



**ICHOM** International Consortium for  
Health Outcomes Measurement

## IMPLEMENTING ICHOM'S STANDARD SETS OF OUTCOMES: CORONARY ARTERY DISEASE IN THE CORONARY ANGIOGRAM DATABASE OF SOUTH AUSTRALIA (CADOSA)

JANUARY 2017



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## HOW TO CITE THIS PAPER:

Arora J, Tavella R. Implementing ICHOM's Standard Sets of Outcomes: Coronary Artery Disease in the Coronary Angiogram Database of South Australia (CADOSA). London, UK: International Consortium for Health Outcomes Measurement (ICHOM), January 2017 (available at [www.ichom.org](http://www.ichom.org)).

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## SPONSORSHIP

We would like to thank Boston Scientific for sponsoring this case study to support the adoption of value-based healthcare (VBHC) across the industry.

## ICHOM STANDARD SET IMPLEMENTER PROFILE

**Location:** South Australia

**Provider type:** Registry comprising 4 public hospitals

**Standard Set:** Coronary Artery Disease

**Standard Set complexity:** Very High

Australia has a mixed public-private healthcare system. Universal, publicly-funded healthcare is provided by Medicare with additional co-payments paid out-of-pocket by patients for a minority of services, which can be secured via private health insurance.

The Coronary Angiogram Database of South Australia (CADOSA) is a state-wide registry in South Australia that covers data collection in all four public tertiary hospitals managing patients with coronary artery disease. CADOSA therefore covers a patient population of 1.6 million, with over 20,000 patients registered. For over 1000 of these patients, CADOSA have also collected patient-reported outcome measures.

## BACKGROUND

John Beltrame is a Consultant Cardiologist and Professor of Medicine at the Queen Elizabeth Hospital in Adelaide, Australia. Throughout his career, Professor Beltrame had seen patients with normal coronary angiography\* but ongoing chest pain that was severely impacting their quality of life. To investigate this further, Professor Beltrame initiated a single-site coronary angiography database comparing the health outcomes of symptomatic patients with positive and negative coronary angiograms†.

The data supported Professor Beltrame's anecdotal findings that many patients with negative coronary angiograms were still experiencing symptoms and impacted QoL<sup>1</sup>, and it was thought that further data could provide important insights into the mechanisms behind this. This was of great interest to the Heart Foundation, a national patient charity, and the South Australia state Department of Health, who subsequently awarded Professor Beltrame a competitive research grant to expand the database in 2011.

Professor Beltrame set about establishing a state-wide database of coronary angiography procedures with longitudinal QoL follow-up in all four public tertiary hospitals in the state of South Australia – Flinders Medical Centre, Lyell McEwin Hospital, Royal Adelaide Hospital and The Queen Elizabeth Hospital. This came to be known as the Coronary Angiogram Database of South Australia (CADOSA).

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\*A scan showing the extent of blockage of the coronary arteries, which are the blood vessels that supply the heart. Blockages in these vessels can lead to angina/chest pain and myocardial infarction/heart attack.

†'Positive' means that sufficient blockage of a coronary blood vessel to cause angina and/or a myocardial infarction has been identified, whereas 'Negative' means that it has not.

## ESTABLISHING CADOSA AND ROLLING OUT ACROSS SOUTH AUSTRALIA

The goal was for every patient undergoing a coronary angiogram in South Australia to enter the database. Of the 1.6 million people in South Australia, 1.2 million were living in Adelaide, and all four publicly funded catheterisation (cath.) labs were located here. From a geographical perspective, therefore, data collection at the four tertiary hospitals in Adelaide made it possible to provide state-wide coverage of coronary angiography practice for non-private care. One of the most common barriers – funding for the data collection infrastructure – had already been covered by the grant, so this was going to be a cost-neutral initiative for each site.

The CADOSA team focussed on four aspects to get the registry up and running: clinician buy-in, human resources for data collection, the data platform, and outcome metrics.

### 1. CLINICIAN COMMUNITY BUY-IN

It was important to avoid hospitals viewing the registry as a research project that would be completed ad-hoc and as a secondary priority to service delivery. Instead, the aim was for this data collection to be viewed as an essential component of daily clinical practice in the form of an integrated quality assurance activity. In order to achieve this, Professor Beltrame and his team reinforced engagement with the project by organising quarterly face-to-face meetings with the cath. lab. managers and providing regular presentations at each hospital's cardiology department meetings that focussed on that respective hospital's data.

The establishment of a CADOSA Steering Committee was another crucial step in ensuring the registry was clinician-led. The Steering Committee included a small group of clinical academic cardiologists representing each participating hospital. The initial function of the Steering Committee was to determine the ideal method of data collection within each hospital. Thereafter, they would report to a centralised clinical data manager on the operation of the registry.

### 2. HUMAN RESOURCES FOR DATA COLLECTION

#### ► HIRING OF STAFF

The Department of Health recognised the need for a comprehensive clinical data infrastructure, and thus funded Dr. Tavella's next role as Clinical Data Manager, responsible for state-wide data management and analysis.

The initial priority for the CADOSA Steering Committee was to determine who would collect the data. Due to the expected volume of data collection, the Steering Committee anticipated that medical officers may not fully embrace the additional work required to capture the data. It was therefore agreed that the registry would be initiated with dedicated, site-based data abstractors located in the cath. lab., and it was vital that the data abstractors were made to feel like members of the cath. lab. team. Ideal data abstractors were thought to be cath. lab. nurses, who would work on CADOSA data collection as a part-time function whilst still maintaining their nursing duties in the lab. Indeed, this model was initiated at the Royal Adelaide Hospital for 12 months. Two other hospitals initiated data collection with nursing staff but with coronary care unit or clinical trials experience. The final hospital initiated data collection with a research scientist (Bachelor of Science graduate).

The applicant short-listing and interview processes, although managed by Dr. Tavella, were undertaken in conjunction with each hospital's cath. lab. Manager and/or Nursing Director and the hospital's CADOSA Steering Committee member. For the first 12 months, Dr. Tavella oversaw the performance of each of these various models by evaluating the quality and efficiency of each hospital's data collection, the integration of the registry within each hospital and also the job satisfaction from each data abstractor. The most successful approach was the allocation of research scientists to data collection, who recorded the highest quality data overall and reported the highest job satisfaction.

CADOSA determined that data collection required approximately 1.0 FTE for every 1,000 procedures. The human resources required for data collection across the CADOSA network is shown in **Table 1**.

**TABLE 1 | HUMAN RESOURCE REQUIREMENTS ACROSS THE CADOSA NETWORK**

<b>Hospital</b>	<b>Annual Procedure Volume</b>	<b>Staff FTE</b>
Central Registry Manager	N/A	1.0
Northern Adelaide	1,000	1.0
Southern Adelaide	1,500	1.5
Western Adelaide	1,000	1.0
Central Adelaide	2,500	2.0

► **TRAINING OF STAFF**

Prior to beginning 'live' registry data collection, all staff would undergo approximately two weeks of training. This would focus on the importance of accurate data collection and definitions, the calculation of performance measures from the data, and how the data would be used for feedback to hospitals. It was vital for staff to understand the end result and how their day-to-day work would impact this. Staff were also educated about patient-reported outcome measures (PROMs) – specifically, on how to engage patients via PROMs tools. Finally, training focussed on methods for obtaining optimal follow-up data from patients following discharge. This was vital because each individual data collector was responsible for longitudinal PROMs follow-up for 'their' patients following discharge.

Following the induction period, Dr. Tavella would hold monthly team meetings, involving a segment for ongoing staff education.

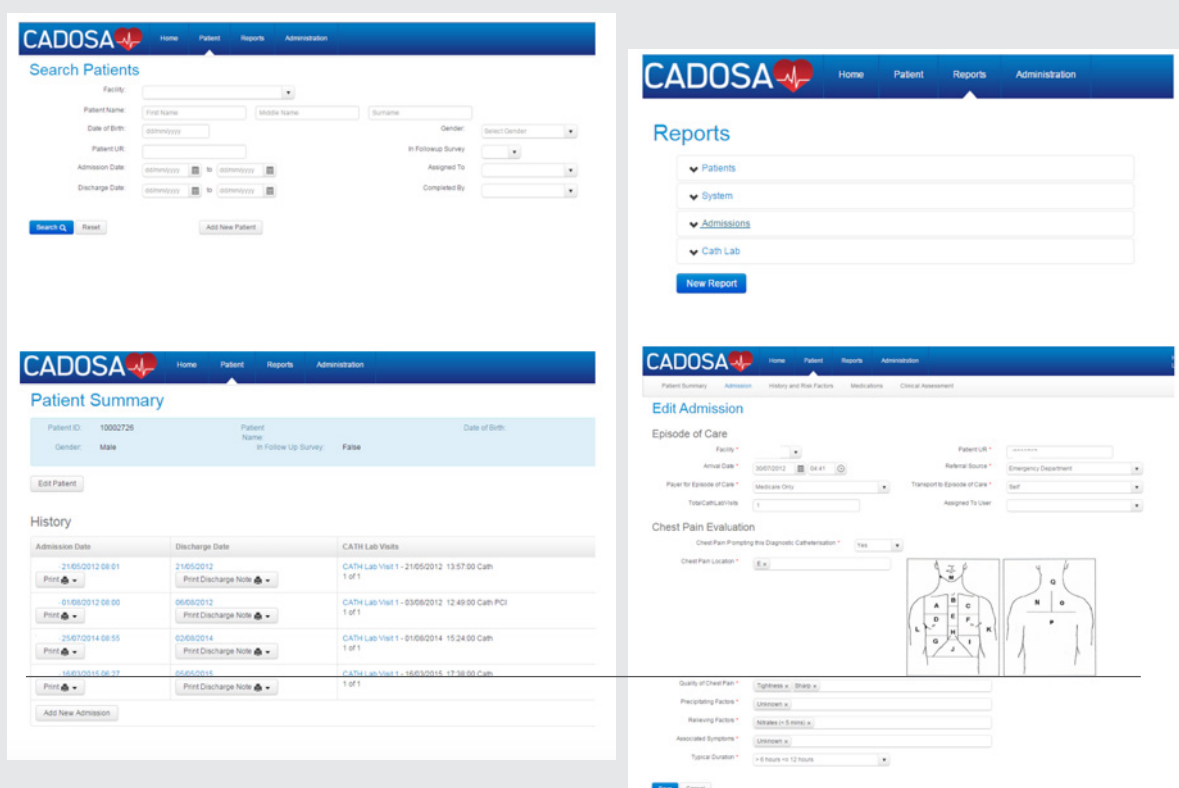


### 3. DATA PLATFORM

Data collection in clinic is paper-based, with data entered into a computer database once the questionnaire has been completed. To support data entry, funds were allocated to the development of a central data repository and web-based data collection tool. CADOSA opted to develop their own database with support from a contracted vendor that specialises in bespoke software. Dr. Tavella identified the vendor, obtained approval from the Department of Health for the deployment of this vendor's application internally, and worked with the vendor to design the application. The vendor had previously undertaken the successful development of a prominent Australian kidney transplant registry, and so had some relevant experience in medical registry data management.

The vendor developed a completely customised application for CADOSA using a Microsoft SQL Server as the database and Microsoft ASP.NET web forms for the user interface. This application ran on CADOSA's internal servers in order to facilitate the protection of patient data. The application is designed for ease of data entry with built-in checks and real-time validation to ensure the data is accurate. It also provides the ability for data to be exported in a suitable format for transfer and statistical analysis.

FIGURE 1 | SCREENSHOTS OF CADOSA DATA PLATFORM



CADOSA's web-based data platform has been fully customised and developed for ease of use.

Though the CADOSA Application is a bespoke tool, it does not yet integrate with other internal informatics systems, such as the EMR or cath. lab. reporting system. Integrating with hospital-based systems would improve the efficiency of the CADOSA Registry, particularly by reducing duplication of data capture. This is a future project for the CADOSA team.

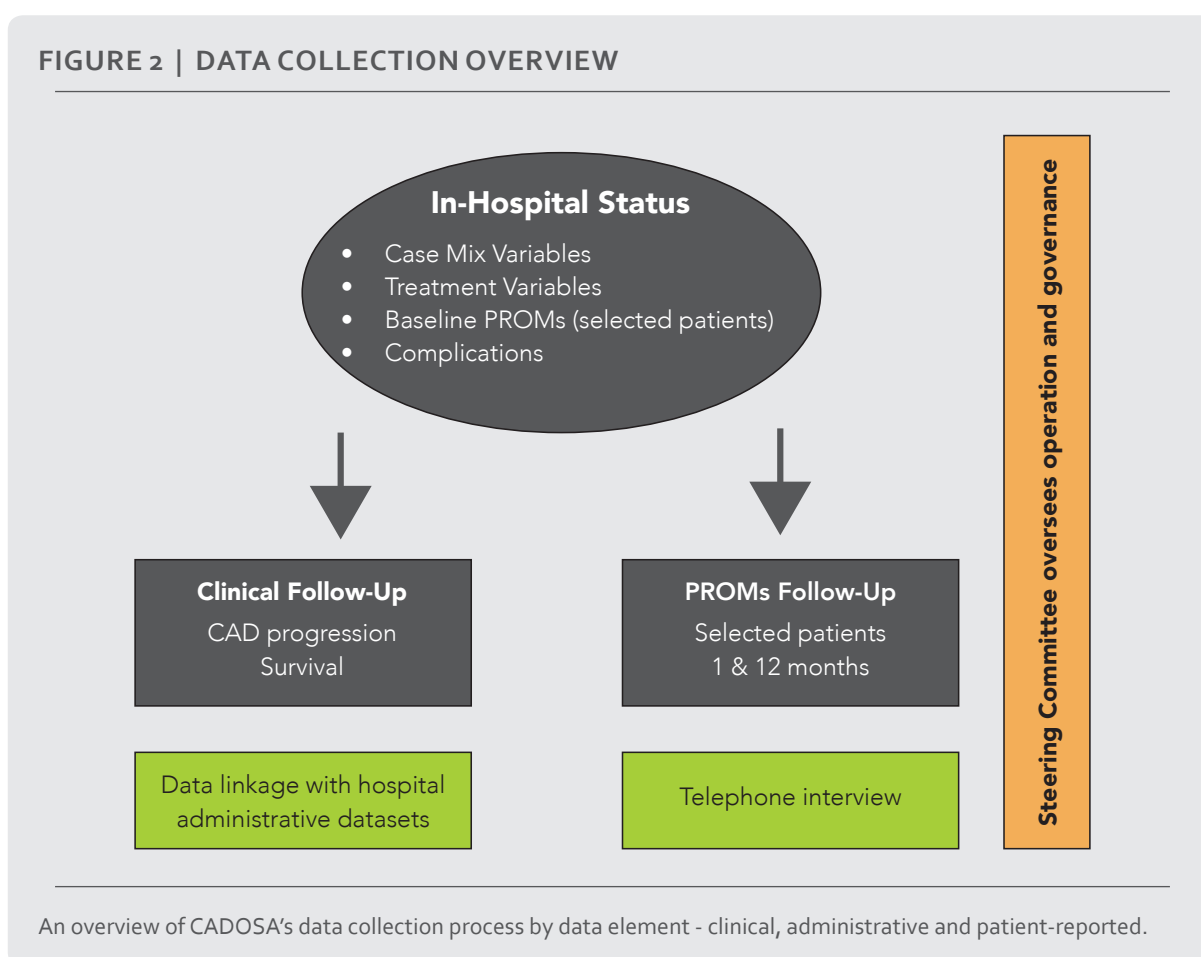
#### 4. OUTCOME METRICS

The team initially modelled clinical data collection on the American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR), CathPCI. PROMs were expanded to include not only the SF-36 and SAQ, but also the Patient Health Questionnaire-9 (PHQ-9) for depression, and the Euro-QoL 5D for cost-effectiveness data generation. The US-based NCDR were happy to endorse this as a parallel effort in another geography. Data collection was established in accordance with the Australia Commission on Safety and Quality in Health Care Operating Principles and Technical Specifications for Australian Clinical Quality Registries (2008), and the National Health and Medical Research Council methodologies and policies for the conduct of research in Australia.

The first phase of implementation focussed on clinical measures as some of these were already being collected by all participating units – there was already a pre-existing infrastructure. By 2012, every public hospital in South Australia was contributing to standardised clinical in-hospital data collection for all coronary angiograms and percutaneous coronary interventions (PCIs).

PROMs measurement was subsequently added as this required an extension of the data collection infrastructure - as of writing, PROMs data collection covers approximately 7% of the CADOSA registry patients, with this percentage growing every month.

FIGURE 2 | DATA COLLECTION OVERVIEW



An overview of CADOSA's data collection process by data element - clinical, administrative and patient-reported.

### IDENTIFYING THE POTENTIAL FOR GLOBAL BENCHMARKING AND LEARNING

In 2013, after one year of continuous clinical data collection, Professor Beltrame approached the ACC to undertake an international comparison of CADOSA's data with the USA's CathPCI data. This comparison was presented as a live video link conference presentation between the American Heart Association (AHA) Quality of Care and Outcomes Research Conference in Baltimore, USA and the National Heart Foundation Conference in Adelaide, Australia.

This effort revealed that - compared to the USA - coronary angiograms in South Australia were frequently performed using the radial approach (entrance of the catheter via the radial artery in the wrist) rather than the femoral approach (entrance of the catheter via the femoral artery in the groin area), resulting in fewer complications such as significant bleeding at the entry site<sup>2</sup>.

This was a significant milestone for CADOSA, as it demonstrated the vast potential for global benchmarking and learning based on a common global dataset. In order for this approach to realise its full potential, however, CADOSA realised they needed a tighter common dataset that was more focussed on PROMs and that was collected not just in the USA and South Australia, but in other regions too. This would lead the way to true patient-centred, data-driven, globally developed cardiovascular care.



Professor Beltrame subsequently joined the ICHOM Coronary Artery Disease (CAD) Working Group, who developed a tighter, core dataset comprising a PROMs 'backbone'. The dataset was also globally standardised, meaning comparisons could be undertaken with any other unit or country collecting the same dataset. A series of changes were subsequently made to the CADOSA measures to shift to the ICHOM CAD Standard Set: the SF-36 was removed, and the full SAQ was changed to the short version, the SAQ-7. The PHQ-9, however, was retained to capture more comprehensive data on depressive symptoms. See **Figures 3 and 4**.

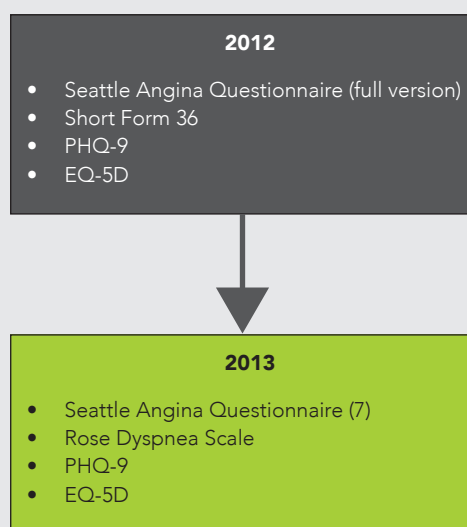
## RESULTS AND EARLY IMPACT

### DATA COLLECTION

Today, CADOSA collects data on all patients undergoing coronary angiography in public hospitals in South Australia. The team have collected data on over 21,000 cases, with 1,200 of these also including PROMs with longitudinal follow-up. In doing so, the CADOSA team has created a culture in which outcomes data abstraction is part of the coronary catheterisation/angiography routine.

Besides the obvious advantage of advancing global collaborations around a common dataset, a key benefit has been a reduction in the workload for data abstractors as the ICHOM dataset is far shorter than the previously collected dataset.

**FIGURE 3 | CADOSA DATA METRICS BEFORE AND AFTER TRANSITION TO THE ICHOM CAD STANDARD SET**



## FIGURE 4A | ICHOM STANDARD SET FOR CORONARY ARTERY DISEASE



### Details

1. Includes number of interventions requiring anesthesia
2. Includes bleeding requiring return to OR, bleeding requiring transfusion, infection requiring return to OR, infection or exposure of graft material requiring return to OR for removal or replacement, wound: complete dehiscence, wound: palatal dehiscence requiring return to OR, palatal flap necrosis, wound: oronasal fistula, respiratory distress: requires mechanical ventilation (major), LRI, death, and the number of hospitalized days following a procedure
3. Includes percentile on growth chart and change in percentile between birth and 3 months
4. Recommended to track via Cleft Q Face, Jaw, and Dental Appearance Scales along with facial photographs
5. Recommended to track via Cleft Q Eating and Drinking Scales
6. Recommended to track via the DMFT, the COHIP Oral Symptoms Scale, the 5 Year Index, the GOSLON, and lateral cephalogram
7. Includes articulation, intelligibility, and velopharyngeal competence. Recommended to track via the modified PCC, the Velopharyngeal Competence Scale, the Intelligibility in Context Scale, and the Cleft Q Speaking and Speech Scales
8. Recommended to track via the Cleft Q Social Life and School Life Scales and the Cleft Q How Do You Feel Scale and Shaped You As A Person Scale

Figure 4A: The ICHOM Standard Set for Coronary Artery Disease outcomes wheel, detailing the outcome domains within the Standard Set.

## FIGURE 4B | ICHOM TIMEPOINTS FOR CORONARY ARTERY DISEASE STANDARD SET

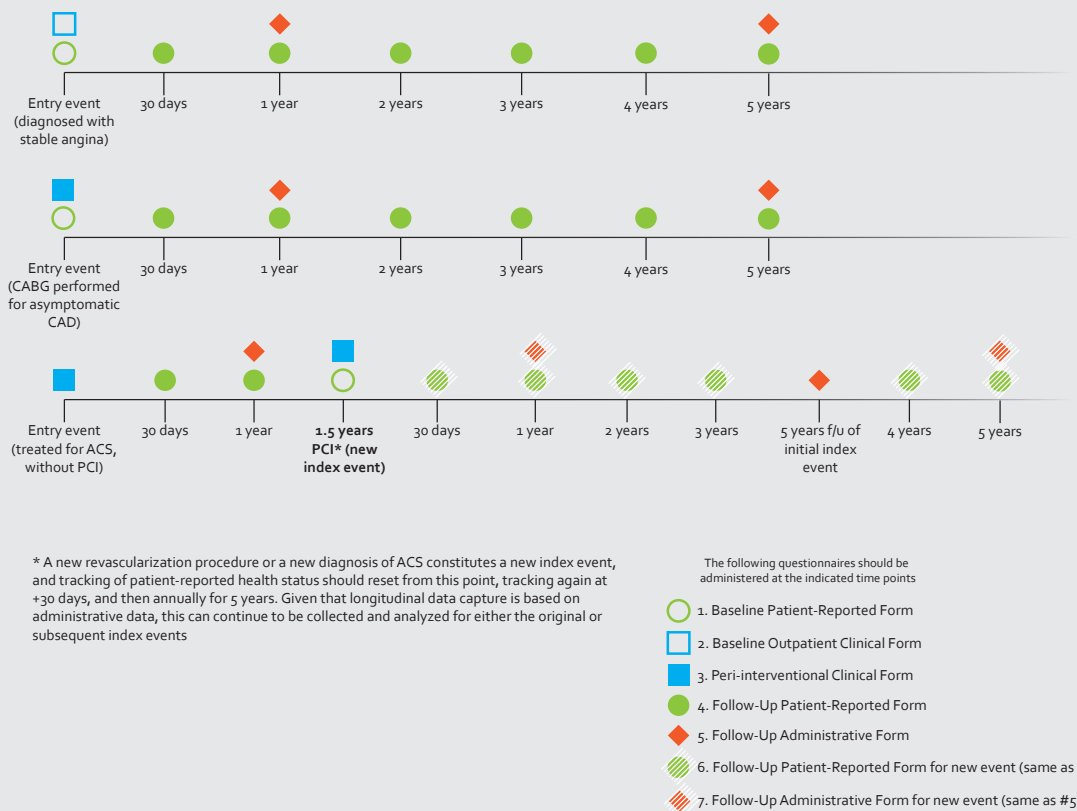


Figure 4B: Time points for data collection of the ICHOM Standard Set for Coronary Artery Disease.

## OUTCOMES IMPROVEMENT

### Identifying quality improvement opportunities

As well as driving data collection, CADOSA's Steering Committee acts as the custodian for the data. All requests for data require a brief research proposal by the requestor that is put forward to the Steering Committee for review/approval at quarterly Steering Committee meetings. Each proposal is assessed for scientific integrity (i.e. a clear rationale for the requested analysis), how the data and/or analysis will be used, and the protection of data contributors (i.e. that analysis will not reveal the identification of any hospital/patient/clinician outside the local health service). The Steering Committee receives 2-3 requests for each meeting, equating to around 8-12 proposals each year.

Examples of both successful and unsuccessful proposals can be found in **Table 2** below.

**TABLE 2 | SUCCESSFUL AND UNSUCCESSFUL PROJECT PROPOSALS**

Outcome	Project Title	Comments
Unsuccessful	Modelling CADOSA data to understand flow of cardiac patients with STEMI	Request for data identifying hospitals outside of quality assurance purpose
Successful	Transforming Health Acute Coronary Syndrome Workshop - Standardising Pathways for STEMI	Internal Department of Health workshop to standardise STEMI pathways
Successful	Door to Balloon Time in Primary PCI Patients in CALHN in 2015	Internal hospital report comparing door to balloon time following introduction of new communication process in ED
Successful	Does the pattern of Angina predict Coronary Artery Disease	Analysis in process - interest of cardiology fellow
Successful	Predictors of Coronary Artery Disease in patients undergoing angiography for stable Angina	Analysis complete - presented at Cardiac Society Conference, 2016
Successful	Clinical insights into Myocardial Infarction with non-obstructive coronary arteries	Analysis complete - to be used in PhD Thesis
Successful	State of Aboriginal Heart Health	Analysis complete - report to inform planning of services for Aboriginal patients in South Australia
Successful	Cardiac rehabilitation following Acute Myocardial Infarction	Preliminary analysis complete - presented at AHA 2014, manuscript in progress

### *Demonstrated care improvements*

Data from successful project proposals has yielded numerous clinical quality improvement opportunities, with some examples listed below.

#### **1. Data regarding procedure complications is being used to update the patient consent form with more contemporary risk information<sup>3</sup>**

In 2012, the CADOSA Steering Committee performed a literature review of the prevalence of procedure complications related to coronary angiography/PCI. The data was converted to percentages so it could be better understood by patients. In 2015, the CADOSA Steering Committee performed an analysis of updated complication rates for procedures performed in 2012-2013<sup>3</sup>.

This analysis revealed a relatively low major bleeding rate, however other major complications, in particular stroke, seemed higher than that reported in the literature. Consequently, CADOSA established a focus project evaluating the prevalence of stroke following angiography/PCI during 2012-2013. The CADOSA Steering Committee is now working with the Department of Health to generate a revised patient risk information sheet; which will provide patients with updated risk information reflecting local practice. Future prospects include advancing this informed consent process by providing patients with personalised risk predictions of adverse events generated with the CADOSA data, providing greater insight into the outcomes patients should expect.

#### **2. PCI access site to reduce bleeding-related complications**

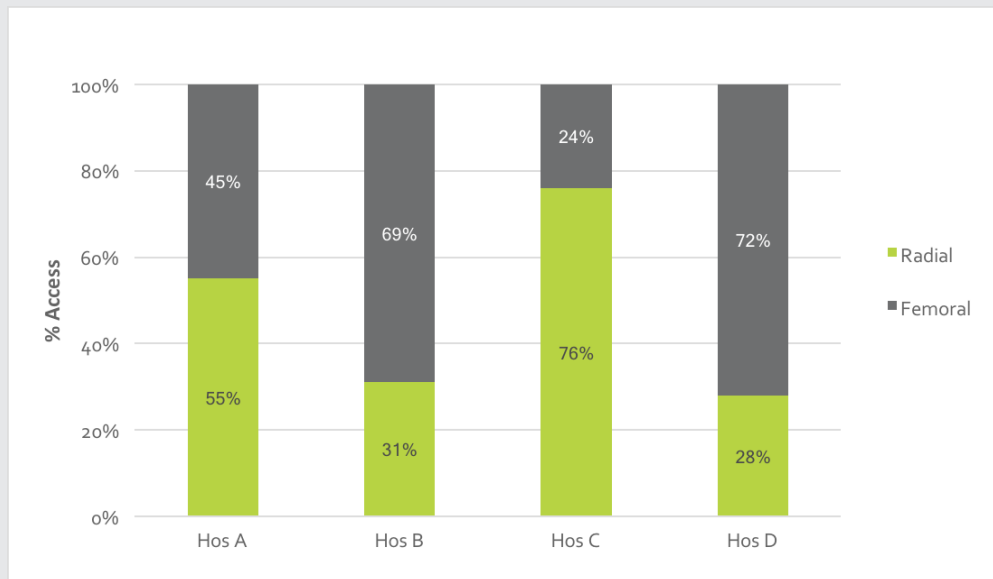
In 2012, CADOSA observed that the prevalence of radial access varied between hospitals from 28% to 76%. They recommended to all 4 hospitals that they should be using the radial approach for PCI, as this resulted in fewer bleeding events than the femoral approach. CADOSA then observed an increase in radial access used across all hospitals by 2014. **Figure 5** shows rates of both radial and femoral access during coronary intervention in 2012 and 2014.

As mentioned earlier in this case study, this data also revealed differences between outcomes and practice in South Australia and the USA.

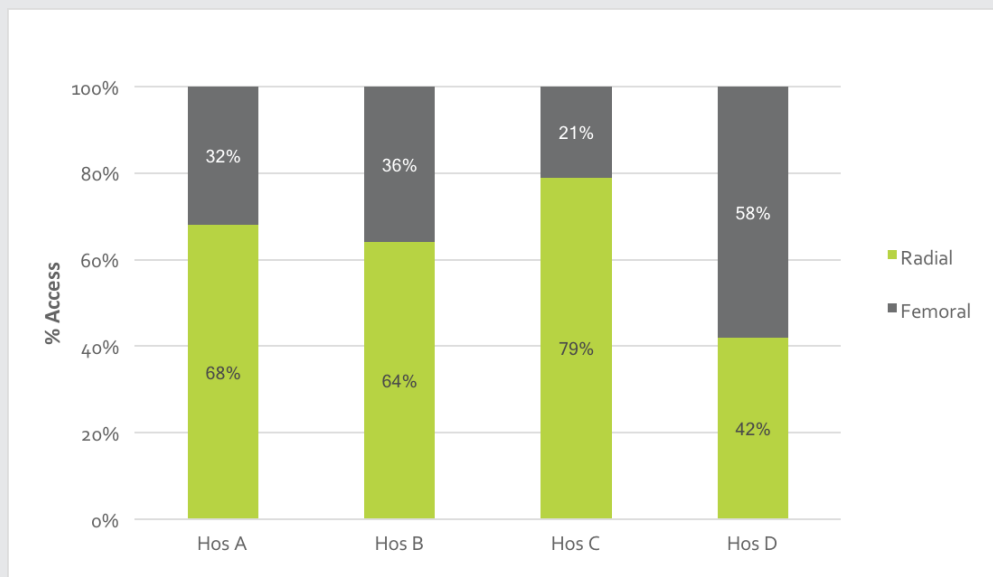
#### **3. Suicidal ideation tracked using PHQ-9 revealed a much higher incidence in coronary artery disease patients than previously thought**

To date, CADOSA has identified 52 PHQ-9-positive screens. All patients are referred to the hospital psychiatric liaison service or a primary care physician for further assessments. At this stage, CADOSA does not monitor the effectiveness of referrals but purely provides a pathway for further assessment.

**FIGURE 5A | CADOSA PCI ACCESS SITE STATISTICS IN 2012**



**FIGURE 5B | CADOSA PCI ACCESS SITE STATISTICS IN 2014**



Because of the higher number of bleeding-related complications with femoral rather than radial access for PCI, all four hospitals were encouraged to use the radial approach as 'best practice'. Between 2012 and 2014, adoption of the radial approach in line with this new best practice increased across all four hospitals as shown here.

## NEXT STEPS

### 1. Make this routine

At present, CADOSA data is presented at cardiology meetings and fed back at the hospital and department level in reports. The next step is to make the feedback of this analysed data a part of the 'routine' just as data collection is. Current physician data dashboards mainly show process metrics focussed on inpatient activity – for example, length of stay, hospital mortality and treatment times. There is a desire to integrate CADOSA outcome metrics into this system, providing patient-centred outcomes data in real time. This will also involve automated data pushing to the registry database, rather than interim data transfers.

### 2. Capture more PROMs

CADOSA aim to increase the number of patients completing the PROMs element of the ICHOM Standard Set. This will require additional staff to focus on consenting and follow-up patients. The long-term plan is to reduce the workload of current staff in terms of the clinical data collection by integrating some of the clinical data requirements into the clinical workflow. This will include using the CADOSA platform to develop admission notes and discharge summary information which would require data inputs from junior medical staff, thus providing data for CADOSA and fulfilling some of the clinical documentation required. CADOSA also aim to develop real-time extracts from the EHR. This reduction in work for clinical data collection will translate to increased PROMs capture.

### 3. Integrate with the EMR

Data is currently collected in parallel to the EMR system because all major hospitals are still using paper-based records. The CADOSA team's goal is to make data collection electronic and fully-integrated into the EMR. In the medium-to-long term, this would reduce the burden of data collection significantly. Even if the data collection is fully integrated into the EMR, the quality of the data needs to be monitored as medical staff are understandably unlikely to provide data capture to the same standard as dedicated data abstractors. Dedicated staff are therefore still required to oversee the quality/integrity of the data and fill in any gaps, but to a lesser extent.

### 4. Global benchmarking

CADOSA also continues to expand benchmarking with other registries, in particular CathPCI. They are aiming to undertake cross validation of risk models to provide the foundation to undertake risk-adjusted comparisons, in order to compare 'apples with apples'. Alongside this, CADOSA aim to benchmark their data with the global ICHOM Coronary Artery Disease (CAD) Standard Set Community – that is, with sites in North and South America, Europe, and Asia.



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## ACKNOWLEDGEMENTS

The CADOSA Steering Committee wish to acknowledgement the funding support provided by the Heart Foundation of South Australia and the South Australian State Government.

Finally, to all past and present Steering Committee Members and data abstractors, for their dedication, enthusiasm and diligence, and commitment to improving health outcomes for patients with coronary heart disease.

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