VCOR
VICTORIAN CARDIAC OUTCOMES REGISTRY

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Data Reporting Policy

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MONASH University

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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 and 2.2. Minor updates throughout report. Added section 6.2. Approved by the VCOR Steering Committee on 7-FEB-2017.

1. Preface

The Victorian Cardiac Outcomes Registry (VCOR) provides high quality data that enables regular detailed analysis of cardiac care across Victoria.

The following policy defines the processes employed to ensure timely and accurate reporting of VCOR data back to sites, relevant stakeholders and the general public. The ultimate goal driving the reporting process is to inform cardiac health service provision and to facilitate process improvement and reduce adverse patient outcomes following cardiac procedures and other treatment(s) or hospital presentations for cardiovascular disease. To do this, VCOR provides regular reports back to participating centres about patient outcomes and process measures.

The purpose of reporting is to first present an overview of the dataset, the VCOR population and patient outcomes, including morbidity and mortality. Secondly, reports evaluate site performance according to key performance indicators related to patient outcomes and process measures. The reporting process allows VCOR to provide hospitals with feedback relating to their performance in comparison with their peers. This provides an opportunity to flag potential process issues early and opens a dialogue between hospitals to share successful processes and procedures and to help drive local process improvement.

Data analysis is undertaken by the coordinating data centre, with guidance from the VCOR Clinical Quality Committee, a subcommittee of the VCOR Steering Committee.

Lessons learned from the VCOR reporting process will be reported publically through the VCOR website and other VCOR publications and communications.

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.

2.1 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. VCOR Data Reports

The primary focus of reporting is to monitor clinically meaningful data and drive process improvement locally within sites and across the cohort. The secondary focus is to ensure data completeness and quality. Analysis is comprehensive and intends to achieve the following:

1. To facilitate the evaluation of the service provision to Victorian cardiovascular patients;
2. To present relevant demographic and other clinical data so that hospitals may compare their results across the cohort;
3. To present an overview of procedures, morbidity and mortality in a meaningful format for sites and other stakeholders; and
4. To validate the quality and completeness of the registry dataset.

De-identified summary reports are produced annually, with annual report being made publicly available. Data reports are delivered to sites after review by the VCOR Clinical Quality Committee (CQC). All results, once reviewed, will be reported to the VCOR Steering Committee.

All reports are based on submitted (complete) cases only. Incomplete cases that are not verified by a Data Manager as 'complete' will be omitted from all reports.

It is important to note that the data presented may not be considered sufficiently complete for inclusion in these reports. VCOR will determine, under guidance from the CQC, whether data or case numbers are sufficient to include in summary reports.

3.1 VCOR project reporting

Along with an annual public summary report of VCOR data, VCOR produces quarterly reports to sites. These clinical data reports are presented to sites, accompanied by a summary of the data and data completeness for that reporting period. Sites will receive feedback about their performance compared to their peers, in relation to clinically relevant key performance indicators. Report recipients will be able to re-identify their site to determine performance, however, the identity of other sites will not be revealed.

Two types of reports will therefore be generated: Data Quality Reports and Clinical Quality Reports.

1. **Data Quality reports** will inform stakeholders about completeness of the VCOR data set and data collection issues. These will be provided regularly with clinical quality reports, and ad-hoc as deemed necessary.
2. **Clinical Quality reports** will include results for clinically important variables and compare site performance against the cohort, based on clearly defined key performance indicators. Where possible, KPI reports will be risk-adjusted (where appropriate) and presented in funnel plot analyses that explore whether a site is performing within an acceptable range.

In the period leading up to data submission deadlines for reports, the VCOR Data Management Centre will review the quality of data for each site 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.

3.2 Real-time online reporting

All local hospital data remains the property of that institution. Sites will have access to their own VCOR data at any time, by way of the VCOR online system. VCOR imposes no limitations on the use of local hospital data, except that it complies with HREC conditions and relevant health information privacy legislation and relevant acknowledgment is given, where appropriate. Please refer to the *VCOR Publications Policy* for information about authorship and acknowledgments.

3.2.1 Site specific online reports

Currently, site specific data from the VCOR dataset can be downloaded from the online system in two formats: Data Extract and Online Site Summary Reports (summary reports are not available for all VCOR modules).

1. **Data Extracts** are essentially a download of raw data that is stored within the VCOR system. It is downloaded in a 'comma separated values' (CSV) format (e.g. *filename.csv*). This raw data can be exported to a series of programs for analysis and review;
2. **Summary Reports** provide the number of cases and values for a pre-selected set of fields (e.g. patient details, pre-procedure, procedure, and outcome data). Reports also will also provide the number of incomplete cases that require completion. Online reports produce pro-forma graphs and statistics based on a series of clinically relevant fields. They compare local hospital data to the VCOR cohort, with an option to filter based on pre-determined parameters (e.g. patient sub-groups and date ranges).

Only Data Mangers and Report Managers can run site-specific summary reports and/or extract raw data from the VCOR system. A Principal Investigator must approve this level of access to VCOR Online.

'Real-time' data will only include submitted, complete cases. Cases that have not been submitted and verified as 'complete' will not be included in these reports.

3.2.2 Clinician reports

The pro-forma reporting functions mentioned above have been developed for VCOR Clinicians to access the same reports, but only for their own VCOR patient cohort (across all sites where they are registered as VCOR operators).

3.3 Special reports

Special reports may be requested by sites and other stakeholders from time to time. Requests for such reports will reviewed on a case by case basis. Requests for additional reports may require approval from the VCOR Data Access, Research & Publications Committee (DRP) or delegates and, where relevant, a fee might be imposed as a cost-recovery process.

Where basic summary data is requested, the information may be provided by VCOR staff without approval. All requests for reports and/or data must comply with the *VCOR Data Access Policy*.

DRP approval will require a formal request in writing and will keep a record of such requests. The VCOR Steering Committee will be provided with a summary of such requests on at least, a biannual basis. A caveat and conditions of use statement will be provided with any approved applications for VCOR data.

4. Data preparation for reporting

In the period leading up to data submission deadlines, the VCOR Data Management Centre will review the quality of data for each site. Any queries or discrepancies will be sent back to local Data Managers for review. Once quarterly data submission deadlines have past, a data cut will be taken form 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.

It is the responsibility of site Data Managers to ensure that data is up to date and complete prior to reporting deadlines.

Reporting periods are quarterly and annually, unless otherwise formally agreed upon by VCOR and participating centres or organisations. 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).

Feedback will be sent to sites about missing data and reminders sent for final submission of data for quarterly reporting. VCOR acknowledge that some follow-ups will not be completed even though the due date has passed. All data for a reporting period is due for final submission at 60 days after the end of the quarter. All submitted data will be included in quarterly reports. Data will be presented to the VCOR Clinical Quality Committee for review within approximately 90 days from the end of the quarterly reporting period. Data and any apparent issues are then tabled at the next Steering Committee meeting.

Please refer to the *VCOR Data Management Policy* for data submission deadlines and more information about the VCOR data management process.

5. Audit Reports

Project auditing and performance monitoring will be carried out by Monash Project Managers, or delegates, under guidance of the CQC and SC. The results of audits will be reported to relevant VCOR committees, local site Principal Investigators (and their nominated representatives), local HREC committees and other relevant VCOR stakeholders.

The primary focus of the VCOR audit is to identify discrepancies between the VCOR dataset and local hospital information systems to provide monitoring and feedback relating to data collection methodologies. Any discrepancies will be reviewed with a view to improve local data collection processes and used to assess the collectability of the VCOR dataset.

The audit report will include the following:

1. **Case Ascertainment**: A review of the total number of captured cases against hospital records;
2. **Brief Audit:** Full review of key data fields against medical records in a randomly assigned subset of the population;
3. **Comprehensive Full Audit:** Full review of pre-selected cases (positive and negative outcomes) against medical records

Case ascertainment audits will be conducted annually and reported back to sites.

Brief audits will be conducted after first full year of VCOR data collection and then at least every three years thereafter.

Comprehensive full audits will only be completed on an ad hoc basis, as deemed necessary if any data collection issues arise requiring more comprehensive assessment.

6. Delivery of Reports

All VCOR data reports will be delivered by VCOR to the local VCOR Principal Investigators and relevant Department Head(s), unless otherwise directed. This includes hospital executive staff engaged with the project, but excludes executive staff not listed in VCOR project documentation or signed registry agreements. Local distribution of these confidential, re-identifiable reports will be at the discretion of the Principal Investigators.

6.1 Storage of reports

It is important to note that the VCOR data reports are strictly confidential and for internal hospital use only. No research data and/or identifiable health information should ever be sent via email or fax or transported on a portable disk or disk drive. Reports should be stored in a secure location and access to reports limited to relevant hospital staff only.

6.2 Reproduction of reports

All clinical quality and data completeness report data remains confidential and must not be reproduced or published without explicit permission from VCOR and, where relevant, the VCOR Steering Committee, DRP or CQC. It is the responsibility of participating sites to ensure that any data or reports provided for the purpose of quality feedback is not published or reproduced in any way.

Cohort data that have been released in the public domain (e.g. public annual report outputs) may be reproduced and reported publicly, however VCOR must be adequately cited. Any published data must not identify any individual hospital, clinician or patient, in accordance with VCOR Data Access Policy and the VCOR Privacy Policy.

6.3 Interpreting reports

It is important to note extrapolations about VCOR clinical quality data must be undertaken with caution, especially with regard to data that is not complete and outputs that are not risk-adjusted.. Any conclusions made about the VCOR data may therefore be misleading if raw cohort data is interpreted without suitable caution. As the dataset matures and lends itself to development of risk-adjustment models, more meaningful deductions can be made from the dataset and the reports presented to sites. ,