APPENDIX A

DATA MANAGEMENT

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.
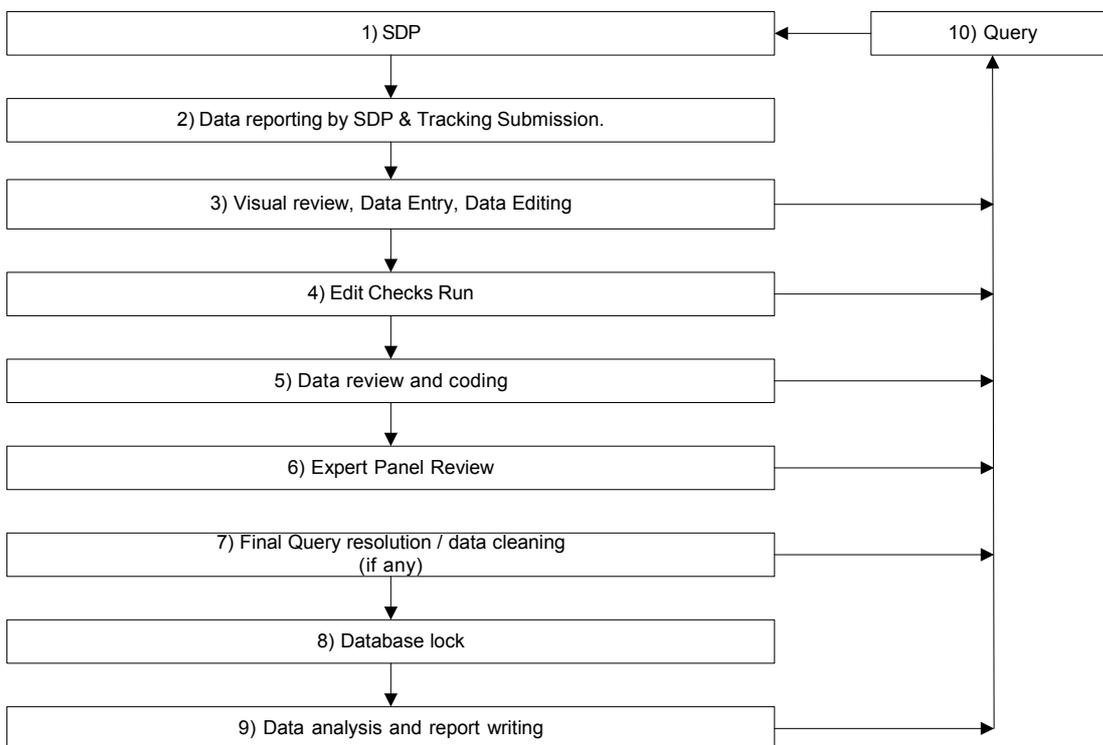
Data sources
SDPs or Source Data Providers of the National Transplant Registry comprise of centres for various transplanted organs throughout Malaysia. Bone and tissue transplant, cornea transplant, kidney transplant and liver transplant SDPs submit Case Report Forms (CRFs) to NTR. Blood and marrow transplant (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.

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

1) SDP	10) Query
2) Data reporting by SDP & Tracking Submission.	
3) Visual review, Data Entry, Data Editing	
4) Edit Checks Run	
5) Data review and coding	
6) Expert Panel Review	
7) Final Query resolution / data cleaning (if any)	
8) Database lock	
9) Data analysis and report writing	

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, 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 discrepancies that were resolved were then entered into the system.

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.