CADOSA

Coronary Angiogram Database of South Australia

South Australian Productivity Commission

2020 Health and Medical Research Inquiry

Submitted on behalf of the CADOSA Steering Committee

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Preface

This submission to South Australian Productivity Commission Inquiry into Health & Medical Research is provided on behalf of the CADOSA Steering Committee. It serves as a 'case study' of the **nexus between clinical research and health service delivery**, and how they can be successful integrated to benefit the objectives of both agendas, thereby leading to better patient care.

The report is structured as a *what, when, who how, why & where* format; commencing with background information on CADOSA, thereafter addressing the Inquiry Terms of Reference using the achievements of the Registry as an example, and finally detailing directions for the future.

CADOSA is a unique South Australian entity, with a symbiotic collaboration between Hospitals and University, where competitive research funds administered by the University to employ staff based in the hospital cardiac cath labs collect clinical data that is used for both clinical and health service research, as well quality assurance activities of the hospital.

As a **clinical research registry**, CADOSA provides the full spectrum of research areas including:

(a) basic laboratory research – using biobank samples and endothelial cell biopsies
(b) clinical trials - using the infrastructure for registry-based randomised controlled trials,
(c) health services research – examining patient outcomes with health service interventions, &
(d) public health studies – measuring quality of life and patient experience.

As a **clinical quality registry**, CADOSA provides important patient care services, including:

(a) safety & quality monitoring, with feedback to clinicians
(b) clinical performance monitoring, with international benchmarking, and
(c) depression screening

These attributes provide a unique South Australian infrastructure of global-standing, which can undertake pioneering research on an international scale, while ensuring best clinical practices is delivered to our patients.

Enquires.

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CADOSA – a nexus between clinical research & health service delivery

(A Report from the CADOSA Steering Committee)

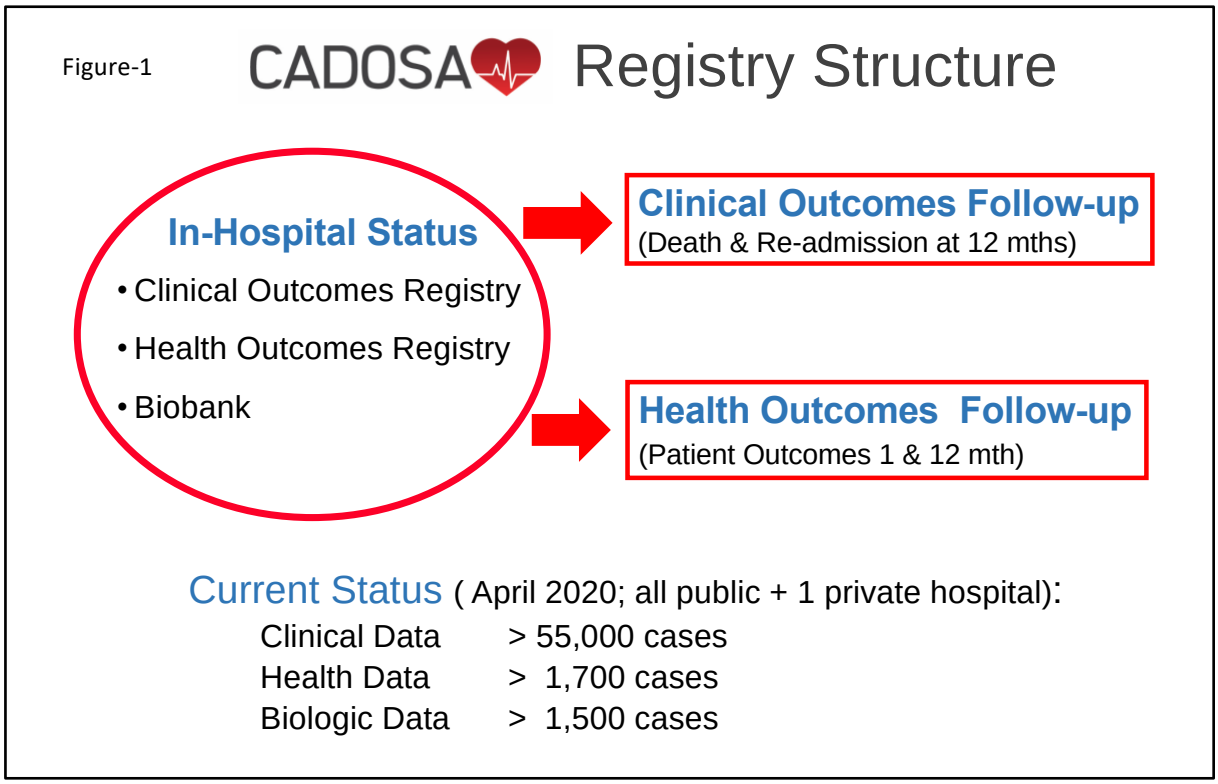
I keep six honest serving-men (They taught me all I knew);
Their names are What and Why and When and How and Where and Who.

Rudyard Kipling, Just-so Stories, 1912

What is CADOSA?

- The *Coronary Angiogram Database of South Australia* (CADOSA) is a clinical quality procedural registry of national & international acclaim, which exemplifies the mutually beneficial *nexus between health service delivery and clinical research*.
- CADOSA captures *all public hospital patients* undergoing coronary angiography and/or percutaneous coronary intervention (PCI), as well as those attending Calvary Hospital, with a Federal government support to commence capturing data at Ashford Hospital in 2020.
- As shown in Figure-1, it currently has 3 components to its structure:
  - *Clinical Outcomes Registry* – where clinical data are obtained on each patient via patient interview and case note abstraction. This clinical data provides the registry with the capacity to assess procedural *safety, performance and appropriateness*. The clinical data is linked to administrative data (ISAAC – Integrated SA Activity Collection) thereby allowing evaluation of mortality & readmission data at 12 months post-procedure.
  - *Health Outcome Registry* – in selected patients (due to limited resources), health data is obtained by patients completing questionnaires concerning cardiac symptoms, limitations caused by the disease (physical social & emotional), impact on quality of life, and depression. These are reassessed at 12 months via phone call and thus provide serial assessment of *patient-related outcome measures* (PROMs).
  - *Biobank* – in selected patients (due to limited resources), biological data is collected and stored for genetic, molecular and bioassay studies. The biologic data provides the capacity for precision medicine approaches, particularly with its detailed clinical data.
- The *CADOSA Steering Committee* is constituted by a Chair (Data Custodian), teaching hospital senior cardiologists and the project manager. The registry has an established governance structure and data security, with requests for data via a formal process, data access limited to authorised personnel and analyses undertaken internally by the CADOSA data analyst.
- CADOSA data is collected by trained data collectors, who are salaried from CADOSA funds but integrated within each of the hospital cardiac catheterisation laboratories, appreciating their involvement in the state-wide entity. They meet monthly for CADOSA management meetings.
- CADOSA staff and infrastructure (including the database) is funded via competitive research grants. These have included grants from the Heart Foundation & SA Government (South Australian Cardiovascular Research Development Program Grant), NHMRC, Hospital Research Foundation, and the University of Adelaide. These research grants have been administered via the University of Adelaide, thus most of the CADAOSA staff are University employees. Hence this clinical quality registry that undertakes clinical quality assurance activity is fundamentally funded via competitive research grants.

Figure-1



When was it Established?

- CADOSA was created following the awarding of a competitive research grant - the South Australian Cardiovascular Research Development Program Grant (Heart Foundation, SA branch & SA Government), in 2011. The Queen Elizabeth & Royal Adelaide Hospital were first inducted in 2011, with the Lyell McEwin Hospital & Flinders Medical Centre included in 2012. Calvary Hospital was included in 2016, with the plan to establish Ashford Hospital in 2020. Thus currently, CADOSA captures data from all public hospital coronary angiogram labs and selected private hospitals, with the expansion limited primarily by funding support.
- From its inception it was created as both a clinical quality registry and research infrastructure; drawing inspiration from the activities of the American Heart Association Quality Care Outcomes and Research Council in clinical performance & appropriateness, and the registry infrastructure of the American College of Cardiology CathPCI Registry.
- For more than 15 years there have been unsuccessful attempts within Australia to develop a nationwide cardiac registry. The most recent of these demonstrated to the Australian Government the importance of drawing on the resources of the successful State-based cardiac registries. In 2019, this led to the development of the National Cardiac Registry (NCR), which CADOSA is the South Australian data source and has representatives on the NCR Steering Committee.

Who Partners with CADOSA?

Figure-2 details the International & Australian Partners who have played key roles in CADOSA's evolution including clinical quality assurance activities, research projects & funding support.

Quality Care Partners

- *National Cardiovascular Data Registry (NCDR)*. The NCDR is an American College of Cardiology entity that manages a suite of cardiovascular registries to improve quality of clinical care in cardiovascular disorders. The Clinical Outcomes of the CADOSA Registry utilises the same data fields and data dictionary as the NCDR's *CathPCI Registry* and includes elements of the *Chest Pain-MI Registry*. Moreover, the CADOSA Clinical Case Report Form is endorsed by the American College of Cardiology and CADOSA is seeking membership to the NCDR's eReport Corporate system to allow international benchmark reporting. Both of these international relationships is unique to CADOSA, in Australia.
- *Quality Care Outcomes and Research (QCOR) Council*. CADOSA Steering Committee members have been members of the American Heart Association's QCOR Council since 2009. This organisation has been at the forefront of innovation for improvements in clinical care, which has been propagated by its annual QCOR Scientific Sessions and Journal (Circulation: Cardiovascular Quality & Outcomes). Indeed, this organisation and its meetings were the inspiration and drivers for establishing CADOSA. The strong relationship between CADOSA and QCOR is reflected by a CADOSA member being the first 'International Representative of the QCOR Leadership Committee'. Furthermore, a CADOSA-based paper has just been awarded the 'Paul Dudley White International Scholar Award' at the QCOR Scientific Sessions.
- *International Consortium for Health Outcomes Measurement (ICHOM)*. The founding partners of this non-for-profit organisation included Harvard University, the Karolinska Institute and the Boston Consulting Group, with Prof Michael Porter (Harvard University) playing a key leadership role. This organisation is focussed on *value-based healthcare*, with value being defined as the outcomes that matter most to patients (Patient-related Outcome Measures -PROMs) relative to cost. With this focus, they have developed 'Standard Sets' of clinical & health outcomes that should be measured for quality care. CADOSA has a close relationship with ICHOM as evident by (a) invitation to the international Working Groups to establish the cardiac Standard Sets (Coronary Artery Disease and Heart Failure – Appendix 1 & 2), (b) publishing a case study on CADOSA's attributes in implementing the ICHOM Standard Set (Appendix-3), and (c) an invitation to Chair the Coronary Artery Disease Value Community – comparing the ICHOM Standard Sets amongst 10 international hospitals. The Health Outcomes in CADOSA collects all the data elements required in the ICHOM Coronary Artery Disease Standard Set
- *State-based Clinical Quality Registries*. These have a close working relationship with CADOSA, which has been further facilitated by the establishment of NCR (see below). The well-established State-based cardiac registries include the Victorian Cardiac Outcomes Registry (VCOR) and the Queensland Cardiac Outcomes Registry (QCOR – not to be confused with the AHA's QCOR). VCOR has been the longest established registry and is managed by Monash University and primarily funded by the Victorian Government with support from Health Insurance Organisations. QCOR is a Queensland Government entity and thus operationally funded by the State, having been established by the Statewide Cardiac Clinical Network. The communal discussions between these registries has been productive in resolving practical registry management issues & facilitated the evolution of the NCR.

Jurisdictional Partners

- *National Cardiac Registry (NCR)*. This Australian Government Health Department established entity, has adopted a 'federation model' in order to develop a national cardiac outcomes registry. Unlike its predecessors, the NCR was able to report on cardiac outcomes across Australia in its augural year (2019); albeit from only 4 States. The Government-funded central management team, meet weekly

with State representatives via teleconference to develop the national model and facilitate the growth of the less established State Registries.

- *Statewide Cardiology Clinical Network*. This was initially founded by SA Health in 2007 but has more recently been recommenced by the Commission on Excellence & Innovation in Health. The Cardiology Clinical Network has a longstanding close relationship with CADOSA, since many of the CADOSA Steering Committee members are also members of the Network's Data & Information Committee. Through this partnership, CADOSA will provide data for SA Health's Acute Coronary Syndrome Dashboard, that will further facilitate clinical practice in SA.
- *SA Health*. In partnership with other SA Health committees, CADOSA has provided data (and often played a lead role) for hospital-based safety & quality meetings. Furthermore, CADOSA data has been used in the assessment of novel therapies for the South Australian Policy Advisory Committee on Technology (SAPACT).
- *Local Health Networks*. Working directly with clinicians and integrated with the hospitals' safety and quality programs, CADOSA has provided data on clinical performance (quality and safety metrics). Recently, this has included monitoring the efficiency of emergency coronary intervention for acute heart attacks during the COVID-19 pandemic.
- *Australian Commission on Safety & Quality in Health Care (ACSQHC)*. As a leader in clinical quality registries, CADOSA Steering Committee members have been invited to participate in ACSQHC advisory groups relating to registry framework and governance. Furthermore, CADOSA is registered in the recently established Australian Register of Clinical Registries.
- *National Health & Medical Research Council (NHMRC) Translational Faculty*. This NHMRC established entity (currently inactive), developed a series of 'Case for Action', for different diseases. These identified significant gaps between research and health policy, with the Cardiovascular Health and Stroke 'Case for Action' authored by members of the CADOSA Steering Committee (Appendix-4). This outlines a number of gaols of CADOSA in improving research translational and quality of clinical care.

Figure-2

Research Partners

- *Japanese Coronary Spasm Association Registry*. CADOSA has contributed the only Australian data to this Registry, since Adelaide has unique expertise in the field of vasospastic angina. Five-year

follow-up of this cohort is continuing and will provide important insights into the clinical outcomes of this potentially life-threatening disorder.

- *Coronary Vasomotor Disorders International Study Group (COVADIS) Microvascular Registry*. Reflecting Adelaide's international expertise in coronary microvascular dysfunction, CADOSA also contributes to this important registry, which will provide important insights into the clinical characteristics and outcome in patients with microvascular angina.
- *Asia Pacific Evaluation of Cardiovascular Therapies (ASPECT)*. This group compares the characteristics and outcomes of patients with coronary arteries disease in Hong Kong, Malaysia, Singapore and Australia. Both VCOR and CADOSA provide the Australian data.
- *Swedish Web-system for Enhancement & Development of Evidenced-based care in Heart disease Evaluated According to Recommended Therapies (SWEDEHEART)*. This government funded registry captures all patients hospitalised with an acute coronary syndrome in Sweden. Furthermore, via linkage with administrative datasets, this internationally-envied registry can readily monitor long term outcome in patients. This is possible due to extensive government funding support and demonstrates what can be achieved. CADOSA partners with SWEDEHEART in the MINOCA-BAT trial (see below) and has proved an opportunity for staff to learn the nuances of registry-based randomised controlled trials, from the experts (ie SWEDEHEART).

Funding Partners

- Unlike other State-based Registries, CADOSA has not received direct funding from SA Health for its clinical quality registry activities but has been funded from competitive research grant funding (Figure-3). This is a unique situation where the State's cardiac quality assurance activities are dependent on research funds, exemplifying the close nexus between research & clinical activities.
- *The South Australian Cardiovascular Research Development Program* (SACVRDP) provided the opportunity to establish CADOSA, with the competitive grant funds made available from a generous Heart Foundation bequest, which was matched by the SA Government.
- *NHMRC Grants*. The Partnership grant scheme has been an important funding source for sustaining CADOSA, since these competitive grants support opportunities for researchers and policy makers to work together in improving healthcare. Thus, SA Health and the local health networks, in particular CALHN, have been involved in partners in these grant applications, providing in-kind contributions. Support for CADOSA has been provided via the NHMRC Centre for Research Excellence in Cardiovascular Outcome Improvement.
- *The Hospital Research Foundation*. CADOSA has not only been This non-for-profit charity has been of major assistance to CADOSA, not only by developing competitive grants rounds, which CADOSA has been successful in but also by providing leverage funding for Partnership grants.
- *University of Adelaide*. CADOSA was successful in a competitive infrastructure funding round from the University, reflecting the utility of the registry not only in research but also training of students.

Figure-3 CADOSA Funding Sources

Year	Grant Source	Amount
2011-14	SACVRDP (Heart Foundation / SA Government)	$1,327,652
2013-18	NHMRC Partnership	$715,971
2015-16	Heart Foundation	$993,502
2017	University of Adelaide	$204,000
2017-20	The Hospital Research Foundation	$750,000
2017-20	NHMRC CRE Cardiovascular Outcome Improvement	$62,000
2018-21	NHMRC Partnership	$1,220,112
2018-21	The Hospital Research Foundation	$200,000

How does CADOSA address the SAPC Terms of Reference & Issues?

CADOSA exemplifies the *nexus between clinical research and health service delivery*, thereby providing an exceptional 'case study' for the SA Productivity Commission Inquiry into health & medical research. In this section, the Inquiry's Terms of Reference are detailed in relation to CADOSA (main text) with specific questions raised in the Commission's Issue paper, addressed in the grey boxed text.

1. Comparative analysis of CADOSA performance in national grant funding, focussing on how:

a. Fosters innovation & improves health service delivery.

- *Safety in Healthcare Delivery*. Without CADOSA, there is no monitoring of coronary procedure complications. This fundamental healthcare responsibility is provided by CADOSA research funds.
- *Preventing Hospital Complications*. The comprehensive clinical assessment undertaken by the CADOSA data collectors has identified potential complications (eg anticoagulants not ceased before femoral angiography) and notified the medical staff thereby averting an incident.
- *Improved Hospital Documentation*. The CADOSA Data Collectors must extract the angiographic findings from the hospital reports. Thus they often need to follow-up with clinicians regarding uncompleted reports and thereby ensure this important documentation is completed.
- *Comprehensive Healthcare Delivery*. The CADOSA Health Outcomes component, screens for depression. When there is evidence of suicidal ideation, the CADOSA staff contact the medical staff to ensure the patient receives appropriate management (ie psychiatry review for in-hospital patients, GP review for outpatients). This screening program has identified over 60 severely depressed patients who have been referred for further evaluation.

b. Encourage staff development that promotes high professional standards

- *CADOSA Data Collectors*. At its inception, CADOSA recruited experienced nurses as data collectors, who were effective in the task but at high salary cost and quickly fatigued at this clerical task. CADOSA then began training health science graduates as data collectors, which has been a tremendous success. These health science graduates enjoy working as data collectors since it provides them with a rare job opportunity, where they directly interact with patients, are part of the clinical team and contribute to patient care. These are opportunities typically afforded only to medical, nursing, or allied health care workers.
- *Junior Medical Staff Research Training*. Increasingly professional colleges require trainees to undertake research projects, as part of their training requirements. CADOSA provides a significant resource to undertake both retrospect and projective research projects.
- *Safety & Quality Assurance*. CADOSA regular provides hospital-level feedback to clinical staff on safety & performance markers thereby promoting staff development.

Information request 5.1: WORKFORCE

- *What strategies are being used by institutions to attract talented researchers*?

  Through workforce innovation, CADOSA has created a new research employment niche of coronary angiography lab-based data collectors who contribute to both research and patient care. The importance of their research contribution is in collecting high quality data, which is regularly audited. Their patient care contribution is both direct (measuring safety & performance via a clinical quality registry) and indirect (eg screening for depression, ensuring completed reports and informing clinical staff of any patient concerns).

- *What connections are there between SA Health and university workforces and how do these affect recruitment & retention of HMR researchers*?

  The enthusiasm shown by the University-employed CADOSA data collectors and their acceptance into the hospital-employed cath-lab team, epitomises how the two institutions can work together to achieve both research and patient care objectives.

2. Identify key factors whereby CADOSA influences SA health & research output, including:

a. Talent & capacity to attract new talent

- *CADOSA Data Collectors*. As detailed above, these novel clinical-research staff positions introduce new staff into the healthcare service, who are enthusiastic and provide key roles.
- *CADOSA Data Analyst*. With its limited funding, CADOSA employs a data analyst to undertake the quality assurance and research project analyses. This new position not only requires statistical and computing knowledge but has also required our staff member to develop an understanding of healthcare services.

b. Industry structure and composition

- *Private Hospital Sector*. Although industry-sponsored clinical trials are conducted in private hospitals, health services research is currently limited in this area. CADOSA has expanded from the public hospitals to involve Calvary Hospital and when funds become available (later this year), will also involve Ashford Hospital. At present, the private hospital involvement in primarily focussed on safety & quality monitoring. Involving the private hospitals also provides insights into the distribution of coronary angiography workload across the State in relation to elective vs emergency coronary procedures. Interstate private hospital organisations have contacted CADOSA with interest in managing their coronary angiogram database but due to limited capacity, this has been difficult. In the future, it is hoped that CADOSA will enable learnings between the public & private health sectors in the efficiency of cardiac cath lab utilisation.

c. Funding, including Australian Government

- *Competitive Research Grants*. As summarised in Figure 3, CADOSA has been very successful in securing NHMRC, Heart Foundation and The Hospital Research Foundation grant funding. Indeed, its initiation and subsequent survival has been dependent on this funding source. This has required innovative thinking, with clinical questions proposed for which the CADOSA infrastructure is essential. Collaboration with both administrative bodies (SA Health) & health delivery providers (the local health networks) is a fundamental component to this success.
- *Australian Department of Health NCR Funding*. As a member of NCR, a small amount of funds have been accessed from the Department of Health to further expand CADOSA into the private sector. It is hoped that competitive research grants submitted via the NCR to the MRFF and NHMRC, will further support the CADOSA infrastructure.
- *University of Adelaide Grant*. Reflecting the University's interest and support of CADOSA, an infrastructure grant was awarded from the University during a desperate funding period.

Information request 5.5: FUNDING

- *What are the key factors influencing SA's success rate in securing NHMRC & MRFF funding*?
  CADOSA has been very successful in these applications, reflecting the benefits of collaborative statewide innovations drawing on the State's health system capacity. Key factors to its success include:
  - collaborative statewide entity providing 'real world' data
  - extensive partnership network (Figure 2)
  - capacity to undertake registry-based randomise clinical trials
  - prioritising current challenges in health care or identifying an unmet needs
  - leveraging what has already been established in other organisations/overseas

  These funding awards have not only provided innovative research but represent the major safety & quality assessment for SA coronary angiography facilities. In addition, it provides data on clinician performance and the potential to assess appropriateness of clinical care. If SA Health were able to fund the fundamental patient care component of CADOSA (ie data collectors for the basic clinical data collection), then the registry could be expanded, with more extensive data collection thereby providing grander innovations in healthcare; such as the healthcare based on patient-related health outcome measures (PROMs) & value-based care.

- *Industry Funding*. Calvary Hospital provides a small grant to assist supporting the fulltime data collector at the Hospital and is also supportive in NHMRC Partnership grant applications. Small collaborative projects have also been undertaken with pharmaceutical and device companies.

d. Access to Data.

Access to data should be considered in conjunction with appropriate data governance. This is important because health data should be acknowledged as a strategic asset and like any other asset, the information requires ongoing monitoring. Data governance provides a formal structure for data management so organisations can extract clinical and business value. In South Australia there has been little headway in promoting data governance as a business imperative, and whilst data access is perceived as a hindrance in South Australia, it should be recognised that data governance has had limited priority in leadership. In contrast, CADOSA has established a solid data governance and management framework from the outset as outlined below:

- *Data Governance and Data Access*. Considerable time and effort has been expended on establishing a secure and privacy-abiding governance model for the CADOSA data. Consequently, the data is secured on a SA Health server and only accessible to authorised SA Health staff. For analyses, the required data is extracted de-identified and available only to the CADOSA data analyst. Any data analysis requires ethics approval and a submission to the CADOSA Steering Committee. The CADOSA Steering Committee oversee the use and access of the CADOSA information, enabling transparency of all data-related processes. This ensures that reported CADOSA data is:
  - reliable and accurate;
  - interpreted consistently, reported appropriately and reliably;
  - available to external agencies but protected from unauthorised access or use;
  - optimised to enable the strategic use of data.

  External parties engage in a data use access agreement prior to the provision of data to specify and obtain acceptance of the responsibilities under which access is provided.
- *Data Linkage*. The CADOSA clinical data registry has been linked to the hospital casemix data (ISAAC database) via SA/NT Datalink. This should facilitate clinical follow-up of death/re-admissions in the future.
- *Commission on Excellence and Innovation in Health (CEIH)*. Following discussions with this recently established entity, it is hoped that CADOSA will be able to access angiogram-related health cost data as well as MBS and PBS data, thus facilitating value-based healthcare models.

Information request 5.2: ACCESS to DATA

- *What barriers are there to sharing data for HMR*?
  CADOSA has expended considerable time in negotiating a variety of data barriers, particularly occurring when new SA Health directives have been suddenly implemented. For example, access to the new electronic health record by the data collectors to extract clinical information.
- *What data related bottlenecks constrain HMR and what can be done to remove them*?
  With close cooperation between SA Health and the CADOSA team, these barriers have been negotiated. The mutual benefit to both healthcare delivery and research, has been an asset that has facilitated resolution of these 'data bottlenecks'.

e. Connectivity of BioMedical Precinct & Flinders Precinct

- *Statewide Infrastructure*. CADOSA is a statewide registry in the public health sector and seeking to encompass the private health sector with funding being the main limitation. Accordingly, it not only provides connectivity amongst the health service providers but also with the University of Adelaide, who is the administrating institution for the grants that fund CADOSA. Moreover, there is connectivity/collaboration in research studies, with projects from the University, Hospitals and SAHMRI being conducted via CADOSA.

f. Potential for greater connectivity between LHN medical workforce & university

- *Australian Institute of Machine Learning*. This University of Adelaide facility is one of top ranked in the world and preliminary discussions on common topics of interest would be further facilitated by successful grant applications.
- *Implementation Science*. The University of Adelaide has experienced implementation scientists who can facilitate the adaptation of new clinical guidelines and practices. Currently CADOSA has an MRFF application utilising the skillset of these experts.
- *Health Economics*. In practicing value-based healthcare, the University's expertise in health economics would be greatly valued and discussions are in progress to utilise these resources.

g. Integration of research partners with SA Health

- The integration of local, national and international research partners and SA Health is detailed in the above section 'Who Partners with CADOSA'.

Information request 5.4: COLLABORATION

- *How important is collaboration to securing research funding*?

  Collaboration is fundamental in securing research funding, with current highly competitive research grant environment. The days of single centre, small group grant applications have passed. CADOSA demonstrates the success achieved with large collaborative grant applications.
- *Are current levels of collaboration by SA researchers/institutions optimal*?

  Although CADOSA illustrates the potential for cooperation amongst SA research institutions, unfortunately this is not widespread and could improve. Although many researchers are pleased to collaborate (especially since they appreciate its importance for grant success), awareness of other researchers outside their institution and other institutional barriers, often limit the extent of collaboration.
- Are there innovative models of collaboration which could be adopted in SA? CADOSA!

3. Identify innovative existing collaborative models with other organisations & industry

- *South Australian Policy Advisory Committee on Technology (SAPACT)*. CADOSA collaborates with SA Health on multiple levels but its collaboration with SAPACT warrants further discussion. This committee provides a review process for new devices to allow their use within SA Health. Typically, many devices have limited literature available to assess their value in healthcare. Thus, the committee regularly requires longitudinal reporting of clinical and health outcomes but does not have the infrastructure to store and report these important outcomes. CADOSA has regularly supplied clinical outcome data to SAPACT concerning coronary intervention products. If appropriate support was available, CADOSA could also provide a data repository for these cardiovascular device outcomes. This information is not only be helpful to the health service but also device companies.
- *Private Hospitals*. The established & future collaboration with private hospitals is articulated above.
- *Health Manufacturing Industry*. Previously CADOSA has undertaken small projects for pharmaceutical and device companies. There is significant potential to expand this partnership into a potential funding source but would require a detailed business model.

4. Identify opportunities for increased commercialisation

- *Private Health Insurance Companies*. In addition to the Health Manufacturers, Private Health Insurance companies are interested in CADOSA's wealth of data. The clinical and health outcomes are of interest in forging a value-based healthcare system as compared with an activity-based one. Hence health insurers would opt for renumerating achievement of clinical/health outcomes rather than mere clinical activity/procedure. This is likely to be the future of healthcare delivery.
- *Data Collectors as Physician Assistants*. As discussed above, CADOSA has developed health science graduates as data collectors, which could easily be transitioned to physician assistants, thereby

providing non-clinical staff to assist the clinical staff. CADOSA has now developed the corporate knowledge on the skillsets required by these workers and could potentially develop a commercial course (via the University) to educate physician assistants and provide in-house practical experience.

5. Assess CADOSA productivity.

- *Database Productivity*. CADOSA is a substantial dataset. In the Clinical Outcome Registry alone, there are over 55,000 records, each containing over 1,000 data elements. The Health Outcomes Registry contains over 1,700 records with follow-up details at 1 and 12 months on each record, thus representing over 1,000 data elements per record. The Biobank contains DNA, RNA, plasma and serum samples on over 1,500 patients. These features are all integrated representing detailed information to address multiple research questions.
- *Clinical Research Productivity*. With this wealth of information, CADOSA has been directly responsible for over 40 conference presentations and publications are still in progress. It has also directly contributed to success in 8 competitive research grants (Figure 3), and indirectly to several others. Considering the quality and extent of data available, its productivity could be further enhanced with more staff to generate manuscripts.
- *Basic Research Productivity*. The CADOSA biobank is an underutilised resource and has the potential to contribute significantly to the evolving field of precision medicine, especially considering its comprehensive associated clinical data. The CADOSA team have also developed a novel technique of endothelial biopsies, which can provide an additional basic lab research tool for human studies. Unfortunately, although South Australia has an excellent genomic and precision medicine facility, the focus is primarily on cancer rather than cardiovascular research.
- *Clinical Quality Registry Productivity*. In addition to the research achievements, CADOSA has been a productive clinical quality registry, establishing regular clinical feedback sessions to clinicians.

6. Identify characteristics of CADOSA that may give it the competitive edge

- *Unique Health Service in South Australia*. Whereas coronary angiography can be undertaken in multiple cities and rural towns in other States, here it can only be performed in Adelaide. This enables CADOSA to capture all public South Australian procedures, which is more challenging in other States. This centralised model also lends itself well to health service research studies, particularly considering the modest population size of SA. Thus, if researching the impact of an intervention (eg early discharge program for heart attack patients), the 4 public hospital coronary angiogram hospitals can be readily randomised to treatment vs non-treatment allocation in a staggered study design (ie a stepped-wedged design) and CADOSA can readily collect the outcome data.
- *Unique CADOSA Design*. This includes (a) trained data collectors who interview patients directly, (b) comprehensive clinical dataset, (c) compatibility with American College of Cardiology CathPCI Registry, thus allowing benchmarking and exchange of research findings, (d) Patient follow-up via linked data, (e) PROMs, (f) biobank linked with extensive clinical data, (g) endothelial biopsies for laboratory studies, (h) infrastructure to conduct clinical trials – ie registry-based Randomised Controlled Trials, and (i) strong partnerships in quality care, research, & jurisdictional administrations. These comprehensive attributes are rarely found in a single registry.

Example: MINOCA-BAT Clinical Trial (https://clinicaltrials.gov/ct2/show/NCT03686696)

Myocardial infarction with non-obstructive coronary artery disease (MINOCA) accounts for every 1 in 10 heart attacks in Australia. No treatment strategy has been evaluated in this population.

The MINOCA-BAT trial is Australia's first cardiovascular registry-based randomised controlled trial.

Initiated by SWEDHEART Investigators, CADOSA provided the first clinical setting in the world to acquire funds for this trial and initiate the trial treatment model in MINOCA patients.

As described above, there are several attributes in South Australia that CADOSA has capitalised on, in particular the centralised invasive cardiology service in Adelaide (also providing care to patients from the Northern Territory). Parallel to this, the CADOSA team for many years have fostered enduring collaborative relationships with world-leading experts in cardiovascular research. This has provided South Australia with the opportunity to work with Prof John Spertus, internationally recognised on several occasions as "The World's Most Influential Scientific Minds," for making significant global impact within his respective field of study in cardiovascular health outcomes. Through his connection with CADOSA, Prof Spertus is now an Affiliate Professor at the University of Adelaide, has made regular visits to Adelaide, is engaged with the CALHN leadership team and is a co-investigator on several NHMRC grants.

Information request 5.8: COMPETITIVE ADVANTAGE – POPULATION

- *Are there particular characteristics of SA's population that may create competitive advantage*?

  In relation to the CADOSA registry, the SA population and health system is ideal since all patients requiring angiography must be transferred to Adelaide, either to one of the 4 public hospital cath labs or the 4 private hospital labs. This facilitates the capture of all South Australian patients undergoing invasive angiography and thus a 'real world' scenario of clinical practice in SA.

Information request 5.11: COMPETITIVE ADVANTAGE – COLLABORATION AND PRECINCTS

- *How competitive is SA in attracting leading researchers and talented postgraduates to HMR*?
  As illustrated in Figure-2, multiple international partners have collaborated with CADOSA, many of whom are internationally acclaimed health services researchers. In particular, Prof John Spertus regularly visits Adelaide and has become an Adjunct Professor of the University of Adelaide.

7. Identify barriers for Industry in undertaking health R&D & ways to facilitate involvement

- *Industry Awareness*. Through clinical contacts, some pharmaceutical and device manufacturers are aware of CADOSA and its capability but this should be increased. Furthermore, software and app developers could assist in translating clinical algorithms developed with CADOSA data.
- *Data Governance*. The CADOSA data is a valuable resource to health product manufacturers and reports of requested analyses useful and an income source. Any such arrangement with industry cannot be managed by SA Health and would require an external party (eg University).

8. Recommend SA Government action in:

a. Increase SA share of Australian Government funding

- *Promote Health Services Research*. Both the NHMRC and MRFF focus upon the impact of research on clinical & health outcomes, which is the focus of CADOSA and other health service research. To promote clinicians with/without research experience to explore health service research studies, the SA Government should offer competitive research project grants and fellowships in this field. These would stimulate subsequent submissions to NHMRC/MRFF.
- *Invest in Research Infrastructure*. CADOSA epitomises the problem of unfunded research infrastructure. The CADOSA team are pre-occupied with ensuring that there are adequate funds to sustain the CADOSA infrastructure, which is also required for clinical services. If the data collectors positions were secured from alternative sources (eg LHN operational funds or the HSCGB), then there would be sufficient time for more comprehensive grant applications.
- *Increase Clinical Academics*. These hospital-based clinical researchers, who are also employed by the University, have the skillsets to undertake health services research.

b. Increase productivity of SA health & medical research

- *Public–Private Health Service Research Partnership*. Although there are some fundamental differences, there are many similarities between public and private healthcare service delivery. If these two entities could learn from each other by combined projects, it would improve value-based healthcare across both systems.

- *Research Efficiency*. While the clinical service has been closely scrutinised in its efficiency, the same needs to occur in clinical research. This includes efficiencies in administrative aspects, governance, patient recruitment and study completion. Business support/advice to clinical researchers would be helpful as these clinicians have no formal training in this area.

c. Health & medical R&D to increase State's economic growth

- *Increasing Health Services Research*. The economic benefits of this strategy not only reside in sourcing alternative R&D funding (ie Australian Government and Industry funds) for the State but also in the reduced health expenditure by increasing the value of healthcare delivery. CADOSA has submitted to MRFF a project seeking to reducing length of hospital stay in patients with heart attack as well as improving the quality of care these patient receive.

9. Recommend changes to structure, governance & operation of publicly-funded HMR

- For this statewide project, CADOSA administration must contend with 3 Local Health Networks and two University administrations. If these were streamlined, then it would not only improve administrative efficiency but also improve the 'silo mentality' of the organisations.

Why CADOSA is the 'nexus' between clinical research & health service?

- CADOSA is a unique South Australian entity, representing a symbiotic collaboration between Hospitals and the University, where competitive research funds administered by the University to employ staff based in the hospital cardiac cath labs collect clinical data that is used for both clinical and health service research, as well quality assurance activities of the hospital.
- The clinical research and health service delivery attributes of CADOSA are outlined below, reflecting why it is an importance infrastructure in South Australia.
- These attributes also illustrate how the boundaries between research and clinical service delivery are blurred, since many of the listed attributes could appear in either category.

Why is CADOSA important to South Australian Clinical Research?

- *Translational Research* – translate clinical guidelines by assessing performance measures
- *Implementation Research* – improving guideline implementation by better patient care projects
- *Appropriateness Research* – developing assessment of procedural appropriateness
- *Patient-related Outcomes Research* – measuring PROMs as focus of future care.
- *Partner Registries* – collecting/collating data for collaborate registries (eg microvascular angina)
- *Personalised Medicine* – develop clinical risk prediction models to personalise care
- *Precision Medicine Research* – potential projects utilising the biobank
- *Human Endothelial Cell Research* – cath lab endothelial biopsy samples used in zinc studies
- *Registry-based Randomised Controlled Trials* (rRCT) – first cardiovascular rRCT in Australia.
- *Transferable IP* – any IP developed from CADOSA (eg clinical algorithms) are transferable to the US market since the registry uses the same data definitions as Cath PCI.
- *Research Training* – provide data for undergraduate & postgraduate research projects.
- *Develop 'Spin-off' Implementation Companies* – utilising corporate knowledge obtained in implementation research projects, including the value of data collectors/physician assistants.

Why is CADOSA important to South Australian Health Service Delivery?

- *Clinical Quality Registry* – providing clinician feedback with safety and quality measures
- *Value-based Healthcare* – a vehicle for measuring value, including PROMs and costs
- *Clinical Safety Audits* – provide safety data for audits
- *Improving Clinical Care* – screening for depression in patients undergoing angiography
- *Staff Improvement & Retention* – by clinical feedback, improve job satisfaction
- *Work Efficiency* – CADOSA staff are an integral component of the cath lab, improving efficiency

Where is CADOSA headed?

- Although CADOSA is a comprehensive clinical quality registry with extensive clinical research utility, it has not achieved its full potential. Considerable time is spent by the management team in administrative tasks, including securing staff positions, facility access, research governance (both hospital and University), and establishing research contracts. If administrative support was provided by the Hospital/University, this would provide time to submit more grant applications, thereby bring further funds to South Australia.

- Future innovations planned for CADOSA are outlined below:
    - Expanding Private Hospital involvement in CADOSA – Ashford Hospital.
    - Incorporating public hospital financial data into CADOSA, enabling cost-effectiveness studies.
    - Integrating CADOSA data – clinical, health outcome, biological and financial data.
    - Exploring value-based medicine approaches.
    - Evaluating coronary angiography and stenting appropriateness criteria.
    - Developing clinical risk prediction models, thus facilitating a personalised medicine approach.
    - Developing a personalised, evidence-based clinical management pathway for acute heart attacks.
    - Partnering with genomic laboratories to develop precision medicine paradigms.
    - Expanding the use of the biobank and endothelial biopsy samples amongst basic researchers

- Despite these extensive attributes and planned future studies, a more immediate issue confronting CADOSA is securing funding since the current grant funds will be expended by the 1st July 2020. Although two research grants are still pending with the MRFF, if these are unsuccessful, then CADOSA will no longer be viable and South Australia will have lost an important unique resource.

APPENDICES

Appendix-1. ICHOM Coronary Artery Disease Standard Set

Appendix-2. ICHOM Heart Failure Standard Set

Appendix-3. Implementing ICHOM's Standard Sets of Outcomes

Appendix-4. NHMRC Case for Action: Appropriateness & Performance in Management of Cardiovascular Disease in Australian Hospitals

Appendix-5. Current and Past CADOSA Staff

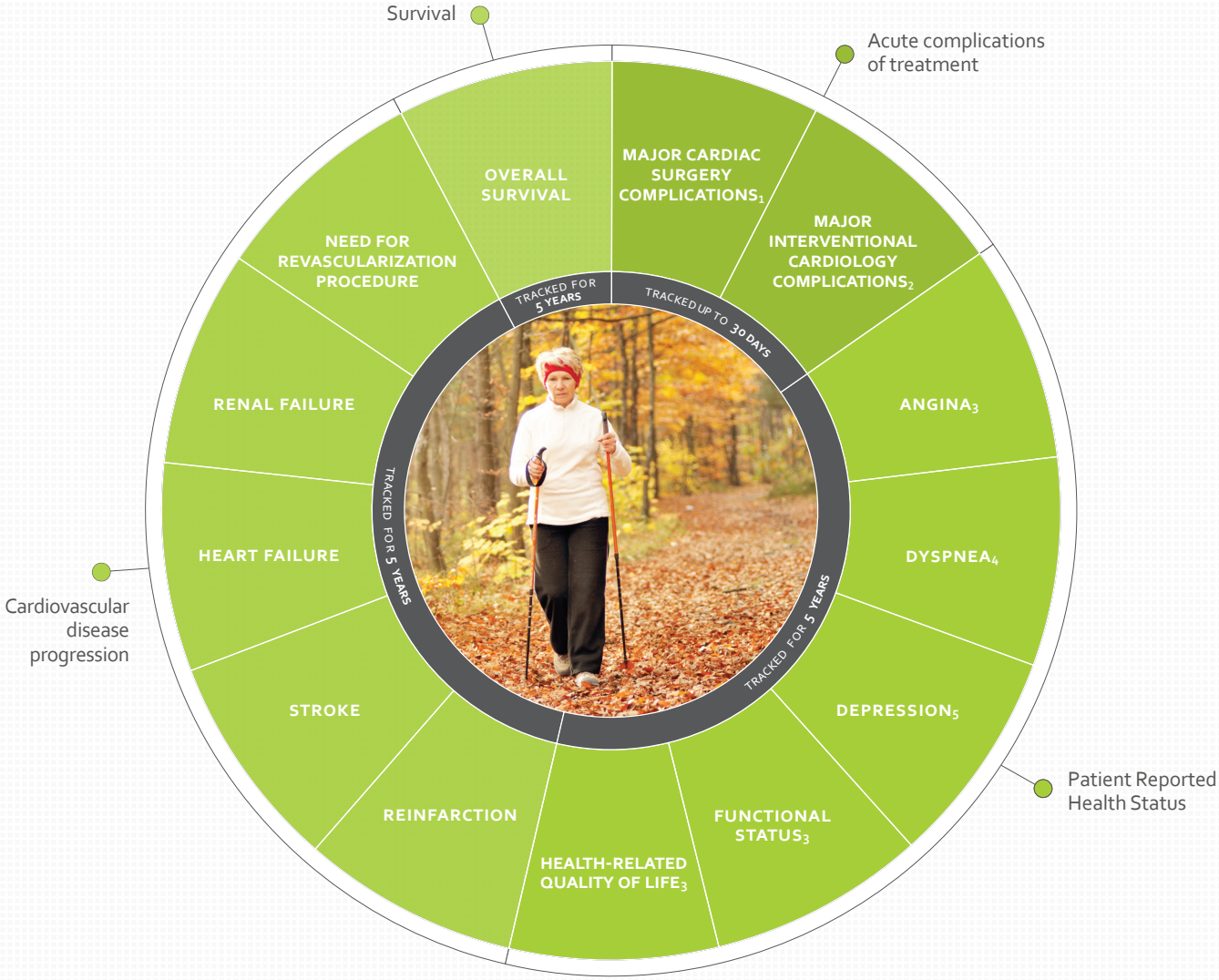
ICHOM Standard Set for

CORONARY ARTERY DISEASE

Treatment approaches covered

Lifestyle modification | Drug therapy | Percutaneous coronary intervention | Coronary artery bypass grafting

For a complete overview of the ICHOM Standard Set, including definitions for each measure, time points for collection, and associated risk factors, visit ICHOM.org/project/Coronary-Artery-Disease



Details

1. Includes occurrence of strokes, acute renal failure, prolonged ventilation, deep sternal wound infection, and other causes of reoperations.
2. Includes occurrence of strokes, acute renal failure, significant dissection, perforation, vascular complications requiring intervention, bleeding event within 72 hours, and emergent CABG for failed PCI.
3. Tracked via the Seattle Angina Questionnaire (SAQ-7)
4. Tracked via the Rose Dyspnea Scale
5. Tracked via the Patient Health Questionnaire (PHQ-2)

ICHOM
CORONARY ARTERY DISEASE

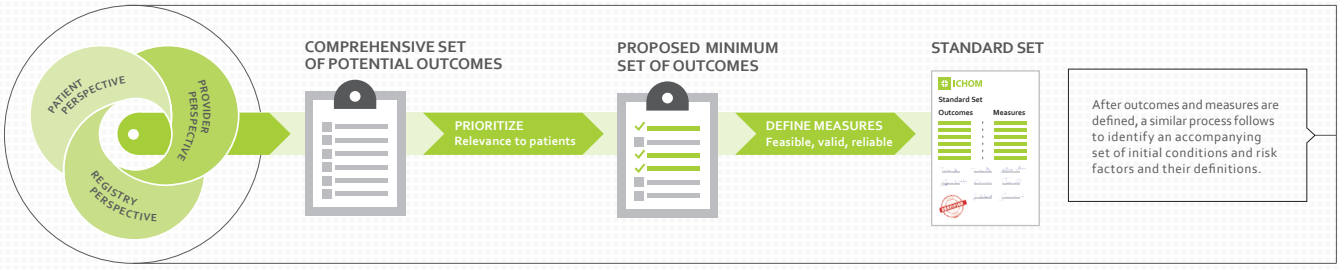
Revised: January 13, 2014

ICHOM Standard Set

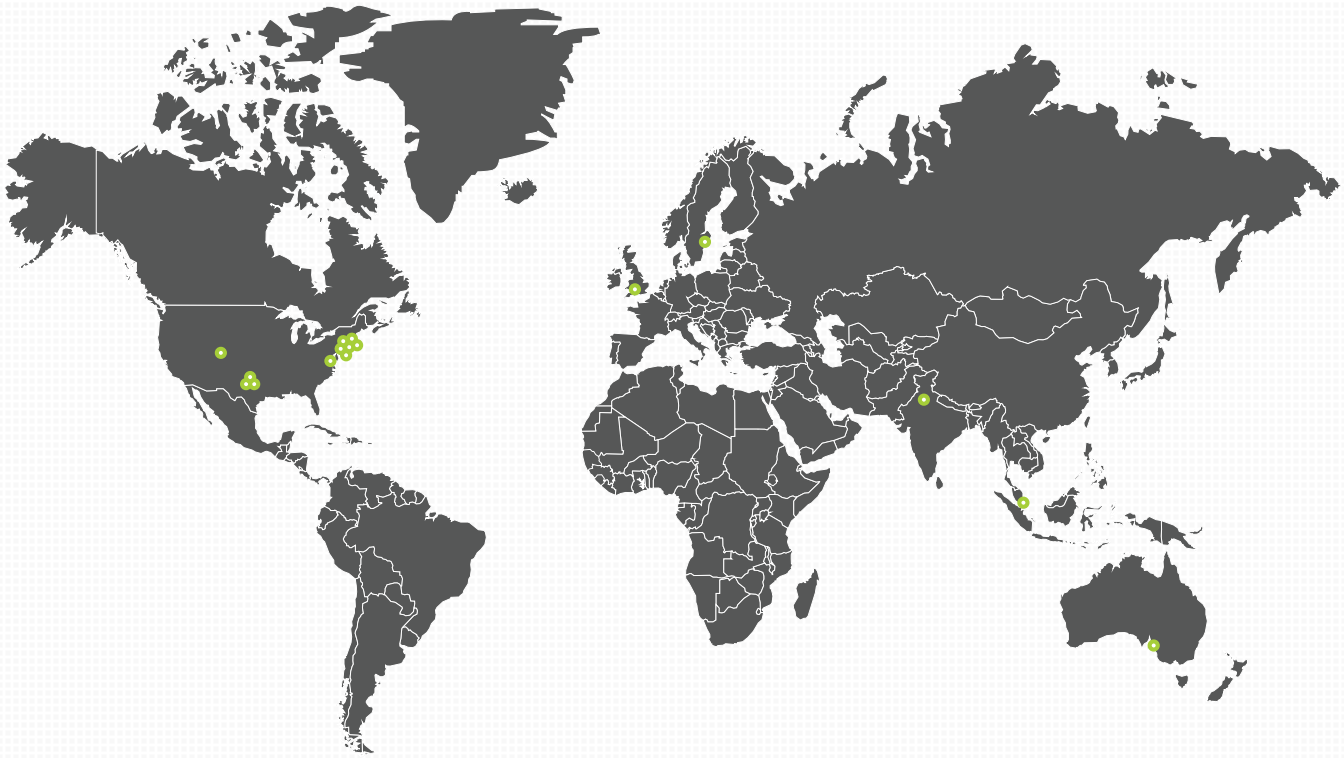
APPROACH

The ICHOM Standard Set is the result of hard work by a group of leading physicians, measurement experts and patients together with the non-profit organization ICHOM. It represents the outcomes that matter most to patients with coronary artery disease. We urge all providers around the world to start measuring these outcomes to better understand how to improve the lives of the patients they serve.

The Process



The Coronary Artery Disease Team



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Paul Heidenreich | **American Heart Association/American College of Cardiology**

John Rumsfeld | **Veterans Health Administration**

Robert Jesse | **Veterans Health Adminsitration**

*Patient representative

APPENDIX-2

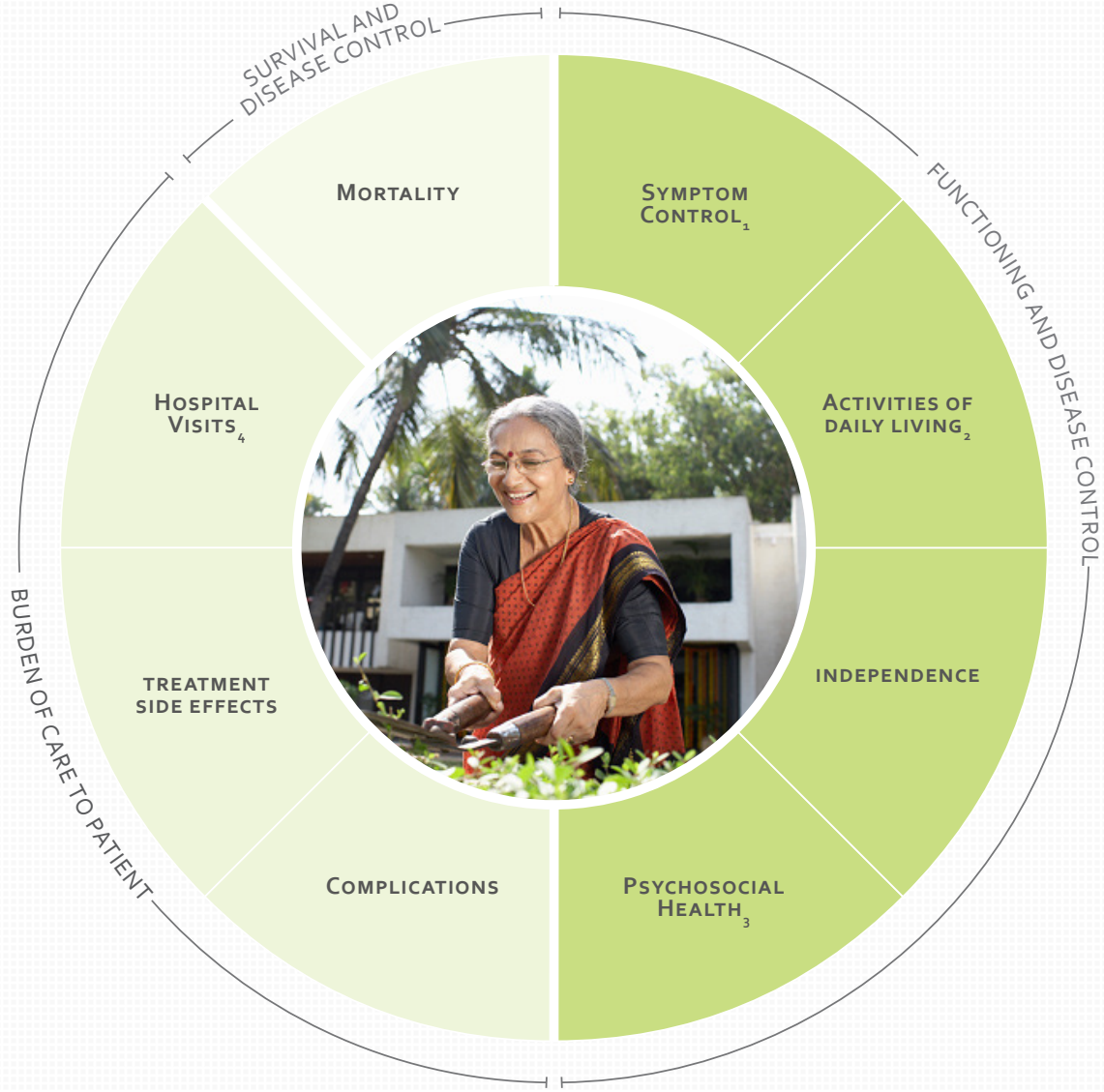
ICHOM Standard Set for

HEART FAILURE

Treatment approaches covered

Pharmacotherapy | Invasive Therapy | Rehabilitation

For a complete overview of the ICHOM Standard Set, including definitions for each measure, time points for collection, and associated risk factors, visit ichom.org/medical-conditions/Heart-Failure



Details

1 Includes dyspnoea, fatigue and tiredness, disturbed sleep, and peripheral oedema.
2 Includes health-related quality of life, maximum physical exertion.
3 Includes depression and anxiety, confidence and self-esteem.
4 Includes admissions, appointments.

ICHOM
HEART FAILURE

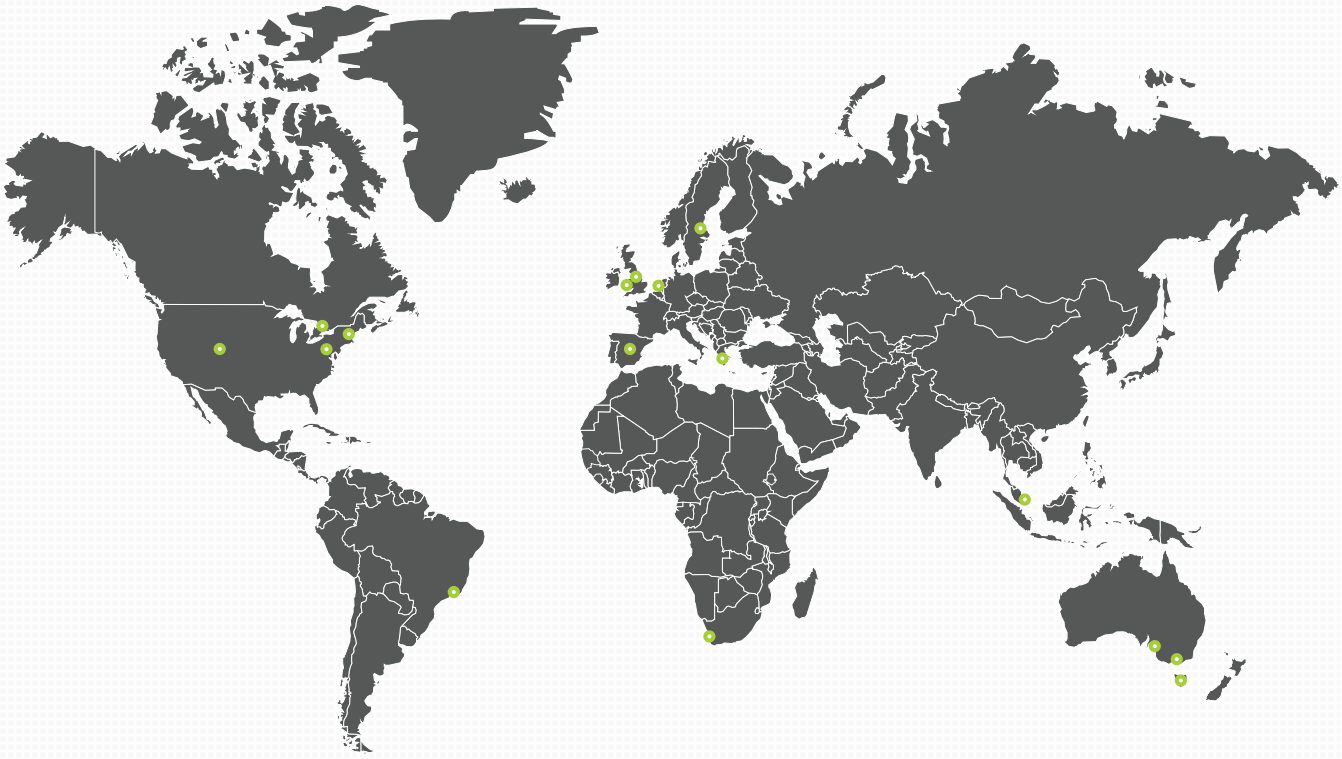
ICHOM Standard Set

CONTRIBUTORS

For more information about the process of developing a Standard Set, visit ichom.org/how-we-work/

The Sponsors

The Working Group



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Mike Knapton | **British Heart Foundation**
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Hugh McIntyre | **National Institute for Health Care Excellence**
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APPENDIX-3

CASE STUDY

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

Implementing ICHOM's Standard Sets of Outcomes: Coronary Artery Disease in the Coronary Angiogram Database of South Australia (CADOSA)

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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[1], 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).

*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

Hospital	Annual Procedure Volume	Staff FTE
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.

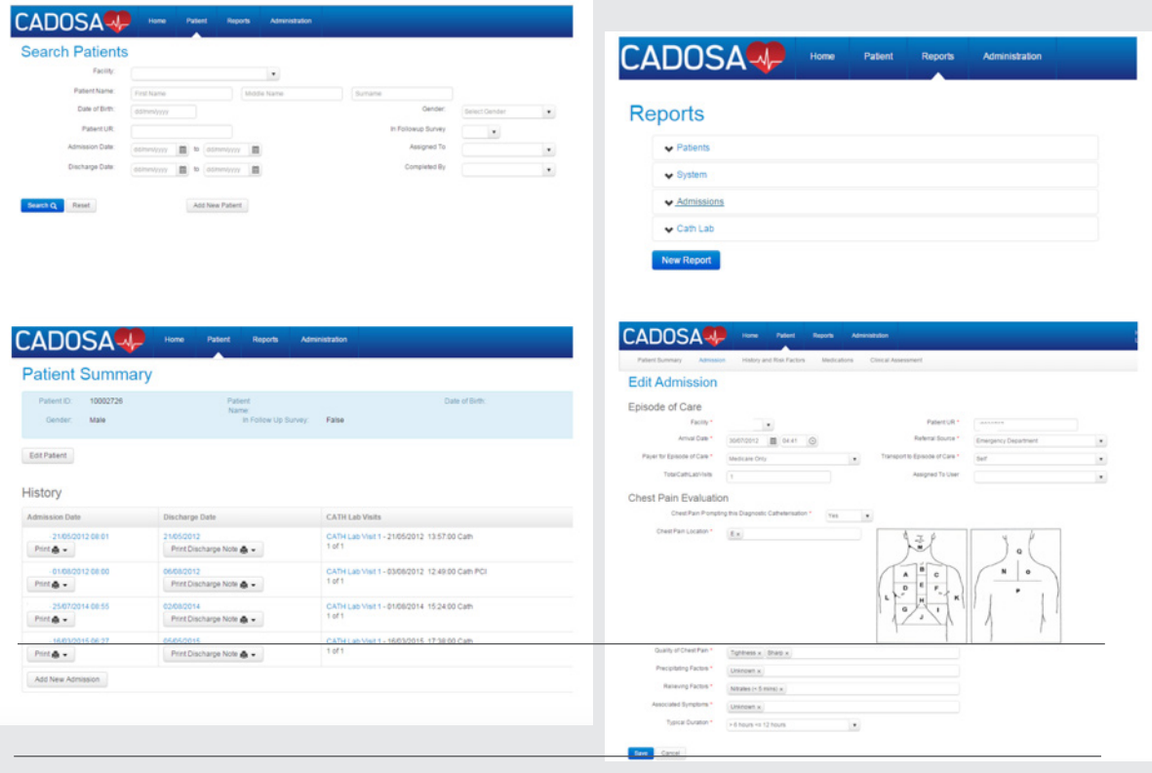
Following the induction period, Dr. Tavella would hold monthly team meetings, involving a segment for ongoing staff education.

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.

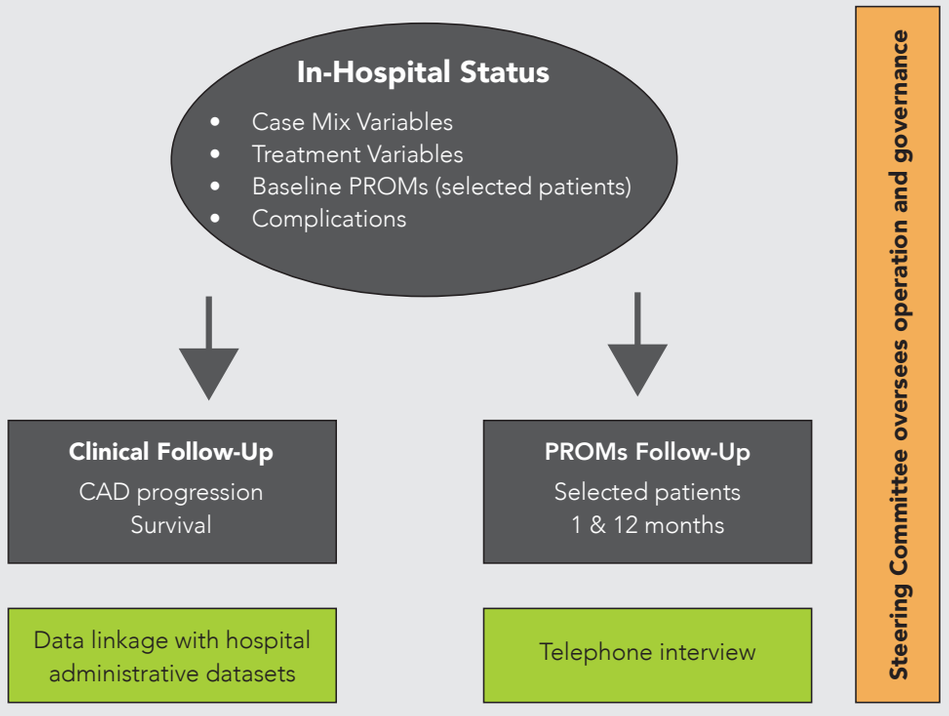
4. Outcome metrics

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[2].

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

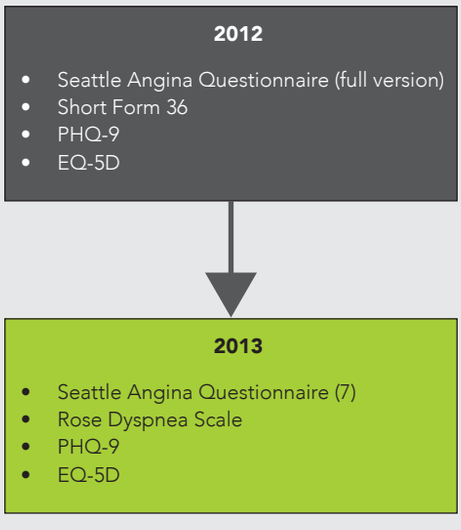


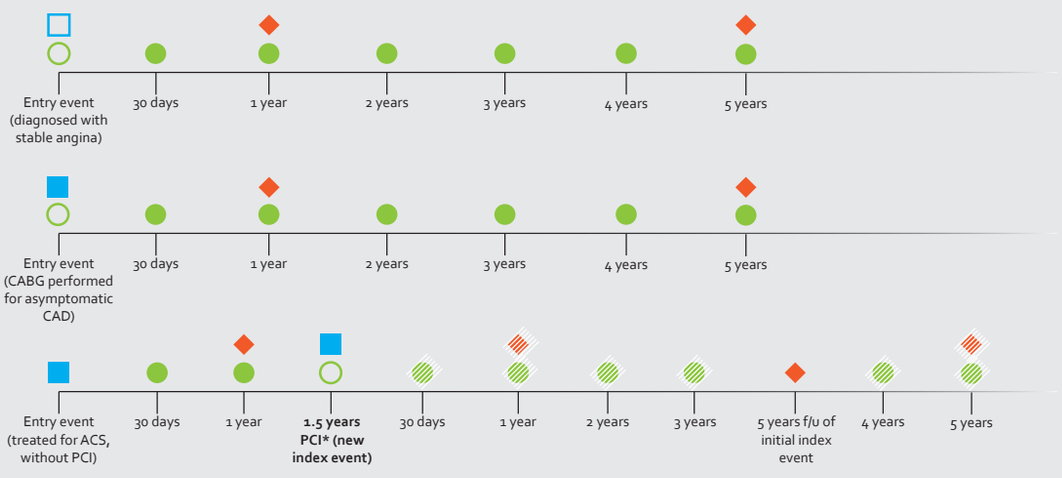
FIGURE 4A | ICHOM STANDARD SET FOR CORONARY ARTERY DISEASE

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



* A new revascularization procedure or a new diagnosis of ACS constitutes a new index event, and tracking of patient-reported health status should reset from this point, tracking again at +30 days, and then annually for 5 years. Given that longitudinal data capture is based on administrative data, this can continue to be collected and analyzed for either the original or subsequent index events

The following questionnaires should be administered at the indicated time points

1. Baseline Patient-Reported Form
2. Baseline Outpatient Clinical Form
3. Peri-interventional Clinical Form
4. Follow-Up Patient-Reported Form
5. Follow-Up Administrative Form
6. Follow-Up Patient-Reported Form for new event (same as #4)
7. Follow-Up Administrative Form for new event (same as #5)

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 UNSUCCESFUL 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[3]

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[3].

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

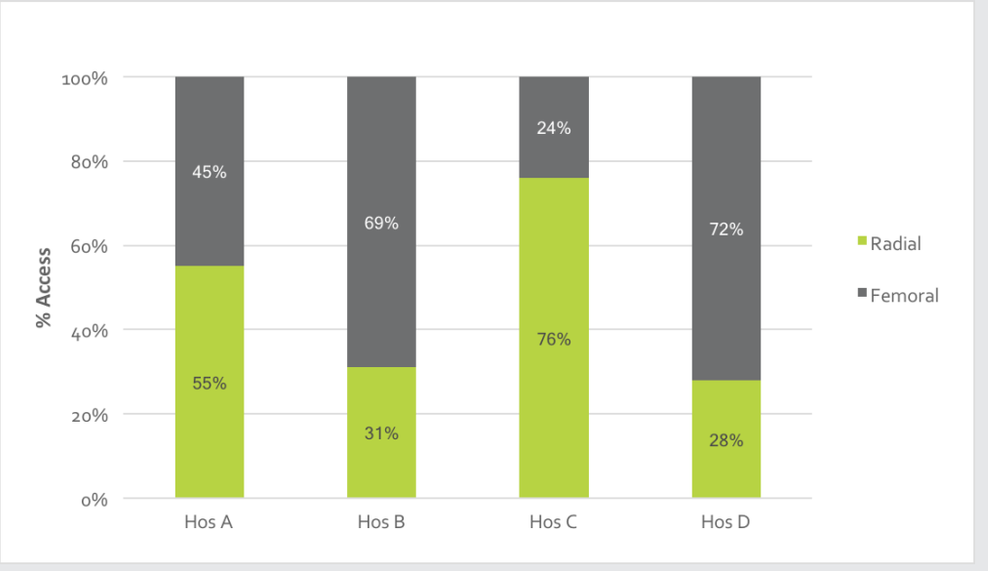
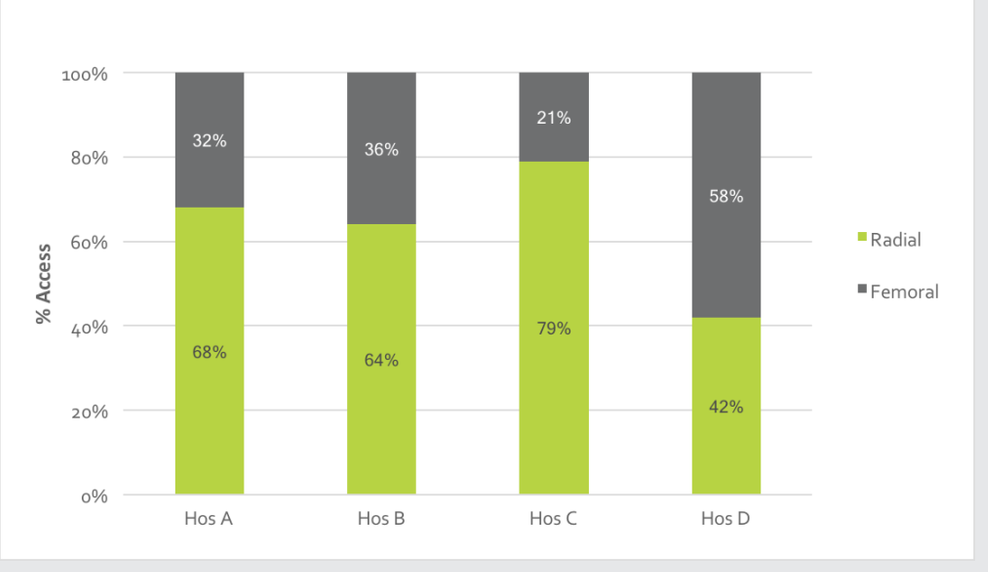


FIGURE 5B | CADOSA PCI ACCESS SITE STATISTICS IN 2014



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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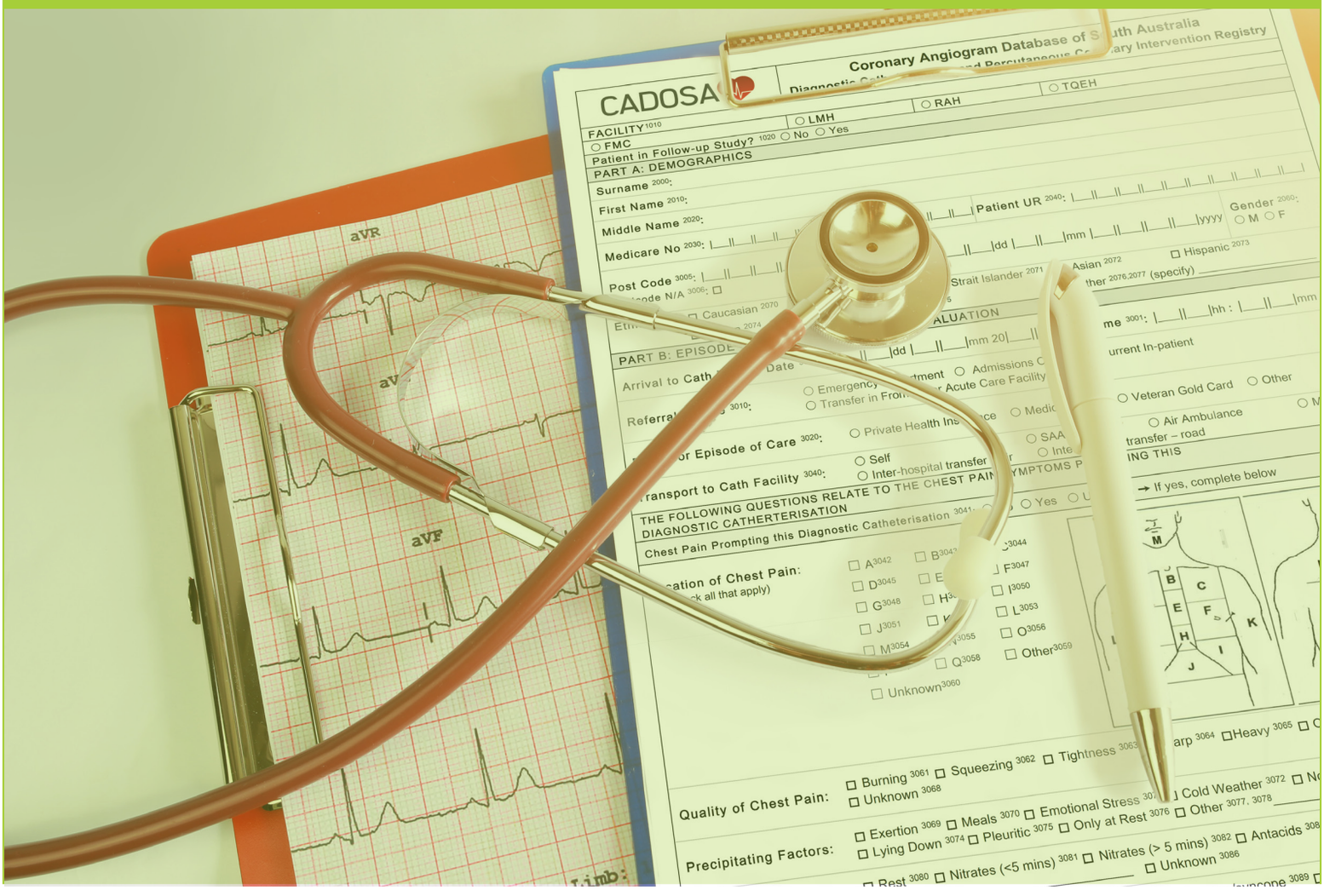

APPENDIX-4

Australian Government
National Health and Medical Research Council

RESEARCH
TRANSLATION
FACULTY

CASE FOR ACTION- PROPOSAL TO NHMRC

Appropriateness and performance in the management of cardiovascular disease in Australian hospitals

Authors:

Associate Professor Christopher Zeitz
Professor John Beltrame

Submitted by the Research Translation Faculty Cardiovascular Health and Stroke Steering Group (October 2014)

CARDIOVASCULAR HEALTH AND STROKE

The National Health and Medical Research Council (NHMRC) Research Translation Faculty (the Faculty) was established as a key advisory forum in 2012. The primary work of the Faculty for the 2013-15 Triennium has been to help NHMRC accelerate the translation of research by identifying the most significant gaps between research evidence and health policy and practice in each of the major health areas in the NHMRC Strategic Plan, and to propose to NHMRC possible action it could consider taking to address that gap – these are called Cases for Action. In April and May 2013, fourteen Faculty steering groups were established as NHMRC working committees to each oversee the development of a Case for Action.

The Faculty's Cardiovascular Health and Stroke Steering Group is comprised of a range of experts and includes primary (1˚) representatives of NHMRC Health Care Committee (HCC), Prevention and Community Health Committee (PCHC) and Research Committee (RC). Further information is available at: www.nhmrc.gov.au/research/research-translation/research-translation-faculty/research-translation-faculty-steering-groups.

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Declaration of interests

The declarations of interests of Steering Group members, authors and contributors are available at Appendix 1.

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11 May 2015

Disclaimer

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NHMRC Research Translation Faculty

Cardiovascular Health & Stroke Steering Group Case for Action

Title: Appropriateness and performance in the management of Cardiovascular Disease in Australian Hospitals

Submitted to NHMRC for consideration: October 2014

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   - Outcome Measurements
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ACTION PLAN

A. Establish the NHMRC CVD Quality Care and Outcomes Network
B. Establish National Appropriateness and Performance Criteria
C. Development of National Cardiovascular Registries
D. Feedback Reporting of Performance & Appropriateness Criteria

POTENTIAL IMPACT

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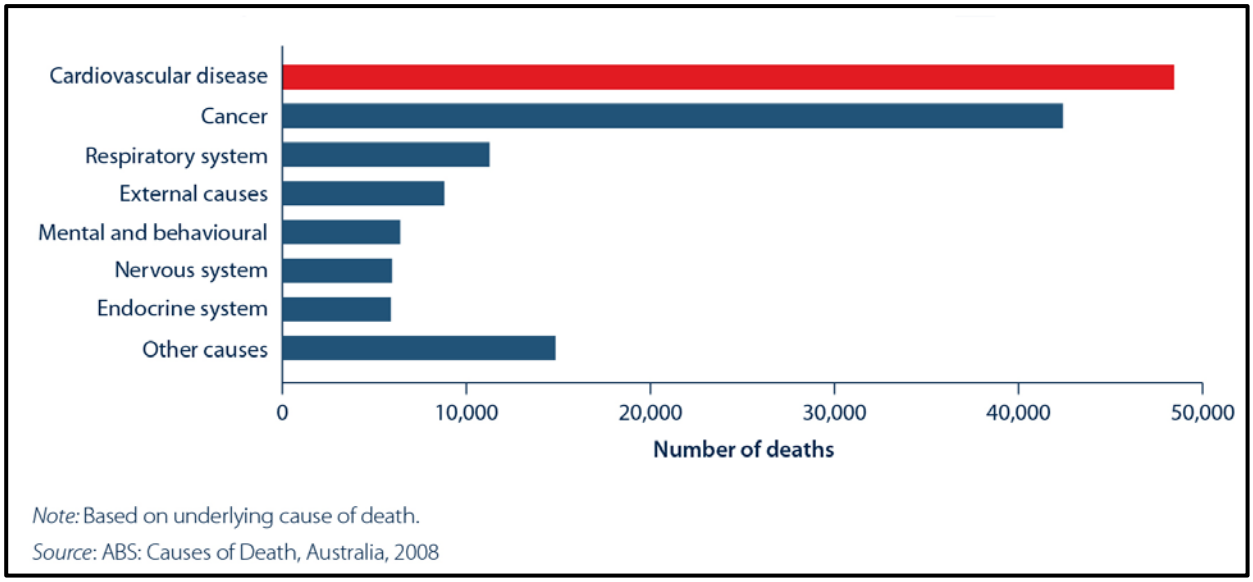
RATIONALE

Cardiovascular disease (CVD) constitutes both cardiac disorders (including cardiomyopathy, congenital and valvular heart disease) and vascular disorders (including coronary heart disease, cerebrovascular disease and peripheral vascular disease). Reports from the Australian Institute of Health and Welfare (AIHW) describe CVD as being one of the greatest contributors to mortality, total health burden of disease and expenditure in Australia (Figure-1). This is despite significant advances in CVD therapies, which have reduced mortality and impacted on health burden, but significantly contributed to health costs.

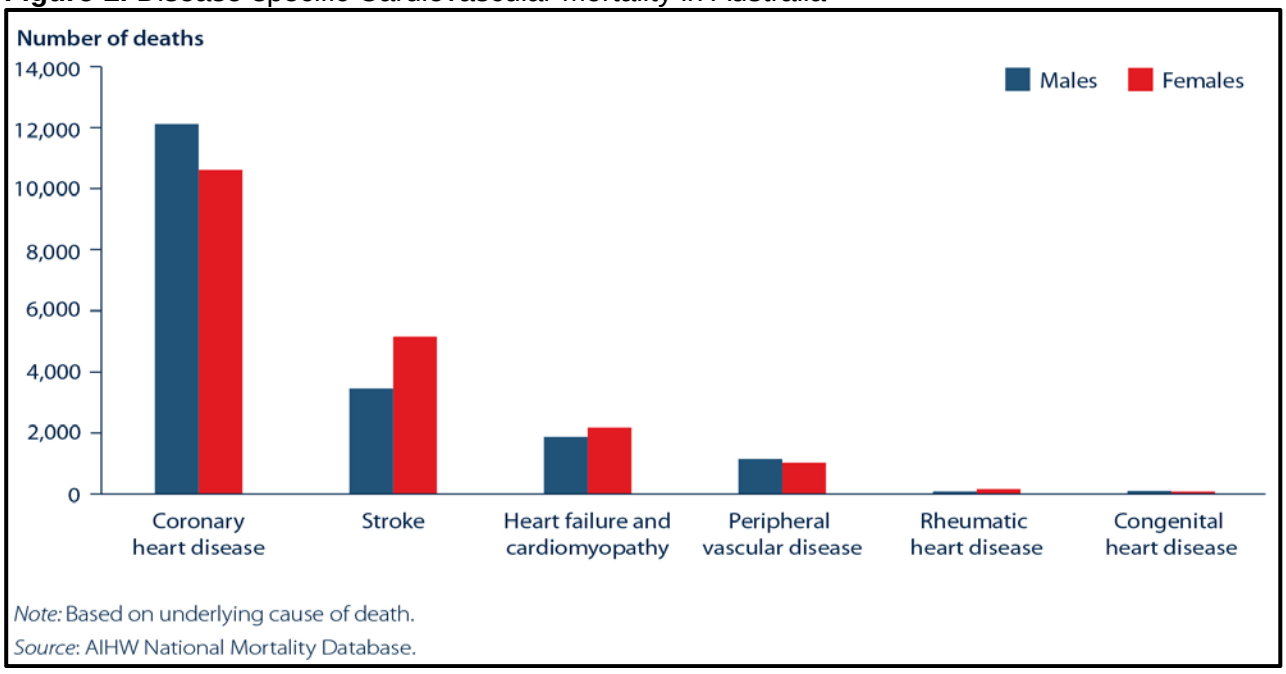
Figure-1. Causes of Death amongst Australians in 2008[1]



1. Contemporary Perspective of Cardiovascular Disease in Australia

Prevalence and Mortality. It has been estimated that 1 in 6 Australians have CVD (ie about 3.5 million) and that 1 in 3 Australian deaths are attributable to CVD[1]. Of particular concern, more than 1 in 10 Indigenous Australians are affected with CVD and have 1.8-fold higher CVD mortality compared with Non-indigenous Australians.

Figure-2. Disease-specific Cardiovascular Mortality in Australia[1]



Coronary heart disease is the most prevalent cardiovascular cause of death in Australia, responsible for 49% of CVD deaths, with stroke accounting for a further 18% of CVD deaths (Figure-2).

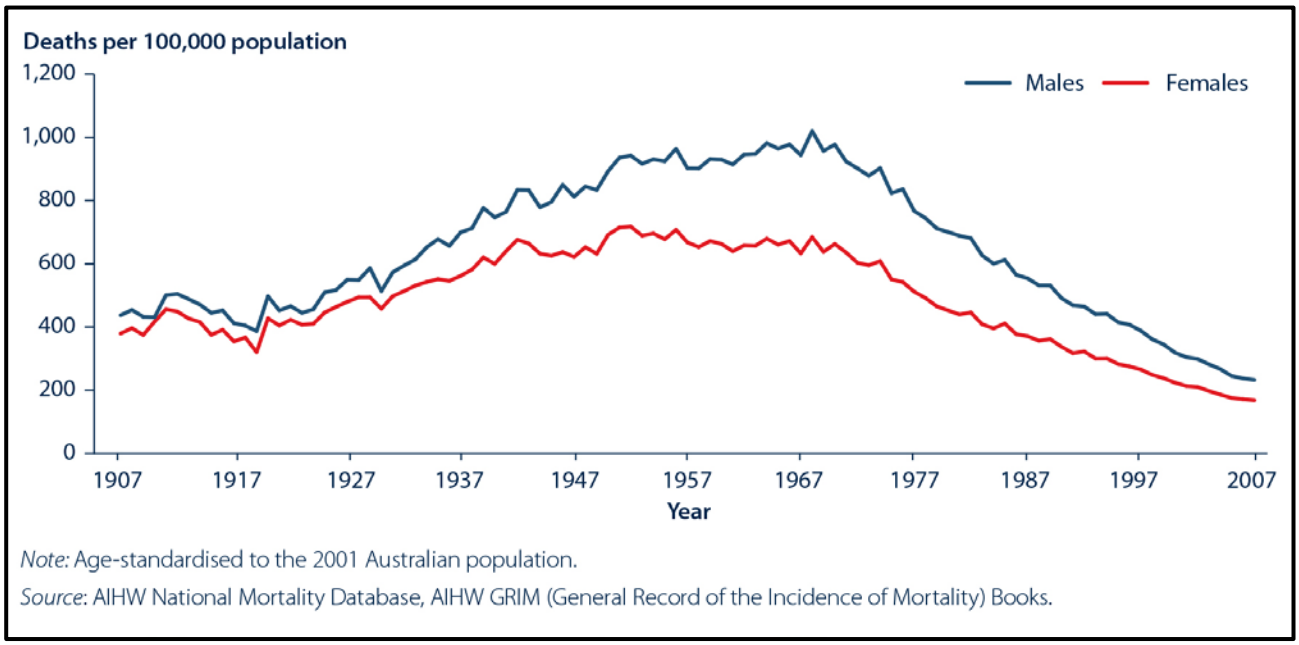
Morbidity. In addition to the significant mortality, CVD has a substantial impact on morbidity as assessed by hospitalisations and disability-adjusted life years (DALYs). There are approximately 500,000 hospital admissions in Australia each year attributable to CVD. Of these, 34% were attributable to coronary heart disease, 10% heart failure/cardiomyopathy, 7% stroke, 5% peripheral arterial disease, and 3% transient ischaemic attacks. Using DALYs assessment, CVD accounts for 18% of the total burden of disease in Australia. This burden is greater than for mental health disorders and slightly less than cancer[1].

Health Expenditure. Cardiovascular disease is the most costly disease in Australia, representing 11% of total health expenditure. Within CVD, coronary heart disease and stroke account for 40% of the total expenditure with hospital costs contributing to over $1,270 million for coronary heart disease and $380 million for stroke[1].

2. Trends in Cardiovascular Disease in Australia

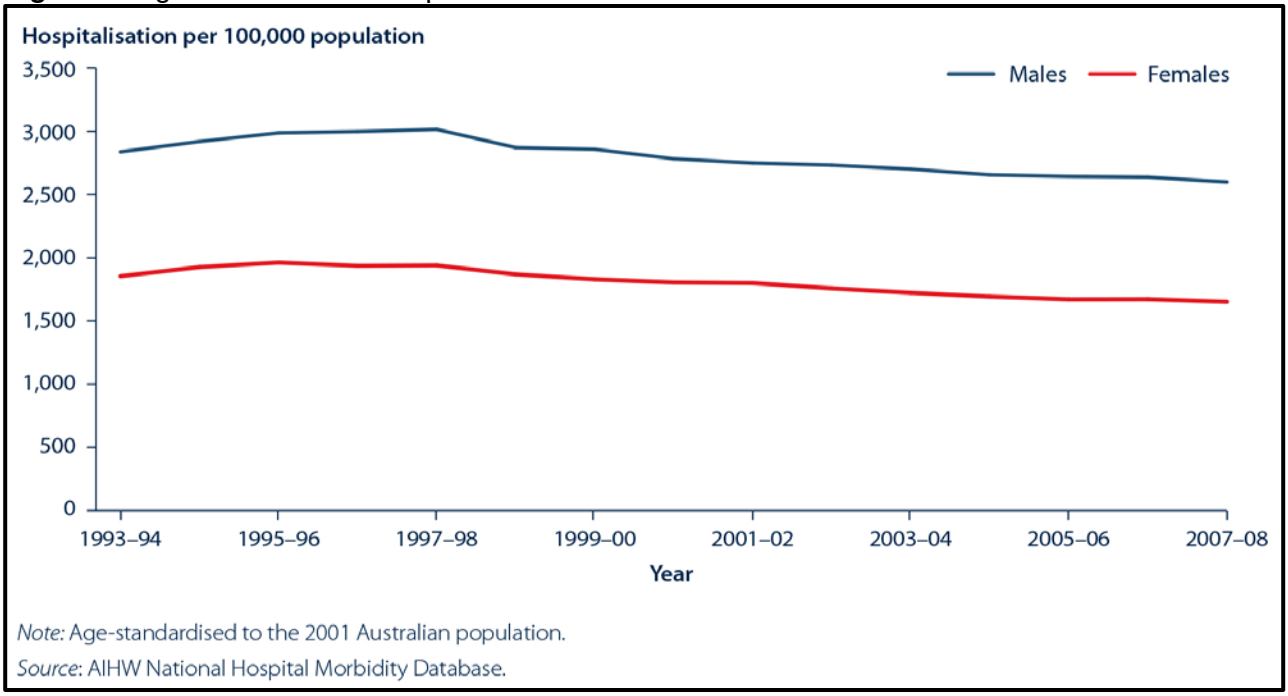
As in many other developed countries[2], CVD mortality has significantly improved within Australia over the past 30 years. As shown in Figure-3, CVD mortality progressively increased in the early decades of the 20th century, peaking in the 1950s – 1960s but has since substantially improved. This improvement in mortality is evident for both coronary heart disease and stroke. In Australia, there were 32,093 coronary heart disease deaths in 1987 as compared with 22,983 in 2006, representing a 28% reduction over the 3 decades. In comparison, stroke mortality fell from 10,593 in 1987 to 8,484 in 2006, a 20% reduction over 3 decades. This improved stroke mortality was greater for ischaemic stroke than haemorrhagic stroke. Considering population growth from 16 million in 1987 to over 19 million by 2006, this improved cardiovascular mortality is even more impressive.

Figure-3. Age-standardised Cardiovascular Mortality Trends in Australia[1]



In addition to the improved mortality rate, age-standardised hospitalisations for cardiovascular disease have improved over the past couple of decades (Figure 4). In 1993-94 there were 2,312 admissions per 100,000 population, which fell to 2,027 per 100,000 by 2009-10, representing a 12% reduction over this period. Again, this was evident for both coronary heart disease and stroke.

Figure-4. Age-standardised Hospitalisations for Cardiovascular Disease in Australia[1]



The above data is age-standardised, reflecting a reduction in cardiovascular mortality amongst young/middle-aged individuals and thus an increase in life expectancy. Consequently, cardiovascular disease and mortality is more prevalent amongst the elderly population. This presents future challenges that require investigation since many preventative strategies and cardiovascular therapies have primarily been assessed in a middle-aged population and their effectiveness in the elderly is unclear. Moreover, the elderly (who frequently have multiple medical problems) are often more concerned with disabilities and impairment in quality of life rather than mortality risk. Thus focussed studies in the elderly population are required.

3. Previous Improvements in Cardiovascular Care in Australia

The improved trends in cardiovascular mortality and morbidity (as evident by reduced hospitalisations) reflect an improvement in Australian healthcare over the past 50-60 years. This has been an evolutionary process with important philosophical changes in the approach to healthcare. This includes the evolution of *Rehabilitation Medicine*, *Preventative Medicine*, *Evidence-based Medicine*, *Guideline Medicine* and *Translational Medicine*, as outlined below.

Rehabilitation Medicine. In the early portion of the 20th century, both myocardial infarct[3] and stroke patients were managed with prolonged bed rest. By the early 1950s it was appreciated that early mobilisation reduced immobilisation-associated complications and improved outcomes in patients with acute cardiovascular events. This led to an understanding of the importance of exercise and the birth of cardiac and stroke rehabilitation services. These have since evolved to multi-disciplinary services that not only include exercise therapy but also patient education, nutritional advice and the management of depression.

Preventative Medicine. In the late 1940s, the Framingham Heart study was established, which was to revolutionise cardiovascular care of the future. At the time, atherosclerosis was perceived as an inevitable pathology of aging. The Framingham study demonstrated a constellation of risk factors that predisposed to atherosclerosis, including hypertension, diabetes, dyslipidaemia, smoking, physical inactivity and a family history of CVD. Subsequent clinical studies demonstrated that early treatment of these risk factors prevented acute cardiovascular events. Moreover, treatment of these risk factors not only prevented future cardiovascular events in those with established CVD (Secondary Prevention) but also in those with no prior history of CVD (Primary Prevention). This underscored the important role of general practitioners as well as the hospital physician in treating CVD, and emphasized the importance of co-ordinated cardiovascular care.

Evidence-based Medicine. At the beginning of the last century, many clinical practices were based upon 'expert opinion', often extrapolated from established physiological principles. With the advent of randomised, controlled clinical trials, many of these traditional clinical practices were subsequently revoked. Moreover, it was appreciated that utilising clinically-relevant endpoints (such as cardiac events) were more useful rather than the use of surrogate endpoints (such as the suppression of ventricular ectopic beats; a valuable lesson learned from the CAST Trial[4]).

Evidence-based medicine has been defined by Rosenberg and Donald[5], as 'the process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions'. Its origins date back to 1972 with Professor Archie Cochrane's publication[6] entitled 'Effectiveness and Efficiency: Random Reflections on Health Services'. This eventually led to the establishment of the Cochrane Centre at Oxford and the development of the Cochrane Collaboration.

Guideline Medicine. In the 1980s and 90s there was an explosion of cardiovascular clinical trials endeavouring to establish a strong evidence-base for cardiovascular therapeutics. These studies required expert interpretation to provide an informed context for the practicing clinician, consequently clinical practice guidelines evolved. The American College of Cardiology and American Heart Association recently celebrated 30 years of developing these guidelines[7], reporting that for every 10% adherence to their Class I acute coronary syndrome recommendations there was a 10% reduction of in-hospital mortality[8].

In Australia, professional medical societies also formulate clinical practice guidelines thereby providing local authoritative recommendations and clinical standards. Professional cardiovascular societies involved in guideline development include the Heart Foundation, Stroke Foundation, National Vascular Disease Prevention Alliance and Cardiac Society of Australia & New Zealand. Contemporary Australian clinical guidelines for cardiovascular disease span both primary and secondary preventative treatments and include the management of cardiovascular risk factors[9,10], acute coronary syndromes[11], cardiac failure[12], rheumatic heart disease[13], and stroke[14]. In addition, the Australian Commission on Safety and Quality in Health Care (ACSQHC) has developed clinical standards for acute coronary syndromes based upon the corresponding guidelines and are undertaking similar standards for stroke management.

Translational Medicine. With the evolution of clinical guidelines, the opportunity arose to compare these standards with contemporary clinical practice. For example, the ASPIRE[15] and EUROASPIRE[16] studies were large clinical surveys undertaken in Britain and Europe respectively, and revealed that guideline recommendations were frequently not implemented so that there was a 'clinical practice gap'. Considering the evidence-base supporting the guidelines, then their translation into clinical practice would improve cardiovascular care. Consequently translational science has evolved and involves T1 to T4, where T1 is the traditional bed to bedside research; T2 involves clinical trials to established the evidence base for therapeutic interventions therefore providing the basis for clinical guidelines; T3 involves dissemination and implementation of evidence-based medicine (clinical guidelines); and T4 is the policy development for health care delivery. Accordingly, this proposal primarily focuses upon T3 approaches.

4. Future Directions in Cardiovascular Care in Australia

By exploiting the 'clinical practice gap' with 'T3 research' there is an opportunity to further improve cardiovascular care within Australia. This has been initiated by the National Health and Medical Research Council (NHMRC) with the establishment of a Translational Faculty. However considerably more effort is required to achieve this goal. This includes understanding and embracing Outcomes Research and the facilitation of routine measurement of clinical outcomes.

NHMRC Research Translation Faculty. The NHMRC incorporated the 'T3 research' concept into its 2013-15 Strategic Plan and thus established the NHMRC Research Translation Faculty, which now has a membership of over 2,860 NHMRC supported researchers. This Faculty provides clinical expertise from NHMRC researchers to assist in the formulation of T3 research strategies, which can then be facilitated by the NHMRC by its links with policy makers, consumer advisory groups and other professional societies. The tools available to the Faculty to achieve its goals of

translating clinical evidence into practice include (i) a dedicated website portal providing forums for the researchers to exchange information, (ii) an annual NHMRC Research Translation Faculty Symposium, and (iii) the establishment of this 'Case for Action', which is supported by health/disease-specific Faculty Steering Groups.

Outcomes Research. This concept has been best described by Clancy and Eisenberg[17], who defined outcomes research as 'the study of the end results of health services that takes patients' experiences, preferences, and values into account – is intended to provide scientific evidence relating to decisions made by all who participate in healthcare'. Accordingly this encompasses not only the health workers but also the policy-makers, health funders, and particularly the patients. The importance of this multidisciplinary approach is exemplified by considering a patient who fails to utilise an evidence-based medication following hospital discharge. This may occur because the clinician did not prescribe the medication, the nurse or pharmacist did not ensure the patient received the medication, the regulatory authorities restricted access to the medication, the medication cost was prohibitive for the patient, the patient had limited insight into their CVD and elected not to comply with the prescribed therapy, or all of the above. Hence evaluation must be of the relevant final clinical outcome if the success of the treatment is to be evaluated.

In an insightful editorial, Krumholz[18] summarises the key attributes to Outcomes Research emphasizing its (i) *multi-disciplinary approach* involving the biological sciences, clinical sciences, epidemiological sciences, psychological sciences, social sciences, health economics and statistical sciences, as well as policy-makers and health funders, (ii) *multi-analytical approach* including clinical randomised controlled trials, prospectively-designed observational clinical registry studies, interrogation of administrative datasets, economic analyses, meta-analysis, propensity analysis, and (iii) *multi-dimensional approach* that extends beyond T3 research to also incorporate safety monitoring, quality assurance, comparative effectiveness, and the integration of emerging technologies. Accordingly, Outcomes Research is a comprehensive, collaborative and essential to the improvement of future health care.

Outcome Measurements. Fundamental to Outcomes Research is the measurement of meaningful outcomes. If clinical outcomes are not quantitatively measured, then Outcomes Research is essentially impotent. Outcomes measurements may be derived from several sources including:

- *Administrative datasets* (e.g. hospital morbidity data, birth/death registries, Medicare)
- *Adverse event reporting systems* (e.g. hospital adverse event reporting systems)
- *Clinical registries* (e.g. Table 1).
- *Data linkage,* which combines the above datasets to create person-based longitudinal, records capturing multiple dimensions of patient care and outcomes

Of these, clinical registries potentially have the most utility for Outcomes Research but also are the most difficult and expensive to establish.

In Australia, there are a number of established, well-constructed clinical registries (Table-1) but there is a desperate need to further develop these. Although the Australian Stroke Clinical Registry is a comprehensive national registry that collects patient follow-up data three months following stroke, no such national registry exists for cardiac or peripheral vascular disease except for two industry-sponsored registries that each have less than 1,000 Australian patients. In contrast, in the United States, there are national registries monitoring both in and outpatient management of acute and chronic heart disease, heart failure, hypertension, and peripheral artery disease. Moreover these societies have developed both 'performance measures' and 'appropriate use criteria' in relation to many of these conditions. Although these criteria have been developed by the professional societies, there remains limited data concerning adherence to these performance measures and appropriate use of cardiovascular tests or procedures.

TABLE-1. **CURRENT AUSTRALIAN CARDIOVASCULAR DISEASE CLINICAL REGISTRIES**
Coronary Heart Disease/Other Cardiac Disorders. • Australian Cardiac Outcomes Registry (ACOR) – in development • Australian Cardiac Procedures Registry (ACPR) • Australian Society of Cardiothoracic Surgeons Database (ASCTS) • Coronary Angiogram Database of South Australia (CADOSA) • Global Registry of Acute Coronary Events (GRACE) • Melbourne Interventional Group Interventional Cardiology Registry (MIG) • Victoria Cardiac Arrest Registry • Victorian Cardiac Outcomes Registry (VCOR)
Stroke. • Australian Stroke Clinical Registry (AuSCR)
Peripheral Artery Disease. • Australasian Vascular Audit • Melbourne Vascular Surgeons Association Audit • Patient-centred Outcomes Related to Treatment Practices in PAD: an International Trajectory (PORTRAIT).

There are several different types of outcome measures, reflecting the purpose for which they were established. The types of outcome measurements include the following, although any particular measures does not necessarily belong exclusively to one type:

- *Cardiovascular Event Measures* – these are traditionally captured in clinical trials and include endpoints such as death and myocardial infarction
- *Safety Measures* – these include both clinical errors (e.g. drug administration errors) and procedure complications (e.g. interventional bleeding rates).
- *Process Measures* – these are often guideline-driven measures reflecting patient management such as door-balloon time, discharge medications and referral to rehabilitation.
- *Efficiency Measures* – these primarily reflect the cost of patient care, such as average length of stay and the completion of hospital discharge letters.
- *Patient-Reported Outcome Measures* (*PROM's*) – these relate to patient symptoms and are often related to the impact of the disease on quality of life.

There is an increasing awareness of the importance of PROM's within health care service delivery and thus why Outcomes Research strategies particularly focus on the importance of patient input. However capturing PROM's is logistically and financially challenging.

Outcome Assessment Criteria. The above outcome measures are often bundled together into specific assessment criteria to benchmark health care delivery between comparable health services or with accepted standards. These assessment criteria are typically categorised into the following:

- *Safety Criteria* – these usually exclusively focus on adverse events, where ideally there should zero events (especially for those that are avoidable).
- *Performance Criteria* – these are targeted at a particular disease management and are typically guideline-driven (e.g. acute myocardial infarction performance criteria)
- *Appropriateness Criteria* – these are also guideline-driven and focus on the indication for a particular investigation or procedure (e.g. percutaneous coronary intervention appropriateness criteria)

Within the United States, many performance and appropriateness criteria have been developed and published (Table-2); however within Australia, none have been developed. Considering that the evidence-base is international, it could be argued that Australia should adopt the US criteria. However the health care systems are different and potentially the expectations of the patients also differ. Thus whether specific Australian criteria need to be developed based upon the local clinical guidelines needs to be considered.

Irrespective of developing specific Australian outcome assessment criteria, it is imperative that these are assessed since few Australian hospitals routinely evaluate performance or appropriateness; although safety is being monitored via hospital standardised mortality ratios[19]).

TABLE-2. **USA CARDIOVASCULAR DISEASE OUTCOME ASSESSMENT CRITERIA**
Performance Criteria. • Acute Myocardial Infarction[20] • Cardiac Rehabilitation[21] • Chronic Heart Failure[22]
Appropriateness Criteria. • Cardiac Computed Tomography[23] • Cardiac Magnetic Resonance Imaging[24] • Cardiac Radionuclide Imaging[25] • Diagnostic Coronary Angiography[26] • Coronary Revascularisation[27]

The Importance of Outcomes Research in Australia. Establishing clinical registries and adopting the key principles in outcomes research outlined above may improve cardiovascular healthcare in three aspects (1) improved outcomes, (2) reduced costs, and (3) clinician engagement. The evidence supporting these improvements is outlined below.

1. Improved Outcomes. As would be expected, Peterson et al[8] confirmed that adherence to acute coronary syndrome clinical guidelines in the United States improved in-hospital mortality with a 6.3% mortality in hospitals with low adherence and 4.1% in those with high adherence. They concluded that for each 10% adherence to the Class I guidelines, there was a 10% reduction in in-hospital mortality.

The benefit of achieving improved guideline adherence with the implementation of clinical registries is well illustrated by the Swedish experience with Swedeheart. This acute coronary care national registry in Sweden was first established in 1991 and resulted in dramatic improvements in adherence to acute myocardial infarct guidelines between over a 12-year period. During this period, 30-day mortality fell by 65% and 12-month mortality by 49%[28]. Moreover in a controlled study involving the Swedish registry, implementation of a systematic quality improvement intervention further improved guideline adherence and outcomes[29].

The above US and Swedish studies exemplify the benefits of adhering to performances measures as derived from clinical guidelines, however compliance with criteria for appropriate use of tests and procedures will also improve outcomes. Ko et al[30] evaluated the adherence to coronary revascularisation appropriateness criteria in Canada and demonstrated both overutilization and underutilisation by clinicians. Moreover, they demonstrated that underutilisation is associated with an increased risk of adverse outcomes.

Clinical registries are the principal tool for outcomes research as they have an unrivalled ability to monitor guideline compliance in relation to performance and appropriateness of care. Furthermore, they have the ability to assess variability in care and thus identify high performers whose practices should be modelled and poor performers who may need assistance. These actions will improve outcomes for cardiovascular healthcare.

2. *Reduced Costs*. Improved quality does not imply increased costs. Reduced expenses have been shown to result from quality of care registries. This is best illustrated by the Swedish joint registry where identification of the optimal joint prosthesis resulted in a reduced requirement for prosthetic hip joint revisions, resulting in a substantial cost saving[31]. In cardiovascular health, guideline adherence would reduce events and thus readmissions resulting in significant costs-savings. Furthermore, more appropriate use of cardiovascular investigations would result in significant cost savings both in relation to avoidance of inappropriate investigations and undertaking appropriate life-saving procedures that may have been overlooked. These costs savings might well pay for the cost of a registry many times over. Appreciation of the potential cost savings in this outcomes research strategy has prompted the Swedish Government to increase its financial support of clinical registries from $10 to $45 million per year[31].

3. *Clinician Engagement*. Involvement of clinicians is essential in outcomes research. Not only is the feedback to the clinicians imperative if clinical practice is to change but also there is the potential for these 'frontline providers' to innovate. Thus by engaging the clinicians with feedback on their clinical practice, there is the potential for them to identify system improvements to further improve quality.

Furthermore, routine collection of data through a registry, particularly using opt-out data collection processes, provides the ability to develop quality improvement initiatives locally, state-wide and nationally. This means that individual project evaluation is possible using registry data and that beyond the scope of these studies, sustainability can also be measured. The Australian Clinical Stroke Registry data are being used in this way in a current NHMRC funded project (Stroke123 Project).

ACTION PLAN

As detailed above, Australia has the potential to achieve significant improvements in cardiovascular care by embracing Outcomes Research principles, thereby translating our clinical knowledge base into clinical practice and achieving improved patient outcomes. The NHMRC Research Translation Faculty has the capability to achieve this goal and this 'Case For Action' will outline the fundamental steps required to establish this for cardiovascular disease. Importantly, it should also be considered in the context of primary preventative measures, which are being deliberated by the Primary Care Steering Group.

The Cardiovascular Health and Stroke Steering Group propose that the NHMRC Research Translation Faculty 'Case for Action' involve the '**Utilisation of Appropriateness and Performance Criteria in the Management of Cardiovascular Disease in Australian Hospitals**'. Routinely undertaking outcome measures and applying performance/appropriateness criteria will benchmark clinicians and health systems, thereby fostering improvement in health care delivery. For this to be successful, the outcome measures must be collected, analysed and reported back to the clinicians/health system, so that clinical care improvement can be facilitated.

To achieve this objective, three steps are required:

A. Establish the NHMRC CVD Quality Care and Outcomes Research Network.
B. Establish National Appropriateness and Performance Criteria.
C. Develop National Cardiovascular Registries.
D. Feedback Reporting of Performance & Appropriateness Criteria.

The details involved in these steps are outlined below.

A. Establish the NHMRC CVD Quality Care & Outcomes Network

The NHMRC Research Translation Faculty is well positioned to establish a *Cardiovascular Disease Quality Care and Outcomes Research Workgroup* (CVD-QCOR Network) to foster the development of Outcomes Research within Australia and oversee the objective of this 'Call for Action'. The terms of reference for this workgroup are outlined below.

Scope. This national network will be a committee within the NHMRC Research Translational Faculty and will be responsible for the establishment and implementation of cardiovascular disease appropriateness and performance assessment.

Objectives. The specific objectives of the CVD-QCOR Network will include the following:

1. Oversee the development of a business case for national clinical cardiovascular registries
2. Develop Australian Appropriateness and Performance Criteria for Cardiovascular Disease.
3. Facilitate the establishment/development and sustainability of clinical cardiovascular registries for appropriateness and performance assessment, ensuring that participating hospitals are provided timely feedback
4. Educate healthcare workers, policymakers, and the broader community on the importance of appropriateness and performance assessment.
5. Promote translational research within the research community.

Reporting Relationship. The CVD-QCOR Network would operate within the NHMRC Research Translation Faculty and therefore would have a reporting line to the NHMRC Principal Committees.

Network Structure. The CVD-QCOR Network structure will include an overseeing executive committee that will co-ordinate the three disease-focussed working groups. The membership of these groups is outlined below.

1. ***CVD-QCOR Network Executive***. The details of the 'Executive' are summarised below.

   Functions: To co-ordinate the activities of the CVD-QCOR Workgroups
   Co-ordinate a CVD educational program on appropriateness and performance
   Promote translational research within the Australian research community
   Facilitate participation of interested ancillary organisations

   Membership (Table 3). Workgroup leads will be the core members of the Executive, with the executive committee chair rotating between these three, each for a period of 2 years.

   Education and Research Outcome Facilitator will be appointed by the Workgroup Leads. This person will be responsible for co-ordinating an educational program on appropriateness and performance assessment as well as promoting translational research within the research community. They will deliver a combined educational/promotional program involving all of the cardiovascular disorders included in the CVD-QCOR Network.

   NHMRC Principal Committees Representative will be appointed to facilitate communication between the Executive and the NHMRC Principal Committees.

   Affiliate Representatives (Table 3). These will be supernumerary members of the Executive will have a bidirectional communication purpose; that is to disseminate the activities of the CVD-QCOR Network to these interested parties and feedback to the Executive the potential support these organisations may provide in the Network achieving its goals.

   Scheduled Meetings: at least 6-monthly, with more meetings as required.

TABLE-3. **Cardiovascular Quality Care & Outcomes Research Network Executive Members**

• Executive Members:	Cardiology Outcome Workgroup Lead
	Stroke Outcome Workgroup Lead
	Peripheral Artery Disease Outcome Workgroup Lead
	Education and Research Outcome Facilitator
	NHMRC Principal Committees Representative
• Affiliate Representatives:	Australian Commission for Safety & Quality in Health Care
	Australian Institute of Health & Welfare
	Private Health Funds
	Indigenous Caucus
	NHMRC Community and Consumer Advisory Group
	National Heart Foundation
	National Stroke Foundation
	Cardiac Society of Australia & New Zealand
	Australia & New Zealand Society of Vascular Surgery
	Australian Stroke Clinical Registry
	Stroke Society of Australasia
	Australian Stroke Coalition
	Royal Australasian College of Emergency Medicine
	Australian College of Ambulance Professionals

2. ***CVD-QCOR Network Workgroups*.** Three groups will be established focussing on CVD.

Workgroups. CVD-QCOR Network - Cardiology Outcome Workgroup
CVD-QCOR Network - Stroke Outcome Workgroup
CVD-QCOR Network - Peripheral Artery Disease Outcome Workgroup

Functions. To develop Australian Appropriateness and Performance Criteria for CVD.
To establish/support a national disease-specific clinical registry with the capacity to undertake appropriateness and performance assessment.
To provide feedback to participating sites against a national benchmark.

Scope. The CVD-QCOR Network workgroups should address the above cardiovascular appropriateness and performance measures in relation to coronary, cerebrovascular and peripheral disorders and procedures. This is an extensive workload, so the Network should aim to establish the criteria and a corresponding clinical registry for one procedure or disease-process within each workgroup, in the first 2 years. It would be proposed that the first targets should include percutaneous coronary interventions, stroke and abdominal aortic aneurysms, drawing on the experience of established registries. Following consolidation of these initial registries, others should be evolved (eg atrial fibrillation, cardiac devices, rheumatic heart disease, carotid revascularisation, peripheral revascularisation).

Membership. This will require significant flexibility as different Workgroups will have different demands and therefore may require more (or less) representatives. The proposed core members for each of the individual workgroups are summarised in Table 4.

Workgroup Lead – this person will be responsible for the Workgroup achieving its objectives.

Director of the Appropriateness & Performance Criteria Committee – this person will be responsible for establishing nationwide appropriateness and performance criteria. This will involve establishing a representative committee that will obtain a consensus opinion. The criteria should be endorsed by affiliated professional societies.

Director of the Clinical Registry Management Committee – this person will be co-ordinate the management of the clinical registries, ensuring national uniformity in data collection.

Director of the Quality Care Monitoring Committee – this person will co-ordinate the data-analysis and assessment feedback to the participating sites.

Governance Officer – this person will ensure that appropriate governance processes are in place for the registries and quality care feedback.

Scheduled Meetings. At least quarterly.

TABLE-4. **Cardiovascular Quality Care & Outcomes Research Network Workgroup Core Members**

- Workgroup Lead
- Director of the Appropriateness and Performance Criteria Committee
- Director of the Clinical Registry Management Committee
- Director of the Quality Care Monitoring Committee
- Governance Officer

Modus Operandi. The CVD-QCOR Network will operate within the NHMRC Research Translation Faculty and therefore have the capacity to utilise its infrastructure (particularly the website portal) to promote communication and undertake activities such as:

- Scheduling meetings
- Teleconference facilities
- Face-to-face annual meetings at the NHMRC Research Translation Faculty Symposium
- Distribution of committee documents
- Conducting forums for feedback on appropriateness and performance criteria
- Engagement with clinical researchers

In addition to the Research Translation Faculty, the CVD-QCOR Network could potentially utilise other NHMRC infrastructures to educate the broader community on the importance of appropriateness and performance assessment.

Key Performance Indices. The success of the CVD-QCOR Network could be assessed by the following key performance indices:

1. Number of published appropriateness and performance criteria
2. Number of appropriateness and performance criteria endorsed by professional societies.
3. Number of established national clinical registries (with representation from each State)
4. Number of institutions participating in each national clinical registry
5. Timing of feedback to participating institutions (i.e. date of collection to returned analysis)
6. Number of institutions modifying practice as a result of feedback
7. Number of institutions demonstrating improved performance.

The timing to assess these indices will be 2 years at the earliest, with some requiring up to 5 years.

B. Establish National Appropriateness and Performance Criteria

Each of the three CVD-QCOR Network Workgroups will be responsible for establishing Australian Appropriateness and Performance criteria. These will require a national consensus and are best undertaken in collaboration with affiliated professional bodies and published in relevant scientific journals. The criteria will assist those developing and managing cardiovascular registries to ensure that appropriate data elements are collected. They will also provide guidance to the groups responsible for analysing and providing quality feedback to the participating institutions.

In developing the Appropriateness and Performance criteria, it would be rational to first develop performance criteria as these are generally simpler, well established and extensively used. In contrast, appropriateness criteria are often more complex and controversial. Which performance criteria should be developed first will also vary between the workgroups but generally those that are based upon hospital admissions are easier to adopt.

Specific directions that each of the CVD-QCOR Workgroups should consider are outlined below.

Cardiology Outcome Workgroup. Many performance and appropriateness criteria have been published from American-based professional societies (Table 2). The first performance criteria that should be evaluated by this group relates to Acute Coronary Syndromes. The Australian Commission for Safety & Quality in Health Care have developed and recently published an Acute Coronary Syndrome Clinical Care Standard[32]. This would be a useful basis for the performance criteria and an ideal candidate to first develop.

Stroke Outcome Workgroup. The Australian Stroke Clinical Registry is well established and already has a well developed performance measure for stroke. Moreover, it is one of the few stroke registries internationally also to collect and report patient three month follow-up data. Participation of additional institutions/stroke collaborations will further strengthen this national registry. The Australian Commission for Safety & Quality in Health Care are currently finalising clinical care standards for stroke and thus the performance criteria should incorporate the elements from these sources.

Peripheral Artery Disease Outcome Workgroup. The Australian Vascular Audit is also well established and may be used as an initial basis for developing peripheral artery disease performance criteria although significantly more details will be required.

It is anticipated that at least one disease-based performance criteria will have been developed from each of these workgroups within the next 12 months. The total number and timeline for subsequent performance measures and eventual appropriateness criteria, will vary for each workgroup. Once the Appropriateness and Performance criteria are established, detailed work will be required to develop and maintain datasets that capture the data elements required to monitor the criteria.

C. Develop National Cardiovascular Registries

This is the major challenge of this 'Call for Action', since clinical registries are labour-intensive, expensive, and appropriate governance is critical. However, the individual CVD-QCOR Workgroups are well placed to facilitate the development of national registries. The current status of CVD registries within Australia is heterogeneous and thus each workgroup will face different challenges as outlined below.

The development of the registries will need to be coordinated with the development and rollout of electronic health records in public and private hospitals across Australia, to ensure that these incorporate the functionality needed to capture the registry minimum datasets.

Cardiology Outcome Workgroup. An Australian national registry of cardiac disease is the least developed of the three CVD. Currently several State-based clinical registries are established for cardiac catheterisation procedures (Table 1) and representatives from each of these should be included in developing a national registry. If the acute coronary syndrome performance criteria are the first to be evaluated, then these procedural registries will be of value but will not capture all patients nor all the data elements required for the Clinical Care Standard. Thus an acute coronary syndrome registry will need to be established.

Stroke Outcome Workgroup. The Australian Stroke Clinical Registry is the benchmark CVD registry as it is well established with regular performance monitoring. Participation of additional institutions will further strengthen this national registry.

Peripheral Artery Disease Outcome Workgroup. The Australian & New Zealand Society of Vascular Surgery has a Peripheral Artery Disease clinical registry although participation is limited. Work will need to be undertaken to recruit more institutions into this registry.

D. Feedback Reporting of Performance & Appropriateness Criteria

This is a fundamental component of the quality care improvement. From the above registries, performance and appropriateness criteria can be determined and must be reported back to the participating institutions to ensure there is an improvement in health care. Institutions would need to be compared with a national average to benchmark their achievements; this would be facilitated by:

- National Analytic Unit: academic institutions with the capacity to undertake rapid data analysis and feedback to participating institutions would be ideal. The NHMRC are well placed to facilitate this arrangement.
- Australian Commission on Safety and Quality in Health Care (ACSQHC) is the government agency responsible for co-ordinating safety and quality of health care in Australia and thus will need to be extensively involved in the process.

Based on experience in establishing registries, a 2-3 year period would be required to efficiently establish a national registry with a quality of care reporting capacity. This should be undertaken as modules with one disease process developed at a time.

POTENTIAL IMPACT

Implementation of this Case for Action would result in substantial improvements in cardiovascular healthcare over the next 5 years including the following:

1. *Improved insights into contemporary cardiovascular practice*. Except for the recently established Australian Stroke Clinical Registry, there are limited insights into current clinical practice in most cardiovascular disorders. Without measuring clinical outputs via clinical registries, we do not have knowledge if our clinical practice is poor or satisfactory; moreover we do not know where our clinical practice could be improved. Initiation of clinical registries will provide this knowledge.

2. *Improved clinical outcomes and care via adherence to clinical guidelines*. With the identification of contemporary cardiovascular practice via well-constructed clinical registries and efficient feedback to participating sites, there would be improved adherence to clinical guidelines that would translate to improved outcomes as detailed above.

3. *Reduced Health Costs*. Although there would be an initial outlay in expenses for the establishment of clinical registries, this would eventually translate to costs savings with more efficient health care delivery via the appropriate use of cardiovascular investigations and procedures, as well as reduced hospital admission due to the prevention of subsequent cardiovascular events.

4. *A Clinical Culture of Innovation in Healthcare*. By identifying deficiencies in clinical practices and outcomes to the 'frontline health staff', there is a potential for them to identify system methods to improve practices. This innovative culture should be fostered thereby enhancing clinician engagement, since these are the primary people responsible for the delivery of healthcare. Importantly, with this culture of innovation, successful practices at one institution could be translated to others resulting in significant healthcare improvements within the community. Furthermore, this would facilitate outcomes research and enlist the assistance of other disciplines to further improve healthcare.

5. *Facilitate Cardiovascular Research*. Well-constructed clinical registries will provide clinical insights into cardiovascular patients who are frequently not included in clinical trials and thus not considered in clinical guidelines. Examples include, the elderly and patients with disabling systemic disorders such as end-stage renal disease or rheumatoid arthritis. Furthermore, the clinical registries will potentially provide an infrastructure to conduct clinical trials. The NHMRC should promote this cost efficient process.

6. *Feedback on Quality Care Processes*. An additional benefit of the clinical registries is to support other quality care processes within the health system. These include procedure safety monitoring, post-market surveillance of medications and new devices, and feedback to clinical guideline writing groups. These can be further enhanced by data linkage to established databases such as the PBS.

The importance of advancing this Case for Action strategy has been already realised by many developed countries and Australia must follow suit if we are to maintain our high standard of healthcare. If we continue without progressing this Case for Action, it is likely to result in continued spiralling health costs and no knowledge of where the problem lies or how to improve it.

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Cardiovascular Health and Stroke Case for Action – Declarations of Interests

The declarations of interests of Steering Group members, authors and contributors to this Case for Action are listed below.

Name and Role(s)	Interests declared
Prof Bronwyn Kingwell • Steering Group Chair	**Relationships** • Baker IDI – Heart and Diabetes Institute • Australian Academy of Sciences. **Grants** • Grants held • Future applications. **Speeches/lectures** • Scientific presentations including therapeutics.
Prof John Beltrame • Steering Group member • Author	**Relationships** • International representative for the American Heart Association Quality Care • Outcomes and Research Council • Collaboration with the American College of Cardiology National Cardiovascular Database Registry • International Consortium for Health Outcome Measurement – Member of Coronary Artery Disease and Heart Failure Working Groups • Principal Investigator of the Coronary Angiogram Database of South Australia (CADOSA) • Chair of Cardiology Network (SA Health) Data and Information Working Group. **Grants** • National Heart Foundation • South Australian Cardiovascular Research Development Program • National Health & Medical Research Foundation • Hospital Research Foundation. **Consultancy Fees/Honorarium** • Clinical presentations for Bayer Pharmaceuticals, Boehringer-Ingelheim, Pfizer and Servier Laboratories (possible). **Support for travel or accommodation** • Bayer Pharmaceuticals, Boehringer-Ingelheim, Servier Laboratoriesm Genram Research Foundation, Japanese Heart Foundation.
Prof Louisa Jorm • Steering Group member • Prevention and Community Health Committee (PCHC) primary contact	**Grants** • Holder of NHMRC Project, Partnership Project and Capacity Building Grants and applicant and likely future applicant for NHMRC Project, Partnership Project and Centre for Research Excellence grants. **Board membership** • Board member, NSW Bureau of Health Information. • Member (Appointed by Minister for Health), Alcoholic Beverage Advertising Code (ABAC) Adjudication Panel.
Prof David Thompson • Steering Group member	**Grants** • Holds NHMRC Centre for Research Excellence (CRE), Program and Project grants.
Prof Sandy Middleton • Steering Group member	**Relationships/activities** • Member, Stroke Society Australasia • Clinical Council Member, National Stroke Foundation (NSF) • Chair, Australian Clinical Stroke Registry • Co-chair, Acute Stroke Nurse Education Network • Board member, Agency for Clinical Innovation and Clinical Excellence Commission • Various Stroke Committee memberships (not paid).

Name and Role(s)	Interests declared
Prof Sandy Middleton *…continued*	**Grants** • Holds NHMRC Grants. **Support for travel or accommodation** • Clinical Council of National Stroke Foundation. **Meals/beverages** • NSF Clinical Council. **Speeches/lectures** • Numerous stroke-related presentations. **Other organisational roles** • Member National Stroke Foundation – Clinical Council.
Prof Amanda Thrift • Steering Group member • Research Committee contact	**Grants** • NHMRC Research Fellow 2013-2017 • Chief Investigator, NHMRC project grants, partnership grant, and Global Alliance for Chronic Disease (GACD) grant • Current, past and likely future application to NHMRC for research and people support **Activities** • Past President and committee member of the Stroke Society of Australasia. • Member, Stroke Society of Australasia and the High Blood Pressure Research Council. **Relationships** • Section Editor for the journal Stroke. No remuneration is received for this activity. • Member, Cardiovascular Monitoring Advisory Committee of the Australian Institute of Health and Welfare. • Committee Member for the Monash Partners Academic Health Sciences Centre - Neurosciences and Mental Health Stream. • Editorial board member of the International Journal of Stroke, and Neuroepidemiology • Member, Australian Stroke Clinical Registry (AuSCR) Steering Committee • Member, Australian Stroke Research Network Steering Committee • Member, Deakin University's Centre for Physical Activity and Nutrition Research (C-PAN) Advisory Committee • Member, National Stroke Foundation Research Advisory Committee • Employment • Employee of Monash University as head of a research group. **Board membership** • Board Member, National Stroke Foundation.
Prof Graeme Hankey • Steering Group member • Health Care Committee (HCC) primary contact	**Relationships** • The University of Western Australia, School of Medicine and Pharmacology • Department of Neurology, Sir Charles Gairdner Hospital. **NHMRC Grants** • Program: Improving Stroke outcomes; attenuating progression and recurrence • Project: Assessment of Fluoxetine In stroke recovery (AFFINITY) • National Centre of Research Excellence to improve management of peripheral arterial disease, James Cook University. **Honoraria** • Received for serving on: the executive committees of the AMADEUS trial (Sanofi- Aventis), ROCKET-AF trial (Johnson & Johnson) and BOREALIS trial (Sanofi- Aventis); the steering committee of the TRA 2 P-TIMI 50 trial; the stroke outcome adjudication committee of the ACTIVE-W, ACTIVE-A, RE-LY and AVERROES trials, and for speaking at sponsored scientific symposia and consulting on advisory boards for Bristol-Myers Squibb, Boehringer Ingleham, Bayer and Pfizer Australia.

Name and Role(s)	Interests declared
Dr Mark Wenitong • Steering Group member • PCHC secondary contact	**Grants** • Chief Investigator on several NHMRC funded program grants as well as CRE ATSI Early Childhood • Chief Investigator on "Getting Better at Chronic Disease" NHMRC funded.
Mrs Debra Cerasa • Steering Group member • HCC secondary contact	• Nil interests to declare.
A/Prof Christopher Zeitz • Author	• Nil interests to declare.

APPENDIX-5. Current and Past CADOSA Staff

Central Adelaide Local Health Network	
Tracy Air	Aakriti Lath
Alexandra Burdakova	Mary Leong
Jennifer Chan	Tini Luong
Carly Cilento	Meredith Matthews
Michael Contibas	Erin Meyer
Natasa Damjanic	Tharshy Pasupathy
Linda Gallina	Winston Reed
Matthew Hay	Laura Simeone
Bang Hoang	Kavi Sivasankar
Rachel Jakobczak	Sophia Tan
Ellen Kessling	Amy Tutunkoff
Clementine Labrosciano	Jing Wu
Northern Adelaide Local Health Network	
Aakriti Lath	Christine Schutz
Ellen Scheir	Lynda Tully
Southern Adelaide Local Health Network	
Lucy Blazincic	Julie Mills
Lauren Hastwell	Fiona Wollaston
Calvary (Adelaide) Hospital	
Natasa Damjanic	Sophia Tan