NATIONAL TRANSFUSION DATASET (NTD)

Building on the Australian and New Zealand Massive Transfusion Registry (ANZ-MTR) and the Australian Transfusion Database (TD)

AUSTRALIAN PROJECT OUTLINE

Version 3.0, dated 20 July 2021

1. Important Note:

This is an observational study and does not involve any direct patient contact or treatment regimens, therefore the following Project Outline takes the place of the 'Protocol' and will be referred as the Project Outline in all Human Research Ethics documentation submitted for consideration by the Ethics Committee.

2. Background

In the 2019-2020 financial year, around 1 million fresh blood components (i.e. red blood cell [RBC], platelet, fresh frozen plasma, cryoprecipitate and cryo-depleted plasma components) were issued by the Australian Red Cross Lifeblood (Lifeblood) to Australian hospitals and healthcare providers [1]. Large numbers of plasma-derived products, such as albumin, coagulation factor and immunoglobulin concentrates were also issued. RBCs are the most commonly transfused fresh blood component [2], accounting for ~85% of all fresh blood components issued by Lifeblood. RBC transfusion is used to treat anaemia and/or blood loss caused by a wide range of circumstances including trauma injuries, surgery, blood disorders, cancer and all types of haemorrhagic conditions. In cases of acute blood loss, recovery of haemostasis may necessitate transfusion of plasma and/or plasma derivatives and platelet concentrates, in addition to RBC transfusion. Other clinical conditions may specifically affect platelets or plasma factors only, such as various thrombocytopenic, deficiency and immunological conditions that require transfusion of the requisite blood components. Although blood transfusion can be life-saving, it is not without risks to the recipient and it is expensive – Australia spends over $1.2 billion annually on blood products [1-4]. Judicious use of blood transfusion is paramount, both from the perspective of patient safety, stewardship of the donors' gifts, and budgetary constraints.

A few countries have national "vein-to-vein" transfusion databases (e.g. Scandinavian SCANDAT retrospective database in Sweden and Denmark; New Zealand Blood Service's "real-time" database), while other countries have significant projects underway to capture large comprehensive transfusion datasets, including the Netherlands, Canada and USA [5-9]. These datasets are very valuable tools to gain new knowledge to inform clinical practice improvement, monitor or reveal changes in clinical epidemiological patterns, transfusion management and patient outcomes.

Australia does not have an integrated national database to record blood usage, nor the ability to link this with clinical outcomes. Although the Lifeblood has a national donor database, it is not linked to hospital blood bank databases. With the large number of public and private health services and pathology providers that manage Australian hospital blood bank inventories, there are a wide variety of electronic information systems in operation, many of which have been customised to

[1] *NHMRC/ASBT Patient Blood Management Guidelines: Module 1 – Critical Bleeding/Massive Transfusion*

individual hospital specifications. This makes the task of developing an Australian "vein-to-vein" transfusion database very complex and challenging.

In 2011 the Australian and New Zealand Massive Transfusion Registry (ANZ-MTR) was established to capture transfusion data on patients who have had a critical bleeding (CB) episode that required a massive transfusion (MT), together with the corresponding patient hospital admission information and pathology laboratory results [11]. The ANZ-MTR has created a comprehensive clinical database for uses such as patient outcome research, benchmarking and monitoring of patient blood management (PBM) strategies and to inform clinical practice improvements [12, 13].

Based on the success of the ANZ-MTR to collect data on massive transfusions, a pilot project to investigate the feasibility of developing a database of comprehensive electronic hospital, laboratory and transfusion records on all patients transfused any type of blood component during their hospital admission (not just MT) was developed. This database was called the Transfusion Database (TD), and dataset for this database was collected for ALL transfusions for >8000 patients from the pilot hospitals.

It was recognised from the success of the ANZ-MTR and the pilot project, that incorporating the TD into the ANZ-MTR to become a combined dataset called the National Transfusion Dataset (NTD) will allow for an invaluable resource with the unique focus of MT from the ANZ-MTR and vital closing of the haemovigilance loop with the TD. Data analyses and findings from the NTD will support policy and research with regards to numbers and characteristics of patients transfused in hospital, reasons for transfusion and outcomes of transfusion. In addition, it is possible to expand analyses to include pre-hospital (ambulance) and community (non-hospital care), data which is not captured by the ANZ-MTR, and by conducting data linkages with other databases, such as ambulance data, and additional clinical registry data, the National Death Index, the Australian and New Zealand Intensive Care Society (ANZICS) database and the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) database.

The ANZ-MTR and TD are based in the Transfusion Research Unit (TRU) of the Department of Epidemiology and Preventive Medicine (DEPM), Monash University, Melbourne. In addition to the ANZ-MTR and TD, TRU maintains several other blood-related clinical registries. DEPM is internationally recognised as a leader in managing major clinical registries, including the Australian and New Zealand Intensive Care Society (ANZICS) database, the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) database and the Australian Trauma Registry.

3. Purpose of the NTD

The purpose of the NTD is to collect clinical and laboratory data on all adult (≥18 years of age) recipients transfused any type of blood component during their hospital admission in order to:

i. better define the incidence, clinical circumstances and outcomes of transfusion;

ii. better understand variation in transfusion practices across clinical disciplines and across different hospitals and jurisdictions;

iii. better understand variations in PBM practices across clinical disciplines and across different hospitals and jurisdictions;

iv. investigate the incidence and type of adverse events following transfusion;

v. provide participating hospitals with a clinical quality tool to benefit patients and health providers by monitoring alignment of 'real world' practice with national blood policies and PBM Guidelines;

vi. inform hypothesis-driven research and clinical guideline development in this area;

vii. better define the incidence, natural history and clinical outcomes of CB/MT;

viii. generate information to assess the range of therapeutic strategies being employed in treatment of patients with CB requiring MT, including indications for and types and volume of blood components administered during CB/MT, and the use of adjunctive haemostatic agents; and

ix. better define the optimal management of CB/MT

4. Aims

i. To establish a comprehensive database of all patients transfused any blood product* during their hospital admission using routinely collected electronic transfusion, laboratory and hospital admission records.

ii. To incorporate a function in the database that will allow filtering and thus focused analysis for the ANZ-MTR data and TD data.

* 'Blood product' means RBCs, platelets, plasma, cryoprecipitate, cryo-depleted plasma or plasma derivatives

5. Study Design

The NTD is a database of adult patients who were transfused any type or amount (one or more units or vials) of blood product during their hospital admission. The database will also have a function that will allow the filtering to identify patients who have had an episode of CB that required a MT in any clinical setting [12, 13]. A waived patient consent model is used [14]. Clinical data will continue to be electronically extracted by staff employed at participating hospitals, Blood Services and/or Government departments. Data management and analysis is undertaken by the Department of Epidemiology and Preventive Medicine (DEPM), Monash University and interpreted with input from subject-specialist clinicians. Data management and analysis will be undertaken by the ANZ-MTR team. The same set of data items collected for the ANZ-MTR will be collected for this project – see *Appendix 1* for list of data items.

6. Project Staging

6.1 Current status

The ANZ-MTR and TD have successfully achieved development and implementation phases of the project and are now well positioned to be incorporated into the NTD.

6.2 Next phase of the project

Recognising the ANZ-MTR's and TD's overlap and valuable dataset available for transfusion policy and practice improvement, the Investigators planned the incorporation of the TD into the ANZ-MTR to become the NTD to align with Australia's national safety and quality framework, whilst still allowing research opportunities. The NTD aims to be a national transfusion practice and clinical outcomes dataset.

6.3 Expansion phase

The Expansion phase of the project includes:

- Expanding hospital participation to ensure a representative spread of sites from individual states, public and private hospitals, women's hospitals and metropolitan/regional/remote sites.
- Continuing to collect, validate and analyse data from participating sites.
- Conducting additional analyses of clinical and laboratory practice in priority areas, including obstetrics, trauma, surgery and gastrointestinal haemorrhage.
- Conducting new linkage activities with relevant clinical, research and administrative datasets to provide additional information for risk adjustment, health economics analyses, and clinical outcomes evaluation.
- Feeding back data to participants for local review, benchmarking and practice improvement.
- Providing reports to policymakers and funders on variation in practice and alignment of clinical and laboratory practice and blood utilisation against national policy, clinical practice and inventory management guidelines.

7. Study Assessments

This project involves only retrospective collection of data routinely collected by clinicians and hospital staff and systems as a necessary part of good patient care. There are no patient interventions and no direct patient contact or involvement.

As this project involves retrospective data collection, patients included in this project are unlikely to receive direct benefit from participation. It is possible that outcomes of the project may enable improved management that could benefit some of the patients in any future hospital admissions as well as other patients that require blood transfusion in the future.

8. Methodology

8.1 Study population

8.1.1 Inclusion criteria

- All patients (≥18 years old) admitted to hospital transfused any type of blood product during their hospital admission.
- To examine further cases of MT: Patients who have had an episode of CB that required a MT in any clinical setting will be selected by application of the existing filter: patients (≥18 years old) who receive ≥5 units of RBCs within any 4 hour time period (existing ANZ-MTR definition of MT). This acute and previously validated definition of MT allows inclusion of medical, surgical and obstetric patients with CB occurring during a hospital admission, as well as those patients presenting via the emergency department, such as trauma patients.
- All Hospitals are welcome to participate in the NTD. The only proviso is that their electronic information systems can identify patients who meet the definitions above.
- The NTD database import algorithm is designed to identify cases that have missing critical data items. In situations of missing data, the ANZ-MTR team contacts the relevant hospital to request the specific data. If the data are not available, the case is not imported into the database.

8.1.2 Patient recruitment

The patient recruitment strategy for the NTD takes advantage of the fact that hospital blood banks dispense and electronically track all issued blood components. Eligible patients will be identified using the hospital's electronic Blood Bank reports. A script (based on those used for the ANZ-MTR) will be utilised to query Hospital Blood Bank electronic records according to the NTD inclusion criteria defined above to generate the list of eligible patients.

Although the majority of massive transfusion cases occur in large metropolitan public tertiary hospitals, which are well represented in the ANZ-MTR, we intend to increase the participation of regional, remote, women's-specialist and private hospitals in order to have fullest representation of all levels of hospital care and to capture cases which may otherwise be missed. Linkage with Ambulance Victoria will permit identification of patients who receive pre-hospital transfusions (e.g. during retrieval) due to bleeding but may not be captured in hospital datasets.

8.1.3 Data collection commencement date

Data extractions commencing from 1 January 2017 will be requested.

8.2 Data sources

Using patient identifiers (medical record number, full name, date of birth and sex) for identified eligible patients, predetermined data items will be extracted from hospital data sources (*Figure 1*) including; i) Pathology information systems (including laboratory results and transfusion records), ii) Health Information Services databases (including patient demographics, diagnosis and procedure codes, outcome measure such as mortality, adverse events and length of hospital stay) and iii) other clinical databases or registries (e.g. local or regional trauma or cardiac surgery registries, National Death Index and Intensive Care Unit [ICU] databases).

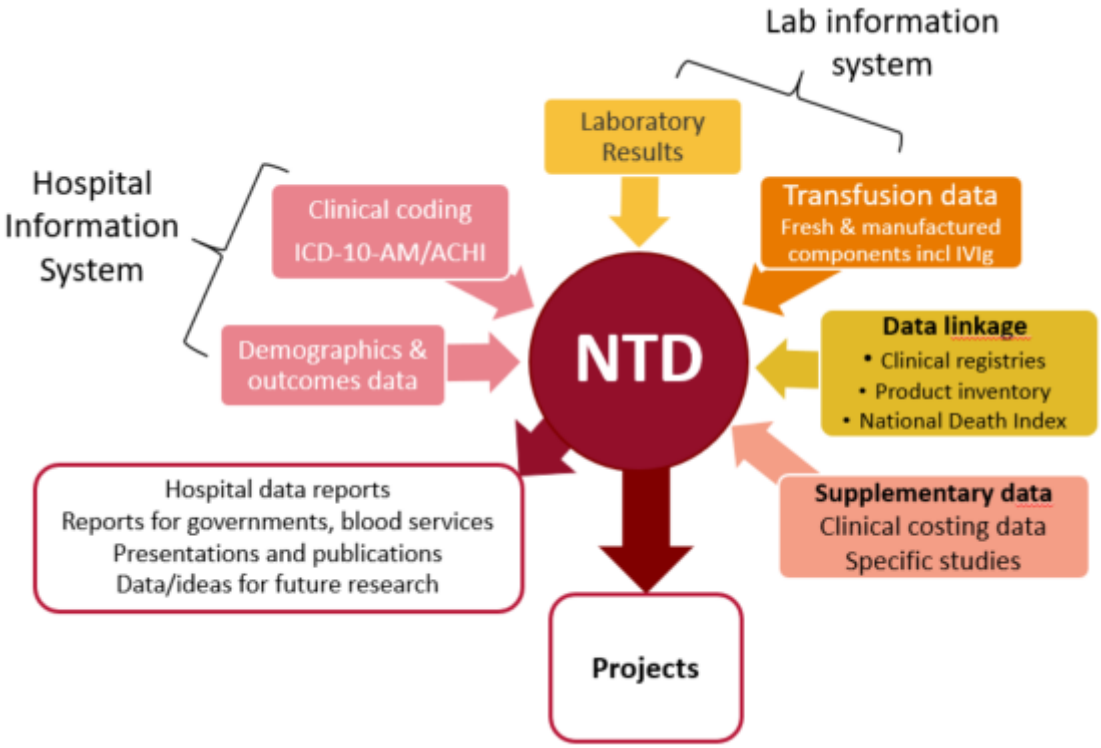

Figure 1. In-hospital electronic data sources

8.3. Data set

All data to be used by the NTD are already recorded as part of routine patient care or hospital administrative procedures. See *Appendix 1 NTD Collated Data Set*.

Patient identifiers including patient medical record number, full name, date of birth and gender will be the only identifying patient details that will be captured by the NTD. These details will be used for data extraction and data linkage purposes (described below). The NTD will NOT capture or store any other identifying patient information such as residential address or contact phone number.

Hospital staff at each site will extract data for each eligible NTD patient in the following categories:

- Demographic details
- Clinical context of hospital admission (acquired from ICD-10-AM codes) including diagnosis, procedures and complications
- Laboratory results *
- Transfusion records*
- Adjunctive therapies*
- Clinical outcome (in-hospital mortality; hospital and ICU Length of Stay)
- Clinical costing data*

* All data for the entire hospital admission period

8.4 Data extraction and data linkage process

Figure 2 outlines the data extraction and data linkage processes involved in acquiring data for the NTD. As described previously, this project does not involve direct patient contact or changes to patient treatment and procedures. All data needed for the NTD are already stored on relevant clinical databases and will be extracted retrospectively by staff employed by participating hospitals.

Eligible patients will be identified by Pathology IT on a mutually agreed periodic basis. Pathology IT will be responsible for extracting laboratory results and transfusion histories for all eligible patients. Pathology IT will also provide a list of these patients (including identifiers) to a delegated staff member in the Health Information Services unit (or equivalent department within the hospital) for extraction of patient demographics, ICD-10-AM codes and clinical outcome data. The individual data packages (laboratory results, transfusion histories, basic demographics, ICD-10-coding and clinical outcome data) will then be securely transferred to a designated site established by the Monash University data management team (described below). The Monash University Clinical Data Management Systems (CDMS) team at DEPM will convert the various data packages into a standard format and link individual patient data using the patient identifiers; medical record number, full name, date of birth and gender.

The NTD will be well positioned to undertake data linkages with other datasets in order to enhance the richness of the data analyses and research findings. The ANZ-MTR team have previously conducted successful data linkages, including with the Australian Institute of Health and Welfare National Death Index and the ANZICS database [12].

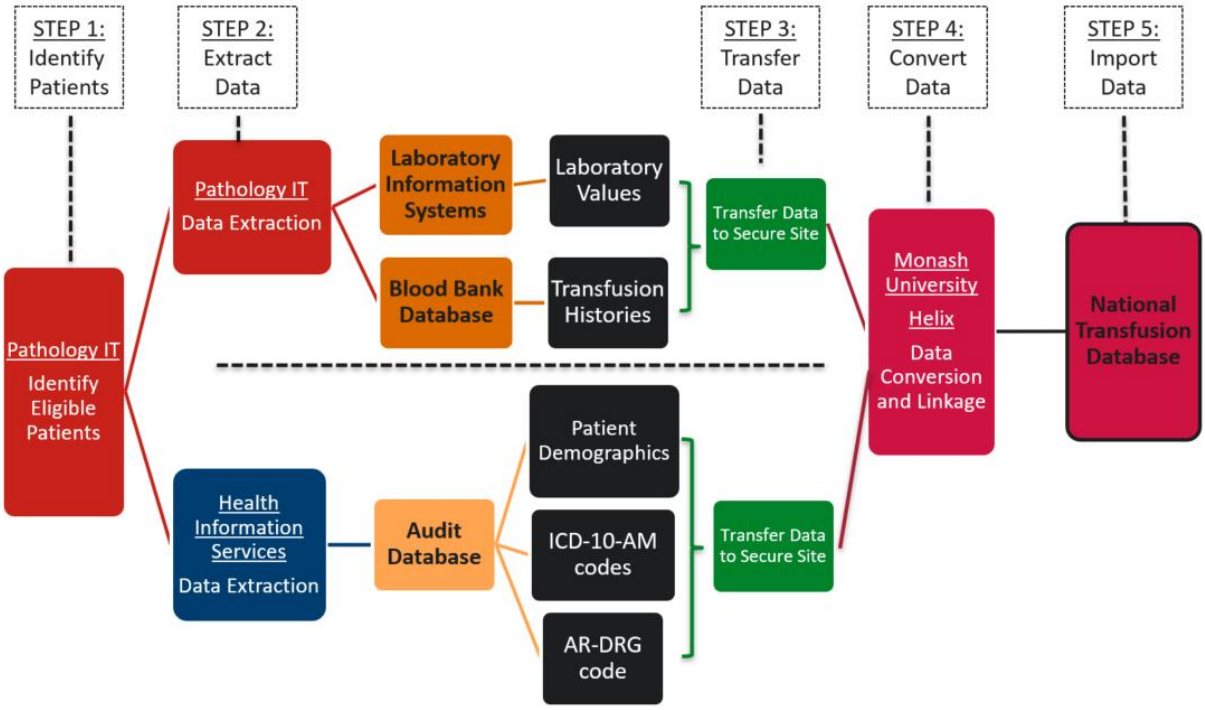

Figure 2. Overview of data extraction and data linkage strategy to produce the NTD

8.5 Data management

The NTD Data Management Procedures have been developed in accordance with the Monash University Policy "Electronic Information Secure Handling and Protection Procedures". Data collected for the NTD is managed according to guidelines stipulated by the NHMRC National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research (2007) and conforms to Commonwealth and State privacy principles. Please refer to the '*NTD Data Management Policy and Procedures*' document for a detailed description of the data transfer and storage processes.

Extracted hospital data will be securely transferred (from participating hospitals to Monash University) using WinSCP (Secure File Transfer Service). Only the named chief investigators of this project, the NTD team, the DEPM biostatistician, and Helix will have access to the data. Site-specific conversion modules will be created by staff employed by Monash University's Helix and used to import the various data packages into the NTD database.

Datasets extracted from the NTD database will be stripped of all patient identifiers (i.e. data will be re-identifiable) prior to analysis and reporting. Re-identifiable data will only be available to the named chief investigators the NTD team and the DEPM biostatistician for the purposes of developing aggregate data reports and analysis. Reports containing non-identifiable aggregate data will be provided to the overseeing ANZ-MTR Steering Committee, to participating institutions, or used for preparation of scientific manuscripts.

The NTD dataset remains the property of Monash University. Data will not be used in a way that will allow individual patients to be identified. Publication will be restricted to statistical tabulation of aggregate data only. The data will at all times be handled by experienced DEPM staff with careful attention paid to privacy and security of the information. The DEPM has an impeccable track record in handling personal information.

8.6 Data analysis

For the NTD project, the aim is to have sites that form a representative section of hospital types and locations in the database. All transfusions at each site will be captured in the dataset, reducing bias. For each analysis performed, confounding factors will be identified and adjusted for using the appropriate statistical approach.

8.7 Quality control

In line with requirements for Australian Clinical Quality Registries [14], and building on the established ANZ-MTR the NTD will have robust quality assurance including in-built data management processes such as data range and validity checks that allow ongoing monitoring of the completeness and accuracy of the data collected. In addition, validation audits against source records will be performed periodically in a sample of cases.

9. Governance

The activities of the NTD will be overseen by the ANZ-MTR Steering Committee. The committee is independently chaired by a clinical expert and consists of relevant stakeholders, representatives of the funding organisations and clinicians from a range of specialities and meets the requirements of clinical quality registries.

The ANZ-MTR Steering Committee meets at least twice per year.

Terms of reference of the committee include to:

- Oversee all NTD activities
- Provide advice on the NTD management, scope, development and funding
- Provide advice on the collection and interpretation of data and monitor NTD data quality management processes and timelines of reporting
- Advise on scientific priorities and monitor the scientific progress of the NTD
- Review all research and external data requests
- Review publications of the project and advise on clinical issues
- Circulate and keep abreast of literature relevant to the research area including new publications and abstracts

The NTD project has been reviewed and approved by the ANZ-MTR Steering Committee.

10. Reporting

The NTD will provide Hospital Data Reports annually to the participating hospitals describing essential statistics relating to case accrual and outcome and to the NBA. An update report will be prepared for meetings of the ANZ-MTR Steering Committee.

10.1. Communication with participating institutions

In addition to the Hospital Data Reports, communication will be maintained with stakeholders via regular emails and teleconferences/meetings, as appropriate.

10.2. Presentations and publications

Outcomes of the project will be presented at Scientific Meetings and Conferences and prepared for publication in a peer-reviewed journal. Draft publications will be provided to the ANZ-MTR Steering Committee for comment prior to publication. Final content, however, will be at the discretion of the authors. Publication sub-committees may be formed in particular areas of interest or expertise. In addition to publications, project data will be presented at Scientific Meetings and Conferences.

11. Special Interest Groups

A number of Special Interest Groups (SIGs) have been formed to allow research/analysis of the ANZ-MTR data in specialised patient cohorts to be examined by relevant clinical experts subject to conditions outlined in the '*Data Access and Publications Policy*'. This broadening of clinical collaboration is a particular strength of the ANZ-MTR and facilitates data-lead practice change by leaders in clinical specialities. Analyses of NTD data will be overseen by SIGs with expertise in those areas.

12. Funding

The ANZ-MTR was funded by the following organisations (2018 – 2020):

- Monash University
- CSL Behring
- Department of Health and Human Services, Victoria
- National Blood Authority
- New Zealand Blood Service
- *NHMRC Centre of Research Excellence for Patient Blood Management in Critical Illness and Trauma* (2014-2017)

The TD is funded by the NBA (2020), with in-principle support from the other funding partners of the ANZ-MTR, including: Monash University, Victorian Department of Health and Human Services, New Zealand Blood Service and CSL Behring Ltd.

The NTD dataset project is funded by the Australian Research Data Comms (2021-2024).

13. Ethics

Ethics approval to establish the ANZ-MTR and TD has been granted by Monash University Human Research Ethics Committee (MUHREC). MUHREC has approved the projects (29287 and 16494) to collect data with waived consent until 27th May 2026 and 6th August 2023, respectively.

Prior to the commencement of NTD data extraction, ethics approval (either via National Mutual Acceptance, lead Human Research Ethics Committees (HREC) or the HREC from the individual participating hospital) will be obtained, as well as governance approval at each participating site.

The NTD will collect a select amount of patient identifiers (medical record number, full name, date of birth and gender) which will be used for the sole purpose of data linkage as outlined in chapter 3.2 of the NHMRC National Statement on Ethical Conduct in Human Research. It is essential that several 'unique' patient identifiers are retained to ensure accurate linkage of data sets. Written, informed consent will not be obtained from patients prior to inclusion of their details within the NTD. It is our

belief that the registry qualifies with the conditions for waived consent as outlined in Chapter 2.3.10 of the NHMRC National Statement on Ethical Conduct in Human Research, including:

i. Involvement in the registry carries no more than low risk to participants

In this project, data will be retrospectively collected using electronic data extraction methods conducted by onsite hospital data managers and will not exceed data routinely collected and stored electronically on hospital data systems. No access to hardcopy medical records is required except for the purposes of data validation studies (as detailed above). Staff employed by the participating hospital identify eligible patients and perform data extraction. No new or sensitive patient information will be collected for the purpose of the ANZ-MTR or NTD and there is no foreseeable risk of harm or discomfit to the participant. The data obtained will be used as an audit of transfused patients with the objective of greater understanding and improvements to patient care.

ii. The benefits from the database justify any risks of harm associated with not seeking consent

Fundamental questions remain unanswered regarding the appropriate prescription of blood products and the lack of standardisation of blood product usage for certain clinical settings. Understanding the clinical outcomes of this treatment is lacking – an astonishing fact given the frequency of blood transfusions in clinical practice. For this reason we believe that the NTD is in the public interest and justifies the small impingement on participant privacy.

iii. It is impracticable to obtain consent

It is the view of the project investigators that it is impractical to seek informed patient consent for participation in the project because of the difficulties that would be encountered given the very large number of eligible participants, including participants receiving life-saving treatment under urgent conditions. Many of the eligible patients, particularly those with adverse outcomes, will be unable to make an informed decision regarding their participation. Identifying and contacting the next of kin will impose a prohibitive cost burden due to the large number of potential participants and the retrospective design of the study. Distribution of an explanatory statement to patients at the time of discharge or treatment, or an 'opt-off' strategy, are not feasible for the reasons given above or treatment is not possible as:

- Identification of patients who have had a critical bleed which matches the criteria of a MT definition for the registry occurs at least three months post the MT event, commonly up to 6 or more months post the MT.
- Not all critical bleeds or transfusions of large numbers of red blood cell units meet the definition of a MT used for inclusion in the registry. So if information were supplied at discharge, the hospital would not know which patients were eligible for inclusion in the ANZ-MTR.

Employing an 'opt-off' strategy is also deemed impractical and would require Monash University to collect additional personal information in order to contact patients to inform them about the Registry. The additional personal information would include:

- patient address and telephone numbers
- next-of-kin address and telephone numbers
- patient's legal guardian's address and telephone numbers

The next of kin and guardian details would be required to cover cases where the patient dies following hospital discharge. Patients will not be identified as eligible for the ANZ-MTR or NTD at

least three months after treatment, so the distribution of patient information at the time of treatment is not possible. There is also estimated to be a large number of patients that we would be unable to contact due to change of address, or death.

iv. There is no known or likely reason for thinking that participants would not have consented if they had been asked.

We believe that all patients would expect that the treatment they receive, including blood transfusion, is based on appropriate levels of evidence and would be unlikely to object to a project designed to improve the evidence base.

v. There is sufficient protection of their privacy and an adequate plan to protect the confidentiality of data.

Patient data will be collected, dealt with and stored in accordance with the Australian Privacy Principles of the *Privacy Amendment (Enhancing Privacy Protection) Act 2012*). Patient confidentiality will be respected and all data reported only as collective, tabulated data. No information about an individual will be made available to outside parties, or be used for other purposes by the ANZ-MTR or NTD project team without prior approval from the relevant Human Research Ethics Committees and the ANZ-MTR Steering Committee unless required by law (e.g. pursuant to a court order, which is unlikely, given that more detailed and relevant information would be available at the treating hospital).

vi. In case the results have significance for the participants' welfare there is a plan for making information arising from the research available to them and the possibility of commercial exploitation of derivatives of the data will not deprive the participants of any financial benefits to which they would be entitled.

As mentioned above, participants in this project are not likely to receive direct benefit from participation in the database nor will it have a financial impact on them. It is possible that outcomes of the project may enable improved management that could benefit some of the participants as well as future patients that require a transfusion. A final report on any findings and recommendations (containing non-identifiable, tabulated data) will be made available to the general public on the ANZ-MTR website.

vii. The waiver is not prohibited by state, federal or international law.

viii. It is the responsibility of each institution to make publically accessible (for example, annual reports) summary descriptions of all its research projects for which consent has been waived under paragraphs 2.3.10.

14. Data Ownership/Access/Usage

The data collected by the NTD will remain the property of Monash University. A protocol to facilitate access to researchers has been developed – please see '*ANZ-MTR Data Access and Publications Policy*' and *'TD Data Access and Publications Policy*'. In general access to non-identified NTD data will be provided to bona fide external researchers with the approval of the NTD project staff, the ANZ-MTR Steering Committee and an human research ethics committee. Participating clinicians or hospitals are at liberty to publish their own hospital data without any reference to the NTD.

15. Confidentiality & Intellectual Property

The intellectual property rights attached to all material created or prepared by the Monash University Department of Epidemiology & Preventive Medicine (DEPM) in connection with performance of the NTD shall vest in DEPM.

16. Chief Investigators

Professor Erica Wood: MBBS FRACP FRCPA

> Professor Wood is Head of the Transfusion Research Unit at Monash University and an experienced haematologist with specialist expertise in transfusion medicine. Professor Wood has ongoing participation in research related to transfusion medicine and will provide clinical input for the NTD including data analysis and interpretation, preparation of presentations, reports or manuscripts for publication, and as a member of the ANZ-MTR Steering Committee.

Professor Peter Cameron: MBBS MD FACEM

> Professor Peter Cameron is the Divisional Head of Health Services Research at the School of Public Health and Preventive Medicine (SPHPM), Monash University and Monash Academic Partners theme lead for critical care which undertakes research in the areas of pre-hospital, emergency and trauma, transfusion, intensive care and peri-operative medicine. He is also Academic Director of the Emergency and Trauma Centre, The Alfred Hospital, Principal Investigator on the Victorian State Trauma Registry, Custodian and co-academic Lead of the Australian Trauma Registry, Academic Director of the National Trauma Research Institute, and is a member of the ANZ-MTR Steering Committee. Professor Cameron will provide clinical guidance to the TD, will be the TD Local Site Investigator for The Alfred Hospital, as the first pilot site of the TD.

NTD Investigators are listed in *Appendix 4*.

17. National Australian Transfusion Dataset contact details

National Australian Transfusion Dataset Team:

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Appendix 1 National Transfusion Dataset Collated Data Set

Data items to be obtained from Hospital Information Services (HIS)

Important: The National Transfusion Dataset endeavours to capture data for not just the episode of care in which the transfusion took place but also the data for the patient's entire hospital admission (i.e. from the time the patient is first admitted to hospital until the time they are discharged home, transferred to another facility or died in-hospital).

Please note: For patient's that are 'statistically discharged' (i.e. have a type change of care), we require all episode of care data until the patient is formally discharged.

DATA VARIABLE	DATA FIELD	VARIABLE DESCRIPTION
HOSPITAL#	Facility Identifier	Name of hospital
MRN#	Medical Record Number	Patient Identifier
NAME#	Surname, First Name	Patients full name
DATE_OF_BIRTH#	Date of Birth	Patients date of birth
SEX#	Gender	Sex of the patient
ADM_EPISODE_ID	Admitted Episode Number	Patients admitted episode of care number (i.e. Stay_Number or Encounter_ID)
EPISODE_SEQ	Episode Sequence Number	A sequential number to distinguish two or more admitted episodes of care linked by the occurrence of a statistical discharge
ADMDATE	Date of Hospital Admission	Formal Date of overall Hospital Admission
ADMTIME	Time Hospital Admission	Formal Time of overall Hospital Admission
EPISODE_STARTDATE	Date of Episode of Care Admission	Date on which the admitted patient commenced the episode of care occurring within a hospital stay
EPISODE_STARTTIME	Time of Episode of Care Admission	Time at which a patient commenced the episode of care occurring within a hospital stay
EPISODE_ENDDATE	Completion Date of Episode of Care	Date on which an admitted patient completes an episode of care
EPISODE_ENDTIME	Completion Time of Episode of Care	Time at which an admitted patient completes an episode of care
SEPDATE	Date of Death or Discharge	End Date of overall Hospital Admission
SEPTIME	Time of Death or Discharge	End Time of overall Hospital Admission
ADMTRANS	Name of transferring Hospital	Name of Hospital from which the patient was transferred from
ADMTYPE	Admission Type	Urgency of admission i.e. Emergency, Planned/Non-Emergency, Maternity etc.
SEPACCOM	Discharge Unit	Accommodation occupied by the patient on their last day of care

[1]*NHMRC/ASBT Patient Blood Management Guidelines: Module 1 – Critical Bleeding/Massive Transfusion*

Data items to be obtained from Hospital Information Services (HIS) continued

DATA VARIABLE	DATA FIELD	VARIABLE DESCRIPTION
SEPMODE	Patient Status at Discharge	Type of Separation i.e. Death, Separation to private residence/accommodation, Separation and transfer to aged care, Separation and transfer to other acute hospital/rehabilitation, Statistical discharge (type change of care)
SEPTRANS	Transfer destination	Name of hospital the patient is transferred after separation from the current hospital
HOSP_LOS	Hospital Length of Stay (hrs)	Hospital Length of Stay (hrs)
ICU_LOS	ICU Length of Stay (hrs)	ICU Length of Stay (hrs)
VENT_TIME	Ventilation Time	Total duration of Mechanical Ventilation (MV) in hours provided in an approved intensive Care Unit (ICU) during this episode of care
CLIN_SPEC	Primary Clinical Specialty	Clinical Specialty i.e. Cardio-thoracic, obstetrics, oncology/Radiology, Haematology
DIAG_PRIORITY_SEQ	Sequence of Diagnoses Codes	A number that denotes the order of priority for each Diagnosis Code.
DIAG_ICD	ALL Diagnoses ICD-10-AM codes	Diagnoses codes including principal diagnosis code (P)ICD-10-AM code
DIAG_DESC	Descriptions of diagnoses Codes	Description of diagnoses codes
DIAG_TYPE	Qualifier for each ICD-10-AM code	Qualifier for each ICD-10-AM code which indicates whether that particular code is for a principal or other diagnosis, procedure, external cause or morphology
COND_ONSET_FLAG	Condition Onset Flag	Indicates the presence of a condition (diagnosis) on admission to an episode of care.
PROC_PRIORITY_SEQ	Sequence of Procedure Codes	A number that denotes the order of priority for each Procedure code.
PROC_ICD	ALL Procedure ACHI codes	Procedure codes including principal procedure
PROC_DESC	Descriptions of procedure codes	Description of procedure codes
PROC_DATE	Procedure dates	Date/time for all procedures
ARDRG	AR-DRG	Determined based on ICD-10-AM codes
DRGTYPE	DRG Type	A code, indicating whether an AR DRG is a medical, surgical or other type of DRG

Data items used as patient identifiers

LABORATORY RESULTS DATA ITEMS: Data items to be obtained from Hospital Pathology IT (Laboratory Information Services)

HOSPITAL#
MRN#
NAME#
DATE_OF_BIRTH#
SEX#

TEST GROUP	TEST_DATE	TEST_TIME	VALUE
[MULTIPLE] BLOOD GASES GROUP *p*O2 *p*CO2 pH H Ion conc Calculated Bicarbonate Sodium potassium chloride Anion gap Measured ionised Ca Base Deficit (or excess)			
[MULTIPLE] COAGULATION GROUP INR Prothrombin time APTT Fibrinogen level D-Dimer (*if available*)			
FBE (FULL BLOOD EXAMINATION) Haemoglobin White Blood Cell Count Platelet Count Red Blood Cell Count Haematocrit MCV MCHC			
TEST GROUP, continued	**TEST_DATE**	**TEST_TIME**	**VALUE**

U+E GROUP (UREA & ELECTROLYTES) Sodium Potassium Chloride Bicarbonate Urea Creatinine			
LFT GROUP (LIVER FUNCTION TEST) Bilirubin ALP ALT GT, gamma Albumin Protein Total			
[MULTIPLE] CHEMISTRY Lactate (mmol/L) eGRF (estimated Glomerular Filtration Rate)			
BLOOD GROUP & ANTIBODY SCREEN ABO / Rh blood group Antibody screen			

Data items used as patient identifiers

TRANSFUSION RECORD DATA ITEMS

Data items to be obtained from LIS/Hospital Blood Bank database

DATA VARIABLES	VARIABLE DESCRIPTION
HOSPITAL#	Hospital name
MRN#	Patient Medical Reference Number
NAME#	Patient Name
DATE_OF_BIRTH#	Patient DOB
SEX#	Patient Gender
UNIQUE_PRODUCT_ID	Product lot number
PRODUCT_TYPE_DESCRIPTION	Type of product: **Packed RBC, Platelets, Fresh Frozen Plasma, Cryoprecipitate, IVIg, Prothrombinex, Fibrinogen Concentrate (RiaSTAP), rFVIIa (NovoSeven)**
PRODUCT_NUMBER	Donation number
PRODUCT_EXPIRY_DATE	Expiry date of product
BLOOD_GROUP	Unit ABO & RhD
PRODUCT_EVENT	Only data for products transfused or issued (and not returned) to be extracted
QUANTITY	Number of units or volume issued
DISPENSE_LOCATION	Place issued i.e. ward, theatre, ICU
PRODUCT_EVENT_ISSUE_DATE	Date Issued
PRODUCT_EVENT_ISSUE_TIME	Time Issued
AGE_OF_BLOOD	The age of the blood issued

Data items used as patient identifiers

Appendix 2 ANZ-MTR Sites

Sites with ethics approval to contribute to the ANZ-MTR	
Flinders Medical Centre, SA	Fremantle Hospital, WA
Barwon Health (University Hospital Geelong), VIC	Prince of Wales Hospital, NSW
Royal Adelaide Hospital, SA	Royal Prince Alfred Hospital, NSW
Alfred Hospital, VIC	Auckland City Hospital, NZ
Austin Health, VIC	Christchurch Hospital, NZ
Concord Hospital, NSW	*Dunedin Hospital, NZ
Fiona Stanley Hospital, WA	Gold Coast Hospital and Health Service, QLD
Goulburn Valley Health, Vic	King Edward Memorial Hospital, WA
Liverpool Hospital, NSW	Mercy Hospital for Women, VIC
Middlemore Hospital, NZ	Nambour General Hospital, QLD
North Shore Hospital, NZ	Prince Charles Hospital, QLD
Princess Alexandra Hospital, QLD	Royal Brisbane and Women's Hospital, QLD
Royal Hospital for Women, NSW	Royal Perth Hospital, WA
Sir Charles Gairdner Hospital, WA	St George Hospital, NSW
St John of God, Ballarat, VIC	St John of God, Geelong, VIC
St John of God, Subiaco, WA	St Vincent's Hospital, NSW
Sutherland Hospital, NSW	Waikato Hospital, NZ
Wellington Hospital, NZ	West Moreton Hospital & Health Service, QLD (Ipswich)
Wimmera Base Hospital, VIC	Women's and Children's Hospital, SA
Barossa Hills Fleurieu Local Health Network, SA	Eyre and Far North Local Health Network, SA
Flinders and Upper North Local Health Network,SA	Limestone Coast Local Health Network, SA
Riverland Mallee Coorong Local Health Network, SA	Yorke and Northern Local Health Network, SA
Bendigo Health Service, VIC	
Northern Hospital, VIC	St John of God Hospital, Bunbury, WA
Cabrini Hospital, VIC	St John of God Hospital, Geraldton, WA
Eastern Health (Box Hill), VIC	St John of God Hospital, Midland, WA
Peter MacCallum Cancer Centre, VIC	St John of God Hospital, Murdoch, WA
Royal Melbourne Hospital, VIC	Mackay Hospital and Health Service, QLD
St John of God Hospital, Bendigo, VIC	Sunshine Coast University Hospital, QLD
St John of God Hospital, Berwick, VIC	Townsville Hospital and Health Service, QLD
St John of God Hospital, Warrnambool, VIC	Launceston General Hospital, TAS
Westmead Hospital, NSW	*Orange Hospital, NSW

* Sites which have approached the MTR requesting to join. Governance approval required/in progress.

Appendix 2 TD Sites

Pilot Sites for ethics approval under the NMA
Alfred Hospital, VIC
Flinders Medical Centre, SA
Wimmera Base Hospital, VIC
Monash Medical Centre, VIC

Proposed sites for future expansion phase of TD project (current ANZ-MTR sites)	
Auckland City Hospital, NZ	Royal Brisbane and Women's Hospital, QLD
Austin Health, VIC	Royal Hospital for Women, NSW
Barwon Health (University Hospital Geelong), VIC	Royal Melbourne Hospital, VIC
Cabrini Hospital, VIC	Royal Perth Hospital, WA
Christchurch Hospital, NZ	Royal Prince Alfred Hospital, NSW
Concord Hospital, NSW	St George Hospital, NSW
Country Health SA, SA	St John of God, Ballarat, VIC
Dunedin Hospital, NZ	St John of God Hospital, Bendigo, VIC
Eastern Health (Box Hill), VIC	St John of God Hospital, Berwick, VIC
Fiona Stanley Hospital, WA	St John of God Hospital, Bunbury, WA
Fremantle Hospital, WA	St John of God, Geelong, VIC
Gold Coast Hospital and Health Service, QLD	St John of God Hospital, Geraldton, WA
Goulburn Valley Health, Vic	St John of God Hospital, Midland, WA
King Edward Memorial Hospital, WA	St John of God Hospital, Murdoch, WA
Liverpool Hospital, NSW	St John of God, Subiaco, WA
Mercy Hospital for Women, VIC	St John of God Hospital, Warrnambool, VIC
Middlemore Hospital, NZ	St Vincent's Hospital, NSW
Nambour General Hospital, QLD	Sir Charles Gairdner Hospital, WA
North Shore Hospital, NZ	Sunshine Coast University Hospital, QLD
Peter MacCallum Cancer Centre, VIC	Sutherland Hospital, NSW
Prince Charles Hospital, QLD	Waikato Hospital, NZ
Prince of Wales Hospital, NSW	Wellington Hospital, NZ
Princess Alexandra Hospital, QLD	West Moreton Hospital & Health Service, QLD (Ipswich)
Royal Adelaide Hospital, SA	Women's and Children's Hospital, SA

Appendix 3

ANZ-MTR Investigators

A/Prof Zoe McQuilten, Senior Research Fellow

A/Prof Rosemary Sparrow, Senior Research Fellow

Dr Cameron Wellard, Data Manager

Helen Haysom, Project Officer

Neil Waters, Senior Project Manager

TD Investigators, DEPM, Monash University

Professor Peter Cameron, Chief Investigator

Professor Erica Wood, Chief Investigator

A/Prof Zoe McQuilten, Senior Research Fellow

A/Prof Rosemary Sparrow, Senior Research Fellow

Dr Cameron Wellard, Data Manager

Helen Haysom, Project Officer

Neil Waters, Senior Project Manager

Appendix 4 ANZ-MTR Steering Committee Members

ANZ-MTR Steering Committee 2018

Member	Affiliation
Prof James Isbister, Chair	Royal North Shore Hospital & University of Sydney, NSW
Dr Krishna Badami	New Zealand Blood Service, NZ
Ms Linley Bielby	Australian Red Cross Blood Service & Department of Health and Human Services, VIC
Ms Karen Botting	Department of Health and Human Services, VIC
Dr Sebastian DiNatale	CSL Behring Pty Ltd, VIC
Ms Jennifer Roberts	National Blood Authority, ACT
A/Prof Larry McNicol	Austin Health, VIC
Dr Claire McLintock	Auckland City Hospital, NZ
Dr Craig French	Western Hospital, VIC
A/Prof David Roxby	SA Pathology, SA
Prof Peter Cameron	DEPM, Monash University & Alfred Health, VIC
Prof Jamie Cooper	DEPM, Monash University & Alfred Health, VIC
Dr James Daly	Australian Red Cross Blood Service
A/Prof Nolan McDonnell	King Edward Memorial Hospital, WA
Dr Kerry Gunn	Auckland City Hospital, NZ
Prof Euan Wallace	Monash Medical Centre, VIC
Prof Erica Wood	DEPM Monash University, Monash Medical Centre, VIC
A/Prof Zoe McQuilten	DEPM Monash University, Monash Medical Centre, VIC
A/Prof Rosemary Sparrow	DEPM Monash University, VIC
Mr Neil Waters	DEPM Monash University, VIC
Ms Helen Haysom	DEPM Monash University, VIC
Dr Cameron Wellard	DEPM Monash University, VIC

Appendix 5 ANZ-MTR ethics approved documents

Document	*Version*	*Date*
Project Outline	2.0	16-May-2018
Data Management Policy and Procedures	2.1	20-Mar-2018
Data Access and Publications Policy	1.0	23-Apr-2018
Data Management Policy and Procedures	2.1	20-Mar-2018
Patient Recruitment and Data Extraction Processes (LIS)	1.4	23-Apr-2018
Patient Recruitment and Data Extraction Processes (HIS)	1.3	23-Apr-2018
File Transfer SOP	1.0	22-Oct-2012
Introductory information about hospital data collection	1.1	23-Apr-2018
ANZ-MTR Summary	1.1	19-Apr-2018
NSW privacy form	-	23-Apr-2018
WA Specific Module	-	23-Apr-2018

Appendix 5 Transfusion Database ethics approved documents

Document	*Version*	*Date*
Project Outline	1.0	25-Jun-2018
Data Management Policy and Procedures	1.0	25-Jun-2018
Data Access and Publications Policy	1.0	25-Jun-2018
Case Identification and Data Extraction Processes (SOP for Blood Bank & LIS)	1.0	25-Jun-2018
Case Identification and Data Extraction Processes (SOP for HIS)	1.0	25-Jun-2018
File Transfer SOP	1.0	22-Oct-2012
Project Summary	1.0	25-Jun-2018
NSW privacy form	-	25-Jun-2018
WA Specific Module (signed 19-Jun-2018)	-	25-Jun-2018
Budget	-	25-Jun-2018

History of changes to ANZ-MTR Project Outline

Version	Date	Author	Summary of Revisions
1.0	05/05/11	Dr Amanda Zatta Dr Louise Phillips	Project Outline created
1.0	28/06/11	Dr Amanda Zatta	Project Outline finalised and locked (pdf version)
1.1	25/7/2012	Dr Amanda Zatta Ms Naomi Aoki	Updated to include change of staff, changes to the data transfer policy, rewording of Ethics and to include New Zealand involvement
1.2	25/10/2013	Ms Naomi Aoki	Update to staff and steering committee and acknowledgement of other contributing data sources. No changes to the project protocol have been made.
1.3	26/11/2015	Ms Tania Richter	Update to steering committee, funding and inclusion of clinical costing data to types of data collected. Updates to contact details and supporting department titles.
2.0	23/04/2018	Dr Rosemary Sparrow Ms Helen Haysom	Full revision.
2.0	16/5/2018	Dr Rosemary Sparrow Ms Helen Haysom	Addition of further clarification as to why an 'opt off' strategy or distribution of an explanatory statement to patients at time of treatment or discharge is impractical.
3.0	6/5/2021	Ms Helen Haysom	Addition of TD Pilot Project to ANZ-MTR project and re-naming of project to National Transfusion Dataset

History of changes to TD Project Outline

Version	Date	Author	Summary of Revisions
1.0	25/06/11	Dr Rosemary Sparrow Ms Helen Haysom	Project Outline created