

VICTORIAN CARDIAC OUTCOMES REGISTRY

Data Reporting Policy

Version 1.0

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Document Version Control

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1.0	26-FEB-2014	Initial Version Release. Approved by the VCOR Steering Committee on 11-Mar-2014

1. Preface

The Victorian Cardiac Outcomes Registry (VCOR) provides high quality data that enables regular detailed analysis of cardiac care across Victoria. Analysis is undertaken in collaboration with Data Access, Reports and Publications Committee, a subcommittee of the VCOR steering committee.

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 negative patient outcomes and adverse events following cardiac procedures.

The purpose of reporting is to first, present an overview of the dataset, the VCOR population and patient outcomes, including morbidity and mortality. This will facilitate an evaluation of the performance of participating units and create a dialogue for units to share successful processes and procedures.

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 will be collected that will allow for risk-adjustment of outcomes to facilitate benchmarking of performance and quality improvement in the delivery of health care services. VCOR will monitor the safety and quality of care given to patients with cardiovascular disease undergoing specific cardiac procedures or with specific cardiac conditions. In time, it will report risk-adjusted outcomes back to stakeholders. This will be 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

The Cardiac Clinical Network in conjunction with Monash University and funding from Medibank Private and the Victorian Department of Health will develop and maintain a secure, online data collection tool and data storage mechanism for analysis and reporting. This clinical quality registry will measure the success of relevant treatments and procedures performed on patients presenting in Victorian hospitals with cardiovascular symptoms. It will do this by capturing data about patient demographics; symptoms; clinical presentation and diagnosis; treatments they receive and related clinical outcomes.

Data will be collected for every patient undergoing relevant procedures in every participating Victorian site. 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 will be collected at baseline (time of presentation for procedure), 30 days and 12 months, with the potential for ongoing

annual follow up in the future. Data will be captured electronically in an online data entry system. Initially, data will be entered manually, but development of a secure file transferring protocol is underway to allow sites to export data directly from internal hospital databases, where their dataset meets the criteria for VCOR data definitions. Paper-based forms are provided to sites for data collection prior to online data entry however, these forms will not be submitted to VCOR.

Data will be stored securely within Monash University servers and retained indefinitely. The project will conform 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 will be in keeping with these principles. All project matters will be 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 Clinical Informatics & Data Management Unit (CIDMU) will act as the coordinating data management centre, answering to the Steering Committee. A Clinical Liaison Officer will be appointed as a registry advocate to liaise between the sites and the registry.

CIDMU is responsible for developing and maintaining the data entry system, 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 will be published yearly.

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

3. VCOR Data Reports

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

1. To facilitate the evaluation of the service provision to Victorian cardiovascular patients. Specifically, to identify units with consistently outstanding results as a trigger for sharing procedures and processes;
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 will be produced quarterly and annually. Data reports will be 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 will be based on submitted (complete) cases only. Incomplete cases that are not verified by a Data Manager as 'complete' will be omitted from reports.

3.1 VCOR project reporting

Along with an annual summary report of VCOR data, VCOR will also produce quarterly reports to sites. Clinical data reports presented to sites will also be accompanied by a summary of the data and data completeness for that reporting period. Eventually, hospital KPI results will be benchmarked.

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.
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. In time, once the dataset lends itself to a risk adjustment model, all KPI reports will be risk-adjusted 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 VCOR Online. 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.

* Existing summary reports are very basic in the early stages of the registry. A more comprehensive reporting system will be developed and an expected released date is 2014-2015. The reports will produce pro-forma graphs and statistics based on a series of clinically relevant fields. They will compare local hospital data to the VCOR cohort. New online report features will include the option to filter based on

pre-determined parameters (e.g. patient sub-groups) and reports will be generated for specified date ranges.

Only Data Managers and Report Managers can run site-specific summary reports and/or extract raw data from the VCOR system.

'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

Currently there are no reporting facilities available for clinicians to review their own patient data. The comprehensive pro-forma reporting functions to be released in 2014 will grant VCOR Clinicians the same access to generate the same summary reports for their own patient cohort (across all sites where they are registered 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 be 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.

Where basic summary data only 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 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 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.

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. 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 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, 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. 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

6. Delivery of Reports

All VCOR data reports will be delivered by VCOR to the local VCOR Principal Investigators, unless otherwise directed. Local distribution of these confidential, de-identified 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 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 Interpreting reports

It is important to note that in the early stages of the registry, extrapolations about VCOR data must be very limited. The data set and clinical reports are not currently risk-adjusted. Any conclusions made about the VCOR data may therefore be misleading if raw data is interpreted without suitable caution. As the dataset matures and lends itself to a risk-adjustment model, more meaningful deductions can be made from the dataset and reports presented to sites.