

A stylized ECG (heart rate) line in blue and teal runs across the top and bottom of the page, framing the central text.

ANNUAL PUBLIC REPORT **2019**

VICTORIAN CARDIAC OUTCOMES REGISTRY

Improving cardiovascular outcomes Victoria-wide

This publication was produced on behalf of the Victorian Cardiac Outcomes Registry (VCOR).

Suggested citation:

A/Prof Jeffrey Lefkovits, Ms Angela Brennan, Dr Diem Dinh, Ms Harriet Carruthers, Mrs Janine Doyle, Mrs Philippa Scanlon, Mr Mark Lucas and Prof Christopher M Reid on behalf of the VCOR. The Victorian Cardiac Outcomes Registry Annual Report 2019. Monash University, SPHPM September 2020, Report No 7, pages 78.

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Report No: 7,
September 2020

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VCOR 2019 Annual Report



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Acknowledgements



VCOR is funded by the Department of Health and Human Services (DHHS) Victoria with in-kind funding from Monash University. VCOR is operated by the Department of Epidemiology and Preventive Medicine (DEPM), Monash University, in association with Safer Care Victoria and the DHHS.

We gratefully acknowledge contributions made by the VCOR Steering Committee, the VCOR Clinical Quality Committee, the VCOR Data Research and Publications Committee, the VCOR Registry Custodian - Prof Christopher M Reid and the VCOR Clinical Director - A/Prof Jeff Lefkovits. We also acknowledge the VCOR Data and Project Management Committee staff at SPPM (Ms Angela Brennan, Dr Diem Dinh, Ms Harriet Carruthers, Mrs Janine Doyle, Mrs Philippa Scanlon, Mr Mark Lucas and Mrs Jill Edmonds).

The Registry Custodian, Prof Christopher M Reid is supported by a National Health and Medical Research Council (NHMRC) Principal Research Fellowship that provides salary support to contribute to initiatives such as the VCOR.

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

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

Foreword

It is my pleasure to introduce the Victorian Cardiac Outcomes Registry (VCOR) Annual Report for 2019.

The role of the Australian Commission on Safety and Quality in Health Care (the Commission) is to lead and coordinate safety and quality improvements nationally. Clinical quality registries (CQRs), of which VCOR is a leading example, provide one mechanism through which to achieve this. The role of CQRs in Australia is to capture and report process and outcomes data for specific clinical conditions and report on the appropriateness and effectiveness of specific healthcare interventions.

In Australia, the landscape for CQRs is undergoing significant change as the value of CQRs is being increasingly recognised and health information technology continues to develop. The Commission is currently reviewing the Framework for Australian clinical quality registries which provides the national operating principles; specifies the national health information arrangements; details principles and guidelines and standards for best practice build and design, development, operation and security of CQRs under national arrangements and identifies a set of prioritisation criteria for a national approach to the development of CQRs. The outcome of this review will ensure CQRs realise their potential to report on the collected data to a wide range of stakeholders including clinicians, patients, consumers, hospital administrators, government, funders and insurers.

The Covid-19 pandemic is driving change in Australian healthcare with a growing understanding in the community that harnessing the power of aggregated data to examine variation in care and outcomes, benefits everyone. Australia has a wealth of health data, much of it currently siloed and inaccessible, which by data-linkage and reporting will lead to improved patient care.

Cardiovascular disease accounts for almost 14% of the total burden of disease in Australia, and 12% of total recurrent health care expenditure, making it the most expensive disease group in terms of health care costs. A national CQR in cardiovascular disease remains one of the highest priorities for CQR development in Australia, as there are now well-defined clinical indicators to measure the management of cardiovascular disease and assess the impact of variation

in health outcomes. VCOR has been instrumental in efforts to establish a harmonised National Cardiac CQR.

VCOR is a state-wide clinical registry collecting information on cardiac treatments and interventions from contributing hospitals across Victoria and reporting on a quarterly basis to participating clinicians with evidence-based benchmarks for comparison across the cohort. VCOR has evolved into an exemplar CQR which has pioneered the collection and analysis of clinical data, patient experience and outcome data and transparent public reporting.

The Commission congratulates the VCOR team and the Victorian Agency for Health Information for supporting the registry. I look forward to continue working with VCOR and others in developing national arrangements for CQRs as a mechanism by which clinicians, epidemiologists and others can access clinical record-level data, within high-priority clinical domains, to measure, monitor and report on the appropriateness and effectiveness of health care.

Dr Robert Herkes

Chief Medical Officer
Australian Commission on Safety and Quality
in Healthcare



Executive Summary

The 2019 Annual Report is being released at a time when Victoria is going through its biggest health crisis in living memory. The COVID-19 pandemic has had profound effects on the delivery of healthcare throughout the state and while its repercussions for cardiac care will be examined in next year's annual report, there still are a number of issues the pandemic has brought into sharp relief that have relevance to VCOR activities in 2019. One of the spin-offs from the pandemic has been a substantial improvement in the community's health literacy and understanding of health statistics. People are now very attuned to how healthcare is measured and are engaged in critically assessing potential shortcomings in the delivery of quality and safe care. We all now better appreciate technical terms like "flattening the curve" and "exponential growth". But perhaps, most importantly, there is a general increased awareness of the vital need to capture and analyse high quality information to keep clinicians, government and other providers and the general public informed.

It is in this context that this Annual Report has been designed to provide up-to-date and comprehensive information about the quality and safety of cardiovascular therapy delivery to Victorians in 2019. VCOR's most established registry module examines percutaneous coronary intervention (PCI) and we are proud to have all public and private hospitals in the state now engaged. This has enabled us to capture and report on all PCIs performed in Victoria in 2019. At the end of 2019, the PCI module contained more than 68,000 case records of PCI, having started data collection in 2013.

The second module presented in this report deals with cardiac implantable electronic devices (CIEDs)- a form of non-pharmacological, device-based therapy primarily used in patients with weakened heart conditions (cardiomyopathy) to treat heart failure and potentially life-threatening arrhythmias. A pilot phase of this module was undertaken in 2018. In 2019 the module was gradually extended to hospitals that showed early interest in monitoring the quality and safety of the implantation of these devices through participation in a clinical quality registry.

Key findings in this report relating to PCI and CIED implantation in Victoria in 2019 are presented on the following pages.

Key Findings

PCI Registry

- All 32 Victorian hospitals that perform PCI contributed to the registry in 2019, comprising 14 public and 18 private hospitals. A total of 12,353 completed procedures were collected on 10,977 patients. 57% of cases were managed in the public system.
- The majority of patients undergoing PCI were male (76%). The mean age was 67 years. Patients treated in private hospitals were six years older on average than public patients.
- The rate of severe obesity (BMI $\geq 35\text{kg/m}^2$) among the PCI cohort was twice the national average (11.8% vs 6%).
- Approximately 20% of cases were performed outside normal working hours in both the public and private hospital sectors. Just over half of all ST elevation myocardial infarction (STEMI) cases were out-of-hours and 87% of those were managed in the public sector.
- Just under half the PCI cases in 2019 presented with an acute coronary syndrome (ACS), with the majority (76%) treated in public hospitals. ACS cases accounted for over two-thirds of the public sector's caseload and less than one-third of the private sector's.
- PCI for acute STEMI (including primary PCI, pharmacoinvasive PCI and rescue PCI) represented 20% of the overall PCI workload in the public sector and 5% in private.
- For patients with stable (non-ACS) disease, 67% had symptoms of stable angina. A high-grade stenosis was recorded in 91% and a positive functional test in 60%. A total of 89% of non-ACS patients had at least two of these three key clinical factors.
- Particular lesion subsets including unprotected left main cases (2%), chronic total occlusions (3.8%) and in-stent restenosis (4.4%) were performed in similar numbers to previous years.
- Drug-eluting stents (DES) accounted for 99% of all stents implanted. The gap between public and private hospital DES use seen in earlier years has closed.
- The number of patients presenting with cardiogenic shock or out-of-hospital cardiac arrest was similar to previous years. High-volume public hospitals generally treated these high-acuity cases. Private hospitals treated only very small numbers of shock and cardiac arrest cases.
- Utilisation of radial artery vascular access continues to increase year-on-year, accounting for 71% of all PCI cases in 2019. Rates still varied among hospitals, with public hospitals generally having higher radial vascular access (75%) compared with private hospitals (65%). There were lower rates in females compared to males (64% vs 73%) and in the elderly (60% ≥ 80 years vs 72% < 80 years).
- For PCI for acute STEMI (primary PCI), the median time taken from patient arrival at the hospital to the first balloon inflation (door-to-balloon time or DBT) was 58 minutes. All hospitals achieved a median DBT ≤ 90 minutes and 80.8% of cases had a DBT ≤ 90 minutes.
- The unadjusted in-hospital mortality rate was 1.7%. The rate was higher among patients presenting with STEMI (6.2%), and highest for patients with cardiogenic shock or out-of-hospital cardiac arrest (42.8%). Excluding these two high-risk groups, the unadjusted in-hospital mortality rate was 0.6%.
- The signature key performance indicator of risk-adjusted 30-day mortality rate for the overall PCI cohort was 3.0%. There was one outlier hospital with a higher than expected risk-adjusted mortality rate. This hospital was notified and managed according to VCOR's Clinical Quality Reporting and Communication of Variance Policy.
- The median in-hospital major bleeding rate was 0.6%, lower among radial access cases (0.4% radial vs 1.3% femoral). The 30-day unplanned cardiac readmission rate was 3.1%, with similar rates in the public and private sectors. Rates of other major adverse cardiac outcomes were low and similar to previous years.

Key Findings continued

CIED Registry

- Thirteen health services across the state (10 public and 3 private hospitals) participated in the 2019 CIED module, with a total of 640 procedures performed on 622 patients.
- Three-quarters of patients were males and the mean age was 66 years. Overall, 58% were first implants and 33% of cases were generator replacements. Other procedure types were new lead (3%), removal of device without replacement (5%) and revision procedures (1%).
- ICD devices (ICD, CRT-D or S-ICD) represented 80% of first implants and 78% of generator replacements.
- 46% of patients undergoing any ICD (ICD, CRT-D or S-ICD) had an ischaemic cause. 35.7% of ICDs were implanted for primary prevention.
- For CRT-P devices, an ischaemic cause was reported in 24% of cases and 50% had an idiopathic cardiomyopathy.
- Among patients treated with CRT-D, 91% had a QRS width ≥ 120 msec, 79% had severe left ventricular dysfunction and 98% had NYHA Class II symptoms. For CRT-P devices, 70% had a QRS width ≥ 120 msec and there was more variability in the degree of left ventricular impairment and heart failure symptoms.
- For the first time, this report determined the strength of the indication for a CIED (strong, medium or weak) by allocating each case to one of 8 possible clinical scenarios supported by up-to-date clinical evidence and current practice guidelines. For ICD devices, approximately three quarters had a strong indication for ICD and only 3% had a weak indication. In contrast, 44% of CRT-D and CRT-P cases had either medium strength or weak indications for CRT.
- There were no in-hospital deaths among CIED cases. The unadjusted 30-day mortality rate was 0.6% with 4 deaths recorded within 30 days of hospital discharge. The overall 30-day unplanned cardiac readmission rate was 4.1% and the device related re-operation rate was 1.9%. The rate of 30-day device related infection was 1.1%. All hospitals were within control limits for each of these endpoints.

In addition to our primary responsibilities of quality assurance, performance assessment and benchmarking, VCOR continued to work closely with internal and external researchers on a variety of projects throughout 2019. This year, studies were published on a wide range of topics including sex based bias in treatment and outcomes of PCI, an economic evaluation of clinical quality registries and a post-marketing survey of the adverse impact of bioresorbable scaffolds (a type of coronary stent), taken off the market in 2017 due to safety concerns. A list of publications and presentations in 2019 is presented at the end of this report.

On behalf of the VCOR Steering Committee, I hope you find this year's report interesting and informative.

Yours sincerely,



A/Prof Jeffrey Lefkovits
VCOR Clinical Director

Introduction

This is the seventh annual report for the Victorian Cardiac Outcomes Registry (VCOR), with the registry now in its eighth year of operation. VCOR's primary aim is to monitor the quality and safety of cardiac-related health care in Victoria. Its activities incorporate the surveillance, analysis and benchmarking of hospitals' performance and outcomes, with particular attention to providing high quality, detailed and regular reports to participating hospitals and the Victorian Department of Health and Human Services. As a tool for quality assurance, VCOR promotes the assessment of variation in practice and is primarily designed to drive continuous quality improvement among the state's providers of cardiovascular care.

The percutaneous coronary intervention (PCI) module was the first module in VCOR and has collected data since the registry launched in 2013. In 2019, the PCI module reached the milestone of achieving complete capture of all PCIs performed in Victoria by engaging all PCI hospitals including one new site – Albury Hospital. Two further registry modules, that are now closed, focused on acute management of ST elevation myocardial infarction in regional Victoria (2013-2018) and in-hospital management of decompensated heart failure (2014-2017). Our fourth and currently active module monitors the management of cardiac implantable electronic devices (CIED). This module was launched in 2018, and during the period covered by this report, the number of hospitals contributing to the CIED module has almost doubled. Hospitals in both the public and private sectors are included in each of VCOR's modules.

In addition to its various module activities, VCOR has also been maintaining its close involvement with the National Cardiac Registry (NCR) - an Australian Federal Government funded clinical quality registry that is in the early stages of development and implementation. The NCR is modelled on a federated system, with each state and territory responsible for their own data collection and submission to a national registry. As well as providing de-identified Victorian data to this registry, VCOR has collaborated with the NCR management team to assist in its design and setup. VCOR plans to provide ongoing support to the NCR, as the registry begins regular activity in data collection, analysis and reporting.

Registry Governance and Structure

VCOR's governance structure and processes have been outlined in its initial annual report [1] and have also been published [2]. VCOR conforms to the Australian Health Ministers' Advisory Councils Framework for Australian Clinical Quality Registries [3] including all relevant standards related to security and protection of data. VCOR also abides by the National Operating Principles for Clinical Quality Registries as set out by the Australian Commission on Safety and Quality in Health Care [4].

Steering Committee

The Steering Committee (SC) membership comprises representatives from participating hospitals, the clinical leads of the various modules, a representative from Safer Care Victoria, a consumer representative and representatives from the Department of Epidemiology & Preventive Medicine at Monash University. In 2019, the SC ratified an updated study protocol that encompassed changes relevant to VCOR from the *National Statement on Ethics Conduct in Human Research 2018* and added a representative from Ambulance Victoria onto the SC. Meetings continue to be held on a quarterly basis.

Clinical Quality Committee

The Clinical Quality Committee (CQC) has responsibility for the oversight, analysis, interpretation and release of hospital performance data. Its role is central to VCOR's overall function as a clinical quality registry. For PCI, the committee undertakes quarterly and biannual review of hospital key performance indicators (KPIs) and other data. Review of results and outcomes pertaining to the CIED module are undertaken on a 6-monthly basis. Regular reports are provided to participating hospitals in both registry modules. In 2019, as in previous years, the CQC assisted hospitals with the management of any outliers including providing feedback and review as requested. The CQC also oversaw the updating of the VCOR Clinical Reporting and Communication of Variance Policy that was subsequently ratified by the SC. Regular meetings were held on a quarterly basis.

Data, Research and Publications Committee

The role of the Data, Research and Publications Committee (DRP) is to review requests for access to and analysis of aggregate group de-identified data for research projects. In 2019, the DRP undertook an update to the Data Access Policy that was subsequently ratified by the SC. The DRP reviewed and approved numerous requests for data (n=16), all of which were collaborative projects. The DRP oversaw abstract development and publications that utilised VCOR data. The various reports and research papers are outlined in the Publications and Presentations section of this report. Due to an increase in the volume of submitted proposals, meetings were held on five occasions in 2019.

Percutaneous Coronary Intervention (PCI)

Registry Module Activity

This report covers PCI activity in Victoria for the 2019 calendar year from January 1 to December 31. It includes comparative analyses with previous years and presents longer term outcomes utilising linkage with the National Death Index (NDI). In 2019, all 32 hospitals that perform PCI in Victoria contributed data, comprising 14 public and 18 private hospitals (Table 1). Albury Hospital commenced their PCI service in 2019 and joined VCOR during this reporting period.

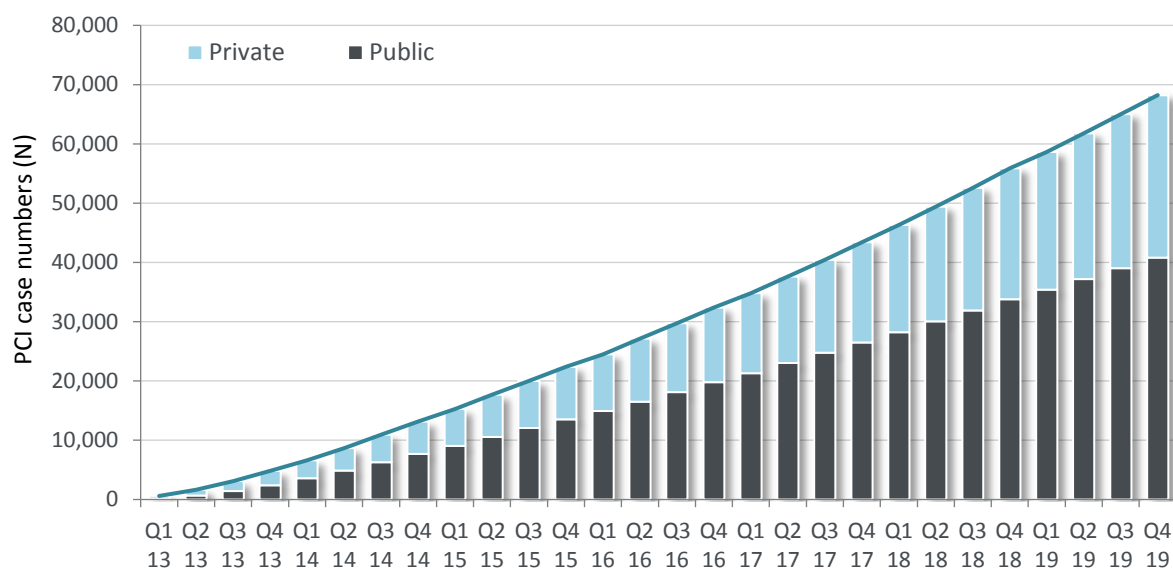
Table 1: Participating Victorian PCI hospitals

Victorian PCI hospitals	Hospital type	2013	2014	2015	2016	2017	2018	2019
Albury Hospital	Public	N/A	N/A	N/A	N/A	N/A	N/A	●
Alfred Hospital	Public	●	●	●	●	●	●	●
Austin Hospital	Public	●	●	●	●	●	●	●
Ballarat Base Hospital	Public	●	●	●	●	●	●	●
Bendigo Hospital	Public	●	●	●	●	●	●	●
Box Hill Hospital	Public	●	●	●	●	●	●	●
Cabrini Hospital Malvern	Private	●	●	●	●	●	●	●
Epworth Hospital Eastern	Private		●	●	●	●	●	●
Epworth Hospital Geelong	Private				●	●	●	●
Epworth Hospital Richmond	Private	●	●	●	●	●	●	●
Footscray Hospital	Public	●	●	●	●	●	●	●
Frankston Hospital	Public	●	●	●	●	●	●	●
Holmesglen Private Hospital	Private				N/A	●	●	●
Jessie McPherson Private Hospital	Private	●	●	●	●	●	●	●
Knox Private Hospital	Private	●	●	●	●	●	●	●
Melbourne Private Hospital	Private		●	●	●	●	●	●
Monash Heart	Public	●	●	●	●	●	●	●
Mulgrave Private Hospital	Private				●	●	●	●
The Northern Hospital	Public	●	●	●	●	●	●	●
Peninsula Private Hospital	Private				○	●	●	●
St John of God Hospital (Ballarat)	Private			○	○	●	●	●
St John of God Hospital (Bendigo)	Private			●	●	●	●	●
St John of God Hospital (Berwick)	Private	N/A	N/A	N/A	N/A	N/A	●	●
St John of God Hospital (Geelong)	Private			○	●	●	●	●
St Vincent's Hospital Melbourne	Public	●	●	●	●	●	●	●
St Vincent's Private Hospital	Private	●	●	●	●	●	●	●
St Vincent's Private Hospital (Werribee)	Private	N/A	N/A	N/A	N/A	N/A	●	●
The Royal Melbourne Hospital	Public	●	●	●	●	●	●	●
Sunshine Hospital	Public	N/A	N/A	●	●	●	●	●
The University Hospital, Geelong	Public	●	●	●	●	●	●	●
Warringal Private Hospital	Private				○	●	●	●
Western Private Hospital	Private	●	●	●	●	●	●	●

Table Legend: ● = contributing data; ○ = engaged but not yet contributing

As at December 31 2019, the registry had 68,224 PCI cases entered. The cumulative rate of recruitment since commencement by quarter and by hospital sector is shown in Figure 1. The lost-to-follow up rate in 2019 was 0.9%, and the overall rate for the entire registry since its commencement is 1.3%. The number of requests from patients to opt-off from inclusion in the registry remains very low – just 0.22% in 2019 and 0.16% overall since registry commencement.

Figure 1: Cumulative case numbers by quarter: 2013-2019



Data Quality

The ongoing maintenance of data accuracy is a key operational activity of clinical quality registries [5] and is a high priority issue for VCOR. As the registry has grown and matured, additional quality controls have been implemented, including in 2019. A brief overview of VCOR's data quality activities is outlined below.

Audit Activities

Case ascertainment audits (assessing whether all eligible cases are entered into the registry, except those that have opted-off) are conducted at all sites on a yearly basis. The rate of missing cases has continued to decline with successive audits from 2.6% in 2016 to 1.0 % in 2019. When missing cases are identified at audit, hospitals are expected to update their records and enter the missing cases into the registry. Brief audits (accuracy of data determined by review of the sites' source data) are undertaken at all sites within, or around, the first year of registry participation and then subsequently every three years. The process involves 5% of case records randomly selected for review and then comparison of a select number of relevant fields with the hospital medical record. The cumulative result of these regular audits, spanning a period from 2013 to the end of 2019, has found a 98.6% agreement rate between VCOR data and the hospital medical record. These results encompass 972 individually audited PCI cases and indicate high-quality data collection across the registry. This rate compares favourably with other national and international registries [6, 7].

Data completeness is reported when both baseline and follow up data are completed and locked. Sites are routinely informed of pending data deadlines related to completeness. In 2019, 100% of PCI procedures entered were complete.

Other VCOR quality control processes include:

- Validation rules and mandatory fields in the VCOR online system that reduce inaccuracies in data collection
- Detailed data definitions supplied to all sites and available online to aid data collection
- Comprehensive training provided to all new data managers prior to commencement of data collection
- Regular emails, newsletters and bulletins to all system users for reminders, updates and clarification of new or existing information
- Annual data manager meetings that provide a forum to meet and engage, promoting an important communication network among the VCOR community

Plans are underway to implement additional data querying related to the CIED module.

Patient Characteristics

In 2019, 12,353 PCI procedures were performed on 10,977 patients. Multiple procedures were performed in 1,376 (11%) of patients. A total of 7066 cases (57.2%) were performed in public hospitals. Males accounted for 75.5% of cases overall. The median age for males was 67 years (IQR: 58, 75) and for females was 71 years (IQR: 63, 79) – largely unchanged from previous years (Figure 2). The peak frequency of PCI procedures occurred in the seventh decade for males and the eighth decade for females.

Figure 2: Age and sex distribution of patients undergoing PCI

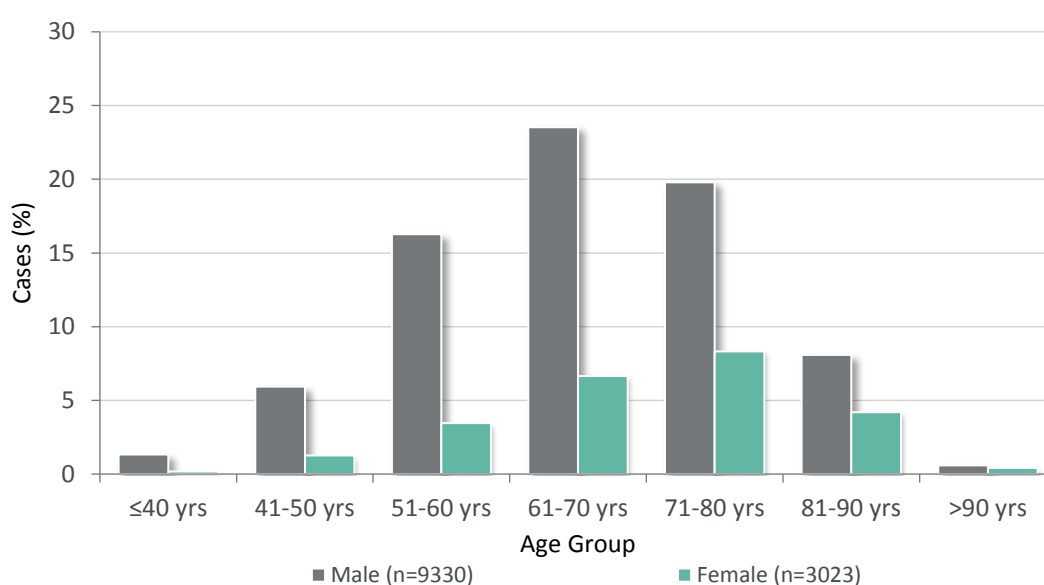


Table 2 compares selected patient demographic information across a 6-year period. There have been only minor variations in proportions of various demographic characteristics over time, although the number of patients with previous coronary artery bypass grafting (CABG) has tended to decline.

Table 2: Comparison of selected patient characteristics: 2014-2019

Patient characteristics	2014 (N=8327)	2015 (N=9229)	2016 (N=10036)	2017 (N=11006)	2018 (N=12463)	2019 (N=12353)
Age- years (Mean ±SD)	65.3 (±11.9)	65.6 (±12.0)	66.0 (±12.0)	66.5 (±11.9)	66.7 (±11.7)	67.2 (±11.7)
	%	%	%	%	%	%
Sex – female	23.1	23.1	23.5	24.4	23.7	24.5
Diabetes	21.6	23.0	21.6	21.7	22.6	23.2
PVD history	3.8	3.6	3.4	3.4	3.4	3.6
CBVD history	3.7	4.0	3.3	3.9	3.4	3.8
Previous PCI	31.9	32.9	32.7	32.8	33.4	33.1
Previous CABG	8.4	7.6	7.6	7.3	7.2	6.8

Body mass index (BMI) data are presented in Figure 3. The overall rate of severe obesity (BMI $\geq 35\text{kg/m}^2$) in 2019 was 11.8% and remains at a level almost twice the national average [8]. Women were more commonly affected in all age groups. While the prevalence of severe obesity declined with age in both sexes, the actual rate of severe obesity in the very elderly female group (>80 years of age) was higher in 2019 than in the previous year (7% in 2019 vs 5% in 2018), whereas the proportion of severe obesity in elderly men halved. Obesity and its association with coronary disease is an ongoing public health concern, as highlighted in a recent Australian study that demonstrated poorer outcomes in patients with severe obesity [9].

Figure 3: Body Mass Index (BMI) $\geq 35\text{kg/m}^2$ by age and sex

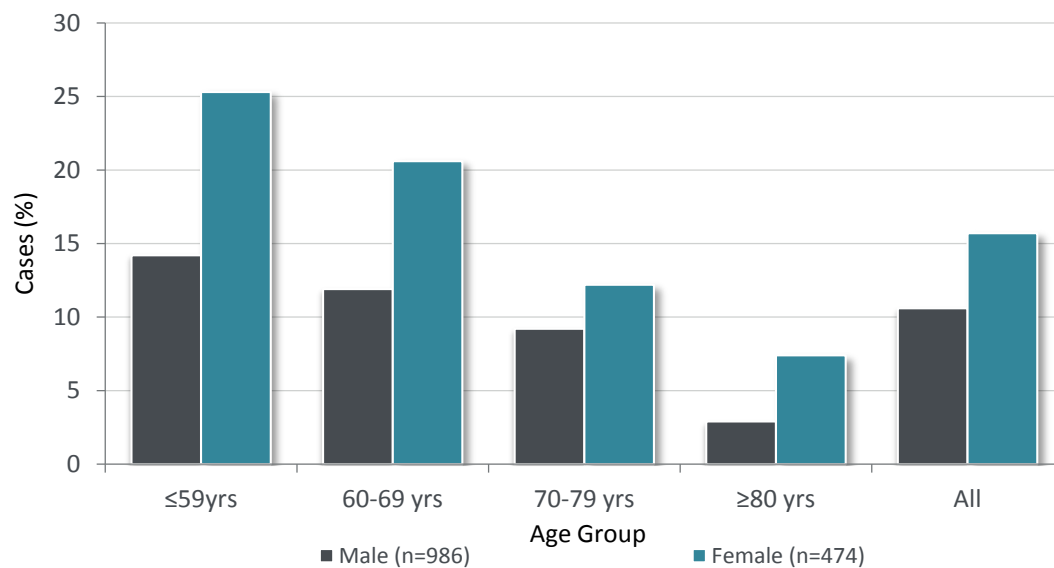


Table 3 presents selected patient characteristics compared by hospital sector. Patients treated in the private sector were 6 years older on average than public hospital patients. The average age of patients has tended to increase over time in both sectors, rising from 63.5 years for public patients in 2014 to 64.6 years in 2019, and from 69.5 years in private patients in 2014 to 70.6 years in 2019. The peak frequency of PCI procedures in the private sector was in the 71-80 year subgroup compared with a peak frequency in the 61-70 year age bracket among public patients.

Table 3: Selected patient characteristics by hospital sector

Patient characteristics	Public (n=7066)	Private (n=5287)
Age - years (Mean $\pm$ SD)	64.6 (± 12.0)	70.6 (± 10.4)
	%	%
Sex – female	24.2	24.8
Diabetes	25.2	20.4
PVD history	3.4	3.8
CBVD history	4.8	2.5
Previous PCI	27.0	41.3
Previous CABG	5.8	8.2
Body Mass Index (BMI) ≥ 35	12.8	10.5

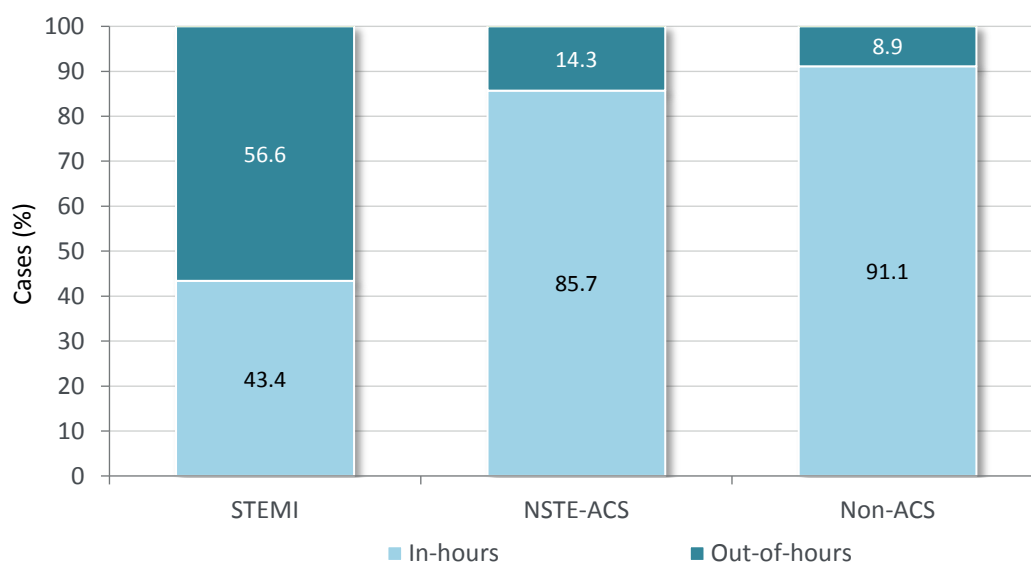
Resource Utilisation

VCOR utilises information relating to the timing of cases (in-hours vs out-of-hours) and delays to timely reperfusion for patients with NSTEMI-ACS as markers for resource utilisation. Trends with these two process measures can assist hospitals in the appropriate allocation of resources and promote hospitals' overall efficiency and performance.

In-hours vs out-of-hours cases

Across the cohort of all out-of-hours cases 76.5% were performed for the treatment of an ACS, with the majority being for STEMI. As expected, less than 10% of non-ACS cases, which are usually elective, were performed out-of-hours. Figure 4 presents the case load for in-hours vs out-of-hours by clinical presentation.

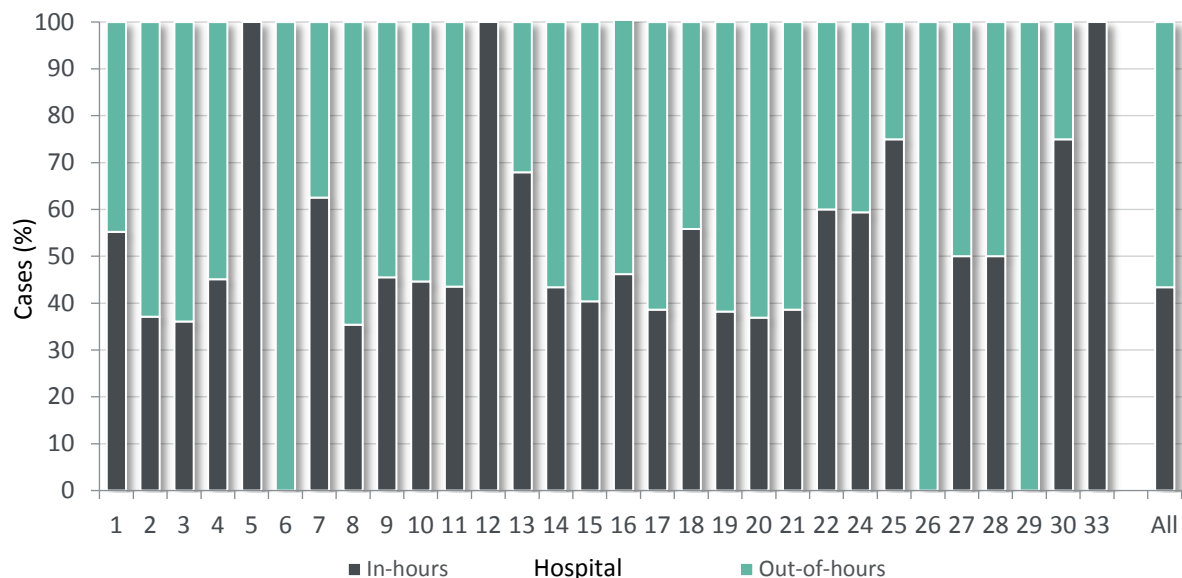
Figure 4: Proportion of cases in-hours and out-of-hours



In hours: 8.00am – 6.00pm (Mon – Fri excluding public holidays). Out-of-hours: 6.00pm – 08.00am (Mon – Fri, public holidays and weekends).

Figure 5 demonstrates the variation in out-of-hours STEMI caseloads across hospitals. Several hospitals had low case numbers overall, but among higher volume hospitals (>50 STEMI cases per year) the proportion of cases done out-of-hours ranged from 32% to 65%.

Figure 5: STEMI cases in-hours and out-of-hours by hospital



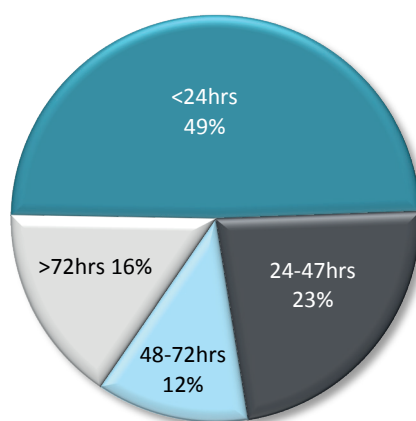
Hospitals 5, 6, 12, 28, 29, 30 & 33 low STEMI numbers ($n < 5$). Site 32 no ACS cases.

The out-of-hours workloads for public and private sectors were similar (20.0% public and 19.3% private). However, most of the out-of-hours public work involved emergency cases, and 87% of this workload was taken up with STEMI. In contrast, the makeup of out-of-hours cases in the private sector included non-ACS cases (51.5%), NSTEMI-ACS (31.2%) and a much smaller proportion of STEMI cases (17.3%).

Time delays to PCI for NSTEMI-ACS

For patients presenting with NSTEMI-ACS, Australian practice guidelines recommend early coronary angiography and potential percutaneous revascularisation whenever practicable, as there is little proven advantage in first stabilising these patients on medical therapy [10]. As a result, hospital resources are utilised most efficiently if time delays to PCI for NSTEMI-ACS are as short as possible.

Figure 6: Time delays from hospital admission to PCI for NSTEMI-ACS cases



In 2019, just under half the patients were treated within 24 hours and 84% were treated within 72 hours (Figure 6). Over the 6-year period from 2014-2019, the proportion of NSTEMI-ACS cases whose treatment was delayed for more than 72 hours has declined - from 19.8% in 2014 to 15.9% in 2019, while the proportion of NSTEMI-ACS cases treated <24 hours has increased (Figure 7).

Figure 7: Trends in time delays from hospital admission to PCI for NSTEMI-ACS cases by year

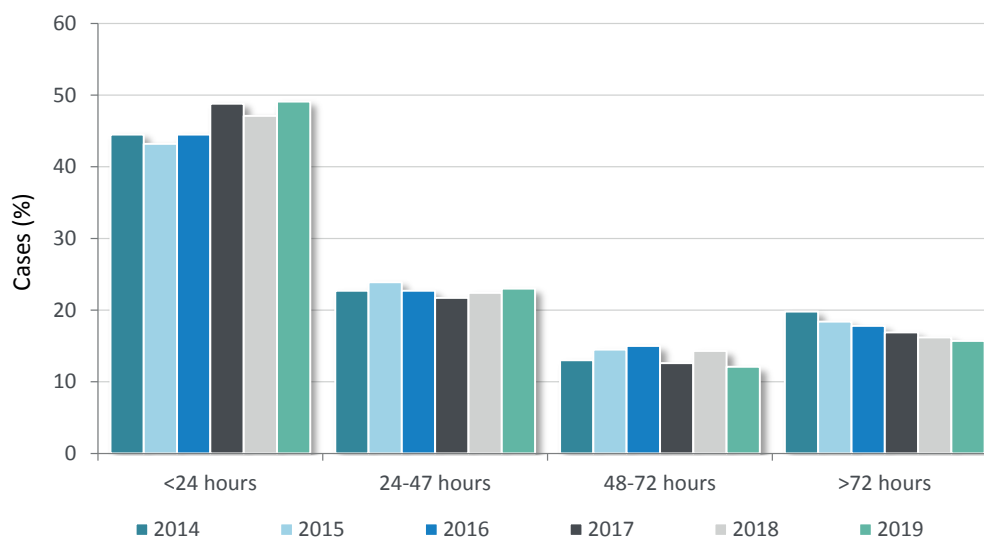
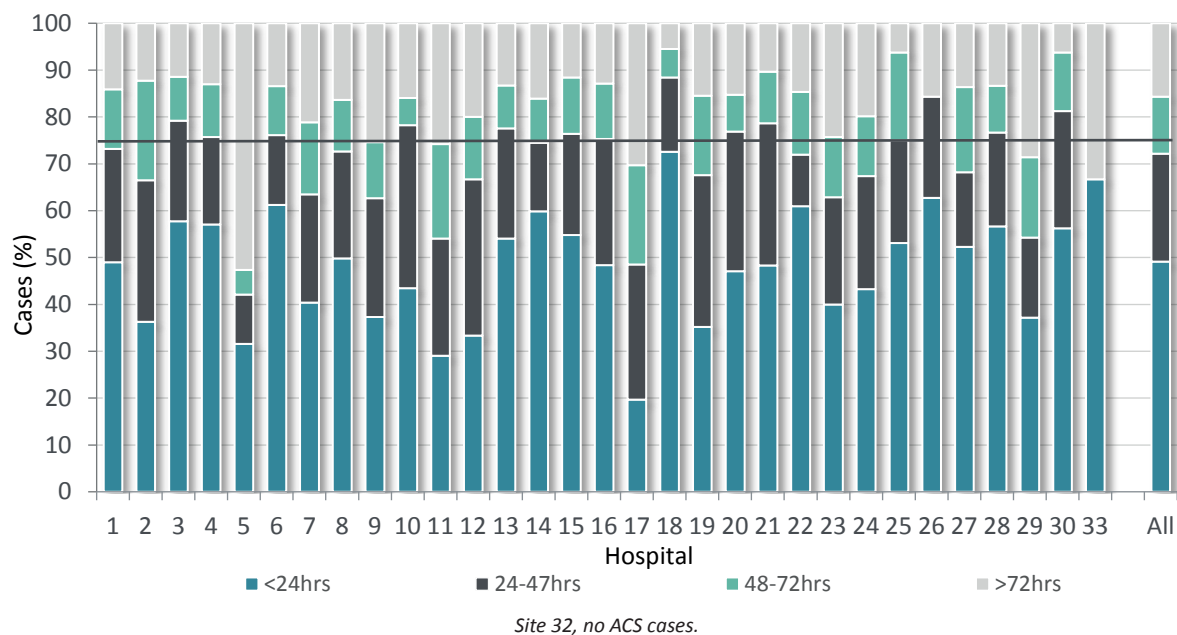


Figure 8 benchmarks hospitals' performance in relation to time delays to PCI for NSTEMI-ACS. A notional performance target has been set to $\geq 75\%$ of NSTEMI-ACS cases undergoing PCI within 72 hours. In 2019, 5 hospitals did not meet this benchmark (Figure 8).

Figure 8: Time delays from hospital admission to PCI for NSTEMI-ACS cases by hospital



When NSTEMI-ACS time delays were examined by hospital sector, cases tended to be treated earlier in public hospitals – 85.6% within 72 hours in public vs 81.6% in private (Table 4), although this gap has narrowed since the previous report.

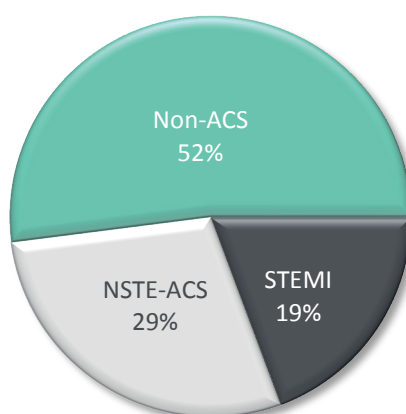
Table 4: Time delays from hospital admission to PCI for NSTEMI-ACS cases by hospital sector

	All sites (N=3537)	Public (N=2406)	Private (N=1131)
	N (%)	N (%)	N (%)
<24hrs	1738 (49.1)	1223 (50.8)	515 (45.5)
24-47hrs	815 (23.0)	556 (23.1)	259 (22.9)
48-72hrs	429 (12.1)	280 (11.6)	149 (13.2)
>72hrs	555 (15.7)	347 (14.4)	208 (18.4)

Clinical Presentation

As VCOR now captures all PCI cases performed in Victoria, the data presented in this report provide a fair representation of the burden and pattern of coronary disease treated by PCI in the state. In 2019, just over half (52%) of cases were performed in patients who had stable coronary disease.

Figure 9: Procedures by clinical presentation



The remainder had an acute coronary syndrome – either STEMI or NSTE-ACS (Figure 9). Trends in the types of clinical presentation over time are shown in Figure 10. The proportion of non-ACS cases within the registry has increased with time as more private hospitals were engaged with VCOR and started enrolling patients.

Figure 10: Trends in procedural rates by clinical presentation: 2014-2019

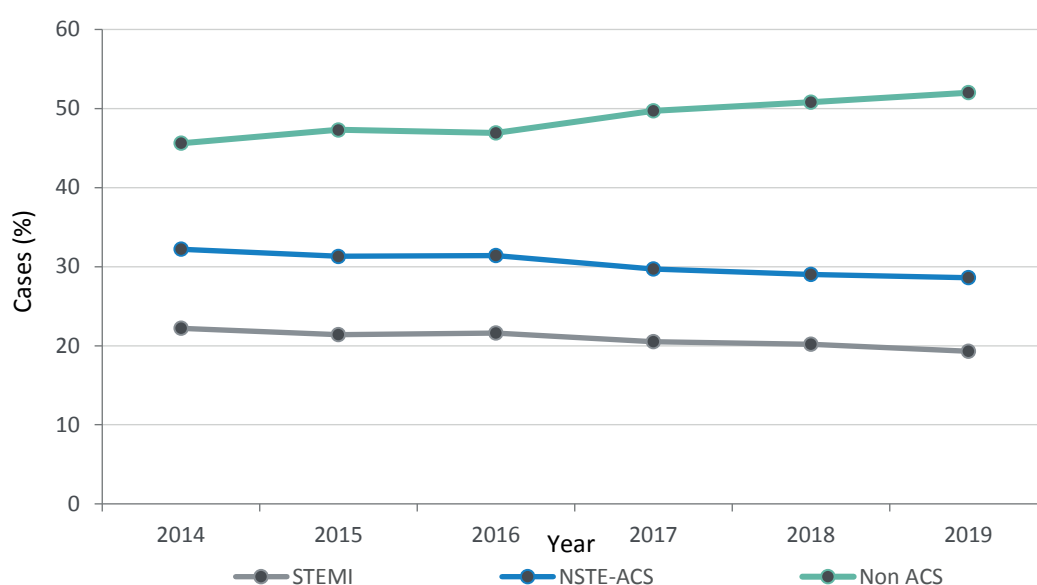
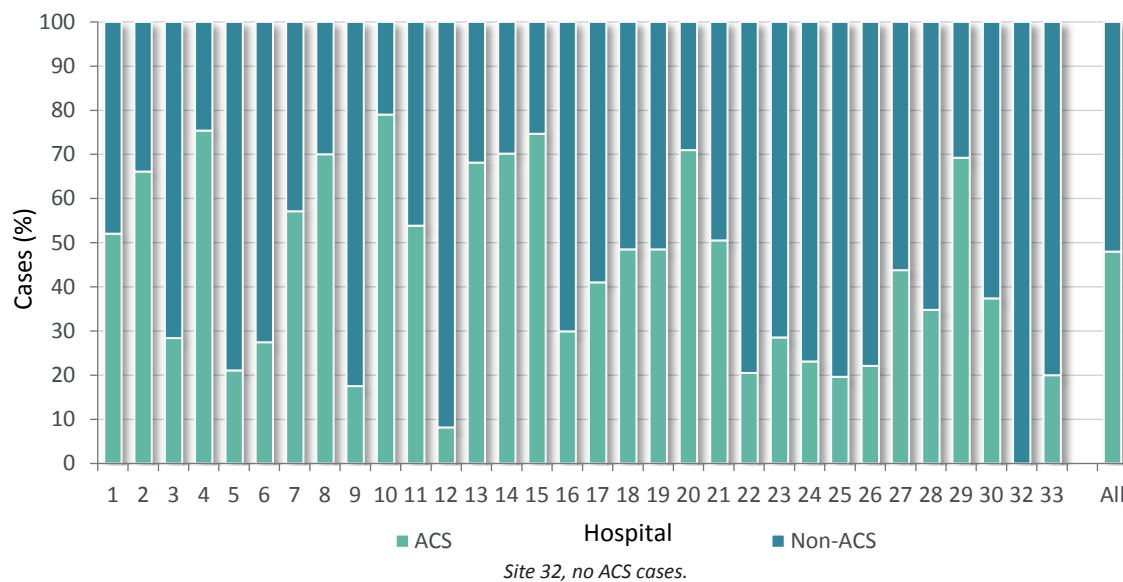


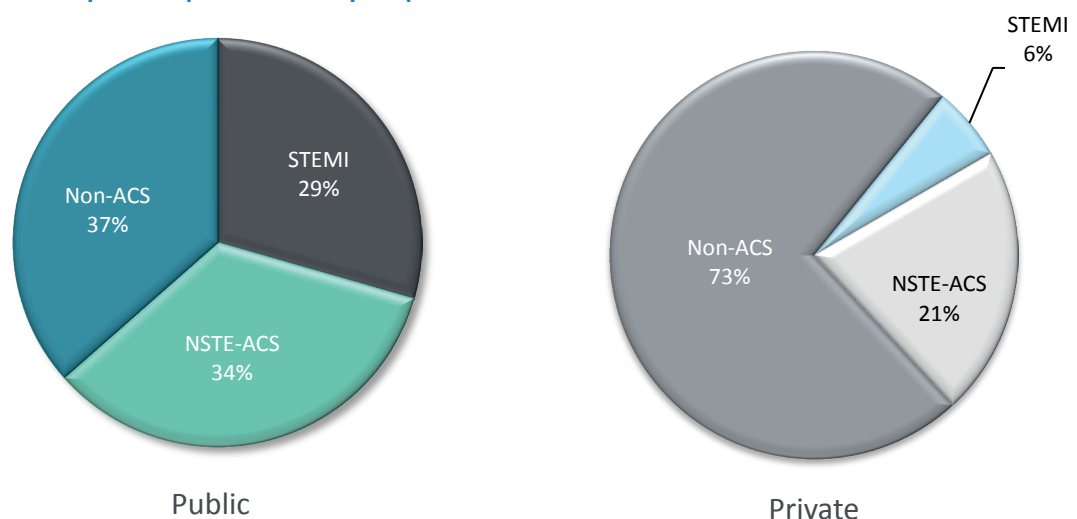
Figure 11 highlights the considerable variation among hospitals in the proportion of work taken up with more complex and resource intensive ACS cases. Some hospitals treated relatively few ACS cases, while for several others, ACS accounted for more than 75% of their workload.

Figure 11: ACS and non-ACS cases by hospital



As in previous years, the majority of public work was ACS-related, whereas private sector activity was mostly for non-ACS conditions (Figure 12).

Figure 12: Procedures by clinical presentation by hospital sector



Indications for PCI

The indications for PCI procedures are collected and reviewed to ascertain whether procedures are undertaken for appropriate reasons. It is generally accepted that PCI performed for patients presenting with an acute coronary syndrome are clinically appropriate and guideline indicated [10]. In 2019, 50.9% of patients had a PCI for an ACS-related, and therefore clinically appropriate indication. Table 5 outlines the indications by ACS category and hospital sector. The number of PCIs performed for an indication of unstable angina has steadily declined over time, with the proportion of cases in 2019 (10.3%) being the lowest since VCOR commenced data collection.

Table 5: PCI indications by ACS category and hospital sector

	All sites (N=6291)	Public (n=4643)	Private (n=1648)
ACS Category	N (%)	N (%)	N (%)
Primary PCI*	1821 (28.9)	1581 (34.1)	240 (14.6)
STEMI PCI 12-24 hours after symptom onset	247 (3.9)	203 (4.4)	44 (2.7)
Pharmaco-invasive PCI	169 (2.7)	160 (3.4)	9 (0.5)
Rescue PCI	116 (1.8)	106 (2.3)	10 (0.6)
PCI for OHCA/shock (non-MI)	48 (0.8)	47 (1.0)	1 (0.1)
PCI for NSTEMI-ACS	3890 (61.8)	2546 (54.8)	1344 (81.6)
NSTEMI-ACS sub-category	N (%)	N (%)	N (%)
NSTEMI	2862 (45.5)	2090 (45.0)	772 (46.8)
UAP	650 (10.3)	298 (6.4)	352 (21.4)
Recent ACS 7-30 days ago	378 (6.0)	158 (3.4)	220 (13.4)

*Primary PCI for STEMI presentations **including** all inter-hospital transfer arrivals and patients with STEMI onset whilst a current in-patient.

In 2019, 6,062 PCIs were performed for non-ACS indications. Among these, the majority were for stable angina and a much lower incidence were for prognostic reasons. Among the non-ACS cohort, 66.7% of cases were for stable angina, an absolute increase of 8.9% compared to the previous year (Table 6). The proportion of patients undergoing PCI for prognostic indications, defined as the absence of symptoms (with or without demonstrable functional ischaemia) decreased markedly (5.4% in 2019 vs 15.4% in 2018). The indication of staged PCI refers to patients with multi-vessel disease undergoing a second (or subsequent) PCI and is further categorised according to the indication of the original procedure. Staged PCI was performed more commonly in the public sector, with the majority of these cases undertaken within 30 days of an initial ACS procedure.

Table 6: Non-ACS PCI indications

	All sites (N=6062)	Public (n=2423)	Private (n=3639)
	N (%)	N (%)	N (%)
Stable angina	4045 (66.7)	1690 (69.7)	2355 (64.7)
No symptoms and no functional test	326 (5.4)	132 (5.4)	194 (5.3)
No symptoms and positive functional test	636 (10.5)	113 (4.7)	523 (14.4)
Staged PCI after ACS (≤30 days after first procedure)	785 (12.9)	345 (14.2)	440 (12.1)
Staged PCI after ACS (>30 days after first procedure)	187 (3.1)	98 (4.0)	89 (2.4)
Staged PCI after original non-ACS indication	83 (1.4)	45 (1.9)	38 (1.0)

VCOR also utilised a number of clinical factors to further assess the quality of the indication for the non-ACS PCI procedure. These included the presence or absence of symptoms, the severity of the coronary lesion(s) and demonstration of functional ischaemia. Symptoms of angina or its equivalent were reported in 83% of PCIs, an increase of 6% since the previous report. Overall, a total of 89% of non-ACS patients had at least 2 of the 3 key clinical factors (Table 7).

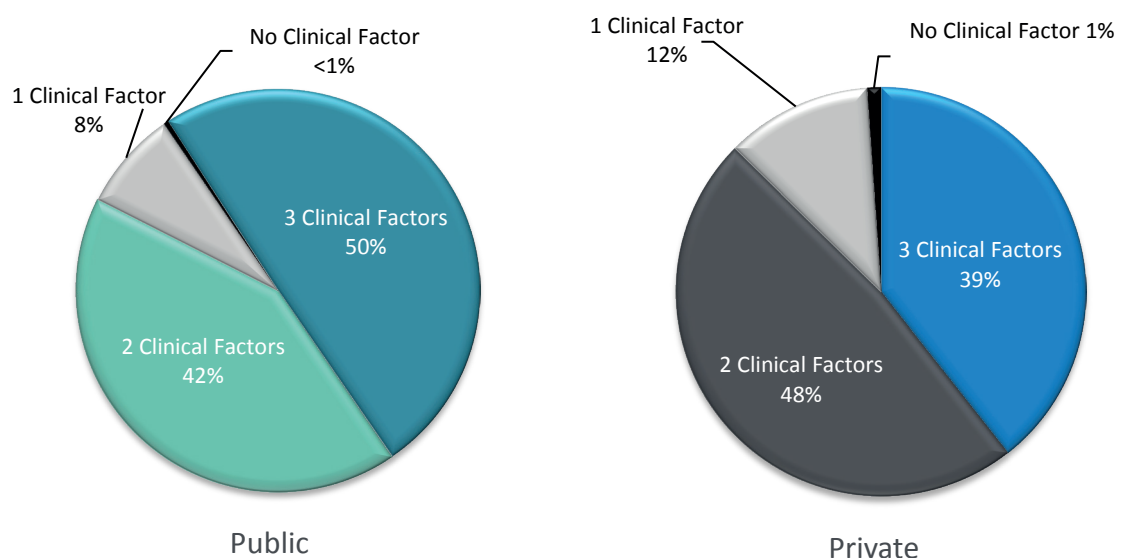
Table 7: Key clinical factors pertaining to non-ACS PCI indications

Symptoms	Positive functional test	High grade stenosis	Total
			N (%)
●	●	●	2169 (43.3)
○	●	●	546 (10.9)
●	●	○	196 (3.9)
●	○	●	1546 (30.9)
●	○	○	134 (2.7)
○	○	●	284 (5.7)
○	●	○	90 (1.8)
○	○	○	42 (0.8)
			5007 (100)

Table Legend: ● = clinical factor present; ○ = clinical factor not present.

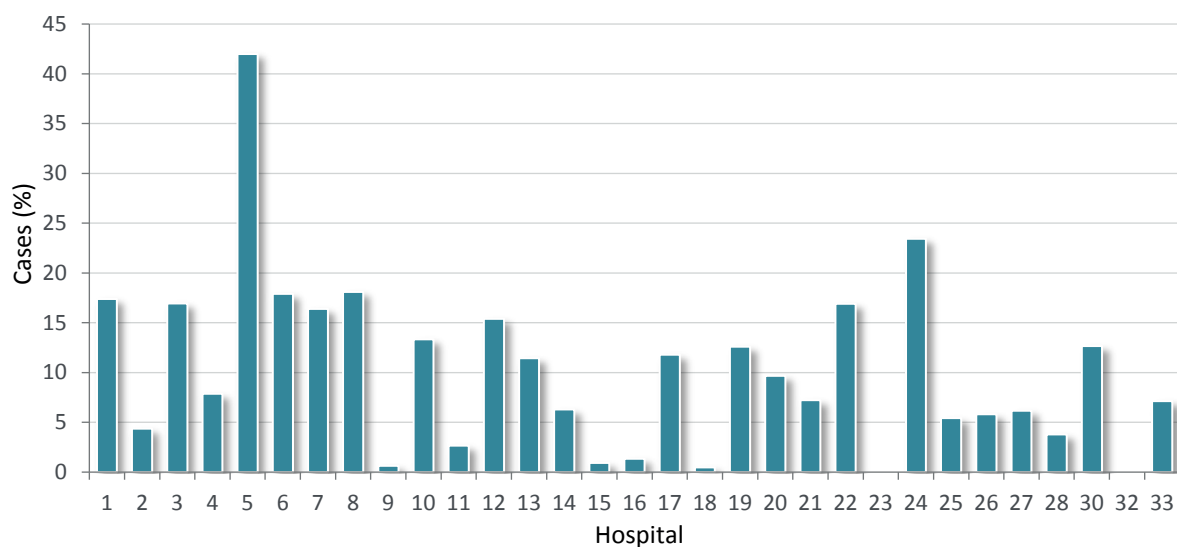
A comparison of clinical features associated with PCI indication by hospital sector shows differing profiles among public and private hospitals. Public sector non-ACS patients were more likely to have 3 key clinical factors (Figure 13) and 92% of non-ACS PCI's performed in public had 2 or 3 clinical factors, compared to 87% in private.

Figure 13: Key clinical factors in non-ACS patients by hospital sector

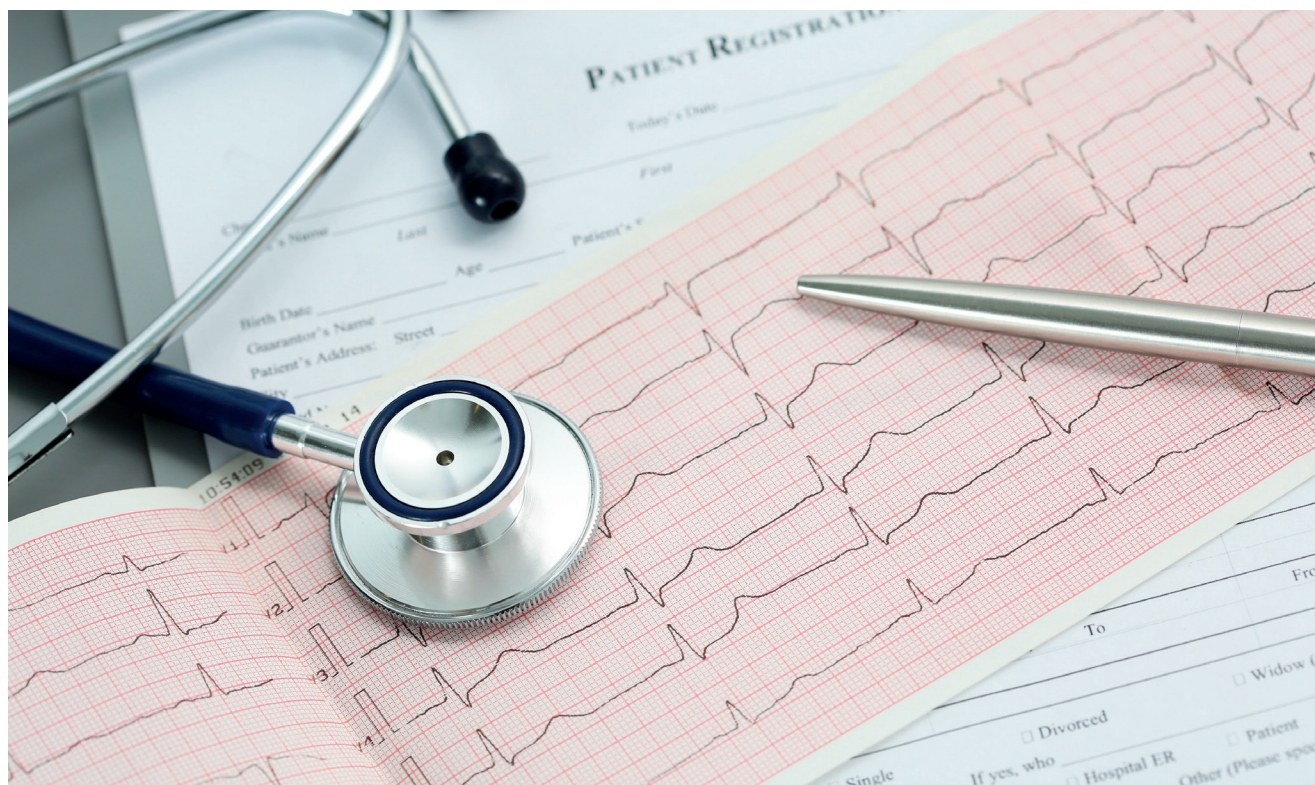


While both hospital sectors equally demonstrated a fall in the proportion of cases with just one or no key clinical factors since the previous report, Figure 14 demonstrates that there was still significant variation among hospitals (range 0%- 42%). For the 550 cases that had either no or one key clinical factor, 388 (71%) were in the private sector. The mean proportion of non-ACS PCI cases with just one or no key clinical factor was 12.6% in private and 8.4% in public.

Figure 14: Proportion of non-ACS cases with 0-1 indicator for PCI by hospital



Hospital 29 excluded <5 cases.

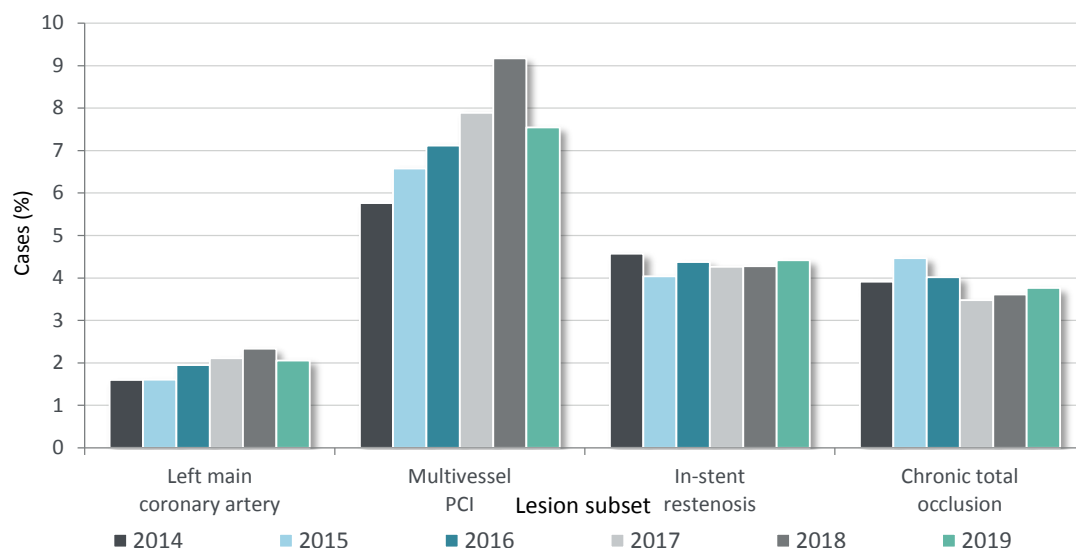


Lesion and Clinical Subsets

Trends in PCI rates for selected coronary lesion subsets over a 6-year period are shown in Figure 15. Apart from PCI for multivessel PCI, the proportion of cases done for various lesion subsets has been stable over time. Multivessel PCI seemed to be steadily increasing, but then decreased between 2018 and 2019. The rate of adjunctive imaging with intravascular ultrasound (IVUS) or optical coherence tomography (OCT) in left main coronary artery PCI increased in 2019 to 34.7%. While this was an increase from the 2018 rate of 25.2%, it is still substantially lower than rates reported in international registries [11]. We did not observe any increase in cases of PCI for chronic total occlusion (CTO), despite the recent proliferation of new techniques and equipment to deal with this clinical condition.

Overall trends were similar among public and private hospitals, apart from in-stent restenosis. These have been more commonly treated in the private sector throughout the 6-year observation period and in 2019, they accounted for 5.6% of cases in private compared with 3.5% in the public sector. Bypass graft PCI continues to decline (2.4% in 2014, 1.6% in 2018 and 1.4% in 2019), reflecting the general trend towards the predominant use of arterial rather than venous conduits in contemporary bypass graft surgery and their lower rates of degeneration and need for PCI.

Figure 15: Comparative trends in PCI for selected lesion subsets: 2014-2019



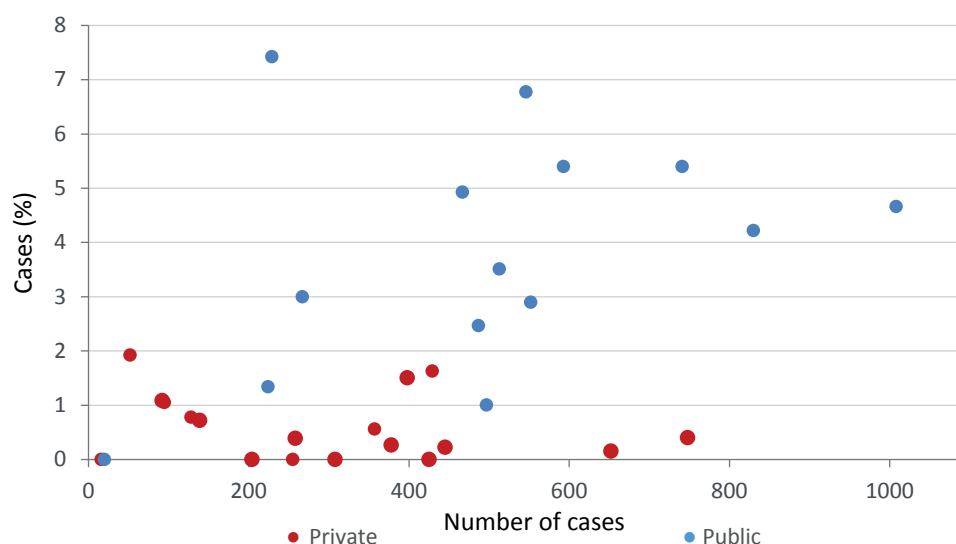
Cardiogenic shock and/or out-of-hospital cardiac arrest (OHCA) is associated with a high risk of death and other serious adverse outcomes [12, 13]. The overall proportion of cases treated with these serious conditions has remained low and consistent across the years (Table 8).

Table 8: Rates of cardiogenic shock or out-of-hospital cardiac arrest (OHCA): 2014-2019

Presentation type	2014 (N=8327)	2015 (N=9229)	2016 (N=10036)	2017 (N=11006)	2018 (N=12463)	2019 (N=12352)
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Cardiogenic shock	198 (2.4)	223 (2.4)	278 (2.8)	258 (2.3)	266 (2.1)	269 (2.2)
Intubated OHCA	89 (1.1)	108 (1.2)	126 (1.3)	142 (1.3)	137 (1.1)	152 (1.2)
Shock and/or intubated OHCA	239 (2.9)	253 (2.7)	309 (3.1)	310 (2.8)	329 (2.6)	320 (2.6)

Figure 16 explores the relationship between cardiogenic shock/OHCA case rates, hospital volume and hospital sector. The overwhelming majority (92%) of these high acuity cases were managed in public hospitals, comprising 4.2% of public hospital workload compared to 0.6% in private.

Figure 16: Shock and/or OHCA cases by hospital volume and hospital sector



In the public sector, higher volume hospitals took a proportionately greater share of these cases than lower volume hospitals. In contrast, there was no apparent association between overall hospital volume and shock/OHCA case numbers among private hospitals, with similarly low numbers in both low-volume and high-volume centres.

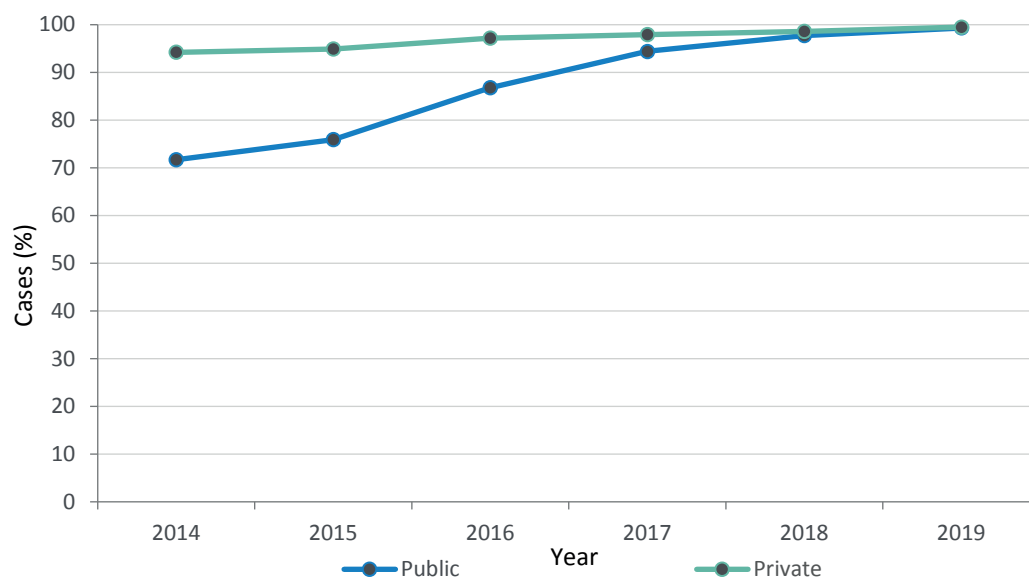
Coronary Device Use

Stents were implanted in 93.5% of PCI cases. The majority of these patients (66%) received a single stent, a further 21% had 2 stents implanted and 5.2% had 3 stents implanted. A small number of patients (1.2%) received ≥ 4 stents in a single case, with no differences in these proportions among public and private hospitals. The average summed total length of stents deployed per case for hospitals ranged between 15-34mm. The overall median total stent length per case was 23mm. There was a small increase in cases of balloon angioplasty alone in 2019 (4.3% vs 3.7% in 2018). Drug-eluting balloons were used in about 20% of isolated balloon angioplasty cases – primarily for in-stent restenosis. Just 6 bioresorbable vascular scaffolds were deployed (presumably either in a research setting or as part of the Special Access Scheme) following their general withdrawal from the Australian commercial market in 2017.

Drug-eluting stents

Drug-eluting stents accounted for virtually all (99.4%) stents implanted in Victoria in 2019. The gap between public and private hospital DES use seen in earlier years has now substantially closed (Figure 17) and correlates with patterns of DES use internationally [11].

Figure 17: Trends in DES usage by hospital sector: 2014 - 2019



Adjunctive devices and drugs

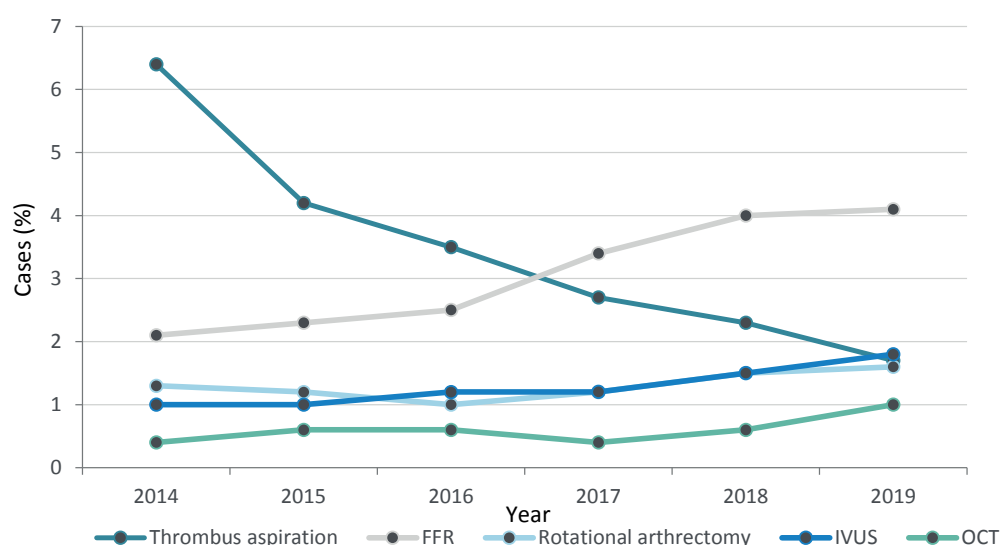
Although still being used in small numbers, intravascular ultrasound (IVUS) and optical coherence tomography (OCT) use has steadily increased, primarily in the public sector. In contrast, thrombus aspiration (catheter-based extraction of blood clots that occlude the coronary artery) declined in both sectors in 2019 (Table 9).

Table 9: Adjunctive device use by hospital sector

Adjunctive device type	All sites (N=12353)	Public (n=7066)	Private (n=5287)
	N (%)	N (%)	N (%)
Intravascular ultrasound	221 (1.8)	135 (1.9)	86 (1.6)
Optical coherence tomography	121 (1.0)	88 (1.2)	33 (0.6)
Thrombus aspiration device	216 (1.7)	183 (2.6)	33 (0.6)
Rotational atherectomy	202 (1.6)	70 (1.0)	132 (2.5)
Fractional flow reserve	505 (4.1)	208 (2.9)	297 (5.6)
IABP	25 (0.2)	20 (0.3)	5 (0.1)
ECMO	15 (0.1)	13 (0.2)	2 (<0.1)

Trends in use of adjunctive devices over the last six years are shown in Figure 18. Rotational atherectomy rates have remained fairly stable, being more commonly utilised in the public sector. Fractional flow reserve (FFR) estimations were also performed at a constant rate, although they were more commonly performed in the private sector. Intra-aortic balloon pump use has declined over time, while extracorporeal membrane oxygenation (ECMO) for patients with cardiogenic shock was used in very small numbers (n=15 in 2019). Glycoprotein (GP) IIb/IIIa receptor inhibitor use has continued to steadily decline – now being mostly used in the setting of acute STEMI. They were administered in 739 STEMI cases, accounting for approximately one-third of STEMI cases and two-thirds of GP IIb/IIIa receptor inhibitor use.

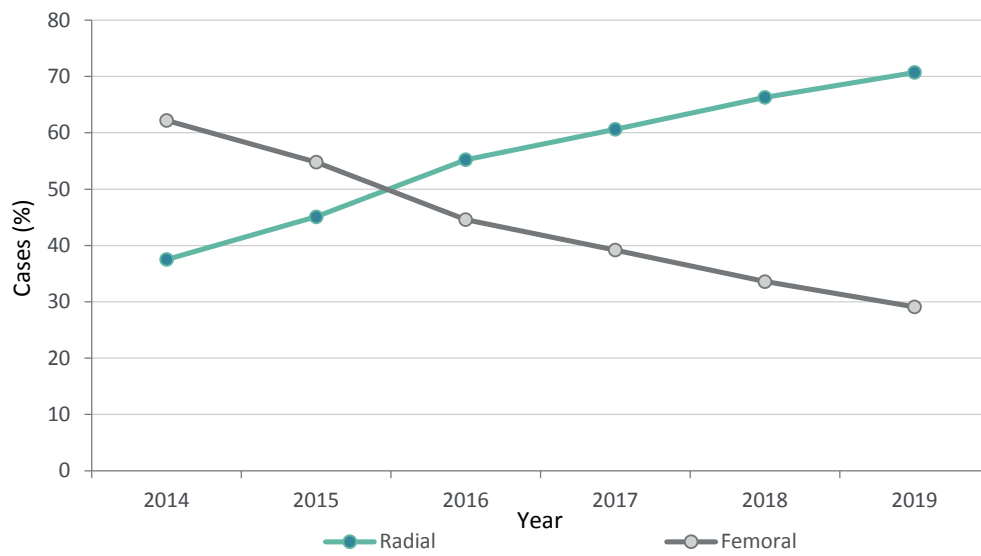
Figure 18: Trends in use of adjunctive devices: 2014-2019



Arterial access

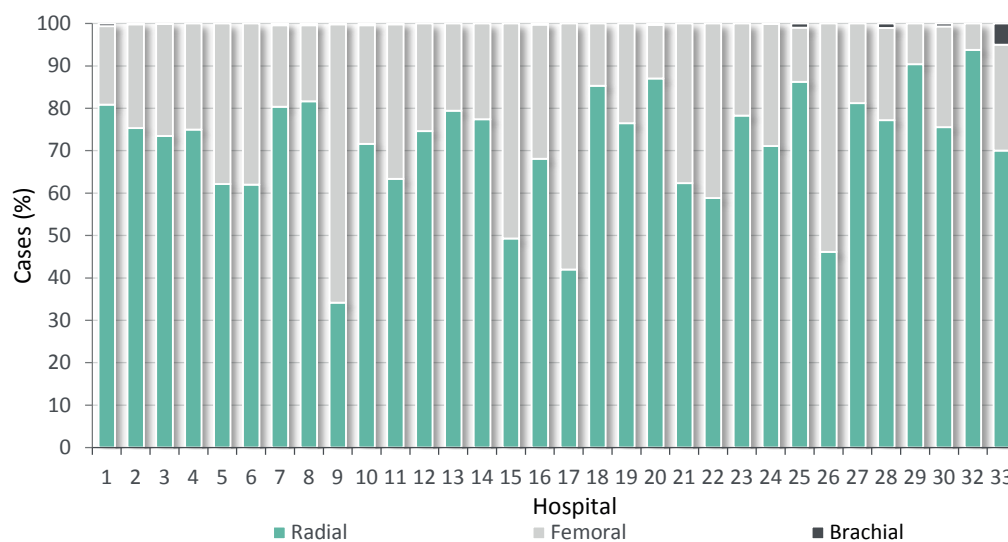
Radial artery vascular access is widely accepted as being superior to femoral access in PCI, primarily due to lower rates of serious bleeding [14].

Figure 19: Trends in arterial access: 2014 - 2019



Its use has steadily increased over the past 5 years (Figure 19), and in 2019, radial access accounted for 71% of PCI cases overall (range 34%-94% among hospitals) (Figure 20).

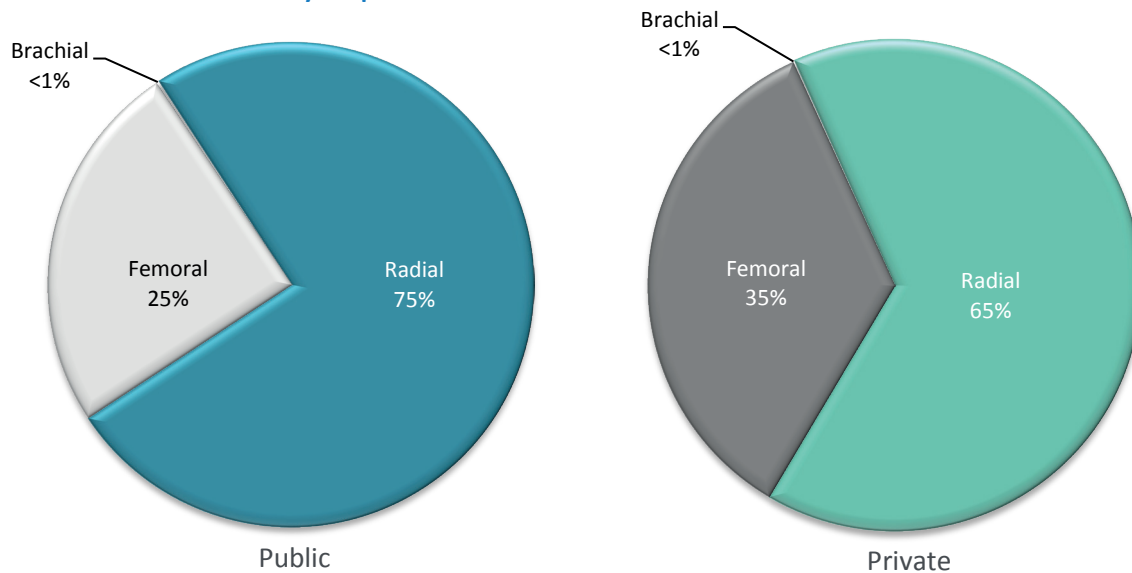
Figure 20: Arterial access route by hospital



Hospital 32 & 33 low case numbers (n≤20).

The previously identified gap in radial access use between the public and private sectors persisted, although both sectors have increased their radial artery use to a similar extent over time (Figure 21).

Figure 21: Arterial access routes by hospital sector



Radial access has generally increased for both males and females over time, but its use remains greater in males across all age groups (Figure 22). Overall, the radial artery was used in 73% of men and 64% of women but trended downward with advancing age in both sexes.

Figure 22: Trend in rates of radial artery access by sex

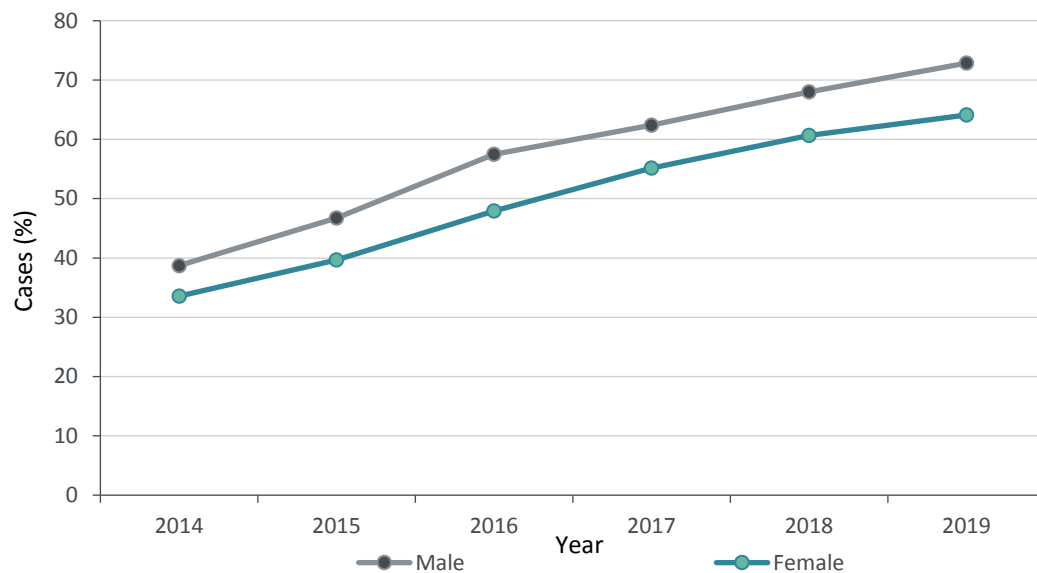
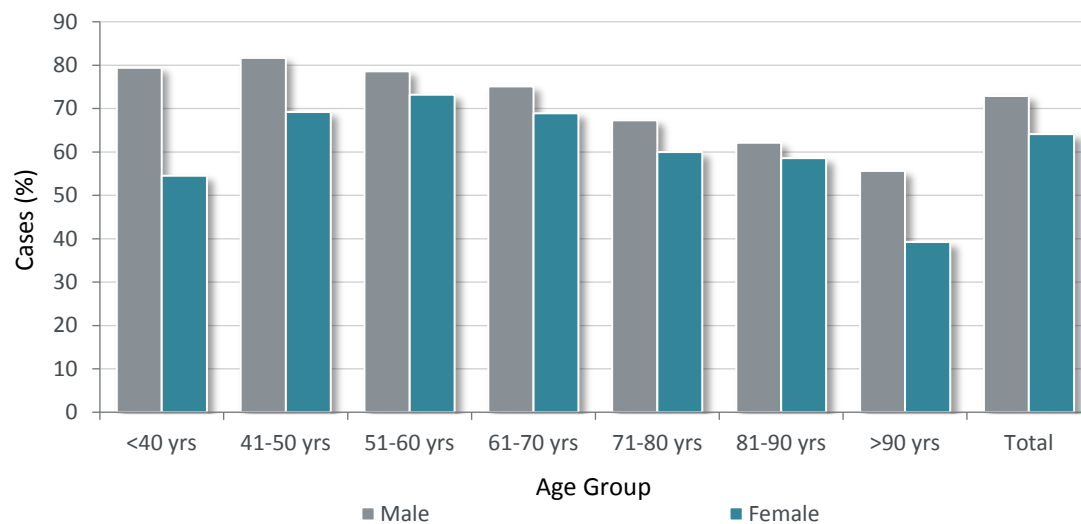


Figure 23 demonstrates that radial artery use tended to decline at extremes of age – under 40 year age group and especially those >90 years of age. This may in part reflect operator practice to avoid cases where technical difficulties may be potentially encountered such as radial artery spasm and tortuosity of the subclavian artery.

Figure 23: Radial artery access by sex and age group



PCI for Acute STEMI

In 2019, a total of 2,077 patients with acute STEMI underwent PCI within 24 hours of symptom onset – a 5% decline compared with 2018. Yet, PCI for STEMI still accounted for a sizeable 16.8% of the total PCI caseload. Among the 2,077 cases, 1,820 patients underwent primary PCI – defined as PCI treatment as primary reperfusion therapy for patients presenting within 12 hours of STEMI symptom onset. Other sub-categories of PCI for acute STEMI are shown in Table 10. Primary PCI comprised 87.6% of the acute STEMI cohort in VCOR, with differences in rates in all categories among the public and private sectors.

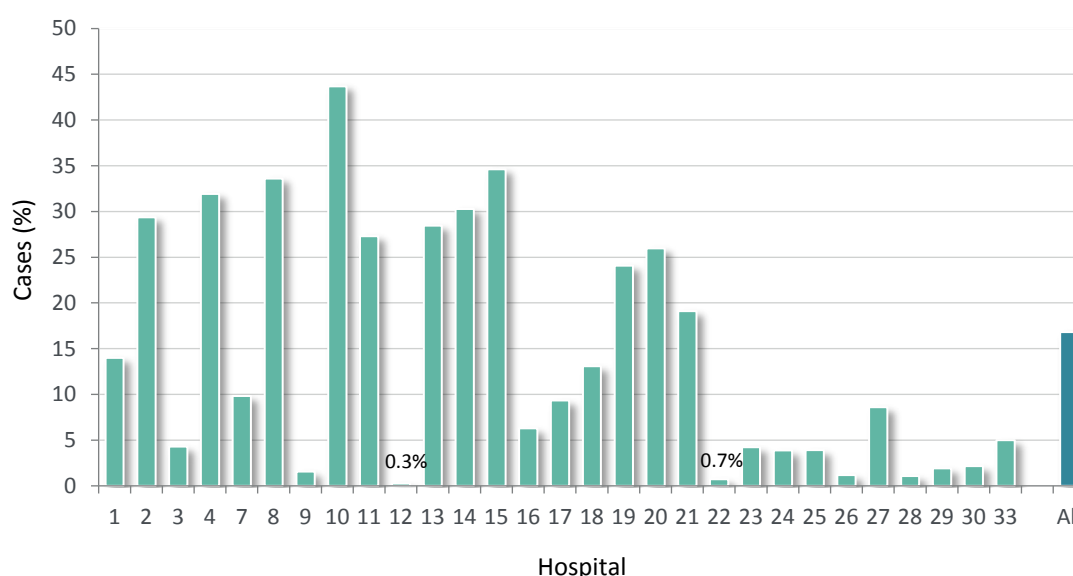
Table 10: Sub-categories of patients undergoing PCI for STEMI within 24 hours

PCI for acute STEMI sub-categories	All sites (N=2077)	Public (n=1819)	Private (n=258)
	N (%)	N (%)	N (%)
Primary PCI* (<12 hrs, no lytic)	1820 (87.6)	1580 (86.9)	240 (93.0)
Rescue PCI (<24 hrs, previous lytic, unstable)	116 (5.6)	106 (5.8)	10 (3.9)
Pharmaco-invasive PCI (<24 hrs, previous lytic, stable)	141 (6.8)	133 (7.3)	8 (3.1)

**Includes inter-hospital transfers and in-patient STEMI.*

The caseload for acute STEMI among hospitals is shown in Figure 24. Rates range from <1% to 43.7% of workload. A number of the smaller private hospitals either did not offer acute STEMI PCI services or treated very few cases.

Figure 24: Acute STEMI cases as a proportion of overall case numbers by hospital



Hospitals 5, 6 & 32 had Nil acute STEMI cases; Hospital 12, 22, 26, 28, 29, 30 & 33 had low acute STEMI numbers (n<5).

Patients treated for STEMI tended to have different demographic profiles to the general PCI population. They were younger overall (63 ± 12.4 years vs 67.6 ± 12 years) and had fewer traditional cardiac risk factors such as diabetes (18.6% vs 24.1%), peripheral vascular disease (2.1% vs 3.9%) and lower rates of previous revascularisation procedures, including previous PCI (13.9% vs 37%) and coronary artery bypass grafting (2.3% vs 7.7%). Patients treated in the public and private sectors had very similar age and sex profiles but differed in the rates of previous stroke (4% public vs 1.6% private), previous PCI (12.4% public vs 24% private) and previous coronary artery bypass grafting (2% public vs 4.3% private). Patients who initially presented to a regional hospital with acute STEMI were more likely to be transferred to a PCI hospital in the public sector.

Door-to-balloon times

The time delay from the patient's arrival to hospital to successful re-opening of the occluded coronary artery responsible for the STEMI is known as the door-to-balloon time (DBT) and is an accepted and frequently reported quality indicator for health services (18). Traditionally, the accepted quality benchmark for door-to-balloon time has been ≤ 90 minutes, although Australian and international guidelines have now moved to recommending target DBTs of ≤ 60 minutes [10, 15]. For 2019, VCOR has continued to utilise target $\text{DBT} \leq 90$ minutes in line with the majority of participant hospitals who still retain this benchmark for their own hospital quality assurance processes. Further evolution of this quality indicator is likely, with a shift towards monitoring delays from first medical contact to balloon inflation rather than DBT. Currently, VCOR does not capture this metric in its dataset but is planning on adding it in its upcoming version upgrade.

In 2019, the median DBT was 58 minutes (IQR: 40, 84). All hospitals achieved a median DBT time of ≤ 90 minutes, as they have for the past 3 years (Figure 25), but only 10 hospitals managed a median DBT of ≤ 60 minutes. Table 11 shows the trend in median DBTs over the past 6 years. In 2016, VCOR undertook a special review of DBT results and provided information and suggestions for improvement to hospitals. There was a noticeable improvement in subsequent years, although gains have appeared to plateau in the last 12 months.

Figure 25: Door-to-balloon time for primary PCI cases by hospital

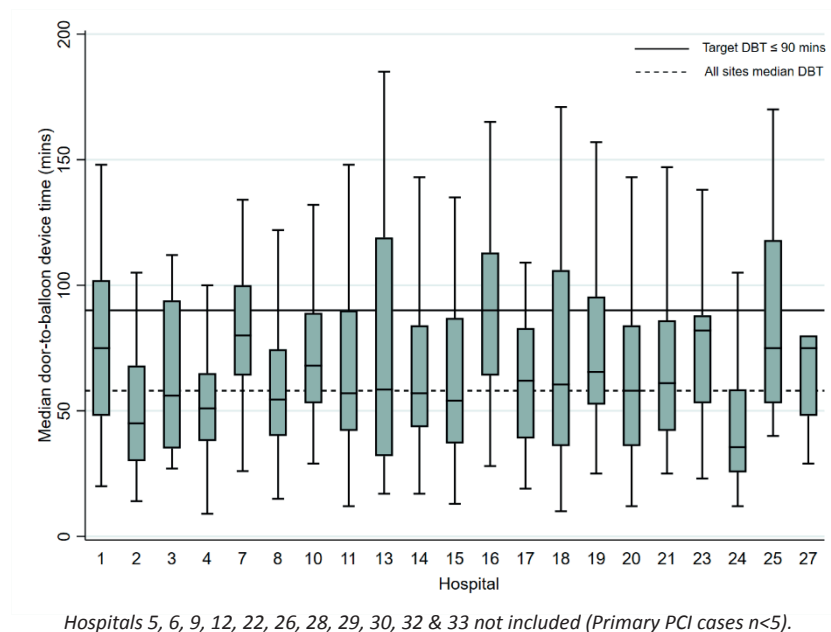


Table 11: Door-to-balloon times for primary PCI cases: 2014-2019

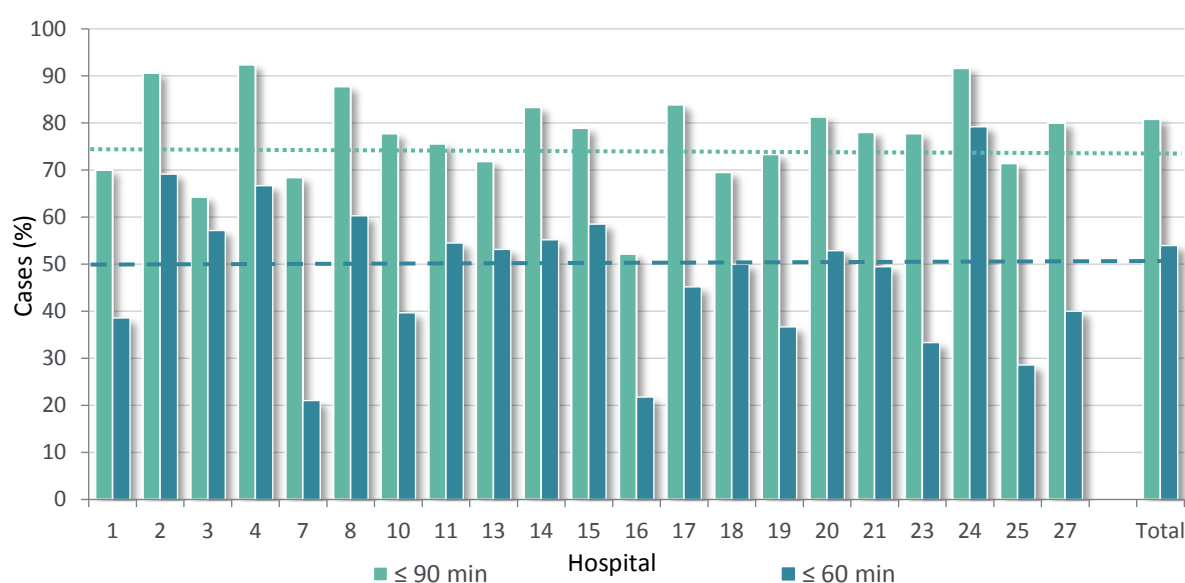
Door-to-balloon time*	2014	2015	2016	2017	2018	2019
	(N=1102)	(N=1168)	(N=1303)	(N=1423)	(N=1596)	(N=1495)
Median – mins (IQR)	68 (47, 95)	72 (48, 103)	67 (47, 96)	63 (44, 89)	58 (39, 83)	58 (40, 84)
Proportion of cases ≤90mins (%)	70.5	66.4	71.9	77.3	80.5	80.8

*Primary PCI for STEMI presentations **excluding** all inter-hospital transfer arrivals and patients with STEMI onset while a current in-patient.

Hospitals were further assessed on their compliance at achieving a DBT ≤90 minutes in at least 75% of their primary PCI cases – an internationally recognised performance benchmark [16] that is arguably more representative of how a hospital is performing. The average rate of compliance with a DBT≤90 minutes was 80.8% of cases per hospital. However, there was marked variation in the compliance rate among hospitals, ranging from 52.2% to 92.4% (Figure 26). Thirteen hospitals (62%) achieved a DBT ≤90 minutes in greater than 90% of primary PCI cases. As in previous years, the sites that did not reach the 75% benchmark tended to be smaller volume centres.

For the first time, hospitals were also benchmarked for their compliance with a DBT ≤60 minutes (Figure 26). In contrast to the more liberal benchmark of ≤90 minutes where the majority of sites achieved 75% compliance rates, just one hospital achieved 75% compliance with the stricter ≤60 minutes benchmark.

VCOR considers that a benchmark compliance rate of 75% is not practically achievable when the target DBT is shortened to ≤60 minutes. Accordingly, we propose that if a shortened benchmark DBT of ≤60 minutes is to be adopted, the target compliance rate should be 50% of cases per hospital. When that compliance rate was applied, 11 of 21 hospitals achieved the target (Figure 26), indicating that it is a practical benchmark that all hospitals can strive to reach or exceed.

Figure 26: Proportion of primary PCI cases with door-to-balloon time ≤90 minutes and ≤60 minutes by hospital


Hospitals 5, 6, 9, 12, 22, 26, 28, 29, 30, 32 & 33 not included (Primary PCI cases n<5).

Pre-hospital notification (PHN)

Pre-hospital notification (PHN) of the imminent arrival of an acute STEMI patient to the receiving hospital has become routine practice for Ambulance Victoria. It allows hospitals to activate the cardiac catheterisation laboratory team before the patient arrives and facilitates rapid transfer directly to the catheter laboratory to minimise delays in the commencement of the PCI. Results in 2019 once again clearly demonstrate the benefit of PHN on door-to-balloon times (Table 12). PHN was undertaken in 73% of primary PCI cases – an increase from the previous year (69% in 2018).

Table 12: Door-to-balloon times for primary PCI cases by pre-hospital notification status

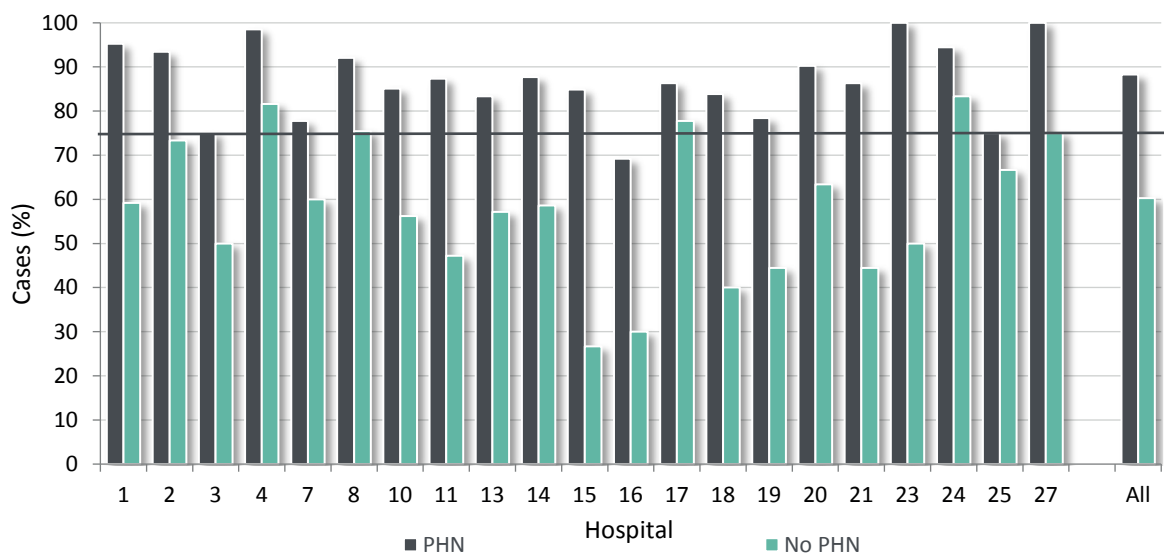
Door-to-balloon time	Primary PCI* (all cases)	Primary PCI* (PHN only†)	Primary PCI* (no-PHN†)
	(N=1495)	(n=1095)	(n=400)
Median – mins (IQR)	58 (40, 84)	53 (37, 72)	82 (56, 110)
Proportion of cases ≤90mins (%)	80.8	88.3	60.3

*Primary PCI for STEMI presentations excluding all inter-hospital transfers and patients with STEMI onset while a current in-patient.

†Pre-hospital notification (PHN).

A comparison of hospitals' DBT results with and without PHN is shown in Figure 27. Only 1 hospital failed to achieve the target of ≥75% cases with DBT ≤90minutes with pre-hospital notification.

Figure 27: Proportion of primary PCI cases with door-to-balloon time ≤90 minutes – pre-hospital notification (PHN) vs no pre-hospital notification

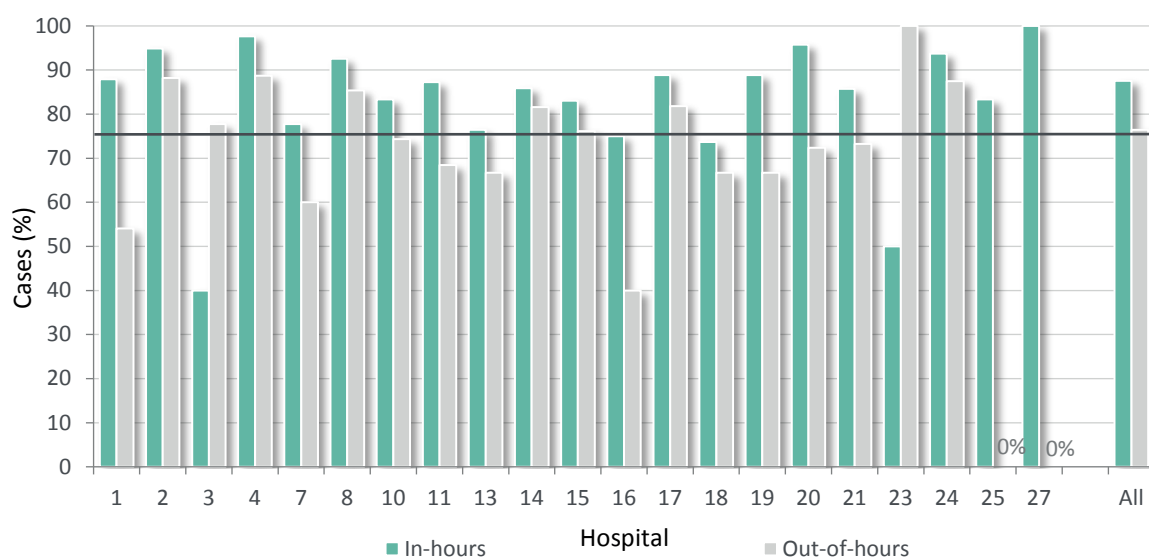


Hospitals 5, 6, 9, 12, 22, 26, 28, 29, 30, 32 & 33 not included (Primary PCI cases n<5).

In-hours versus out-of-hours presentation

In 2019, the majority (61%) of STEMI cases were treated out-of-hours (range by hospital 14-71%). Most hospitals had longer delays to the commencement of the procedure in this period. However, two hospitals actually performed better out-of-hours and a further two hospitals did not do any out-of-hours cases (Figure 28). The gap in DBT performance of hospitals between their in-hours and out-of-hours cases tended to be smaller than in previous years. The compliance rates with DBT ≤ 90 minutes out-of-hours has also been improving over time (76.4% in 2019, 74.9% in 2018 and 71.5% in 2017).

Figure 28: Proportion of primary PCI cases with door-to-balloon time ≤ 90 minutes – in-hours vs out-of-hours presentation



Hospitals 5, 6, 9, 12, 22, 26, 28, 29, 30, 32 & 33 not included (Primary PCI cases $n < 5$).

Hospitals 25 & 27 had low out of hours cases ($n < 3$).

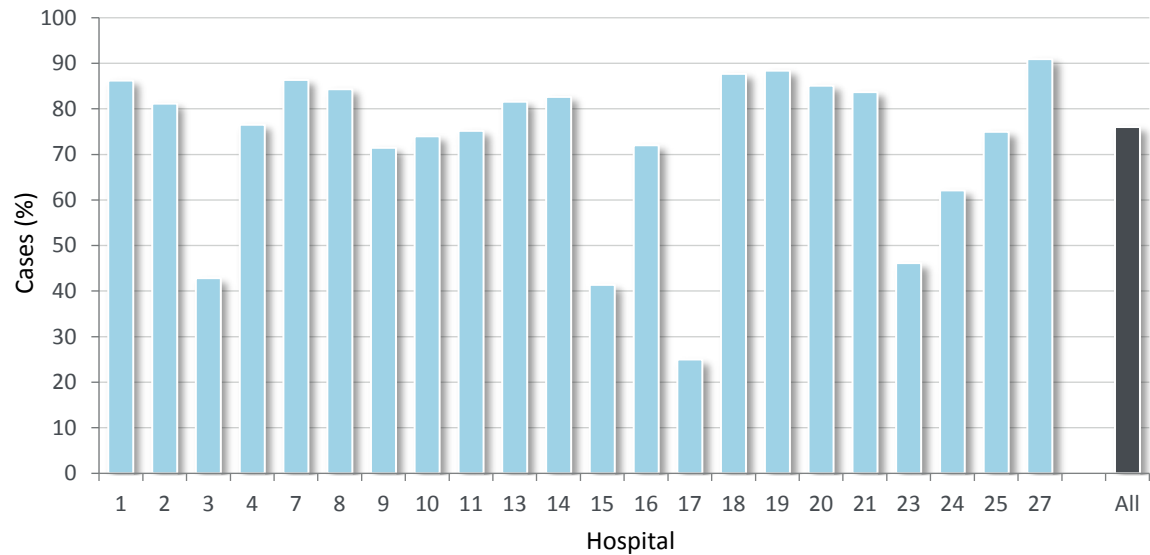
In-hours: 8.00am - 6.00pm (Mon-Fri excluding public holidays).

Out-of-hours: 6.00pm - 8.00am (Mon-Fri, public holidays and weekends).

Radial access in STEMI cases

The evidence base for the use of radial access rather than femoral access is strongest among cases of STEMI [14]. VCOR has tracked the use of radial vascular access in acute STEMI over the past 6 years and has noted steady year-on-year increases. In 2019, radial access was utilised in 75.8% of STEMI PCIs – 5% higher than in 2018 and almost 10% higher than in 2017. A comparison of radial access rates in STEMI PCI among hospitals shows that despite the growth in its use overall, there was still wide variation across sites, ranging from 25% to 91% of cases (Figure 29). Yet, the proportion of hospitals using the radial artery in $\geq 75\%$ of their STEMI cases has increased (50% in 2019 vs 23% in 2018).

Figure 29: Radial access rates in acute STEMI by hospital



Hospitals 5, 6 & 32 had no acute STEMI cases; Hospitals 12, 22, 26, 28, 29, 30, 33 had low acute STEMI cases (n<5).



Outcomes

Lesion and procedure success rates

The mean lesion success rate (residual stenosis <10% following stenting and <50% following balloon angioplasty) was 94.9% (range among hospitals 84.8% - 100%). The mean procedural success rate – defined as the successful treatment of all lesions and the absence of any major in-hospital complications – was 92.3% (range among hospitals 84%- 100%). These rates have remained stable over the past 6 years.

A comparison of the clinical and lesion features associated with successful and failed PCI cases is shown in Table 13. There were no major differences in age or sex profiles, but unsuccessful procedures were more commonly associated with certain comorbidities, including moderate and severe left ventricular impairment and cardiogenic shock. Chronic total occlusion (CTO) lesions were nearly 8 times more commonly associated with failed procedures.

Table 13: Comparison of clinical and lesion features among successful and failed PCI cases

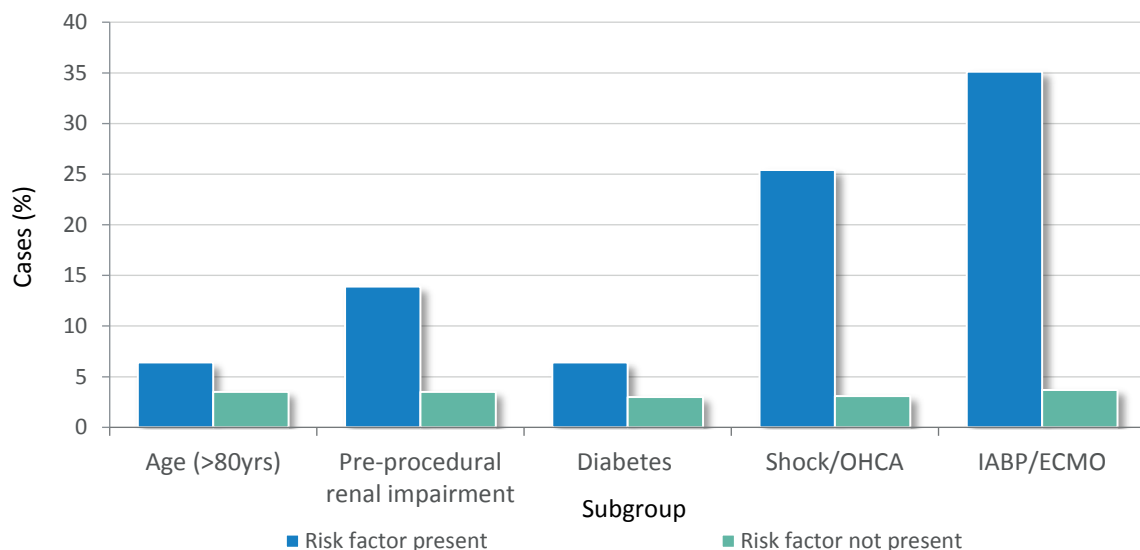
Patient characteristics	Successful procedures (n=11401)	Failed procedures (n=952)
Age- years (Mean ± SD)	67.03 (±11.7)	69.2 (±11.8)
	N (%)	N (%)
Sex - female	2761 (24.2)	262 (27.5)
Diabetes	2595 (22.8)	265 (27.8)
PVD history	386 (3.4)	54 (5.7)
CBVD history	425 (3.7)	47 (4.9)
Previous PCI	3768 (33.0)	325 (34.1)
Previous CABG	749 (6.6)	94 (9.9)
eGFR<45/Renal replacement therapy	1010 (8.9)	165 (17.3)
Normal LVEF (>50%)	7467 (71.9)	458 (55.9)
Mild LVEF (45-50%)	1528 (14.7)	124 (15.1)
Moderate LVEF (35-44%)	937 (9.0)	126 (15.4)
Severe LVEF (≤35%)	447 (4.3)	111 (13.6)
Shock/OHCA	163 (1.4)	157 (16.5)
Out-of-hours	2150 (18.9)	279 (29.3)
Public hospital	6546 (56.6)	610 (64.1)
Chronic total occlusion	306 (2.7)	159 (16.7)
ACC/AHA B2/C lesion	6763 (59.3)	756 (79.4)

New renal impairment

The use of contrast agents in PCI can induce new or worsening renal impairment, especially in high acuity cases such as patients with cardiogenic shock or requiring mechanical support and in those with risk factors of pre-existing kidney disease, hypertension and diabetes [17]. New renal impairment (NRI) was defined as serum creatinine rise $>44.2 \mu\text{mol/L}$ or 25% above pre-procedural value within 5 days of PCI procedure. In 2019, the NRI rate was 3.9%.

The incidence of NRI among known high-risk groups is shown in Figure 30. NRI rates were especially high among patients with shock or out-of-hospital cardiac arrest and those needing mechanical support. However, for the subgroup of patients with pre-existing renal impairment, the rate of worsening renal impairment has actually declined in the past 3 years (14% in 2019, 15.5% in 2018, 19% in 2017), suggesting that awareness and active monitoring of this potential clinical problem may contribute to more effective prevention.

Figure 30: Rates of new renal impairment in selected high-risk sub-groups

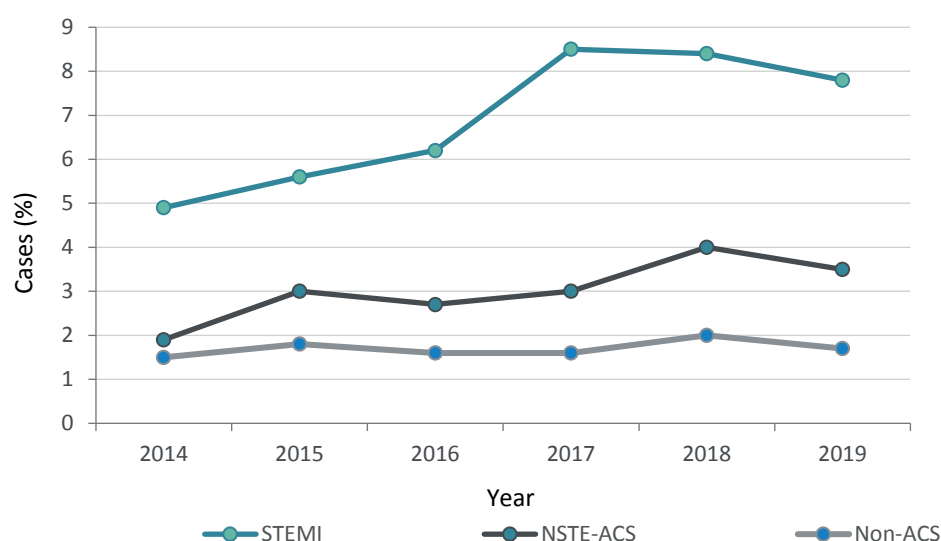


Data available for 8932 cases.

New renal impairment defined as a serum creatinine rise $>44.2 \mu\text{mol/L}$ or 25% above pre-procedural value within 5 days of PCI procedure.

When assessing the rates of NRI by clinical presentation, patients with STEMI had the highest incidence with a rate of 7.8%. This group includes most patients with cardiogenic shock and out-of-hospital cardiac arrest. Trends in NRI rates over time are shown in Figure 31. Although these data represent only about 75% of the cohort (the remaining 25% did not have renal function measured post-PCI), there is a suggestion that the pattern of increasing rates of NRI in the past few years may now be starting to decline.

Figure 31: Trends in rates of new renal impairment by clinical presentation: 2014-2019



Referral to cardiac rehabilitation

The overall rate of referral to a cardiac rehabilitation program in 2019 was 84%. However, Table 14 shows the referral rates varied by clinical presentation, with rates higher among the patients presenting with acute coronary syndromes. Referral to a cardiac rehabilitation program is strongly recommended in Australian practice guidelines [15]. Referral rates appear to be improving over time, from around 74% in 2016-17, yet remain lower in the private sector, (87.5% public vs 79.7% private). Referral rates are not the same as attendance rates, with some estimates suggesting that only one-third of patients referred to cardiac rehabilitation actually complete the program. Given the clear health and economic benefits related to cardiac rehabilitation program attendance [18], it is hoped that continued attention on referral rates will encourage greater utilisation of this important measure for secondary prevention of coronary disease.

Table 14: Rates of referral to cardiac rehabilitation by clinical presentation

Clinical presentation	Cases with data available	Rehabilitation referral rate
	N	N (%)
STEMI	1950	1793 (91.9)
NSTEMI-ACS	3065	2663 (86.9)
Non-ACS	5789	4620 (79.8)
All cases	10804	9076 (84.0)

Compliance with guideline-recommended medications at discharge

Optimal medical therapy is an important component of treatment for patients with coronary disease. Following PCI, Australian practice guidelines provide strong evidence-based recommendations for the use of dual antiplatelet therapy (DAPT) and statins in all cases unless contraindicated [10]. In 2019, there was a high compliance rate for DAPT use (defined as aspirin plus another antiplatelet drug). Statin use was also high, although there was a gap between public and private hospitals that has also been observed in previous years (Table 15). It is unclear why the divergence in statin prescription rates by hospital sector occurs, although differences in demographic and clinical factors may contribute.

Table 15: Rates of prescription of dual antiplatelet therapy and statins at discharge

	All sites	Public	Private
	N (%)	N (%)	N (%)
Dual antiplatelet therapy*	11442 (94.3)	6593 (95.8)	4849 (92.4)
Statin	11068 (91.9)	6520 (95.1)	4548 (87.6)

* DAPT is aspirin plus another antiplatelet drug.

In addition to DAPT and statins, patients presenting with an acute coronary syndrome are recommended to be treated with beta blockers and ACE inhibitors/angiotensin receptor blockers (ARB). Greater use of these medications is linked with improvements in outcomes [19]. The rates of use of these medications by clinical presentation are shown in Table 16. The highest rates of prescription were in patients presenting with STEMI and lowest among patients with non-ACS conditions.

Table 16: Rates of prescription of selected medications at discharge by clinical presentation

	DAPT	Statin	BB	ACE-I/ARB
	%	%	%	%
STEMI	96.5	96.7	85.3	83.7
NSTE-ACS	94.7	94.1	71.1	71.9
Non-ACS	93.4	88.9	53.6	62.7

Compliance with prescription guidelines was considered good if patients were discharged with at least 4 of the 5 recommended medications (aspirin, second antiplatelet agent, statin, beta blocker and ACE inhibitor/ARB). In 2019, 69.2% of STEMI patients were discharged on at least 4 of the 5 recommended medications, lower than in the previous year (81% in 2018). The rate was lower still for NSTEMI-ACS at 48.8%. While there may be several determinants at play influencing these rates, including patient-specific factors, prescribing patterns and concerns about the strength of the evidence supporting some of these medications, the lower rates in 2019 may indicate a trend that is not consistent with practice guidelines and will continue to be monitored closely in future reports.

Key Performance Indicators

VCOR reports on the following key performance indicators (KPIs):

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

VCOR has developed and published its risk-adjustment model for 30-day all-cause mortality [20]. Compared to other international risk-adjustment models for the same outcome, our model retains its robustness even with the inclusion of the extreme high-risk conditions of cardiogenic shock and out-of-hospital cardiac arrest [21]. The clinical characteristics used to construct the VCOR risk-adjustment model for 30-day mortality are:

- Cardiogenic shock
- Out-of-hospital cardiac arrest
- Estimated glomerular filtration rate (eGFR)
- Left ventricular ejection fraction
- Acute coronary syndrome
- Mechanical ventricular support
- Age ≥ 80 years
- Complex lesions
- Percutaneous entry location
- Peripheral vascular disease

In-hospital mortality

The unadjusted in-hospital mortality rate following PCI in 2019 was 1.7%. High rates were seen in certain patient subgroups – particularly patients with cardiogenic shock and intubated OHCA patients (42.8%) and STEMI (6.2%). When cases of cardiogenic shock, intubated OHCA and STEMI were excluded from the analysis, the overall in-hospital death rate fell to a low rate of 0.6%. Table 17 outlines the in-hospital mortality rates for selected clinical groups.

Table 17: Unadjusted in-hospital mortality rates for selected patient groups

Patient category	Total	In-hospital mortality rate
	N	N (%)
All PCI patients	12353	212 (1.7)
STEMI patients	2390	148 (6.2)
Shock/intubated OHCA patients	320	137 (42.8)
NSTE-ACS	3537	27 (0.8)
Non-ACS	6426	37 (0.6)

Trends in rates of in-hospital mortality over a 6-year period are shown in Table 18. In-hospital mortality - especially for the lower-risk subgroups of NSTEMI-ACS and non-ACS - has tended to be stable over time.

Table 18: Trends in in-hospital mortality rates for selected clinical presentations: 2014-2019

Patient category	2014 (N=8329)	2015 (N=9230)	2016 (N=10036)	2017 (N=11002)	2018 (N=12447)	2019 (N=12353)
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
All PCI patients	174 (2.1)	155 (1.7)	193 (1.9)	204 (1.9)	174 (1.4)	212 (1.7)
STEMI	140 (7.6)	113 (5.7)	138 (6.4)	145 (6.4)	119 (4.7)	148 (6.2)
Shock and/or intubated OHCA	107 (44.8)	102 (40.3)	119 (38.5)	133 (42.9)	115 (35.1)	137 (42.8)
NSTEMI-ACS	16 (0.6)	25 (0.9)	29 (0.9)	34 (1.0)	29 (0.8)	27 (0.8)
Non-ACS	18 (0.5)	17 (0.4)	26 (0.6)	25 (0.5)	26 (0.4)	37 (0.6)

In-hospital major bleeding

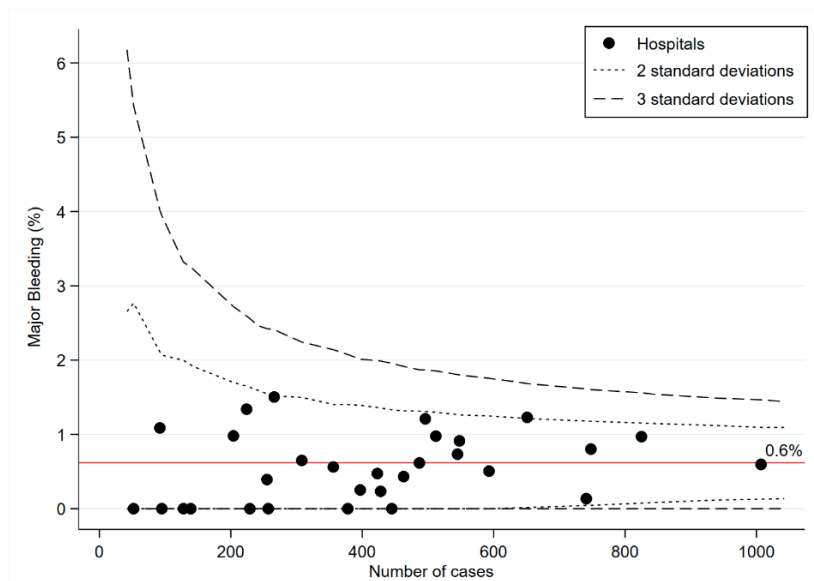
Utilising the standardised definitions of the Bleeding Academic Research Consortium (BARC) [22], VCOR includes BARC Type 3 and Type 5 bleeding in its measurement of major bleeding episodes. The in-hospital major bleeding rate in 2019 was 0.6%, representing a continuing downward trend since 2015 when the highest yearly rate of 1.2% was recorded. The in-hospital major bleeding rates for selected patient subgroups are detailed in Table 19. STEMI remains the clinical presentation associated with the highest bleeding rate, although it also has fallen compared with the previous year (1.3% in 2019 vs 2.0% in 2018). This may at least in part reflect the greater use of radial artery access in STEMI. Bleeding rates in patients who required ECMO halved (20% in 2019 vs 43% in 2018), with similar case numbers per year treated but low numbers overall. The major bleeding rate for female patients was twice that for men. Similarly, bleeding with femoral arterial access was three times the rate associated with radial access.

Table 19: In-hospital major bleeding rates for selected patient groups

Sub-group	N	Major bleeding rate
Clinical Presentation		N (%)
STEMI	2386	30 (1.3)
NSTEMI-ACS	3582	28 (0.8)
Non-ACS	6375	21 (0.3)
Sex		N (%)
Male	9323	45 (0.5)
Female	3020	34 (1.1)
Arterial Access Route		N (%)
Radial access	8731	32 (0.4)
Femoral access	3589	47 (1.3)
Brachial access	23	0 (0)
Total	12343	79 (0.6)

The rates of major bleeding by hospital are shown in Figure 32. They ranged from 0- 1.5% among hospitals and all sites were within control limits. There was no apparent association between bleeding rates and hospital case volumes, with acceptable bleeding rates in both low and high volume centres.

Figure 32: Rates of in-hospital major bleeding by hospital

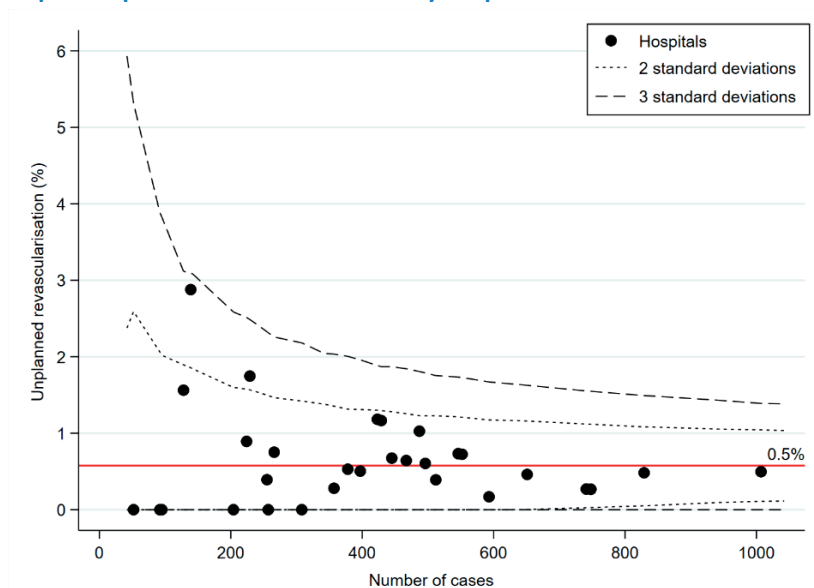


Site 32 & 33 ($n \leq 20$) are excluded due to low PCI case numbers. Excludes ECMO cases ($n=15$).

In-hospital unplanned revascularisation

A revascularisation procedure (PCI or CABG surgery) performed after the initial PCI is considered “unplanned” if it is unexpected and not pre-arranged. This typically occurs if a complication develops such as stent thrombosis, artery perforation or dissection-related acute vessel closure. The overall rate of in-hospital unplanned revascularisation in 2019 was 0.6%. This rate has not changed much over time. All participating hospitals had rates of unplanned revascularisation that were within control limits (Figure 33).

Figure 33: Rates of in-hospital unplanned revascularisation by hospital



Site 32 & 33 ($n \leq 20$) are excluded due to low PCI case numbers.

Among the patients that required unplanned revascularisation, 28 underwent emergency or urgent cardiac surgery – a reduction from the 40 patients in 2018 and comparable to rates seen in other PCI registries. Selected clinical features and outcomes that were associated with emergency surgery are shown in Table 20. Sixty percent had underlying complex coronary lesions (Type C); one case required urgent surgery following PCI for unprotected left main disease and another following treatment of CTO. One quarter (n=8) of emergency surgery cases were performed in centres without on-site surgical backup, with those patients requiring inter-hospital transfer before undergoing CABG surgery. Mortality and bleeding rates were higher in the emergency surgery group compared to the overall patient cohort.

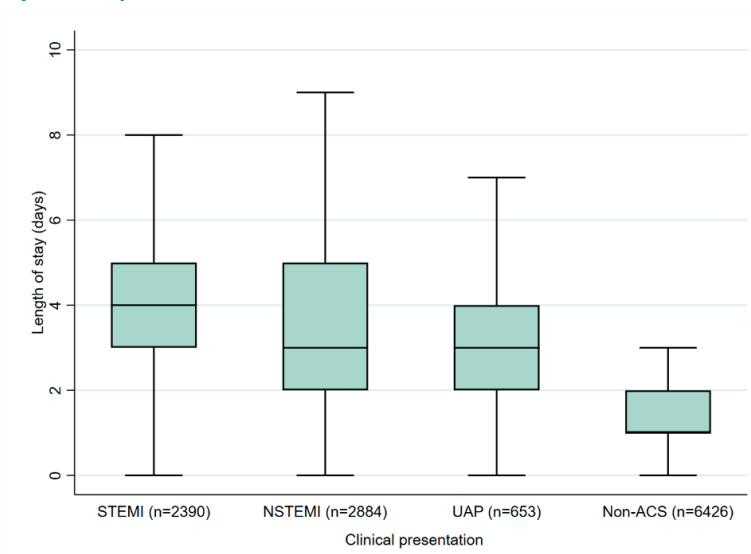
Table 20: Selected clinical features and outcomes associated with emergency CABG surgery

Presentation	Emergency CABG (N=28)
	N (%)
STEMI	10 (35.7)
Shock/OHCA	3 (10.7)
Complex lesions (Type C)	17 (60.7)
Chronic total occlusion	1 (3.6)
Unprotected left main PCI	1 (3.6)
PCI performed in hospitals without on-site surgery	8 (28.6)
In-hospital outcomes	N (%)
Mortality	5 (18.5)
New MI	0 (0.0)
Major bleeding	4 (14.8)
Stroke	0 (0.0)
Definite and probable stent thrombosis	0 (0.0)

Length of stay

Length of stay in hospital varied by clinical presentation (Figure 34) and has remained very similar for each clinical condition over time. As seen in previous years, length of stay was longest among patients with acute coronary syndromes – particularly STEMI (mean 4.77 SD 4.5, median 4 days). Median length of stay was shorter among patients treated in private hospitals (3 days public vs 2 days private) reflecting the greater proportion of elective PCI undertaken in the private sector. The percentage of elective PCI cases discharged on the same day as their procedure was low (2.4%), especially when compared with international practice [23]. This has been a consistent pattern in Victoria over the past 6 years, where same-day discharge rates following PCI have ranged between 1.5%- 2.4% [24]. The majority of same-day discharges were from public hospitals (246 of 302 same-day discharge cases, 81.5%).

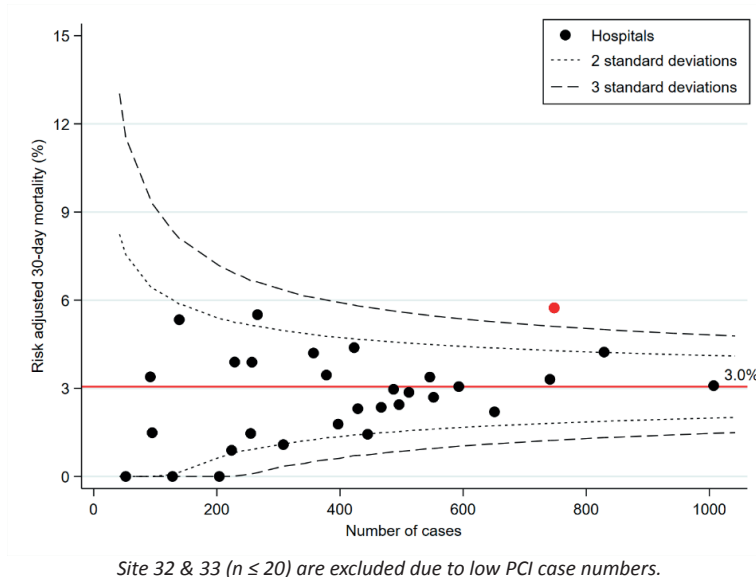
Figure 34: Length of stay by clinical presentation



30-day mortality

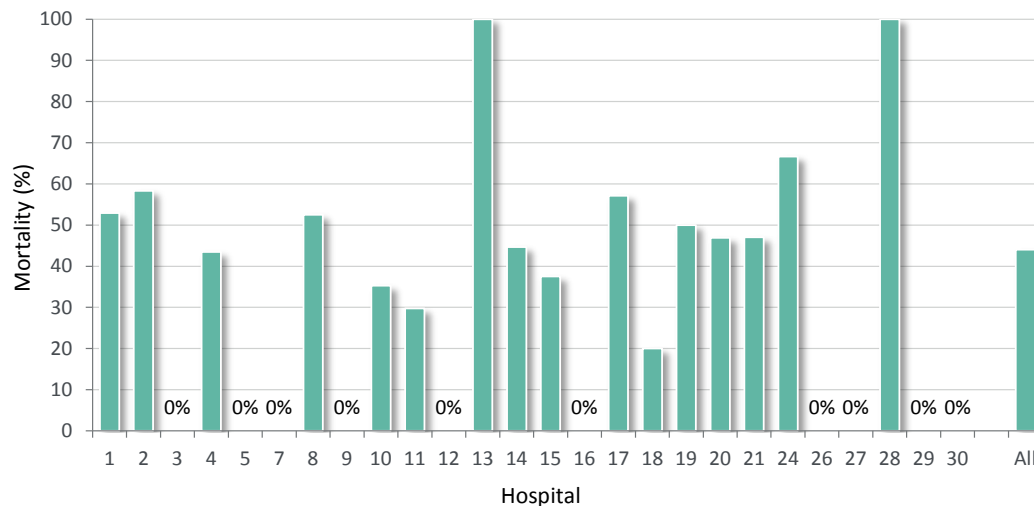
The risk-adjusted 30-day mortality for the 2019 cohort was 3.0%. There was one outlier hospital (result >3 standard deviations from the mean) in this reporting period (Figure 35). The registry's response to this outlier result followed VCOR's Clinical Quality Reporting and Communication of Variance Policy and included timely notification of the result to the hospital Principal Investigator and Hospital Executive. The hospital was given the opportunity to review their results to ensure data accuracy before its outlier status was confirmed. Subsequently, the VCOR Steering Committee and the Victorian Department of Health and Human Services were formally notified.

Figure 35: Risk-adjusted 30-day mortality rates by hospital



The unadjusted 30-day mortality rates for shock and/or intubated OHCA cases by hospital are shown in Figure 36. The mean mortality rate was 44%. A number of hospitals (n=10) were noted to have zero mortality, while 2 hospitals had 100% mortality for these cases. As observed in previous reports, the hospitals with extremely low or high mortality tended to have very low case numbers. Rates of 30-day mortality excluding shock and/or intubated OHCA have remained stable over time.

Figure 36: 30-day mortality rates for cardiogenic shock and/or intubated OHCA patients by hospital

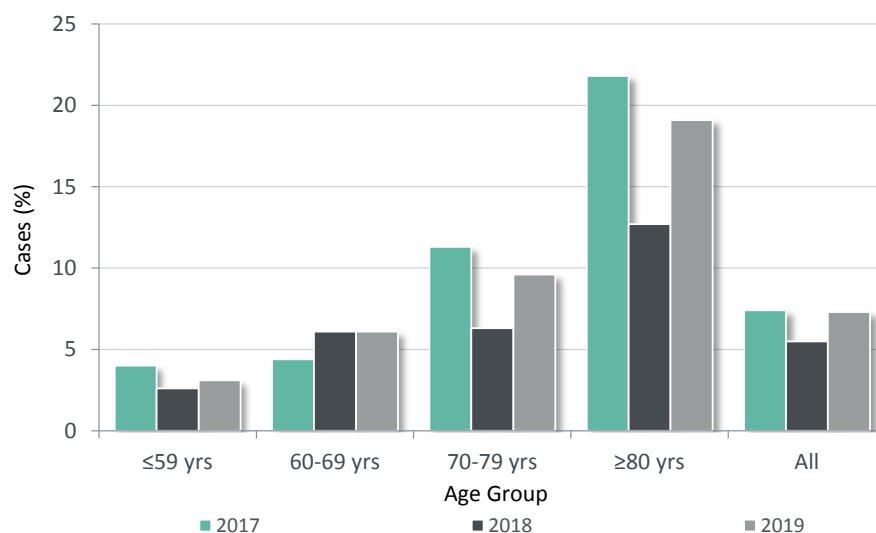


Hospital	1	2	3	4	5	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	24	26	27	28	29	30	ALL
Cases (N)	34	12	1	23	1	3	40	1	17	37	1	8	47	16	6	7	5	2	32	17	3	1	1	1	1	1	318

Hospitals 6, 22, 23, 25, 32 & 33 had no shock or intubated OHCA cases.

Focussing on patients that presented with STEMI, the overall 30-day mortality rate was 7.3%, comparable to recent international series [11]. Thirty-day mortality rates for 2017-2019 by selected age groups are shown in Figure 37. There has been a consistent association between advancing age and 30-day mortality among STEMI patients. Death rates among the elderly (≥ 80 years) was almost double the rate for patients in the 70-79 year age group and 6 times greater than patients under 60 years of age.

Figure 37: 30-day mortality for STEMI by age group



30-day major cardiac and cerebrovascular events (MACCE)

The composite endpoint of major adverse cardiac and/or cerebrovascular events (MACCE) comprises the adverse outcomes of death, new or recurrent myocardial infarction or stent thrombosis, target vessel revascularisation or stroke. The overall 30-day MACCE rate in 2019 was 4.0% (Table 21). When the high-risk conditions of cardiogenic shock or out-of-hospital cardiac arrest were excluded (n=318), the MACCE rate declined to 2.9%. Females had worse outcomes than males in most categories of adverse events, apart from stent thrombosis (rates were the same) and target vessel revascularisation (males 0.7% vs females 0.3%).

Table 21: Major adverse cardiac and cerebrovascular event rates

MACCE component**	In-hospital events	30-day events*
	N (%)	N (%)
Mortality	205 (1.7)	260 (2.1)
Myocardial infarction	68 (0.6)	119 (1.0)
Stroke	29 (0.2)	49 (0.4)
Definite stent thrombosis	23 (0.2)	40 (0.3)
Probable stent thrombosis	8 (<0.1)	13 (0.1)
Target vessel revascularisation (TVR)†	73 (0.6)	145 (1.2)
MACCE	333 (2.7)	499 (4.0)

*30-day events reported include in-hospital events.

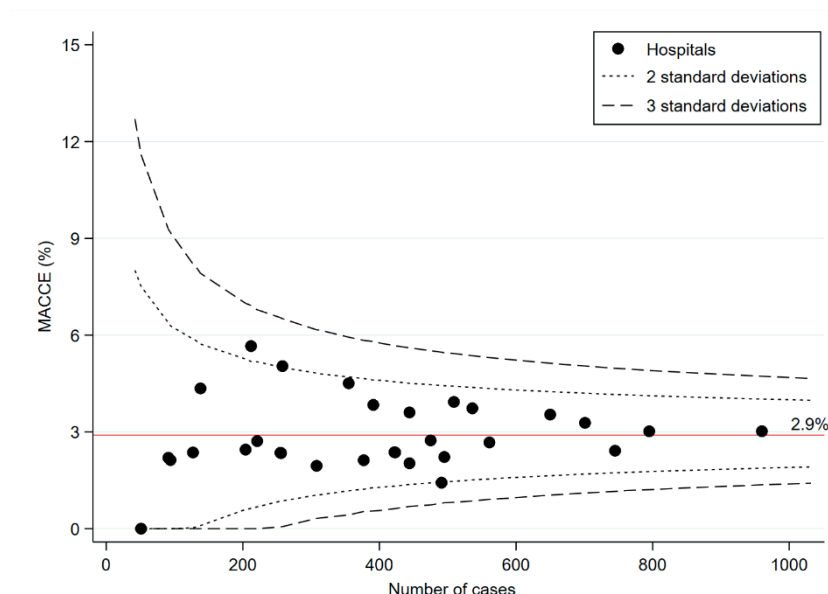
†TVR refers to any 'unplanned' PCI or CABG revascularisation of the target vessel.

**Cases with multiple procedures were excluded to avoid mortality being counted more than once (n=10).

Categories are not mutually exclusive.

For the benchmark analysis relating to MACCE, all hospitals were within control limits. There were no outliers in the 2019 reporting period (Figure 38).

Figure 38: 30-day MACCE rates by hospital



Site 32 & 33 (n ≤ 20) are excluded due to low PCI case numbers
 Excludes all shock/OHCA cases (n= 318).

30-day stent thrombosis

Stent thrombosis was reported as a “definite” event (acute coronary syndrome presentation and angiographic or pathologic confirmation of stent thrombosis) or a “probable” event (unexplained death within 30 days or target vessel myocardial infarction without angiographic confirmation of stent thrombosis). The 30-day definite stent thrombosis rate was 0.3% and there were a small number of cases of probable stent thrombosis (Table 21). Rates were generally similar among hospitals and by hospital sector (public vs private).

30-day rehospitalisation

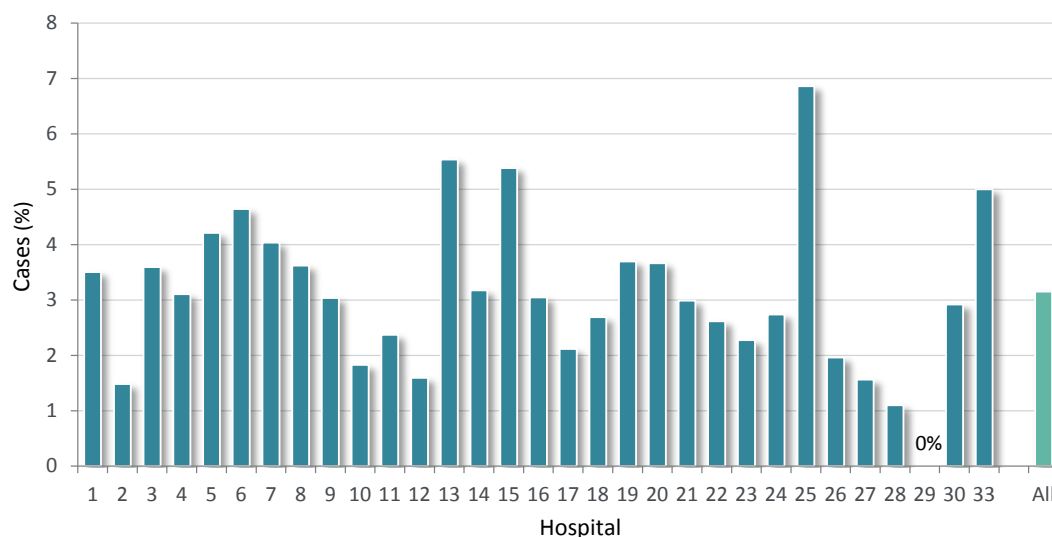
The mean rate of any rehospitalisation for the entire cohort at 30 days was 13.3% (range by hospital 6.3% to 26.9%). Two-thirds were for cardiac conditions and of those, almost two-thirds were planned readmissions (Table 22). Fourteen hospitals had rates above the cohort average – 10 of which were in the private sector. A small proportion (5%) of patients were readmitted more than once in the 30-day period after discharge.

Table 22: Rehospitalisation rates by hospital sector

	All patients (N=12026)	Public (n=6827)	Private (n=5199)
	N (%)	N (%)	N (%)
Total readmissions	1605 (13.3)	812 (11.8)	793 (15.3)
Non-cardiac readmissions	557 (4.6)	365 (5.3)	192 (3.7)
Cardiac readmissions	1048 (8.7)	447 (6.5)	601 (11.6)
Unplanned cardiac readmissions	379 (3.1)	225 (3.3)	154 (3.0)
Planned cardiac readmissions	669 (5.6)	222 (3.2)	447 (8.6)

Unplanned 30-day cardiac readmission rates are often taken as an indicator of hospital performance and quality of care. Comparative rates of unplanned cardiac readmissions by hospital are shown in Figure 39. The overall rate of unplanned cardiac readmission across the whole cohort was 3.1% which compares favourably to rates observed in international series [25]. However, there was variation across hospitals ranging from no unplanned rehospitalisations to 6.9%. The public sector had a higher rate of unplanned cardiac readmission compared to the private sector.

Figure 39: 30-day unplanned cardiac rehospitalisation rates by hospital

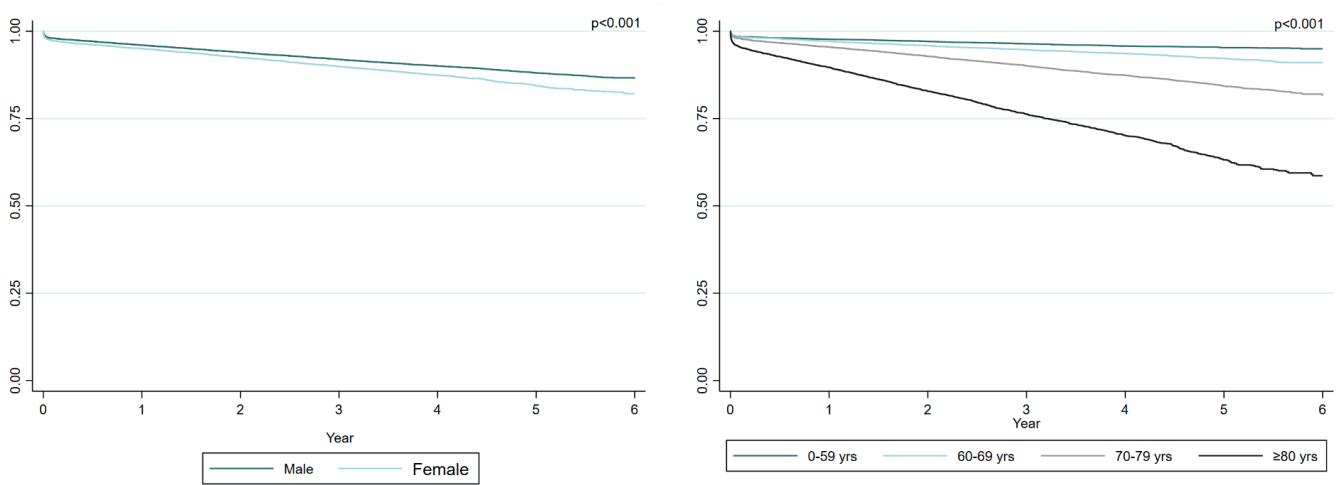


Hospital 32 low case numbers (n<20) and nil readmissions.

Long-term mortality

With data linkage to the National Death Index (NDI), VCOR can now present survival data to 12 months and beyond. For the period between 2014-2019, a total of 63,413 patients underwent PCI with 5,231 patients (8.2%) subsequently dying. Figure 40 compares long-term survival by sex and separately by age group. Overall, women had worse survival compared to men out to 6 years, with 1,479 deaths (9.8%) among females and 3,752 deaths (7.8%) in males ($p=0.001$). These results are consistent with several other long-term sex-based series [26], although recent literature suggest that this may be related to baseline age and comorbidities of women rather than an additional sex-specific factor [27]. As expected, there were significant differences in long-term survival with advancing age ($p=0.001$), with the most rapid decline in survival seen among the elderly (≥ 80 years).

Figure 40: Kaplan-Meier survival curves by sex and age



Sex differences in long-term survival were also evident in the STEMI ($n=13,160$) and NSTEMI-ACS cohorts ($n=19,152$), Figure 41. In the STEMI cohort there were 520 deaths (18.1%) among females and 1,130 deaths (11.0%) among males ($p=0.001$). In the NSTEMI-ACS cohort, the difference between the sexes was not as large with 466 deaths (9.5%) among females and 1,075 deaths (7.5%) in males, although this was still statistically significant ($p=0.001$).

Figure 41: Kaplan-Meier survival curves by clinical presentation: STEMI and NSTEMI-ACS

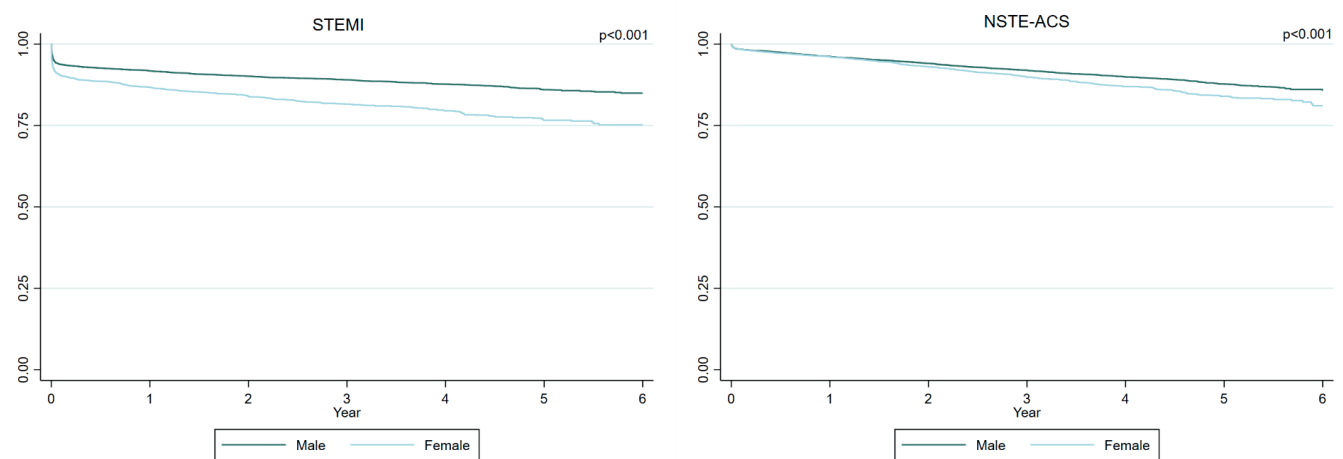
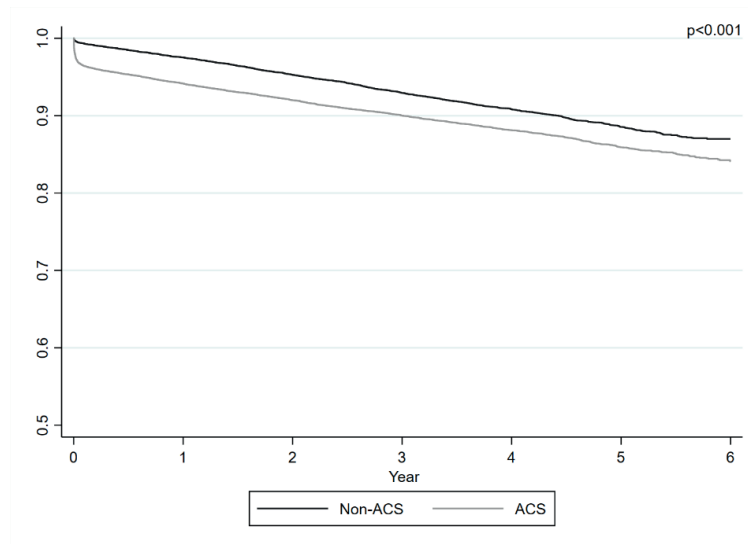


Figure 42 demonstrates that long-term survival was lower in the overall ACS cohort (n=32,312) compared with non-ACS patients (n=31,101). There were 3,191 deaths (9.9%) in the ACS group and 2,040 deaths (6.6%) in the non-ACS group (p=0.001).

Figure 42: Kaplan-Meier survival curves by clinical presentation: ACS and Non-ACS

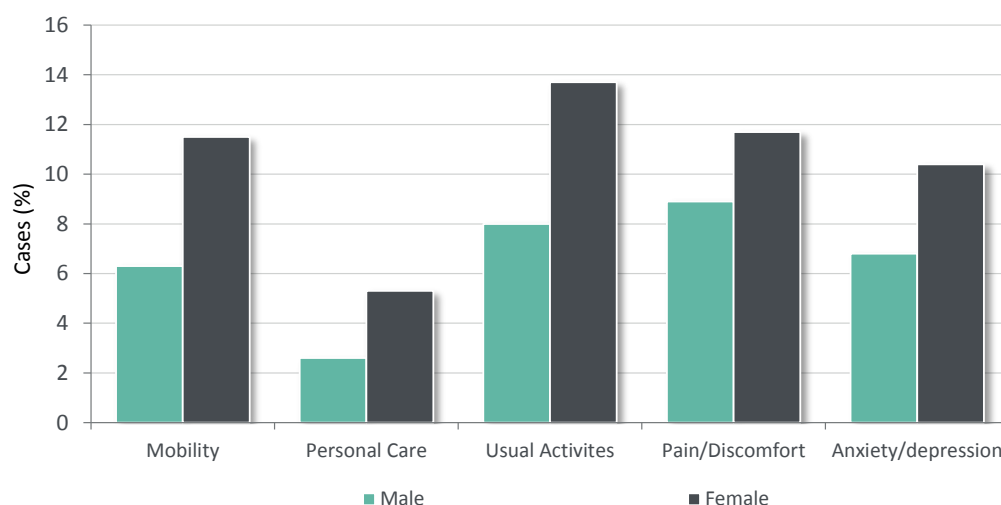


Quality of Life

Quality of life was assessed with the EQ-5D – a validated self-assessed, health related, quality of life questionnaire that utilises a set of standardised measures [28]. Data were collected at 30-day follow-up. Responses were completed in 60% of cases, with a number of hospitals unable to conduct the questionnaire due to resource constraints. Patients were asked to assess their mobility, ability to perform usual domestic and personal care tasks, level of pain or discomfort and whether they experienced any anxiety or depression.

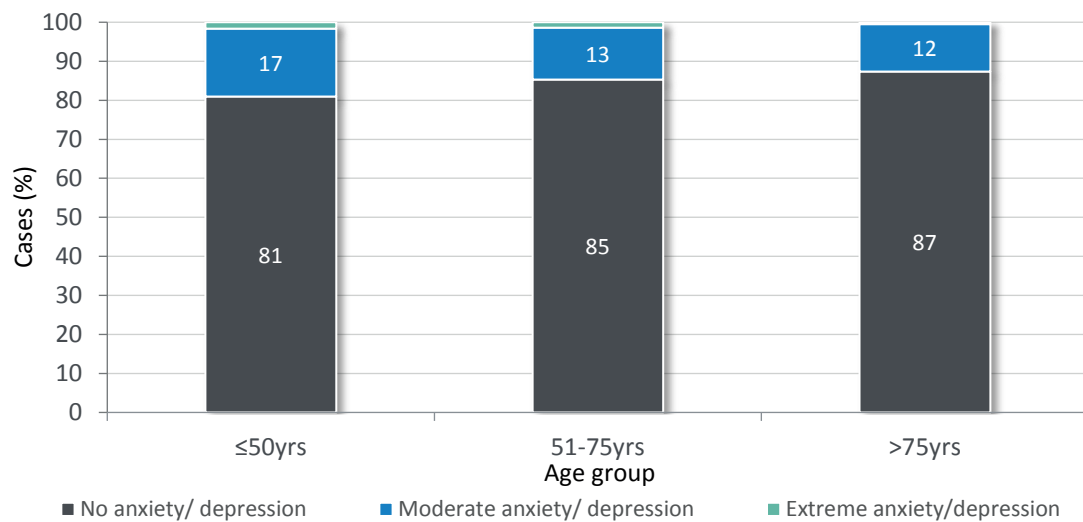
For each domain of the survey, at least “some problem” was more commonly reported among women than men (Figure 43). The initial clinical presentation (ACS vs non-ACS) did not influence responses.

Figure 43: Quality of life metrics: Reporting of some problem by sex



The median rating score for a patient's own health status at 30 days post discharge was 80 out of 100 (IQR: 70, 90). However, just under half of the patients reported experiencing at least some anxiety or depression within 30 days of their PCI procedure. Younger patients were more likely to report depression and/or anxiety in the moderate or severe range. Overall, 13.4% of patients reported moderate rates of anxiety/depression and 1.2% reported extreme anxiety/depression, which is higher compared to the previous year (Figure 44).

Figure 44: EQ-5D responses to anxiety/depression by age group



Cardiac Implantable Electronic Devices (CIED)

Background

VCOR commenced data collection on cardiac implantable electronic devices (CIEDs) in 2018 with the recognition that these devices were in need of comprehensive performance assessment and quality assurance. Areas of focus included the extent of variation in their clinical application, the appropriateness of their use and the need for rigorous outcome monitoring of device-related and patient outcomes. The module initially enrolled 7 Victorian hospitals, and during 2019, 13 hospitals contributed data (Table 23).

The CIED module concentrates on two types of device therapy. The first is implantable cardioverter defibrillators (ICDs) - an effective treatment for abnormal rapid, potentially lethal, heart rhythms and prevention of sudden cardiac death in patients with a previous history or family history of out-of-hospital cardiac arrest. The second is cardiac resynchronisation therapy (CRT). CRT devices involve the synchronised pacing of both the left and right ventricles. This form of treatment can improve the coordination of the pumping function of the heart in patients with diseased heart muscle (cardiomyopathy), resulting in marked improvement in symptoms and signs of heart failure. Devices that employ CRT can either be ICDs or pacemakers. VCOR collects data on both forms of CRT but does not extend its data collection to pacemakers without CRT functionality.

As with VCOR's other modules, key metrics relating to appropriateness, performance and safety have been formulated. Only a limited number of process and outcome measures are utilised to keep hospitals' resource commitments to a manageable level while ensuring that the results are meaningful to clinicians and other key stakeholders.

Registry Module Activity

The module enrolls all patients who receive a CIED device as a first implant (new device for the patient) or as a replacement, upgrade or explant procedure (removal of a device without any replacement). Cases limited to the insertion of new leads or revision of existing leads are also included. The indication for insertion of an ICD (either with or without concomitant CRT) is determined as either for primary or secondary prevention of sudden cardiac death. Indications for CRT devices (either in the form of an ICD or pacemaker) are assessed in patients with an underlying cardiomyopathy who have evidence of significant conduction system disease or a likelihood of worsening cardiac function with standard right ventricular pacing. As with all VCOR modules, a standard set of essential and epidemiologically sound variables are collected.

Table 23: Participating Victorian CIED hospitals

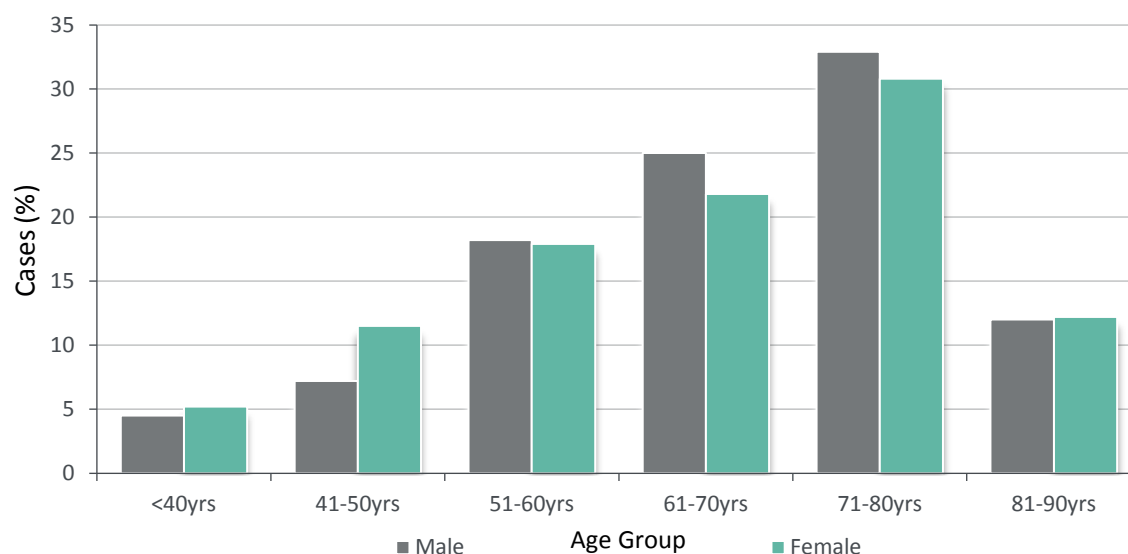
Victorian CIED hospitals	Hospital type	2018	2019
Alfred Hospital	Public	●	○
Austin Hospital	Public	●	●
Ballarat Base Hospital	Public		●
Bendigo Hospital	Public		●
Box Hill Hospital	Public		●
Cabrini Hospital Malvern	Private		●
Footscray Hospital	Public	●	●
Frankston Hospital	Public		●
Jessie McPherson Private Hospital	Private		●
Monash Heart	Public	●	●
Mulgrave Private Hospital	Private	●	●
The Royal Melbourne Hospital	Public	●	●
Sunshine Hospital	Public	●	●

Table Legend: ● = contributing data; ○ = data contributed for two months.

Patients and Procedures

In 2019, the CIED module collected data from 13 participating hospitals (10 public and 3 private hospitals), with a total of 640 procedures performed on 622 patients. The average age of patients was 66±14 years with three-quarters of all procedures being performed on male patients. The age and sex distribution for all CIEDs is shown in Figure 45. Sixty eight percent of procedures were performed electively. First implants accounted for 58.3% of procedures, while generator replacement and/or lead insertion totalled 32.8%. The remaining cases were a collection of new leads only (3.1%), system explants (4.7%) and device revisions (1.1%).

Figure 45: Age and sex distribution of patients undergoing CIED



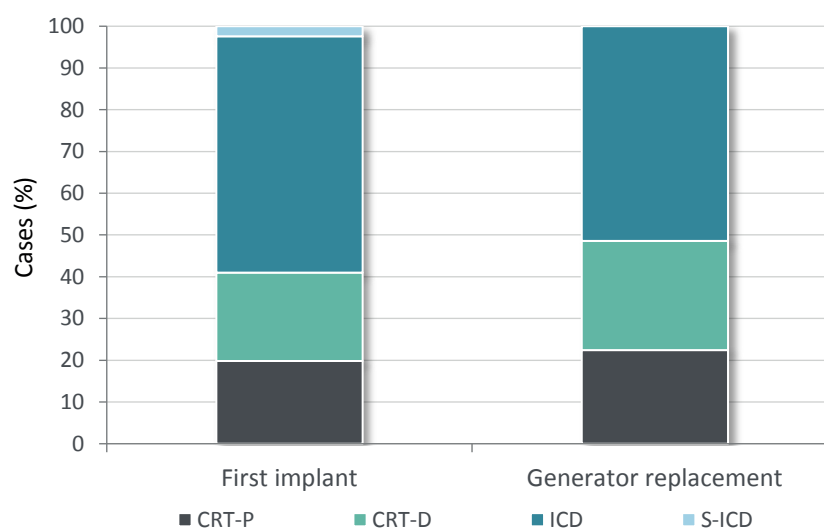
Device Types

Four devices are included in the CIED module:

- CRT-D – CRT combined with implantable cardioverter defibrillator
- ICD – implantable cardioverter defibrillator without any concomitant CRT
- S-ICD – subcutaneous implantable cardioverter defibrillator (never combined with CRT)
- CRT-P – CRT combined with pacemaker

ICD devices (includes CRT-D, ICD or S-ICD) represented 80% of first implants and 78% of generator replacements (Figure 46). Devices utilising CRT (CRT-D and CRT-P) were preferentially implanted in the left pre-pectoral region (92.1%). A small number (3.9%) were implanted in the left sub-pectoral region (underneath the pectoral muscle) or the right pre-pectoral region (4.0%). ICDs without CRT were also generally placed in the left pre-pectoral region (87.7%), but had a higher rate of left sub-pectoral region placement (8.0%).

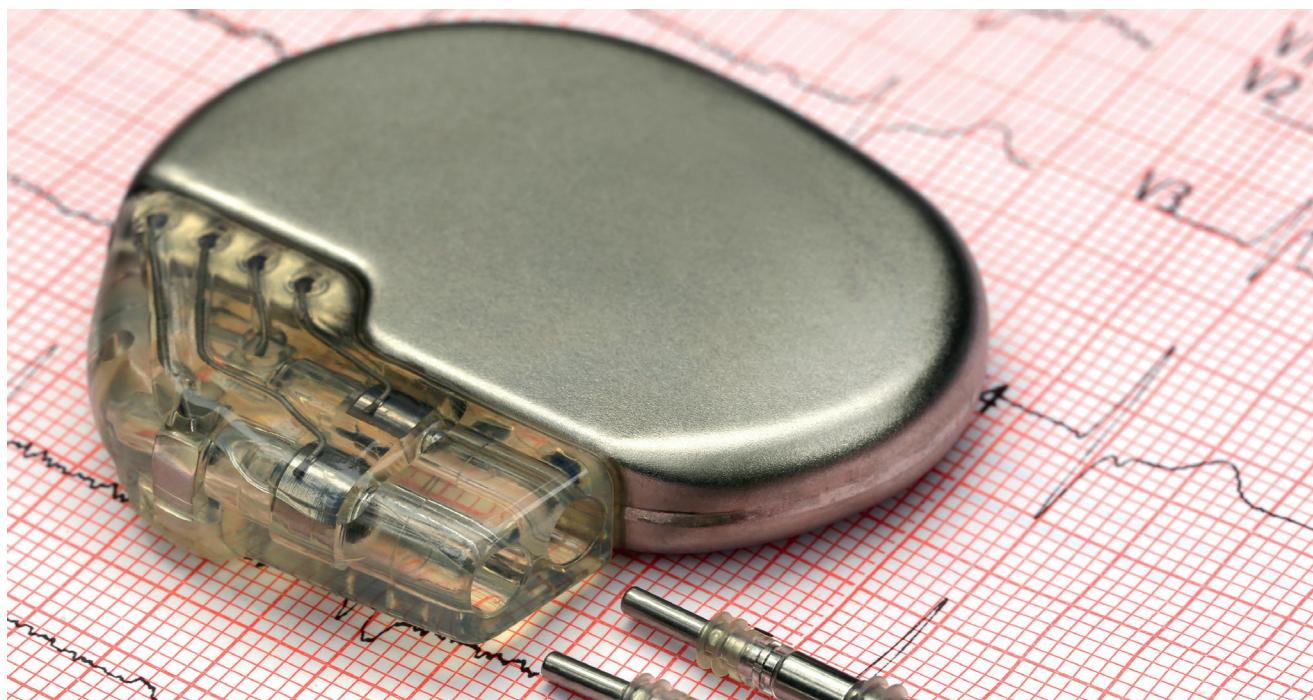
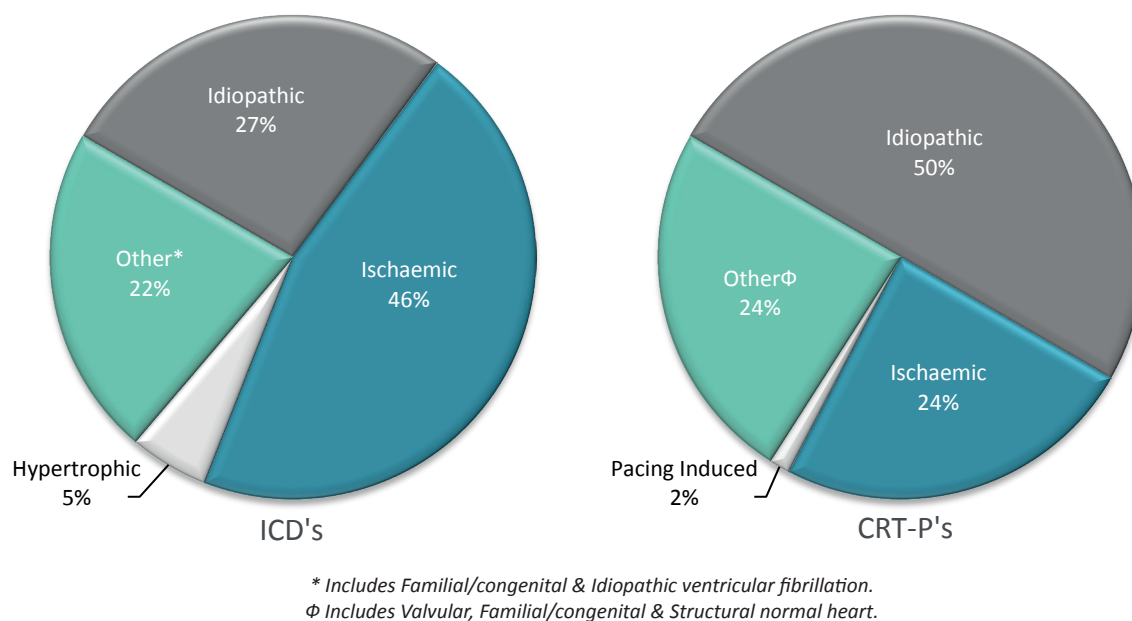
Figure 46: Device type – first implant vs generator replacement



Aetiology of Underlying Cardiomyopathy

The aetiology of the underlying cardiomyopathy in patients undergoing their first ICD implant is shown in Figure 47. Almost half the patients (46%) had an ischaemic cause. For CRT-P devices, an ischaemic cause was reported in 24% of the cases while idiopathic cardiomyopathy was present in 50% of the cases.

Figure 47: Aetiology in patients undergoing first CIED implant



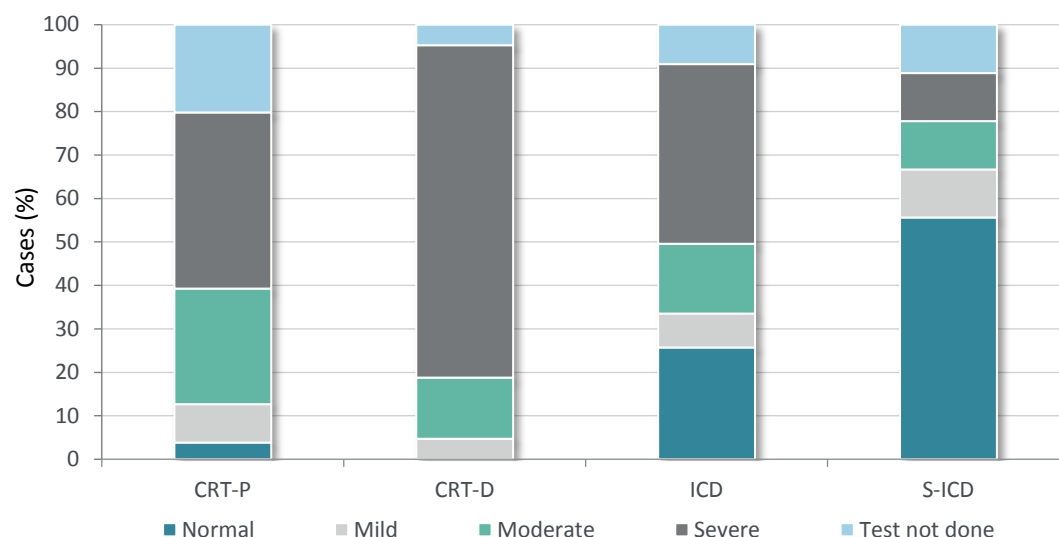
Left Ventricular Function

Left ventricular ejection fraction (LVEF) is a measure of the left ventricle's pumping ability and generally is graded as normal or having mild, moderate or severe impairment. Both national [29] and international guidelines [30, 31] rely heavily on LVEF when providing detailed indications and appropriate use criteria for ICDs and CRT devices. However, several other factors are also taken into account, including the underlying cardiac condition, severity of heart failure symptoms, a history of previous cardiac arrest and the presence of certain ECG changes.

The proportions of patients with normal and abnormal left ventricular function for each of the various CIED groups is shown in Figure 48. The patterns were different for each of the device types. For CRT-P devices, which are generally only recommended in patients with a reduced LVEF, the majority were implanted in patients who had moderate or severely impaired LVEF. Similarly, no patients undergoing CRT-D implantation had a normal LVEF, with most (76.5%) having severely impaired LVEF.

In contrast, among patients who received ICD implants without concomitant CRT, 25.7% had a normal LVEF. This likely reflects this device's use in survivors of cardiac arrest irrespective of the presence of left ventricular dysfunction (an indication that does not extend to CRT-D). In a similar way, a large proportion of patients receiving a S-ICD had a normal LVEF (56%). These particular devices only deliver a defibrillation shock and do not have any pacing functionality. They are therefore commonly used in cardiac arrest survivors with otherwise normal hearts. Nevertheless, their use in patients with reduced LVEF has increased significantly since last year (44% in 2019 vs 17% in 2018). This may represent a gradual modification of the use of these relatively new devices as clinicians become more familiar with them. It is a trend that VCOR will continue to monitor.

Figure 48: Left ventricular function by CIED type (first implants only)



Indications for CIED Therapy

ICDs

Generally, ICDs (with or without CRT functionality) are implanted for primary or secondary prevention of sudden cardiac death. In 2019, just over one third (35.7%) of ICDs were implanted for primary prevention. Ischaemic cardiomyopathy was the underlying condition in 42.5% of these cases. Among ICD implants for secondary prevention, 51% had prior VF and 44% had ventricular tachycardia.

Cardiac resynchronisation therapy

For patients with cardiomyopathy, accepted criteria for CRT include QRS width ≥ 120 milliseconds, severe left ventricular dysfunction and New York Heart Association (NYHA) Class II symptoms or greater. In 2019, among the patients that received CRT-D devices, 91% had a QRS width ≥ 120 msec, 79% had severe left ventricular dysfunction and 98% NYHA Class II symptoms or greater. For the patients that received CRT-P, only 70% had a QRS width ≥ 120 msec, 53% had severe left ventricular dysfunction and 94% NYHA Class II symptoms or greater (Table 24).

Table 24: Inclusion criteria for CRT by device type

Strength of Indication	CRT-D (N=79)	CRT-P (N=74)
	N (%)	N (%)
QRS WIDTH ≥ 120 msec	72 (91)	52 (70)
Severe left ventricular dysfunction (LVEF<35%)*	59 (79)	31 (53)
NYHA Class II or greater#	58 (98)	51 (94)

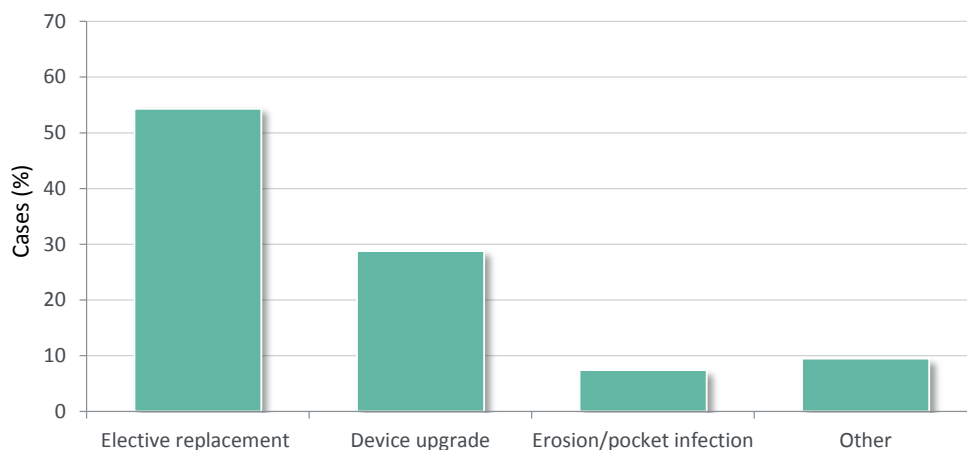
**LVEF data missing for CRT-D (n=4) and for CRT-P (n=16).*

#NYHA data missing for CRT-D (n=20) and for CRT-P (n=20).

Replacements and Revisions

The majority of CIED replacements were elective procedures for pulse generator change (54.3%). Device upgrades represented a further 28.8% of replacements, while erosions or infection accounted for 7.4% of cases (Figure 49).

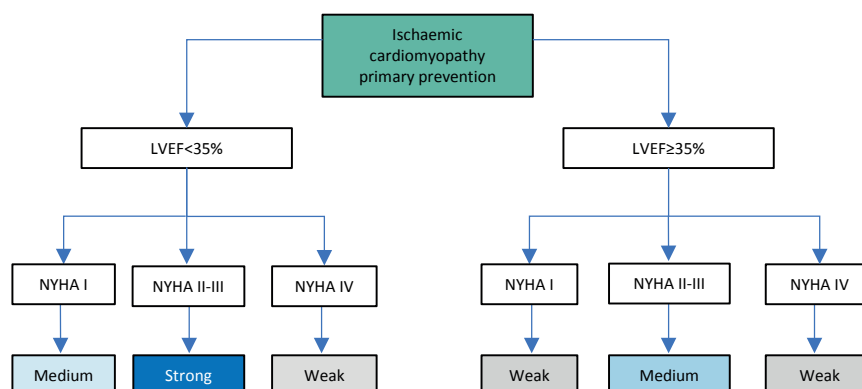
Figure 49: Indications for generator replacement, explant or revision



Assessing the strength of indication for CIED therapy

In its capacity as a clinical quality registry, the VCOR CIED module has had a particular focus on trying to assess the strength of indication for CIED therapy, based on established national and international guidelines and appropriate use criteria [32]. In 2019, VCOR significantly expanded its efforts in this area by developing a series of evidence-based flowcharts that encompass all potential clinical presentations combined with relevant inclusion and exclusion criteria and then listing the strength of indication according to the various combinations of these criteria. An example of one of these flowcharts is shown in Figure 50.

Figure 50: Strength of indication flowchart: Ischaemic cardiomyopathy - primary prevention



Strength of indication: strong, medium or weak.
NYHA = New York Heart Association Class of heart failure symptoms.

A total of 8 flow charts were developed through a consensus process with an expert working group, composed of clinicians specialising in the area of CIED implantation. These VCOR-affiliated clinicians made recommendations based on the most up-to-date evidence, combined with their own clinical experience and practice. A list of the 8 flowchart scenarios (5 for ICD therapy and 3 for CRT therapy) that were formulated are presented below.

ICD therapy: (CRT-D, ICD and S-ICD)

1. Ventricular fibrillation, sustained VT or cardiac arrest (secondary prevention)
2. Unexplained syncope
3. Ischaemic cardiomyopathy – primary prevention
4. Non-ischaemic cardiomyopathy – primary prevention
5. Genetic condition – primary prevention

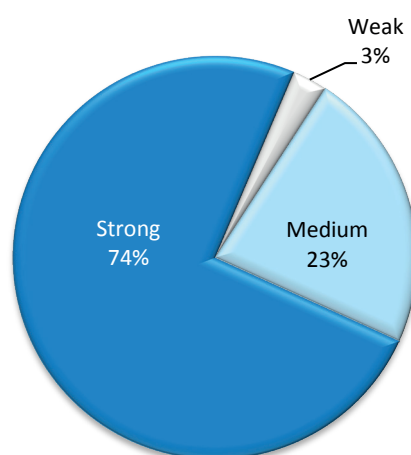
CRT therapy: (CRT-D and CRT-P)

6. CRT for ischaemic cardiomyopathy with LVEF <35%
7. CRT for non-ischaemic cardiomyopathy with LVEF <35%
8. CRT for pre-existing or anticipated need for RV pacing

Health services participating in the CIED module have received individualised reports presenting the data on strength of indication for CIED therapy for their patient cohort. Sites were apprised that a medium strength or even a weak indication was not intended to imply that the CIED should not have been implanted. There are many circumstances where individual patient factors that influence clinical decision-making cannot be represented in a flow chart. Rather, the exercise of grading the strength of indication for CIED therapy was intended as a quality assurance tool for sites to monitor their activity and provide them with an overall evaluation of the appropriateness of their practices.

Figure 51 shows the proportions of strong, medium and weak strength indications for defibrillator implantation for the total cohort of ICDs (n=464), which includes ICD, CRT-D and S-ICD for the data period 2018-2019. Strong or medium strength indications were present in 97% of cases of implantable defibrillator therapy.

Figure 51: Strength of indication for ICD therapy



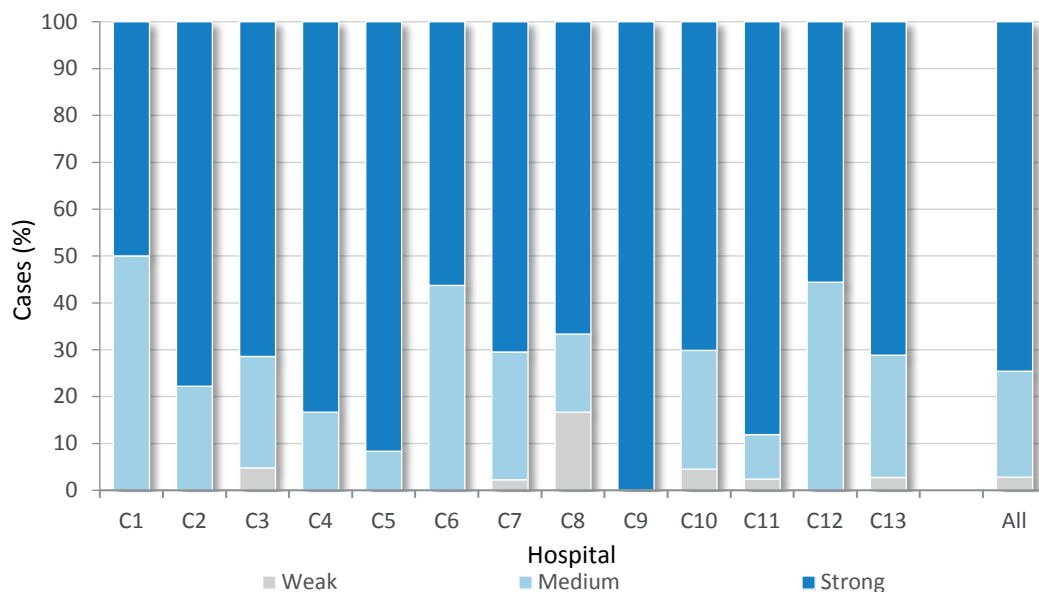
A comparison of the strength of indication for defibrillator therapy for the data period 2018-2019 by the various forms of this therapy (CRT-D, ICD and S-ICD) is presented in Table 25. The proportions of patients with strong, medium or weak strength indications for each of the 3 types of ICD device were generally similar, with approximately three quarters of cases having a strong indication for ICD and very few having a weak indication.

Table 25: Strength of indication for ICD therapy by form of therapy

Strength of Indication	CRT-D (N=101)	ICD (N=336)	S-ICD (N=27)
	N (%)	N (%)	N (%)
Strong	77 (76)	250 (75)	19 (70)
Medium	20 (20)	78 (23)	7 (26)
Weak	4 (4)	8 (2)	1 (4)

Figure 52 shows benchmarking data comparing the strength of indication for defibrillator therapy (CRT-D, ICD and S-ICD) by hospital. Individual hospital profiles were all broadly similar, with strong indications for ICD therapy ranging from 50-100%.

Figure 52: Strength of indication for ICD therapy by hospital



A breakdown of cases with strong, medium or weak indications for CRT (n=200), incorporating CRT-D and CRT-P for the data period 2018-2019 is presented in Figure 53. Strong or medium strength indications were present in 76% cases of CRT.

Figure 53: CRT – Strength of indication

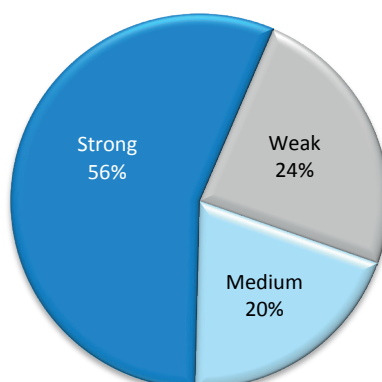


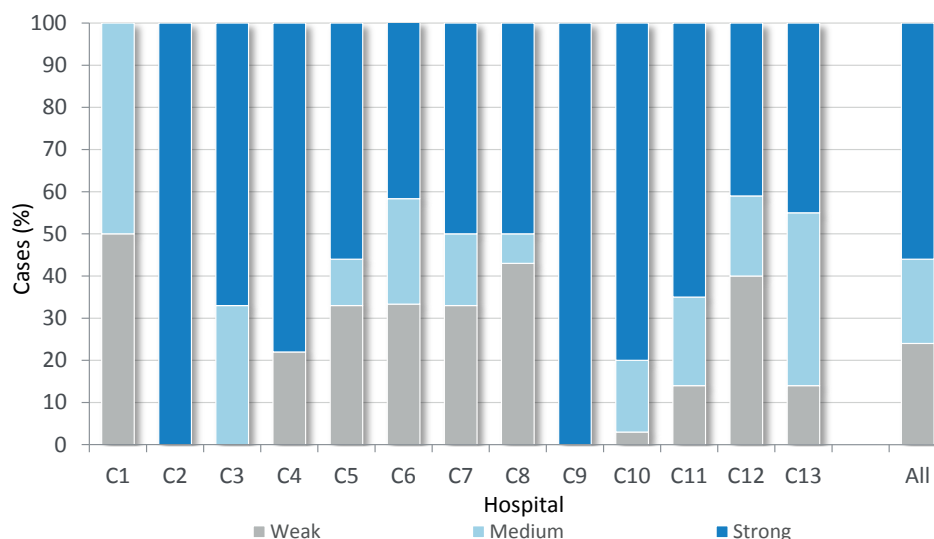
Table 26 compares the strength of indication for CRT by the two forms of this therapy (CRT-D and CRT-P). The proportions of strong, medium or weak strength indications for the 2 types of CRT are shown. In contrast to ICD indications where a large proportion of cases had strong indications, over one third of CRT-D and almost two thirds of CRT-P cases had either medium or weak strength of indication for CRT.

Table 26: Strength of indication for CRT by device type

Strength of Indication	CRT-D (N=102)	CRT-P (N=98)
Strong	69 (67%)	42 (42%)
Medium	13 (13%)	28 (29%)
Weak	20 (20%)	28 (29%)

Hospitals' benchmarking data are shown in Figure 54. Although the proportion of strong or medium strength indications varied significantly by hospital, the overall case numbers in many hospitals were quite low and therefore apparent differences need to be interpreted with caution.

Figure 54: CRT – Strength of indication by hospital



Outcome Measures

The key performance indicators (KPIs) used to monitor and benchmark the outcomes of CIED therapy included:

- In-hospital mortality
- 30-day mortality
- Successful device implantation without in-hospital complications
- 30-day unplanned cardiac readmissions
- 30-day device related re-operations
- 30-day device related infection rate

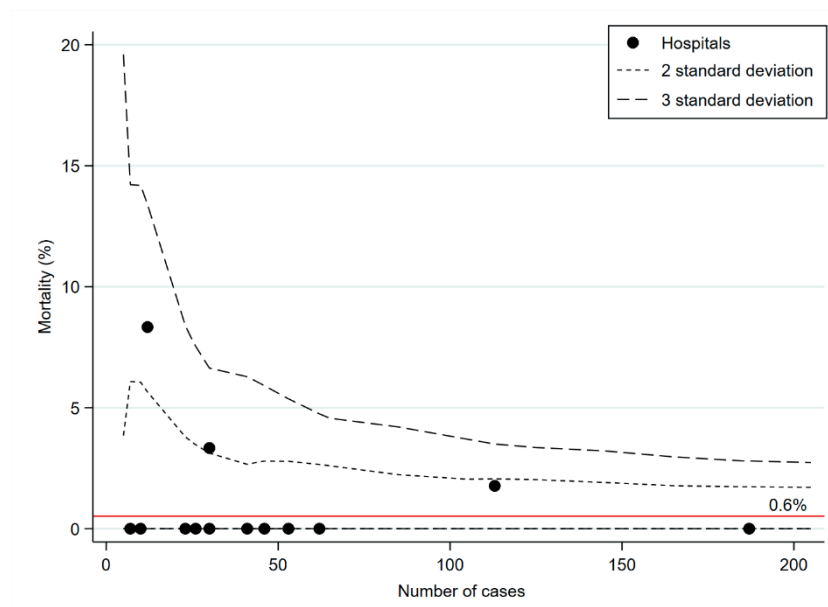
In-hospital mortality

In 2019 there were no in-hospital deaths related to CIED activity.

30-day mortality

There were 4 deaths within 30 days from hospital discharge, resulting in a 30-day mortality rate of 0.6% (Figure 55). All hospitals were within control limits for this outcome measure.

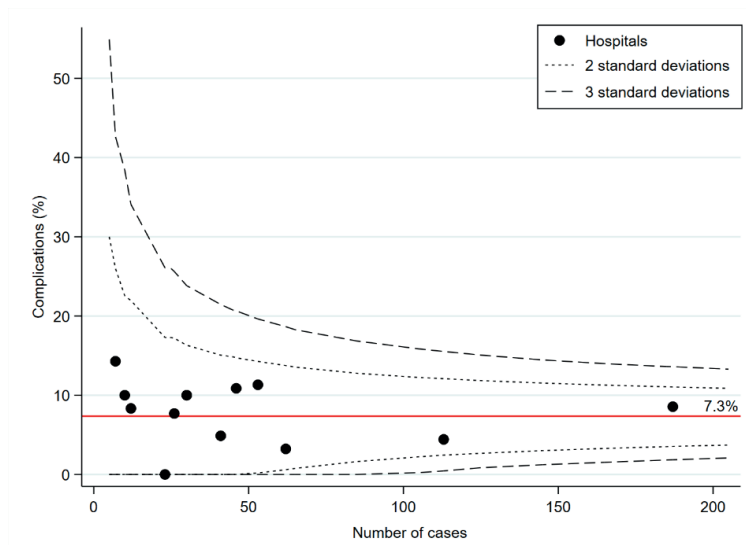
Figure 55: 30-day CIED related mortality



Successful device implantation without in-hospital complications

A majority (92.6%) of the 640 devices enrolled in the CIED module were successfully implanted without any in-hospital complications. Among the 7.3% with in-hospital complications, cases included severe hypotension, pneumothorax, wound haematoma, lead dislodgement, failure to position lead and phrenic nerve pacing. There were no outlier hospitals for this measure (Figure 56).

Figure 56: In-hospital rates of CIED related complications



30-day unplanned cardiac readmissions, device-related re-operations and infections

The 30-day rates for the following outcome measures were - unplanned cardiac readmission 4.1% (n=26), device related reoperations 1.9% (n=12) and device-related infection 1.1% (N=6). Figures 57- 59 demonstrate that all hospitals were within control limits for each of these endpoints.

Figure 57: 30-day rates of CIED related unplanned cardiac readmissions

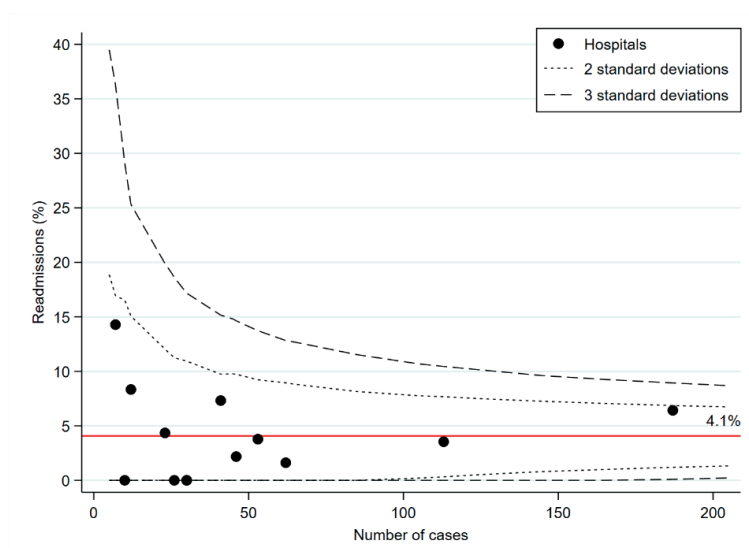


Figure 58: 30-day rates of CIED related reoperations

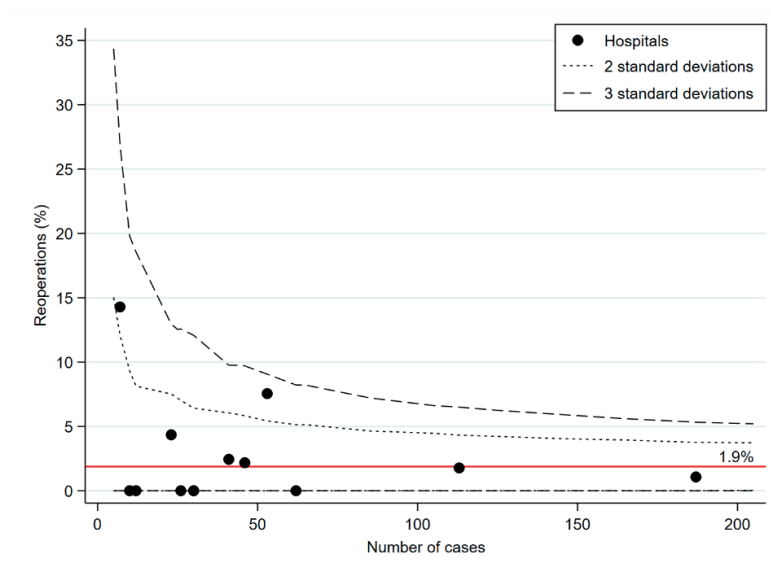


Figure 59: 30-day rates of CIED related infections

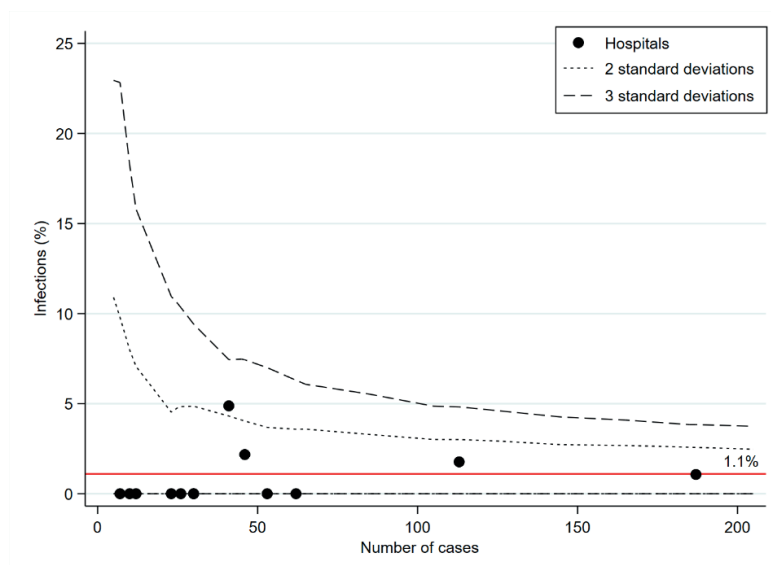


Table 27 presents comparative performance data that benchmark the 13 participating hospitals in terms of complications rates by device type.

Table 27: In-hospital complications by hospital and device type

Hospital	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	Total
	N	N	N	N	N	N	N	N	N	N	N	N	N	N (%)
CRT-P	2	0	1	0	0	0	0	0	0	0	3	3	2	9 (7.4)
CRT-D	0	0	1	3	1	1	2	2	0	0	0	1	2	10 (7.5)
ICD	0	1	0	3	1	5	0	3	1	0	3	0	9	21 (6.6)

12-month mortality

Mortality rates at 12 months for the data period 2018-2019 were obtained through linkage with the National Death Index (NDI). The overall 12-month mortality rate was 2.3%. There was no difference in death rates between men and women (2.3% vs 2.4%). Among patients receiving ICD therapy, the 12-month mortality rates for various clinical conditions included 2.8% for ischaemic cardiomyopathy, 2.6% for idiopathic cardiomyopathy and 0% for hypertrophic cardiomyopathy. For CRT-P devices, 12-month mortality rates were 12.9% for an ischaemic aetiology and 1.7% for idiopathic cardiomyopathy. There were no deaths in 12 months among patients receiving CRT-P devices as a result of pre-existing or anticipated need for right ventricular pacing.

Summary

The CIED module, which commenced patient enrolment in 2018, significantly expanded its activities in 2019. VCOR now provides detailed reports to participating sites on the volume and makeup of their CIED related activity, assessment of the relationship between the indications for their procedures and clinical guideline recommendations and detailed benchmarking data on key process and outcome measures. In 2019, participating hospitals all generally performed well, with close adherence to clinical guideline recommendations for ICD implantation but with more variation for CRT. Overall, hospital outcomes were good, with low rates of complications for each device type. However, with just 13 hospitals currently enrolled, case numbers remain relatively small and this limits the robustness of the benchmarking functionality of this registry module. VCOR aims to actively recruit more centres both in the public and private sectors in the coming year and will lobby the Victorian Department of Health and Human Services to secure funding support for this module's continuing activity.



Future Directions

The effects of the COVID-19 pandemic on Victoria's health system are not reflected in this Annual Report but will be apparent in next year's report. We anticipate that we will have an additional focus on the extent to which the incidence and presentation of cardiovascular conditions relating to PCI and CIEDs were affected and whether the patterns in the delivery of these cardiovascular therapies were significantly altered.

VCOR has been planning a major upgrade to its database infrastructure for some time, but has been unable to complete the project in 2019 due to resource and capacity constraints. However, a comprehensive revision of the data elements has been completed, leaving implementation of the new software design to be implemented in the coming year.

The CIED module moved from pilot phase to a fully functional registry in 2019. VCOR plans to expand site recruitment in 2020 to include all hospitals that are in a position to participate – in both the public and private sectors. VCOR will continue to work closely with all hospitals to refine and improve these reports to provide the most relevant and clinically useful information, tailored to sites' needs.

In 2019, VCOR formalised a collaborative agreement with the Tasmanian Government to commence data collection and analysis services for public hospitals in that state. The Tasmanian hospital system did not have capacity to initiate their own clinical quality registry service, and their participation in VCOR provides Tasmanian hospitals with valuable data on process and outcome measures and importantly, allows these hospitals to benchmark their performance against peer hospitals in a neighbouring state. By the end of 2019, 2 Tasmanian public hospitals were contributing data on their PCI cases to VCOR and 1 hospital was also participating in the CIED module.

VCOR will continue to encourage collaborations with researchers – both internal and external to the organisation - following another successful year of research projects. VCOR now employs a secure remote research environment called a SafeHaven to assist researchers in the analysis of their data in a safe, secure environment that is compliant with all appropriate data access and governance principles [3, 4]. There are a number of PhD students currently utilising data from the registry in their theses. One PhD collaboration was completed in 2019 that examined the role of clinical registries in optimising outcomes in percutaneous coronary intervention, with VCOR-related data contributing to 6 published studies. VCOR will continue to seek out and work with PhD students who have an interest in clinical quality registry-related research.

While all these activities enhance the role of VCOR as a beneficial service to hospitals, government, researchers and the general public, our main focus as a clinical quality registry is to identify variance in performance and outcomes and highlight areas for improvement in the quality of cardiac healthcare for Victorians. In the past few years there has been greater commitment to ensuring patient safety and patient-centred care at both state and federal jurisdictional levels. VCOR is well-positioned to assist in achieving these aims and we anticipate further growth in clinical quality registry activity in the coming years as quality assurance becomes embedded and integrated into the day-to-day provision of high-quality cardiovascular care.

Glossary

ACC/AHA	American College of Cardiology and the American Heart Association	IVUS	Intravascular Ultrasound
ACEI	Angiotensin-Converting-Enzyme Inhibitors	KPI	Key Performance Indicator
ACS	Acute Coronary Syndrome	LTF	Lost to follow-up
AF	Atrial Fibrillation	LVEF	Left Ventricular Ejection Fraction
ARB	Angiotensin Receptor Blockers	MACCE	Major Adverse Cardiac and Cerebrovascular Event
BARC	British Academic Research Consortium	MI	Myocardial Infarction
BB	Beta-adrenergic Blockers	NDI	National Death Index
BiPAP	Bi-level Positive Airway Pressure	NHF	National Heart Foundation
BPM	Beats Per Minute	NHMRC	National Health & Medical Research Council
BVS	Bio-resorbable Vascular Scaffold	NRI	New Renal Impairment
CABG	Coronary Artery Bypass Graft	NSTE-ACS	Non-ST Elevation Acute Coronary Syndrome
CBVD	Cerebrovascular disease	NSTEMI	Non-ST Elevation Myocardial Infarction
CIED	Cardiac Implantable Electronic Devices	NYHA	New York Heart Association
COPD	Chronic Obstructive Pulmonary Disease	OCT	Optical Coherence Tomography
CPAP	Continuous Positive Airway Pressure	OHCA	Out of Hospital Cardiac Arrest
CRT	Cardiac Resynchronisation Therapy	PCI	Percutaneous Coronary Intervention
CTO	Chronic Total Occlusion	PHN	Pre-hospital notification
DAPT	Dual Antiplatelet Therapy	POBA	Plain Old Balloon Angioplasty
DEPM	Department of Epidemiology & Preventive Medicine	PVD	Peripheral Vascular Disease
DES	Drug Eluting Stent	SCV	Safer Care Victoria
DHHS	Department of Health & Human Services	SD	Standard Deviation
DBT	Door-to-balloon time	SDD	Same day discharge
ECG	Electrocardiograph	STEMI	ST-Elevation Myocardial Infarction
ECMO	Extracorporeal Membrane Oxygenation	TVR	Target Vessel Revascularisation
FFR	Fractional Flow Reserve	UAP	Unstable Angina Pectoris
IABP	Intra-Aortic Balloon Pump	VAED	Victorian Admitted Episodes dataset
ICD	Implantable Cardiac Defibrillator	VAHI	Victorian Agency for Health Information
IQR	Inter Quartile Range	VCOR	Victorian Cardiac Outcomes Registry

Publications and presentations in 2019

Publications

- Batchelor R, Dinh D, Brennan A, Lefkovits J, Reid C, Duffy S, Cox N, Liew D, Stub D. Incidence, Predictors and Clinical Outcomes of Stent Thrombosis Following Percutaneous Coronary Intervention in Contemporary Practice. *Heart, Lung and Circulation*. 2019; <https://doi.org/10.1016/j.hlc.2019.10.009> [Epub ahead of print].
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- Al-mukhtar O, Vogrin S, Noaman S, Dinh D, Brennan A, Reid C, Lefkovits J, Cheng Y, Cox N, Chan W. Association of Pollen Count with Short Term Clinical Outcomes in Different Subtypes of Acute Coronary Syndrome (ACS). Paper presented at 67th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand; Adelaide; 2019 August 8-11. *Heart, Lung and Circulation*. 2019; 28(4); S385.
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 Dr Chris Hengel
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Albury Hospital
 Alfred Hospital, The
 Austin Hospital, The
 Ballarat Base Hospital
 Bendigo Hospital
 Box Hill Hospital
 Cabrini Hospital Malvern
 Epworth Hospital Richmond
 Epworth Hospital Eastern
 Epworth Eastern, Geelong
 Footscray Hospital
 Frankston Hospital
 Holmesglen Private Hospital
 Jessie McPherson Private Hospital
 Knox Private Hospital
 Melbourne Private Hospital
 MonashHeart (Monash Medical Centre Clayton)
 Mulgrave Private Hospital
 Northern Hospital, The
 Peninsula Private Hospital
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Funding

Funding was originally sought and obtained in 2011 from Medibank Private and the Department of Health and Human Services Victoria. Additional funding from the Victorian Cardiac Clinical Network was provided in 2014, 2015, 2016, 2017, 2018 and 2019 to support the ongoing operations of the PCI, Early Management of STEMI (Regional Victoria) and the Cardiac Implantable Electronic Devices (CIED) modules (Table 28). Considerable in-kind support from Monash University has also been provided throughout the years.

Table 28: VCOR Funding 2011 – 2019

Funding Body	2011	2012	2013	2014	2015	2016	2017	2018	2019
	\$	\$	\$	\$	\$	\$	\$	\$	\$
Medibank Private	\$100,000	\$400,000	\$400,000	\$300,000	-	-	-	-	-
Department of Health & Human Services	\$200,000	\$200,000	\$205,000	\$509,466	\$460,202	\$834,815	\$616,900	\$365,218*	\$516,793
Sub total	\$300,000	\$600,000	\$605,000	\$809,466	\$460,202	\$834,815	\$616,900	\$365,218	\$516,793
Total									\$5,108,394

** Amount received in 2018 updated from \$350,469.*

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