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Improving quality and outcomes of stroke care in hospitals: Protocol and statistical analysis plan for the Stroke123 implementation study

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Abstract

Rationale: The effectiveness of clinician-focused interventions to improve stroke care is uncertain.

Aims: To determine whether an organizational intervention can improve the quality of stroke care over usual care.

Sample size estimates: To detect an absolute 10% difference in overall performance (composite outcome), a minimum of 21 hospitals and 843 patients per group was determined.

Methods and design: Before and after controlled design in hospitals in Queensland, Australia.

Intervention: Externally facilitated program (StrokeLink) using outreach workshops incorporating clinical performance feedback, patient outcomes (survival, quality of life at 90–180 days), local barrier assessments to best practice care, action planning, and ongoing support. Descriptive and multivariable analyses adjusted for patient correlations by hospital (intention-to-treat method).

Context: Concurrent implementation of financial incentives to increase stroke unit access and use of the Australian Stroke Clinical Registry for performance monitoring.

Study outcome(s): Primary outcome: net change in composite score (i.e. total number of process indicators achieved divided by the sum of eligible indicators for each cohort). Secondary outcomes: change in individual indicators, change in composite score comparing hospitals that did or did not develop action plans (per-protocol analysis), impact on 90–180-day health outcomes. Sensitivity analyses: hospital self-rated status, alternate cross-sectional audit data (Stroke Foundation). To account for temporal effects, comparison of Queensland hospital performance relative to other Australian hospitals will also be undertaken.

Discussion: Twenty-one hospitals were recruited; however, one was unable to participate within the study time frame. Workshops were held between 11 March 2014 and 7 November 2014. Data are ready for analysis.

Keywords

Stroke, quality of care, quality of life, long-term outcome, observational study

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Introduction and rationale

Stroke is a leading cause of global disease burden, and efforts to reduce associated death and disability through improved evidence-based care are urgently needed.[1] In particular, variability in the care that is provided to patients with stroke admitted to hospital must be addressed, since there is moderate-to-poor adherence to clinical guideline recommendations in many countries.[2] At the time this study was being planned (2011), adherence to clinical guideline recommendations in Australia ranged from 7% for intravenous thrombolysis to 94% for electrocardiogram on admission.[3,4] Most indicators (12 of 28) had a reported adherence of 40–65%, including access to stroke units (60%). In the 2015 national audit, 8% of patients with acute ischemic stroke received thrombolysis and 67% of all patients with stroke were admitted to a stroke unit,[5] suggesting challenges to improving care.

Implementation science, or knowledge translation, is gaining momentum as an approach to support quality improvement interventions that are directed at changing clinician behavior in order to reduce evidence–practice gaps.[6] Effective strategies for improving clinical practice include educational outreach, local opinion leaders, use of audit and feedback, interprofessional collaboration, and tailored interventions.[6] The success, of knowledge translation interventions can be optimized by having a coherent theoretical base, assessing potential barriers and facilitators for the desired practice, and being delivered iteratively to enable adaption to the local context.[6,7] Success is further dependent on the degree to which barriers to implementation are overcome,[6] and on how well the available evidence is aligned with local context through the active component of facilitation.[8]

Few studies of interventions to change clinician behavior have been undertaken in the area of stroke. The most notable, however, are the multifaceted interventions used in the Get with the Guidelines – Stroke program in the United States, and the Quality in Acute Stroke Care Trial of a nurse-led intervention to improve management of fever, sugar, and swallowing in acute stroke.[9–11]

Aims and hypotheses

To determine if an organizational intervention targeting acute stroke care, that used external facilitation and provided feedback on clinical performance on 90–180-day patient outcomes, would be more effective relative to usual quality improvement and care provided in participating hospitals.

Primary hypothesis: Hospitals participating in the intervention program are more likely to demonstrate greater adherence to a defined set of process of care indicators for acute stroke (net change in composite score) when compared to an historical control period or to hospitals in other parts of Australia without access to this program.

Methods

The study was undertaken in hospitals, predominantly public, in Queensland, the third most populated state in Australia. Clinicians in these hospitals were familiar with audit and feedback programs, and the new and existing data collection systems used (see "Datasets" section).

Design

The study comprised a mixed-methods design with a nested nonrandomized, multicenter, controlled before and after comparison, with a process evaluation.

Baseline data

Prior to the Stroke123 study, hospitals contributed to the continuous audit of a selection of clinical indicators for the Queensland Statewide Stroke Clinical Network (QSSCN) (Table 1). The variables are similar to those recorded in the ongoing national prospective Australian Stroke Clinical Registry (AuSCR). In addition, in a biennial national acute services audit staff collected information on all recommendations within the clinical guidelines on 40 consecutive cases within a set time period. Clinicians then met to collectively review these hospital performance data biannually and prioritize strategies to improve care including training, education, and health system strategies. In addition, the Stroke Foundation of Australia, in cooperation with the Queensland government, implemented the StrokeLink program in 2008, to increase capacity for quality improvement.[12] StrokeLink was based on the Plan Do Study Act (PDSA) model,[13] comprising audit and feedback together with external facilitation that included an outreach workshop and regular support via email or telephone.

Nationally, there are no other large-scale funded programs similar to StrokeLink, although many hospitals participate in local, state, and national audit activities. Hospitals that participate in AuSCR[14] have access to on-demand electronic summary reports to review their results for a small set of performance indicators, benchmarked against the average national performance. Aggregated national information on patient stroke outcomes is available from AuSCR national annual reports.

Prior to Stroke123, there was no single quality improvement program inclusive of data feedback to

Table 1. Patient-level cohort data sources and applicable evaluation period

Time period (T)	Year	Intervention phase	Data source for performance monitoring analysis
T0	June 2004 to 30 June 2012	Historical (baseline data) period[a] *StrokeLink + QSSCN forums*	Teleform QLD and Stroke Foundation audit data (2011 sample)
T1	1 July 2012 to 10 March 2014	Immediate preintervention data period *Intervention: financial incentives + StrokeLink + QSSCN forums*	AuSCR data + Stroke Foundation audit data (2013 sample)
T2	11 March 2014 to 7 November 2014	*Intervention: enhanced StrokeLink program + financial incentives + QSSCN forum (x 2 per year)*	AuSCR data
T3	8 November 2014 to December 2015	Postintervention period[b]	AuSCR data + Stroke Foundation audit data (2015 sample)

AuSCR: Australian Stroke Clinical Registry; QLD: Queensland; QSSCN: Queensland Statewide Stroke Clinical Network.
[a]Prior to Stroke123 project funding being obtained.
[b]When funding for Stroke123 ended.

hospitals,[15] and only three Queensland hospitals were using AuSCR[16] separate from the QSSCN audit program. After obtaining funding for the Stroke123 study, 20 more Queensland hospitals were able to participate in AuSCR from 2012, whereby a web-based data collection system is used with central capture of patient-reported outcomes at 90–180 days. Concurrently, the Queensland government implemented a financial incentive to increase access to stroke units in 2012.

Datasets

Three datasets in Queensland from 2004 to 2015 will be used for the primary analysis, while two national datasets will be used to assess temporal trends on quality of care (Table 1):

(1) AuSCR, a clinical quality registry designed to monitor and improve the quality of acute stroke care, commenced in 2009 with a pilot phase before being implemented nationally in 2010. Patient demographic and clinical data are entered into a web-based system by staff at participating hospitals. All first recorded episodes of stroke are eligible for follow-up at 90–180 days after onset, and deaths are obtained through annual linkages with the National Death Index. Four nationally endorsed clinical indicators are collected. These comprise receipt of stroke unit care, thrombolysis if an ischemic stroke, antihypertensive medication at discharge, and a discharge care plan if discharged to the community. In Queensland, an additional four indicators are collected: aspirin administration within 48 h of admission, patient mobilization on the same or next day after admission if unable to walk on admission, swallow screen or assessment given prior to oral intake, and prescription of antiplatelet or antithrombotic medication at discharge if an ischemic stroke. As well as routine checking of AuSCR data centrally, state coordinators provide support and training to participating hospitals and undertake random audits for checking data quality. A Management Committee separately scrutinizes summary data reports at monthly meetings, and additional oversight is provided by the AuSCR Steering Committee.
(2) Stroke Foundation Acute Audit, a national retrospective audit of the majority of stroke-receiving hospitals in Australia, commenced in 2007. The cross-sectional audit is performed biennially and collects information on multiple clinical indicators, including those collected in AuSCR, in approximately 40 consecutive cases per hospital.
(3) The QSSCN audit was a continuous teleform-based audit of data pertaining to a selection of clinical indicators from 2004 that has now transitioned to AuSCR among hospitals in Queensland.

Clinician-level and process evaluation data

Complementary standardized survey data to describe the local context of care and readiness for change were collected on two occasions in the period

immediately before (T1) and after delivery of the intervention (T3) (Table 2). These self-reported surveys were obtained directly from stroke service clinicians (including doctors, nurses, physiotherapists, speech pathologists, dieticians, psychologists, pharmacists, general practitioners, visiting medical officers, social workers, and occupational therapists), and hospital administrators or quality improvement staff. The information on organizational context was systematically obtained in this survey using the questions from the Alberta Context Tool. The Alberta Context Tool has 56 items (eight dimensions, 10 concepts) and can be used to reliably assess context within complex healthcare settings with a focus on concepts that are potentially modifiable (Table 2).[19] In addition, process evaluation data gathered by external facilitators during the study will be used to describe the intervention dose and fidelity, as monitored using a specific log of the number and type of contacts with clinicians (see online supplement).

Table 2. Summary of preintervention (T1) and postintervention (T3) hospital staff surveys

Item	Description
Preintervention hospital staff survey (T1 undertaken in 2013–14)	
ACT Dimension items	
Leadership	Actions of formal leaders to influence change and excellence in practice
Culture	Reflects a supportive work culture
Evaluation	Using data to assess team performance and achieve outcomes
Social capital	Active connections among people
Informal interactions	Informal exchanges that promote transfer of knowledge
Formal interactions	Scheduled activities that promote transfer of knowledge
Structural/electronic resources	Elements that facilitate the ability to assess and use knowledge
Organizational slack	The cushioning of resources that allows an organization to adapt to internal pressure. Includes additional concepts of staff, space, and time
Additional questionnaire items	
Demographics of respondents	Staff/workforce characteristics including position, experience, etc.
Perceptions of support from the Queensland Statewide Stroke Clinical Network	Broader support and infrastructure for local quality improvement activities
Education and professional development opportunities	Professional development
Use of data to review care activity	Performance monitoring specific to the use of AuSCR or audit data
Postintervention staff survey (T3 undertaken in 2015)	
Hospital Staff survey	T1 items readministered as per above
Institute of Healthcare Improvement (IHI) score[17,18]	Used to measure self-rated progress in achieving "significant" quality improvement 5-point Likert scale from 1 (No activity yet) to 5 (Outstanding progress)[18]

Italicized items are adapted from the Alberta Context Tool (ACT).[19]

Study population

Hospital eligibility

To be eligible, a hospital was required to have performance data collected using AuSCR. In 2012, when the study commenced, there were 23 eligible hospitals in Queensland, but several required ethical approval to commence data collection in AuSCR. Concurrently, the public hospitals were also provided with financial incentives from Queensland Health to establish new, or enhance existing, stroke units. Across other parts of Australia, 31 hospitals contributed data to AuSCR in 2012, and 99 hospitals to the Stroke Foundation acute services audit, in 2011.[20,21]

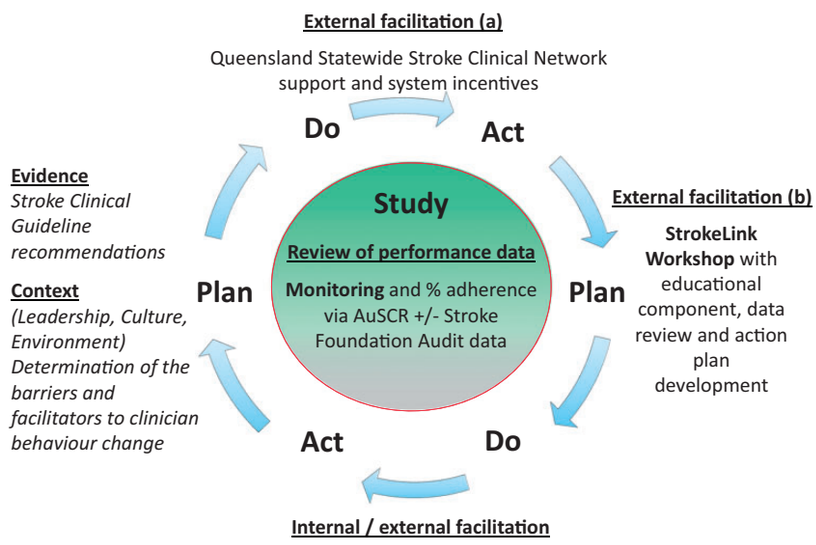
Patient-level data

Data pertaining to adult patients (age ≥18 years) admitted to participating hospitals with an acute stroke or transient ischemic attack (TIA) submitted into the AuSCR or QSSCN databases were eligible for inclusion in the primary analyses.

Intervention

As described previously, the Stroke123 intervention included several elements, of which the central component was the enhanced StrokeLink program. This intervention was augmented by hospital performance data obtained continuously (compared to previous biennial audit samples) and patient outcome data, both from the AuSCR. The external facilitation components are consistent with knowledge translation theory (Figure 1).[22] Specifically, the enhanced StrokeLink program included outreach visits in the form of a workshop that was facilitated by trained Stroke Foundation staff (with a clinical background in nursing or allied health) using interactive education and local consensus processes. Consistent with other effective behavior change programs,[13,23] the workshop included identification of local barriers to implementation of the desired practices and ways to develop an agreed local action plan to improve care. Ongoing support by an external facilitator was provided in the form of telephone calls, emails, follow-up visits, and networking between clinicians facing similar issues. As part of this process, and consistent with PDSA principles,[13] clinicians were encouraged to regularly review their local AuSCR data. During all phases of the Stroke123 project, the biannual QSSCN fora were held to review care, prioritize and focus on improving quality of care at a state level.

Figure 1. Overview of the Stroke123 intervention and theoretical frameworks.
Note: The figure displays the theory underpinning the principles of the Promoting Action on Research Implementation in Health Systems (PARIHS) framework and the use of Plan Do Study Act (PDSA) applied in the context of this study.[7,8] The PDSA cycle involves developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should subsequently be made (Act).[7]
AuSCR: Australian Stroke Clinical Registry.



Hospital performance outcomes

Hospital performance will be measured based on three different composite scores and compared between the different time periods (Table 1). Composite scores will be calculated by dividing the total number of relevant performance indicators achieved by the sum of eligible indicators for each comparator cohort. Coding decisions, including how missing data will be handled, for each of the eight main indicators that will form the components of the composite scores, are defined in the Supplemental Tables (Table I).

Composite A (primary outcome) will be calculated based on all eight indicators, collected in the AuSCR, across the study period in Queensland (regardless of whether or not these were the focus of individual hospital action plans).

Composite B (secondary outcome) will be calculated based on only those indicators that a hospital self-nominated for their action plan that is within the eight obtained in AuSCR and Stroke Foundation audit variables.

Composite C (sensitivity analysis) will be calculated based on only the four national indicators for comparisons with hospitals in other Australian states. The composite score will be measured at multiple time points, prior to and after the interventions have been implemented, to provide an estimation of the underlying secular trends in indicator adherence. The non-Queensland states (none of which received either financial incentives or the StrokeLink intervention) will act as a temporal control.

Process evaluation (intervention fidelity) outcomes

Intervention adherence, or fidelity, is to be described using clinician-level survey data, and the log of interventions used to maintain or improve fidelity by the external facilitators. These data will be used to provide evidence to explain our findings and to identify the critical factors associated with success or otherwise in achieving the outcomes (e.g. number of workshops that resulted in an action plan). Importantly, we will be able to describe whether the StrokeLink intervention was implemented as planned.[24] The online supplement provides a description of the data collection methods used in this part of the study.

Data management and ethics

Analysis of data will be undertaken in a deidentified format by researchers not employed by The Florey (the AuSCR Data Custodian). This approach is to ensure separation of roles and responsibilities, to maintain privacy-preserving principles, and reduce the risk of bias.[25]

Ethics approval was obtained from all participating hospitals, with the lead ethics committee in Queensland being the Metro South Human Research Ethics Committee (HREC/13/QPAH/31).

Sample size estimates

Our sample size calculation was based on the international literature and data from the New South Wales (NSW) Stroke Audit Program (Table 3). In "Get with the Guidelines - Stroke," a prospective nonrandomized, national quality improvement program, an absolute 10.45% improvement (83.52% baseline to 93.97% postintervention) was found in adherence, based on a composite score of seven predefined indicators.[11] In the NSW Audit program, a nonrandomized, historical controlled, multicenter study using a before and after audit design, the overall net change in adherence to 11 clinical indicators was 23% (premeasure 39% and post 62%) 3 – 6 months after enhancement of stroke services.[27] The main program feature in NSW was employment of a stroke coordinator and establishment of stroke units.[27] Samples sizes also took into account: the potential effects of clustering of the patient data at each hospital; use of 80% power to detect a statistically significant difference between time periods (alpha 0.05, two-tailed); and a

Table 3. Summary effect size estimates used to calculate the sample size

Reference data	Effect size (net change score, %)	Uncorrected N per group	Corrected for design effects[a] N per group	Intraclass correlation coefficient[b]	Sites needed for N = 40 cases per site
United States[11]	10	172	843	0.1	21
NSW[27]	20	82	722	0.2	18

NSW: New South Wales.

[a]Adjusted for clustering of patient data at the hospital level.

[b]Obtained from actual NSW audit data. Another reference source was used for United States as intraclass correlation coefficient not reported. We used the 75th percentile reported for process variables (median 0.06 Q1 0.02–0.1).[26]

minimum average of 40 audited consecutive patients per period. Thus, we estimated that 23 eligible Queensland hospitals would be sufficient to detect an absolute 10% difference between the pre- and postperiod, provided each site provided a minimum of 40 cases and that 4500 annual episodes of stroke care would be provided to AuSCR from participating Queensland hospitals.

Statistical analyses

We will perform intention-to-treat and per-protocol analyses. Since this enhanced program was preceded by system-based financial incentives to increase access to stroke units that operated throughout the intervention period, methods to adjust for this aspect were required as part of the statistical analysis plan. Additionally, we sought to understand the context of care from the perspective of clinicians working within the intervention hospitals, and to determine whether the amount of facilitation support, or the number of targeted behaviors selected for action plans, influenced the level of success in improving the quality of acute stroke care.

Time periods for analyses

To control for the overlapping influence of preexisting intervention elements, and concurrent incentive funding for stroke units, the data will be analyzed across four time periods: preintervention period (T0: provision of audit data with/without the original StrokeLink program); commencement of financial incentive intervention (T1); Stroke123 intervention (T2: enhanced StrokeLink program using AuSCR data with continued financial incentive roll out); and postintervention period (T3) (Table 1).

Descriptive characteristics of patient cohorts

Baseline characteristics of patients will be compared between phases using Chi Square and Kruskal-Wallis equality-of-populations rank test, as appropriate (see Supplemental Table II). Mean (standard deviation) and median (25th percentile and 75th percentile) will be used to show the distribution of composite score data for each comparator period (see Supplemental Table III).

Hospital performance analyses (composite scores)

Median regression adjusted for patient clustering by hospital, to protect against residual confounding, will be used to compare differences in outcomes between time periods for the different composite scores outlined above. Multilevel logistic regression analysis, with levels defined as patients and hospital to adjust for patient clustering, will be used for dichotomized outcomes such as those relating to individual indicators. Since the process indicators are universally applicable to eligible patients, we will not include patient characteristics in the models (see Supplemental Table III and Table IV).

Patient-level outcome analyses (survival and quality of life)

Patient outcomes will be assessed using AuSCR data and will only be available for time periods T1 – T3. Since AuSCR data collection only commenced from July 2012 in Queensland hospitals for the T1 period, patient outcome data within 90 – 180 days following stroke are unavailable for the T0 period (Table 1). Cox proportional hazards regression (survival outcomes) and median regression (quality of life outcomes) will be used. As quality of life data were only collected in AuSCR for first patient episodes, data will be analyzed by individual patient and not an episode of care. Two models will be run for quality of life outcomes. For the primary model, the dependent variable will be scores on the EuroQoL 5-dimensions questionnaire and, for the secondary model, the dependent variable will be scores on the Visual Analogue Scale (VAS). In both models, the dependent variable will be the score with deaths coded as 0 to represent the impact across the whole cohort and not just the survivors. Logistic regression models will also be used to determine differences between hospital readmissions within 90–180 days. Models will be adjusted for patient factors known to be associated with outcomes collected in the AuSCR, including age, sex, birth in Australia, previous stroke, stroke type (where applicable), ability to walk on admission (as a measure of stroke severity), socioeconomic position, and whether or not the stroke occurred while the patient was in hospital for another condition (i.e. in-hospital stroke). Correlations that are expected within individual hospital cohorts will be adjusted using multilevel modeling, whereby hospital will be included as a separate level (survival analysis) or independent variable in logistic regression models (median regression).

Significance level will be two-sided alpha 0.05. All statistical analyses will be undertaken using Intercooled STATA 12.1 for Windows (Statcorp, College Station, USA, 2014).

Process evaluation analyses

We will summarize the reported enablers and barriers to applying the intervention using data gathered for the process evaluation from the participating clinicians and

external facilitators throughout the study. Text responses obtained from clinician surveys will be analyzed using qualitative techniques to summarize the major themes and subthemes, as part of an inductive approach in producing explanatory information for the interpretation of patient-level results. See online supplement for more details. The process data will also support description of the intervention in accordance with the TiDieR checklist, a template for intervention description and replication.[24]

Study organization and funding

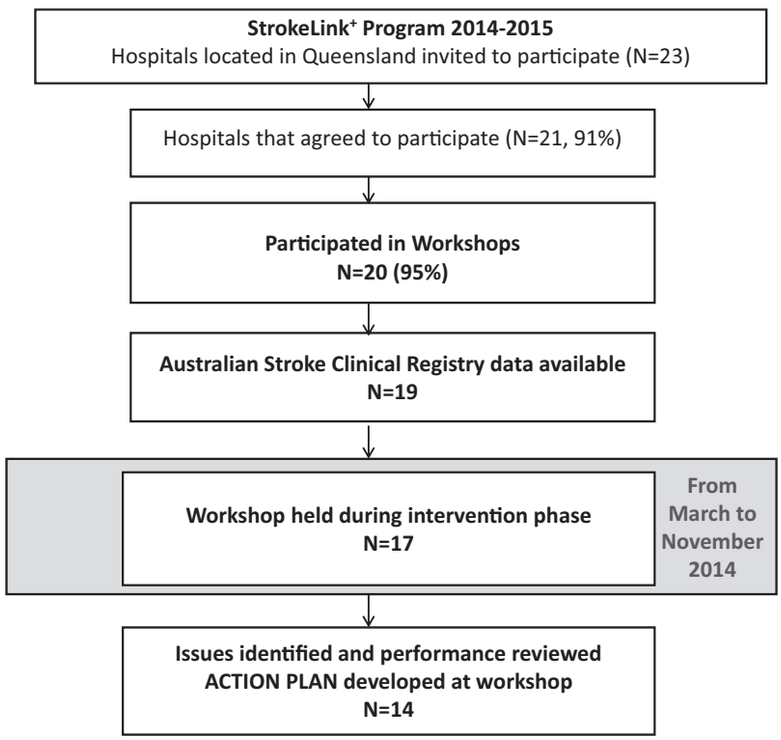
The Stroke123 Steering Committee, consisting of the Chief Investigators, and Associate Investigators named on the grant obtained from the National Health and Medical Research Council (NHMRC) of Australia, as well as several invited collaborators and relevant project managers, provide overall governance for the project. The Florey Institute of Neuroscience and Mental Health provides secretariat and coordinating agency support. A subcommittee of experts with experience in implementation research, program evaluation, qualitative and quantitative research related to quality of care assessments, and statisticians was established for this aspect of Stroke123 (the overall program of work for Stroke123 is described in Supplemental Table V). Membership varied according to expertise required for particular aspects of the study.

The Stroke123 Partnerships for Better Health project was supported by grants from the NHMRC (1034415), Monash University, Queensland Department of Health, and the Stroke Foundation of Australia.

Discussion

Few large-scale multicenter studies with prospective data collection have been undertaken to assess the benefits of complex, multifaceted interventions designed to change clinician behavior. This historical-controlled before-and-after study offers a pragmatic design to provide evidence regarding the effects of clinician behavior change interventions linked to national programs of performance monitoring in acute stroke. The study will provide essential information to underpin efforts to reduce the variations and improve overall quality of care for patients. The value of the unique, prospective, and systematic collection of 90-day outcome data in AuSCR cannot be overstated.

Figure 2. Flow diagram of hospital participation.

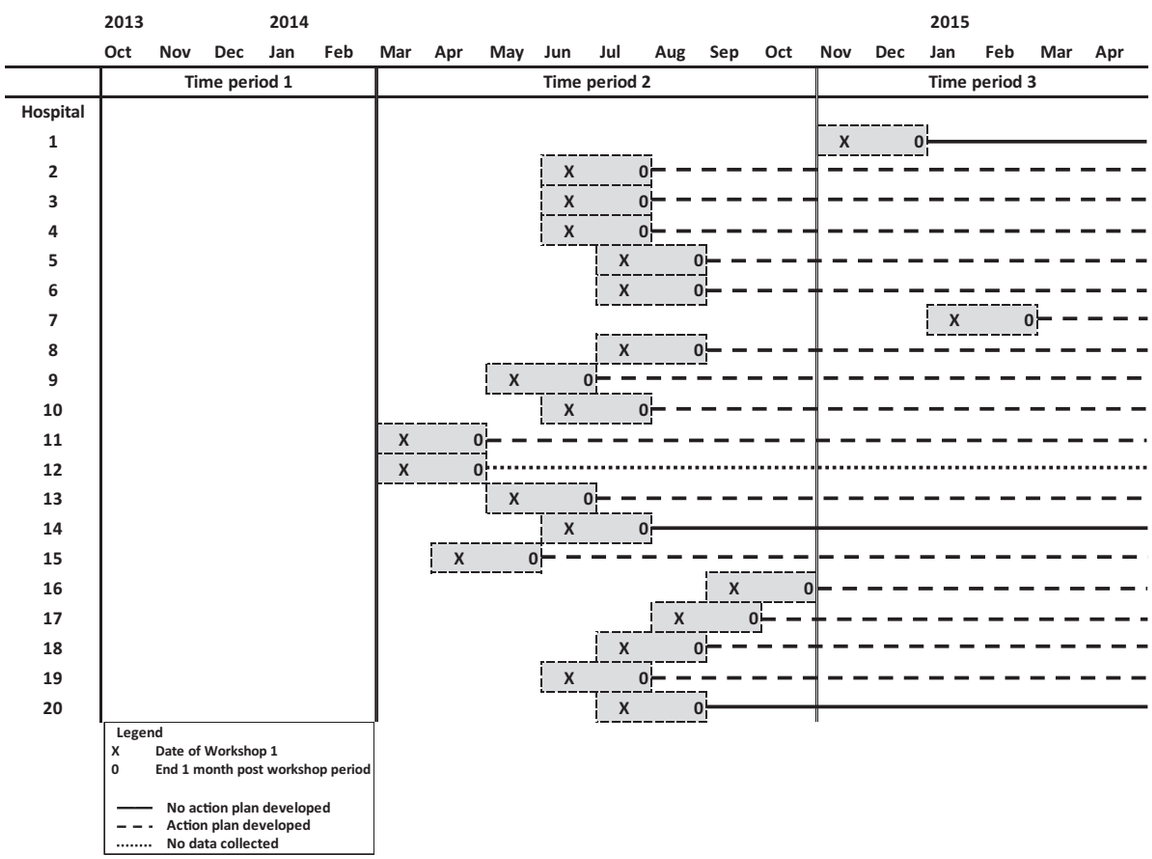


This period after stroke represents a time when a full assessment of the impact of the system of care for acute stroke (and TIA) can be made with consideration of outcomes that capture both mortality and morbidity. As Australian clinicians have had limited access to such data, we propose that feedback of outcomes will serve to motivate and promote change in their practice as part of fostering a greater understanding of the implications of variation in clinical practice. Very few national clinical registries collect quality of life and other important patient-centered outcomes.[28]

We faced several challenges. First, it took almost 12 months to establish the study including obtaining the ethical approvals and site governance clearances. During this time a new financial incentive program was also instigated to increase access to stroke units. Therefore, obtaining historical data on hospital performance was important to enable a complete assessment of changes in clinician behavior over time, but these data lacked information on long-term patient outcomes. Among 23 eligible Queensland hospitals, 21 agreed to participate and 20 hospitals received governance authorization to participate within the required time frame (Figure 2). StrokeLink workshops were undertaken in 17 hospitals between 11 March 2014 and 7 November 2014 (Figure 3). Data are currently being finalized for analysis.

In summary, the Institute of Medicine (USA) has recommended that hospitals and organizations set up systems of continuous monitoring and improvement to study and prevent system problems that can lead to poor patient outcomes.[29] Hospital-based stroke registries are an extremely useful method for longitudinal tracking of stroke severity, mortality, and processes of care. However, it remains unclear how well these registries are actively used to support knowledge translation and quality improvement efforts. Our pragmatic study will provide important insights into the potential benefits of an externally facilitated, evidence and theory informed, behavior change intervention (using registry data) to influence practice change in a real-world setting. If successful, these methods could be directly embedded within policy and practice in multiple settings and disease processes.

Figure 3. Summary of StrokeLink intervention delivery by individual hospital.



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Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: DAC is the current Data Custodian for AuSCR, CSA is Chair of the AuSCR Management Committee, and SM is Chair of the AuSCR Steering Committee. RG is the clinical lead for the Queensland Statewide Stroke Clinical Network.

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