APPENDIX 1: DATA MANAGEMENT

Introduction

Data integrity of a register begins from the data source, data collection tool, data verification and data entry process. Data held in a registry is never perfect. Hence, caution should be used when interpreting the results.

Data source

The initial phase of the data collected in the Register covered all Renal Replacement Therapy (RRT) patients in the Ministry of Health program since its inception in 1976. The Register subsequently received the data from other sectors of RRT providers like the private, non-government organization, armed forces and the university.

The Register continues to actively ascertain new RRT centres in the country. The mechanism of ascertainment is through feedback from the dialysis related companies, Source Data Providers (SDP) and public propagandas. This will gradually and eventually result in a complete RRT centre database. The identified RRT centre is then invited to participate in data collection. Those RRT centres that have expressed interest in participating will be recruited as Source Data Providers (SDP).

The NRR currently receives data from 267 SDPs comprising 218 HD centres, 18 CAPD centres and 31 centres that performed transplants or provide follow-up care for post transplant patients. This represents coverage of 81% of potential SDPs in the country as shown in the table below:

Facilities	Known centre	Submitting data in 2003	
	N	N	%
HD	257	218	85
CAPD	24	18	75
TX follow-up	51	33	65
All modality	332	269	81

Data collection

The data collection tools were designed to mimic the data capture format in the patient case notes to facilitate data transcription and minimise transcription error. All the SDPs are provided with an instruction manual on data collection and submission to the Register.

The Register collects the RRT patients' demographic details, clinical data, dialysis treatment data, transplant data, peritonitis data and outcome data. The Register holds individual patient's identifiable data that allow complete follow-up despite unit transfers or change of modality which are especially common among the RRT patients. These registered patients are monitored and tracked from the time they commenced on RRT till their death. For those patients who are lost to follow-up, the Register will verify their outcome with the National Vitals Registration System. Patients profiles are submitted to the Register through out the year.

Centre-specific reports are generated and forwarded to the SDPs on a quarterly basis. This has generated increased feedback from SDPs and improved the patient ascertainment rate and the accuracy of the data transmitted to the Registry.

At the end of each year, the Register conducts a survey on the Staff and Facility Profile. The survey questionnaire provides summary information about the number of patients on various treatments. This acts as the basis for the calculation of patient ascertainment rate.

Database System

The initial database of the Register was created in DBASE IV in a single computer environment. It was then upgraded to Microsoft Access as a client server application. Currently the NRR data system is a Pentium Xeon 2.4 with dual processors, with a total of 1GB RAM memory and 72GB of RAID-5 (Redundant Array of Independent Disks, level 5). In view of capacity ability, performance and security issues of Microsoft Access, the database will be migrated to SQL Server 2000 by the end of this year.

Data management personnel

The data management personnel in the Register office are trained based on the standard operating procedures (SOP). The data entry process is also designed to enhance data quality. Quality assurance procedures are in place at all stages to ensure data quality.

Visual review, Data entry and de-duplication verification, Data Editing

On receiving case report forms (CRF) submitted by SDP, visual review is performed to check for obvious errors or missing data in the important fields. Data entry will not be performed if a critical variable on the CRF is missing or ambiguous. The CRF is returned to the SDP for verification.

After passing duplicate checks the data is than entered and coded where required. Edit checks are performed against pre-specified validation rules to detect missing values, out of range values or inconsistent values. Any data discrepancy found is verified against the source CRF and resolved within the Register office where possible. Otherwise the specific data query report will be generated and forwarded to the SDP to clarify and resolve the data discrepancy.

Data coding, data cleaning / data analysis

Most of the data fields have auto data coding. Those data in text fields will be manually coded by the Register manager. A final edit check run is performed to ensure that data is clean. All queries are resolved before database is locked to ensure data quality and integrity. Data is subsequently exported to the statistician for analysis.

Limitation

The majority of the RRT centres in this country are still paper base. Currently there is no satisfactory electronic patient information systems in the country. Computer literacy among staff is still low.

The data submission to the Register is voluntary and is done manually using the standard data collection tools. The process is tedious and time consuming for the SDP and the Register office. Some SDPs do have difficulty in data submission for the current year in time for inclusion in the yearly report. Thus, this inevitably results in slight differences when the existing data is being reported in subsequent year. The continuing efforts to improve the timely data submission is important.

Data release policy

One of the primary objectives of the Registry is to make data available to the renal community. There are published data in the annual report in the NRR website: http://www.crc.gov.my/nrr. The Registry would appreciate that users acknowledge the Registry for the use of the data. Any request for data that requires a computer run must be made in writing (by e-mail, fax, or registered mail) accompanied with a Data Release Application Form and signed Data Release Agreement Form. These requests need prior approval by the Advisory Board before data can be released.

Distribution of report

The MSN has made a grant towards the cost of running the registry and the report printing to allow distribution to all members of the association and the source data producers. The report will also be distributed to Health Authorities and international registries.

Further copies of the report can be made available with a donation of RM60.00 to offset the cost of printing. The full report is also available on the registry web site: http://www.crc.gov.my/nrr