Quality in Acute Stroke Care (QASC): Process evaluation of an intervention to improve the management of fever, hyperglycaemia, and swallowing dysfunction following acute stroke

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Trial Registration: Australia New Zealand Clinical Trial Registry (ANZCTR) No:
ACTRN12608000563369
Summary

Background

Our randomised controlled trial of a multifaceted evidence-based intervention for improving the inpatient management of fever, hyperglycaemia, and swallowing dysfunction in the first three days following stroke improved outcomes at 90 days by 15%. We designed a quantitative process evaluation to further explain and illuminate this finding.

Methods

Blinded retrospective medical record audits were undertaken for patients from 19 stroke units prior to and following the implementation of three multidisciplinary evidence-based protocols (supported by team-building workshops, and site-based education and support) for the management of fever (temperature ≥37.5°C), hyperglycaemia (glucose >11mmol/L), and swallowing dysfunction in intervention stroke units.

Results

Data from 1804 patients (718 pre-intervention; 1086 post-intervention) showed that significantly more patients admitted to hospitals allocated to the intervention group received care according to the fever (n = 186 of 603, 31% vs. n = 74 of 483, 15%, P < 0.001), hyperglycaemia (n = 22 of 603, 3.7% vs. n = 3 of 483, 0.6%, P = 0.01), and swallowing dysfunction protocols (n = 241 of 603, 40% vs. n = 19 of 483, 4.0%, P ≤ 0.001). Significantly more patients in these intervention stroke units received four-hourly temperature monitoring (n = 222 of 603, 37% vs. n = 90 of 483, 19%, P < 0.001) and six-hourly glucose monitoring (194 of 603, 32% vs. 46 of 483, 9.5%, P < 0.001) within 72
hours of admission to a stroke unit, and a swallowing screen (242 of 522, 46% vs. 24 of 350, 6.8%, \( P \leq 0.0001 \)) within the first 24 hours of admission to hospital. There was no difference between the groups in the treatment of patients with fever with paracetamol (22 of 105, 21% vs. 38 of 131, 29%, \( P = 0.78 \)) or their hyperglycemia with insulin (40 of 100, 40% vs. 17 of 57, 30%, \( P = 0.49 \)).

**Interpretation**

Our intervention resulted in better protocol adherence in intervention stroke units, which explains our main trial findings of improved patient 90-day outcomes. Although monitoring practices significantly improved, there was no difference between the groups in the treatment of fever and hyperglycaemia following acute stroke. A significant link between improved treatment practices and improved outcomes would have explained further the success of our intervention, and we are still unable to explain definitively the large improvements in death and dependency found in the main trial results. One potential explanation is that improved monitoring may have led to better overall surveillance of deteriorating patients and faster initiation of treatments not measured as part of the main trial.

**Funding**

National Health & Medical Research Council ID 353803, St Vincent’s Clinic Foundation, the Curran Foundation, Australian Diabetes Society-Servier, the College of Nursing, and Australian Catholic University
Introduction

Randomised controlled trials (RCTs) evaluate the effects of interventions on pre-specified clinical outcomes yet many are unable to explain why (or why not) the intervention worked.\textsuperscript{1,2} Process evaluations are studies conducted parallel to or following RCTs to help interpret research results.\textsuperscript{2} We report here results from our process evaluation conducted parallel the Quality in Acute Stroke Care (QASC) trial.

From July 2005 to October 2010, we conducted the QASC cluster randomised controlled trial across 19 acute stroke units (ASUs) in New South Wales, Australia.\textsuperscript{3} We tested the effectiveness of a multifaceted intervention developed for improving the management of fever, hyperglycaemia, and swallowing dysfunction following stroke.\textsuperscript{3} The intervention comprised introduction of three evidence-based treatment protocols to manage Fever, hyperglycaemia (Sugar) and Swallowing (the FeSS clinical protocols) developed from Australia’s national guidelines for stroke, supported by team-building workshops, and site-based education and support. The protocols were intended to trigger prompt nursing assessment and treatment of fever, hyperglycaemia, and swallowing dysfunction in the first three days following admission to hospital for stroke. In stroke units allocated to the intervention, two site-based team-building workshops were conducted prior to intervention focusing on identifying enablers and barriers to protocol uptake,\textsuperscript{4} development of teamwork,\textsuperscript{5} identifying champions,\textsuperscript{6} and local adaptation.\textsuperscript{7} Two interactive and didactic outreach educational sessions\textsuperscript{8–10} focusing on protocol orientation and staff education were also held in each unit. ASU staff was contacted every six weeks by the QASC project manager, via a site visit, telephone call or email, which all acted as reminders.\textsuperscript{11} Protocol implementation and
reminders continued over three years from 2007 to 2010. Control groups received only an abridged version of existing guidelines and no educational or implementation support.

Results from the QASC trial showed that, irrespective of stroke severity, patients admitted to intervention ASUs that received the nurse-initiated protocols were 15.7% more likely to be alive and independent at 90 days after admission. Our process evaluation was designed prior to the commencement of the trial and aimed to examine protocol adherence by measuring the proportion of patients managed according to the protocols (boxes 1–3).

Method

Trial design and participants

To ascertain protocol adherence, retrospective medical record audits were undertaken, using prospectively documented data, of the QASC trial pre-and post-intervention patient cohort.

Outcome measures

All outcomes were measured at the individual or event level and were derived from the protocols (boxes 1–3). For each of fever, hyperglycaemia, and swallowing dysfunction, the primary outcome was the proportion of patients for whom all relevant management and treatment protocols were delivered. Secondary outcomes were the proportions of patients who received each of the relevant individual protocol elements of care.

Data collection

Four auditors blind to study design conducted the audits. Auditors completed a 2-day training program. Audits were conducted by two pairs of auditors. Each pair of auditors
independently audited one record at anytime in the same medical record department so that they were available to each other to clarify uncertainties. For quality assurance purposes, 10% of patient records were re-audited. The audit tool and data dictionary are available at http://www.acu.edu.au/qasc.

**Statistical analysis**

Analyses were undertaken using STATA 11.0 software. Frequency distributions of sociodemographic and clinical characteristics of the sample are presented. All outcomes were adjusted for pre-intervention levels and for clustering within ASUs, using a logistic regression model fitted within a generalised estimating equation framework for binary outcomes and a random intercept linear regression model fitted for continuous outcomes. The linear and logistic models included the predictor variables of period (before and after), intervention, and the interaction between period and intervention. The P-value from the Wald test for the interaction term was used to determine if the pre-post change in the intervention group was statistically different to the change in the control group. For binary outcomes, the models were refit using the identify link so that the intervention effect could be presented as differences in proportions with 95% confidence intervals.

For outcomes involving treatment of patients meeting specific criteria (i.e. administration of paracetamol for individuals with temperature ≥37.5°C), patients also were defined as having met this care element if no treatment was required. As administration of paracetamol is restricted to four to six hourly per 24 hours the analysis was restricted to treatment of the first febrile event only. Since one patient may have experienced multiple hyperglycaemic events, similarly, the analysis was restricted to treatment of the first hyperglycaemic event.
This trial was approved by the Human Research Ethics Committee of the Australian Catholic University and the relevant ethics committees of each of the 19 participating hospitals.

**Results**

The majority of eligible ASUs agreed to participate (n=19, 95%). Of the 1861 eligible QASC consenting patients across the entire study period, medical records were unavailable for 57 patients (3.6%) (17 [2.4%] from the pre-intervention cohort and 40 [3.7%] from the post-intervention cohort) resulting in collection of data for 1804 patients. Of the 1804 patients, 718 were audited prior to commencement of the intervention (pre-intervention cohort) and 1086 were audited post implementation of the intervention (post-intervention cohort) (intervention: n=603; control: n=483) (figure 1). As previously published, age, sex, premorbid level of dependency (Modified Rankin Score [mRS]), stroke location, stroke severity, and time between onset of stroke symptoms and ASU arrival were similar for post-intervention patients in the intervention and control groups (table 1).

**Fever protocol adherence**

The fever protocol comprised two care elements (box 1). Significantly more patients from intervention ASUs had the primary outcome, that is, they met all fever care elements (n=186 of 603, 31% vs n=74 of 483, 15%, p=≤0.001). Significantly more patients from intervention ASUs had their temperature monitored at least once every four hours within the first 72 hours of stroke unit admission when compared with control stroke unit patients (n=222 of 603, 37% vs n=90 of 483, 19%, p=<0.001). Significantly more patients admitted to intervention ASUs also had their fever treated with paracetamol (n=528 of 603, 88% vs n=397 of 483, 82%, p=0.001); however, we noted that significantly fewer patients from intervention ASUs
developed a febrile event (n=105 of 589, 18% vs n=131 of 475, 28%, p=<0.001). Of those who developed a fever, there was no difference between groups in proportion of patients administered paracetamol within two hours of the first febrile event if temperature reached or exceeded 37.5°C (n=22 of 105, 21% vs n=38 of 131, 29%, p=0.78) (table 2).

**Hyperglycaemia (Sugar) protocol adherence**

The sugar protocol comprised five care elements (box 2). Significantly more patients from intervention ASUs had the primary outcome, that is, they met all sugar care elements (n=22 of 603, 3.7% vs n=3 of 483, 0.6% p=<0.001). Significantly more patients from intervention ASUs had a venous blood glucose measurement in the emergency department (ED) or within two hours of stroke unit admission (n=190 of 603, 32% vs n=68 of 483, 14%, p=<0.001). There was no difference between the groups in the proportion of patients who had a finger-prick glucose on admission to the ASU (n=192 of 603, 32% vs n=90 of 483, 19%, p=0.07). Significantly more patients from intervention ASUs had at least one finger-prick glucose every six hours within the first 72 hours of stroke unit admission (n=194 of 603, 32% vs n=46 of 483, 9.5%, p=<0.001). There was no difference between the groups in the proportion of patients who had intravenous normal saline commenced if finger-prick glucose level exceeded 8mmol/L (n=551 of 603, 91% vs n=450 of 483, 93%, p=0.85). There was no difference between the groups in the proportion of patients who were treated with insulin when first finger-prick glucose exceeded 11 mmol/L (patient with known diabetes) or first finger-prick glucose level exceeded 16 mmol/L (patient without known diabetes) (n=586 of 603, 97% vs n=471 of 483, 98%, p=0.35) (table 3).

A subgroup analysis showed that of those who received a finger-prick glucose level, there was no difference between groups in the proportion of patients who developed a
hyperglycaemic event (finger-prick blood glucose level >11 mmol/L) (n=100 of 507, 20% vs n=61 of 294, 21%, p=0.60) nor was there a difference between the groups in proportion of patients commenced on insulin (SCI or IVI) when finger-prick glucose exceeded 11 mmol/L (n=40 of 100, 40% vs n=17 of 57, 30%, p=0.47) (table 3).

Protocol adherence among patients without known diabetes

Patients without known diabetes admitted to intervention ASUs were significantly more likely to have their finger-prick glucose level monitored at least once every six hours within the first 72 hours of stroke unit admission (primary outcome) (119 of 403, 30% vs 15 of 218, 7%, p=0.003). Only three patients without known diabetes amongst the cohort developed a glucose level >16 mmols/L, our protocol insulin treatment level, therefore, we conducted an exploratory analysis investigating treatment with insulin at 11 mmols/L. There was no difference between groups in the proportion of patients without known diabetes who had a hyperglycaemic event >11 mmols/L (37 of 403, 9% vs 18 of 218, 8%, p=0.29) within the first 72 hours of stroke unit admission. Patients from intervention ASUs without known diabetes were significantly less likely to receive treated with insulin following a hyperglycaemic event (3 of 37, 8% vs 3 of 16, 19%, p=0.03) (table 4).

Protocol adherence amongst patients with known diabetes

Patients with known diabetes from the intervention ASUs were significantly more likely to have their finger-prick glucose level monitored at least once every six hours (n=75 of 104, 72% vs 31 of 76, 41%, p=0.03). There was no difference between the groups in the proportion of patients with known diabetes who had a hyperglycaemic event (finger-prick glucose >11 mmols/L) within the first 72 hours of stroke unit admission (63 of 104, 61%, vs 43 of 76, 57%, p=0.76), nor was there any difference between the groups in the proportion of
patients with known diabetes treated with insulin when glucose levels exceeded 11 mmols/L (37 of 63, 59% vs 14 of 41, 34%) (table 5).

**Swallow protocol adherence**

The swallow protocol comprised two care elements (box 3). Significantly more patients from intervention ASUs met the primary outcome criteria and received all relevant swallow care elements (n=2) (n=241 of 603, 40% vs n=19 of 483, 4.0%, p=<0.001). Significantly more patients from intervention ASUs underwent a swallowing screening within 24 hours of stroke unit admission (n=242 of 522, 46% vs n=24 of 350, 6.8%, p=<0.0001). Significantly more patients from intervention ASUs were referred to a speech pathologist for a comprehensive swallow assessment following a failed screen (n=289 of 603, 48% vs n=126 of 483, 26%, p=0.04). A subgroup analysis of those patients admitted to the ED prior to transfer to the stroke unit indicated that patients from intervention ASUs were significantly less likely to receive a swallow screen in the ED (n=105 of 308, 34% vs n=139 of 148, 94%, p=<0.001) prior to transfer to the stroke unit and more likely to receive a screen after ASU admission (n=15 of 148, 10% vs n=227 of 308, 74%, p=<0.001). Patients from intervention ASUs were significantly more likely to fail the swallow screen (n=89 of 308, 29% vs n=36 of 148, 24%, p=0.02) initiated by a non-speech pathologist. A lower proportion of patients from intervention ASUs underwent a comprehensive assessment by a speech pathologist following a failed screen (n=84 of 89, 94% vs n=36 of 36, 100%, p=0.03). Of those who failed the swallowing screening, there was no difference between the groups in the number of patients confirmed to have dysphagia by a speech pathologist (n=70 of 89, 79% vs n=14 of 36, 39%, p=0.15). There was no difference between the groups in the number of patients who had food or fluids prior to a screen (55 of 308, 18% vs 10 of 148, 7%, p=0.007); however, significantly
more patients admitted to intervention ASUs were administered medications prior to being screened (115 of 308, 37%, vs 14 of 148, 9.5%, \( p = 0.001 \)) (Table 6).

**Discussion**

Previous evaluations of multifaceted interventions to improve clinical outcomes have reported only modest improvements in clinical performance.\(^{15–18}\) Hence, there has been international interest about how change occurs.\(^{13,14}\) This process evaluation goes someway to illuminating the reasons for significant improvements in outcomes for patients that we reported in the main QASC trial results.\(^3\)

Our process evaluation shows that significantly more patients were managed according to the fever, sugar, and swallow protocols, demonstrating a clear positive influence of our intervention on behaviour change. However, although protocol adherence significantly improved, management of fever, hyperglycaemia, and swallowing dysfunction following stroke remained suboptimal with low absolute rates in both groups.

That we also found non-significant differences in treatment practice between groups is of interest. Although there was no improvement in treatment of fever within intervention ASUs fewer patients developed fever, this in itself is a positive outcome. We postulate that perhaps fewer patients in the intervention group developed fever because nurses were observing them more closely and providing other measures to control their temperature. We note also that there was no difference between the groups in the proportion of people treated for hyperglycaemia. In addition, following our intervention, non-known diabetics from intervention ASUs were significantly less likely to receive treatment for hyperglycaemia.
despite the evidence that stroke patients without known diabetes who have even moderately elevated glucose levels (>6.7 to 8 mmol/L) on admission have a three-fold risk of death relative to known diabetic patients with this same level of elevated glucose.\textsuperscript{19}

As with other process evaluations,\textsuperscript{16} we are still unable to explain definitively the large improvements in death and dependency found in the main trial results.\textsuperscript{3} One potential explanation is that improved monitoring may have led to better overall surveillance of deteriorating patients and faster initiation of other treatment not measured as part of the main trial.\textsuperscript{13}

Although our intervention was targeted at the ASU, we demonstrated that swallowing screening in the ED significantly declined. This could have occurred because ED clinicians from intervention hospitals may have known patients were now being screened in the ASU as part of participation in the QASC trial and decided to leave the screening for ASU staff. This may also have had an unintentional effect resulting in patients receiving medications, such as aspirin in the ED, prior to swallow screening. Further attention to the clinical behaviours of staff in EDs is now warranted to reduce the risk of aspiration pneumonia and worse outcomes for stroke patients.\textsuperscript{20} Our group now has secured funding to rigorously evaluate, amongst other things, introduction of the QASC FeSS protocols into 26 Australian EDs as part of the Triage, Treatment and Transfer cluster randomised controlled trial (T3 Trial).

Significantly more patients admitted to intervention ASUs failed a swallow screen conducted by a non-speech pathologist. Two systematic reviews have been reported in the literature on the evidence supporting swallowing screening procedures and their link with improved outcomes.\textsuperscript{21,22} Although significantly more patients from intervention ASUs were referred to
a speech pathologist following a failed screen, significantly fewer patients in intervention
ASUs were reviewed by the speech pathologist following a failed screen. It is possible that an
increase in referrals placed additional demands on speech pathologists and thus they were
unable to assess all patients identified at risk of swallow dysfunction from intervention ASUs.
Despite this finding, as previously reported rates of aspiration pneumonia did not differ
between groups.3

Our process evaluation sheds explanatory light on the trial results, however we acknowledge
some limitations. Organisational factors, such as ‘attitudes and beliefs’, may have affected
the successful uptake of our intervention.24 Although we addressed organisational barriers
through team-building meetings, more detailed measures of organisational change at a
systems level were beyond the scope of the trial.

We acknowledge the following strengths of our study. Our sample size was large, recruiting
19 of the 20 NSW ASUs and two large patient cohorts with low loss to follow-up for the
audit component (3.1%). Further, our evaluation was pre-specified rather than post hoc.
Unlike the majority of published process evaluations which are poorly reported,2 ours
adopted a published reporting framework.2 Much of the current literature on process
evaluations of complex interventions utilize qualitative methods. Fewer quantitative process
evaluations like ours have been published.2 Unlike prior process evaluations,16 we also had
access to baseline data thus strengthening the methodological rigour of our trial.

The majority of implementation interventions to change clinical behaviour are
undertheorised.24-30 More use of theory-based approaches has been recommended when
designing interventions to improve practice.5,31 Following the development of our
intervention, new evidence emerged suggesting that multifaceted interventions were no more effective than single interventions. Although we remain unable to explain the main trial outcome results fully, our process evaluation indicates that our multifaceted intervention had a positive effect on clinician behaviour change.

As the treatment of fever, hyperglycaemia and swallowing dysfunction remained suboptimal following the implementation of the intervention, we recommend further investigations to identify barriers to treatment of these care elements in acute stroke patients. However, our intervention clearly demonstrated better protocol adherence and significantly improved patient outcomes and, as such, roll out of the intervention in stroke services is warranted. In light of this, working in conjunction with the Agency for Clinical Innovation, the researchers have commenced roll out and evaluation of the QASC intervention on a larger scale in up to 36 stroke services in NSW.

**Conclusion**

Our trial results demonstrate the effectiveness of a multidisciplinary team building intervention to implement clinical protocols to improve fever, hyperglycaemia and swallowing dysfunction management following acute stroke. Our intervention resulted in better protocol adherence in intervention ASUs, which goes some way towards explaining our main trial findings of improved patient 90-day outcomes. Our results also support implementation of the FeSS clinical protocols on a wider scale.
References


Assessed for eligibility:
NSW category A and B^2 acute stroke units (ASUs) (clusters) (n=20)

Excluded:
ASUs withdrew (n=1 cluster)*

ASUs consented (n=19 clusters)

Patients assessed for eligibility (n=2366)

Patients excluded:
Ineligible (n=1432)^
Refused to participate (n=199)

Patients consented to medical record audit: (n=735)
Mean cluster size: (n=39 patients; median 31; minimum 10; maximum 83)

Medical records unable to be located:
(n=17, 3.7%)

Patient processes of care data analysed:
(n=718). Mean cluster size: (n=36 patients; median 30; minimum 6; maximum 83)

* this cluster withdrew prior to recruitment of any patients

^ Ineligible reasons and numbers: No stroke (n=472); presented ≥48hrs to stroke unit (n=373); palliative care (n=199); no English (n=153); unable to provide informed consent (n=136); unknown (n=82); no telephone (n=12); aged ≤18 yrs (n=5)

# Australian National Stroke Unit Program Category A or B = stroke units with immediate CT access and on-site high dependency units; Category B do not have on-site neurosurgery.1
Clusters analysed: (n=10)
Patient 90-day data analysed: (n=603)
Mean cluster size: (n=56 patients; median 62; minimum 15X; maximum 131)

Clusters and patients excluded from analyses: (n=0)

\* Patient ineligible reasons and numbers: No stroke (n=420); presented >48hrs to stroke unit (n=430); palliative care (n=160); no English (n=109); unable to provide informed consent (n=99); unknown (n=49); no telephone (n=6); aged ≤18 years (n=2).

Clusters analysed: (n=9)
Patient 90-day data analysed: (n=483)
Mean cluster size: (n=50 patients; median 56; minimum 11; maximum 101)

Clusters and patients excluded from analyses: (n=0)

\† Patient ineligible reasons and numbers: No stroke (n=776); presented >48hrs to stroke unit (n=395); palliative care (n=230); no English (n=94); unable to provide informed consent (n=66); unknown (n=58); no telephone (n=11); aged ≤18 years (n=1).
Table 1: Demographic and clinical characteristics of the post-intervention cohort behaviour change

<table>
<thead>
<tr>
<th>Variable</th>
<th>Statistic/Category</th>
<th>Control (n=483)</th>
<th>Intervention (n=603)</th>
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<td><strong>Age group</strong></td>
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<tr>
<td>&lt;65</td>
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<td>190/596 (32%)</td>
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<tr>
<td>65–74</td>
<td>123/480 (26%)</td>
<td>141/596 (24%)</td>
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<td>75–84</td>
<td>151/480 (32%)</td>
<td>171/596 (29%)</td>
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<td>≥85</td>
<td>69/480 (14%)</td>
<td>94/596 (16%)</td>
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<td><strong>Gender</strong></td>
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<td>Male</td>
<td>284/483 (59%)</td>
<td>356/483 (60%)</td>
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<tr>
<td>Female</td>
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<td>241/483 (40%)</td>
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<tr>
<td>Total Anterior Circulation Infarct</td>
<td>25/288 (9%)</td>
<td>37/561 (7%)</td>
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<td>Partial Anterior Circulation Infarct</td>
<td>119/288 (41%)</td>
<td>286/561 (51%)</td>
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<td>88/561 (16%)</td>
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<td>38/561 (7%)</td>
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<td><strong>Premorbid modified Rankin Scale (mRS)</strong></td>
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<tr>
<td>No symptoms at all</td>
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<td>461/515 (90%)</td>
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<tr>
<td>No significant disability despite symptoms</td>
<td>18/415 (4.3%)</td>
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<td>20/515 (3.9%)</td>
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<td>Moderate disability</td>
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<td><strong>Stroke severity (Los Angeles Motor Scale)</strong></td>
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<td>0 (mild stroke)</td>
<td>275/476 (58%)</td>
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<td></td>
</tr>
<tr>
<td>≥1 (more severe stroke)</td>
<td>275/476 (58%)</td>
<td>341/594 (57%)</td>
<td></td>
</tr>
<tr>
<td><strong>Time from onset of symptoms to stroke unit (hours)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>14.10 (11.76)</td>
<td>15.86 (10.70)</td>
<td></td>
</tr>
</tbody>
</table>
Box 1: Outcome measures for fever protocol

**Primary outcome measure**
- Proportion of patients who met all fever care elements (n=2 elements)

**Secondary outcome measures**
- Proportion of patients who met element one of the fever protocols: Temperature monitored and charted every four hours after stroke unit admission for first 72 hours. This element was defined as having been met if a patient had at least six readings within each of the first three 24-hour periods (72 hours in total) following stroke unit admission.
- Proportion of patients who met element two of the fever protocol: Temperature $\geq 37.5^\circ C$ treated with paracetamol. This element was defined as having been met if the patient was treated with paracetamol (at the first febrile event) within two hours of having temperature $\geq 37.5^\circ C$; or if panadol not indicated.
Box 2: Outcome measures for sugar protocol:

Primary outcome measure
- Proportion of patients who met all sugar care elements (n=5 elements)

Secondary outcome measures
- Proportion of patients who met element one of the sugar protocols: Formal glucose measured (venous blood not finger prick) on admission to hospital or on admission to the stroke unit. This is defined as having been met if the patient had glucose measured from venous blood either in the emergency department or within two hours of stroke unit admission.
- Proportion of patients who met element two of the sugar protocol: Finger-prick blood glucose on admission to stroke unit. This is defined as having been met if the patient has a finger-prick blood glucose within two hours of admission to the stroke unit (this is independent of the venous blood glucose measure).
- Proportion of patients who met element three of the sugar protocol: Finger-prick glucose every one to six hours for first 72 hours following stroke unit admission depending on previous blood glucose value: this element of care is defined as having been met if the patient had at least four finger-prick glucose measures within each of the first three 24-hour periods following stroke unit admission.
- Proportion of patients who met element four of the sugar protocol: On admission, if blood glucose between 8 mmol/L and 11 mmol/L and patient is diabetic, or between 8 mmol/L and 16 mmol/L and patient is not diabetic, start saline infusion. This element of care is defined as being met if, for the first finger-prick blood glucose, the patient has the specified combination of blood glucose level and diabetes status, and saline is administered within two hours of the relevant blood glucose reading, or if the patient did not have an elevated blood glucose and intravenous saline not indicated.
- Proportion of patients who met element five of the sugar protocol: If, at any time in first 72 hours after admission, blood glucose ≥11 mmol/L and patient is diabetic, or blood glucose ≥16 mmol/L and patient is not diabetic, start insulin infusion: This element of care is defined as being met if the patient has the specified combination of blood glucose level and diabetes status, within the first 72 hours from admission to the ASU, and insulin is administered within two hours of the relevant blood glucose reading, or if the patient did not have elevated blood glucose and insulin not indicated.
Box 3: Outcome measures for swallow protocol

Primary outcome measure
- Proportion of patients who met all swallow care elements (n=2 elements)

Secondary outcome measures
- Proportion of patients who met swallow clinical care element one: Patients underwent a swallowing screening within 24 hours of stroke unit admission. To meet the criteria for a successful swallowing screening the three individual elements all had to be documented in the patient’s medical records: level of consciousness, cranial nerve assessment, and a water swallow test; or a hospital-approved swallowing screening tool had to be completed. This element of care is defined as having been met if the patient did not have a swallow screen in the emergency department but did have a swallow screen within 24 hours of stroke unit admission.
- Proportion of patients who met element two of the swallow protocol: Patients who failed the swallowing screening were referred to a speech pathologist for a comprehensive swallowing assessment. This element is defined as being met if the patient was referred to a speech pathologist following a failed screen or if the patient did not fail the swallowing screening.
<table>
<thead>
<tr>
<th>Outcome (ICC^)</th>
<th>Group Control (n=483)</th>
<th>Intervention (n=603)</th>
<th>P†</th>
<th>Difference in absolute change (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcome measure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients who met all fever clinical care elements</td>
<td>74 (15%)</td>
<td>186 (31%)</td>
<td>&lt;0.001</td>
<td>14.8% (7.9% to 22%)</td>
</tr>
<tr>
<td><strong>Secondary outcome measures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients who met fever clinical care element 1: Temperature monitored four hourly for 72 hours following stroke unit admission</td>
<td>90 (19%)</td>
<td>222 (37%)</td>
<td>&lt;0.001</td>
<td>15.0% (7.9% to 22%)</td>
</tr>
<tr>
<td>Proportion of patients who met fever clinical care element 2: Temperature ≥37.5°C treated with paracetamol (2a); or no febrile event recorded for 72 hours following stroke unit admission</td>
<td>397 (82%)</td>
<td>528 (88%)</td>
<td>0.001</td>
<td>12.2% (5.0% to 20%)</td>
</tr>
<tr>
<td><strong>Subgroup analysis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients with a febrile event (temperature ≥37.5°C) for the first 72 hours after stroke unit admission (for those who had at least one temperature reading)</td>
<td>131 of 475 (28%)</td>
<td>105 of 589 (18%)</td>
<td>&lt;0.001</td>
<td>16.7% (8.5% to 25%)</td>
</tr>
<tr>
<td>Proportion of patients administered paracetamol within two hours when temperature ≥37.5°C (at first febrile event)</td>
<td>38 of 131 (29%)</td>
<td>22 of 105 (21%)</td>
<td>0.78</td>
<td>−3.0% (−18% to 13%)</td>
</tr>
</tbody>
</table>

† P-values are for the interaction term between intervention group and time period (pre or post intervention) and are adjusted for clustering within ASUs

^ Intra-cluster correlation co-efficient (ICC)
Table 3: Sugar protocol adherence

<table>
<thead>
<tr>
<th>Outcome (ICC^)</th>
<th>Group</th>
<th>Control (n=483)</th>
<th>Intervention (n=603)</th>
<th>P†</th>
<th>Difference in absolute change (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcome measure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients who met all sugar clinical care elements</td>
<td>3 (0.6%)</td>
<td>22 (3.7%)</td>
<td>0.01</td>
<td></td>
<td>3.6% (0.8% to 6.3%)</td>
</tr>
<tr>
<td><strong>Secondary outcome measures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients who met sugar clinical care element 1: Formal venous blood glucose on admission to the hospital or stroke unit</td>
<td>68 (14%)</td>
<td>190 (32%)</td>
<td>&lt;0.001</td>
<td></td>
<td>23.8% (16% to 31%)</td>
</tr>
<tr>
<td>Proportion of patients who met sugar clinical care element 2: Finger-prick blood glucose on admission to the stroke unit (within two hours of stroke unit admission)</td>
<td>90 (19%)</td>
<td>192 (32%)</td>
<td>0.07</td>
<td></td>
<td>8.8% (0.7% to 17%)</td>
</tr>
<tr>
<td>Proportion of patients who met sugar clinical care element 3: Finger-prick blood glucose every one to six hours within the first 72 hours of stroke unit admission</td>
<td>46 (9.5%)</td>
<td>194 (32%)</td>
<td>&lt;0.001</td>
<td></td>
<td>24.0% (17% to 31%)</td>
</tr>
<tr>
<td>Proportion of patients who met sugar clinical care element 4: intravenous normal saline commenced if finger-prick glucose &gt;8 mmol/L, or if intravenous normal saline not indicated</td>
<td>450 (93%)</td>
<td>551 (91%)</td>
<td>0.85</td>
<td></td>
<td>0.2% (–4.7% to 5.1%)</td>
</tr>
<tr>
<td>Proportion of patients who met sugar clinical care element 5: insulin administered for diabetic patients if finger-prick glucose &gt;11 mmol/L (or insulin not indicated); insulin administered for patients with no history of diabetes if finger-prick glucose &gt; 16 mmol/L (or insulin not indicated)</td>
<td>471 (98%)</td>
<td>586 (97%)</td>
<td>0.35</td>
<td></td>
<td>–1.4% (–4.3% to 1.6%)</td>
</tr>
<tr>
<td><strong>Subgroup analysis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of patients with a hyperglycaemic event (finger-prick blood glucose &gt;11mmol/L) within the first 72 hours after stroke unit admission (for those who had at least one finger-prick glucose reading)</td>
<td>61 (21%)</td>
<td>100 (20%)</td>
<td>0.57</td>
<td></td>
<td>–2.8% (–13% to 7.3%)</td>
</tr>
<tr>
<td>Proportion of patients treated with insulin when finger-prick blood glucose &gt;11 mmol/L (of those who had a hyperglycaemic event)</td>
<td>17 of 57 (30%)</td>
<td>40 of 100 (40%)</td>
<td>0.49</td>
<td></td>
<td>9.1% (–15% to 34%)</td>
</tr>
</tbody>
</table>

† P-values are for the interaction term between intervention group and time period (pre or post intervention) and are adjusted for clustering within ASUs
^ Intra-cluster correlation co-efficient (ICC)
### Table 4: Sugar protocol adherence among non-known diabetic patients

<table>
<thead>
<tr>
<th>Outcome (ICC^)</th>
<th>Group Control (n=394)</th>
<th>Intervention (n=495)</th>
<th>P†</th>
<th>Difference in absolute change (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Glucose monitoring</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-known diabetics with at least one finger-prick glucose reading within 72 hours of stroke unit admission</td>
<td>218 (55%)</td>
<td>403 (81%)</td>
<td>&lt;0.001</td>
<td>40% (31% to 49%)</td>
</tr>
<tr>
<td>Non-known diabetics with at least one finger-prick glucose reading recorded within two hours of stroke unit admission (of those who had at least one finger-prick glucose measurement)</td>
<td>61 of 218 (28%)</td>
<td>148 of 403 (37%)</td>
<td>0.06</td>
<td>−12% (−25% to 1.0%)</td>
</tr>
<tr>
<td>Non-known diabetics with at least one finger-prick blood glucose reading recorded every six hours within the first 72 hours of stroke unit admission (of those who had at least one finger-prick glucose measurement)</td>
<td>15 of 218 (6.9%)</td>
<td>119 of 403 (30%)</td>
<td>0.003</td>
<td>16% (5.0% to 26%)</td>
</tr>
<tr>
<td>Non-known diabetics with a hyperglycaemic event (finger-prick blood glucose &gt;11mmol/L) within the first 72 hours after stroke unit admission (for those who had at least one finger-prick glucose reading)</td>
<td>18 of 218 (8.3%)</td>
<td>37 of 403 (9.2%)</td>
<td>0.29</td>
<td>−4.0% (−12% to 4.0%)</td>
</tr>
<tr>
<td><strong>Glucose treatment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-known diabetics treated with insulin when finger-prick blood glucose &gt;11 mmol/L (of those who had a hyperglycaemic event)</td>
<td>3 of 16 (19%)</td>
<td>3 of 37 (8.1%)</td>
<td>0.03</td>
<td>−37% (−69% to −4.0%)</td>
</tr>
</tbody>
</table>

† P-values are for the interaction term between intervention group and time period (pre or post intervention) and are adjusted for clustering within ASUs

^ Intra-cluster correlation co-efficient (ICC)
Table 5: Sugar protocol adherence among known diabetic patients

<table>
<thead>
<tr>
<th>Outcome (ICC^)</th>
<th>Group</th>
<th>Control</th>
<th>Intervention</th>
<th>P</th>
<th>Difference in absolute change (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(n=89)</td>
<td>(n=108)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose monitoring</td>
<td>Known diabetics with at least one finger-prick glucose reading within 72 hours of stroke unit admission</td>
<td>76 of 89 (85%)</td>
<td>104 of 108 (96%)</td>
<td>0.22</td>
<td>8.0% (-5.0% to 20%)</td>
</tr>
<tr>
<td></td>
<td>Known diabetics with at least one finger-prick glucose reading recorded within two hours of stroke unit admission (of those who had at least one finger-prick glucose measurement)</td>
<td>29 of 76 (38%)</td>
<td>44 of 104 (42%)</td>
<td>0.57</td>
<td>-7.0% (-31% to 17%)</td>
</tr>
<tr>
<td></td>
<td>Known diabetics with at least one finger-prick blood glucose reading recorded every six hours within the first 72 hours of stroke unit admission (of those who had at least one finger-prick glucose measurement)</td>
<td>31 of 76 (41%)</td>
<td>75 of 104 (72%)</td>
<td>0.03</td>
<td>25% (3.0% to 48%)</td>
</tr>
<tr>
<td></td>
<td>Known diabetics with a hyperglycaemic event (finger-prick blood glucose &gt;11 mmol/L) within the first 72 hours after stroke unit admission (for those who had at least one finger-prick glucose reading)</td>
<td>43 of 76 (57%)</td>
<td>63 of 104 (61%)</td>
<td>0.76</td>
<td>4.0% (-20% to 27%)</td>
</tr>
<tr>
<td>Glucose Treatment</td>
<td>Known diabetics treated with insulin when finger-prick blood glucose &gt;11 mmol/L (of those who had a hyperglycaemic event)</td>
<td>14 of 41 (34%)</td>
<td>37 of 63 (59%)</td>
<td>0.06</td>
<td>28% (-1.0% to 57%)</td>
</tr>
</tbody>
</table>

^P-values are for the interaction term between intervention group and time period (pre or post intervention) and are adjusted for clustering within ASUs
^Intra-cluster correlation co-efficient (ICC)

Table 6: Swallow protocol adherence

<table>
<thead>
<tr>
<th>Outcome (ICC^)</th>
<th>Group</th>
<th>Control</th>
<th>Intervention</th>
<th>P</th>
<th>Difference in absolute change (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(n=483)</td>
<td>(n=603)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary outcome measure</td>
<td>Proportion of patients who met all swallow clinical care elements (n=2)</td>
<td>19 (4.0%)</td>
<td>241 (40%)</td>
<td>&lt;0.001</td>
<td>13% (5.5% to 21%)</td>
</tr>
<tr>
<td>Secondary outcome measures</td>
<td>Proportion of patients who met swallow clinical care element 1: swallowing screening by non-speech pathologist within 24 hours of stroke unit admission (of those who did not receive a screen in the emergency department)</td>
<td>24 of 350 (6.8%)</td>
<td>242 of 522 (46%)</td>
<td>&lt;0.0001</td>
<td>29% (22% to 36%)</td>
</tr>
<tr>
<td></td>
<td>Proportion of patients who met swallow clinical care element 2: referred to a speech pathologist following a failed screen; or had a screen and passed</td>
<td>126 (26%)</td>
<td>289 (48%)</td>
<td>0.04</td>
<td>14% (5.6% to 21%)</td>
</tr>
<tr>
<td>Subgroup analysis</td>
<td>Proportion of patients with a screen in the emergency department and prior to transfer to stroke unit</td>
<td>139 of 148 (94%)</td>
<td>105 of 308 (35%)</td>
<td>&lt;0.001</td>
<td>65% (52% to 78%)</td>
</tr>
</tbody>
</table>
Table 6: Swallow protocol adherence

<table>
<thead>
<tr>
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<th>Difference in absolute change (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of patients with a failed swallowing screening (of those who had a screen in the emergency department or stroke unit)</td>
<td>36 of 148 (24%)</td>
<td>89 of 308 (29%)</td>
<td>0.03</td>
<td>19% (2.7% to 36%)</td>
</tr>
<tr>
<td>Referred to speech pathologist following a failed screen</td>
<td>14 of 36 (39%)</td>
<td>70 of 89 (79%)</td>
<td>0.35</td>
<td>22% (−9.7% to 53%)</td>
</tr>
<tr>
<td>Proportion of patients who underwent a speech pathologist assessment following a failed screen by a non-speech pathologist</td>
<td>36 of 36 (100%)</td>
<td>84 of 89 (94%)</td>
<td>0.03</td>
<td>6.7% (1.2% to 27%)</td>
</tr>
<tr>
<td>Proportion of patients confirmed to have dysphagia by speech pathologist (of those who underwent a speech pathologist assessment and results were available)</td>
<td>8 of 34 (24%)</td>
<td>11 of 82 (13%)</td>
<td>0.07</td>
<td>21% (−2.8% to 45%)</td>
</tr>
<tr>
<td>Proportion of patients who had food or fluids prior to a screen or assessment (of those who had a screen or assessment in the emergency department or within 24 hours of stroke unit admission)</td>
<td>10 of 148 (6.8%)</td>
<td>55 of 308 (18%)</td>
<td>0.07</td>
<td>11% (−0.7% to 22%)</td>
</tr>
<tr>
<td>Proportion of patients who had medications prior to a screen or assessment (of those who had a screen or assessment in the emergency department or within 24 hours of stroke unit admission)</td>
<td>14 of 148 (9.5%)</td>
<td>115 of 308 (37%)</td>
<td>&lt;0.001</td>
<td>28% (14% to 42%)</td>
</tr>
</tbody>
</table>

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