APPENDIX A

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 Microsoft SQL Server.

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. 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. NTR then obtains the data for analysis from NRR. Blood and marrow transplant, heart and lung transplant, bone and tissue transplant, cornea transplant and liver transplant SDPs submit data via eNTR web application. Kidney transplant SDPs submit Case Report Forms (CRFs) to National Renal Registry (NRR).

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

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

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│  2) Data reporting by SDP & Tracking Submission.  │               │
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│     3) Visual review, Data Entry, Data Editing    │ ─────────────►│
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│               4) Edit Checks Run                  │ ─────────────►│
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│            5) Data review and coding              │ ─────────────►│
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│             6) Expert Panel Review                │ ─────────────►│
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│  7) Final Query resolution / data cleaning        │ ─────────────►│
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│               8) Database lock                    │               │
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│         9) Data analysis and report writing       │ ─────────────►┘
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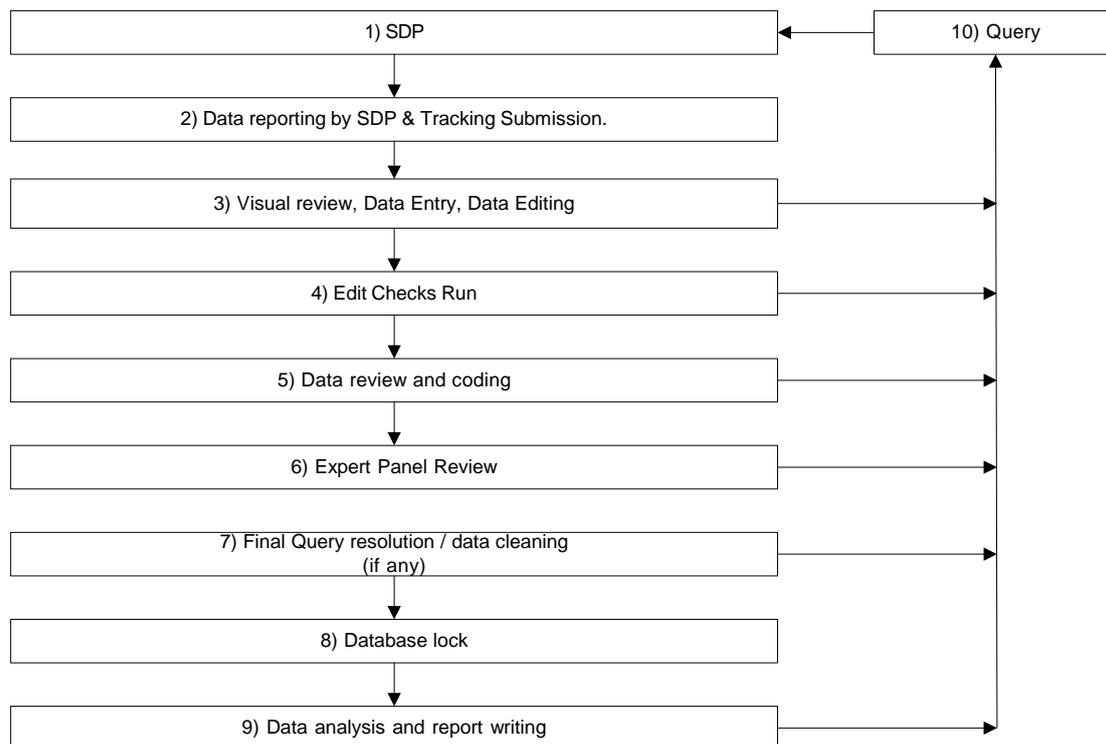
SDP Data reporting and Submission tracking
Data reporting by SDP is done via Web Application e-Case Report Forms. Different
types of forms are used for different organs/tissues.

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 eNTR.

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

For cornea transplant, NTR collects data via Cornea Transplant Notification Form and
Cornea Transplant Outcome Form through web application eNTR.

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 eNTR.

For liver transplant, NTR collects data via Liver Transplant Notification Form
through web application eNTR.

For kidney transplant, NTR obtains data from NRR which collects data via Renal
Transplant Notification Form and Renal Transplant Outcome Form. For annual
survey purposes, NRR also collects data via Renal Transplant Annual Return Form
and Renal Transplant Annual Quality of Life and Rehabilitation Assessment Form.

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.

Data download functionality is also provided in the web application to enable authorised users to download their own centre's data in comma separated value (CSV) format, MS Excel format and ASCII Text format.

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.

There are also reports on tracking of submission available to the registry manager for each of the organ transplant data.

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 module in eNTR. Data with problems was sent to SDP as queries.

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 NTR Steering Committee 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.