

Victorian
Cardiac
Outcomes
Registry

**ANNUAL
PUBLIC
REPORT**

2013



Improving cardiovascular outcomes Victoria-wide

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This report would not have been possible without the efforts of doctors, nurses and other relevant hospital staff who have contributed data to the VCOR.

Lead clinical staff from hospitals participating in the VCOR are also gratefully acknowledged.

Executive Summary



Coronary heart disease is still the number one killer in Australia. Each year, there are approximately 55,000 heart attacks across the country, and in 2011, heart disease and related conditions were the underlying causes of death for more than 7,290 Victorians, equating to 20% of all deaths in the state. Chronic coronary disease also exacts a huge toll on our community – certainly as a cause of death, but also very significantly, as a major cause of morbidity and reduced quality of life for people living with heart failure. Current predictions suggest that it is going to get worse, with chronic heart disease prevalence estimated to rise by up to 36% over the next decade. The critical need for high quality, effective therapies, easily and equally accessible to all sectors of our community is obvious.

Percutaneous coronary intervention (PCI) - together with coronary artery bypass surgery - has become a key treatment in the battle against coronary heart disease. The technique involves directly treating the narrowings that develop inside coronary arteries due to atherosclerosis. These narrowings obstruct blood flow to the heart muscle itself – triggering symptoms of angina, increasing the risk of heart attack and the development of heart muscle damage and heart failure. By opening up these narrowings with a balloon and a stent, PCI can significantly improve a person's quality of life and overall outcome.

The number of PCIs performed in Australia has been steadily increasing over the last two decades and the technique continues to grow and evolve rapidly. It is in this setting that healthcare providers have begun focusing on the use of health data to monitor the quality and safety of the care delivered to patients. At a federal level, the Australian Health Ministers' Advisory Council has endorsed better use of health information as a key priority to improve the quality of the health system. Several other bodies and organisations, including the NHMRC, Australian Institute of Health and Welfare and the Australian Commission on Safety and Quality in Health Care have all been actively involved in identifying and advising on effective methods and techniques to monitor key aspects of performance in the delivery of healthcare to the community.

To this end, **clinical quality registries** have emerged as proven tools for data analysis, outcomes reporting and performance assessment. The ultimate goal for this type of registry is to improve the safety and quality of health care provided to our patients. They build on data collected from events in the daily delivery of healthcare and use this information to assess care provision, benchmark the performance of health services against each other and implement quality improvements where required.

As a clinical quality registry, the purpose of the Victorian Cardiac Outcomes Registry (VCOR) is to monitor the performance of health services in Victoria – both public and private – in the delivery of high quality, cardiac-based therapies. The registry has initially focused on PCI as it is a high-volume procedure; it is performed in a significant number of centres across the state, and has readily measurable outcomes and performance indicators.

VCOR began collecting data on patients undergoing PCI in 2013. We are pleased to be able to report that by the end of its first year, a total of 12 public hospitals (100% of Victorian public hospitals offering PCI services) and 6 private hospitals (35% of Victorian private hospitals offering PCI services) were engaged with and committed to VCOR. This first Annual Report of VCOR describes the establishment and makeup of VCOR, how it has functioned in its first year of operation and highlights key findings in relation to the performance and outcomes of health services in Victoria that perform PCI.

Key Findings

- 75% of Victorian hospitals performing PCI were engaged with VCOR by the end of 2013, of which, 62% had commenced actively contributing data in that period.
- A total of 4183 completed cases were collected during the registry's first year of operation. However, this represented an incomplete yearly dataset, as many of the contributing health services only started contributing part way through the year.
- The mean age of patients was 66±12.0 years, and consistent with our ageing population, 21% of patients were over 75 years. Most (77%) patients were male. One half of patients underwent PCI as part of their treatment for an acute coronary syndrome (acute ST elevation myocardial infarction, non-ST elevation myocardial infarction or unstable angina). There was a wide variation among VCOR hospitals in the proportion of their cases classified as acute or elective.
- Drug-eluting stents were used in 77% of cases that involved stent implantation in 2013. This reflects a diminution in concern regarding the longer-term safety of these stents in the last few years. Yet, there are ongoing cost constraints in relation to the use of these stents – particularly in the public sector. There are significant differences in drug-eluting stent usage rates among participating health services in VCOR.
- A total of 78% of hospitals offered emergency PCI service for acute ST elevation myocardial infarction (STEMI). Most of these provided a 24-hour service, 7 days a week. Patients undergoing PCI for STEMI accounted for 15% of all cases in VCOR in 2013.
- In relation to PCI for STEMI, the key process measure of hospital performance is the time taken from the patient's arrival at the hospital to the first inflation of the balloon that re-opens the artery (door-to-balloon time). The median door-to-balloon time across VCOR hospitals was 64 min, which is well below the upper recommended threshold of a delay of 90 min or less. This compares favourably with international data. The goal of a door-to-balloon time <90mins was achieved in 71% of cases.
- VCOR data support the worldwide trend towards the use of the radial artery as access for PCI, with approximately one-third of cases performed in this manner. However, there was wide variation in the uptake of the radial approach among hospitals in VCOR. Registry results indicate a trend towards lower rates of major bleeding among patients undergoing PCI via a radial approach. It is anticipated that both the number of centres performing radial cases, and the number of patients treated this way will continue to grow in Victoria in coming years.
- PCI in VCOR was associated with high success rates and low complication rates. Individual lesions were successfully treated in 95% of cases. Procedural success (all lesions in an individual patient treated without any significant complications) was achieved in 92% of patients.
- The in-hospital mortality rate in 2013 was 1.37%, and at 30 days, the rate was 1.66%. This compares very favourably with other international PCI registry results. As expected, higher mortality rates were seen for urgent patients compared with elective patients.
- Analysis of other key performance outcomes including unplanned revascularisation procedures (in-hospital and at 30 days), major bleeding rates and target vessel failure (at 30 days) demonstrated excellent results among the participating health services. Major cardiovascular and cerebrovascular adverse event rates were acceptable and comparable to international results.

The following report provides greater detail regarding the establishment, structure and governance of the Victorian Cardiac Outcomes Registry, as well as an in-depth analysis of the findings from the first year of the registry.

Introduction

As a clinical quality registry, VCOR was established to improve the safety and quality of cardiovascular healthcare provided to patients in Victoria. The registry aims to monitor the performance of health services by collecting key clinical information from individual healthcare encounters that allow evaluation of process and outcome measures. Feedback of these results to participating hospitals facilitates the benchmarking of hospital performance; health services can measure their progress against internal goals, compare results with national standards, inform key managers, payers and health planners of their progress and assess their performance against other health services.

The registry began collecting data on patients undergoing percutaneous coronary intervention (PCI) in January 2013 and the results presented in this report relate to the 2013 calendar year.

Addressing the burden of cardiovascular disease: Clinical quality registries

In Australia, as in several Western countries, cardiovascular disease is still the number one cause of death and disability. The Australian Institute for Health and Welfare reported that in 2004-5, cardiovascular disease expenditure exceeded 5.9 billion dollars, accounting for 11.2% of the total allocated healthcare expenditure¹. A significant proportion of this expenditure relates to procedures and treatments for heart disease. Over the past decade, the number of cardiac procedures – particularly percutaneous coronary intervention (PCI) and coronary artery bypass surgery – has continued to rise. These procedures represent high-cost, high-volume and relatively high-risk components of Australia's healthcare system².

In recent years, there have been calls for a centralised monitoring system to capture information and report on the quality and appropriateness of care provided to patients presenting with cardiovascular disease^{3,4}. Health professionals have recognised the need to provide timely information and feedback to clinicians, hospitals, health payers and planners to aid stakeholders in monitoring performance, with the ultimate aim of improving patient care.

Clinical quality registries offer one of the most accurate and effective methods of providing outcome data to improve healthcare performance⁵. They assist with establishing and updating national standards for understanding treatment patterns, clinical outcomes, drug safety and overall quality of care provided to high-risk patients⁶. Clinical quality registries provide clinically credible data to allow benchmarking of relevant outcomes, measurement of compliance with operating principles and procedures, and allow for reporting on the incidence of adverse events⁷. Clinical quality registries may also assist in the early identification of health services whose performance is below an acceptable

standard, well before the deviation becomes noteworthy. Information gathered from registries provides a strong impetus for maximising performance. These benefits create a convincing rationale for embedding registries into the architecture of Australia's healthcare system.

The Victorian Outcomes Registry – from concept to creation

In 2008, the Australian Commission for Safety and Quality in Health Care oversaw a process to test, validate and draft operating principles and technical standards for clinical quality registries. Several groups were awarded funding, including the Department of Epidemiology and Preventive Medicine, Monash University, which in turn, conducted the pilot Australian Cardiac Procedures Registry (ACPR) project in 2009-10. This pilot was the forerunner to VCOR.

By 2011, the Australian Health Ministers Advisory Council approved a set of revised Operating Principles for Clinical Quality Registries. These principles provided an overarching framework for clinical quality registries. It was initially anticipated that ACPR would receive ongoing funding to continue to operate and expand as a clinical quality registry monitoring a number of cardiac procedures. However, this did not prove to be the case. In late 2011, separate funding was sought and obtained to set up a state-wide cardiac outcomes registry in Victoria and VCOR was established.

Primary management of VCOR is undertaken at the Department of Epidemiology & Preventive Medicine, Monash University, in association with the Victorian Cardiac Clinical Network, Department of Health, Victoria. It is jointly funded by Medibank Private and the Department of Health, Victoria, with in-kind funding from Monash University.

The registry is designed and maintained by the Clinical Informatics and Data Management Unit at the Department of Epidemiology & Preventive Medicine, Monash University. The data are housed within a secure online database. Further information about the structure and operation of VCOR is available online at www.vcor.org.au.

VCOR Governance

VCOR conforms to the National Operating Principles for Clinical Quality Registries as set out by the Australian Commission on Safety and Quality in Health Care. All project matters are governed by the VCOR **Steering Committee**, in liaison with two subcommittees - the **Clinical Quality Committee** and the **Data Access, Research & Publications Committee**. Day-to-day project management is undertaken by the Department of Epidemiology & Preventive Medicine at Monash University and Monash University's Clinical Informatics & Data Management Unit. Additionally, a clinical champion acts as a registry advocate and liaises between committees, data management centre, funders and health care providers (both engaged sites and potential registry participants).

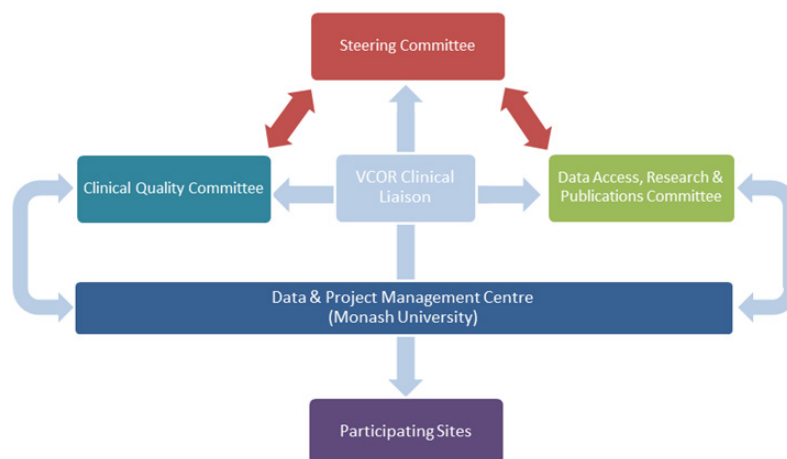
The Steering Committee comprises various stakeholders including clinicians, hospital representatives, funders and others. The membership is as follows:

- 1x Chair: Co-chairs from Victorian Cardiac Clinical Network
- 1x Epidemiologist from Department of Epidemiology & Preventive Medicine
- 1x Representative from Coordinating Data Centre

- 1x Representative from funding body #1: Medibank Private
- 1x Representative from funding body #2: Department of Health, Victoria
- 1x Representative from Victorian branch, Cardiac Society of Australia and New Zealand
- 1x Representative from National Heart Foundation (Vic)
- 1x Representative from the general population (e.g. a health consumer representative, as nominated by a nationally recognised consumer body)
- 3x Representatives from private hospital sector (e.g. clinicians or hospital administration)
- 3x Representatives from public hospital sector (e.g. clinicians or hospital administration)
- 3x Representatives (Chair) of each of the subcommittees reporting to the Steering Committee

The Steering Committee approves any major operational changes and resolves matters put forward by VCOR sub-committees relating to project operations, clinical quality and safety, data access and reporting/publication. In addition, the Steering Committee is ultimately responsible for the financial viability of the registry, the project's strategic direction and delivery of contractual obligations.

Figure 1. VCOR Governance structure overview





Registry Activities

Committee meetings

The VCOR **Steering Committee** has met quarterly since commencement of the registry. The committee has approved numerous policies that guide the conduct of the registry. These include:

- VCOR Data Security Policy
- VCOR Communications Policy
- VCOR Data Management Policy
- VCOR Data Access Policy
- VCOR Reporting Policy
- VCOR Publications Policy

The **Clinical Quality Committee** assesses the data quality and key performance indicator (KPI) reports. Any trends for individual hospitals' outcomes falling outside control limits are monitored by this committee. This process is one of the primary functions of the registry and is undertaken at regular (quarterly) intervals. An individual hospital's performance outcomes falling outside control limits for two consecutive quarters will trigger further action by the committee to address the issue, as set out in VCOR's Terms of Reference.

The Committee initially met in June 2013 and agreed on a set of KPIs and approved the reporting format. The first clinical quality report was released in September 2013. Subsequent meetings have been held on a quarterly basis. Various risk adjustment models for key outcome data such as mortality are being evaluated for use in VCOR.

The VCOR **Data Access, Research & Publications Committee** will be convened in October 2014.

Additionally, a number of special purpose meetings, aimed at the needs of the site data managers, were held in 2013. These sessions provided opportunity for data managers to provide feedback and improve their knowledge and skills pertaining to data collection and data entry, providing support particularly for sites that were new to VCOR. They also proved an excellent networking opportunity for data managers and were well attended. It is planned to continue them in 2014.

The VCOR site audit program materials were developed in 2013, with annual site audits to commence in March 2014. The outcomes of these audits will be incorporated into future VCOR reports.

Engagement of PCI sites

The process of engagement of sites with VCOR required executive support at each hospital, together with Human Research and Ethics Committee and local research governance approval. This process often took a number of months. Hospitals were engaged incrementally, with sites going live at different time points depending on when their individual engagement process was completed. The PCI module of VCOR commenced in January 2013, with 5 hospitals initially contributing data. By the end of 2013, a total of 18 hospitals were actively contributing data to VCOR, comprising every

public hospital performing PCI in Victoria and six private hospitals. Discussions are ongoing with the remainder of the private hospitals in Victoria that have PCI facilities but have not yet engaged with VCOR. Figures 2 and 3 display site recruitment into VCOR - from initial engagement to Human Research and Ethics Committee approval and finally, to active data collection while Table 1 outlines site participation in 2013 and 2014.

Figure 2. PCI Site engagement and participation in VCOR in 2013

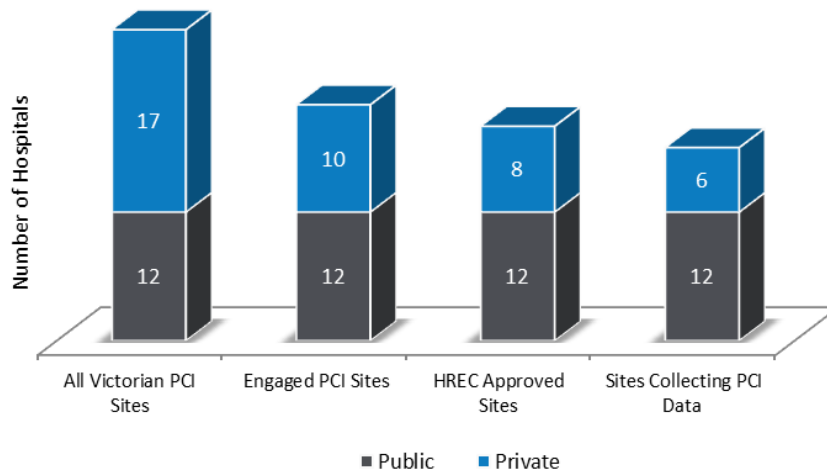
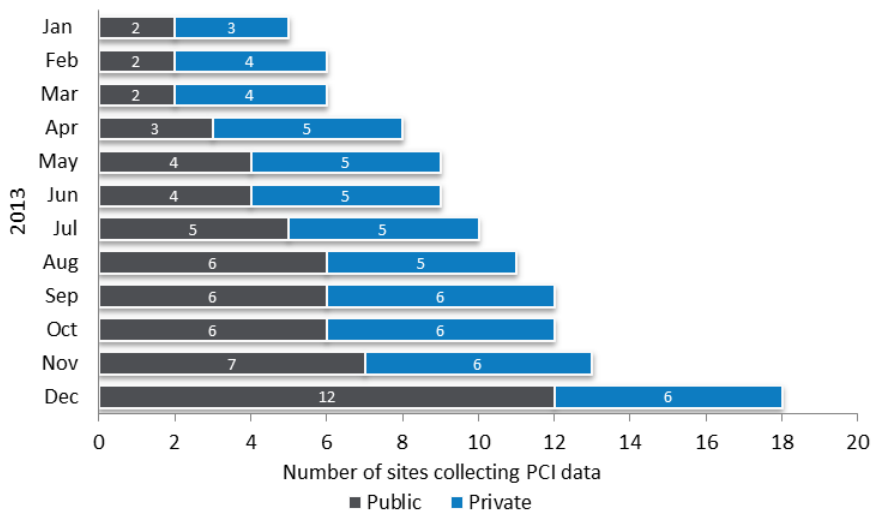


Table 1. PCI hospitals contributing to VCOR

Victorian PCI Sites	Sites collecting data in 2013	Sites collecting data in 2014
Alfred Hospital, The	•	•
Austin Hospital	•	•
Ballarat Base Hospital	•	•
Bendigo Hospital	•	•
Box Hill Hospital	•	•
Cabrini Hospital Malvern	•	•
Epworth Hospital Eastern		•
Epworth Hospital Richmond	•	•
Frankston Hospital	•	•
Geelong Hospital	•	•
Geelong Private Hospital		•
Jessie McPherson Private	•	•
Knox Private	•	•
Melbourne Private Hospital		•
Monash Medical Centre Clayton (MonashHeart)	•	•
Northern Hospital, The	•	•
St Vincent's Hospital (Melb)	•	•
St Vincent's Private Hospital	•	•
The Royal Melbourne Hospital	•	•
Western Hospital (Footscray)	•	•
Western Private	•	•

Correct at 30 June 2014

Figure 3. Site participation numbers by month in 2013



Patient recruitment

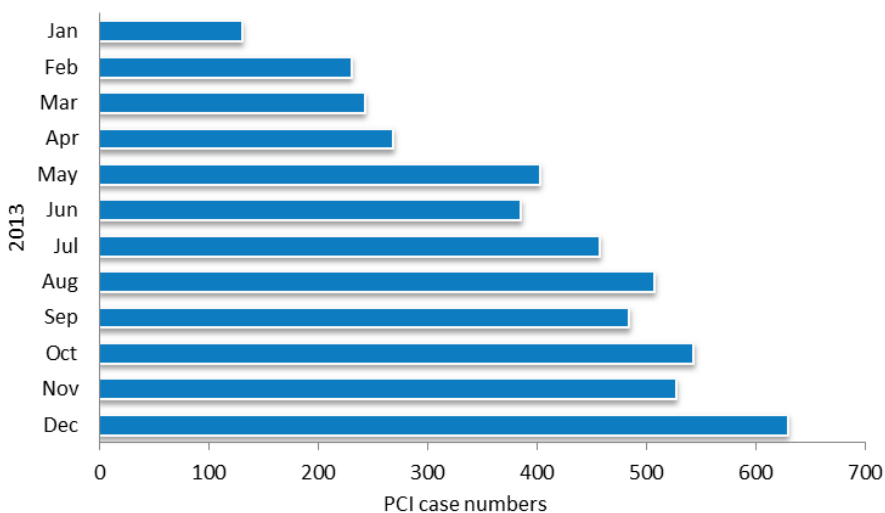
Figure 4 shows the number of PCI cases entered into the registry by month. The increase in monthly recruitment towards the latter part of 2013 reflects the staggered engagement of PCI sites into VCOR throughout the year. A total of 4,816 PCI procedures were entered into VCOR during 2013 (Figure 4). Of these, 99.6% of cases (n=4,796) had completed baseline data and 95.3% of cases (n=4,530) had completed follow-up data (Table 2). Accordingly, 95.0% of cases entered into VCOR in 2013 were considered as

“all data complete”, whereby both baseline and follow-up data were completed (n=4,760).

A total of 76 cases (1.7%) were lost to follow-up defined as being unable to contact a patient for 6 months or greater. An additional 183 cases (3.8%) had incomplete follow-up data.

All analyses in this report have been based on the 4,760 completed cases (baseline and follow-up) unless otherwise stated.

Figure 4. Number of PCI cases entered by month



Data completeness

As individual cases are entered onto the VCOR online system, internal processes are in place to ensure data completeness and integrity. The first step involves initial data entry by site data managers. These cases can be saved (**entered case**), with further input possible at a later time to complete the data entry process. The information entered must meet all the relevant business rules built into the system. These business rules ensure the integrity of the data and will pick up any internal inconsistencies or errors.

Data completeness is generally assessed for both baseline and follow-up data. A case record is considered complete (**completed case**) when all business rules

have been met, there are no missing data points and there are no data outside the pre-defined limits for both the baseline and follow-up stages. For an individual case, it is possible that the baseline data entry may be considered complete, while the follow-up data process may still be ongoing or incomplete.

Sites are routinely informed of impending data deadlines for reporting purposes and are encouraged to complete as much data entry as possible and as many outstanding follow-ups as possible. Only completed data are analysed for review and reporting. Sites are notified as to the status of their data entry completeness on a regular basis. Table 2 shows the rate of data completeness by hospital.

Table 2. Data completeness by hospital

Hospital	% Baseline cases complete	% Follow-up cases complete	% All data (whole case) complete
A	100.0	100.0	100.0
B	100.0	100.0	100.0
C	100.0	99.9	99.9
D	100.0	100.0	100.0
E	100.0	100.0	100.0
F	98.7	98.9	97.6
G	99.5	99.7	99.2
H	98.4	98.3	96.7
I	100.0	25.2	27.6
J	94.8	93.6	89.7
K	100.0	100.0	100.0
L	99.8	100.0	99.8
M	100.0	75.0	75.0
N	100.0	100.0	100.0
O	100.0	100.0	100.0
P	100.0	64.9	66.7
Q	100.0	100.0	100.0
R	100.0	100.0	100.0
Cohort	99.6%	95.4 %	95.0%

Total number of VCOR cases coded as 'all data complete' in 2013 = 4760

Findings

Patient Characteristics

The 4,760 PCI procedures included in this report were performed on 4,183 patients, with 12.1% patients (n=577) undergoing two or more PCI procedures. The majority of PCI patients were males (77%) and most PCI procedures (78%) were performed on patients aged between 51- 80 years, see Table 3 and Figure 5.

The median age for males was 65 years and for females 70 years. Overall, 21% of patients treated with PCI were elderly (>75 years of age). While the overwhelming majority of patients were male, the proportion of females in the elderly population was higher than in the overall registry cohort (33% for elderly cohort vs 23% overall). Figure 6 illustrates that the age range for men was greater than for females.

Table 3. Patient characteristics

Characteristic	2013 Cohort
Age – years (Mean ±SD)	66.2 (±12.0)
Gender – female	22.9%
Diabetes medication	22.3%
Peripheral vascular disease history	3.5%
Cerebrovascular disease history	3.8%
Previous PCI	34.4%
Previous CABG	8.9%

Figure 5. Age and gender distribution of patients undergoing PCI

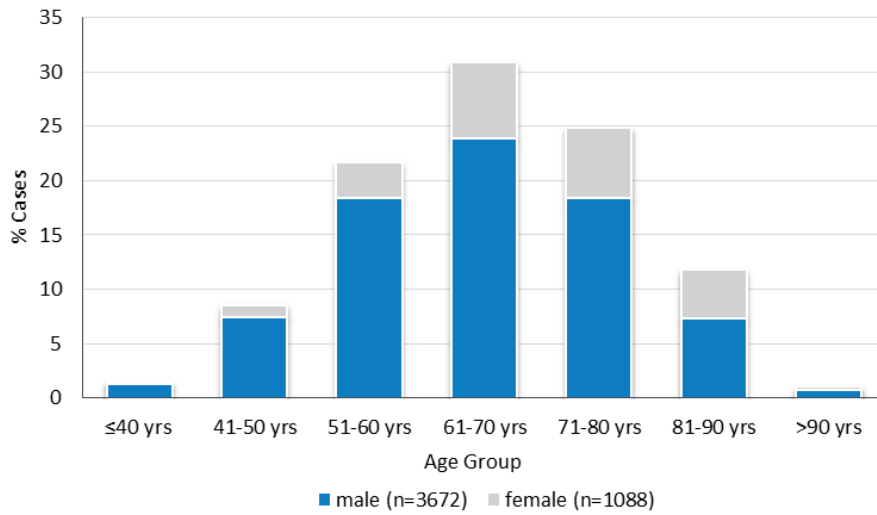
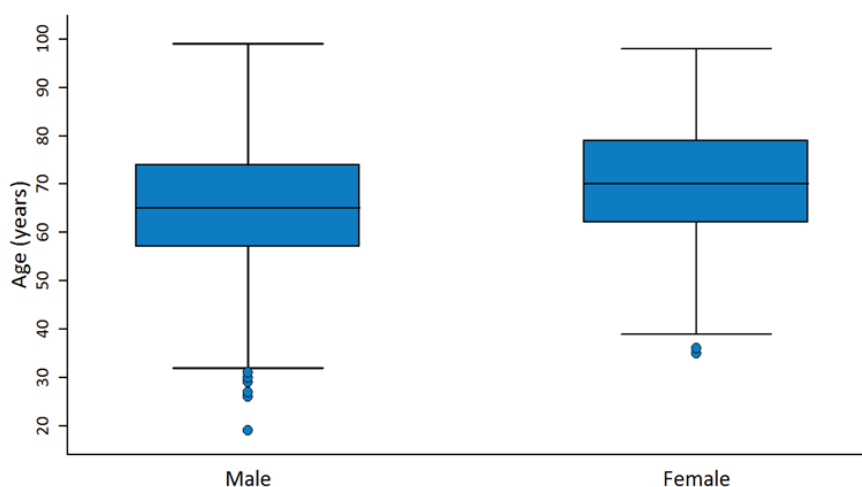


Figure 6. Age distribution by gender



Box plot displaying median, 25th, 75th centile values and 95% confidence intervals

Clinical presentation

Figure 7 shows the proportion of cases undertaken in various clinical categories. Overall, half of PCIs were performed in patients with an acute coronary syndrome (ACS) – ST elevation myocardial infarction (STEMI) or non-ST elevation ACS (NSTEMACS) which encompasses non-ST elevation myocardial infarction and unstable angina pectoris.

Patients presented in a number of ways for their PCI treatment. Cases were deemed as **elective** when they were performed on clinically stable patients. Cases were considered **urgent** when the patients were clinically unstable - usually with an acute coronary syndrome or those who presented following a cardiac arrest. Among those patients undergoing urgent PCI, there are specific groups that warrant separate analysis – those undergoing **PCI for acute ST elevation myocardial infarction (STEMI)** and those who undergo PCI within 24 hours of unsuccessful thrombolysis for acute STEMI, known as **rescue PCI**. These are discussed in a later section of this document.

Overall, 50% of cases in 2013 were considered elective. However, the distribution of elective and urgent cases varied quite considerably among the sites (Figure 8). It is noteworthy that several sites (sites M to R) only contributed data for one month during 2013. As a result of the small numbers for these sites, the proportion of urgent and elective cases may not be a true reflection of the usual casemix for that site.

Figure 7. Procedures by clinical presentation

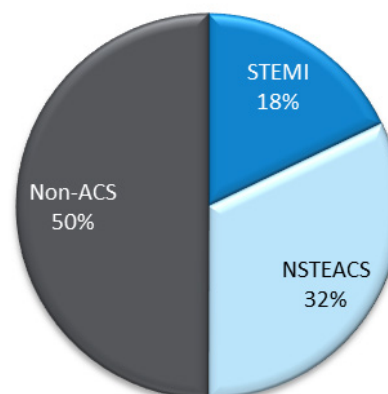
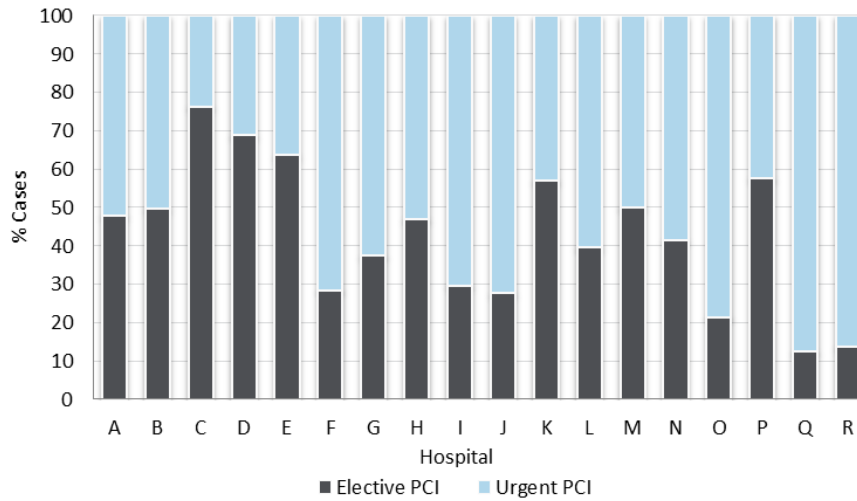


Figure 8. Elective vs urgent cases by hospital



Drug eluting stents

Drug eluting stents (DES) effectively reduce the risk of in-stent restenosis and have been broadly available in Victoria since 2003. However, their use has been somewhat constrained, particularly in the public hospital system, because of their higher cost compared with conventional bare metal stents (BMS). Overall, drug-eluting stents were used in 77% of cases in 2013. A further 16% of cases underwent PCI with bare metal stents only and 7% of cases underwent a coronary intervention that did not require (or did not end up deploying) a coronary stent. As expected, there was significant variation in DES use among the various hospitals participating in VCOR (Figure 9).

In general, the use of DES has been primarily directed towards (but not limited to) patients who are considered at increased risk of restenosis because of the presence of specific lesion subtypes such as long lesions, lesions in smaller diameter arteries, ostial lesions, chronic total occlusions and restenotic lesions. Certain patient subgroups are also considered at increased risk of restenosis, including patients with diabetes and those with renal impairment. Accordingly, DES use is expected to be higher in these patient and lesion subsets, although some variation among hospitals is likely depending on their clinical approaches and financial constraints.

VCOR collected data on several of the patient and lesion characteristics associated with in-stent restenosis and rates of DES use in these subsets are shown in Table 4.

Interestingly, some high-risk subgroups (renal failure and chronic total occlusion) actually had a lower than average DES use. The explanation for this remains uncertain, but this finding underscores the complexities surrounding the determination of appropriateness when assessing different PCI therapies.



Figure 9. Drug eluting stent use by hospital

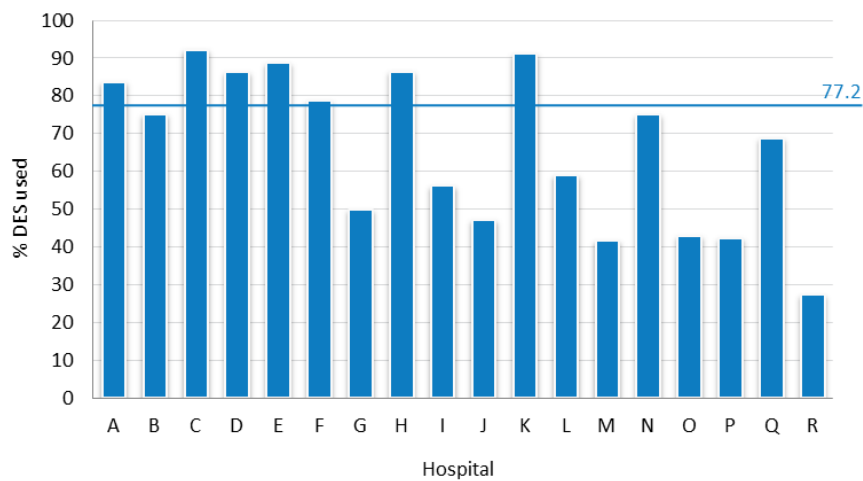


Table 4. Drug eluting stent use in different patient and lesion subgroups

Cohort Subgroups*	PCI cases (n=4760)	DES** use (n=3673)
Patient subgroups	N	N (%)
Diabetes Medication	1062	858 (80.8)
Renal Failure	73	51 (69.9)
Lesion subgroups	N	N (%)
Chronic total occlusion	212	137 (64.6)
Complex lesion	2755	2163 (78.5)
In-stent restenosis	283	229 (80.9)

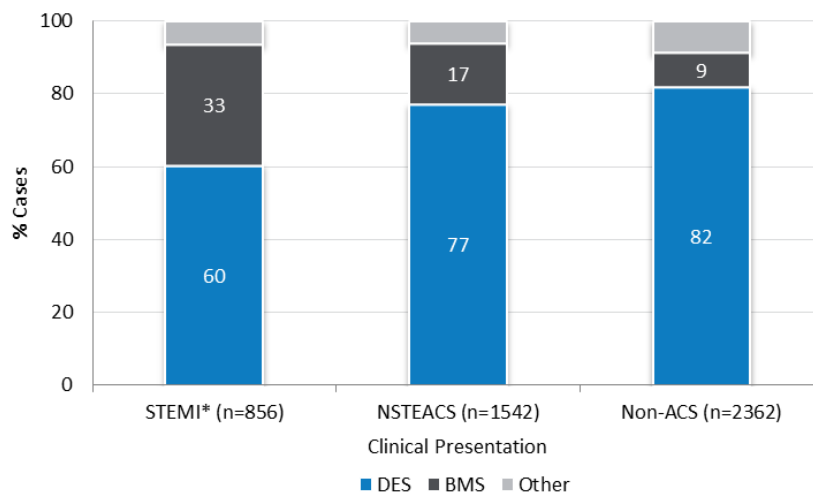
*Subgroups are not mutually exclusive (patients may belong to more than one subgroup)

**DES use includes any case where DES deployed to one or more lesions

Figure 10 compares the use of DES among different clinical presentations. There was a trend towards higher rates of DES use in less acute clinical settings, with the lowest rate of DES use among patients with acute STEMI. This may be a reflection of residual concern interventional cardiologists have harboured regarding the safety of these stents in the STEMI setting.

This followed the emergence of some negative registry and pathology data back in 2006-7 that DES use in STEMI was potentially hazardous. Since then, there have been several studies that have established the safety and efficacy of DES in acute STEMI⁸⁻¹¹; yet data from VCOR demonstrate that operators still have a greater bias towards conventional bare metal stents in this particular clinical setting.

Figure 10. DES use based on clinical presentation



'Other' category includes plain balloon angioplasty and bioresorbable vascular stents
**Includes all patients undergoing PCI within 7 days of STEMI symptom onset*

PCI for acute STEMI

Acute ST elevation myocardial infarction occurs when a coronary artery becomes acutely occluded by blood clot formed as a result of rupture of atherosclerotic plaque. It still remains the leading cause of death in Australia, and even if not fatal, myocardial infarction results in significant heart muscle damage and patient morbidity. Acute STEMI is considered a medical emergency and the most important early treatment, known as reperfusion therapy, aims to rapidly restore blood flow to the acutely occluded vessel. Wherever possible, the preferred method of reperfusion is by percutaneous coronary intervention. Many (but not all) hospitals in Victoria that have PCI facilities have developed systems and processes to provide emergency PCI for acute STEMI.

PCI that is performed as primary reperfusion therapy within 12 hours of onset of symptoms of STEMI is known as **primary PCI**. For those patients with acute STEMI who initially undergo reperfusion therapy with thrombolysis (clot dissolving medication), PCI may still be performed as part of their early (<24 hours) treatment. PCI performed because thrombolysis

was unsuccessful in restoring blood flow is known as **rescue PCI**. If PCI is performed as part of a strategy that combines thrombolysis, routinely followed by PCI 3-24 hours later, it is known as **pharmaco-invasive therapy**.

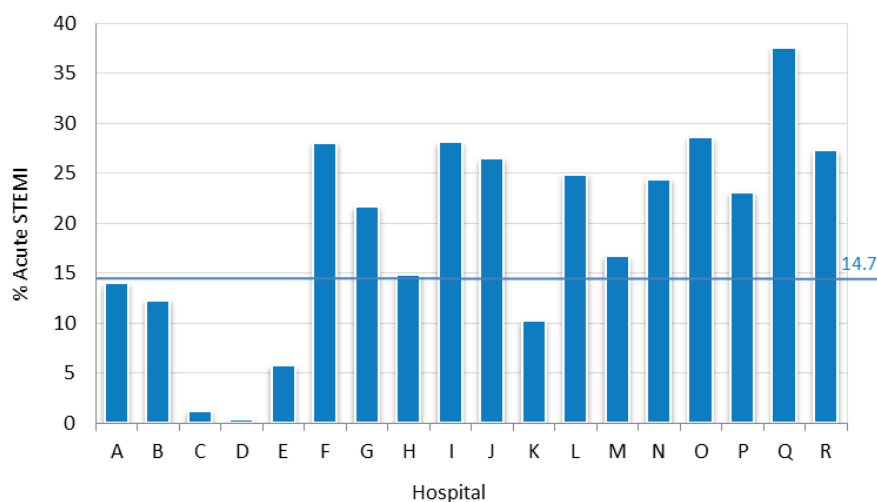
As part of its performance monitoring function, VCOR has been set up to collect data on specific outcomes in relation to PCI for acute STEMI. In 2013, there was a total of 702 cases of PCI for acute STEMI. This cohort accounted for 14.7% of PCIs reported in VCOR. Eighty-one percent of this cohort was male (n=567). The median age of males was 59 years, while the median age of females in this group was 64 years. Table 5 compares the clinical and demographic characteristics of this cohort with the rest of the PCI cohort.

There was significant variation in the proportion of each hospital's workload dedicated to emergency PCI (Figure 11). As pointed out above, several sites (sites M to R) contributed data for only one month during 2013. As a result of the small numbers for these sites, the proportion of cases for STEMI may not be a true reflection of the usual casemix for those sites.

Table 5. Acute STEMI cohort patient characteristics

Characteristic	STEMI cohort (n=702)	Remainder of cohort (n=4058)
Age – years (Mean ± SD)	61.2 (±13)	67.1 (±12)
Gender – female	19.2%	23.5%
Diabetes medication	17.5%	23.1%
Peripheral vascular disease history	2.6%	3.7%
Cerebrovascular disease history	1.4%	4.2%
Previous PCI	11.4%	38.4%
Previous CABG	2.7%	10.0%

Figure 11. Acute STEMI cases as a proportion of overall case numbers by hospital



Hospitals also differed in the proportion of cases initially treated with thrombolysis (rescue PCI and pharmaco-invasive therapy). Some hospitals receive a greater proportion of their cases as referrals from regional and rural centres and are therefore expected to have a greater number of patients pre-treated with thrombolysis prior to transfer. Hospitals primarily treating metropolitan-based patients, who are usually within 30 minute travel times of a hospital with emergency PCI facilities, are expected to have relatively fewer patients initially receiving thrombolytic therapy.

The proportion of cases that were primary PCI, rescue PCI or pharmaco-invasive therapy are shown in Figure 12. Figure 13 shows the treatment type for acute STEMI by hospital.

Figure 12. Proportion of PCI treatment type (acute STEMI cohort)

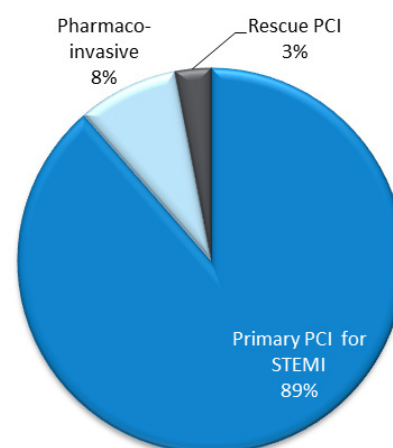
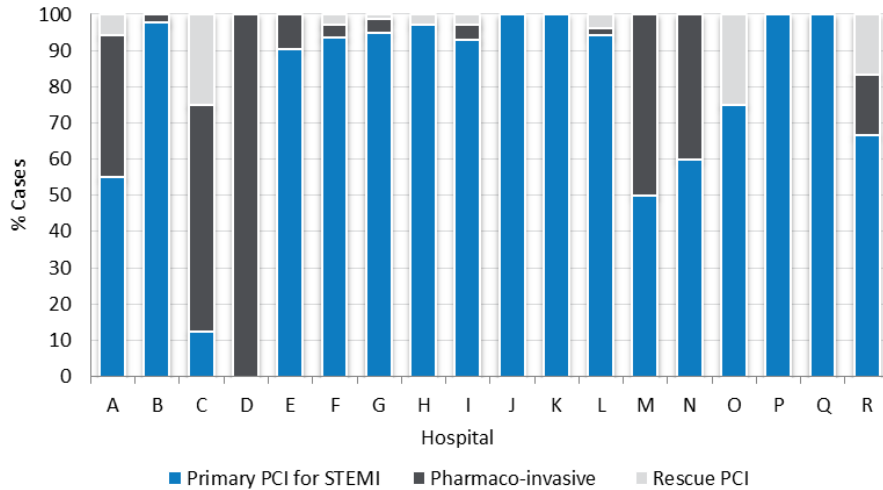


Figure 13. PCI treatment type for acute STEMI cohort by hospital



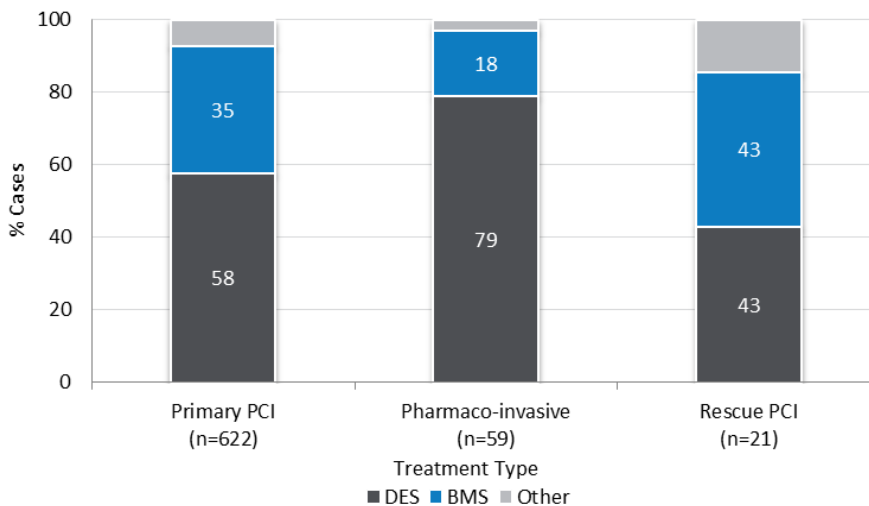
Sites D, M & O had low case numbers (n<5)

Twenty-two percent of the STEMI cohort arrived from another health service as inter-hospital transfers. However, not all these patients necessarily received thrombolysis prior to transfer. For those patients who were within 90 minutes travel time of a PCI receiving hospital, there was an option for immediate transfer for primary PCI treatment. As such, 76 STEMI patients who arrived as inter-hospital transfers received primary PCI. There was wide variation among hospitals in the proportion of STEMI cases arriving as inter-hospital transfers.

DES use was less common in acute STEMI compared with other clinical presentations (Figure 10), and may in part reflect a residual hesitation among cardiologists

to use this device in arteries with acutely ruptured plaque and high thrombus load. Use of DES in primary PCI was well below the average for the overall cohort, but Figure 14 reveals an interesting trend towards proportionally higher DES use in rescue PCI and with the pharmaco-invasive approach. Both these STEMI strategies involve pre-treatment with thrombolysis and although there are no compelling data to suggest that DES is particularly beneficial in PCI that follows shortly after thrombolysis, the VCOR cohort has demonstrated a greater willingness to use DES in these situations. Admittedly, the number of patients in the rescue PCI and pharmaco-invasive groups are comparatively small, but this will be an interesting trend to follow in coming years.

Figure 14. Drug eluting stent within acute STEMI cohort



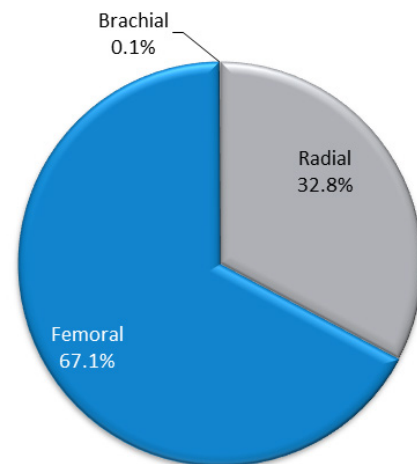
Arterial access

In order to perform a PCI, access through an artery is required. PCI can be performed via the femoral artery (groin), radial artery (wrist) or brachial artery (inner elbow). Historically, most PCIs were performed via a femoral approach. However, in the last few years, there has been a move to using a radial approach in increasing numbers. This method has a number of potential advantages, including lower bleeding rates, improved patient comfort and may actually improve outcomes – particularly in patients presenting with acute STEMI^{12, 13}. Given that this change in vascular access is occurring to differing extents among various health services, it is important to follow this trend and monitor whether it does indeed have an influence on outcomes.

In 2013, the femoral approach was still used in a majority of cases, (Figure 15), although radial cases accounted for approximately one third of all cases. Figure 16 demonstrates that the uptake of radial cases varied considerably among participating VCOR sites, with some sites below 20% and others approaching 100% of their cases. The radial technique was more frequently observed in men than women (Table 6). The apparent bias towards the radial approach in men may in part be due to the preference of operators to use the technique on larger sized radial arteries in males, while avoiding the approach in females because of their higher chance of radial artery spasm. However, international data suggest the potential benefits of a radial over a femoral approach are as applicable to women as men.

Given the worldwide trend towards the radial approach in the past few years, it is anticipated that both the number of centres performing radial cases routinely, and the number of patients treated in this manner will continue to grow in Victoria in the coming years.

Figure 15. Arterial access route (cohort)



When observing radial access by gender groups, men were generally younger than females, with a median age of 65 years and 70 years, respectively for each group.

Figure 16. Arterial access route by hospital

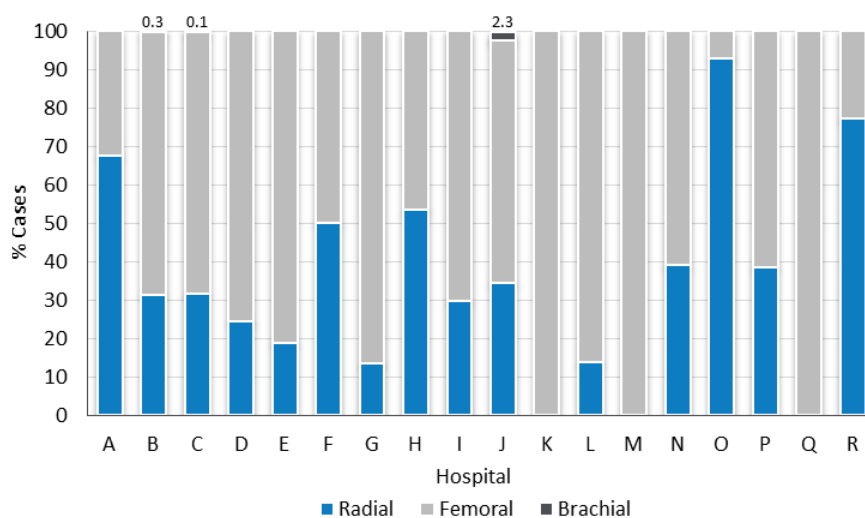


Table 6. Access route by gender

Access Route	PCI cases (n=4760) N (%)	Male PCI cases (n=3672) N (%)	Female PCI cases (n=1088) N (%)
Radial access	1561 (32.8)	1260 (34.3)	301 (27.7)
Femoral access	3195 (67.1)	2410 (65.6)	785 (72.2)
Brachial access	4 (0.1)	2 (0.1)	2 (0.2)

Outcomes

Lesion and procedural success

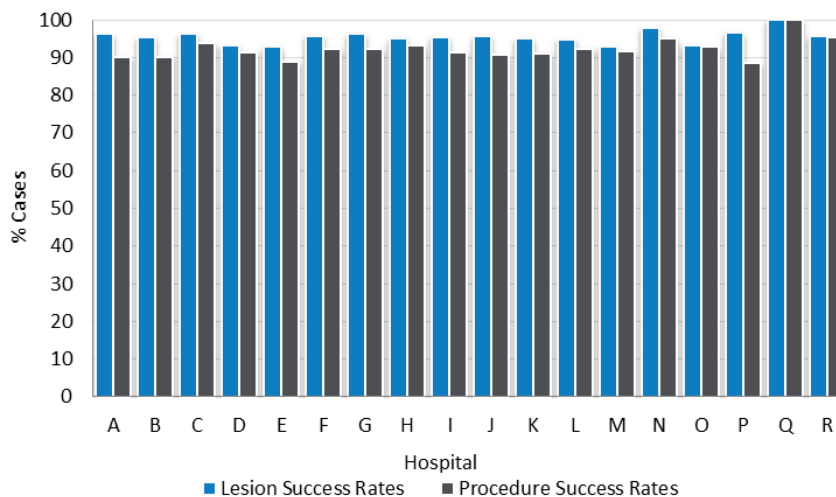
The efficacy of PCI relates to its ability to open up narrowed or blocked coronary arteries with a coronary stent or balloon, with a high chance of procedural success, a low risk of complications and a strong likelihood of a good long-term durable result. Historically, this procedure has been found to be highly successful in the Australian context¹⁴. As procedural success is an important outcome, it is tracked closely in VCOR.

Success is measured in terms of individual **lesion success** where the lesion is reduced to less than 10% residual stenosis following stenting, or less than 50% residual stenosis following balloon angioplasty alone.

Procedural success is defined as all attempted lesions successfully treated, without any significant in-hospital complications.

Overall, hospitals reported that 95.2% of lesions attempted were successfully treated (lesion success rate) while the overall procedure success rate for the cohort was 91.6%. Figure 17 displays lesion success and procedure success rates for each hospital.

Figure 17. Lesion and procedural success rates by hospital



Key Performance Indicators (KPIs)

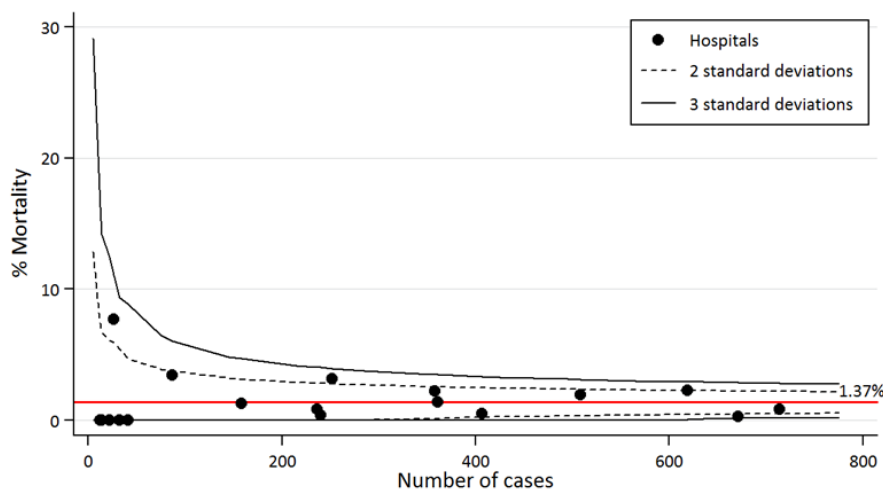
In order for VCOR to monitor and benchmark the performance of health services in their delivery of quality cardiac care, a number of key performance indicators (KPIs) have been developed, based on clinically relevant procedural outcomes.

The key performance indicators that have been developed for the VCOR PCI module are:

- In-hospital mortality
- In-hospital unplanned revascularisation
- In-hospital major bleeding
- Length of stay
- Door to balloon time for STEMI patients
- 30-day mortality
- 30-day target vessel failure
- 30-day major adverse cardiac and cerebrovascular event (MACCE)

Data are displayed in the form of funnels plots¹⁶ to assist the benchmarking of performance of the contributing VCOR sites. This format provides an easy way to appreciate the relationship between hospital outcomes and the number of procedures performed in each hospital.

Figure 18. In-hospital mortality



Outcome Measures

A. In-hospital Mortality

The overall rate of in-hospital mortality was 1.37%. Figure 18 demonstrates that in-hospital mortality for each of the participating health services was within acceptable confidence limits and no particular trend was apparent in relation to number of cases and outcomes. It is again important to note that as 2013 was the first year of the registry and a number of hospitals commenced enrolment of patients part way through the year, the actual case numbers for these hospitals as shown in the figure represent only a proportion of that hospital's usual caseload.

It is expected that the mortality rate in patients with cardiogenic shock or out of hospital cardiac arrest (OHCA) will be higher¹⁵. This was borne out in the VCOR analysis with Table 7 showing that patients with shock/OHCA had a 30% in-hospital mortality rate compared with 0.6% in the non-shock/OHCA group of patients. We analysed mortality excluding the shock/OHCA group of patients and the results are shown in Figure 19.

The rate of in-hospital mortality was highest for patients presenting with STEMI (Table 8). These data are comparable with international registry data¹⁶.

Table 7. In-hospital mortality rates by shock/out-of-hospital cardiac arrest

	All cases (n=4758) N (%)	No Shock/OHCA* (n=4628) N (%)	Shock/OHCA* (n=130) N (%)
In-hospital mortality	65 (1.4)	26 (0.6)	39 (30.0)

*Patients coded as 'cardiogenic shock' or 'out-of-hospital cardiac arrest' (OHCA) at presentation

Figure 19. In-hospital mortality (excluding shock/OHCA)

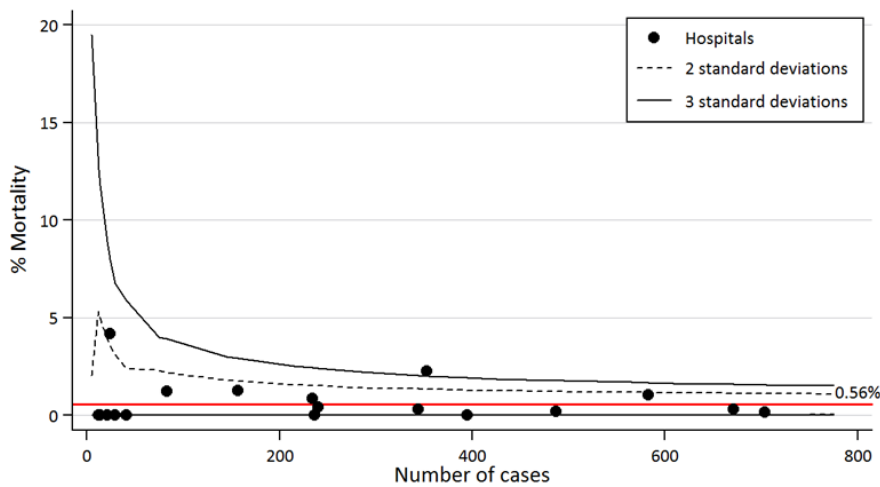


Table 8. In-hospital mortality rates by clinical presentation

Clinical Presentation	Total N	In-hospital Mortality N (%)
STEMI	856	49 (5.7)
NSTEACS	1541	10 (0.6)
Non-ACS	2361	6 (0.3)
Total	4758	65 (1.4)

B. In-hospital Unplanned Revascularisation

In-hospital unplanned revascularisation refers to any unexpected revascularisation procedure (either PCI or CABG surgery) that the patient undergoes after the index PCI procedure, but still within the same admission. Typically, this occurs as a result of the complication of acute or subacute stent thrombosis and often presents as an evolving acute myocardial infarction and is a medical emergency. The metric of unplanned in-hospital revascularisation also includes cases where the patient undergoes a further

unplanned revascularisation procedure on coronary vessels other than the one initially treated with PCI.

The overall rate of in-hospital unplanned revascularisation was 1.4%. Figure 20 demonstrates that all hospitals in VCOR had rates of unplanned revascularisation that were within the control limits. The outcome results were not influenced by case numbers of the individual hospitals.

A number of interesting observations were noted with respect to major bleeding events in VCOR in 2013. The highest bleeding rates were seen in patients presenting with acute STEMI (Table 9) – an expected finding, as this patient cohort generally receives the most intensive anti-platelet and anticoagulant therapies. Major bleeding events were almost 3 times more frequent in females than males (Table 10), with a lower observed rate of bleeding in the radial cohort (Table 11). In the absence

of an appropriate risk adjustment model for bleeding it is uncertain as to whether these cases of bleeding occurred at a rate above that expected for the casemix. A risk adjustment model for bleeding outcomes is being developed for use in VCOR and this will aid in better interpretation of bleeding rates across hospitals.

Table 9. In-hospital major bleeding by clinical presentation

Clinical Presentation	Total N	Major Bleeding N (%)
STEMI	856	12 (1.4)
NSTEACS	1541	10 (0.7)
Non-ACS	2361	13 (0.6)
Total	4758	35 (0.7)

Table 10. In-hospital major bleeding rates by gender

Gender	Total N	Major Bleeding N (%)
Male	3670	19 (0.5)
Female	1088	16 (1.5)
Total	4758	35 (0.7)

Table 11. In-hospital major bleeding rates by arterial access site

Access Route	Total N	Major Bleeding N (%)
Radial access	1561	6 (0.4)
Femoral access	3193	29 (0.9)
Brachial Access	4	0 (0.0)
Total	4758	35 (0.7)

D. Length of Stay

Length of stay has traditionally been used as a process measure of the efficiency of hospitals relative to a particular procedure or operation. For most elective cases, length of stay is expected to be one day. While same-day discharge following elective, uncomplicated PCI occurs in a number of centres in Australia and internationally, the overwhelming majority of cases in VCOR included an overnight stay.

Length of stay, as a metric, is influenced by a complex set of factors surrounding the management of the patient, including the clinical presentation of the patient, complexity of the procedure and patient

co-morbidities. Complications that may develop as a consequence of the procedure (such as bleeding) may also affect length of stay. Notwithstanding these potential confounders, the metric is generally accepted as an important performance indicator and is included among the KPIs in VCOR.

Figure 22 show length of stay (in days) by clinical presentation for the VCOR 2013 cohort. The median length of stay was longer for patients presenting with STEMI compared with other clinical presentations.

Figures 23 to 25 show the length of stay by clinical presentation (STEMI, NSTEMI, UAP) for each hospital.

Figure 22. Length of stay by clinical presentation

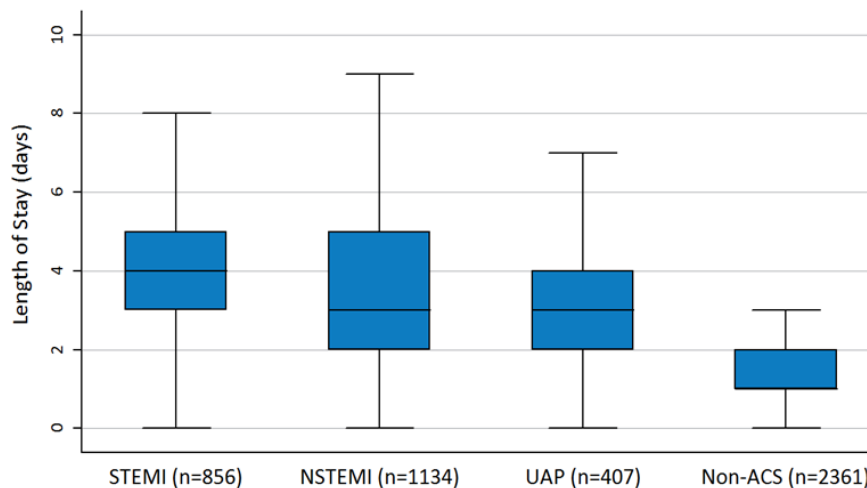


Figure 23. STEMI patients' length of stay by hospital

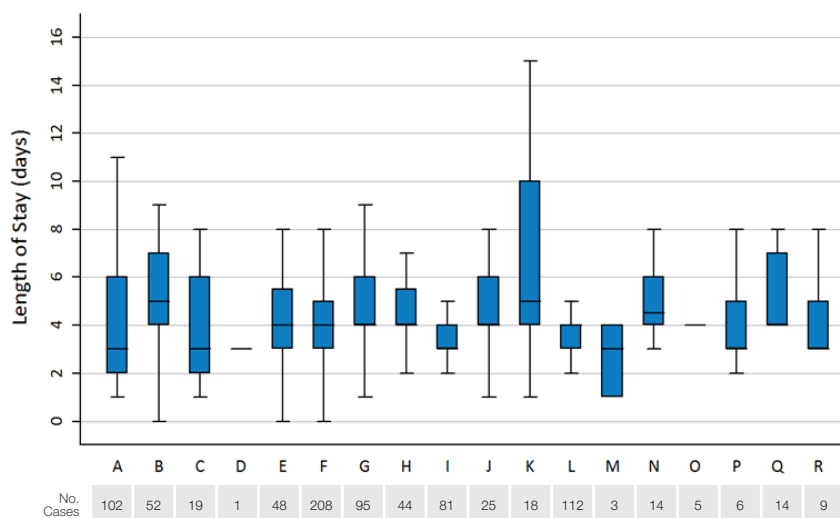


Figure 24. NSTEMI patients' length of stay by hospital

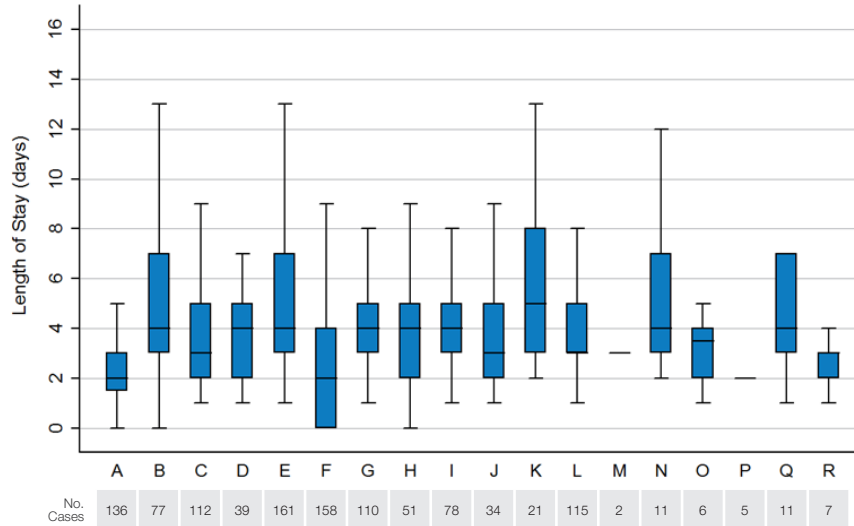
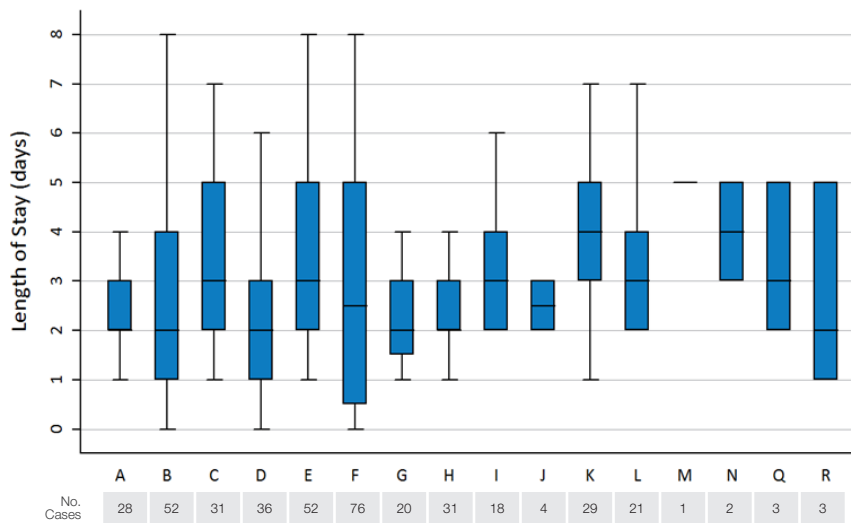


Figure 25. Unstable angina patients' length of stay by hospital



Sites O and P performed no PCIs on Unstable Angina patients

E. Door to Balloon Time (for STEMI patients treated with primary PCI)

For patients presenting with STEMI and undergoing primary PCI, the time taken from their arrival to the hospital until the insertion of a device to unblock the vessel (usually a balloon catheter or other device to extract clot) is known as the **door-to-balloon time**. This is a key performance measure that assesses the ability of a hospital, its systems and its processes, to treat acute STEMI in a timely and efficient manner.

It is generally accepted that the benchmark door-to-balloon time hospitals should aim for is 90 minutes or less in at least 80% of cases.

The door-to-balloon times for the primary PCI cohort are shown in Table 12, and compared among participating VCOR hospitals in Figure 26.

Patients with acute STEMI generally present to the hospital in one of two ways – either transported by ambulance or by self-presenting. In the last five years, metropolitan Melbourne and Geelong have benefited significantly from a major initiative of Ambulance Victoria that instituted a system for advance notification of arrival of a patient with STEMI to the treating hospital. This involves attending ambulance officers performing a 12 lead ECG in the field, diagnosing a STEMI by the presence of ST elevation on the ECG and then electronically transmitting the ECG to the receiving hospital. This advance notice facilitates the activation of the catheterisation laboratory at the receiving hospital to prepare for the patient’s arrival, allows the patient to bypass the triage and administrative processes in the emergency department and minimises any delays in commencing

the angioplasty. Results of a pilot study of this initiative demonstrated significant reduction in average door-to-balloon times among patients who were managed in this way¹⁹.

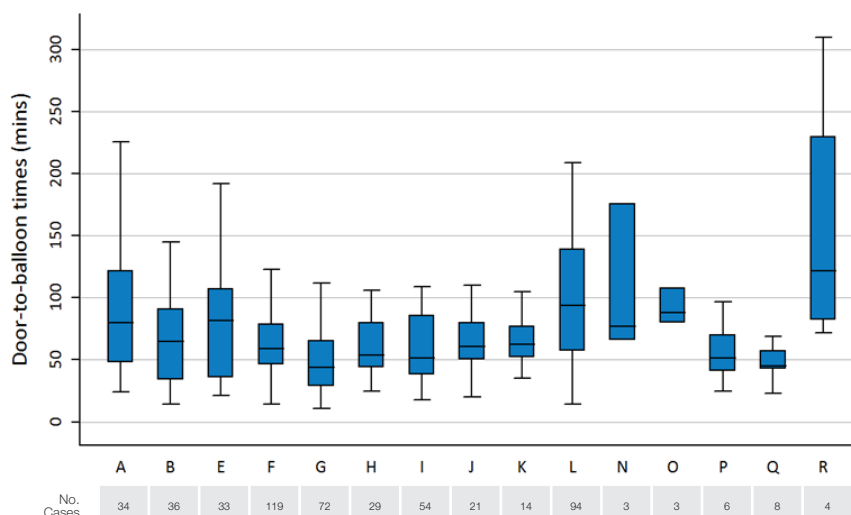
For 2013, all public hospitals and a majority of private hospitals contributing to VCOR were enrolled in this pre-notification scheme. A total of 269 of the 531 PCI cases (60.3%) treated for acute STEMI were admitted through the pre-hospital notification system. Table 12 shows that treatment delays were shorter in this subgroup – in relation to both the median door-to-balloon time and the proportion of cases that achieved a door-to-balloon time ≤90 minutes. Figure 27 shows the proportion of cases achieving a door-to-balloon time ≤90 minutes by hospital.

Table 12. Door-to-balloon times for primary PCI cases

Door-to-Balloon Time	PPCI* (All) (n=531)	PPCI (No pre-hospital notification) (n=262)	PPCI (Pre-hospital notifications only) (n=269)
Median (mins, IQR)	64 (44, 99)	83 (56, 123.5)	52 (37,72)
Proportion of cases ≤90 mins	70.9 %	55.5%	85.9%

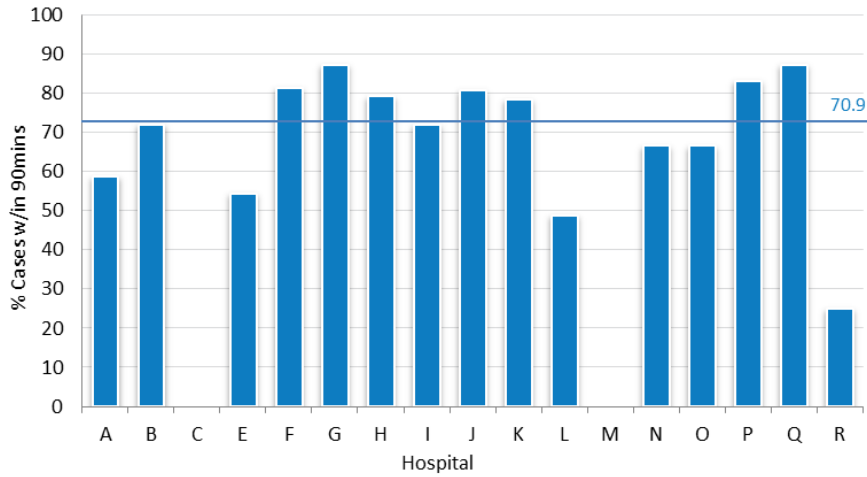
*Primary PCI (PPCI) cohort excludes any patients arriving as inter-hospital transfers
Interquartile range (IQR) represents 25th and 75th centiles

Figure 26. Door-to-balloon times for primary PCI cases by hospital



Site D performed no primary PCIs
Site C & M each performed only 1 primary PCI case in 2013

Figure 27. Proportion of primary PCI cases with door-to-balloon time ≤ 90 minutes by hospital



Site D performed no primary PCIs

Site C & M each performed only 1 primary PCI and neither achieved a door-to-balloon time ≤ 90 min

F. 30-Day Mortality

The 30-day mortality for the 2013 cohort was 1.66%. Figures 28-29 and Tables 13-14 show the mortality across various groups including in the shock/OHCA group and by clinical presentation. It is critical to note that case numbers for many of the participating hospitals in this 2013 period were incomplete. Some hospitals only contributed one month of data and as

a result, hospitals with very low case numbers are at risk of having distorted and non-representative results. Notwithstanding this caveat, the results for 2013 demonstrated that all hospitals participating in VCOR had 30-day mortality rates within acceptable control limits.

Figure 28. 30-day mortality

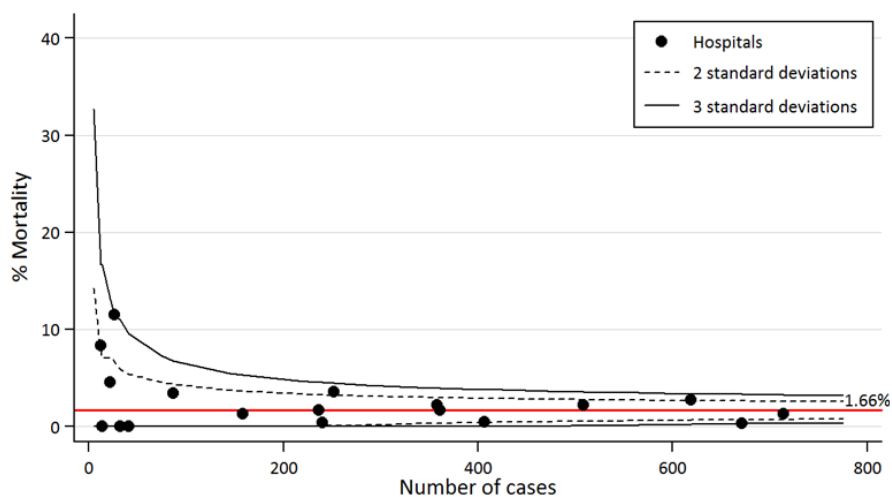


Table 13. 30-day mortality rates by shock/out-of-hospital cardiac arrest

	All cases (n=4758) N (%)	No Shock/OHCA (n=4628) N (%)	Shock/OHCA* (n=130) N (%)
30-day mortality	79 (1.7)	37 (0.8)	42 (32.3)

*Patients coded at presentation as 'cardiogenic shock' or 'out-of-hospital cardiac arrest' (OHCA)

Figure 29. 30-day mortality (excluding shock/OHCA patients)

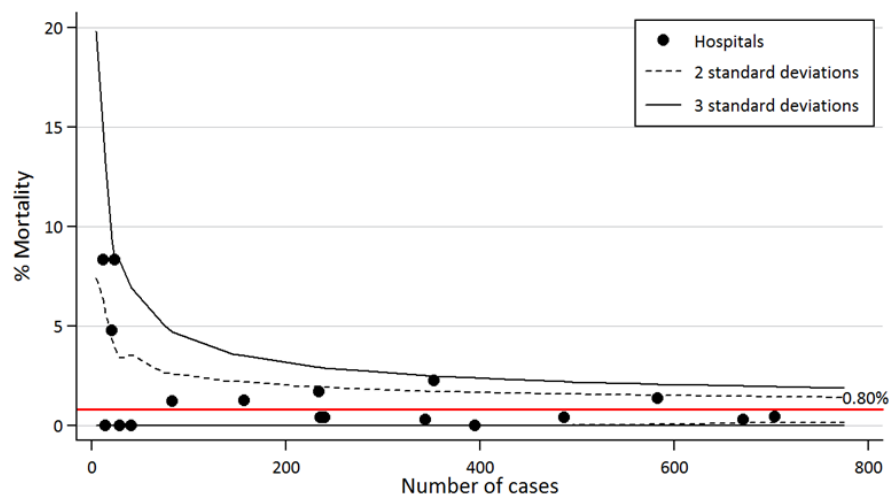


Table 14. 30-day mortality rates by clinical presentation

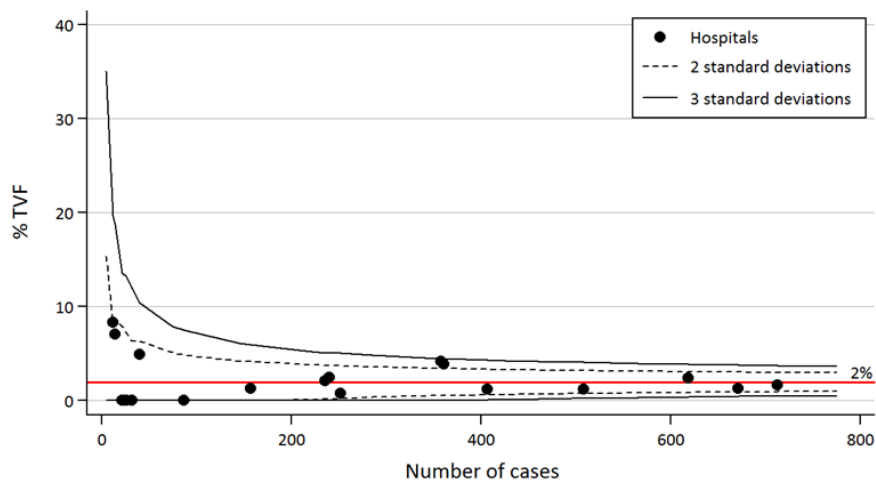
Clinical Presentation	Total N	30-day Mortality N (%)
STEMI	856	56 (6.5)
NSTEACS	1541	16 (1.0)
Non-ACS	2361	7 (0.3)
Total	4758	79 (1.7)

G. 30-Day Target Vessel Failure

Target vessel failure is a measure representing the number of PCI cases subsequently found to have restenosis or re-occlusion of the artery initially treated. It includes all cases that undergo target vessel revascularisation within the 30-day period - either by

repeat PCI or coronary artery bypass surgery. The rates of target vessel failure at 30 days are shown in Figure 30. Overall, the rate of 30-day target vessel failure was 2%. All hospitals in the 2013 cohort were within acceptable control limits.

Figure 30. 30-day target vessel failure



H. 30-Day Major Adverse Cardiac Cerebrovascular Events (MACCE)

Major adverse cardiac and cerebrovascular events (MACCE) is a composite measure that refers to an ordered grouping of unwanted clinical outcomes considered harmful to the patient. In VCOR, the MACCE rate encompasses all cases that suffer death, new or recurrent myocardial infarction, target vessel revascularisation or a cerebrovascular event (stroke). Overall, the rate of 30-day MACCE was 4.6%.

The component endpoints and rates of in-hospital and 30-day MACCE are shown in Table 15.

Figure 31 shows major adverse cardiac cerebrovascular event (MACCE) rates to 30 days among the participating hospitals in the registry.

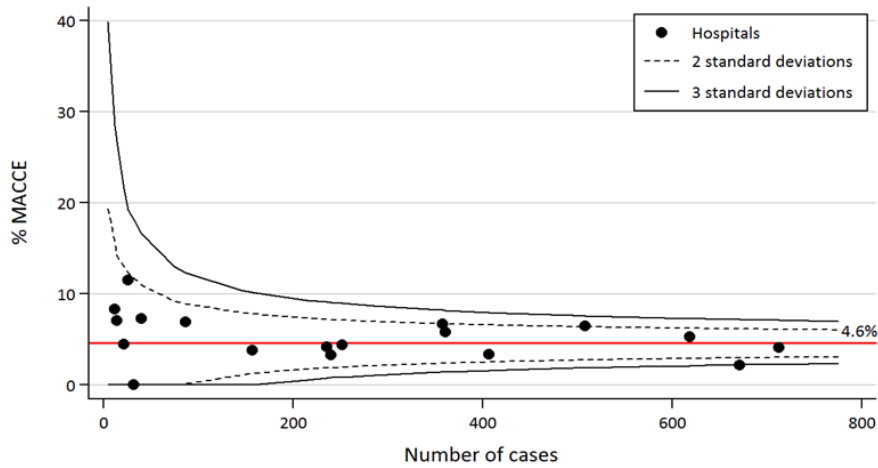
Table 15. 30-day MACCE rates

30-day Event*	In-hospital N (%)	30 days N (%)
Mortality	65 (1.4)	79 (1.7)
Myocardial Infarction	48 (1.0)	69 (1.5)
Stroke	13 (0.3)	17 (0.4)
Stent thrombosis	13 (0.3)	17 (0.4)
Target vessel revascularisation**	52 (1.1)	83 (1.7)
Total	152 (3.2)	219 (4.6)

*30-day events reported include in-hospital events

**Target vessel revascularisation refers to any PCI or CABG revascularisation of the target vessel

Figure 31. 30-day MACCE rates by hospital



MACCE includes cases that have reported mortality, new or recurrent MI, stent thrombosis, stroke and/or target vessel revascularisation to 30 days

Other Outcomes

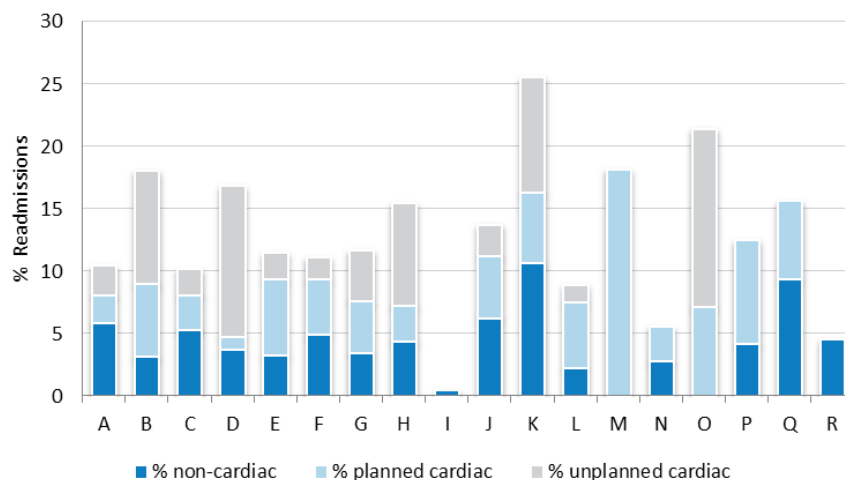
30-Day Rehospitalisation Rates

Data regarding hospital readmissions were analysed. Overall, 11.7% of patients were readmitted within 30 days of the index procedure, with 5.7% being readmitted more than once.

The majority (64%) of readmissions in the 30 day period were for cardiac causes, including heart failure,

acute coronary syndromes, arrhythmias or additional cardiovascular interventions or surgery (e.g. PCI or CABG). Forty-seven percent of readmissions that were for a cardiac problem were unplanned (or emergent). Figure 32 shows the 30-day readmission rates among the participating hospitals in the registry.

Figure 32. 30-day rehospitalisation rates by hospital



Rehospitalisation data only completed in 27% of cases for site I
Sites M-R collected data for one month only

Quality of Life Metrics

At 30-day follow-up, patients were asked to rate their perceived quality of life in a series of questions based on a standardized measure, the EQ-5D²⁰. Patients reported how they fared in terms of mobility, ability to perform usual activities and personal care tasks, level of pain/discomfort and whether they experienced any anxiety/depression. The results are shown in Figures 33-37. Overall, the majority of patients reported 'no problem' in these areas.

On a scale from 1-100, with 100 being the best a patient could remember ever feeling, patients reported their 'own health state' as, on average, 78 out of 100 (Mean=77.7 ±16.1 SD). Fifty percent of patients reported their own health state between a range of 65 to 85 out of 100, while 31% of patients were 'not asked' to quantify their own health state.

Figure 33. Quality of life (mobility)

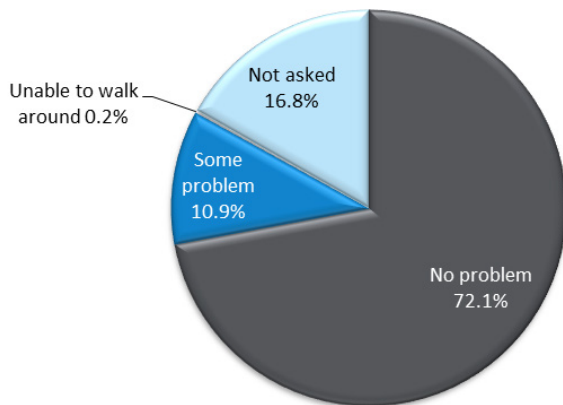


Figure 34. Quality of life (personal care)

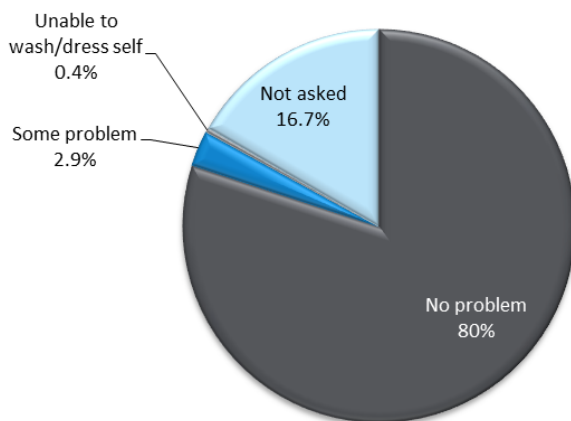


Figure 35. Quality of life (usual activities)

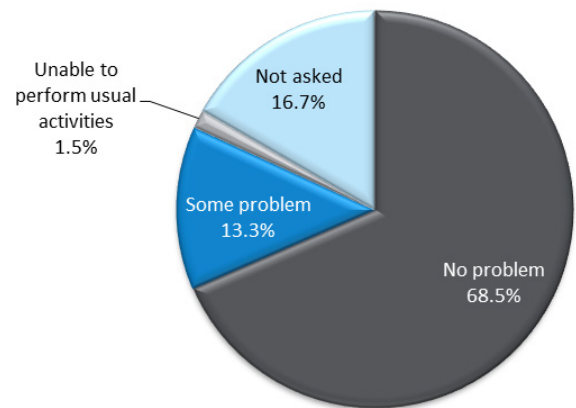


Figure 36. Quality of life (pain/discomfort)

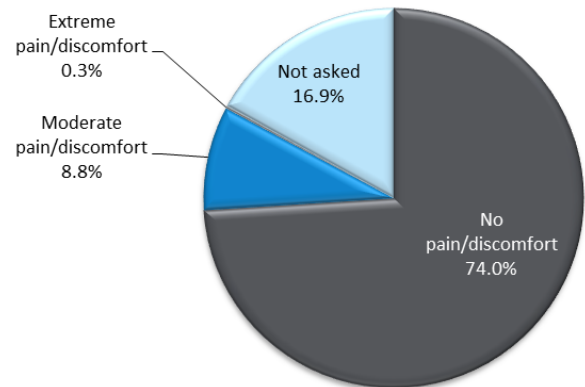
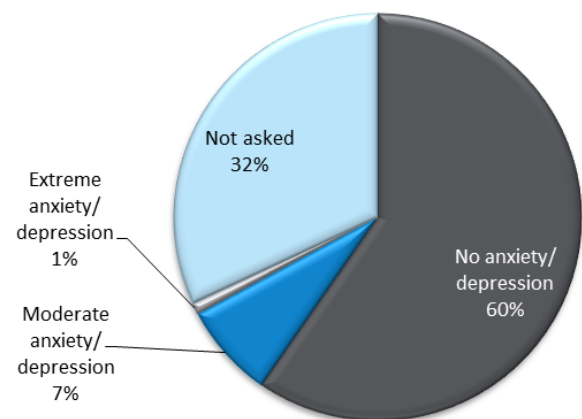


Figure 37. Quality of life (anxiety/depression)



Future Directions

The establishment of the Victorian Cardiac Outcomes Registry represents a major milestone of cooperation and coordination among the state's cardiology community – across both the public and private sectors. It has accompanied a period of increased focus on quality in healthcare evident among clinicians, healthcare funders and the health bureaucracy. This focus remains strongly patient-oriented, and as VCOR builds on its early achievements, we can look forward to a healthcare environment that ensures patients receive cardiac care of the highest quality irrespective of their location, insurance status or healthcare provider.

Continuous Improvement

We recognise that the reporting role of VCOR is a central function of the registry. We have been actively improving the design and content of our quarterly reports to participating health services and will continue to provide personalised and individualised tables and graphs of results to each health service. Comparative data from other health services remain de-identified in these reports, but individual hospitals can clearly benchmark their results against others and the overall cohort.

We plan to introduce risk adjustment modeling in 2014 for overall mortality and bleeding events. Risk adjustment is frequently used when assessing outcomes in health care delivery to account for differences in the mix of important patient characteristics before outcomes are compared. As a statistical tool, risk adjustment will allow our data to be presented in a way that controls for variations in patient populations. It will be a fairer and more representative way of benchmarking the relative performances of hospitals against one other.

We are also continually reviewing our data elements and the quality and utility of the data that we are collecting. Some data fields have proven difficult to collect, while others can be enhanced or refined to further strengthen the meaningfulness of the data collected. Processes will continue to be implemented to allow future versions of the dataset to be developed, validated and then eventually rolled out to participating health services.

We have worked closely with the national Cardiac Society of Australia of Australia and New Zealand, who are in the early stages of implementing a national registry of percutaneous coronary intervention. Our dataset has been closely aligned and calibrated with the dataset of the Australian Cardiac Outcomes Registry, and it is envisaged that these two projects will work synergistically and in close collaboration to ensure that the results that have been achieved in Victoria will be translated onto the broader national stage.

Beyond PCI

From its outset, one of the principal aims of VCOR has been to extend its quality assurance activities beyond the setting of PCI, and to encompass cardiac healthcare activities in rural and regional settings. To this end, VCOR has developed a second module of activity focusing on the early management of acute ST elevation myocardial infarction, particularly in relation to the quality of delivery of reperfusion therapy, and the eventual outcome of patients with STEMI initially treated in hospitals without PCI facilities. Both these factors have well-recognised influences on patient outcomes.

The module for early STEMI management has been designed and is currently being tested in a number of pilot sites in rural Victoria. Recruitment of additional sites across regional Victoria will continue throughout 2014 and beyond, with the intention of VCOR expanding its quality and benchmarking role to these centres through regular reports and performance monitoring.

VCOR is also exploring the possibility of reaching into other cardio-therapeutic areas including heart failure, implantable devices (pacemakers and defibrillators) and arrhythmias (primarily atrial fibrillation). A project assessing the feasibility of a minimum dataset to monitor the management and outcomes of patients with acute heart failure is already underway.

Conclusion



The establishment of VCOR represents an unprecedented level of cooperation among healthcare providers, payers and planners in Victoria to improve the treatment and outcomes of patients undergoing PCI. While it is still in its early phases, this clinical quality registry has great potential to ensure that cardiac patients receive the highest quality of care. This report has highlighted the registry's achievements in its first year of operation. As we build on these achievements, we anticipate an era of enhanced care, rooted in evidence-based practice, which can be effectively measured, monitored and improved upon to deliver the best care to all patients – effectively, efficiently and in a timely manner.

Glossary

ACPR	Australian Cardiac Procedures Registry
ACS	Acute Coronary Syndrome
BARC	British Academic Research Consortium
BMS	Bare Metal Stent
CABG	Coronary Artery Bypass Graft
DEPM	Department of Epidemiology & Preventive Medicine
DES	Drug Eluting Stent
KPI	Key Performance Indicator
MACCE	Major Adverse Cardiac & Cerebrovascular Event
NHMRC	National Health & Medical Research Council
NSTEACS	Non-ST Elevation Acute Coronary Syndrome
NSTEMI	Non ST-Elevation Myocardial Infarction
OHCA	Out of Hospital Cardiac Arrest
PCI	Percutaneous Coronary Intervention
PPCI	Primary Percutaneous Coronary Intervention
STEMI	ST-Elevation Myocardial Infarction
UAP	Unstable Angina Pectoris
VCOR	Victorian Cardiac Outcomes Registry

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Organisation	Funding			
	2011	2012	2013	2014
Medibank Private	\$100,000	\$400,000	\$400,000	\$300,000
Department of Health	\$200,000	\$200,000	\$200,000	\$350,000
Department of Health - Victorian Cardiac Clinical Network (VCCN)				\$159,466
Total	\$300,000	\$600,000	\$600,000	\$809,466
Total Funding Received				\$2,309,466

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