Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)

Principal Investigator: Dr Samuel Milliken

Version Number: 4.1

Date of Protocol: December 2013 Version 2
Amended: September 2015 Version 2.1
Amended: February 2017 Version 2.2
Amended: February 2018 Version 2.3
Amended: February 2019 Version 3.0
Amended: May 2020 Version 4.0
Amended: September 2020 Version 4.1

Synopsis

Protocol title: Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)
Protocol version: 4.1

Investigators

The ABMTRR is operated by St Vincent's Hospital Sydney Limited (SVHS) and overseen by a Steering Committee comprising members from SVHS and the Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ) and other associated bodies. The BMTSANZ is responsible for scientific direction of the registry,

Principal Investigator/ Data Custodian: Dr Samuel Milliken

Signature: Date:
Organisation: St Vincent's Hospital Sydney Limited
Address: Level 5, The Kinghorn Cancer Centre
370 Victoria St
Darlinghurst NSW 2010
Telephone no:9355 5625
Fax no.: 9355 5736
Email: smilliken@stvincents.com.au

Data Custodian: Ms Leonie Wilcox

Signature: Date:
Organisation: ABMTRR
St Vincent's Hospital Sydney Limited
Address: Level 6, The Kinghorn Cancer Centre
370 Victoria St
Darlinghurst NSW 2010
Telephone no: 9355 5696
Fax no: 9355 5735
Email: lwilcox@stvincents.com.au

Current ABMTRR steering committee:

Position	Incumbent	Institution
President BMTSANZ Council Chair ABMTRR Steering Committee	Dr Nada Hamad	St Vincent's Hospital Sydney
Deputy president BMTSANZ Council Deputy chair ABMTRR Steering Committee	Dr Duncan Purtill	Fiona Stanley Hospital Perth
Paediatric representative BMTSANZ Council	Prof Tracey O'Brien	Sydney Children's Hospital
New Zealand representative BMTSANZ Council	Dr Richard Doocey	Auckland City Hospital
ABMTRR Manager	Ms Leonie Wilcox	ABMTRR
Head Haematology and BMT St Vincent's Hospital Sydney	Dr Sam Milliken	St Vincent's Hospital Sydney
Chief Executive Officer Australian Bone Marrow Donor Registry (ABMDR)	Ms Lisa Smith	ABMDR
BMTSANZ councillor	Dr Ashish Bajel	Royal Melbourne Hospital
BMTSANZ councillor	Prof Ian Kerridge	Royal North Shore Hospital
BMTSANZ councillor	Dr Jason Butler	Royal Brisbane & Women's Hospital
Invited member	Prof Jeff Szer	Royal Melbourne Hospital
Invited member	Prof David Ma	St Vincent's Hospital Sydney
Invited member	Prof Con Tam	Peter MacCallum Cancer Centre

Summary

Protocol title:	Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)
Protocol version:	4.1
Purpose	To collect baseline and outcome data relating to all bone marrow, peripheral blood and cord blood haemopoietic stem cell transplants and other cell therapies performed throughout Australia and New Zealand. To collect data to monitor clinical practice and inform best practice guidelines. 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 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. To routinely provide systematic benchmarking data to contributing centres for safety and quality audits and to assist with accreditation requirements.
Design	Clinical registry
Registry population	All patients in Australia and New Zealand receiving haemopoietic stem cell transplants or other cell therapies such as CAR-T. The database currently holds information on more than 39,000 transplants, accruing at more than 2,000 per year.
Data custodians	Dr Samuel Milliken Leonie Wilcox
Data collection	Patient data may be submitted to the ABMTRR by contributing centres either 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 procedures.

Contents

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. In line with overseas registries, the ABMTRR now also collects information from patients receiving other cell therapies.

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. From 2001 to 2014, the Australian Bone Marrow Donor Registry (ABMDR) 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 Australian governments through the Australian Commonwealth Department of Health by means of funding arrangements between St Vincent's Hospital Sydney Limited (SVHS) and the ABMDR.

The ABMTRR is operated by SVHS and located at Level 6, The Kinghorn Cancer Centre, 370 Victoria St. Darlinghurst NSW 2010. Staff are employees of SVHS. A Steering Committee including members from SVHS and the Bone Marrow Transplant Society of Australia and New Zealand oversees the strategic management of ABMTRR.

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 and cell therapies 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 these procedures and may be shared with governmental agencies, relevant local and international organisations (eg Australian Bone Marrow Donor Registry, AusCord, Asia-Pacific Blood and Marrow Transplantation Group) in accordance with this protocol, as permitted by relevant privacy or data protection regulations and/or with specific approval from the contributing hospital.

2. Purpose

Data is collected by the ABMTRR:

- To monitor haemopoietic stem cell transplant and other cell therapy activity and outcomes in Australia and New Zealand.

- To collect data to monitor clinical practice and inform best practice guidelines.
- 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 procedures.
- To collaborate with disease registries to help determine who is likely to benefit most from these procedures.
- To routinely provide systematic benchmarking data to contributing centres for safety and quality audits and to assist with accreditation requirements.

3.Design

3.1. Participant population

Data from every patient who undergoes autologous or allogeneic haemopoietic stem cell transplant in Australia and New Zealand will be collected and contributed to the ABMTRR. Patients undergoing other cell therapies can also be included.

3.2. Participating centres

Data have been or are currently collected from the following centres. For those centres no longer performing these procedures, clinicians may still provide follow up data for patients,

New South Wales

Children's Hospital at Westmead
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
Westmead Hospital
Wollongong Hospital

Queensland

Brisbane Private Hospital
Gold Coast University Hospital
Greenslopes Private Hospital
Mater Private Hospital
Mater Misericordiae Public Hospital
Queensland Children’s Hospital
Princess Alexandra Hospital
Royal Brisbane and Women’s Hospital
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
Adelaide Cancer Centre
Flinders Medical Centre
Queen Elizabeth Hospital
Royal Adelaide Hospital
Women and Children's Hospital

Western Australia
Fiona Stanley Hospital
Fremantle Hospital
Perth Children's Hospital
Royal Perth Hospital
Sir Charles Gairdner Hospital

Tasmania
Royal Hobart Hospital

Australian Capital Territory
Canberra Hospital

New Zealand
Auckland City 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 and cell therapy 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

Data from all patients in Australia and New Zealand receiving autologous or allogeneic haemopoietic stem cell transplants will be collected and contributed to the ABMTRR. Patients undergoing other cell therapies can also be included. Data collected will be used as a means of validating ascertainment and for safety and quality monitoring purposes, and where patients have provided their direct consent their data will also be used for other consented purposes such as research and contribution to other

collections. This process aligns with the Australian Privacy Principles and NHMRC Guidelines.

5. Procedure Outline

5.1. Data collection procedure

Most data is now entered directly by staff at the contributing centre into the online database ASTRO (Australasian Stem cell Transplant Registry Online). 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.

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.

Registration data are collected at the time of the procedure. 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 for the contributing centre, 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 procedure data include diagnosis, date and type of procedure, donor relation, HLA matching information, preparatory treatments and cell doses.

As set out below, data is collected from all patients. However, if a patient does not provide direct consent to participate in the ABMTRR, only the diagnosis, year of birth, date and type of procedure will be collected for administrative and safety and quality purposes. It is necessary to collect this information to ensure the epidemiological integrity of the database and to minimise bias in benchmarking analyses. For patients who have not consented for participation in the ABMTRR, data use will also be limited to safety and quality monitoring activities and will not be used for participation in other data collections, projects or research.

Follow up information is collected from all patients and includes disease response, engraftment, complications such as graft vs host disease or infections, disease relapse and survival. This information is used to enable benchmarking and for safety and quality purposes, unless consent was provided from the patient, in which case it will also be used for research or other consented purposes. This information may be provided at the time an event occurs, or in response to update requests from the ABMTRR to contributing centres. Patients may be monitored for their entire lives in the case of stem cell transplant or for shorter periods depending on the type of cell therapy administered. 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. Medium and long term effects of other cell therapies will also be monitored.

The online system is hosted offsite, with appropriate security and backup systems. A more detailed description of the database security is provided in Appendix 2. Data downloaded for analysis are stored on a SVHS network drive and are only accessible by ABMTRR staff. REDCap is also used for data management with access controlled by ABMTRR personnel.

Many Australian and New Zealand hospitals contribute transplant and cell therapy data to the Center for International Blood and Marrow Transplant Research (CIBMTR) in the US, as well as to the ABMTRR. There is considerable overlap between these collections, resulting in duplicate data entry burden. Subject to obtaining the necessary

approval from the contributing centre, the ABMTRR may collect data from the CIBMTR via a web portal.

5.2. Risks

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

The only risk to participants is through an unintended and unauthorized disclosure of their information. However, the ABMTRR is subject to the requirements of the *Privacy Act 1988* (Cth) in relation to the handling and security of personal information. ABMTRR have implemented the various security measures set out in Appendix 2 to satisfy its obligations for ensuring the security of personal information.

Any information that is disclosed by ABMTRR will be either de-identified or subject to HREC approval and/or strict confidentiality obligations to protect patient privacy.

5.3. Benefits

There is no direct 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 also 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 a patient who presents at the contributing centre for relevant treatment. This is likely to be the treating clinician or BMT coordinator. The patient will be provided an Information and Consent Form (recommended template at Appendix A) and given a reasonable opportunity to consider whether or not to provide their direct consent for participation in the ABMTRR.

Patients will be advised that some data will be collected by the ABMTRR and their outcomes monitored for safety and quality purposes, regardless of whether or not they provide their direct consent, but that they may elect whether or not to participate in any data sharing or research projects through the ABMTRR.

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

By contributing data to the ABMTRR, contributing centres are expected to ensure that appropriate processes have been followed for the contribution of that data.

5.5. Disclosure of data

In most cases, ABMTRR data are disclosed to external parties only as aggregated summary statistics or reports, meaning that no individual patient can be identified. De-identified data may be provided to researchers for approved projects after formal consideration by the steering committee. In the future it will also be possible to share de-identified data directly between the ABMTRR and CIBMTR via AGNIS (A Growable Network Information System), an open-source messaging system specifically designed to exchange hematopoietic cell transplant and cell therapy data using a secure, standards-based system.

Where permitted under privacy regulations (including where necessary consent has been provided by the patient and approval has been obtained from a human research ethics committee), identifiable personal information may also be shared with other data registries in order to link data for administrative or scientific benefit.

For example, stem cell transplantation and other cell therapies are treatment options for a large number of malignant and non-malignant diseases, some of which have their own registries to collect comprehensive disease-specific information. By utilising all available information such as diagnostic details and response to various treatments, researchers may be able to identify characteristics of patients who are likely to respond best to transplant and cell therapies, and how these treatments should be managed to optimise outcomes. When possible, the associated disease registry id can be collected at transplant registration to enable de-identified linkage between registries. For cases where the disease registry id is not available at transplant registration, the minimum data required to identify the patients in each dataset would be used to link the data by the respective data registry custodians (eg month of birth, sex and date of diagnosis). Only de-identified data would then be provided to researchers for analysis. Established disease registries where treatment options include transplant and cellular therapies currently include:

- National Blood Cancer Registry
- Myeloma and Related Diseases Registry
- Aplastic Anaemia Registry
- Lymphoma and Related Diseases Registry
- MSBase – Multiple Sclerosis registry

Data may also be shared with sponsors or manufacturers of the relevant cell therapy as required, to enable them to meet their regulatory requirements under the *Therapeutic Goods Act 1979* (Cth). Further details about the registry requirements for approved cell therapy products can be found on the Medical Services Advisory Committee website:
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1519-public
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1519.1-public
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1587-public

Disclosure of identified or identifiable patient information from the ABMTRR would be assessed by the steering committee on a case-by-case basis and, where necessary, subject to approval from a human research ethics committee.

6. Storage and archiving of study documents

The consent forms and clinical review forms are kept in the patient files at the contributing centre under their own institutional guidelines.

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 SVHS server with network drive access restricted to ABMTRR personnel who are employed by SVHS to operate the ABMTRR. This system is backed up daily. REDCap (https://www.project-redcap.org/), hosted on a secure hospital server, is also used for data management.

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

Australian Commission on Safety and Quality in Health Care, *Framework for Australian clinical quality registries*. Sydney. ACSQHC, March 2014

NHMRC, *National Statement on Ethical Conduct in Human Research* (2007) - Updated 2018

Office of the Australian Information Commissioner, *Australian Privacy Principles Guidelines* (July 2019)

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 been provided with the opportunity to consent directly to their participation in the ABMTRR, or otherwise that the data has been collected by the contributing centre in circumstances allowing for their data to be submitted to the ABMTRR (for example, that the patient has been advised that their data may be used for quality and safety purposes). 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, cell therapy or tissue banking.

[Form of Participant Information Sheet on Following Page]

Participant Information Sheet

Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)

The Australasian Bone Marrow Transplant Recipient Registry (ABMTRR) database collects information on all stem cell transplant and cell therapy procedures performed in Australia and New Zealand to monitor for quality assurance and resource planning. The existence of data collections such as this has enabled improvements in the safety and efficacy of transplantation and cell therapy over time and is permitted under Australian privacy laws for safety and quality purposes.

This data collection is also valuable for medical research and data linkage projects with other related datasets, both within Australia and overseas, which contributes to a greater understanding of these procedures and informs clinical improvements.

This Participant Information Sheet provides you with information about how the ABMTRR operates and how your information is collected and handled to help you decide whether you would like to provide your consent to the additional use of your personal information for research, linkage and other related purposes.

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 procedure. Most of the information required is available from your medical record so no additional information will be collected directly 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 (only if your hospital chooses to, 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 or cell therapy data include diagnosis, date and type of procedure, donor relation, HLA matching information, preparatory treatments and cell doses. The outcome data include complications, disease response and survival.

In the case of cell therapy, a brief questionnaire for Patient Reported Outcomes is also collected at the direction of the Commonwealth in order to better assess the benefits of these treatments.

'What will happen to my information?'

Your information will be stored for an indefinite period of time in the secure ABMTRR database which is managed by St Vincent's Hospital Sydney Limited (St Vincent's) in accordance with the ABMTRR Protocol (as may be amended from time to time), the current version of which can be found at www.abmtrr.org. The ABMTRR is operated by St Vincent's and is overseen by a Steering Committee comprising members from St Vincent's and the Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ) and other associated bodies.

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

Any information which will identify you will not be included in any report or publication.

Staff employed by St Vincent's to operate the ABMTRR collate and maintain the data and prepare regular reports for clinicians, health administrators, regulatory agencies and, in the case of cell therapy, sponsors or manufacturers of the therapy. Health administrators and regulatory agencies may use the information for resource planning and quality assurance purposes.

Authorised personnel at participating hospitals have access only to patient data from their own hospital, to enable follow-up.

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 procedure. Investigators on HREC approved studies have

access only to the records of the approved study patients. De-identified or summary information may also be shared with other approved local and international organisations such as disease registries (eg blood cancers), AusCord (to monitor cord transplants in Australia) or other registries or collections such as the Global Activity Survey (based in Switzerland) and the Asia Pacific Blood and Marrow Transplantation group (APBMT).

'What will happen if I don't consent?'

Your treatment and relationship with your doctor and hospital will not be affected. Information about your procedure will still be sent to the ABMTRR for administrative and quality purposes, but no data will be shared for other projects.

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

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

If you have concerns about this registry database you can also contact:

The Research Governance officer
St Vincent's Hospital Sydney Limited
SVHS.Research@svha.org.au

'Who should I contact if I have concerns about my Privacy?'

St Vincent's is committed to protecting the privacy of the personal information and sensitive information which it collects and holds. A copy of the Privacy Policy of St Vincent's can be found at https://www.svhs.org.au/privacy-policy.

If you have a complaint about St Vincent's information handling practices or consider your privacy has been breached, you can lodge a complaint with:

The Privacy Officer
St Vincent's Health Network
(02) 8382 1111 (Hospital switchboard)
(02) 8382 2250 (Executive Unit)

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 the use of my personal information collected and uploaded to the ABMTRR, for the purpose of research, data linkage and other related projects, 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 for my consent. The nature and risks of this database and proposed uses 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 the risks and I have received satisfactory answers.

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

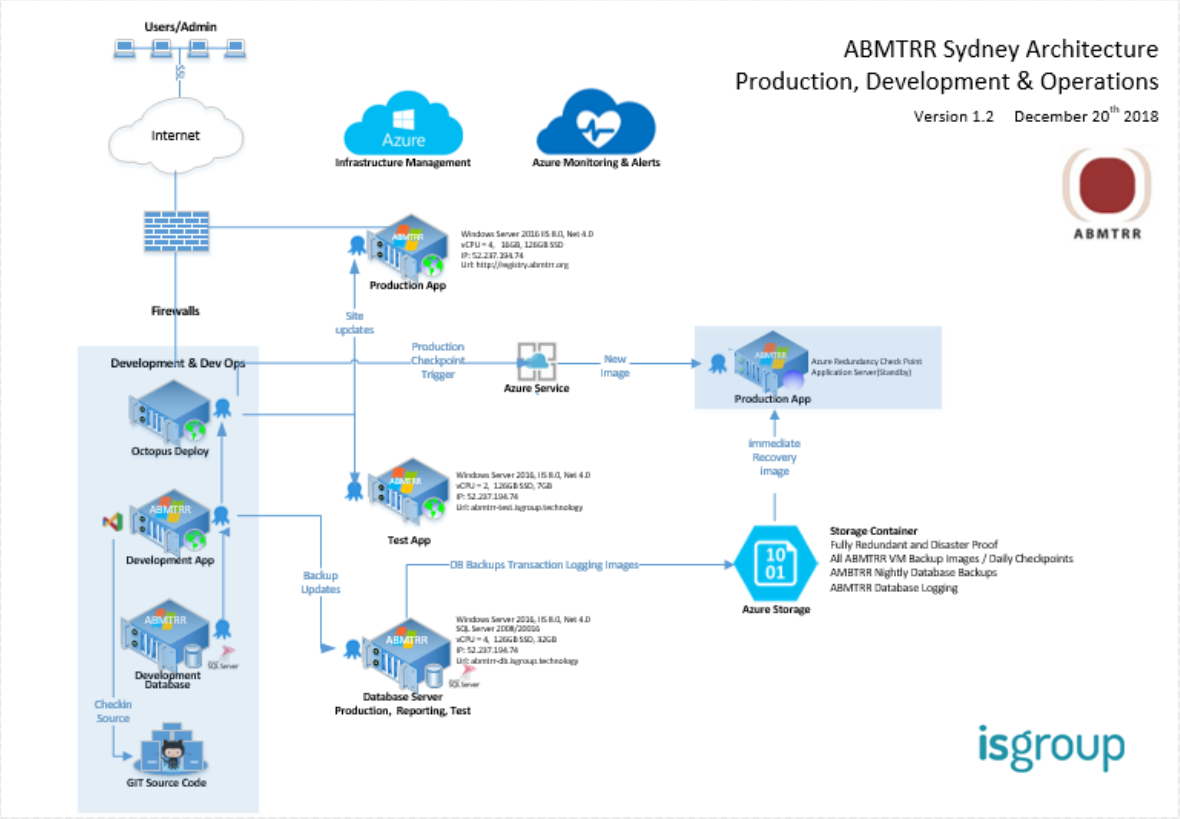
Database security statement from IS Group Pty Ltd

IS Group is committed to the protection of data/applications. To achieve the highest protection possible and implement leading industry best practices. Most of our clients including ABMTRR deal with sensitive user data that needs highest level of protection. To achieve the highest level of protection security and protection of data is implemented at a number of levels to ensure that privacy/security/integrity of customer data is not compromised.

ABMTRR Data Registry is developed, maintained and managed on Microsoft Azure by IS Group Pty Ltd. The registry application employs a number of procedures/mechanisms for Security and Integrity of user/hospital data both on physical and technical level. Furthermore, Azure provides Enterprise level of security, fault-tolerance, data and intrusion protection. By moving the ABMTRR system to Azure we increased the level of operational security and lowered operational risk.

Network Architecture

The diagram below depicts the ABMTRR system architecture as configured on Azure as of January 1st, 2019. The key components are shown along with key redundancy and backup mechanisms.



Security

To ensure security of the data, Registry implements application/data security at different levels and adheres to the Azure security policies.

1. **Physical Security:** The applications are physically hosted on servers on Azure infrastructure located in Australia. The following link describes the physical security applied access all of Microsoft data centres:

   https://docs.microsoft.com/en-us/azure/security/azure-physical-security

2. **Server/Database Access:** Our servers and databases are protected by stringent firewall/access policies as prescribed by Microsoft Azure which are described here:

   https://www.microsoft.com/en-us/trustcenter/security/azure-security

   All remote access to data is strictly limited to specific IP addresses. All data transiting the network is encrypted with SSL using a 4096 strength certificate and further protected by strong username password combinations.

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 using Azure services which are the leading methods. This includes daily backups of all servers images, databases and network infrastructure settings. To protect against loss of data within the 24-hour period between backup we implement database log shipping at 15 minute intervals.

An overview of the Azure backup services we utilise can be reviewed at this link.

https://docs.microsoft.com/en-us/azure/backup/backup-introduction-to-azure-backup

Systems and data is guaranteed using these services in-conjunction with an Azure Storage account.