

Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)

Principal Investigator: A/Prof Anthony Dodds

Version Number: 2.1

Date of Protocol: December 2013

This version: September 2015

Synopsis

Protocol title: Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)

Protocol version: 2.1

Investigators

The ABMTRR is overseen by a Steering Committee from the Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ).

Summary

Protocol title:	Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)
Protocol version:	2.1
Purpose	<p>To collect baseline and outcome data relating to all bone marrow, peripheral blood and cord blood haemopoietic stem cell transplants performed throughout Australia and New Zealand.</p> <p>To provide data to clinicians and researchers for studies involving specific subsets of patients, or to determine the feasibility of such studies.</p> <p>To provide data to clinicians to inform patient care.</p> <p>To provide data to health administrators for resource planning and quality assurance purposes.</p> <p>To participate in local and international data collections by contributing summary and outcome data to enhance the global knowledge base for these types of transplants.</p>
Design	Clinical registry
Registry population	All patients in Australia and New Zealand receiving haemopoietic stem cell transplants. The database currently holds information on more than 29,000 transplants, accruing at more than 1,900 per year.
Data custodians	A/Prof Anthony Dodds On behalf of ABMTRR Steering Committee Leonie Wilcox ABMTRR Manager
Data collection	Data may be submitted to the ABMTRR on paper forms or entered directly into the online database.
Duration	Data collection commenced in 1992 and data will be stored indefinitely. Long term information is important to monitor the safety and efficacy of these transplant procedures.

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1. Background

1.1. History

Haemopoietic stem cell transplants are used to treat a range of both haematological and non-haematological malignancies and other serious conditions in adults and children. The stem cells may come from bone marrow, peripheral blood or cord blood. Transplants can be autologous, when the patient's own stem cells are harvested and then returned after high-dose conditioning chemotherapy, or allogeneic, when the stem cells are sourced from a donor. Allogeneic donors may be related to the patient, such as a sibling or parent, or unrelated, where the donors are sourced from donor registries and cord blood banks worldwide.

The ABMTRR was established in 1992 to record details of bone marrow, peripheral blood and later cord blood haemopoietic stem cell transplants performed in Australia. New Zealand began contributing data in 1998. Initially the ABMTRR was fully funded by the Arrow Bone Marrow Transplant Foundation. Since 2001, the Australian Bone Marrow Donor Registry (ABMDR) has subsidised a collection of more detailed information for unrelated donor transplants. NSW Health contributed to the part time salary of a statistician from 2003-2010. Since July 2010 the ABMTRR has received operational funding from all Australian Governments through the Commonwealth Department of Health and Ageing.

The ABMTRR is located in The Kinghorn Cancer Centre. Staff are employees of St Vincent's Hospital. A Steering Committee from the Bone Marrow Transplant Society of Australia and New Zealand oversees the management of the Registry.

1.2. Rationale

ABMTRR data is used for clinical, administrative and research purposes.

Collaboration and interaction between transplant units has led to a greater understanding of the transplant procedure and its related complications and this has led to improved recipient outcomes. Treatment decisions may be guided and supported by registry data.

The ABMTRR is able to provide historical time series to be used for projections and planning of resource allocation.

The ABMTRR database is used as a basis for more detailed research studies or to ascertain the feasibility of such studies.

Globally, stem cell transplants are recorded and followed up by national and international registries. Data sharing mechanisms are being developed that will streamline reporting processes between registries.

The outcome data are used to monitor the safety and efficacy of transplant procedures and may be shared with relevant local and international organisations (eg Australian Bone Marrow Donor Registry, AusCord, Asia-Pacific Blood and Marrow Transplantation Group) with approval from the contributing hospital.

2. Purpose

- To monitor haemopoietic stem cell transplant activity and outcomes in Australia and New Zealand.
- To provide data to clinicians and researchers for studies involving specific subsets of patients, or to determine the feasibility of such studies.
- To provide data to clinicians to inform patient care.
- To provide data to health administrators and associated organisations for resource planning and quality assurance purposes.

- To participate in local and international data collections by contributing summary and outcome data to enhance the global knowledge base for these types of transplants.

3. Design

3.1. Participants

Every patient who undergoes autologous or allogeneic haemopoietic stem cell transplant in Australia and New Zealand should be invited to participate.

3.2. Participating centres

Data have been or are currently collected from the following centres:

New South Wales

Concord Repatriation and General Hospital
 Gosford Hospital
 John Hunter Children's Hospital
 Liverpool Hospital
 Nepean Hospital
 Newcastle Mater Hospital
 Prince of Wales Hospital
 Royal North Shore Hospital
 Royal Prince Alfred Hospital
 St George Hospital
 St Vincent's Hospital, Sydney
 Sydney Adventist Hospital
 Sydney Children's Hospital
 The Children's Hospital at Westmead
 Westmead Hospital
 Wollongong Hospital

Queensland

Brisbane Private Hospital
 Gold Coast University Hospital
 Greenslopes Private Hospital
 Lady Cilento Children's Hospital
 Mater Private Hospital
 Mater Misericordiae Public Hospital
 Princess Alexandra Hospital
 Royal Brisbane and Women's Hospital
 Royal Children's Hospital, Brisbane
 The Townsville Hospital
 Wesley Private Hospital

Victoria

Alfred Hospital
 Austin Hospital
 Box Hill Hospital
 Geelong Hospital
 Peter MacCallum Cancer Centre
 Royal Children's Hospital, Melbourne
 Royal Melbourne Hospital
 St Vincent's Hospital, Melbourne

South Australia

Ashford Cancer Centre
Flinders Medical Centre
Queen Elizabeth Hospital
Royal Adelaide Hospital
Women and Children's Hospital

Western Australia

Fiona Stanley Hospital
Fremantle Hospital
Princess Margaret Hospital for Children
Royal Perth Hospital
Sir Charles Gairdner Hospital

Tasmania

Royal Hobart Hospital

Australian Capital Territory

Canberra Hospital

New Zealand

Auckland Hospital
Christchurch Hospital
Palmerston North Hospital
Starship Hospital
Waikato Hospital
Wellington Hospital

3.3. Duration

Both registration and outcome data are required on an ongoing basis. The transplant field continues to evolve so it is necessary to monitor the safety and efficacy of various regimens across all patient and disease groups. As survival rates improve it is becoming increasingly important to monitor patients in the long term for possible late effects.

4. Population

All patients in Australia and New Zealand receiving autologous or allogeneic haemopoietic stem cell transplants should be invited to participate. As a means of validating ascertainment, patients who do not consent should have minimal, non-identifying information collected (defined below) and will not be included in any further data collection. This method is used for some overseas registries, unless registry reporting is mandatory.

5. Procedure Outline

5.1. Data collection procedure

Data may be collected on paper forms at the contributing centres and either posted or emailed to the ABMTRR. Data are then entered into the database by ABMTRR staff. Paper forms are stored in a locked cupboard in a restricted area. Older forms may be scanned and stored onto a network drive that is only accessible by ABMTRR staff; the paper forms are then shredded.

An online system is now available and its use is increasing. Registered users are provided with a link to this system to enter patient data or access data from their own centre. Data collection forms and explanatory notes are also available from the ABMTRR website.

Registration data are collected at the time of transplant. A sufficient amount of identifying information is collected to allow for follow up data to be recorded, as per Operating Principles and Technical Standards for Australian Clinical Quality Registries. The demographic data collected are name codes (optional, maximum is 4 letters of the surname and 2 letters of the first name, depending on hospital preference), sex, date of birth, and postcode of usual residence. The transplant data include diagnosis, date and type of transplant, donor relation, HLA matching information, preparatory treatments and cell doses.

If a patient chooses not to participate in the ABMTRR, the diagnosis, year of birth, date and type of transplant will be collected for administrative purposes, but no personal identifiers or follow up information will be recorded. It is necessary to collect this information to ensure the epidemiological integrity of the database.

Follow up information includes disease response, engraftment, complications such as graft vs host disease or infections, disease relapse and survival. This information may be provided at the time an event occurs, or in response to update requests from the ABMTRR. Patients should be monitored for their entire lives. As a guide, the European registry (EBMT) requests annual follow up for 10 years post transplant, second yearly follow up from 10-20 years and five yearly follow up thereafter. It is now recognized that there are significant long term complications of bone marrow transplantation.

The online system is hosted offsite, with appropriate security and backup systems. A more detailed description of the database security is provided in an appendix. Data downloaded for analysis are stored on a St Vincent's Hospital network drive and are only accessible by ABMTRR staff.

5.2. Risks

There are no physical risks to the patients as the Registry is for data collection only, i.e. observational not interventional.

5.3. Benefits

There is no individual patient benefit. Benefits to the community include gains in knowledge, insight and understanding so that future patients receive the best and most appropriate treatments. Monitoring of outcomes enables quality benchmarking processes and prioritisation of resource allocation.

5.4. Informed Consent

An appropriately qualified or experienced person will explain the ABMTRR data collection to the patient. This is likely to be the treating clinician or BMT coordinator. The patient will be given time to consider consent for the collection and storage of demographic and transplant related data.

If a patient chooses not to participate in the ABMTRR, the diagnosis, year of birth, date and type of transplant will be collected for administrative purposes, but no personal identifiers or follow up information will be recorded.

A copy of the Patient Information Sheet and Consent Form should be stored in the patient's medical records and they should be given a copy to keep.

6. Storage and archiving of study documents

The consent forms and clinical review forms are kept in the patient files at the contributing centre.

The forms received at the ABMTRR are stored in a locked cupboard in a secure office (requiring swipe card access). Older forms may be scanned and shredded.

The previous Access database, scanned forms and correspondence are stored on a secure hospital server with network drive access restricted to ABMTRR staff. This system is backed up daily.

The online database is hosted on a secure server off site. Staff at the contributing centres will only have access to individual records of their own patients. Investigators on ethics approved studies have access only to the records of the study patients. Summary figures for the whole database will be available to registered users.

Further details of data security are provided in an appendix.

7. References

Operating Principles and Technical Standards for Australian Clinical Quality Registries (2008, full version);

as endorsed by Australian Health Ministers in 2010:

<http://www.safetyandquality.gov.au/wp-content/uploads/2012/03/Strategic-and-Operating-Principles-for-Australian-Clinical-Quality-Registries-AHMC-endorsed-Nov-2010.pdf>

National Statement on Ethical Conduct in Human Research (2007)

NSW Health Policy Directive – Privacy Manual (Version 2):

http://www0.health.nsw.gov.au/policies/pd/2005/pdf/PD2005_593.pdf

Appendix 1: Patient information and consent form

This form is a suggested template only for each centre to adapt to its own requirements. It is expected that all patients will have consented for their data to be submitted to the ABMTRR. The patient consent procedure is dependent on the hospital policy of each contributing centre, and consent for data submission may be included with another consent process such as consent for transplant or tissue banking.

Participant Information Sheet

Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)

We ask that you consider giving permission for storage of your haemopoietic stem cell transplant information in the Australasian Bone Marrow Transplant Recipient Registry (ABMTRR) database. The ABMTRR aims to collect information on all of these transplants performed in Australia and New Zealand to monitor for quality assurance, resource planning and medical research. The existence of data collections such as this has enabled improvements in the safety and efficacy of transplantation over time. This form provides you with information to help you decide whether you would like to participate. Please take the time to read the following information carefully and discuss it with others if you wish.

‘What kind of information will be collected, and how?’

The information collected relates to your diagnosis and transplant procedure. All the information required is available from your medical record so no additional information will be requested from you. A hospital staff member will either complete a paper form to submit to the Registry or enter the information directly into an online database. There is sufficient identifying information to allow for follow up data to be recorded. The demographic data collected are name codes (optional, maximum is 4 letters of the surname and 2 letters of the first name), sex, date of birth, and postcode of usual residence. The transplant data include diagnosis, date and type of transplant, donor relation, HLA matching information, preparatory treatments and cell doses. The outcome data include any complications, relapse and survival.

‘What will happen to my information?’

Your information will be stored for an indefinite period of time in the ABMTRR database. The ABMTRR is located at The Kinghorn Cancer Centre at St Vincent’s Hospital in Sydney, and is overseen by the Bone Marrow Transplant Society of Australia and New Zealand.

‘Who will have access to my information once it has been stored?’

Staff of the ABMTRR collect and maintain the data and prepare regular reports for clinicians and health administrators. Authorised personnel at participating hospitals have access only to patient data from their own hospital, to enable follow-up. Investigators on ethics approved studies have access only to the records of the study patients. All other data uses involve de-identified data, summary information or analyses only. This type of information may be provided to clinicians or researchers, e.g. for specific subsets of patients such as those with a particular disease or type of transplant. Health administrators may use the information for resource planning and quality assurance purposes. De-identified or summary information may be shared with other approved local and international organisations such as AusCord (to monitor cord transplants in Australia) or other registries or collections such as the Global Activity Survey (based in Switzerland).

‘What will happen if I don’t consent?’

Your treatment and relationship with your doctor and hospital will not be affected. Some non-identifiable information about your transplant will still be sent to the ABMTRR for administrative purposes, but no follow-up data will be collected.

‘Who should I contact if I have concerns about this registry database?’

Your transplant doctor should be able to answer any questions about the ABMTRR. Further information is also available on the ABMTRR website: www.abmtrr.org

**Thank you for taking the time to consider this data collection.
If you wish to participate, please sign the attached consent form.
This information sheet is for you to keep.**

Participant Consent Form

Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)

I, _____ (patient name)

of _____ (usual place of residence)

agree to store my information as described in the Participant Information Sheet attached to this form.

I acknowledge that I have read the Participant Information Sheet, which explains why I have been asked to participate. The nature and risks of this database have been explained to me to my satisfaction.

Before signing this consent form, I have been given the opportunity to ask any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

I agree that research data gathered may be published, provided that I cannot be identified.

I acknowledge receipt of a signed copy of this Consent Form and the Participant Information Sheet.

Signature of participant	Please print name	Date
Signature of witness	Please print name	Date
Signature of investigator	Please print name	Date

Appendix 2: Online database security

Database security statement from IS Group Pty Ltd

As a reputed software and database solutions providers, we have a commitment to our customers to protect their data/applications and in so doing, we comply with industry best practices. Most of our clients including ABMTRR deal with sensitive user data that needs highest level of protection so we provide security and protection of data at a number of levels to ensure that privacy/security/integrity of our customers' data are never compromised.

ABMTRR Data Registry is developed and hosted by ISGROUP (formerly Listening Post Pty Ltd, formerly Prowess Development Pty Ltd). The registry application employs a number of procedures/mechanisms for Security and Integrity of user/hospital data both on physically and technical level.

Security

To ensure security of the data, Registry implements application/data security at different levels.

- 1. Physical Security:** The applications are physically hosted at our hosting facility at Pacnet Data Centre, 127 Liverpool Street Sydney, who are the biggest provider of data centre facility in the Asia Pacific region, with excellent infrastructure and security arrangements. The physical servers are kept within cages and locked set of racks that are only accessible to authorised personnel. For further information visit their website: <http://au.pacnet.com/>
- 2. Server/Database Access:** Our servers and databases are protected by stringent firewall/access policies which include, but not limited to the following:
 - All access to our Physical/Virtual servers is blocked by default except for the services that we intentionally want to expose. This is implemented via Juniper firewall and establishing a DMZ for external services only and all databases are in the protected zone not accessible via public addresses.
 - Remote Desktop Access (RDP) to the Physical/Virtual servers is restricted only to a set of known internal IP addresses, all other access requests are denied. This is only to allow admin users to perform required maintenance tasks over a secure IPsec tunnel between our Lane Cove office and the Data Centre.
- 3. Data Communication Security:** All data communication between client (user's browser) and server (Registry System) occurs on secure channel commonly referred to as Secure Sockets Layer (SSL). SSL ensures that all data is encrypted by a private key on the server before it is sent on a wire to the client, where it is then decrypted by a public key so that security of data is not compromised along the way.
- 4. Application Security:** ABMTRR Registry implements comprehensive Prowess Development Security Framework. All users of the ABMTRR Registry need to login to the system through a login screen with a pre-configured username and password controlled by administrators of the system. Once logged in, each user has a security

profile that determines their access to different areas/pages of the ABMTRR Registry and also determines their access level as below:

- Manager – has full access
 - Author – can create new records and Edit them
 - Editor – can only Edit existing records
 - Read only – can't change anything but read
 - No Access – access to the page/data will be denied.
5. **Data Security:** The Registry application also implements Data Security where each user from hospital can only view patients/data associated to their own site/hospital. This data access is controlled by the administrators of the site.

Data Integrity and System Backup

The system implements backup on 2 different levels.

1. **Transaction Log Shipping:** The system ships transaction logs from the Live database to a Backup (Read only) database every 15 minutes. What this means is that we have the ability to restore the data if a disaster was to happen and the maximum amount of data lost will be 15 minutes.
2. **Offsite Backups:** The Database is also backed up every night onto a physical storage device back in our office and copy of the data is taken offsite every night for security reason if under unforeseen circumstances we were to lose all backups at the data centre and at our office, we would still have an off-site copy of the data