hospitalization and mortality after the two-day break in individuals receiving three times a week haemodialysis. *Nephrol Dial Transplant*. 2019 Feb 28. pii: gfz007. doi: 10.1093/ndt/gfz007. [Epub ahead of print]

⁵² NHS data oversight continued to be restructured. The range and provenance of data now held by NHS Digital is substantially expanded compared to that originally held in the NHS IC, and includes a number of disease and organ specific registries. In principle this could make it easier for the Registry to obtain approval for informative data linkages, since negotiation is required with a single structure. Nevertheless delays because of bureaucratic requirements and information governance continue to blight the approval process.

which would help end the proliferation of standalone databases and drug company- funded registries. Patient consent would be required before entry into the registry to be PIAG compliant. Rare Disease Groups (including clinicians, researchers, patients and carers) would be established for each rare disease (or for a group of related diseases). These groups would be responsible for developing disease-specific data fields, expert information for patients and carers, as well as health professionals; and for initiating relevant research projects. Mark Taylor (Birmingham) played a key role in the development of RaDaR, which was underpinned by a UK Rare Renal Disease Strategy which had been developed by a RA/BAPN working party⁵³.

Renal PatientView (PV)

PV was a digital system allowing patients and carers to have password-protected access to their clinical information held in their local renal unit IT system through an intermediate web server. The concept of PV had been developed by the Renal Information Exchange Group (RIXG)⁵⁴ in 2006, under the leadership of Keith Simpson and Neil Turner (Edinburgh), with start-up funding from the DoH. PV had soon been embraced as an effective and user-friendly means for patients to access their own clinical information. PV was a unique development which once more placed the renal community at the forefront of digital clinical applications. It was agreed in 2008 that a sustainable technical and governance future for PV could best be guaranteed by co-locating its administrative support in the Registry office. A capitation funding model was agreed and in 2009 the first capitation fees were charged - £2.50 per RRT patient, applied to any unit in England where patients used PV. 50% of units were already signed up to using PV. Scotland and Wales were paying a lump sum for PV rather than by capitation (although the Scottish contribution was significantly less than would have been generated by capitation fees), and bureaucratic issues at this point prevented the use of PV in Northern Ireland.

RaDaR and PV were both drawn towards the Registry for sound organisational reasons, to share aspects of the technical platform and there were opportunities for interaction. It was sometimes thought that the Registry had subsumed RaDaR and PV. This was rather misleading as RaDaR and PV each remained distinct entities, with different governance arrangements and lines of clinical and

⁵³ Rare Kidney Diseases: An Integrated Strategy for Patients in the UK (2010). The RA/BAPN working party was co-chaired by Mark Taylor (Birmingham) for the BAPN, and John Feehally (Leicester) for the RA. https://renal.org/wp-content/uploads/2017/06/UK_Rare_Kidney_Disease_Strategy_APRL_2010.pdf

⁵⁴ RIXG (Renal Information Exchange Group) - an inclusive group with representation from professional and patient kidney organisations established in 2003 to discuss information developments in UK healthcare and to identify fruitful new IT initiatives for the kidney community. Its most substantial product was PV. RIXG was disbanded in 2014 and its remaining activity subsumed into a new RA Clinical Informatics Standards Committee.

information governance accountability. It is perhaps better expressed that the Registry, PV and RaDaR are independent elements of the RA, sharing some aspects of the digital platform.

Succession planning & leadership appointments

Registry chair

In 2009 Charlie Tomson became the RA president-elect and agreed to remain as Registry chair until he became president in 2010. It was agreed his successor would be offered three programmed activity (PA) sessions by the Registry. In September 2009, Damian Fogarty (Belfast) was selected from a strong field to succeed Tomson as Registry chair in 2010. His appointment brought with it the need to modify some of the Registry's ways of working, since this was the first time the Registry chair had not been based in Bristol.

Registry director

By 2010 David Ansell had worked at the Registry for fifteen years. His technical computing skills and clinical background had been critical to the Registry becoming a viable entity. The very large workload borne by Ansell had been highlighted by the external review in 2002, and a general manager appointed as mitigation. But Ansell's work still included much internal day to day technical and leadership responsibilities, since most day to day queries about data continued to come to him as the only staff member who fully understood the IT systems. There were also ever increasing demands on his time in external facing partnership building, as well as supporting the growth in the Registry's scope of work which was now attracting additional projects and grant income. The situation was not helped by the propensity of external partners to expect informal work to be delivered by the Registry before contracts had been signed. In 2009, to lessen Ansell's work burden, a senior project manager was therefore appointed (Christopher Maggs) with some immediate benefits in enhanced capacity. In 2010 Maggs was promoted to be the first Registry deputy director.

Role evaluations

David Ansell's role had developed over the years without a written job description, and the RRMB decided it should now approve new and updated job descriptions for the Registry chair, director, deputy director and business manager which properly reflected the Registry's current ways of working.

Ansell felt that this job description represented a substantial change to his existing role, declined to sign a contract reflecting that description, and as a consequence was no longer employed by the Renal Association. He appealed against this decision but in 2011 an employment tribunal ruled in favour of the RA's handling of the events.

Interim director

The unplanned departure of the Registry director was inevitably associated with a period of some instability and uncertainty in the Registry. The deputy director also retired in 2010. But despite these challenges any interruption to its routine work and outputs, notably the 2011 Annual report, was minimised by the committed work of Damian Fogarty, the new chair, and other senior staff. Terry Feest, who had stood down as Registry chair in 2006, was appointed interim director of the Registry from September 2010. This afforded the RA trustees some time to reflect on possible changes to the senior management structure. In due course it was agreed that the director and chair roles would be realigned. There would be a full time chief executive to lead the maturing Registry as a growing business organisation - a role not requiring clinical qualification. There would also be a medical director supported by reimbursement of time to the employing NHS organisation.

Phase 5: Unleashing the Registry's potential – 2012-2020

Ron Cullen became the first Registry chief executive in 2012⁵⁵, and Damian Fogarty continued as chair until Fergus Caskey became the first substantive medical director in 2013. In 2019 Caskey completed his term as medical director, and was succeeded by James Medcalf (Leicester). Medcalf's 0.4 FTE role was restricted to the audit elements of the Registry's work. A new 0.2 FTE role, RA Director of Informatics Research, was then established including responsibility for the research agenda of the Registry. The first appointee was Dorothea Nitsch (London). The number of Registry staff continued to increase – 35 employees by late 2019.

Data extraction & validation

In 2011 the interim Registry director, Terry Feest, had introduced substantial improvements in data collection. Redundancy in data validation processes was eliminated, and much of the validation work was automated, reducing the time required for validation of all data to six months, provided it was received promptly from units. Units noticed improvements in the response time from the Registry, and in the summary data in the Report. The rate limiting step became slow return of data from units due both to lack of informatics staff support and IT issues which needed continuing attention; one commercial renal unit system for example introduced an 'upgrade' which then blocked Registry returns.

Although the return of RRT data to the Registry was now a well-established routine in all units, reporting of comorbidity was still incomplete, making difficult for example the accurate correction of mortality rates for case-mix.

Obtaining and validating paediatric data remained time-consuming for both the units and the Registry. Several paediatric units continued making manual data entries, the main issue still being lack of local investment in IT systems. By 2019 a limited dataset was being retrieved digitally from all paediatric units.

Renal Data Collaboration

From 2011 onwards there were discussions about a possible UK 'Renal Data Collaboration' (UKRDC) which would lead to the single most ambitious technical innovation during the Registry's first 25

⁵⁵ Ron Cullen brought to the Registry experience in clinical governance and quality improvement (he was part of the original NHS Clinical Governance Support Team, and then the DoH Head of Healthcare Quality and Standards) before gaining private sector management consultant experience

years with the potential to transform the Registry's data management. The goal was to create a renal data warehouse which would improve and standardise the scope and detail of renal unit data collection, would support a move to paperless electronic patient records, and would standardise data communications between member organisations and between renal units, allowing full access for patients to their own data.

The technical requirements to achieve this included:

- use of standard terms and standard methods for labelling and formatting data via the creation of a data model and standard messaging systems
- development of two-way communications between all participants using common messaging systems, including patients via Renal PatientView
- building and maintaining data repository software with suitable operating systems, security, communication network and database. This would act as the communications hub for the member organisations⁵⁶.

Among issues which would be resolved by establishing this renal data warehouse were the data interactions between the Registry, RaDaR and PV which had consumed much time and effort over recent years.

Success would require the strong support of the patient community. The Registry worked hard emphasising the benefits to units of achieving complete returns through the warehouse, for example the ability to participate in research and in future quality improvement projects. Success also required the commitment and investment of the renal IT providers, but there was some understandable anxiety about a renal data warehouse, because in future, with a suitable web viewer, units might in principle not need a separate renal IT system. There was support but no funding from the NHS. This very substantial project was initially led by Afzal Chaudhry and Keith Simpson with Reetha Steenkamp as project manager⁵⁷. The Registry dataset underwent a step change in preparation for the introduction of the renal data warehouse but implementation of the new dataset was slow in many centres.

The RDC project is very ambitious, and it is perhaps unsurprising that implementation timelines have lagged. As of late 2019, the warehouse is being used for RaDaR and PV, and is still being piloted.

⁵⁶ The UK Renal Data Collaboration member organisations:

UK Renal Registry, Scottish Renal Registry, PatientView, Renal Association, UK Registry for Rare Kidney Diseases (RaDaR), British Association for Paediatric Nephrology, NHS Blood & Transplant, Northern Ireland Nephrology Forum, Welsh Renal Clinical Network

⁵⁷ Full description of the technical and organisational solutions needed to deliver the data warehouse and the UK Renal Data Collaboration are beyond the scope of this account of the Registry

Registry data collection in 2019

New Registry activities mean continuing adjustments to required data returns to the Registry, and this has always proved challenging for many units. For example, in 2014 units were asked to implement the new EDTA primary renal diagnosis codes in their IT systems, but by the following year only 50% of units had achieved this, although by 2019 almost all had done so. In 2015, units were asked to implement the collection of dialysis-dependent AKI and plasma exchange in their renal IT systems, but only 50% of units had progressed to automatic data returns by the end of that year, despite inclusion of this requirement in service specifications.

In 2019 the Registry was collecting the following datasets from all units as part of its routine work:

- Adult RRT
- Paediatric RRT
- Haemodialysis and peritoneal access at initiation of RRT (England, Wales, N Ireland only)
- AKI up to 15 months of care (data from hospital laboratories, covering both primary and secondary care)
- AKI receiving haemodialysis in renal units (c.50% of units)
- CKD 4 & 5
- Five renal ‘indicators’ on behalf of NHS England (PD peritonitis rate, rate of Staph aureus bacteraemia in haemodialysis patients, access to transplant listing for patients starting dialysis, PatientView uptake, PatientView usage)

The Registry also now obtains (in England & Wales only) valuable data on infections (linkage with Public Health England) as well as HES data (linkage with NHS Digital, as well as Patient Episode Data Wales).

Annual report

The Registry report continues to be published annually and usually in good time despite continuing challenges with data extraction and validation. The core chapters of the report remained unchanged until 2017 (appendix 3).

Notable additional analyses of RRT patients included in the annual reports from 2012 to 2017 included: infections on dialysis (2013-2016), ethnicity (2013), PD access (2012), home therapy (2016).

From 2011, distribution of printed copies of the annual report became an ‘opt-in’ process, with provision of a CD or USB stick drive as alternatives.

From 2013 onwards, units which failed to make timely adequate data returns were to be named and their data not published in the annual report; this sanction has only been applied once.

The 21st report was published in May 2019 with significant departures from the format of previous years. It was a simpler, greener, predominantly online report, with the audit measures directly linked to RA clinical practice guidelines.

As part of the Registry's formal communications strategy (since 2016) efforts continue to improve the profile and dissemination of the annual reports. A summary of the annual report for patients is now produced in plain English and with infographics. NHS e-dashboards, so far only seen by clinical directors, are to be in the public domain, as well as data on PROMs. Visibility has increased at the RA annual conference, and there is a growing social media presence.

In 2019 the Registry established a new [web data portal](#) which presents data by unit over the previous five years for some key measures (incidence and prevalence of RRT, home therapies, vascular access) as well as PREM data from 2017.

Timeliness improves, some data are now entered into the portal before appearing in the annual report, but truly timely data will only be achieved when the RDC warehouse is fully operational.

Terry Feest award

In 2013, the Registry established the Terry Feest award for those who have made sustained and exceptional efforts for the work of the Registry giving freely their own time and with very little other direct recognition. The award was named after Feest, acknowledging his own remarkable contribution to the development of the Registry. Awardees thus far are: 2013 Afzal Chaudhry, 2014 Andrew Williams, 2015 Paul Roderick, 2016 Malcolm Lewis, 2017 Nick Jones, 2018 Denise Abbott, 2019 Dorothea Nitsch.

Finance

Throughout this most recent phase of the Registry, the financial position has been sound and stable. Annual income and expenditure have relentlessly increased. In 2018 for example income was £2.2 million (90%) from capitation fees. External grant and other non-capitation income have increased from £165,000 in 2012 to £335,600 in 2018. In 2016, when substantial additional expenditure was required for the Renal Data Collaboration it was possible to make £200,000 available without compromising other Registry business or the reserves.

Capitation fees

The increasing portfolio of the Registry began to complicate capitation fee arrangements. The capitation fee now covers not only the longstanding costs of RRT work, but also AKI and CKD 4 & 5. Since 2016, the capitation fee in England has been £27.50 for the Registry plus a nationally mandated capitation fee of £2.50 for PatientView. In Wales & Northern Ireland the Registry capitation fee is £22.50, and there is a non-mandated capitation fee of £2.50 for PV (as it is not mandated it is only paid by units using PV). In Scotland there is no capitation fee charged by the Registry for adults since the data are collected by the SRR; the capitation fee for children in Scotland is £22.50. PV is funded through a grant from the Scottish government.

Feedback from units regarding increases in the capitation fee has typically been positive; a reflection of the continuing perception it represented value for money. But in 2016 there was negative feedback from a small number of centres; the Registry communicated with commissioners to justify the increase, which helped ensure that all units eventually paid.

Accommodation

There has been persistent uncertainty about accommodation for the Registry. For most of this latest phase of its history the Registry has still been based in the Learning and Research Building at Southmead Hospital, Bristol. The growth of the Registry staff team, and the decision in 2017 to co-locate the RA secretariat⁵⁸ meant a substantial shortfall in office space. Changes in work practice (such as some home working, and more ‘hot desking’) could mitigate this to some extent but more accommodation needed to be found. There was no other available accommodation at Southmead Hospital. Available offices away from the Southmead were outside the NHS ‘firewall’, creating potential for data security issues.

The Registry had originally been placed in Bristol for practical reasons – Terry Feest (the first Registry chair) and UKTSSA (which hosted the nascent Registry for its first year) were both in Bristol. While occasionally RA members had voiced concerns that the Registry was too ‘Bristol-centric’, the practicalities of leaving Bristol would be formidable. There was no interest in a tendering exercise of the sort used for example by the USRDS which results in its entire analytic and reporting functions moving from one university to another every few years. Suitable office accommodation has been identified on a business estate in north Bristol and the Registry will move in 2020.

⁵⁸ The RA’s management was provided for over 20 years by external association management companies – Triangle 3 (1995-2003), then MCI (2003-2017). In 2017 the RA then moved to self-management, Ron Cullen was appointed chief executive of the RA as well as the Registry, and it was decided to place other RA secretariat staff in the Registry offices

Governance

Information governance

The growing requirements of information governance continued to consume substantial senior Registry staff time. Data governance required a great deal of work to ensure all the necessary permissions were obtained. A DoH information governance toolkit had to be completed annually. Data breach and consequent loss of confidence in the Registry's work continued to be a significant organisational risk. This risk became more immediate when the GDPR (General Data Protection Regulations) became law in 2018, and all aspects of the Registry's information governance required a thorough review in light of GDPR requirements. Following the introduction of GDPR, a new Registry staff role has been created with responsibility for all aspects of quality assurance and information governance, to relieve senior staff of this work.

The Health Research Authority (HRA) Section 251⁵⁹ approval gives a continuing legal basis for the Registry's work, but requires an annual resubmission. However the section 251 approval covers only England and Wales. Adult data is submitted via the Scottish Registry covered by a separate approval process endorsed by the Caldicott Guardian for Scotland since 2014. Scottish paediatric patients whose data goes to the Registry continue to be individually consented (a process only practically tenable because of the small numbers of children for whom this is required). In Northern Ireland legal standards for data processing cannot be finalised until executive powers have been restored, and so until then responsibility for data sharing remains with individual hospitals, where the Registry representative ensures local compliance.

In 2015 a serious untoward incident (SUI) in breach of the Data Protection Act was identified. Due to a repeated staff error, patient identifiable data (date of birth) had been given to the ERA-EDTA Registry over a number of years. Date of birth and/or postcode data had been given to four UK academic researchers without a legal basis for so doing. The SUI was reported because, despite the low risk of a patient actually being identified, the very large number of patient records included made it a serious incident. The SUI was promptly and appropriately reported to the RA trustees, the chair of the Registry Patient Council, and the Caldicott Guardian⁶⁰ as well as to the HSCIC which in turn triggered a notification to the Information Commissioner's Office. All new research was

⁵⁹ Formerly designated as Section 251 (and before that as Section 60) of the 2001 Health & Social Care Act

⁶⁰ A Caldicott Guardian is a senior person responsible for protecting the confidentiality of people's health and care information and making sure it is used properly, and must be appointed in all NHS organisations following the recommendations of a 1997 review, chaired by Dame Fiona Caldicott. As a non-NHS organisation the Registry does not need a Caldicott Guardian, but it was decided it would still be good practice, and the Registry medical director takes the role for the RA, PV, and RaDaR as well as the Registry (although only medical director for the Registry).

delayed for 12 months and all current research halted for about six months while the HRA considered and accepted the Registry's response. Processes were strengthened to ensure no data could leave the Registry in future without the signature of the medical director or the chief executive.

Clinical governance

The Registry continued its established process for handling units which were outliers for survival data. If the outlier status was confirmed after data checks, the unit clinical director was asked before the Report was published to inform their clinical governance lead and chief executive. Registry work on linkage to HES data had shown that much of the apparent survival variation was attributable to case-mix, but units have been unable to provide complete comorbidity reporting, which will only be achieved through linkage to HES.

Governance re-structure

In 2011, the RA dealt with the changing governance requirements by re-naming the RRMB as the Renal Information Governance Board (RIGB) with explicit responsibility for RaDaR and PV governance as well as the Registry. A complex relationship had developed between the Registry, PV, and RaDaR, each with distinct leadership yet interlinked. The Registry for example was needed for delivery of some elements of PV while not responsible for others. The Registry has become responsible for the data collection and retrieval aspects of RaDaR but not for the broader implementation of the rare disease strategy, including the work of rare disease groups. In 2013 the Registry Committee was dissolved and its functions subsumed by RIGB. The operational responsibility for the Registry now lies with the Senior Management Team (the chief executive, the medical director and the head of operations).

Registry speciality interest groups were disbanded to avoid any overlap with UKKRC⁶¹ clinical study groups which were increasingly successful in developing and driving the kidney community's clinical research agenda.

In 2018, the RA commissioned an external review of its overall governance, and accepted its recommendation to integrate the responsibilities of RIGB within the RA Trustee Board. While a separate RRMB and then RIGB had been invaluable when the Registry, RaDaR and PV were in earlier stages of development, this arrangement did not now support the concept of the RA as 'one

⁶¹ The UK Kidney Research Consortium (UKKRC) established in 2007 and jointly hosted by the RA, KRUk, and BRS. Its mandate is to facilitate collaborative clinical research in kidney disease. Its clinical study groups have proved very effective drivers for the design and prosecution of multicentre clinical trials.

organisation', with trustees having an integrated oversight of all activities. Governance of the Registry, RaDaR and PV was therefore to be merged more explicitly into overall RA governance with one strategy for the organisation, one integrated budget, and one risk register. Staff from the three bodies and, when necessary chairs of particular committees, attend trustee board meetings as required. The current RA organisational structure is shown in appendix 7.

Research

The research capacity of the Registry is still increasing, and there are greater training opportunities for younger researchers. The range of research opportunities reflects the growing scope of the Registry's work. Costs are assigned on a case-by-case basis, and a scale of charges has been developed for independent researchers wishing to access Registry data.

From 2013 the Registry stopped appointing research SpRs, whose role had shifted towards contributing to the routine work of the Registry including the writing of annual reports, rather than PhD work using Registry data. However in 2017 a Registry fellow, Rhodri Pyart was appointed (50% funded by the Registry) to support the core function of the Registry, with no requirement to register for a PhD. From 2016 some time was bought to enable NIHR-funded PhD students to work for the Registry, each for one day a week working on the annual report and other Registry-related research.

The Registry increasingly became a valued partner in large studies. For example in 2016 the Registry played a key role in securing two awards from NIHR HTA: a trial comparing preparing for dialysis versus preparing for conservative care, and a trial of haemodiafiltration (HDF) versus haemodialysis (HD). Although only a small part of the grant came to the Registry for direct research costs, the Registry's role in data collection and handling was critical to the success of these projects. Appendix 6 shows external grants held by the Registry over recent years.

Most Registry database and report activity is judged to be audit and not research, and so is covered by HRA Section 251 support for audit and quality assurance. But it became clear that separate Section 251 support was necessary for research and linkage to other datasets; in 2014 the Registry therefore obtained research database REC (research ethics committee) approval as well as separate Section 251 approval for research. This allowed a range of activities to be undertaken without prior approval, the REC being informed in a report at the end of each year.

In 2012 an agreement was signed (which continued to 2019) with the University of Bristol, to include support and training for statisticians and trainees, to help with peer review for data, project support, and support for nationally competitive research grants. The Registry during this phase also

had grant funding which included other academic partners (King's College London, SCHARR⁶², London School of Hygiene and Tropical Medicine, ICNARC, and the Universities of Cambridge, Keele, Oxford and Southampton).

Randomised Clinical Trials

The Registry can play a key role in collection of data for large randomised controlled trials (RCTs) involving RRT patients. In 2019 the Registry was providing such support for a number of UK-led RCTs including 3C, BISTRO, H4RT, Prepare for Kidney Care, RRAM, and SIMPLIFIED⁶³.

Cohort studies

The Registry is also ideally placed to be a data repository for new cohort studies and biobanks in people with renal disease. A role it is now fulfilling in partnership with Kidney Research UK for NURTuRE⁶⁴, a platform funded by Kidney Research UK with industry partners which in 2019 was recruiting a CKD cohort and a nephrotic syndrome cohort and provides the opportunity for other new cohorts to be added.

Scope of work

In this most recent phase of the Registry's growth and development, the expansion of its scope of work has accelerated. This has included a number of major projects of greater complexity than anything previously in the remit of the Registry with consequent demands on its leadership, project management, and governance arrangements. If all grant applications submitted at any one time by the Registry were successful, the Registry workforce would not be able to deliver them all; the inevitable lag time (often as much as 12 months) between grant application and approval creates challenges for workforce planning and project management allocation. This remains a recurring issue. The challenges are considerable, but the potential reward is the future delivery by the Registry of work able to transform kidney care in the UK. The most substantial of the new projects are described below:

⁶² SCHARR – School of Health & Related Research, University of Sheffield

⁶³ 3C, Campath & calcineurin inhibitor reduction in chronic allograft nephropathy

BISTRO, Bioimpedance to measure fluid status in HD

H4RT, high volume HDF vs. high flux HD

Prepare for Kidney Care, responsive management versus standard care in older people with advanced CKD

RRAM, heparin versus citrate anticoagulation in continuous RRT

SIMPLIFIED, colecalciferol versus standard care in dialysis patients

⁶⁴ NURTuRE (the National Unified Renal Translational Research Enterprise) www.nurturebiobank.org

Acute kidney injury

In 2014 the Registry launched a programme funded by NHS Kidney Care to collect AKI data (including patients seen in both primary and secondary care). This used separate processes from the long-established extraction of RRT data, and dashboards of aggregated AKI data were prepared for commissioners. NHS England then mandated the introduction and use of the National Patient Safety AKI e-alert algorithm. Not all trusts were ready, and they received no additional funding for these steps, but trusts necessarily responded since it was a level 3 patient safety alert, meaning that it would be monitored to ensure compliance by the Care Quality Commission⁶⁵ during its inspections. Details of non-compliant trusts were published by the Registry from 2016. By 2016 50% of laboratories were submitting the required data to the Registry and another 20% had been in touch to discuss their data returns. By 2019, 90% of laboratories are returning AKI data to the Registry. One weakness is that there is not yet a process for identifying age-specific creatinine values in children, so that e-alert and data collection are only robust in adults. From these AKI data returned to the Registry an AKI Master Patient Index is generated which itself contains a limited dataset but offers great opportunities for further description of AKI rates, outcomes, and inequalities in these patients since links to external datasets such as HES and ONS⁶⁶ were established in 2018.

Data are also being collected by the Registry on dialysis-requiring AKI, but renal IT suppliers still struggle to provide the necessary data and there are concerns over data quality. Even so this only provides data on intermittent HD for AKI delivered by renal unit staff. Data on RRT for intensive treatment unit (ITU) patients will become available via ICNARC⁶⁷.

This AKI work is now funded from the Registry capitation fee, with some additional fixed-term funding made available by NHS Kidney Care⁶⁸.

This rich AKI dataset has much potential, for example providing the basis for a recent RCT examining the potential of an organisational intervention to improve AKI care⁶⁹.

⁶⁵ Care Quality Commission (CQC) – an executive non-departmental public body of the Department of Health and Social Care – succeeded the Healthcare Commission in 2009 as the regulator and inspector of health and social care services in England

⁶⁶ Office of National Statistics – a government office holding civil registry data such as births, deaths, and census information

⁶⁷ ICNARC- Intensive Care National Audit & Research Centre

⁶⁸ NHS Kidney Care – a transient NHS entity which supported the work of the NHS Clinical Director for Renal Services for England (a role held first by Donal O'Donoghue (Salford) succeeded by Richard Fluck (Derby)

⁶⁹ Selby NM et al. An Organizational-Level Program of Intervention for AKI: A Pragmatic Stepped Wedge Cluster Randomized Trial. J Am Soc Nephrol. 2019;30:505-515

Chronic kidney disease

A registry for non-dialysed CKD patients under nephrology care had first been discussed in 2005, and was potentially straightforward since data could be collected from renal unit systems, many of which now held data on more than just RRT patients. From 2016, renal units were asked to adopt an update of the Registry dataset, which included the request to submit data on anyone with CKD stages 4&5 to be identified by a single eGFR <30 ml/min (the previous dataset had used RRT as the inclusion criterion). This version of the Registry dataset also contained significant other changes in preparation for establishment of the UKRDC's data warehouse. In 2016, data for CKD 4&5 patients were collected for the first time from some units; extrapolation of preliminary data from Liverpool and Bristol suggested there were some 8,000 new CKD5 patients per year in England. However, with delays in the UKRDC, transition to the new Registry dataset remains patchy and in 2019 only a small number of sites were submitting CKD 4&5 data. Nor are there yet the resources at the Registry to clean, validate and analyse these data.

Extraction of data from primary care systems would be needed to establish a comprehensive CKD registry and thence the generation of a CKD Master Index. Just like the AKI Master Index, there is considerable potential impact from such a CKD Master Index when external database linkages are secured. Technical issues are potentially solvable, for example if there were access to the central NHS Digital repository of all laboratory data, but it has not yet been possible to obtain a mandate from the NHS or commissioners for collection of data for all CKD. Such a mandate is given on the basis of an expected public health benefit, a benefit self-evident to most of the kidney community, but not yet to the NHS and commissioners.

Patient-focused outcome data

From 2014 the Registry, supported by a grant from NHS England had developed tools (initially only for adults) to collect data on patient-focused outcomes – PROMS, PREMS, and PAMS⁷⁰. This started with dialysis patients, and then included undialysed CKD5 patients. Since 2016, PREMS data were being returned annually from all units. In 2019 PROMS data were being collected from ten units in a pilot study of the Transforming Participation in Chronic Kidney Disease (TPCKD) programme.

⁷⁰ PROMS – patient-reported outcome measures; PREMS – patient-reported experience measures ; PAMS – patient-activation measures

KQuIP – Kidney Quality Improvement Partnership

An important initiative for the renal community from 2015 onwards is KQuIP, the Kidney Quality Improvement Partnership, joint work of the RA and the BRS, project managed by the Registry, and mainly funded by the RA. Benchmarking data provided by the Registry provides a basis for peer review visits which are expected to provoke measurable improvements in care.

Summary & conclusions

This record of the Registry ends in January 2020, the end of the Registry's 25th year.

Impressive progress – continuing challenges

The UK Renal Registry, although not of course without some weaknesses, continues to be one of the success stories of the Renal Association. To move from an initial concept and the appointment of a small number of enthusiasts to drive a pilot project (1992), to the formal establishment of the Registry (1995), to a viable, financially stable organisation publishing its 1st Report (1998), and then on to complete UK coverage (2008) is an impressive pace of development. The inevitable periods of uncertainty have in general been managed internally with equanimity, and have not significantly disadvantaged the Registry's external reputation.

Now in 2020, the UK kidney community has a mature Registry, whose broadened purpose was presented in the 2013 Annual Report⁷¹. It describes the relationships of the Registry with a wide range of UK healthcare organisations, and lays out succinctly the Registry's engagement with patients, nephrologists, NHS trust managers, commissioners of healthcare and national healthcare quality assurance agencies.

The Registry now delivers year on year the core of its original raison d'etre - to collect and analyse data on all those in the UK receiving RRT; and present it in forms which support the future planning of kidney care. This epidemiological work was the first focus of the Registry and the main interest of its leadership, thus the initial technical efforts were concentrated on establishing a platform able to support it.

Nevertheless data quality will be a continuing challenge. When units chose to join the Registry, implicit in that choice was the responsibility to provide high quality data promptly to enable the Registry to make timely reports. But units were typically unable to find sufficient internal resources to undertake the high quality data management needed for the Registry, leading to mutual frustration that data delays slowed publication of the annual reports.

The Registry is now reaching well beyond the primary dataset of RRT for ESKD. It is collecting data on those with CKD not receiving RRT, as well as data on AKI, to support national drives to improve AKI outcomes.

The Registry also now provides a platform to support a number of data rich research projects.

⁷¹ UK Renal Registry 16th Annual Report 2013: Appendix A The UK Renal Registry Statement of Purpose
<https://www.renalreg.org/wp-content/uploads/2014/09/16-App-A.pdf>

The Registry also publishes sequential data, de-anonymised at the unit level, to demonstrate variation in achievement against accepted clinical practice guidelines, thus driving quality improvement. Progress in the development of tools to drive quality improvement has been significantly slower than could have been expected, despite the availability of the Registry data, and the RA Standards (now Clinical Practice Guidelines) to help drive the audit cycle. This area of work has not lacked for ideas, but has certainly lacked resources both locally and nationally.

A recurring theme in this story is the frustration over slow adoption of several of the Registry's excellent plans. These plans sometimes have foundered for internal reasons at the Registry: for example insufficient senior staff time to work up new concepts and provide necessary technical innovation. More often, rate-limiting factors are outside the Registry: potential partner organisations are slow to commit, and not necessarily willing to give high priority to Registry proposals. Linkages to other datasets held by the NHS, DoH, other government departments and arms length bodies provide obvious opportunities to refine and expand registry analyses, yet permission for such linkages can seem harder and harder to achieve as bureaucratic processes, often justified by sensitivities about data protection, delay or halt progress.

In hindsight the independence of the Registry has proved a 'two-edged sword'. In the early years this independence meant that the RA through the Registry had control of data collection processes and data quality, as well as editorial independence in the analysis and presentation of the data; these were critical to success.

More recently the Registry's independence affords some disadvantages since it stands apart from the majority of other disease registries as well as other key datasets such as HES and ONS, which are under more direct NHS oversight. This poses a potential risk to the Registry's ability to link efficiently to these national datasets which when delayed could have substantial impact on the care of kidney patients.

In response to the success of the Registry there are more and more proposals about how else it might contribute to the measurement of the kidney community's activities, and bring new perspectives to epidemiology, audit and clinical quality improvement, research, and much more. The Registry now has the mature organisational structure, finance and governance to make the most of these opportunities. Managing expectations and helping enthusiasts understand the true cost of each development will be necessary, and if the Registry can continue to broaden appropriately its

portfolio, without losing grip on its core data analysis and its presentation, there is every prospect it will continue growing in reputation and achievements.

'Unsung heroes'

A number of people without whom the Registry would never have succeeded are named in this report – particularly those present at its initial gestation, and those who have held identified leadership posts, either among the employed Registry staff, or among its volunteer leadership. But there are many, many more unnamed without whom the Registry's chance of birth, growth and success would have been much diminished, whose contributions should be acknowledged and respected. They include

- the many staff who have worked for the Registry, some giving prolonged service and commitment
- many in the renal community who have been, for example, committed members of the Registry Committee, its various user groups and research groups; who have helped Registry projects to fruition, who have been contributing authors to the annual reports
- the 'hidden' Registry workers in each renal unit (clinicians, data managers, administrators and others) who have provided unstinting support to the review and correction of data in response to Registry requests, usually over and above any formal contractual commitment
- the clinical directors of renal units who typically have unhesitatingly supported the Registry, and borne without demur the increasing capitation fees from within their budgets.

They all deserve thanks and respect for their contributions.

Sources & acknowledgements

I have had access to minutes of RA meetings held between 1990 and the present day – including the Registry Working Group, the Registry Committee, Executive Committee, Trustees, Renal Registry Management Board and its successor the Renal Information Governance Board.

I am grateful to Es Will for access to a number of other documents from his personal papers, particularly related to the earlier years of the Registry.

I have sought advice from most who have had leading roles in the Registry during these 25 years.

They include:

- the past chairs and secretaries of the Registry Committee – Terry Feest, Charlie Tomson, Damian Fogarty, Colin Brown, Es Will, Andy Williams, Afzal Chaudhry
- the Registry medical directors - Fergus Caskey, James Medcalf
- the first Registry chief executive, Ron Cullen
- the first chair of the Scottish Renal Registry Keith Simpson
- RA presidents who have spanned the first 25 years of the Registry: Netar Mallick, Stewart Cameron, Gwyn Williams, Andy Rees, Peter Mathieson, Charlie Tomson, David Wheeler, Bruce Hendry, Donal O'Donoghue, Graham Lipkin.

Nevertheless this account is my responsibility, and I apologise for any inaccuracies, omissions and solecisms it may contain.

John Feehally
Oakham
2020

Appendix I. Leadership & oversight of the UK Renal Registry 1995 – 2020

	Chair, Registry Working Group, then Registry Committee	Secretary, Registry Working Group, then Registry Committee	Director	Medical Director	Chair, Renal Registry Management Board	Chair, Renal Information Governance Board
1992	Terry Feest	Colin Brown				
1993						
1994						
1995			David Ansell			
1996						
1997		Es Will				
1998						
1999						
2000						
2001						
2002						
2003						
2004					Andy Rees	
2005						
2006	Charlie Tomson					
2007		Andy Williams			John Feehally	
2008						
2009						
2010	Damian Fogarty		Terry Feest (interim)		Peter Mathieson	
2011		Afzal Chaudhry	Ron Cullen			

2012					Charlie Tomson	
2013				Fergus Caskey		Charlie Tomson
2014						
2015						David Wheeler
2016						
2017						Bruce Hendry
2018						
2019				James Medcalf		
2020						

Appendix 2. Registry Annual Reports 1998-2019

The reports are available at: <https://www.renalreg.org/publications-reports/>

Report No.	Year	Year(s) of data	Coverage	Comments	Reported RRT acceptance rate pmp
1	1998	1996, 1997	9 units	Centres anonymised	
2	1999	1998	31 units		
3	2000	1999	40% of England & Wales centres + Scotland		
4	2001	2000	48% of England & Wales centres	No Scottish data (for technical reasons) Acceptance rates by health authority for the first time Centres named from 4 th Report onwards (only for incidence and prevalence of RRT in 4 th Report)	
5	2002	2001	Scotland & Northern Ireland complete data from 5 th Report	Phased increases in centre naming	
6	2003	2002			101
7	2004	2003	E & W 73% of population		
8	2005	2004	E & W 83% of population		
9	2006	2005	Only 3 English units not sending data		
10	2007	2006	Only 3 English units not sending data	NDT On-line supplement	
11	2008	2007	Only 1 English unit not sending data		
12	2009	2008	COMPLETE coverage from 12 th Report onwards	Nephron Clinical Practice On-line supplement from 2009 onwards	108
13	2010	2009			109

14	2011	2010			107
15	2012	2011			108
16	2013	2012			108
17	2014	2013			109
18	2015	2014		Nephron On-line supplement since 2015	115
19	2016	2015			120
20	2017	2016			118
21	2018	2017			121

pmp - per million population

Appendix 3. Registry annual reports: coverage & contents 1998-2017⁷²

Chapters on RRT in the UK which have been a standard feature in almost all annual reports:

- Adults & children - incidence & prevalence
- Survival & cause of death
- Dialysis dose and adequacy
- Calcium, phosphate, bicarbonate & lipids
- Anaemia management
- Blood pressure
- Kidney transplant – incidence, prevalence & outcomes
- Comorbidity

Aspects of RRT often reported within the chapters above, and sometimes in additional specific chapters:

- Vascular access (2005, 2006, 2010, 2013 onwards)
- PD access (2012 onwards)
- Satellite units (2001)
- Home therapies (2001, 2010, 2016)
- Predicting future demand for RRT (2002)
- Elderly RRT (2004)
- RRT in people with diabetes (2003, 2005)
- Performance against RA Standards (1998-2003)
- Ethnicity (2003, 2013)
- Socioeconomic factors (2000, 2003)
- MRSA bacteraemia (2008, 2009, 2011, 2013-2016)
- Infections (2013-2016)

Other aspects of kidney disease sometimes reported in additional specific chapters

- Non-dialysed CKD under care of nephrologists (2004, 2013)
- Timing of referral and initiation of RRT (2003, 2013)
- Variations in access to transplant (2001, 2012)

Other occasional chapter topics

- RRT analysis using HES linkage (2011)
- International registry comparisons (1999, 2003, 2004, 2006-2009)

⁷² The arrangement of chapter content was significantly re-shaped for the 2018 Report onwards

Appendix 4. UK Renal Registry peer-reviewed publications 1998-2019

The 2007 Annual Report was published as a supplement in *Nephrology Dialysis Transplantation*. From 2015 onwards, annual reports were published as supplements in *Nephron Clinical Practice* or *Nephron*.

Other publications using data collected by the Registry or describing Registry planning and strategy have been published as follows:

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Nitsch D, Burden R, Steenkamp R, Ansell D, Byrne C, Caskey F, et al. Patients with diabetic nephropathy on renal replacement therapy in England and Wales. *QJM*. 2007;100(9):551-60.

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Udayaraj UP, Steenkamp R, Caskey FJ, Rogers C, Nitsch D, Ansell D, et al. Blood pressure and mortality risk on peritoneal dialysis. *Am J Kidney Dis*. 2009;53(1):70-8.

Ravanant R, Udayaraj U, Ansell D, Collett D, Johnson R, O'Neill J, et al. Variation between centres in access to renal transplantation in UK: longitudinal cohort study. *BMJ*. 2010;341:c3451.

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Appendix 5. UK Renal Registry Registrars 1999-2019

In 1999, Alison Armitage was the first specialist registrar to work in the Registry, although funded externally. From the appointment of Catherine Byrne in 2001 until 2013 the Registry funded specialist registrars with a dual role both to contribute to the preparation of the Registry annual report, and also to undertake original research using registry data. From 2013 onwards, registrars were required to obtain at least part of their funding from external sources, and there was a major focus on original research. All registered for PhDs. The required contribution to the annual report lessened.

Name	No. of first author peer-reviewed publications (other than Registry report chapters)	PhD completed (yes/no)	Funding	Future career
Alison Armitage	3	Yes	NHS HTA & patient donation	Consultant, Bristol
Catherine Byrne	1	No	Registry	Consultant, Nottingham
Mahesh Rajamahesh	-	No	Registry	Returned to India
Az Ahmad	1	No	Registry	Pharmaceutical industry
Raman Rao	1	No	Registry	
Udaya Udayaraj	8	Yes	Registry	Consultant, Oxford
Daniel Ford	-	No	Registry	Consultant, Coventry
Lynsey Webb	-	No	Registry	Consultant, Exeter
Alex Hodsman	-	Yes	Registry	Consultant, Bristol
Clare Castledine	4	Yes	Registry	Consultant, Brighton
Catriona Shaw	-	Yes – using MINAP data	Registry	Consultant, Guy's & St. Thomas's, London

Anirudh Rao	1	Yes – using EQUAL ⁷³ project data	Registry	Consultant, Liverpool
Rishi Pruthi	2	Yes – using ATTOM project data	Registry	Consultant, Guy's & St. Thomas's, London
Alex Hamilton	5	Yes	Kidney Research UK, Kidney Care UK	Academic clinical lecturer, Bristol
Lucy Plumb	-	In progress	NIHR (10% Registry)	-
Barnaby Hole	-	In progress	NIHR (15% Registry)	-
Rhodri Pyart	-	No ⁷⁴	University of Cardiff (50% Registry)	-
Katie Fielding	-	In progress	NIR/HEE	A nurse – the first non-medical registry fellow
Manuela Savino		In progress	Registry	-
Javeria Parachia		In progress	GIRFT ⁷⁵	-

⁷³ The EQUAL study – a CKD cohort study, based in six European countries, including patients with eGFR of ≤20 ml/min who are 65 years or older

⁷⁴ Research optional, he was not required to do a PhD. Instead he was appointed to support the core function of the Registry

⁷⁵ GIRFT – Getting It Right First Time, an initiative funded by NHS Improvement England, in which individual units are visited by senior colleagues from elsewhere and their systems and activities evaluated in the context of benchmarking data derived from the Registry and HES

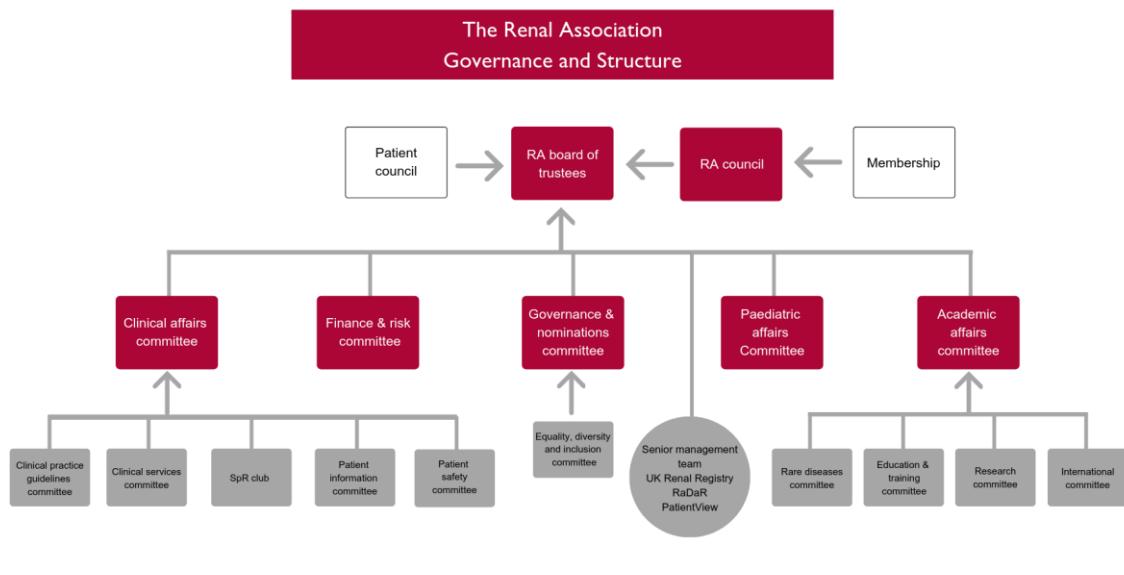
Appendix 6 Registry research grant funding & other external funding 2014-2019

Year	Project	Funder	Award to Registry (£)
	AKI		
2014		NHS England	1,200,000
2019	STAART AKI	Guy's Hospital	7,500
2016	Tackling AKI	Derby Hospitals -Health Foundation	61,500
	KQuIP		
2016		Association of Renal Industries	5,000
2016		RA	5,000
2016		BKPA	5,000
2017		BKPA	19,818
2016		BRS	5,000
2016		BTS	5,000
2016		Health Foundation	5,000
2016		KRUK	5,000
2016		RA	5,000
	Home therapies		
2018		Baxter	50,000
2018		Nx Stage	50,000
2018		Kidney Care UK	50,000
	PatientView		
2016		University of Edinburgh	40,000
2017		University of Edinburgh	15,000
2016	IBD	University of Manchester	50,471

	RaDaR		
2017		Birmingham Women & Children's Hospital	24,679
2017		KRUK	5,000
2019		KRUK	34,000
2015		KRUK	119,034
2016		PKD Charity	10,000
2017		University of Leicester	30,500
	Patient measures		
2015	Patient measures	NHS England	185,000
2016 -	PREM	BKPA	40,000 per year
2016	PROM	BKPA	25,000
2016	PROM	NHS England	40,000
	Clinical trials		
2016	Assist CKD	KRUK	60,000
2016	BISTRO	University of Keele	24,200
2019	H4RT	North Bristol Trust	10,500
2018	PrepareMe	North Bristol Trust	17,000
2017	RRAM	ICNARC	1,700
2018	SIMPLIFY	University of Cambridge	84,000
2018	CTE Rituximab	King's College London	144,000
	Other projects		
2016	aHUS	Royal Victoria Infirmary, Newcastle	50,833
2016	ANTRIM	Baxter	16,313
2015	ATTOM	Addenbrooke's Hospital	32,100
2018	DonorView	NHS England	25,000
2018	GIRFT	RNOH	145,000

2019	NephWork	KRUK	41,000
2017	NuRTuRE	KRUK	86,000
2018	OPTePROs	University of Manchester	42,000
2015	PDOPPS	Sheffield Teaching Hospitals	3,500

Appendix 7. The Governance structure of the Renal Association in 2020



Revised September 2019

