ANZSCTS National Cardiac Surgery Database Program

Dr Lavinia Tran, Project Manager & Research Fellow
Prof Chris Reid, Principal Investigator.

Centre of Cardiovascular Research and Education (CCRE) in Therapeutics

ANZSCTS RESEARCH PROGRAM
ORGANISATIONAL PROFILE

CCR E Director: Prof Henry Krum
Assoc. Director: Prof Chris Reid

Caulfield Clinical Trials Centre

Translational Research Clinical Pharmacology Unit

CIDMU - Data Management Centre
- Informatics Unit

Over 50 staff members
10 Research Fellows
11 General admin
15 Informatics Unit
9 Research Assistants
10 Nurses
Students and Visiting academics
ANZSCTS National Database Program
(Australian and New Zealand Society of Cardiac and Thoracic Surgeons)

Adult Cardiac Surgery database.

1. Quality Assurance through peer review
2. Benchmarking of cardiac surgical performance
3. Research

Funding: Public & Private
Participating (28)

Public Hospitals (20)
- Austin, VIC
- Royal Melbourne, VIC
- Monash Medical Centre, VIC
- St Vincent’s, VIC
- Geelong, VIC
- The Alfred, VIC
- John Hunter, NSW
- Prince of Wales, NSW
- Westmead, NSW
- St George, NSW
- St Vincent’s, NSW
- Liverpool, NSW
- Royal North Shore, NSW
- Royal Prince Alfred, NSW
- Flinders Medical Centre, SA
- Royal Adelaide, SA
- Royal Perth, WA
- Sir Charles Gairdner, WA
- Canberra, ACT
- Townsville, QLD

Private Hospitals (8)
- Mater Health Services QLD
- Lake Macquarie, NSW
- Cabrini Health, VIC
- Jessie McPherson, VIC
- Holy Spirit Northside, QLD
- Epworth, VIC
- St John of God, WA
- Peninsula Private, VIC

Non-participating (20)

Public Hospitals (4)
- *Prince Charles, QLD
- *Princess Alexandra, QLD
- Fremantle, WA
- Royal Hobart, TAS
  *joining soon

Private Hospitals (16)
- Melbourne, VIC
- Knox, VIC
- St Vincent’s, VIC
- Warringal, VIC
- St George, NSW
- Strathfield, NSW
- Westmead, NSW
- Prince of Wales, NSW
- Sydney Adventist, NSW
- Wakefield, SA
- Mount, WA
- Hollywood, WA
- Ashford hospital, SA
- John Flynn, QLD
- Brisbane Waters, QLD
- Greenslopes, QLD

20/24 (80%) of Public Hospitals are participating in the Program.
ANZSCTS National Database Program
(Australian and New Zealand Society of Cardiac and Thoracic Surgeons)

TIMELINE:

• Pilot study in 2000 for Victorian public hospitals only. Minimum dataset defined.
• Funding from DoH VIC
• Private hospitals joined
• NSW public hospitals joined in 2008 with funding from CEC
• Revision of data definitions in 2008
• New Zealand joined ANZSCTS society & database in 2011
• Research Program established 2011
Maturation of the database = Increased database value = Research requests.

- **Data requests from:**
  - Individual surgeons
  - Hospitals
  - Government
  - Industry
  - Students

- **Reasons:**
  - Hospital internal audits
  - Benchmarking
  - Research (publications, theses, conferences)
  - Linkage studies
  - General aggregate information
ANZSCTS Research Program

- Pre 2011:
  - Informal data/research requests
  - Request come through via telephone, email, meetings etc
  - Analyses were conducted on an ad-hoc basis
  - Investigators could requested copy of de-identified dataset.
  - Analyses could be conducted by investigators themselves or CCRET

- In 2011, we saw a significant increase of research requests (10-20 per year)

- Processes to manage the Research component became apparent.

- Establishment of the ANZSCTS Research Program
ANZSCTS Research Committee

- Formal Research Committee was formed
  - Membership by nomination
  - Committee members include surgeons, retired surgeons, non-surgeons, and academics

- Development of a Research Proforma and processes

- ANZSCTS-RC meets quarterly, review new projects and the progress of ongoing projects
ANZSCTS Research Program Process

Investigator contacts Registry and request data for research

Proforma sent to primary investigator

Porforma returned to ANZCTS in time to be tabled at the next ANZSCTS-RC meeting

Provisionally approved pending responses to qns.

ANZSCTS-RC meet and review projects

Approve project

Meeting set up with investigators and DMC staff.

Results

Investigators sent data package

Investigators work on scripts

Scripts are checked by CCRET and run on current dataset

Output sent to investigators.


Progress reports
ANZSCTS Research Proforma
ANZSCTS Research Program Process

1. Investigator contacts Registry and request data for research
2. Proforma sent to primary investigator
3. Proforma returned to ANZCTS in time to be tabled at the next ANZSCTS-RC meeting
4. ANZSCTS-RC meet and review projects
5. Approve project
6. Provisionally approved pending responses to qns.
7. Meeting set up with investigators and DMC staff.
8. Investigators sent data package
9. Investigators work on scripts
10. Scripts are checked by CCRET and run on current dataset
11. Output sent to investigators.
12. Results
13. Progress reports
ANZSCTS Research Program - Research Committee

- New project proposals are critically reviewed at the meeting for any issues regarding:
  - objectives (similar to other studies?)
  - methodology (stats)
  - ethics (require extra HREC approval?)
  - timeline (feasibility)
  - relevance (clinically and/or of interest to who?)
  - costs/staff time (fee for service?)

- New projects are either ‘approved’, ‘provisionally approved’ (pending revisions), or ‘rejected’ by ANZSCTS-RC.

- Outcome of applications are ratified at the National SCM the following week. Investigators notified afterwards.
ANZSCTS Research Program Process

Investigator contacts Registry and request data for research

Proforma sent to primary investigator

Porforma returned to ANZCTS in time to be tabled at the next ANZSCTS-RC meeting

Provisionally approved pending responses to qns.

ANZSCTS-RC meet and review projects

Approve project

Results

Meeting set up with investigators and DMC staff.

Investigators sent data package

Investigators work on scripts

Scripts are checked by CCRET and run on current dataset

Output sent to investigators.


* Progress reports
ANZSCTS Research Program

- Investigators meet with Data Management Center to discuss project requirements and timelines.
  - considerations for Honours & PhD projects
- Statistical support required?
- Additional data required?
  - linkage studies
  - clustered RCT studies
  - collaborations with external researchers
- Expertise required
  - involvement of other clinicians or academics
- Ethics
  - most research covered under our
  - if using patient identifiers, submission to HREC required.
ANZSCTS Research Program Process

Investigator contacts Registry and request data for research

Proforma sent to primary investigator

Porforma returned to ANZCTS in time to be tabled at the next ANZSCTS-RC meeting

Provisionally approved pending responses to qns.

ANZSCTS-RC meet and review projects

Approve project

Meeting set up with investigators and DMC staff.

Results

*Investigators sent data package

Investigators work on scripts

Scripts are checked by CCRET and run on current dataset

Output sent to investigators.

ANZSCTS Research Program

- Investigators given the **ANZSCTS Data Analysis Package**. Consists of:
  - 10% de-identified sample of the database (~8000 cases)
  - Data definitions manual
  - ANZSCTS data release policy
  - Sample syntax for use

- Investigators are expected to have a working knowledge of SPSS and/or Stata.

- We do not teach external investigators/students how to use statistical packages
ANZSCTS Research Program Process

Investigator contacts Registry and request data for research

Proforma sent to primary investigator

Porforma returned to ANZCTS in time to be tabled at the next ANZSCTS-RC meeting

Provisionally approved pending responses to qns.

ANZSCTS-RC meet and review projects

Approve project

Meeting set up with investigators and DMC staff.

Results

Investigators sent data package

Investigators work on scripts

Scripts are checked by CCRET and run on current dataset

Output sent to investigators.

* * *

Publications, theses, conference presentations.
Acknowledgment and authorship.
ANZSCTS Research Program

- Investigators email syntaxes/script back to DMC and we run them on the current dataset.
  - The research dataset is ‘locked data’. All reports and projects will utilise this locked dataset for the year.

- The scripts are checked by DMC

- The result outputs are sent to the investigators

- Time consuming depending on the complexity of the project.

- For modelling projects, investigators must attend the DMC to work on the data.
ANZSCTS Research Program - DMC Site visit

- For investigators to wish to come in and work on the data, the DMC offers:
  - Secure desktop or laptop (USB and internet disabled)
  - Work station (hot desk in the DMC)
  - License for SPSS and/or Stata

- Access to DMC is bookable via our ANZSCTS database coordinators.
- Access to staff time during the visit is limited and must be booked.

- At present, we have 1-2 site visits per week. Usually half to whole day.
ANZSCTS Research Program Process

- Investigator contacts Registry and request data for research.
- Proforma sent to primary investigator.
- Porforma returned to ANZCTS in time to be tabled at the next ANZSCTS-RC meeting.
- Provisionally approved pending responses to qns.
- ANZSCTS-RC meet and review projects.
- Approve project.
- *Progress reports.*
- Results.
- Investigators sent data package.
- Investigators work on scripts.
- Scripts are checked by CCRET and run on current dataset.
- Output sent to investigators.
- Publications, theses, conference presentations.
  Acknowledgment and authorship.

Meeting set up with investigators and DMC staff.
ANZSCTS Research Progress Report
ANZSCTS Research Program Process

- Investigator contacts Registry and request data for research
- Proforma sent to primary investigator
- Porforma returned to ANZCTS in time to be tabled at the next ANZSCTS-RC meeting
- Provisionally approved pending responses to qns.
- ANZSCTS-RC meet and review projects
- Approve project
- Meetings set up with investigators and DMC staff.
- Investigators sent data package
- Investigators work on scripts
- Scripts are checked by CCRET and run on current dataset
- Output sent to investigators.
- Results
- Progress reports
- Publications, theses, conference presentations.
- Acknowledgment and authorship.
ANZSCTS Research Program Challenges
ANZSCTS Research Program Process

1. Investigator contacts Registry and request data for research
2. Proforma sent to primary investigator
3. Proforma returned to ANZCTS in time to be tabled at the next ANZSCTS-RC meeting
4. Provisionally approved pending responses to qns.
5. ANZSCTS-RC meet and review projects
6. Approve project
7. Meeting set up with investigators
8. Investigators sent data package
9. Investigators work on scripts
10. Results
11. Scripts are checked by CCRET and run on current dataset
12. Output sent to investigators.
13. Progress reports
15. Acknowledgment and authorship.
ANZSCTS Research Program - Challenges

- Time taken for critical reviews
- ANZSCTS-RC meeting time (surgeons, academics, after hours meetings). Need a quorum.

- Meeting time
  - allocation of staff time / project time
- If student / investigator comes into the department work on the data. This can increase staff time.

- "Supervision" time for external students/investigators
- Resources (computers, statistical package licenses, desk etc)
- Who’s responsible? (DMC, investigator, student, supervisor?)
ANZSCTS Research Program - Challenges

- Project hiatus (investigator priorities)
- Funding
- Students move on.....
ANZSCTS Research Program - Challenges

- Research Program currently unfunded.
  - support via project/program grants.
  - some projects will have funding for the student/investigator, but not DMC.

- What do we charge?
  Fee-for-service reports (conference data, hospital reports etc)

- Payment by publication or acknowledgements
  - Therefore, it is vital that project progress through to publication

- Projects have ‘expiry dates’ and are monitored via 6 monthly progress reports.
ANZSCTS Research Program – Future Directions

- Remote secure access to data for investigators.
  - site visits not required
  - beneficial for non-VIC investigators
  - alleviates the need for computers, laptops, individual licenses.

- Capped number on research projects annually.

- ANZSCTS society sponsored research for trainees?

- Year Research Focus?