

VICTORIAN CARDIAC OUTCOMES REGISTRY

Publications Policy

Version 2.0

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Document Version Control

Version	Date	Reason/Comments/Approvals
1.0	26-FEB-2014	Initial Version Release. Approved by the VCOR Steering Committee on 11-MAR-2014.
2.0	1-DEC-2016	Updated section 2.1, 2.2 & 4.1. Approved by the VCOR Steering Committee 7-FEB-2017.

1. Preface

This policy document provides guidelines for the publication of data from the Victorian Cardiac Outcomes Registry (VCOR) dataset and refers to all research outputs. This includes traditional publications such as journal articles, books, chapters and conference papers, as well as web-based publications, multi-media, works of art, performances, presentations, software and compositions, etcetera.

This policy is specific to aggregate, VCOR cohort data. It does not apply to site-specific data collected locally by each participating hospitals. Each site remains the owners of the data they contribute to the VCOR and are free to access, report and publish their own data at any time, provided that, where the Registry is referenced, VCOR is suitably acknowledged in accordance with this policy. VCOR imposes no limitations on the use of local hospital data, except that it complies with HREC conditions and relevant health information privacy legislation.

All publications and research outputs based on aggregate VCOR data must first be approved by the VCOR Data Access, Reports & Publications Committee and/or Principal Investigators and/or Registry Custodian before submission. Relevant acknowledgments and authorship must be recognised as laid out in this policy.

This policy covers all VCOR staff, members of the VCOR committees, the extended VCOR network at participating sites, all other stakeholders, including external individuals requesting access to the VCOR data. Any requests for VCOR data must be made in accordance with the *VCOR Data Access Policy*.

2. Project Information

2.1 Purpose of VCOR

The purpose of the VCOR is to improve the safety and quality of health care provided to patients with cardiovascular disease. Key clinical information from individual healthcare encounters is collected to allow for risk-adjustment of outcomes to facilitate benchmarking of performance and quality improvement in the delivery of health care services. VCOR monitors the safety and quality of care given to patients with cardiovascular disease undergoing specific cardiac procedures or with specific cardiac conditions. Selected risk-adjusted outcomes are reported back to stakeholders. This has been achieved by undertaking a Victoria-wide clinical quality registry: a proven mechanism for data analysis, reporting and benchmarking quality in the provision of health services.

2.2 Project Overview

Monash University in conjunction with the Cardiac Clinical Network and funding from the Victorian Department of Health and Human Services have developed and maintain a secure, online data collection tool and data storage mechanism for analysis and reporting. The success of relevant treatments and procedures performed on patients presenting in Victorian hospitals with cardiovascular symptoms is assessed and reported. This is achieved by capturing data about patient demographics; symptoms; clinical presentation and diagnosis; treatments they receive and related clinical outcomes.

VCOR is designed to collect a minimised, standard set of information from all patients undergoing specific cardiac procedures or treatments at participating hospital sites. The data is gathered using predetermined procedures and standardised definitions and includes collecting patients' identifying information, presenting and treatment details and related clinical outcomes. Data is collected at baseline (time of presentation for procedure), 30 days and potentially 12 months, with the additional potential for ongoing annual follow up in the future. Data is captured electronically in an online data entry system.

Data is stored securely within Monash University servers and retained indefinitely. The project conforms to national operating principles for clinical quality registries (CQRs) as set out by the Australian Commission on Safety and Quality in Health Care (ACSQHC). As such, the governance of the registry is in keeping with these principles. All project matters are governed by the VCOR Steering Committee (SC) by way of liaison with two subcommittees: The Clinical Quality Committee (CQC); and the Data Access, Research & Publications Committee (DRP). Monash University's Centre of Cardiovascular Research and Education in Therapeutics (CCRET) will act as the coordinating data management centre, answering to the Steering Committee. A Clinical Director has been appointed as the Chair of all three committees and site liaison.

Monash University, eSolutions, under the guidance of CCRET is responsible for developing and maintaining the data entry system. CCRET is responsible for performing data quality controls, and reports for providing structured feedback to participating sites. Feed-back is provided quarterly to each participating hospital. Emphasis is on performance relative to other hospitals and performance over continuous reporting periods. An annual report is published yearly.

All hospital data remains the property of that institution. All collective registry data and data management systems operate under the custodianship of Monash University.

3. Use of VCOR data for presentation or publication

Access to VCOR data must first be made in accordance with the *VCOR Data Access Policy*. A caveat and conditions of use statement will be provided with data when applications are approved.

To ensure that the data and any limitations in scope or quality of the data provided has been properly understood by the recipient, abstracts and all pre-publication drafts of any derivative works must be submitted to the VCOR Data Access, Reports & Publications Committee for review. VCOR must be acknowledged in the appropriate way in all publications and presentations (see below).

Please note that the following apply:

- Any material or manuscript to be published using VCOR aggregate data must be submitted to VCOR Data Access, Research and Publications Committee (or delegates) for review prior to submission for publication;
- Any material or manuscript to be published using VCOR data must contain appropriate acknowledgements of VCOR. Preferred wording for the acknowledgement will be provided with the caveat and conditions of use specified
- Any PowerPoint Slide from VCOR for presentations are provided on the condition that individual slides are not altered in any way (including background) prior to use. VCOR will provide a PowerPoint presentation template for the presentation of all VCOR data at conferences, presentations, etcetera;
- VCOR requires that researchers provide a copy of any manuscript or presentation in which data, figures, or PowerPoint slides are used. VCOR maintains a record of all requests for VCOR data and its subsequent use as a means to monitor the value of the project to the wider clinical community.

4. Acknowledgement and Authorship

Where the interpretation of the data is central to the data request, it is expected that at least one member of the VCOR DRP Committee, Steering Committee, Registry Custodian, Principal Investigators and/or one member from the VCOR project team are named as a co-authors on any publication arising from use of requested data. The actual contributor(s) to be named would depend on the input to the particular data exercise and should conform to the Australian Code for the Responsible Conduct of Research (<http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/r39.pdf>)

and Monash University Research Outputs and Authorship Policy (<http://policy.monash.edu.au/policy-bank/academic/research/research-outputs-and-authorship-policy.html>).

Authorship for each submission will be dependent upon the contribution of participating parties and DRP committee membership will have final say over any authorship disputes (refer to section 4.3 below).

All publications and presentations arising from VCOR aggregate cohort data must include an appropriate acknowledgment in the 'Acknowledgement' section, as outlined in the caveat and conditions of use that will be provided with data once applications have been approved.

4.1 VCOR specific notes

There are several options for authorship using VCOR data.

1. Where possible, in addition to members of the writing group, at least one or more members of the VCOR Steering Committee and Data Management Centre should be included.
2. The corresponding author is responsible for following publication rules, including that no inappropriate author is included or an appropriate contributor omitted.
3. Where possible, aligned with VCOR's collegiate approach, the entire VCOR Steering Committee should be acknowledged as such "on behalf of the VCOR Steering Committee".

4.2 Authorship criteria

All persons who make substantial contributions to the manuscript should be offered authorship. Authorship should be discussed openly among investigators as soon as it becomes apparent that the data obtained may be suitable for publication.

Based on the comments received on the draft version(s) of a manuscript the first and last authors will decide together who qualifies for authorship. As a guide, authorship is based on substantial contribution to two or more of the following criteria (as outlined by the ICMJE):

- Conception and design of the research or acquisition of data;
- Analysis and interpretation of the data;
- Drafting of the manuscript, or revising it critically for important intellectual content; and/or
- Final approval of the version for publication.

According to ICMJE criteria, sending only an affiliation without providing comments on the content of the draft paper is insufficient for authorship. VCOR recognises that individuals may also make significant contributions to a research output through significant or non-routine collection or analysis of data. Where this activity contributes to the intellectual shaping of a research output authorship may be appropriate.

There will be no maximum regarding the number of authors as the ICMJE rules state that all who qualify for authorship should be listed. The Registry will, however, follow instructions of the journal that accepted the paper. Any consequences this may have for authorship will be communicated to the relevant persons and the DRP committee.

In case where a VCOR registry representative does not qualify for authorship, he or she will be mentioned as "contributor" or "collaborator" and acknowledged appropriately.

5. Abstract submission and progression of manuscripts

It is expected that abstracts be progressed into manuscripts within one year following the completion of any approved data analysis.

Prior to submission, all manuscripts must be reviewed by ALL AUTHORS and members of the VCOR Data Access, Reports and Publications Committee (or delegates). Failure to do so may result in a retraction of all submitted manuscripts until all authors and members have been given the opportunity to review and comment.

The VCOR representative(s) will be listed as the *Author for Correspondence* on manuscript submissions, unless otherwise agreed and approved upon prior to submission. Authors therefore must use the phrase "Victorian Cardiac Outcomes Registry, Monash University, Melbourne, Australia" within the research output (manuscript or otherwise) when stating the location of the originating institution.

The VCOR DRP committee and/or VCOR representatives will be consulted when deciding at which publication(s) or conference(s) the VCOR data will be presented. A preference will be given to submissions to high-impact, peer-reviewed publications to ensure that the standard of quality and credibility of VCOR is highest.

6. Declaration of interests in research output

Authors must be aware that perceived or real conflicts of interest (for example, sources of funding or other commercial interests or affiliations) may interfere with the perceived integrity of the research findings of VCOR and Monash University. Therefore, in the confirmation of authorship, all authors must take responsibility for declaring any potential or actual conflict of interest.