

APPENDIX I:

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 clinical trial data. Caution should be used when interpreting the results.

Data Source

The initial phase of the data collected in the Malaysian Dialysis and Transplant Registry (MDTR) 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 sectors of RRT providers like the private, non-government organization (NGO), armed forces and the universities.

MDTR continues to actively ascertain new RRT centres in the country. The mechanism of ascertainment is through feedback from the dialysis related companies, 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 the MDTR which was entirely voluntary prior to 2006 is now made compulsory by the Private Health Care Facilities and Services Act 1998 and its Regulations 2006 which was implemented on 1st May 2006. This however only applies to private and NGO centres and data submission from centres managed by the Ministry of Health, Ministry of Defence or the Universities is still voluntary. RRT centres which have expressed interest in participating will be recruited as SDP.

In 2021, there are 62 new HD and 4 new PD centres. 14 HD centres had ceased operation. Centre contributed data are shown below:

Table I: Data Submission, 2021

	Known centres	Centres contributed data*		Centres contributed annual return	
	n	n	%	n	%
Haemodialysis	875	860	98.3	851#	97.3
Chronic PD	55	54	98.2	54+	98.2
Transplant	52	44	84.6	43~	82.7
All modality	982	958	97.6	948	96.5

* Data contributed – Patient Notification, Outcome Notification, Annual Return Form

716 HD centres had 100% submission of annual treatment return

+ 54 PD centres had 100% submission of annual treatment return

~ 40 Transplant centres had 100% submission of annual treatment return

Table II: Participation in annual treatment return, 2021

	Total annual return	Annual return submitted	Submission rate (%)
HD patient data submission	54174	52298	96.5
PD patient data submission	7619	7619	100.0
TX patient data submission	2112	1891	89.5

Data Collection

In 2017, NRR has upgraded the data collection processes from a paper based to a web-based system and is called eNRR. The eNRR is more efficient and will enable SDPs the ability to access and tabulate their data on line. The notifications forms are submitted periodically or whenever there is an incident. Annual return forms for the assessment year should submitted not later than February by the following year. The forms are:

- Patient notification form
- Outcome notification form
- Annual Return form
- Work related rehabilitation and quality of life assessment form – annual assessment

MDTR collects patients' demographic details, clinical data, dialysis treatment data, transplant data, peritonitis data and outcome data. MDTR 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 until their death. For those patients who were lost to follow-up, MDTR will verify their final outcome with the National Registration Department's data. 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 transmittal in the registry.

Database System

The Register initial database was created in DBASE IV in a single computer environment in the 1990s. It was then upgraded to Microsoft Access, Microsoft Visual Basic .NET enterprise system and local server Java platform enterprise system over the years and used by NRR office personnel. Starting from 2017, NRR has been opened for data entry by all site users through eNRR web application which is running on Java platform and using Microsoft SQL Server as database.

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 notification form(s) submitted by SDP, eNRR system able performed to check for obvious error or missing data in the compulsory fields, data submission will not be allowed by system if a critical variable is missing or ambiguous.

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 will be listed in [Data Query] module, SDP has to verify with each query.

Data coding, data cleaning / data analysis

Those data in text fields will be manually coded by the Register manager and reviewed by the MDTR Editors. A final edit check run is performed to ensure that data is clean. All queries are resolved before dataset is locked and exported to the statistician for analysis.

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>. 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 Hooi LS and Ong LM (Eds) Twenty-Ninth Report of the Malaysian Dialysis and Transplant 2021, Kuala Lumpur 2023

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) 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.