Chapter 17: Reflections on a Renal Unit Based Data Validation Exercise and Implications for National Renal IT

Summary

- All 5 renal units used at least one additional stand-alone system to record other data external to the renal IT system. One site had 5 additional systems.
- The primary record (against which the data were validated eg case note, renal IT system, PAS) varied for different data items, was different at each centre and varied by renal replacement therapy modality.
- Biochemistry data held by the Registry were accurate.
- Routine review for completeness of Registry data was unusual.
- All sites lacked contingency planning for renal IT system management (leave, sickness, succession).
- No out of hours systems support was available.

Introduction

The UK Renal Registry was commissioned to review and analyse data quality from the five Welsh renal units and to provide recommendations on how it might be improved. This project was initiated by the Project Board leading the development of the National Service Framework in Wales and part funded by the Welsh Assembly Government. The conclusions reached from this project may be applicable to many other renal units in England.

From its inception the Renal Registry had acknowledged that the central component of setting up, maintaining and refining a database along with statistical analysis and data presentation would be the easier part of the project to accomplish. It was recognised that it would be more difficult to monitor and manage data ascertainment and to ensure quality issues at the individual renal unit level, whilst IT infrastructure was so variable across the country.

Initially, this challenge had been addressed using a formal contract with units to supply items according to the Renal Registry dataset. It was anticipated that this would require regular contact with a specific, senior representative of each unit, who would take responsibility for liaising with the Registry. For a variety of reasons such contact has been patchy despite willingness on the part of both the Registry and renal units to participate. The dataset has been expanded and refined, requiring active development that has not always been smooth. Renal units have tended to concentrate on the collection of specific subsets of data, sometimes those of specific interest to their staff or that have been easier to acquire and maintain. The Renal National Service Framework in England has now formalised the role of the Registry in monitoring the performance of the renal units. The Registry dataset is in the process of being formally approved by the NHS Information Standards Board as part of a 'National Renal Dataset'. A project for the Healthcare Commission is currently examining the requirements for national renal audit.

In this context it was of particular interest to examine data validation (completeness and accuracy) in five renal units in detail. A number of other observations arose about the 'structure, process and function' of renal units in respect of their relationship with the Renal Registry. This gave the opportunity for a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis of the relationship between the Registry and the Renal units. These are indicated here in a condensed form, with some subsequent suggestions that may be helpful to those charged at renal unit and Registry level with sustaining and developing the Renal Registry project.

Historical Note

The support of specialty (eg Nephrology) clinical computing in hospitals has never been a priority for hospital managers and IT departments. Resources have tended to be focused on generic trust-wide, administrative and financial solutions rather than specialty-specific support. This has resulted in inadequate resource for renal unit computing which has limited development and left the workforce vulnerable. Both the national intensive care audit (ICNARC) and the myocardial infarction audit (MINAP) are now utilising specialty level support from administrative staff.

Renal unit computing throughout the 1980s and 90s was based on the widespread use of a single commercially available clinical database (Proton). The informatics infrastructure at unit level was developed more by intuition, opportunity and experience than by reference to a formal model. As a result the majority of renal units have had inadequate support for their clinical databases and input of data to the Renal Registry has lacked supervision. Although a 'best practice' model has not been piloted, experience suggests that the most complete and accurate records will be achieved by data entry at points of clinical activity, such as the outpatient department or dialysis unit, supported by regular informed and multidisciplinary review of the end data record for missing entries and inaccuracies.

The data acquisition task for renal units is complex as patients are treated by a variety of modalities, on a variety of sites (some non-hospital based), by a range of personnel. These circumstances are similar to those being tackled by the national programme for IT ('Connecting for Health') and resulted in the creation of an undeclared renal data spine and associated clinical material. Some of these data are numerical and an automated laboratory linkage is seen as an essential and integral part of renal systems.

These data vary qualitatively and include demographic details (typically not linked to the hospital Patient Administration System and so requiring duplicate entry), clinical data relating to the different modes of renal replacement therapy and workup for transplantation, etc. Some of these data are permanent features of the patient (eg ethnicity) and other items vary day by day (eg blood pressure prior to haemodialysis). Clinical records are complex in this environment, where individual treatment-related data are often not registered in the formal hospital case note folder. Depending on the information, the primary record for a given activity is not necessarily the patient case note, but may be the nursing records, haemodialysis folder or even the local renal computer system itself. This diversity in the 'primary record' source makes any analysis of data quality more complex.

Given the rapid increase in provision of renal replacement therapy during the past two decades, it is not surprising that renal units have lacked the time to focus on informatics. This has resulted in inadequate training for informatics staff which has sometimes contributed to difficulties with staff retention.

The Renal Registry has only an indirect influence on the maintenance and development of renal computing at local sites. The funds received by the Registry through the Registry annual capitation fee have not been directed to the renal unit component of the information network.

All these factors lie behind the enquiries that were made about the ***structure*** and ***processes*** within the renal units, which also relate to the ***outcome*** of data completeness and accuracy.

Structure of the Review

The five renal units in Wales are Bangor, Cardiff, Clwyd, Swansea and Wrexham.

The review was structured around two separate visits to each renal unit. The first visit would enable the Renal Registry to review the operational, administrative and management procedures in the renal units and the second visit would look at data quality.

The first site meeting was scheduled to be with both the informatics and clinical staff. A questionnaire pro-forma was sent to each site in advance and the meeting based on a structured interview encompassing:

1. Organisation structure

2. IT budgetary control
3. Responsibilities of informatics staff
4. IT training
5. Communications within the renal unit
6. Best practice
7. Renal Registry liaison
8. IT infrastructure and systems.

The second visit was to validate the data held by the Renal Registry against that in the patient case notes and the electronic record from the renal IT system. Renal patients typically have a large set of case notes, which makes data validation a lengthy process. Within the available budget, a time frame of one day was available which allowed for validation of data on 20 patients. The data validation visit was undertaken by a qualified renal nurse in conjunction with a request that local informatics staff provide time to support the cross-checking of Registry data with the local IT system.

The Registry randomly selected 20 patients, to cover the different renal replacement therapy modalities and the renal unit was provided with at least 7 days notice to locate the requested patient case notes and supporting documentation. A list of 'reserve' patients was also provided so that alternatives were available should an individual's case notes be unavailable on the day of the visit.

The four patient groups were:

Patient group	Numbers
New haemodialysis patients in 2003, including 2 from a satellite unit and 2 diabetic	5
Peritoneal dialysis patients, including 2 diabetic	5
Transplant patients	5
Deceased patients in 2003	5

Results of Survey

Structure

1. There was a range of software and hardware in use. Sometimes multiple systems were employed to create comprehensive clinical coverage, but that created opportunity for error and missing data.
2. **Access** to the clinical systems for data entry was often remote from the clinical encounter and delayed.
3. The **budgetary control** for IT varied from one unit to another and was not necessarily vested in those responsible for support and development of the IT system.
4. The **primary record** (against which the data were validated eg case note, renal IT system, PAS) varied for different data items, renal replacement therapy modality and centre. An example of this is EPO prescription for which at one site the renal IT system is used for some patients, a separate EPO database for HD patients and the case note/GP letter for PD patients.
5. **Informatics staff** varied in experience, formal status and remuneration. They were not always fully integrated into the functions of the unit, nor aware of UK Registry functions and meetings. There was poor planning for contingencies, such as the absence of staff members.
6. **Documentation** required for the review was available in some centres but not always to hand or familiar to staff.
7. Resources for **training** were not allocated and most learning was in-service.
8. **Job descriptions** were typically incomplete.
9. All units were at risk because of limited succession and contingency planning.

Process

1. **Routine review** of data entries for completeness and accuracy was unusual. Informatics staff were not always present at multidisciplinary clinical review meetings which provide an opportunity to update the database. Likewise, the first encounter or change of modality was not typically used as a **prompt** to complete the dataset.
2. There was scrupulous concern for data quality and validation amongst the informatics staff but a lack of PAS interfaces and up-grades were felt to compromise IT potential. Information from satellite renal units required special care and procedures for collection, particularly in the absence of laboratory links.
3. IT was included in business meetings in some sites but planning was haphazard.
4. All renal units had a **named individual** responsible for running and submitting Registry reports, loading Renal Registry numbers (the unique patient ID supplied by the Registry) into the local system and also for correction of any data errors identified by the Registry.

Outcome

1. The results for the **completeness and accuracy** of the unit databases are given in abbreviated form in the Appendix, as the 'Outcome of Unit IT Activity'.
2. The traditional demographic data were well managed, with minor discrepancies only. The modality changes were best delivered through a timeline mechanism. There was specific selection of data items for collection at some sites, with parts of the Registry Dataset effectively being ignored, whereas other fields were just poorly served by current mechanisms of data collection.

Comment

These results are likely to be broadly representative of renal unit computing nationally.

The bird's eye view of several IT systems revealed much of what might have been expected after many years of rather haphazard development of renal clinical IT. It might be hoped that a new generation of clinicians will take this in hand and attempt more proactive management especially given the changes of context in the NHS. The Renal NSF in England, the Healthcare Commission, the Agenda for Change and Payment by Results all depend to a major extent on the health of IT at unit level. There is confusion and uncertainty arising from the Connecting for Health programme though effort needs to be maintained locally to improve functionality and data returns to the UK Renal Registry (UKRR).

The UKRR acknowledges that much may be facilitated from the 'centre' and in that regard the **Renal Registry** should:

1. Increase awareness and knowledge of Renal Registry purpose and activities.
2. Provide the sites with the dates of quarterly data collection to allow some preparation.
3. Share future plans and timetables as early as possible to allow sites time to implement any necessary changes.
4. Provide relevant feedback to sites to ensure that ongoing data issues are adequately addressed.
5. Help sites resolve data mapping issues and provide necessary software upgrades where appropriate.
6. Help sites share information to facilitate best practice and to ensure that data validation is standardised in all sites.
7. Respond to questions from sites promptly.
8. Provide template information sheets for incorporation into induction documentation, job descriptions, data entry procedures, etc.
9. Assist with the specification of site data validation rules.
10. Assist with the specification of routines to identify incomplete and inaccurate data.
11. Review its remit to see if there is scope to offer additional services.

At renal unit level it seems that more active management of informatics activity must be attempted. The greatest difficulties would seem to be social and cultural rather than clinical or technical, although there is overlap in the procedures designed for data collection and entry. In particular the grading of staff requires clarification as part of, and after, ''Agenda for Change''. Their NHS status as informatics, IT or management staff needs to be established, perhaps in relation to UKCHIP. As part of their professional support a regular review of current and future IT plans would seem essential.

One suggestion would be the production of an **Annual Informatics Plan**, which would deal with the development of, review and collection of the UKRR dataset. This would be invaluable, even if dealing with only one or two items per annum. How this might be achieved at each site will depend on historical and current issues. Greater liaison with hospital-wide informatics staff may be used to support the renal activity and provide career linkages for local staff. Very often the experiences from managing IT within the renal clinical environment will surpass those from other clinical areas within the Trust and the lessons learnt may be offered as a resource, where Trust staff are open to suggestion.

The weaknesses identified in this review are all susceptible to improvement, some more readily than others. The greatest benefit is likely to come from greater staff integration in clinical routine review and processes to make every data entry subject to informed inspection at some juncture, typically when the clinical status of a patient changes.

Resources are needed to enable conversion of the current largely implicit procedural based IT system into a modern explicit form. The national developments give some grounds for optimism for the local request for funds to advance these purposes. The UKRR will do all that it can to facilitate and develop links with the units to allow the maintenance and improvement of 'peripheral' renal unit IT.

Appendix: Outcome of Unit IT Activity

Results on data completeness and accuracy

For the purposes of this analysis, recorded data had to be compared for accuracy against a defined 'primary record'. The patient case note is not necessarily the primary record, since some data may be found only in the renal IT system, which does not enter the patient notes. Moreover, the primary record is not necessarily consistent between sites, for example at one site the IT system may be the primary record for Erythrocyte Stimulating Agent (ESA) prescription (updated by the anaemia specialist nurse), while others may use the patient case notes.

Demographics

1. The **surname** and **first name(s)** of patients were usually correctly recorded in the local renal system. In patients with more than two names the additional ones were not always recorded even when it would have aided identification. Some patients had additional indicators within the name fields, to help with patient identification at the site.
2. **Dates of birth** were usually correctly recorded on the local renal system, although there were some inaccuracies with the day, month or year differing by one digit. This may be due to data input error or due to the necessity to align the date of birth with that held in the laboratory system, to allow automated uploads from the laboratory interfaces.
3. **Postcodes** showed few discrepancies. The Renal Registry validates the address fields received using a commercial post-coding package (QAS systems) that is updated on a monthly basis. Some of the local postcode errors may have been due to recent re-coding of postcodes by the Royal Mail, which would not have been updated in the local renal system.
4. The **NHS number** was often recorded on the patient case notes but had not been entered on to the local system and therefore was not sent to the Renal Registry. One renal unit held no NHS numbers on their local renal IT system.
5. **Ethnicity** is part of the mandatory PAS dataset, although it was rarely recorded in the patient case notes. Only one site recorded ethnicity comprehensively on their renal system.
6. The **primary diagnosis** causing renal failure, had at some sites initially been recorded as unknown for some patients, even though information was available in the patient case notes.
7. **The date of death** often showed a small discrepancy of 1–2 days from the case notes.
8. **Cause of death** (using the European Renal Association codes) was poorly recorded in the patient case notes. Only one unit recorded this information on the local IT system and hence sent this to the Renal Registry.
9. While the **start of renal replacement therapy date** was often recorded in the patient case note, it was not always recorded on the local renal system within the specific field allocated by the Renal Registry. Many sites use the date of first treatment modality in the renal replacement therapy timeline to record this information. Validation has been against the timeline data item. There was often a discrepancy of up to 10 days in the dates recorded for the start renal replacement therapy date in the timeline against the case notes and occasionally much greater than 10 days. It was unknown which of these sources is the most valid, although the earliest might be assumed so.
10. The **first seen date by nephrologists** was not being recorded on the local IT system at some sites. For other sites this was not being received at the Renal Registry again suggesting a data mapping issue. Low accuracy rates were due to minor discrepancies of a few days in the dates recorded which would not be clinically significant.
11. **Height** was often not recorded in the patient case notes but was available

generally on the local IT system. The Renal Registry did not always receive this information.

12. The **timeline** (RRT modality history) usually included all the information required by the Renal Registry. Where patients were seen by more than one hospital (transplanted patients) there were occasionally slight discrepancies in date of transplant supplied by the different renal units.
13. The **last RRT modality** was usually accurate and discrepancies were likely to be due to a recent change in modality.

Biochemistry

The biochemistry readings for most patients at the hospitals were complete and accurate when compared to the primary record in the local renal IT system, although there were exceptions.

1. The **parathyroid hormone** (iPTH) measurement gave cause for concern. There are two different laboratory units of measurement, which vary by a factor of 10. Combining this item from two different laboratory data sources (satellite/main hospital) into a single field in an IT system without adjusting the units is a source of clinical error.
2. **HbA1c** (only measured for diabetic patients) was only available from one patient throughout the five hospitals. This does not imply that HbA1c was not being monitored in patients, as it may have been measured in the diabetic clinic and not repeated when the patient was seen at a renal clinic. Laboratory linkage should make results available.

Blood Pressure

1. **Systolic** and **diastolic blood pressures** were complete and accurate for dialysis patients at one centre, although no data were recorded for transplant patients. At the other renal units, blood pressure data were not being recorded on the local renal IT systems.
2. While **post haemodialysis systolic** and **diastolic blood pressure** were nearly complete when available, it was not always being picked up by the Renal Registry, suggesting a data mapping issue with Proton sites.

Erythrocyte Stimulating Agents

ESA prescriptions were the data showing the most variation in completeness and accuracy across the sites and there are many different factors governing this.

1. In HD patients monitoring may be done by the HD nurses who are involved in anaemia management. Recording may vary at satellite units.
2. Some sites employ an 'EPO nurse' whose salary is funded by a pharmaceutical company. These nurses may keep ESA prescription updated in the company-supplied standalone database, rather than the main renal IT system.
3. Part of the ESA budget at several sites resides with the GPs. Data on prescription of ESA may therefore be absent from the main renal IT system. Monitoring of haemoglobin achievement at renal unit level is difficult as GPs may also refuse to prescribe the ESA dose recommended by the consultant nephrologist.
4. Within an individual renal unit, monitoring of ESA prescription may be by GPs, nephrologists or 'EPO nurses' depending on whether a patient is on haemodialysis, peritoneal dialysis or has a transplant.
5. Several sites use a free text (un-coded) field for storage of ESA data within the renal IT system. Registry data extraction routines are prone to error in the interpretation of free text fields.

Serology

The number of patients where it was possible to determine the **hepatitis B** and **CMV status** was low at all sites, particularly for CMV, which is clinically only required for patients on the transplant waiting list.

Co-morbidity

Co-morbidity prior to the start of renal replacement therapy was only recorded regularly at two of the renal units.