

# VICTORIAN CARDIAC OUTCOMES REGISTRY

## Data Management Policy

Version 2.0

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## 1. 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	2-Nov-2016	Updated section 2.1 & 2.2 Approved by the VCOR Steering Committee on 07-FEB-2016

## 1. Preface

The data management policy outlines the procedures used by the VCOR to ensure that the data entered into the VCOR database is of high quality and that this quality is maintained throughout the life of the project.

Data will be collected via the VCOR secure website. This online database is designed and maintained by Monash University, eSolutions, under the guidance of CCRET. Each user of the website will be issued with a unique access code to provide a mechanism for controlling access and tracking online usage. The system is designed to ensure that all compulsory data elements are captured and data managers will not be able to omit important data elements or out-of-range values.

All central data management and analysis is undertaken by staff at Monash, under the guidance of the Registry Custodian and Chief Investigator, Professor Chris Reid, the Steering Committee and relevant sub-committees.

## 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. Data collection and submission of data

Site Data Managers will ensure all relevant VCOR cases are entered onto the online VCOR data collection system and submitted within the expected timelines to be eligible for reporting periods. Regular internal audits by site Data Managers against hospital records and procedural lists will help to ensure that all cases are captured.

Registry data is regularly cross-checked against local hospital information systems in order to confirm complete ascertainment of cases from each participating site. Where omissions are discovered, the Data Manager must ensure that these are corrected. This will involve either completing the case report form or liaising with the relevant medical staff who should have undertaken the data collection in the first instance.

For every patient meeting VCOR inclusion criteria, an entry must be made to the VCOR registry. The system allows for an unlimited number of cases to be entered against a registered patient record.

Once data has been entered, users can save data for review and/or editing at a later date. Once the case has been completed, Data Managers are required to verify the accuracy of the data and submit it to the central database, where the data will be available for reporting and data extraction. Users are alerted to cases that are missing data or require verification and submission by way of the "dashboard" at login. Data Managers will also be able to run reports on outstanding cases for their own records.

The system is set-up to allow sites to extract raw data in real-time. This will facilitate reporting and tracking of data entry practises. User access levels will determine what reports and data users will be able to access. Data will only appear in online reports and data extracts if it has been verified and submitted by a Data Manager.

#### 3.1 Data Submission Deadlines

To comply with reporting requirements of the registry, it is expected that data will be submitted consecutively and in a timely manner. Please refer to the *VCOR Data Reporting Policy* for detailed information about VCOR reports.

In the period leading up to data submission deadlines, the VCOR Data Management Centre will review the quality of data for each site. The following data management reports will be run internally by the data management centre on a regular basis to provide continuous feedback on data completeness, outstanding

follow-ups, etcetera. This will circumvent data collection issues from escalating unnecessarily in the lead up to data submission deadlines for reporting periods.

1. Submitted versus unsubmitted data (verified cases)
2. Expected vs entered case numbers per site
3. Statistical reports on missing data (field based)

Any queries or discrepancies will be sent back to local Data Managers for review. Once data submission deadlines have past, a data cut will be taken from the data set for analysis and review. Incomplete data will be excluded from clinical quality reporting. The VCOR data management centre will report on missing data and incomplete cases during all reporting periods.

Reporting periods are quarterly and annually. Inclusion of cases in reports is dependent upon baseline data falling within that period. Data will be reviewed by the VCOR team between 30 and 45 days after the end of the quarterly period (to allow time to submit follow-up data, where relevant). The following table outlines the VCOR Data Submission deadlines for Quarterly reporting:

**Table 1: Approximate Data Submission Deadlines for inclusion in VCOR Quarterly Reports\***

<b>Quarter</b>	<b>Follow-up due</b>	<b>VCOR review</b>	<b>Final submission</b>	<b>Data presented</b>
<b>Q1</b> 1 Jan – 31 Mar	30 Apr	~15 May	Due 31 May	Review by 30 Jun
<b>Q2</b> 1 Apr – 30 Jun	31 Jul	~15 Aug	Due 31 Aug	Review by 30 Sept
<b>Q3</b> 1 Jul - 30 Sept	31 Oct	~15 Nov	Due 30 Nov	Review by early Jan
<b>Q4</b> 1 Oct – 31 Dec	31 Jan	~15 Feb	Due 1 Mar	Review by 31 Mar

\* From year to year, submission deadlines will vary slightly based on scheduled committee meeting dates. VCOR will issue an updated submission deadline list at the beginning of each year.

## 4. Quality Assurance

To achieve high quality data, standardised data dictionaries have been established and training will be given to all Data Managers and Data Collectors to ensure comprehension and understanding of the dataset. Ongoing queries around data items and definitions will be resolved by the VCOR Project Manager and the Steering Committee (or delegate sub-committee). In addition, regular meetings will be held with Data Managers to identify problems and inconsistencies in data that has been collected and to resolve systematic issues or flaws in data collection methodologies.

Ongoing reports will be run regularly in the lead up to reporting periods to assess data quality and completeness and feedback will be provided to sites regularly, as described in section 3.1 of this policy.

### 4.1 Missing data

The online system will ensure that all compulsory data elements are captured before data can be submitted. A legitimate reason must be given for omission of any of these elements and cases with missing data will be submitted to the registry by VCOR Project staff (Administrators) on behalf of Data Managers. It is the duty of the Data Managers to endeavour to ensure that all missing values are accounted for. In the event where a patient cannot be reached for follow-up (where relevant) missing values are accepted and patients can be coded as “lost-to-follow-up”. It is expected that data linkages with relevant external databases are likely to resolve some of these missing cases.

### 4.2 Data Audits

Project auditing and performance monitoring is carried out by Monash Project Managers, under guidance of the VCOR Clinical Quality Committee and Steering Committee. The results of audits are reported to relevant VCOR committees, local site Principal Investigators (and their nominated representatives) and local HREC committees.

The primary focus of the VCOR audit is to identify discrepancies between the VCOR dataset and local hospital information systems. Any discrepancies are reviewed with a view to improve local data collection processes and used to assess the collectability of the VCOR dataset.

Data Managers at each site are encouraged to conduct their own internal audits on a more regular basis.

### 4.3 Continuing education and support

Ongoing communication between the VCOR project team, Project Manager, Principal Investigators and Data Managers at participating sites is fundamental to ensure the quality of data collected remains at a high standard. VCOR provides the following:

- Initial and ongoing training of new staff at participating sites prior to commencement of data collection;
- Training materials and operations manuals, user guides and definitions manuals to ensure staff always have a point of reference if needed;
- Technical support for VCOR online by way of a telephone hotline and/or dedicated email address;

- Frequent contact in the form of newsletters and reports which will outline the importance of the quality and accuracy of the data provided to VCOR (please refer to the *VCOR Data Reporting Policy* and *VCOR Communications Policy* for more information);
- Regular meetings with Data Managers to discuss issues and provide feedback with a consistent view to improving the registry and minimising the burden of data collection.

## 5. VCOR Data Security

Data security and storage remains the responsibility of the Data Custodian and data management centre at Monash University, eSolutions, under the guidance of CCRET. In order to maintain data security and integrity, all data analyses is conducted and/or supervised by the VCOR Project Manager or staff at the delegated Data Management Centre. All data remains under the custodianship of the VCOR Custodian. Please refer to the *VCOR Data Security Policy* for more information.

### 5.1 Data storage and data sharing

No identifiable **or potentially re-identifiable** research data and/or health information should ever be sent via email or fax or transported on a portable disk or disk drive.

Any transfer of electronic registry data that contains identifiable or **potentially re-identifiable** information will follow a Secure File Transfer Protocol (SFTP). SFTP is a secure network protocol that provides file access, file transfer and file management functionalities by way of a secure online file sharing portal. Files will be manually uploaded, and will only appear for a limited period before access is removed and the file is archived. Hospital staff will be granted a username and password to access the SFTP website and will be notified via email when files are available for download.

Any paper-based VCOR records will be managed by the site, in accordance with the Health Records Act (2001). Sites will archive and destroy any paper records according to site-specific general record retention schedule(s). This will be the responsibility of the Principal Site Investigators who oversee each site's registry operations.