PROJECT TITLE: The Australian and New Zealand Collaborative Perfusion Registry (ANZCPR)

A collaborative project to promote the reporting and understanding of the effect of cardiopulmonary bypass on patient outcomes through encouraging evidence based practices, quality assurance, quality improvement and research by maintaining a prospective registry of Cardiac Surgical Procedures performed in centres throughout Australia and New Zealand.

PROTOCOL: Protocol Version 1.4; dated 08 January 2016

Previous Versions: *Version 1.0; dated 12 May 2009*

Version 1.1; dated 03 September 2012

Version 1.2; dated 24 November 2014

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The Australian and New Zealand Collaborative Perfusion Registry is a Quality Improvement Initiative.

Australian New Zealand Clinical Trials Registry Number: ACTRN12614000832673

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AGREEMENT

This document is confidential. The Investigators declare that they have read the final study protocol and any amendments. The Investigators will conduct the study according to the procedures specified in the study protocol, and in accordance with ICH GCP notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA comments and NH&MRC National Statement on Ethical Conduct in Research Involving Humans.

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INVESTIGATOR DATE

CONTENTS:

PROTOCOL SUMMARY/SYNOPSIS

The Australian and New Zealand Collaborative Perfusion Registry (ANZCPR)

Quality Perfusion through Reporting

A collaborative project conducted by the Perfusion Downunder Collaboration (PDUC) to improve patient outcomes and foster and grow high quality research by establishing and maintaining a prospective database of Cardiac Surgical Procedures performed in centres throughout Australia and New Zealand.

Aims of the Project:

1. To cultivate and grow a non-identifiable data source to be known as the Australian and New Zealand Collaborative Perfusion Registry (ANZCPR).
2. To encourage adoption of evidence based practices through the collection and reporting of data relevant to the practice of cardiopulmonary bypass.
3. To empower cardiac surgical team members through the utilisation of the data to understand clinical practice, provide a foundation for research, and to facilitate quality improvement and benchmarking.

Vision:

Empower all cardiac surgery team members to improve the understanding and practice of cardiopulmonary bypass to improve cardiac surgical patient outcomes.

Mission:

Maintain and develop the Australian and New Zealand Collaborative Perfusion Registry for cardiac surgical procedures performed throughout Australia and New Zealand.

Promote the reporting and understanding of the effect of cardiopulmonary bypass on patient outcomes through encouraging evidence based practices, quality assurance, quality improvement and research.

Objectives:

ANZCPR aims to empower cardiac surgical team members through the collection and reporting of data relevant to the practice of cardiopulmonary bypass. This will be achieved through the maintenance of a prospective data set on cardiac surgical procedures performed in multiple sites throughout Australia and New Zealand and through the collaborative network of perfusion and interested researchers, who share the commitment to cooperation and collaboration in the pursuit of excellence in perfusion.

The ANZCPR aims to improve patient outcomes through its ability to provide research infrastructure and support to the Australian and New Zealand perfusion community, and by its ability to produce relevant and timely research publications.

Patient Population:

All cardiac surgical patients will be invited to participate in the project.

Duration:

Due to the ongoing nature of this project, data collection will be performed and stored indefinitely.

Inclusion/Exclusion Criteria:

All adult patients undergoing cardiac surgical procedures, with or without cardiopulmonary bypass (CPB), will be registered in the database.

Project Design:

The strength of the collaborative data set will be in its availability to all members that will allow them to utilise the data for appropriate research initiatives. The ANZCPR will bring together key data from multiple sites around Australia and New Zealand. Data from remote sites will be gathered, de-identified, and stored at the central database at Flinders Medical Centre (FMC) in a purpose designed and built secure SQL database.

Dataset:

The ANZCPR dataset has been developed to allow the following criteria to be met:

1. A minimum preoperative data set needs to be collected to allow appropriate risk stratification of patients to occur;
2. A perfusion dataset needs to encompass as much detail related to the performance of CPB as is considered able to be collected on an ongoing basis and will include continuous electronic perfusion data;
3. A minimum post-operative data set needs to be collected to allow appropriate outcome measures to be reported

Statistical Considerations and Data Analysis:

Methods of statistical analysis to be used in research activities by groups seeking access to the data stored on ANZCPR will be reviewed by the Steering Committee and the groups local Human Research Ethics Committee. Reports to contributing units will be generated summarising individual unit activities. A non-identified report for all sites is available on request.

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1. INTRODUCTION

The Australian and New Zealand Collaborative Perfusion Registry (ANZCPR) is founded by a group of individuals who, through the creation of a collaborative network of perfusion and interested researchers, share the commitment to cooperation and collaboration in the pursuit of excellence in perfusion. The collaboration is uniquely positioned to promote the establishment of a unique source of information for the Cardiac Surgical (Perfusion) community, and thus meet the following vision and mission statements:

Vision

Empower all cardiac surgery team members to improve the understanding and practice of cardiopulmonary bypass to improve cardiac surgical patient outcomes.

Mission

Maintain and develop the Australian and New Zealand Collaborative Perfusion Registry for cardiac surgical procedures performed throughout Australia and New Zealand.

Promote the reporting and understanding of the effect of cardiopulmonary bypass on patient outcomes through encouraging evidence based practices, quality assurance, quality improvement and research.

2. BACKGROUND

Cardiopulmonary bypass (CPB) plays a vital role in cardiac surgery, providing an extra-corporeal circuit to temporarily replace the function of the “heart” and the “lungs” for patients during procedures including coronary artery bypass graft (CABG) surgery and valve replacement surgery. In Australia between 81%-93.3% of CABG surgery patients undergo CPB (Baker et al., 2005; Dinh et al., 2006). Even though the CPB procedure is performed in 100,000’s of patients annually, and has been used routinely for the past five decades, there are key questions relating to the performance of CPB that have not been clearly defined in the literature.

Successful cardiac surgery requires a team of specialised clinicians (surgeons, anaesthetists, perfusionists, nurses and intensivists) to successfully complete the clinical pathway for the cardiac surgical patient. Research in cardiac surgery has largely overlooked a critical time period of the procedure - the actual time the patient is on bypass. In part, this omission is due to the extreme difficulty of collecting data during that period. The perfusion record details this period and is recorded by the perfusionist during the CPB procedure. Advances in technology have seen this record evolve to be collected electronically, able to be integrated to other data systems, with the ability to be stored in formats that are available for analysis and evaluation for quality control and research initiatives (Newland et al., 2006; Ottens et al., 2005). Individually, units have a wealth of untapped data, and collectively, we can make this an enormous resource of information.

It was therefore determined the most efficient way of bringing these clinical data from multiple sites together was through the use of a purpose dedicated perfusion database. With current computer technology, data could be easily collected, processed, stored, retrieved and analysed. Pace and

Staton (2005) recognised that electronic data collection and processing improved the quality of the data and the process itself, decreases cost, eliminated secondary data entry, and allowed the effective and efficient conduct of research. Clinical databases have a number of advantages, however many perfusion departments have not embraced databases that relate clinical, perfusion and outcome data. Advantages include the ability to generate large samples rapidly from high numbers of participating centres; the opportunity to study rare conditions and interventions; the provision of accurate information for clinical practice, audit and administration; the relative low cost for each study as the expense of data collection is spread over a range of research studies and other applications; the wide ownership and high generalisability of results through the participation of many centres; and the capability to allow easy and timely access to a considerable amount of data (Black, 1997; Black, 1999; Dziuban, 1999; Russek et al., 1997). The Australia and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) has recognised the importance of data collection and has developed a comprehensive cardiac surgical database. The ANZSCTS database collects in excess of 260 variables, however only 4 of these variables relate to CPB.

The ANZCPR collaboration (previously known as the Perfusion Downunder Collaboration (PDUC)), evolved from the successful Perfusion Downunder (PDU) organisation which was established in 2005. The objectives of PDU were summarised in their mission statement, “to promote original prospective research into the effects of perfusion management on patient outcomes and so validate perfusion practices and interventions throughout Australia and New Zealand". This is being achieved through a meeting of scientific rigour that engages a faculty of excellence with objectives that meet those of the mission statement. The long term objective is to continue to grow perfusionist generated research initiatives, and to seek scientific based consensus on various perfusion strategies. An overriding objective is to foster networking both scientifically and personally within the perfusion profession. The ANZCPR collaboration is an associated entity with the Australian and New Zealand College of Perfusion, and the PDU organisation which is sponsored by Cellplex Pty Ltd. The ANZCPR is governed by a clinical steering committee independent of the sponsor.

The data management designed for the ANZCPR has overcome many limitations, such as the inability to access raw data, and for the first time permits appropriate management of perfusion data from a wide range of proprietary perfusion data systems. For example, the ANZCPR data set is able to accurately quantify the perfusion pressure during CPB. The primary focus of the ANZCPR initiative is to create a comprehensive perfusion focussed registry that will provide the opportunity to evaluate relationships between CPB practice and risk adjusted outcomes using a large multi-centre dataset. In recognition of the value of the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) database, where possible, complementary definitions of overlapping variables have been incorporated. It is hoped that the value of the ANZCPR will be recognised and collaboration and data sharing may occur in the future. The potential for use of this dataset is enormous, with the use of clinical databases for evaluative research, audit, management and clinical practice being well recognised (Black, 1999; Dziuban, 1999; Black & Payne, 2002; Black, 2003). In evaluative research, clinical databases can be used to formulate hypotheses (as in non-randomised analyses) and to promote randomised trials (Black, 1997; Black, 1999). These are premises upon which we have developed the research strategies associated with the ANZCPR.

3. AIM(S) OF PROJECT

To maintain and develop the Australian and New Zealand Collaborative Perfusion Registry for cardiac surgical procedures performed throughout Australia and New Zealand.

To promote the reporting and understanding of the effect of cardiopulmonary bypass on patient outcomes through encouraging evidence based practices, quality assurance, quality improvement and research.

4. OBJECTIVES

To collect and report data relevant to the practice of cardiopulmonary bypass. This is achieved through utilisation of a prospective data set from cardiac surgical procedures performed in multiple sites throughout Australia and New Zealand to understand clinical practice, provide a foundation for research, and to facilitate quality improvement.

To empower all cardiac surgery team members to improve the understanding and practice of cardiopulmonary bypass to optimise patient outcomes.

5. PROJECT DESIGN

The strength of the collaborative data set is in its availability to all members allowing them to utilise the data for appropriate research initiatives. The ANZCPR brings together key data from multiple sites around Australia and New Zealand. Data from remote sites is gathered, de-identified, and stored at the central database at Flinders Medical Centre (FMC) in a secure SQL database.

Dataset

The ANZCPR dataset has been developed to allow the following criteria to be met:

1. A preoperative data set is collected to allow appropriate risk stratification of patients to occur
2. A perfusion dataset encompasses as much detail related to the performance of CPB as is considered able and is collected on an ongoing basis and includes continuous electronic perfusion data
3. A post-operative data set is collected to allow appropriate outcome measures to be reported.

The ANZCPR data set was originally drafted by the Steering Committee and incorporated input from attendees at the 2006 Perfusion Downunder Collaboration (PDUC) Winter Meeting (August 2006, Queenstown, NZ). Since that time, the data set has been revised as required with input from participating sites and attendees at the ANZCPR collaboration (previously PDUC) sessions held as part of the annual ANZCPR Winter Meetings. This process has allowed interested perfusionists, surgeons, anaesthetists, intensivists and epidemiologists to participate in the development of the data set.

The data set contains:

1. A demographic data set
2. A preoperative data set to allow appropriate risk stratification of patients
3. A procedural data set to define the surgical procedure(s) for each patient
4. A perfusion data set, designed to encompass as much detail related to the conduct of CPB as is considered able to be collected in a sustainable and ongoing manner.
5. A post-operative data set to allow appropriate outcome measurements to be reported
6. Electronic perfusion data from the heart-lung machine (HLM) data management system (continuous variables such as blood flow; pressure; temperature; etc.)

Data Collection

The local site database has been developed in Microsoft Access to facilitate data collection and comprises three database files: a data entry interface (provides data entry and reporting functions), a separate database to store the institutional data, and a transfer database. The transfer database uses specialised queries and Visual Basic code to import data from commercial perfusion data management systems (currently the Stockert DMS, Sorin CONNECT and Maquet JOCAP Data Management Systems are supported). All database functionality has been built using Microsoft Access objects. The database is able to accept the direct transfer of electronic data from the heart lung machine.

Australian and New Zealand Collaborative Perfusion Registry Members and Responsibilities

Steering Committee

A Steering Committee has been established to achieve the administrative and governance roles of the ANZCPR including administration of research projects and data requests, ensuring ethics requirements are met, reporting, and maintaining sustainability.

Site Co-ordinator

Each centre contributing data to the dataset will have a nominated perfusionist/interested clinician who will act as site co-ordinator.

The site co-ordinator must:

- ensure that all staff collecting data for the registry are appropriately trained in the collection of the data
- submit the study protocol to the appropriate Ethics or Clinical Governance Committee as appropriate and obtain approval prior to commencing data collection
- ensure that all staff involved with the collaboration are fully instructed on the goals of the collaboration
- ensure that the data collection is complete and accurate on completion of data entry
- ensure that the quality control procedures are performed on data collection processes

Member

Each member must ensure that:

- they are fully aware of the goals of the collaboration
- the data collection sheets/screens are complete and accurate on completion of data entry

Collecting the Data

Complete datasets will be collected from all procedures involving Cardiopulmonary Bypass (CPB). Basic procedural data will be collected on cases without CPB to allow the denominator to be defined at participating sites.

Exporting the Data

The overall process will be as follows:

1. User initially enters individual case data for the site into the ANZCPR
2. The site's data is stored locally
3. Records will be de-identified and exported as text files which are sent to the central ANZCPR Database Administrator
4. Non-identifiable data will be imported into the ANZCPR. Previously data harvesting has been annually – in future it will occur at 6 month intervals

Storing the Data

The destination table of the local ANZCPR on the SQL Server at FMC will contain only non-identifiable data; records will simply be identified with an auto number.

Data Access

Data will only be available via password protected processes, and made available only for ethically rigorous enquiries.

Data Ownership

Non-identified data and intellectual property associated with the ANZCPR is owned by the ANZCPR Steering Committee. Individual site data remains the property of each contributing site.

6. PROJECT SETTING

Sites with an Existing Database

The ANZCPR dataset will be compared with the local dataset and data definition dictionary will be used to assess local data sets and to determine what areas may need to be addressed. All data definitions will be consistent with the ANZSCTS National Database where variables overlap between the datasets. The dictionary will allow the identification of existing fields and any constraints and codes

relating to those fields. If an existing database is going to be used, then the ability to add new fields to the database will need to be assessed. Data from the existing database will be transferred to the local ANZCPR where data quality will be monitored, de-identified and permanent local storage will occur and transmission to the data centre initiated.

Sites without an Existing Database

A purpose built Access database for gathering the data will be supplied to sites without an existing database. The local ANZCPR will be basic, robust and straightforward, to minimise both system and user error, thus minimising the reliance on IT support or training on-site. Support during initial installation will be available. All sites will have exactly the same database in terms of the fields collected. It may occasionally be necessary to tailor interfaces to suit a particular environment; however, the default database model would include a front-end (which could be copied onto multiple machines) and a "tables" back-end, which would accommodate multiple users from multiple machines. The local ANZCPR will include a function for automatically exporting non-identifiable data.

Responsibility of Remote Sites

It will be the responsibility of the remote sites to:

- Ensure that any data they send is complete and valid.
- Each site will nominate one person to take responsibility for liaising with the ANZCPR data centre (a site co-ordinator) for sending the data, setting up the database, implementing any changes, informing of changes, attending to troubleshooting, etc.

7. DURATION

Due to the ongoing nature of this project, data collection will be performed and stored indefinitely.

8. POPULATION

All cardiac surgical patients will be invited to participate in the project.

The ANZCPR holds data from over 25,000 patients and it is predicted that from all participating sites that approximately 5,500 per year will be added to the database. Recruitment will continue indefinitely.

9. ELIGIBILITY CRITERIA

9A. INCLUSION CRITERIA

All adult patients undergoing cardiac surgical procedures, with or without CPB, will be included in the registry. A full data set will only be collected on patients who undergo surgical procedure with CPB.

9B. EXCLUSION CRITERIA

Male or females under the age of 18 years

9C. WITHDRAWAL CRITERIA

Only patients scheduled for cardiac surgery, entered into the registry and subsequently having their procedure abandoned will be withdrawn from the registry.

10. PROJECT PROCEDURES

10A. CONSENT PROCESS

The ANZCPR is working towards instigating at all sites the provision of a Patient Information Sheet with the option to 'Opt-Out' of the registry should a patient so desire. This is so the ANZCPR can meet the "Australian Commission on Safety and Quality in Healthcare Operating Principles for Australian Clinical Quality Registries" recommendations, and the new updated (since March 2014) NHMRC National Statement on Ethical Conduct in Research Involving Humans (2007). Currently each site meets their local Ethics Committee's recommendations, where all sites have been granted waiver of consent for this research project under the "Waiver Conditions for Consent" guidelines in the NHMRC National Statement on Ethical Conduct in Research Involving Humans.

Data collected will be non-identifiable in the multi-centre database, having been fully de-identified, thus protecting the privacy of the participants.

Non-identifiable data in the central ANZCPR will only be made available to ethically rigorous enquiries by research groups and only non-identified data will be provided to these research groups. The research team is familiar with the requirements of the NHMRC National Statement on Ethical Conduct in Research Involving Humans and the ICH GCP Guidelines and will conduct this project according to the statement and guidelines requirements.

10B. PARTICIPANTS

Procedures involving the participant:

Participants will undergo routine clinical management in all cases. Data currently routinely collected for each patient will be transferred to the local ANZCPR.

Assessment of Participants:

Clinical Assessment:

Participants will undergo routine clinical assessment in all cases.

Laboratory Assessment:

Routine laboratory assessment will be performed in all cases.

10C. SAFETY CONSIDERATIONS/PATIENT SAFETY

Monitoring adverse effects (e.g. emotional, psychological and physical):

The quality of the data will be monitored, de-identified and permanent local storage will occur and transmission to the data centre initiated. No adverse effects are anticipated as this project only involves the collection of data already routinely collected by existing methods.

10D. DATA MONITORING

Maintenance of Records:

Data collected for this project will only be accessed by the member of the project research team, the nominated perfusionist who will be the site-coordinator, and the ANZCPR data managers.

Data is stored in the password protected local and central ANZCPR. Data that is sent to the ANZCPR will only contain non-identifiable data - records are simply identified by an auto number. Data is only available via password protected processes, and made available only for ethically rigorous enquiries.

Data in the ANZCPR is stored indefinitely and no long term storage of data in paper form occurs. In the event that the Principal Investigator ceases to be engaged at the current organisation, the information collected for, used in, or generated by this project will continue to be managed by the ANZCPR collaboration and stored in the secure ANZCPR.

11. STATISTICAL CONSIDERATIONS AND DATA ANALYSIS

Methods of statistical analysis to be used in research activities by groups seeking access to the data stored on ANZCPR will be reviewed by the Steering Committee and the groups local Human Research Ethics Committee. Reports to contributing units will be generated summarising individual unit activities. A non-identified report for each site individually or collectively is currently available on request.

12. ETHICAL CONSIDERATIONS

Anticipated Benefits

ANZCPR aims to improve patient outcomes through its ability to provide research infrastructure and support to the Australian and New Zealand perfusion community, and by its ability to produce relevant and timely research publications.

This research may have benefits for the wider community by being able to improve outcomes in cardiac surgery. It is not expected that this research will have direct benefit for participants.

Risks of Any Harm *(physical disturbance, discomfort, anxiety or pain, and potential for damage to reputation or relationships)*

Patients who participate in this registry will not be exposed to any additional risk or burden as a result of this project. Standard institutional practice will be followed in all matters in relation to the patient.

Research Involving Dependent Relationships *(includes patients of the researcher, staff, students, children, mentally ill, intellectually impaired)*

Participants of this project may be patients of the investigators. The investigators, as well as other surgeons, perfusionists, and anaesthetists will not be involved in recruiting participants, although they will be informed that patient data is being collected.

Separation of Research and Clinical Responsibilities

Data collected for the ANZCPR are data already routinely reported, collected or generated by data management systems. All data processing and exporting of de-identified data to the central ANZCPR is performed outside of clinical cases, thereby not interfering with performance of clinical activity.

Source of Payment for Normal Participants:

Participants in the project will receive no payment.

Protection of privacy and preservation of confidentiality:

The process developed to gather data for the ANZCPR allows for data to be imported into a permanently non-identified database without the need for any clinician screening of identified data off site. The identified data is de-identified on site and only de-identified data is sent to the central database. The data file is not viewed during this process and the data screening is performed electronically. All of the data collected is already available (albeit not necessarily collected into one common data file) to clinicians involved in the management of patients.

Restriction of Use of Data:

The information collected about the participants in the database will be used in publications on peer reviewed journals in the key areas identified for the collaboration as well as on additional information derived from the dataset. Data will only be available via password protected processes, and made available only for ethically rigorous enquiries. Perfusionists and other interested clinicians who have submitted appropriate requests to investigate the non-identifiable data set will have access to the data. Annual reports are generated on the data collected. To support the aims of the ANZCPR collaboration, this report is available to all Cardiac Surgery units in the country to enable them, if they wish to, to benchmark there current practice against what will be the largest and only detailed data set on perfusion available in Australia and New Zealand.

Authorship of the principal publications from the group on the key areas identified for the collaboration to address will depend on the leadership group for each study. The information will remain the property of the ANZCPR collaboration investigators. Other publications which describe additional information derived from the dataset must be approved by the ANZCPR Steering Committee and authorship includes those investigators who have participated.

The custodian of the data will be the ANZCPR collaboration and intellectual property generated by this initiative will be owned by the ANZCPR collaboration. A Memorandum of Understanding has been generated to underpin the activity of the ANZCPR with contributing individuals, currently this is managed through individual site ethics applications.

Any other ethical considerations:

Results will not be reported to participants as no benefit would be gained by them by such information. Additionally, the data for evaluation will be non-identifiable and as such the original patient about whom the data results may relate would not be able to be identified.

The participants' interests are a priority over those of science/society and the ANZCPR collaboration will always ensure those interests are safeguarded.

This project will be conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP) and within the laws and regulations of the country in which the research is conducted.

Researcher indemnity/participant injury compensation:

As this project involves the collection of data from routine clinical assessments, there is no anticipated injury that will result from this project.

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- Australian Commission on Safety and Quality in Healthcare: Operating Principles for Australian Clinical Quality Registries: http://www.safetyandquality.gov.au/our-work/information-strategy/clinical-quality-registries/strategic-operating-principles-for-clinical-quality-registries/