

DATA MANAGEMENT

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 result.

The data management personnel in the Register are trained based on the standard operating procedure (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.

The NTR maintains different databases for each of the organs i.e. blood and marrow transplant, bone and tissue transplant, cornea transplant, heart and lung transplant, kidney transplant and liver transplant. Depending on the volume of data, each organ's data were stored in either Microsoft Access or SQL Server 2000.

Registry ICT infrastructure and data centre

The operations of the NTR are supported by an extensive ICT infrastructure to ensure operational efficiency and effectiveness.

NTR subscribes to co-location service with a high availability and highly secured data centre at Cyberjaya and at Jalan Pahang, Kuala Lumpur. This is in order to provide NTR with quality assured internet hosting services and state-of-the-art physical and logical security features without having to invest in costly data centre setup internally. State-of-the-art physical security features implemented includes anti-static raised flooring, fire protection with smoke and heat alarm warning system, biometric security access, video camera surveillance system, uninterrupted power supply, environmental control.

Other managed security services include patch management of the servers, antivirus signature monitoring and update, firewall traffic monitoring and intrusion detection, security incidence response, data backup service done on a daily, weekly and monthly basis, data recovery simulation to verify that backup works which is done at least once yearly, network security scan and penetration test done on a half-yearly basis, security policy maintenance, maintenance and monitoring of audit trail. Managed system services are also provided such as usage and performance report, operating system maintenance and monitoring, bandwidth monitoring and systems health monitoring.

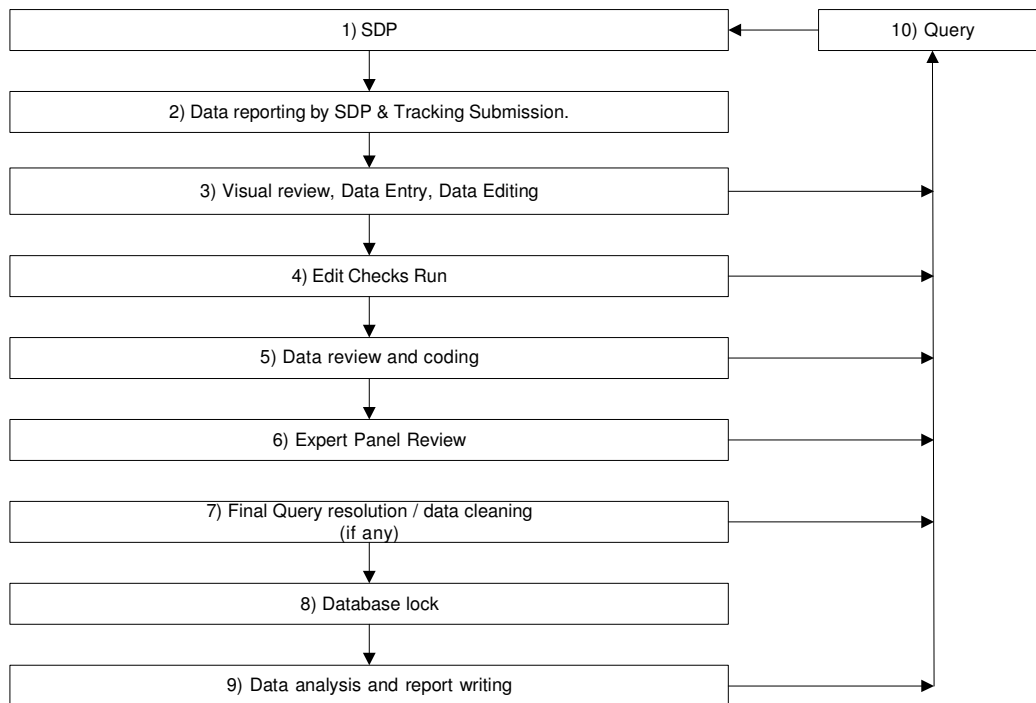
Data sources

SDPs or Source Data Providers of the National Transplant Registry comprise of centres for various transplanted organs throughout Malaysia. Bone and tissue transplant, cornea transplant, kidney transplant and liver transplant SDPs submit Case Report Forms (CRFs) to NTR. Blood and marrow transplant (BMT) and heart and lung transplant (HLT) SDPs submit data via web applications NTR-BMT and NTR-HLT respectively.

For the purpose of verifying patient's outcome regarding death and lost to follow-up, NTR uses data from the National Vital Registration System.

APPENDIX A**Data Flow Process**

This section describes the data management flow process of the National Transplant Registry.

**SDP Data reporting and Submission tracking**

Data reporting by SDP is done via Case Report Forms or Web Applications e-Case Report Forms. Different types of forms are used for different organs/tissues.

For blood and marrow transplant, NTR collects data via Blood and Marrow Transplant Notification Form and Blood and Marrow Ad Hoc Event Notification Form through web application NTR-BMT. Data collected from NTR-BMT is synchronised daily to a master database in CRC to track data submission and generate queries to site. All retrospective data was mapped and transferred to the current system.

For bone and tissue transplant, NTR collects data via Bone and Tissue Transplant Notification Form.

For cornea transplant, NTR collects data via Cornea Transplant Notification Form and Cornea Transplant Outcome Form.

For heart and lung transplant, NTR collects data via Malaysian Heart and Lung Transplant Notification Form and Malaysian Heart and Lung Transplant Follow-Up Form through web application NTR-HLT. Data collected from NTR-HLT is synchronised daily to a master database in NTR to track data submission and generate queries to site.

For kidney transplant, NTR collects data via Renal Transplant Notification Form and Renal Transplant Outcome Form. For annual survey purposes, NTR also collects data

via Renal Transplant Annual Return Form and Renal Transplant Annual Quality of Life and Rehabilitation Assessment Form. To further ensure timeliness of notification, any patient who has been notified to National Renal Registry as transplanted will be automatically flagged to NTR. Similarly, NTR also automatically flags to NRR if there's a patient with graft failure.

For liver transplant, NTR collects data via Liver Transplant Notification Form.

Data submissions by SDPs of Bone and Tissue, Cornea, Kidney and Liver Transplant were tracked by NTR Computer System collectively.

Visual review will then be performed to check for completeness and obvious errors or problems. Data without obvious problems were entered into the relevant NTR organ's system. 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. Prior to registering patient, a verification process is done to ensure there are no duplicate patients and/or notifications. After verification, data is then entered into the relevant NTR organ system.

There are a few in-built functionalities at the data entry page that serve to improve data quality. One such function is auto calculation functionality to reduce error of human calculation. There is also inconsistency check functionality that disables certain fields if they are answered in a certain manner. When value entered is out of range, user is prompted for correct value.

Real time reports are also provided in the web application. The aggregated data reports are presented in the form of tables and graphs. The aggregated data reports are typically presented in two manners, one as centre's own data aggregated data report and second as registry's overall aggregated data report. Each participating site submitting data via the web application is therefore able to compare itself against the overall registry's average.

Visual Review, Data Entry, Data Editing

Data received by the NTR was logged in and manually reviewed to check for completeness and obvious errors or problems. Data without obvious problems was entered into the relevant NTR's organ transplant system. Data with problems was sent to SDP as queries. As data for kidney transplant is inter-related with National Renal Registry's patient data, an additional verification process is performed to ensure no duplicate patient and renal replacement therapy is reported.

Edit Check Run

Edit checks were performed periodically to identify missing data, out of range values, inconsistent data, invalid values and error with duplication. Data cleaning is then performed based on the results of edit checks. Data discrepancies that were resolved were then entered into the system. Data update and data checking of the dataset is performed when there is a query of certain fields when necessary. It could be due to request by user, correction of data based on checking from data query or after receiving results for preliminary data analysis. 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 standardisation process is also done for missing data based on derivation from existing data.

Data Review and Coding

Data coding of retrospective data and free text data was performed by registry manager and further verified by expert panel member. The expert panel comprising of members with expertise and knowledge in the relevant area provided the quality control on the assessment of coding by data manager. They ensure that complex medical data are reviewed and assessed to detect clinical nuances in the data.

Final Query Resolution / Data Cleaning / Database Lock

A final edit check run was performed to ensure that data is clean. All queries were resolved before the database is locked to ensure data quality and integrity. Data is subsequently exported to the statistician for analysis.

Data Release Policy

One of the primary objectives of the Registry is to make data available to the transplant community. 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 MST has made a grant towards the cost of running the registry and 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.