

APPENDIX 1: DATA MANAGEMENT**Introduction**

Data integrity of a register begins from the data source, data collection tools, data verification and data entry process. Registry data is never as perfect as the clinical trial data. 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 the early 1970s. The Register subsequently received the data from other sector of RRT providers like the private, non-government organization (NGO), 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 company, current Source Data Provider (SDP) and public propagandas. This will gradually and eventually result in a complete RRT centre database. The identified RRT centre is invited to participate in data collection. Participation in NRR is voluntary. Those RRT centres which have expressed interest in participating will be recruited as SDP.

There were 4 haemodialysis centres which ceased operation in the year 2005. The NRR currently receives data from 474 SDP comprising 351 HD centers, 22 CAPD centers and 44 centers that provide follow-up care for post transplant patients. This represents an estimated coverage of 88.0% of potential SDP as shown in the table below. Of these, about 16.1% of the SDP did not submit the annual returns on the treatment parameters and Work Related Rehabilitation & Quality of Life Survey.

	Known dialysis centre (N)	Submitting data in 2005 (N)	Submitting annual returns (N)	submitted any data (%)
Haemodialysis	384	351	291	91.4
Peritoneal Dialysis	26	22	22	84.6
Transplant	64	44	37	57.8
All modality	474	417	350	88.0

Data collection

The data collection tools are designed to mimic the data capture format in the patient case notes to facilitate the data transcription and minimise transcription error. All the SDPs are provided with instructions 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 patient transfers from one centre to another or change of modality which are especially common among the RRT patients. These patients are monitored and tracked through from the time they were registered and commenced their RRT treatment till their death. For those patients who were lost to follow-up, the Register will verify their final outcome with the National Vital Registration System. Patient Profiles are submitted to the Register throughout the year. The identity of patients in the database is not released publicly or in the registry reports.

Centre-specific reports are generated and forwarded to SDP on a quarterly basis. This has generated increased feedback from SDP 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 to calculate the patient ascertainment rate.

Database System

The Register initial database 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, it was subsequently migrated to SQL Server 2000 in the year 2004.

Data management personnel

The data management personnel in the Register office are trained base 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 the quality of data.

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

On receiving the CRF submitted by SDP, visual review is performed to check for obvious error or missing data in the compulsory 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 the duplicate check, 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 based. Currently there is no satisfactory active electronic patient information system in the various centres. Computer literacy among staff is still low.

The data submission to the Register is totally 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 SDP have difficulty submitting data on time for inclusion in the yearly report. This inevitably results in slight differences when the existing data is been reported in subsequent year. Work to improve the timely data submission is ongoing.

Data release and publication policy

One of the primary objectives of the Registry is to make data available to the renal community. There are published data in the registry's annual report in the website: <http://www.msn.org.my/nrr>. This report is copyrighted. However it may be freely reproduced without the permission of the National Renal Registry. Acknowledgment would be appreciated. Suggested citation is: YN Lim, TO Lim (Eds). Thirteenth Report of the Malaysian Dialysis and Transplant Registry 2005. Kuala Lumpur 2006

A distinction is made between use of NRR results (as presented in NRR published report) and use of NRR data in a publication. The former is ordinary citation of published work. NRR, of course encourages such citation whether in the form of presentation or other write-ups. The latter constitutes original research publication. NRR position is as follows:

- The NRR does not envisage independent individual publication based entirely on NRR published results, without further analyses or additional data collection.
- NRR however agrees that investigator shall have the right to publish any information or material arising in part out of NRR work. In other words, there must be additional original contribution by the investigator in the work intended for publication.
- NRR encourages the use of its data for research purpose. Any proposed publication or presentation (e.g. manuscript, abstract or poster) for submission to journal or scientific meeting that is based in part or entirely on NRR data should be sent to the NRR prior to submission. NRR will undertake to comment on such documents within 4 weeks. Acknowledgement of the source of the data would also be appreciated.
- Any formal publication of a research based in part or entirely on NRR data in which the input of NRR exceeded that of conventional data management and provision will be considered as a joint publication by investigator and the appropriate NRR personnel.

Any party who wish to request data for a specific purpose that requires computer-run should make such requests in writing (by e-mail, fax, or classic mail) accompanied by a Data Release Application Form and signed Data Release Agreement Form. Such request will require approval by the Advisory Board before the 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 relevant Health Authorities and international registries.

Further copies of the report can be made available with donation of RM60.00 to defray the cost of printing. The full report is also available in the registry web site: <http://www.msn.org.my/nrr>