ANZVASC-QDR Policies on Data Requests for Quality Assurance and Research

1. Introduction

1.1 The ANZVASC-QDR was founded in 2023 as a resource to improve quality of care and to enable vasculitis research in Australia and New Zealand, and internationally. ANZVASC plays a major role in governing the ANZVASC-QDR and Monash University is the data custodian. ANZVASC encourages participation and collaboration and aims to be an inclusive and fairly governed registry.

1.2 The ANZVASC-QDR encourages use of registry data for audit, quality assurance and for research.

1.3 Individual participating units have access to their unit's own data via the REDCap system using its data access functions.

1.4 For studies that plan to use data from multiple units, data extracts from the ANZVASC-QDR will be made available to units who have contributed to the ANZVASC-QDR for at least one year[1], on reasonable request.

1.5 These policies have been developed to ensure fair and equitable access to data, to encourage and foster collaboration, and to recognise the work of people who established the registry and who are contributing to the registry.

1.6 The procedures and policies outline below will be reviewed periodically and may evolve and change over time.

2. Formation and Membership of the ANZVASC Registry Group

2.1 The ANZVASC-QDR contributors will be known as the ANZVASC Registry Group. It exists to:

- enhance collaboration to improve quality of vasculitis care, promote knowledge gain, research and education
- recognise the effort and time involved in participation in the registry, including in data entry.

2.2 The group and its members should aim to work collaboratively together to further the study of vasculitis in Australia and New Zealand, and internationally, improve quality of care, increase and enhance research and foster education in vasculitis

2.3 The ANZVASC Registry Group will also form the basis of the authorship policy outlined below in Section 5.

2.4 The ANZVASC Registry Group will consist of

a) One member from each contributing unit
b) The Members of the ANZVASC Registry Committee
c) At the discretion of the ANZVASC Registry Committee and ANZVASC Board, one or more clinicians or academics working on the registry at Monash (Health or University), with the principle that such a person would be a regular and key contributor to the registry and its upkeep.

[1] This "one year" policy comes into effect one year after the first patient's data has been entered into the ANZVASC-QDR e.g., if the first patient's data entered in 1 Aug 2023, the policy comes into effect on 1 Aug 2024.

3. General Principles and approach to registry data access and publications

3.1. Ethics consultation and approval is usually required for research work. The contact local site co-ordinator (as a member of ANZVASC) is responsible for ensuring that any required ethics approvals are in place. The requirement for ethics committee approval will depend on the nature of the project. For multi-unit/centre studies, ethics approval will be required. For clinical audits or similar quality related projects based on a single unit's data, formal ethics committee approval may not be required. Formal ethics approval and oversight is obligatory in data linkage studies. If requiring clarity, the requestor should seek advice from their local health research ethics committee(s).

3.2. Data access requests will be considered only from ANZVASC members associated with a unit that is participating in the ANZVASC-QDR, and that has enrolled new patients in the last 12 months

3.3. Involvement of a New Zealand ANZVASC-QDR contributor is required in requests for release of New Zealand individual line data. Consultation with Māori may be required for data that includes Māori participants.

3.4. In most situations de-identified data only is provided to ANZVASC-QDR contributors using the reporting function of REDCap. Units have access, via REDCAP, to their own identifiable data. Other situations may exist, where there is ethics committee approval specifically for release of identifiable data, particularly for data linkage.

3.5. Individual line data will not be released to pharmaceutical companies or other commercial entities. If requests are received and approved by the ANZVASC board and Registry Group, these analyses will be funded by the company/entity and performed within the Registry.

3.6. Data released is approved only for use in the project requested by the member. Further use for other projects requires further approval.

3.7. Data should be analysed and prepared for publication in a timely manner.

3.8. ANZVASC will keep and show on its website a list of approved data requests in the form of the requestor's name and title of the request and date of approval, once approved. ANZVASC does not take responsibility for any errors in the data provided.

2.9. The ANZVASC-QDR must be appropriately acknowledged in reports and publications.

3.10. To ensure adequate recognition of the ANZVASC-QDR, the ANZVASC Quality and Disease Registry itself and the members of the registry group should be acknowledged in publications using data from the registry as specified in 4.1 and 4.2 below.

3.11. For projects where registry data has been derived from more than one unit, the ANZVASC members who have made the most substantive contributions to the registry's establishment will be involved as co-authors to assist and advise on the project.

4. Procedure for Data Requests from the ANZVASC-QDR

4.1. Research or quality assurance projects involving the use of data from a single site

A simple form will be provided so that the unit can provide the following details to ANZVASC: site, title of study, anticipated date of completion of study, whether the study is a quality assurance or research study, and confirmation that any relevant HREC approval has been obtained.

4.2 Research or quality assurance projects involving the use of data from more than one site

This includes request for data from the registry as a whole.

1. Data or research project requests are submitted received through the designated ANZVASC registry email address. Details are entered into an Excel spreadsheet set up for this purpose with documents relevant to each request being stored in a separate folder.
2. The Initial assessment of the request will consider:
    - Is the request from an ANZVASC member who is an ANZVASC-QDR contributor with REDCap access?
    - Has the requestor's unit been contributing to the ANZVASC-QDR for more than 12 months?
    - Is the requestor's unit currently active in recruiting patients to the ANZVASC-QDR (in the last 12 months)?
    - Are there any similar requests recorded in the spreadsheet?
    - Is the project scientifically valid?
    - Is ethics approval required prior to the release of data?
    - Is data linkage or identified data being requested? Data linkage increases the complexity and costs of the project and it would be suggested that the researcher consider working explicitly with ANZVASC to link the complete dataset.
3. The request will be reviewed by the ANZVASC Registry Committee or nominated members of the committee approved by the ANZVASC Board within 3 months, but ordinarily earlier under most circumstances.
4. If a proposal is approved, data will be extracted from REDCap, when possible, after discussion with the requestor, recognising that the nature of the request and that resource constraints in the registry may result in delays.
5. Data will in most cases be made available using the secure REDCap reporting function. Recipients of reports are members of a contributing healthcare organisation. They are responsible for the security of the data and must take all steps to ensure any data is kept confidential and secure.
6. If a concurrent or immediately subsequent request is received for a similar project, it is ANZVASC's policy to strongly encourage collaboration. In the event of overlapping requests that does not result in a collaboration, data will not be released for the latter request until 12 months from the initial data release.

5. Publication, Acknowledgement and Authorship Policies for Research derived from ANZVASC-QDR data

Copies of final draft publications or abstracts should be made available to the Chair of the ANZVASC Registry Committee for approval at least 14 days prior to submission. A member of the committee will endeavour to contact the researcher promptly. ANZVASC Registry Committee approval must be confirmed in writing prior to publication or presentation of the work.

In the event of non-approval, the Chair of the Registry Committee or a nominated member of the committee will liaise with the unit to outline the issues and work to resolve them with the unit.

5.1 Authorship on Publications using data from a single unit

The ANZVASC Quality and Disease Registry must be acknowledged in publications using data from the registry, preferably as an affiliation of one or more named authors (as ANZVASC members), as well as in the acknowledgements section.

5.2 Publications using registry data from more than one centre

1. The ANZVASC Quality and Disease Registry should be listed as an affiliation of one or more named authors on each study
2. To recognise the contributions of all contributing centres to the ANZVASC-QDR, all publications involving data from >1 centre will include, as a named author, one member from each contributing unit, providing that the unit is actively entering data into the registry. Each unit will be responsible for nominating the relevant author for each publication, who must be a current member of ANZVASC.
3. The ANZVASC Registry Group will be listed as an author (e.g., Smith J, Nguyen T and/for the ANZVASC Registry Group) and members of the group (not already named as authors) listed by name in the appropriate section of the journal.
4. Those who have made the most substantive contributions to founding the registry should be recognised in initial publications resulting from access requests submitted prior to Dec 31, 2027. Specifically, Richard Kitching (for all studies), Tze Goh (for any studies using New Zealand data) and Tony Sammel (for any studies involving LVV data). They shall be involved in the work such that they meet ICMJE authorship criteria and are included as named co-authors on any publications derived from the data.

Date of Review

These policies will be reviewed by the ANZVASC Registry Committee and ANZVASC Board by the end of 2025 (or prior to this if the Committee or Board desires).

Acknowledgement

ANZVASC acknowledges ANZDATA for their guidance and being able to adapt some of the ANZDATA policies and principles of data release for ANZVASC's purposes.

Appendix

Example of the application of authorship policy via author list using ANZVASC-QDR data from >1 centre

Title: Large vessel vasculitis in Australia and New Zealand

Authors: Smith J, Nguyen T, Jones PL [authors directly involved in the work: e.g. concept and analysis], [followed by one named author from each contributing unit that recognises data entry, *5.2.2*], Goh T [*5.2.4;* New Zealand data included,], Sammel T [*5.2.4;* LVV focus,], Kitching AR [*5.2.4*], Williams SJ [Senior author on the work] and the ANZVASC Registry Group [*5.2.3*].

The members of the ANZVASC Registry Group are listed at the appropriate place in the journal (typically the end of the paper). In this format, PubMed will pick up the members of the ANZVASC Registry Group as authors. See for example: PEXIVAS https://pubmed.ncbi.nlm.nih.gov/32053298