The Australian Stroke Clinical Registry: health services research and clinical trials

Registry Special Interest Group, 1pm 16th November 2018, Melbourne

Professor Dominique Cadilhac

@AustStrokeReg
www.auscr.com.au
Overview

• Background to AuSCR for the uninitiated
  – Advancing ‘registry science’

Stroke survivor follow-up in a national registry: Lessons learnt from respondents who completed telephone interviews

Karen M Barclay-Moss¹, Natasha A Lannin²,³, Brenda Grabsch¹, Monique Kilkenny¹,⁴ and Dominique A Cadilhac¹,⁴
Background

• In Australia, stroke affects 1 person every 9 minutes
• Leading cause of adult disability and death
• Variability in the quality of care impacts outcome
• Returning home after stroke is challenging and the majority of survivors have unmet needs
  – psycho-social, mobility, speech, activities of daily living, memory and cognition, financial
• Many facets of health services research are possible
• The **Australian Stroke Clinical Registry** was established to monitor care and outcomes for acute stroke and transient ischemic attack
• Opt-out approach, with waiver for deaths in hospital
• Online data collection integrated stroke data management system: the **Australian Stroke Data Tool (AuSDaT)**
• Hospital staff access online real-time data reports and data exports
• Patient follow-up via survey 90-180 days
• A secondary purpose is to be a resource for research
AuSDAT facilitates ‘collect once use many’

Integrated, online data management system
AuSCR – Progress over 10 years

83 Approved hospitals
71671 Stroke/TIA Episodes
31902 Patients completed Follow Up

Opt-out rate: 2.3%
Annual linkage to national death index

Patient Information Sheet:
“Collecting this information is necessary in order to contact you for follow-up, but also to accurately link your hospital stay with other hospital and health information systems related to, for example, any subsequent rehabilitation, health care needs and/or health outcomes so that we know how well you have recovered.”

At 90-180 days: “Would you be willing to be contacted in the future to hear about possible stroke research projects that you may be eligible for?”
2017 AuSCR User Survey

**What do you use the AuSCR live reports for?**

- Informing team meetings: 68%
- To inform quality improvement: 50%
- Ad hoc presentations: 54%
- Reporting to hospital executives: 40%
- Checking for missing data: 20%
- Informing accreditation processes: 12%
- Presenting at conferences/forums: 10%
- Other (please specify): 0%
- Obtaining numbers for ethics reports: 0%
- Unsure: 0%

**Do you believe that involvement with the AuSCR has led to improvements to the hospital’s stroke services?**

- Yes: 68%
- No: 20%
- Unsure: 12%
Telephone follow-up was more expensive but more efficient than postal in a national stroke registry

Natasha A. Lannin\textsuperscript{a,b,c,d,*}, Craig Anderson\textsuperscript{d,e}, Joyce Lim\textsuperscript{d}, Kate Paice\textsuperscript{f}, Chris Price\textsuperscript{g}, Steven Faux\textsuperscript{h}, Christopher Levi\textsuperscript{i}, Geoffrey Donnan\textsuperscript{f}, Dominique Cadilhac\textsuperscript{f,j}

RCT: follow up method modified Dillman protocol telephone versus post (559 randomised)

- Response rate similar between the telephone and post (0.57%, 95%CI -4.8% to 6%).
- Shorter time to complete follow-up via telephone
- Average cost of telephone follow-up was greater ($13.82 versus $9.18 post)
Discharged weekend: fewer problems with mobility, self-care, undertaking usual activities, pain/discomfort and anxiety or depression. But had increased risk of death.

More problems with self-care, pain, anxiety or depression and impacts on usual activities.
Does improving care make a difference?

Within 180 days:
70% reduced hazard of death
18-point increase in quality-of-life

Cadilhac DA, Andrew NE, Lannin NA, et al. Stroke; 2017;48:1026-1032
Hospital performance over 3 years

- Treated in a stroke unit
  - 2014: 1.07
  - 2015: 1.16

- Discharged on an antihypertensive medication
  - 2014: 1.18
  - 2015: 1.25
  - 2014: 1.23
  - 2015: 1.09

- Received thrombolysis if an ischaemic stroke
  - 2014: 0.77
  - 2015: 0.76

- Discharged with a care plan
  - 2014: 1.03
  - 2015: 1.31

AuSCR
Australian Stroke Clinical Registry
Improvement Science: facilitated quality improvement program

Strokelink (QLD) STELAR (VIC)

Multidisciplinary, externally facilitated workshops

Implementation of evidence-based agreed action plan by local team

Study

Review of performance data

Plan

Do

Act

Plan

Do

Act

The net change in the composite outcome increased 16% after implementation with a non-significant decay effect at 12 months post implementation (12% improvement compared with pre-implementation or 4% decay effect).
Motivating clinician behavior change – feedback of achievable benchmarks

- Stroke Unit Care: 33, 63, 68, 68
- tPA for ischaemic stroke: 11, 9, 18, 13
- Aspirin in less than 48 hours (excludes ICH): 35, 42, 37
- Mobilised same day or day after: 52, 59, 48
- Oral screen before medications: 40, 39, 23, 38

My hospital: 94
Peer Hospital: 79
State: 93
All: 76

Benchmark: 94

Australian Stroke Clinical Registry

MONASH University
Medicine, Nursing and Health Sciences
Motivating clinician behavior change – feedback of 90-180 day patient reported outcomes

AuSCR QLD: Median HRQoL score (VAS) by hospital

HRQoL: Health related quality of life, VAS: Visual analogue scale of the EQ-5D

Scores adjusted for age, gender, stroke severity, stroke type, in-hospital stroke, and previous stroke

Normative population aged 70-79 years 83: (sd 23)
QLD Median VAS score
Clinically meaningful difference = 8 points (Kim et al, 2015)
YOUR HOSPITAL
Sites below the median
Sites above the median
Competing projects and responder burden
Victorian Stroke Telemedicine

17 Hospitals

2018

Mildura
Swan Hill
Echuca
Albury-Wodonga
Horsham
Hamilton
Bendigo
Shepparton
Wangaratta
Ballarat
Warrnambool
Werribee
Bairnsdale
Bendigo
Warragul
Traralgon
Wonthaggi
The VST Project: 2010-2017

Stroke symptom onset < 4.5 hours

Paramedics notify hospital

Regional Hospital

- Rapid triage and assessment
- CT brain and CTA

Phone 1300 TELEMED

Rapid review of brain

Assessment by VST stroke specialist

90 day outcomes

Acute stroke therapies delivered within acceptable timeframe - tPA, ECR -

Video consultation with family and regional clinician

Phone 1300 TELEMED

Assessment by VST stroke specialist

90 day outcomes
Aim: To evaluate a nurse-initiated multidisciplinary organisational intervention to improve the Triage, Treatment and Transfer of stroke patients in Emergency Departments

Design
- Implementation study using a Cluster RCT
- EDs randomised into two groups: intervention or control
- Intervention becomes new ‘business as usual’
- Evaluated at the level of the patient

90-Day Computer assisted telephone interview (CATI)
- Death and dependency
  - Modified Rankin Scale (mRS) ≥ 2, Barthel Index (BI); Short Form 36 Health Questionnaire (SF-36)
- Other outcome data - processes of care
  - Retrospective medical record audit from a prospectively recruited patient sample

Principal investigator: Prof Sandy Middleton
**Methods: Working smarter not harder...**

- Meetings to avoid multiple contacts with patients at the same time-point
- Process of data collection and data sharing developed
- Relevant ethics and project governance committee approvals
- Memorandums of Understanding established

<table>
<thead>
<tr>
<th></th>
<th>AuSCR</th>
<th>VST</th>
<th>T³</th>
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</thead>
<tbody>
<tr>
<td><strong>Acute stroke</strong></td>
<td>+ TIA admitted</td>
<td>&lt; 4.5 hrs of onset admitted and non-admitted cases</td>
<td>Treated on Stroke Unit</td>
</tr>
<tr>
<td><strong>Follow up</strong></td>
<td>mail/phone</td>
<td>mail/phone</td>
<td>phone</td>
</tr>
<tr>
<td><strong>Consent procedure</strong></td>
<td>Opt-out</td>
<td>Opt-out</td>
<td>Opt-in/ Opt-out</td>
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</table>
AuSCR governance structure

Steering committee
Prof Sandy Middleton

Management Committee
Data Custodian Florey

Reperfusion & Telemedicine
Research Task Group
Data Linkage
ED dataset working group
Data Analysis (Monash Uni)

Researchers apply to the AuSCR to recruit participants for individual research projects.

Following project approval the AuSCR contacts eligible registrants on behalf of researchers.

Eligible registrants interested in research project participation contact researchers directly or complete research surveys that they post back to researchers.

Prevent 2nd Stroke: a pilot study of an online secondary prevention program for stroke survivors

Alexandra M.J. Denham,1,2 Sean Halpin,3 Laura Twyman,1,2 Ashleigh Guillaumier,1,2 Billie Bonevski1,2

Aust NZ J Public Health. 2018; Online; doi: 10.1111/1753-6405.12794
Researchers apply to the AuSCR to link data to external datasets for individual research projects.

Following project approval the AuSCR provides:
- Eligible de-identified datasets with a project linkage key (ID) to Monash University.
- Submits personal information & project linkage key (ID) to the relevant Data Custodian, External Data Linkage Unit or Data Integrating Authority.

External Data Linkage Unit or Data Integrating Authority provides de-identified datasets with project linkage key (ID) to Monash University.

Authorised Monash University staff merge content data using the project linkage key (ID) and store the data in a secure environment.

Researchers access merged data for analysis using via a secure environment e.g. Safe Haven or SURE.
Enabling data access for research

- Since 2011 data have been requested for research
  - 21 applications received, 19 approved and 2 currently under review
  - 11 peer reviewed publications from 12 completed projects to date
Potential for research and a greater understanding of long term patient outcomes

- Medicare and Pharmaceutical benefits data (2017)
- National death data
- State-government pre-hospital & hospital data
- Paediatric
- Follow-up surveys

Other projects:
- Screening study for Fabry’s disease
- Clinical trials
- Unmet needs survey

National data set

AuSDaT
AUSTRALIAN STROKE DATA TOOL

AuSCR
Australian Stroke Clinical Registry
<table>
<thead>
<tr>
<th>Example projects*</th>
<th>RCT</th>
<th>Comparative effectiveness/data linkage</th>
<th>Surveys</th>
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</thead>
<tbody>
<tr>
<td><strong>Australian Survey of Unmet needs (Stroke Foundation)</strong></td>
<td></td>
<td>X</td>
<td>X N=791</td>
</tr>
<tr>
<td><strong>Stroke123 (NHMRC Partnership grant 2012-15)</strong></td>
<td></td>
<td>X</td>
<td>X N=215 clinicians</td>
</tr>
<tr>
<td>• QI study within Queensland: 23 hospitals</td>
<td></td>
<td>15,482 patients from 40 hospitals</td>
<td></td>
</tr>
<tr>
<td>• Cross-jurisdictional data linkage: Vic, WA, QLD, NSW</td>
<td></td>
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</tr>
<tr>
<td><strong>Comparing compensatory and restorative approaches to memory rehabilitation post stroke (PhD project Monash University: Toni Withiel)</strong></td>
<td>X N=65</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inspiring Virtual Enabled Resources following Vascular Events (iVERVE) pilot project</strong></td>
<td>X N=54</td>
<td></td>
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<tr>
<td><strong>Shared Team Efforts Leading to Adherence Results (STELAR)</strong></td>
<td>Step Wedge 9 hospitals</td>
<td>X pilot project</td>
<td></td>
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<tr>
<td><strong>Fabry's pilot screening project</strong></td>
<td></td>
<td></td>
<td>X n=59</td>
</tr>
<tr>
<td><strong>PRECISE (NHMRC Project grant #1141848) (2018-20)</strong></td>
<td></td>
<td>X</td>
<td>X</td>
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*numerous research fellows, early career researchers, PhD, and honours projects
Pilot randomised clinical trial of an e-health discharge support intervention for stroke:

iVERVE (Inspiring Virtual Enabled Resources following Vascular Events)

Professor Dominique Cadilhac

Co-authors:
NE Andrew, D Busingye, J Cameron, AG Thrift, T Purvis, J Li, I Kneebone, V Thijs, ML Hackett, NA Lannin, MF Kilkenny on behalf of the ReCAPS investigators
Background

- Returning home after stroke is challenging and the majority of survivors have unmet needs\(^1\).
- In Australia, short acute lengths of stay (average ~5 days) contribute to sub-optimal discharge planning:
  - ~1 in 2 receive discharge care plans in hospital
  - Health promotion education is limited and rarely reinforced
  - ~1 in 3 return to hospital after discharge for acute stroke within 90 days
- Electronic technology to support recovery and self-management after stroke may be useful but has rarely been used and effectiveness is unknown:
  - Existing research limited to medication adherence\(^2\) or depression\(^3\) reduction in stroke

iVERVE: Inspiring virtual enabled resources following vascular events

Comprehensive post-discharge support system comprising:

- Standardised goal setting for patient-centred recovery and secondary prevention
- Aligned electronic support and educational messages
  - Ability to be tailored and delivered via SMS or email
  - Messages can be personalised (include name) and individualised
- Developed by interdisciplinary team including engineers and consumers with independent review of messages

Aim and methods

To assess the feasibility and acceptability of the iVERVE electronic post-discharge support system designed for survivors of stroke

- Early phase I, pilot RCT with assessor and patient blinding and intention-to-treat analysis
- Patients recruited from the Australian Stroke Clinical Registry mailout n=340
  - Confirmed stroke
  - Aged ≥18 years
  - 6-12 months post discharge from acute care
  - Living within 50 km of Monash University
  - Agreed to be contacted for future research

- **Feasibility**: message transmission failures, data completeness, responder burden, retention
- **Acceptability**: satisfaction survey and focus group
- **Potential effectiveness**: goal attainment and self-efficacy

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Australian Stroke Clinical Registry

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iVERVE trial design and participation

N = 68 (11 excluded)

Phone 1: Baseline interview

Phone 2: Goals set (3 uncontactable)

RANDOMISED N = 54

Intervention group
N = 25
Messages aligned to goals + administrative
4 weeks

Control group
N = 29
Administrative messages
4 weeks

Phone follow-up after 4 weeks (n = 45)
• Goal Attainment Scale
• EQ-5D
• Health Education Impact Questionnaire
• Hospital Anxiety and Depression Scale
• Nottingham Extended Activities of Daily Living

Satisfaction survey 1-2 weeks post follow-up

Intervention participants focus group invitation

N = 20 (80%) completed

N = 25 (86%) completed
Acceptability

Using text/email is a good way to teach me about stroke

I was comfortable using my phone to read/respond to text messages

Intervention group

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree
Summary

- The iVERVE tailored electronic messaging support system for self-management after stroke was feasible and acceptable in a chronic stroke population.
- The use of electronic messaging to support comprehensive goal achievement after stroke has potential in terms of effectiveness.
- Preference is to use with patients after discharge from acute hospitals to home.
- ReCAPs Phase II RCT in progress to assess the potential feasibility and effectiveness of this intervention after acute stroke.

Further information: dominique.cadilhac@monash.edu

@DominiqueCad
Aims

From the perspective of community dwelling stroke survivors and their carers we seek to:

- To describe the levels of long-term unmet needs
- To identify the greatest areas of long-term unmet needs
## Survey methods

<table>
<thead>
<tr>
<th>Direct</th>
<th>Indirect</th>
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<tbody>
<tr>
<td>Australian Stroke Clinical Registry (AuSCR)</td>
<td>Stroke Foundation (SF) website and email</td>
</tr>
<tr>
<td>Selected hospitals (not covered by AuSCR)</td>
<td>signature</td>
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<tr>
<td>StrokeConnect support groups (SF)</td>
<td>Advertisements</td>
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<td>StrokeConnect On-line forum (SF)</td>
<td>Stroke Support Groups</td>
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<tr>
<td></td>
<td>Word of mouth (snowballing)</td>
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<td></td>
<td>Professional publicity opportunities</td>
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## Participants

<table>
<thead>
<tr>
<th></th>
<th>Survivors</th>
<th>Carers</th>
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<tbody>
<tr>
<td><strong>Number</strong></td>
<td>500</td>
<td>291</td>
</tr>
<tr>
<td><strong>Median age (Q1, Q3)</strong></td>
<td>67 (58, 75)</td>
<td>64 (54, 71)</td>
</tr>
<tr>
<td><strong>% male</strong></td>
<td>61</td>
<td>27</td>
</tr>
<tr>
<td><strong>Median time since stroke (Q1, Q3)</strong></td>
<td>2 (1, 4)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

173 AuSCR registrants completed the Needs Survey (median age 69 years, 67% male; 77% ischaemic stroke)
Overall, 84% had unmet needs

**Health, Leisure, Work, Support (external emotional), Finances, Everyday living**

Substudy using the AuSCR registrants (data linkage project)

- To investigate the association between HRQoL following stroke at 3-6 months and self-reported long-term unmet needs
Data linked from AuSCR (subset) who participated in the Needs Survey ID numbers using

Data linkage approvals were granted by the AuSCR research task group, the Stroke Foundation and Monash University HREC.
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<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Age median (Q1, Q3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At stroke onset</td>
<td>NA</td>
<td>69 (60, 79)</td>
<td>70 (59, 80)</td>
</tr>
<tr>
<td>At survey completion</td>
<td>69 (60, 77)</td>
<td>70 (60, 78)</td>
<td>NA</td>
</tr>
<tr>
<td>Male</td>
<td>326 (60)</td>
<td>115 (67)*</td>
<td>227 (54)*</td>
</tr>
<tr>
<td>Born in Australia</td>
<td>382 (72)</td>
<td>119 (73)</td>
<td>270 (66)</td>
</tr>
<tr>
<td>Ischaemic Stroke</td>
<td>NA</td>
<td>134 (77)</td>
<td>347 (82)</td>
</tr>
<tr>
<td>Able to walk independently on admission</td>
<td>NA</td>
<td>71 (45)</td>
<td>146 (39)</td>
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<td>* Statistically significant difference</td>
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Proportion of participants with unmet needs across each domain (n=173)

- **Psychological**
- **Physical**
- **Living**
- **Leisure**
- **Support**

% 0 20 40 60 80 100

*Psychological needs = fatigue, emotional, concentration, cognition, reading and memory needs*

*Physical needs = mobility, falls, bladder, pain, speech, vision and swallowing needs*
• For each 2-point decrease in the VAS at 3-6 months post-stroke there was one additional unmet need reported at median 2 years

\[ \text{IRR: 0.98, (95\% CI: 0.97, 0.99), } p<0.01 \]

*Models adjusted for age, gender, stroke type, ability to walk on admission, admitted to a stroke unit, level defined as hospital*
Summary of findings

- Linear relationship between the EQ-5D VAS at 3-6 months and the overall number of unmet needs at 2 years
- Lower EQ5D subscales scores for mobility, self care and usual activities were associated with unmet physical and psychological health needs
Frontiers in data linkage research

- Data already available and adds extra information to routinely collected data
- Validates quality e.g. missing data, clinical coding practices
- Allows longitudinal analysis
- Supports various study designs
  - Trends over time
  - Comparison of groups treated vs not treated e.g. thrombolysis
  - Cost and economic evaluations
- Research into rare events or small sub-populations – large sample sizes
Factors influencing self-reported anxiety or depression following stroke or TIA using linked registry and hospital data.

Thayabaranathan T, Andrew NE, Kilkenny MF, Stolwyk R, ..., Cadilhac DA on behalf of the Stroke123 investigators and AuSCR consortium.

Quality of Life Research 2018 August 4. doi.org/10.1007/s11136-018-1960-y
Rationale for study

- 30-50% of survivors experience problems with mood\(^1\)

*Important to understand the factors associated with anxiety/depression post-stroke to find ways to reduce their prevalence*

Methods – Data sources

- Observational study, using data prospectively collected from the Australian Stroke Clinical Registry
  - 2009-2013
  - Queensland hospitals (n=23)
  - Quality of care indicators (e.g. access to stroke unit, discharged on care plan)
  - Quality of Life (EQ-5D-3L) at 90-180 post-stroke
    - Anxiety/Depression domain

- Patient level data were linked to Queensland Government held hospital admission and emergency data
  - Comorbidities - ICD-10 codes from last 5 years
Obtaining cross-jurisdictional data linkage takes time

**NDI (2013-2015)**
- Feasibility discussions
- Applications & approvals
- QLD sign off to link QLD AuSCR registrants to NDI
- Amendment for 2013 data
- Data received

**QLD (2013-2015)**
- Feasibility discussions
- Application submitted + revisions x1
- Emergency data custodian approval
- Admitted Patient data custodian approval + revisions x3
- Director General sign off
- Data linkage
- Data received
- Re-linkage
- Data received

**NSW (2013-2015)**
- Linkage request
- Application for data submitted
- Data custodian approval + revisions x6
- Ethics
- Data linkage
- Data received

**VIC (2013-2015)**
- First round Feasibility discussions
- Complex linkage methods developed
- Second round Feasibility discussions
- Data request form approval
- Conditions of release negotiated
- Clinical Network brief signed by Secretary
- Data received

**WA (2013-2015)**
- Feasibility discussions
- Application for data revisions x4
- Ethics x3 revisions
Result: ~50% self-reported issues with mood post-stroke

N=2853; median age 74; 45% female; 60% ischaemic stroke

EQ-5D-3L domains

- Mobility: 42.9%
- Self-care: 67.2%
- Usual activities: 41.9%
- Pain/discomfort: 51%
- Anxiety/depression (Mood disorder): 53.1%

Visual analogue scale

- Normative population aged 70-79 years: 83
- AuSCR QLD: Yes anxiety/depression 60
- AuSCR QLD: No anxiety/depression 80

Visual analogue scale

- Best imaginable health state
- Worst imaginable health state (0=Died)
The curvature shows how the effect of age on the predicted probability of reporting anxiety or depression differs across levels of comorbidities.

A 35 year old who has 10 comorbidities has ~80% chance of reporting anxiety or depression

A 35 year old with a low socioeconomic position is highly likely to report having issues with anxiety or depression

Two-way contour to graphs of predictions from statistical models
Summary of findings

- Main factors associated with self-reported anxiety or depression on EQ-5D-3L at 90-180 days post-stroke
  - Previous anxiety or depression
  - Hemiplegia
  - Dementia
  - Low socioeconomic status
  - Smoking

- No difference for quality of care received in hospital between those who self-reported anxiety or depression on EQ-5D-3L and those who had reported no issues at 90-180 days post-stroke
The next challenges

BEFORE event

Stroke event

AFTER event

A comprehensive view of the patient journey
Summary

• Registries have an essential role in facilitating the monitoring of healthcare to improve patient outcomes
  – No change in patient outcomes without feedback loop & further benefit from facilitated QI programs (important ‘registry’ science)
• Must keep data minimal and focussed on clinical usefulness
• Lack visibility and impact if not contributing to academic debate
• Has advantages since stroke is complex and we lack evidence for many aspects of care and longer term outcomes
• Can explore a range of important research questions using various designs
Success factors

• Important platform for health services research if designed well
• Clear governance and policies for supporting research
• Data optimisation through linkage
• Foresight in seeking consent to contact registrants for future research and undertake data linkage
• Strong clinical and academic leadership
• Grants in the early years provided the opportunities for research in a range of applied and technical areas while building capacity
• Valued as an important resource for clinical care and research
Thanks to Monique Kilkenny, Nadine Andrew, Sibilah Breen and Tharshanah Thayabaranathan for some slides

For further information

• Visit www.auscr.com.au
• Contact the National Coordinator Sibilah Breen
  sibilah.breen@florey.edu.au

Or Me: dominique.cadilhac@monash.edu

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Australian Stroke Clinical Registry
Acknowledgements

AuSCR Consortium partners

Hospital staff & patients

Initial AuSCR support

Australian Commission on Safety and Quality in Healthcare

State government support

Victoria Government
Queensland Government
Tasmanian Government
Victorian Cardiac Clinical Network
Victorian Stroke Clinical Network
ACI (NSW Agency for Clinical Innovation)

Industry support:
- Allergan
- Ipsen
- Boehringer Ingelheim
- Medtronic

Grant funding support

Australian Government National Health and Medical Research Council
MONASH University
University of South Australia

Other support

Australian Stroke Clinical Registry

Nancy & Vic Allen Stroke Prevention Grant

Consumer donations

T³ Stroke Trial

Ionostat Foundation

Australian Government
Queensland Government

The Ian Potter Foundation

University of South Australia

Australian Institute of Health and Welfare