

A protocol to implement and evaluate nurse-initiated evidence-based stroke care in Europe, to manage fever, hyperglycaemia and swallowing difficulties



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A collaboration of the Nursing Research Institute and the European Stroke Organisation

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1.0 Introduction

Approximately 15 million people worldwide suffer a stroke each year.¹ There is compelling evidence that improved patient outcomes are achieved through early intervention in acute stroke care including thrombolysis, endovascular clot retrieval² and access to specialised inpatient stroke units.³ Hyperglycaemia, swallowing dysfunction and elevated temperature are physiological variables known to be associated with poorer stroke outcomes.⁴⁻⁷ Optimal management of fever, hyperglycaemia and dysphagia have been identified in international guidelines as priorities for inpatient stroke management.⁸⁻¹⁰

The Quality in Acute Stroke Care (QASC) Trial, conducted by our team, demonstrated that multidisciplinary, nurse-led interventions to manage fever, hyperglycaemia and swallow difficulties following acute stroke significantly improved health outcomes. Results showed that supported implementation of the Fever, Sugar, Swallow (FeSS) Clinical Protocols resulted in 16% decreased death and dependency at 90-days, and in-hospital: reduced mean temperatures, reduced mean glucose levels and improved swallow screening management. There also was a non-significant reduction in length of stay by two days.¹¹ Results were fast-tracked for publication in *The Lancet*, with a commentary, winning the Canadian Stroke Congress Award for Impact in 2011 and the 2012 American Heart Association Council on Cardiovascular Nursing Stroke Article of the year. Included in the Faculty of 1000 Library, the work is in the top 2% of international articles in biology and medical research. This is one of the few studies to demonstrate that evidence-based nursing care reduces death and dependency.

More recently, patients from our post-intervention cohort were followed up longer-term (median follow-up time of 4 years) through linkage with the National Death Index. Results showed those patients who were treated in stroke units allocated to receive the intervention had significantly improved long-term survival (>20%). ¹² Collectively, these results demonstrate the potential for significant and sustained benefit of these nurse-initiated protocols following acute stroke.



In 2014, the New South Wales (NSW) Agency for Clinical Innovation partnered with the Nursing Research Institute, a joint initiative between St Vincent's Health Australia (Sydney) and Australian Catholic University, to conduct a translational quality improvement project to implement the FeSS Clinical Protocols in all 36 Stroke Services throughout NSW. Our clinical translational initiative, the QASC Implementation Project (QASCIP), targeted stroke services to embed the FeSS Clinical Protocols into routine practice. Clinical site champions attended a one-day multidisciplinary training workshop, received standardised educational resources and ongoing support. Patient data were collected by self-reported retrospective medical record audits for up to 40 consecutive stroke patients per site both pre-and post-QASCIP (n=2144 patients). The FeSS Clinical Protocols were successfully implemented resulting in significantly increased proportion of patients receiving care according to the protocols. Importantly, this study demonstrated the possibility of successful evidence translation across an entire state of a proven nurse-initiated intervention known to decrease death and dependency following acute stroke.¹³ The significance of this translational implementation project was acknowledged in multiple accolades: the 2014 NSW Premier's Public Sector Award for Improving Performance and Accountability; finalist in the NSW Health Awards 2014 Translational Research Category; and runner up in the National Lead Clinicians Group, 2014 Awards for Excellence in Innovative Implementation of Clinical Practice.

Awareness and Information of Hospitals

The Angels Initiative is currently running in multiple countries in Europe and several countries outside Europe. The Angels Initiative aims to increase the number of patients treated in stroke-ready hospitals and to optimise the quality of treatment in all existing stroke centres. They are building a global community of stroke centres and stroke-ready hospitals, working every day to improve the quality of treatment for every stroke patient. We will work with Angels Initiative to raise awareness and inform about them about the QASC Europe study. The Angels Initiative will not be involved in the evaluation of the study but will inform hospitals about the study, raise awareness and be responsible for translation of any required resources into languages other than English.



2.0 Aims

- To implement the QASC Fever, Sugar, Swallow (FeSS) Clinical Protocols (Box 1) in stroke services internationally
- To evaluate successful uptake of the clinical protocols
- To draw comprehensive lessons on translation of evidence-based results on a large scale across multiple countries

• Fever

- Temperature readings 4-6 hourly for the first 72 hours
- If temperature \geq 37.5°C treat with paracetamol

• Sugar (Hyperglyceamia)

- Formal venous glucose on admission to ED or stroke service
- Blood sugar readings 4-6 hourly for the first 72 hours for people with known diabetes
- Blood sugar readings 4-6 hourly for the first 48 hours for people not known to have diabetes
- If glucose > 10 mmol/L treat with insulin

Swallowing

- Swallow screen or swallow assessment within 24 hours of admission and prior to being given oral food, drink or medications
- Referral to speech pathologist for full assessment for those who fail the swallow screen

Box 1: Summarised Elements of the Fever, Hyperglycaemia (Sugar) Swallow (FeSS) Clinical Protocols



3.0 FeSS Protocol Implementation Process

Project Aim 1: To implement the QASC Fever, Sugar, Swallow Clinical Protocols internationally

The FeSS Clinical Protocols will be implemented in collaboration with the European Stroke Organisation (ESO). Local clinical champions at each hospital will be briefed about use of the specific intervention elements demonstrated to be effective in the QASC trial and described in full below. Importantly, the necessity of not enhancing the intervention in any way will be stressed, as faithful replication of the QASC Implementation Study (QASCIP) is a pivotal premise of this project.

Recruitment of Hospitals

Eligible hospitals will be those participating in the Angels Initiative who have signed an agreement to:

- Nominate up to three clinical stroke site champions to act as local change agents to implement the FeSS Protocols at their hospital
- Implement the FeSS Protocols as part of routine care for all stroke patients at their hospital
- Routinely record data on fever, glucose and swallowing management in the patient medical record
- Participate in the project evaluation by conducting sequential medical record audits at their hospital (details described below under Aim 2). This must include provision of pre-implementation data.
- Authorise the RES-Q data custodian to release their relevant hospital data to the researchers for analysis or provide de-identified patient data to the NRI on a paper copy of the form

Clinical stroke site champion education

Translated implementation tools and educational materials will be presented to the clinical champions for use in their sites. These include: pre-packaged PowerPoint® presentations and



FeSS clinical protocol checklists, a 'Barrier and Enabler' assessment tool, an implementation plan template and a suggested implementation and evaluation timeline. The aim of this suite of clinical and educational tools is to facilitate clinical champions to lead implementation in their local stroke services based on an effective intervention.

Resources specific to the FeSS Clinical Protocols, including ASSIST swallow screening training will be shared (if hospitals do not have their own swallow screening tool (see below); and education on use of the implementation tools; provided along with reinforcement of the importance of multidisciplinary teamwork.

As previously stated, hospitals may use their own swallow screening tool, however, if they do not have one or choose not to use it, the ASSIST swallow screening tool will be provided. This will require stroke nurses and medical staff to be educated in how to use the ASSIST tool. The NRI will provide the ASSIST swallow screening training package developed previously by the QASC trialists to stroke staff. The ASSIST swallow screening training package consists of an on-line education with case scenarios and a knowledge test to train non-speech pathologists (i.e. nurses and medical staff) to competently perform a swallow screen for acute stroke patients. Patients who fail the swallow screen are kept nil by mouth and referred to a speech pathologist for a swallow assessment. The NRI will work individually with sites that do not have a speech pathologist/ therapist on staff to arrive at a mutually acceptable arrangement approved by the QASC Europe project management/steering committee.

Clinical champions will be asked to target all clinicians in their stroke services and undertake the elements outlined in Box 2 to facilitate FeSS Clinical Protocol implementation at their hospital.



The QASC-EUROPE implementation intervention conducted by clinical champions at each hospital will consist of:

- Informing hospital Chief Executives and key health service managers
- Engaging with local Human Research Ethics Committees as necessary
- Engaging stroke multidisciplinary clinicians
- Conducting multidisciplinary workshop for clinicians to assess local barriers and enablers, provide education, and reinforce interdisciplinary teamwork
- Working with relevant stakeholders to overcome identified barriers
- Conducting interactive educational meetings about the FeSS Clinical Protocols for bedside clinicians

Box 2: Summarised Elements of the QASC-Europe Implementation Strategy

Following conduct of the barriers and enablers workshop at local sites by the clinical champions, and subsequent addressing of barriers, a 'start date' will be negotiated with the clinical champions and the multidisciplinary team. Consistent with the QASC Trial,¹¹ at least three months will be allowed for a 'bedding down' period to establish the FeSS Clinical Protocols into routine care.

Some hospitals not currently participating in the Angels Initiative may also be eligible to receive a modified version of the intervention consisting of the on-line resources only (eg United Kingdom hospitals). They would be expected to agree to participate in the evaluation process.

4.0 **Project Governance**

A Working Group will be established to co-ordinate the day-to-day running of the implementation component of the Project. This Group will consist of the NRI QASC-Europe team, representatives of the original QASC trialists, and others as required.

A Steering Committee will be established and will meet twice a year during the life of the project. The purpose of the Steering Committee is to provide high level direction and oversee project deliverables and timeline, and, in particular to guide the Project evaluation. Importantly, the evaluation component of this study will be undertaken by the QASC-Europe



study team, independently from the Angels Initiative and the European Stroke Organisation (see Project Evaluation Plan).

5.0 **Project Evaluation Plan**

Project Aim 2: To evaluate successful uptake of the clinical protocols and draw comprehensive lessons on translation of evidence-based results on a large scale across multiple countries.

To evaluate the impact of the project on clinical practice change, a comprehensive audit of medical records at pre-determined time points will be conducted at each participating site. In addition, a short organisational survey will be completed at each hospital site at baseline to collect organisational characteristics (Appendix B).

NOTE: This is NOT a clinical trial as we are not testing a device or a drug. This is a quality improvement Project that is being rigorously evaluated using patient level data.

Design

Pre-test/ post-test design

Outcome measures

The following outcome measures will be collected (See Appendix C for the audit tool elements).

Clinical processes of care outcome measures

- Proportion of patients monitored according to the fever protocol
- Proportion of patients treated according to the fever protocol
- Proportion of patients monitored according to the sugar (hyperglycaemia) protocol
- Proportion of patients treated according to the sugar (hyperglycaemia) protocol
- Proportion of patients who received a swallow screen prior to being given food, fluids or oral medications
- Proportion of patients referred to a speech and language therapist for swallow assessment following failure of a swallow screen



5.1 Method

5.1.1 Medical Record Audits

Data will be collected by medical record audit to be conducted by clinicians from each participating hospital.

<u>Procedure</u>

All data will be entered into the on-line REegistry of Stroke Quality (RES-Q) database. RES-Q is an initiative of the European Stroke Organization, partnered with the world-renowned Safe Implementation of Treatments in Stroke (<u>SITS</u>) registry to capture recognized performance and quality measures that allow standardized comparison of quality of stroke care internationally. This multilingual database of patient's non-identifiable data is currently in use in 27 countries throughout Europe and Central Asia. The data and the data custodian of RES-Q are located in the Czech Republic and have agreed to add our QASC-Europe outcome measures to their current variable set (Appendix D). They also have agreed to provide the QASC-Europe data to the researchers in a manner that identifies hospitals but not individual patients at regular time points as required by the researchers.

Clinical champions will have received training at the workshop about the audit process and the importance of using consecutive admissions to avoid bias. Any additional, on-line audit training and assistance will be provided by NRI.

Medical Record Audits

Pre-test Baseline Audit

During the first phase of the QASC Europe Project hospitals will be asked to conduct audits of the medical records of up to 100 consecutive patients admitted with stroke and discharged between specific dates yet to be determined by the NRI project team (actual numbers and dates will vary as will be determined by hospital size and project commencement dates).

All acute stroke patients who have **presented to hospital within 48hrs of stroke symptom onset and have** <u>NOT</u> **been documented for palliative care only are to be included.**



The cases for medical record audit need to fall within specific ICD10 codes. These include: 161 (Intracerebral haemorrhage), 163.0 – 163.9 (Cerebral infarction), 164 (Stroke not specific as haemorrhage or infarction) and 162.9 (Intracerebral haemorrhage unspecified). Cases to be excluded from medical record audit are: subarachnoid haemorrhage (160), subdural and extra-dural haematoma (162 & 162.1), and transient ischaemic attacks (G45.9).

Post-test Evaluation Audit

The follow-up medical record audits will be conducted six months post implementation of FeSS protocols using the process outlined as per the baseline audits above. This time period allows for three months implementation and three months 'bedding down' of the intervention for it to became routine care.

5.1.2 Process Evaluation

Project Aim 3: To draw comprehensive lessons on translation of evidence-based results on a large scale across multiple countries.

As this is a multifaceted intervention, successful implementation depends on the social context and behaviours of those delivering or receiving the intervention. Hence, study outcomes (i.e. intervention success or failure) may be affected by factors related to the implementation or delivery of an intervention. Therefore, evaluation of the processes related to intervention delivery is important to provide insight into why interventions work or fail and how they can be improved.

<u>Procedure</u>

A purposive sample of English speaking site clinical champions from a selection of hospitals that have i) completed all project requirements, or ii) partially completed some project requirements, or iii) sites that were not able to begin implementation will be asked to participate in interviews and/or focus groups about their experience implementing the FeSS Clinical Protocols and the impact on workload and organisational context.

Angel Initiative senior management and consultants will be asked to participate in interviews and/or focus groups on their experiences in relation to the project's successful and



unsuccessful elements. Snowballing techniques from interviews with both of these groups may be used to identify other key people whose contribution would be considered highly relevant to the process evaluation e.g. medical personnel

6.0 Data Analysis

The number and proportion of patients with each outcome pre and post implementation will be reported. Hypothesis testing will be undertaken to compare the change in process of care outcomes at the aggregated Europe-wide level only (i.e. for all hospitals combined and not for individual hospitals). Differences in proportions from pre to post implementation will be reported for aggregated data with 95% confidence intervals. Analyses will be adjusted for clustering of patients within hospitals.

Hospitals taking part in the project will need to audit medical records for at least five or more patients both pre and post implementation (i.e. ten in total) to receive individual hospital profiles.

Qualitative data from the process evaluation will be thematically analysed and will identify success factors and areas for strengthening the intervention for future use.

7.0 Ethical Clearance including Data Storage

This project has received ethical approval from Australian Catholic University Human Research Ethics Committee. All participating hospitals will be asked to provide details about local ethical clearances that will be required. The NRI will provide all relevant details about the study to participating sites, including the study protocol, but study sites will have to obtain any local ethical approvals required prior to participation. The NRI may be able to assist for those applications in the English language.

The medical record audit data will be collected by participating hospitals using an online web tool. The online integrated data management system in which the audit data will be collected (RES-Q) is comprised of secure access controls to ensure that only authorised people are able to retrieve information from the database. Access to the data is password protected and the server has an effective firewall and security policies that are regularly reviewed and



maintained to ensure adherence to all local and national privacy laws and principles. The researchers will be able to access these data but not see any patient identifiable information. Further information can be provided on request.

Data will be held in a locked filing cabinet in the NRI office and/or on password protected computers at the NRI. All identifying information will be coded and removed prior to data entry (egg hospital name) and only de-identified data will be analysed. No identifying patient data will be required to be entered into the study database, however, study sites may need to use a statistical linkage key to enabling linking of hospital processes of care data with 90-day modified Rankin Scale.

Data transcripts from the process evaluation will not be identified through name but through an identification number which will be linked to participants name on a separate file which will be stored separately from the transcripts. No identified data will be published or released. Data will be archived according to Australia's National Health and Medical Research Council requirements. All study materials will be stored in a locked filing cabinet and/ or on a password protected computer accessible only to the QASC-Europe team for fifteen years following publication then destroyed. All study material will be disposed of in a confidential manner by shredding all interviews transcripts and erasing all audio tapes and computer files.

8.0 **Project Outputs**

Hospital sites that have entered sufficient audit numbers to provide meaningful data (see Data Analysis section) will be provided with individual hospital profile reports upon request. A peer reviewed journal publication(s) will be prepared consisting of aggregated European-wide data and potentially by country. No individual hospital data will be provided in these publications. No individual patient data will be published. The main Project manuscript will form our final report to the Angels Initiative who will not be involved in the decision to publish nor the location of the publication.



9.0 Timeline

The exact timing of these activities is yet to be determined as timeline is finalised	Planning phase	Year 1				Year 2				Year 3			
Activities	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pre commencement activities (video filming; Project scoping; resource development; study design finalisation)													
Convene QASC-Europe Working and Steering Group Preliminary meeting with Angel consultants													
Recruitment of sites and identification of clinical site champions Briefing of clinical site champions													
Pre-implementation audit data collection													
Commencement of FeSS implementation strategy at individual hospitals e.g barrier assessment/ education													
FeSS protocol implementation													
3 month bedding down of FeSS Clinical Protocols Post-implementation audit													
data collection Data cleaning													
Data analysis													
Preparation of site profiles													
Final Report Writing													



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APPENDIX C

Audit Tool Elements

Fever

- Proportion of patients who had a temperature recorded at least four times on day 1 of stroke service admission
- Proportion of patients who had a temperature recorded at least four times on day 2 of stroke service admission
- Proportion of patients who had a temperature recorded at least four times on day 3 of stroke service admission
- Proportion of patients who had a temperature recorded at least four times per day for the first 72 hours after stroke service admission
- Proportion of patients who developed a fever (temperature >37.5 C)
- Proportion of patients who developed a fever (temperature >37.5 C) who received paracetamol within one hour
- Proportion of patients who met all relevant fever elements

Sugar

- Proportion of patients who had a formal venous blood glucose level recorded in the Emergency Department
- Proportion of patients who had a finger prick blood glucose level (FP-BGL) recorded at least four times on day 1 of stroke service admission
- Proportion of patients who had a FP-BGL level recorded at least four times on day 2 of stroke service admission
- Proportion of patients with known diabetes who had a FP-BGL level recorded at least four times on day 3 of stroke service admission
- Proportion of patients not known to have diabetes who had a FP-BGL level recorded at least four times per day for the first 48 hours after stroke service admission
- Proportion of patients who had a FP-BGL level recorded at least four times per day for the first 72 hours after stroke service admission
- Proportion of patients who had a FP-BGL of > = 10 mmol/L in the first 72 hours of stroke service admission



- Proportion of patients who had a FP-BLG of > = 10 mmol/L in the first 72 hours of stroke service admission who received insulin within one hour
- Proportion of patients who met all relevant glucose elements

Swallowing

- Proportion of patients who received a swallow screen or a swallow assessment within 24 hours of hospital admission
- Proportion of patients who received a swallow screen or a swallow assessment before they were given food or drink (orally)
- Proportion of patients who received a swallow screen or a swallow assessment before they were given oral medications
- For those who failed the screen, the proportion of patients who received a swallow assessment by a Speech Pathologist
- For those who failed the screen, time from admission/presentation taken to receiving a swallow assessment by a Speech Pathologist
- Proportion of patients who met all relevant swallowing elements

Demographics (de-identified)

- Age
- Sex
- Known diabetes (yes/ no)
- Pre-morbid modified Rankin Score (mRS)
- Type of stroke (ischemic/ haemorrhagic)

