

The Australian and New Zealand Society of Cardiac and Thoracic Surgeons Database Program – Two Decades of Quality Assurance Data



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Received 27 February 2019; online published-ahead-of-print 18 March 2019

Over two decades, the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) cardiac surgery database program has evolved from a single state-based database to a national clinical quality registry program and is now the most comprehensive cardiac surgical registry in Australia. We report the current structure and governance of the program and its key activities.

Keywords

Clinical quality registry • Cardiac surgery • Database program

Introduction

The Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) Database began in 1999 [1–4]. Formulated as a demonstration project in the state of Victoria, Australia with six public hospitals, it is now the national database with 96% of the public hospitals and several private hospitals contributing. The first New Zealand site is set to come on board in 2019 and other New Zealand sites are currently being engaged. To date, the database has collected data from over 130,000 procedures performed in 40 hospitals.

The quality and safety purposes of the Database are similar to other international registries, including the National Adult Cardiac Surgery Audit in the United Kingdom, and the Society of Thoracic Surgeons Adult Cardiac Surgery Database in the United States, which collects data worldwide [5,6]. Clinical quality registries have been demonstrated to be cost-saving endeavours, in part due to their beneficial

impact on reducing complications and mortality through feedback to units identified as outliers during benchmarking activities [7]. This Database is thus an invaluable quality assurance program for Australia.

Data Capture and Submission

Hard copy case report forms are used, which include key data definitions for reference. Each site has a dedicated data manager who manually checks and enters data into an electronic web form (<https://anzscts.registry.org.au>) or by file upload via a custom secure file transfer process.

Activities

The principal function is collection and analysis of data to facilitate comparative performance review. Data is also used

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as a platform for surgical outcomes research. The program is a declared activity under Commonwealth Legislation.

Peer Review

To effect peer review, patient data is reviewed quarterly and annually against a set of key performance indicators (KPIs). The data is analysed and reported according to procedure type. The reviews are evaluated by the Steering Committee and units whose outcomes fall outside the upper 99.7% control limit are monitored in accordance with the Database's outlier escalation policy.

Key Performance Indicators

Units are evaluated against key parameters of performance (Table 1). The original performance indicators introduced in 2001 have been modified to be more clinically relevant [1]. The five clinical outcomes (mortality, reoperation for bleeding, deep sternal wound infection, derived new renal insufficiency and permanent stroke) are used for peer review while the remaining administrative data points are used in online and annual reports to compare unit activity at a national level. The data completeness for these KPIs is more than 95%, thus ensuring minimisation of selection bias.

A validated preoperative risk prediction model is used to calculate risk adjusted 30-day mortality rates for isolated coronary artery bypass graft (CABG) procedures, isolated valve procedures, CABG plus valve procedures, and the Group of all other procedures [8]. This model was developed using data collected by the ANZSCTS Database between July

Table 1 Key Performance Indicators used by the ANZSCTS Database Program in 2001 and 2018.

2001	2018
30-day mortality and risk adjusted mortality	30-day mortality and risk adjusted mortality
Haemorrhage requiring return to theatre	Return to theatre for bleeding or tamponade
Sternal infection	Deep sternal wound infection
Postoperative stroke	New renal insufficiency
	Permanent stroke
	Blood product usage
	Time in intensive care
	Ventilation/intubation time
Length of hospital stay	Pre-procedural length of stay
	Post-procedural length of stay
Postoperative myocardial infarction	

Abbreviation: ANZSCTS, Australian and New Zealand Society of Cardiac and Thoracic Surgeons.

2001 and June 2008 and is thus specifically suited to estimate risk for the Australian cardiac surgery population.

Annual Reporting

Reports for isolated coronary artery bypass grafting, aortic valve, and combined operations are published (<https://anzscts.org/database/about/#reports>). The focus is on the overall performance of all contributing hospitals and individual unit level comparisons in a de-identified manner. Since 2017, the annual reports have introduced a "theme", which is a detailed examination of an outcome or a procedure. In 2017, the theme was blood product use in elective isolated coronary artery bypass grafting.

Auditing

The regular data audit process involves approximately 5% of cases for each hospital, randomly selected and independently audited 3-yearly against 58 key variables as well as verifying total annual case submission numbers [9]. In addition, a regular dialogue is established with data managers to continually query and correct incomplete or inconsistent data.

Management and Governance of the Program

The School of Public Health and Preventive Medicine within Monash University, Melbourne, Australia manages the database with three full-time staff members. The committee structure includes the National Steering Committee, the Research Committee and the Peer Review and Quality Assurance Committee.

National Steering Committee

Membership is via nomination by the ANZSCTS and endorsement by existing voting members on the Committee. The voting members include the data custodian, a representative from the ANZSCTS Executive Committee, surgical or clinical representatives from each jurisdiction, an epidemiologist, and a registry expert from Monash University. Membership to the Committee is reviewed every 3 years.

The responsibilities include:

- Monitoring performance of units
- Identifying and reporting on opportunities for quality improvement arising from data
- Establishing and maintaining liaison with governments, health authorities, and other relevant organisations on issues of quality and safety within the cardiac treatment arena
- Supervision of the content and production of quarterly and annual reports

- Determining, reviewing, and endorsing policies, standard operating procedures, data definitions, risk adjustments, and information to be distributed to patients
- Providing advice on the strategic development of the ANZSCTS Database

Research Committee

The Committee includes cardiac surgeons, the data custodian, the database program manager, researchers and an epidemiologist. It approves and supervises projects that utilise the data held by the Database.

The responsibilities include:

- Propose and implement data access, publication, and reporting policies
- Make recommendations on the content of reports produced by the ANZSCTS Database management team
- Review all applications for data access according to ANZSCTS Database policies and procedures
- Review and approve all publications and reports that have used the ANZSCTS Database, prior to publication

Peer Review and Quality Assurance Committee

This Committee is activated as part of the outlier escalation plan. It is comprised of members of the ANZSCTS including:

- President, ANZSCTS
- Vice-President, ANZSCTS
- Royal Australasian College of Surgeons (RACS) Cardiothoracic Surgery Specialty-elected Councillor
- Chair of the Board of Studies in Cardiothoracic Surgery
- Chair of the Science and Education Committee of ANZSCTS
- Chair of the Board of The Australasian Cardiac Surgery Research Institution Limited
- Ordinary or senior member of ANZSCTS, elected by ballot of all members of the Society

The responsibilities include:

- Oversee the confirmation, further investigation and review of performance outliers (both favourable and unfavourable), as required
- Liaise and communicate with the management of cardiac surgical units identified for review
- Coordinate its activities with the ANZSCTS Database Steering Committee
- Generate an action plan to remediate the problem identified

Database Storage and Security

The web interface is housed on an IIS Web Server at Monash University Clayton and Noble Park sites, with failover

between the two sites. Data storage is restricted to the ISO 27001 compliant Microsoft SQL Server Failover Cluster, which is located within the institutions' high security 'Red Zone' on the Monash University's server. Nightly data backup to an off-site data storage facility ensures that data is retained in the event of a disc failure or fire. The backup facility is encrypted using 2,048 bit encryption.

To ensure the privacy and confidentiality of the web based system, the ANZSCTS Database Program conforms to the framework for Australian clinical quality registries set out by the Australian Commission on Safety and Quality in Health Care [10].

Funding

The Program is supported by funding from various stakeholders. The public hospitals located in the states of Victoria, New South Wales, and Queensland are funded by the state governments. Elsewhere, the hospitals are self-funded. Funds are primarily used for the quarterly peer review and monitoring activities, delivery of the annual reports, ongoing maintenance and development of the online web system, and the audit program.

Research and Outputs

Currently, there are 26 active research projects, each with approval from institutional Human Research and Ethics Committees and the ANZSCTS Database Research Committee. Over 70 projects have been successfully completed, generating over 75 papers (Figure 1).

Linkage with the Australian Institute of Health and Welfare National Death Index (NDI) database now occurs biannually. This linkage provides long-term outcomes for cases recorded in the ANZSCTS Database.

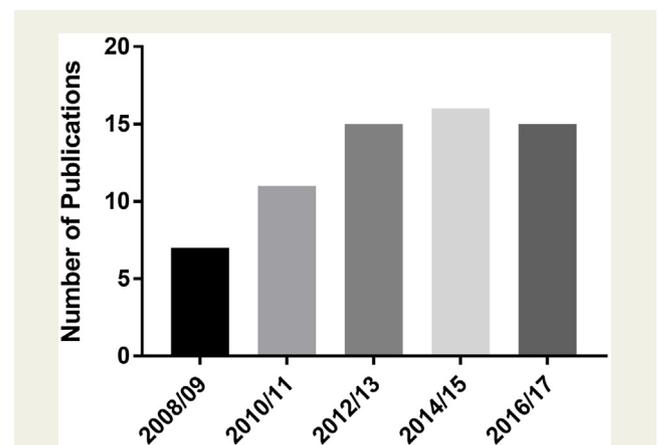


Figure 1 Number of ANZSCTS Database publications over the last 10 years.

Abbreviation: ANZSCTS, Australian and New Zealand Society of Cardiac and Thoracic Surgeons.

Current and Future Initiatives

Current activities and future initiatives are discussed by the Steering Committee and its subcommittees at regular meetings.

A previous notable initiative of the Database was a pilot study of a nested randomised controlled trial with the Database [11]. This successful endeavour highlighted how involvement of the ANZSCTS Database can benefit the data collection process for future clinical trials. In addition, research into how best the registry can provide feedback to surgeons and stakeholders has provided valuable insights into future reporting strategies for the registry [12].

Initiatives in 2019 include the expansion of the ANZSCTS transcatheter aortic valve replacement module of the dataset, including piloting a 12-month follow-up process.

At present, long-term follow-up data is collected through linkage with the NDI; however, the Database intends to incorporate a 12-month follow-up for all cardiac surgery patients in the future. This will enable the collection of patient reported outcome measures (PROMs) which will allow cost-effectiveness research initiatives to be undertaken for the first time as part of the registry framework.

Long-term goals for the Database include expanding the dataset through linkages with other registries and establishing a cardiac surgical prosthesis registry.

At present, the Database captures cases from 96% of the public hospitals in Australia and approximately half of the private cardiac surgery units. A key focus of the Database continues to be site engagement of private hospitals, with the aim of achieving complete coverage in Australia and New Zealand.

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