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Book Chapter

Fever, Hyperglycaemia (Sugar), Swallow (FeSS) Protocols use in Australian hospitals: analysis of national stroke data and clinician perspectives of critical factors that influence their use
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Coughlan, Kelly (2025). Fever, Hyperglycaemia (Sugar), Swallow (FeSS) Protocols use in Australian hospitals: analysis of national stroke data and clinician perspectives of critical factors that influence their use [PhD Thesis]. Australian Catholic University.

<https://doi.org/10.26199/acu.922yy>

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Australian Catholic University Melbourne
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**Fever, Hyperglycaemia (Sugar), Swallow (FeSS) Protocols use in
Australian hospitals: analysis of national stroke data and clinician
perspectives of factors that influence their use.**

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8th July 2025

Statement of Authorship

This thesis contains no material that has been extracted in whole or in part from a thesis that I have submitted towards the award of any other degree or diploma in any other tertiary institution. No other person's work has been used without due acknowledgment in the main text of the thesis. All research procedures reported in the thesis received the approval of the relevant Ethics/Safety Committees (where required).

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Full Thesis Abstract

FEVER, HYPERGLYCAEMIA (SUGAR), SWALLOW (FeSS) PROTOCOLS USE IN AUSTRALIAN HOSPITALS: ANALYSIS OF NATIONAL STROKE DATA AND CLINICIAN PERSPECTIVES OF FACTORS THAT INFLUENCE THEIR USE.

Background/aims

The landmark Quality in Acute Stroke Care (QASC) Trial published in 2011 demonstrated that supported implementation of protocols to manage **F**ever, hyperglycaemia (**S**ugar) and Swallowing (**FeSS**) reduced death and disability post-stroke. Subsequently, in 2017, a ‘Strong Recommendation’ to support their use was included in the Australian Clinical Guidelines for Stroke Management. FeSS Intervention studies have been conducted (four locally and two internationally) as part of a fifteen-year implementation program to translate these protocols into everyday clinical practice. Despite this, many Australian patients do not receive this recommended care. In a national audit of acute stroke services in Australian hospitals (2021), prompt treatment for fever was reported for only 50% of patients and 25% of patients with hyperglycaemia and 40% of patients received oral intake before having their swallowing ability screened or assessed.

The overarching focus of this thesis is to evaluate and explore diffusion of the FeSS Protocols for stroke in Australian hospitals. Specifically, this program of work aims to evaluate ‘*passive*’ dissemination techniques (i.e. the strong recommendation in national clinical guidelines using data from the biennial national acute stroke service audits), and the sustainment of ‘*active*’ implementation strategies (such as those used by hospitals in FeSS Intervention studies and as reported by clinicians)

Methods

National stroke audit data and front-line clinician perspectives have been used to assess adherence and factors that influence sustainment of implementation strategies for the FeSS Protocols. The thesis is comprised of three studies: i) A systematic-narrative hybrid review of behaviour change interventions designed to improve clinician adherence to any stroke clinical practice guideline; ii) A quantitative pre-test/post-test study to evaluate adherence to the FeSS Protocols for stroke in Australian hospitals after the inclusion in the guidelines using national stroke audit data and iii) a qualitative descriptive process evaluation to investigate factors perceived by clinicians to influence sustained adherence to the FeSS Protocols.

Results:

Study One yielded seven systematic reviews and ten randomised controlled trials. Most studies reported an improvement in care processes but not patient outcomes. The wide variation in outcome measures and interventions, quality and study duration contributed to uncertainty in the evidence. The inclusion of mixed study designs in systematic reviews is likely to have influenced this uncertainty. However, in the absence of stronger evidence their important contribution to the overall body of evidence should not be discounted.

Study Two reported a modest but significant improvement in FeSS Protocol adherence post-guideline inclusion (Pre: 35% vs Post 40%, OR:1.2, 95%CI: 1.2, 1.3). Higher FeSS Protocol adherence was independently associated with hospitals' previous participation in a FeSS Intervention study and patients receiving care in a stroke unit. These findings

highlight that research participation can facilitate greater guideline adherence; and confirms the superior care received in stroke units.

Study Three consisted of interviews with Stroke Co-ordinators from hospitals stratified by adherence to the FeSS Protocols (high, low and variable). Two major *themes* (and sub-themes) were mapped to factors from the Sustainability of Innovation Framework. *Stroke Coordinator as sustainability champions and boundary spanners*; and *Hospital executive and middle management respect of stroke specialty* themes mapped to workforce, organisational, innovation-specific and political factors from the Framework. The importance of organisational support, designated stroke care areas, and recognition of stroke specialist nursing skills in fostering a culture of evidence-based practice were identified as key factors that influence sustained adherence to the FeSS Protocols. Additionally, the unique skillset of Stroke Coordinators to drive engagement and sustain evidence-based practice across services and disciplines was identified.

Conclusions:

A ‘strong recommendation’ in the 2017 Clinical Guidelines for Stroke Management for all acute stroke services to implement FeSS Protocols came several years after the seminal QASC Trial results were published in 2011. The substantial timeline used to evaluate the ‘natural history’ of the diffusion of the protocols into acute stroke care services provides new insights into longer-term adherence to this clinical practice guideline which may have wider applicability for other stroke clinical practice guidelines.

Collectively, the findings substantiate existing evidence on passive dissemination and highlight the value of specialised stroke unit care. The contribution of new knowledge relates to the importance of supporting hospitals to implement clinical practice guidelines, the long-term outcomes of both passive and active implementation strategies and evidence on the pivotal role of Stroke Co-ordinators as sustainability champions and boundary spanners.

The study of the diffusion of FeSS Protocols into acute stroke care services, offers new insights into the broader field of stroke care and implementation science by highlighting the influence of clinician behaviour on the integration and sustained use of evidence-based practices in clinical care.

1.1 Background

Globally, stroke is the second leading cause of mortality, and third leading cause of mortality and morbidity combined. One in four people will have a stroke in their lifetime.¹ Only a third of these patients will still be alive 10 years after their first stroke.^{2,3} The highest risk of death from stroke is within the first 30 days (17-30%).^{2,4} In Australia, a stroke occurs every eleven minutes and it is estimated that 2% of the population are living with the effects of stroke.⁵ This medical emergency occurs when blood flow to the brain is obstructed, (ischaemic stroke), or when a blood vessel bursts (haemorrhagic stroke).⁵ Ischaemic stroke is the most common stroke type accounting for approximately 85% of stroke types, and haemorrhagic stroke accounting for 15%.^{1,5}

Significant advances in acute stroke therapies such as thrombolysis ('clot busting' medication), endovascular procedures for clot retrieval,⁶ and the introduction of specialist stroke units⁷ are some examples of acute stroke treatment that have contributed to the decline in stroke mortality and morbidity over the last decade.⁵ The underlying hypothesis for the ability of stroke units to significantly reduce in-hospital mortality and morbidity is the centralised access to multidisciplinary stroke specialists and effective management of common stroke complications.⁷ Despite these improvements in stroke outcomes, there is still room for improvement with Australia lagging behind internationally in treatment rates with acute therapy and access to stroke units.⁵ Treatment within 60 minutes for thrombolysis was achieved for 29% of patients in the most recent 2023 National Audit of acute stroke services in Australian hospitals. In comparison, both the United Kingdom and the United

States have reported treatment rates for 60% of patients within this time frame. Additionally, in the same audit year only 48% of patients in Australia spent the majority ($\geq 90\%$) of their hospital admission in a stroke unit compared to 73% in the United Kingdom.⁸⁻¹⁰ These inconsistencies in care are attributed to disparities in service availability between regional and metropolitan areas, as well as limited community awareness that stroke is a time-critical medical emergency, contributing to delayed presentation and reduced access to timely treatment.¹⁰

Patients cared for in stroke units are more likely to be alive, independent and living at home one year after their stroke irrespective of stroke type or severity, age or sex.¹⁰ The updated Cochrane review in 2020 evaluated 29 trials (5,902 participants) and included analysis on the different models of stroke unit care. The benefits were most obvious in stroke units that were based in a discrete area (stroke ward).¹¹ Despite the substantial body of evidence supporting stroke unit care, ongoing research in this area is driven by the limited understanding of the specific contributions of individual components to improved patient outcomes.¹² These are presumed to consist of access to stroke specialist care, early mobilization and initiation of rehabilitation, multidisciplinary team coordination, continuous physiological monitoring, standardised care protocols, patient and caregiver education and effective monitoring and management of common complications in the acute stroke setting. Although these elements are believed to contribute to improved outcomes, their individual effects are yet to be definitively isolated or quantified.¹¹⁻¹³

Three common acute stroke complications are elevated temperature, raised glucose levels (hyperglycaemia) and swallowing difficulties. Elevated body temperature (fever >37.5 C) is reported in more than 30% of patients with acute stroke^{14,15} and is associated with a marked increase in morbidity, mortality and length of hospital stay.^{14,16} Elevated blood glucose levels (hyperglycaemia >7.2 mmol/L) affects between 40 to 60% of patients with acute stroke and is a predictor of death and disability^{17,18} irrespective of their diabetic status.¹⁹ Swallowing difficulty (dysphagia) post stroke occurs in over 40% of patients and can result in aspiration pneumonia, dependency and mortality.²⁰ Internationally, clinical practice guidelines have been developed for many conditions including stroke. These guidelines provide recommendations for frontline clinicians to deliver best-practice care informed by the latest research.²¹ Current recommendations outline best practice for monitoring and proactive management of fever and hyperglycaemia, as well as evaluating every stroke patient's swallowing status before allowing oral intake.²²⁻²⁷ However, compliance with these recommendations has been found to be inconsistent. Prompt treatment for fever was reported for only 50% of patients and 25% of patients with hyperglycaemia in the 2021 National Audit of acute stroke services report. Additionally, 40% of patients received oral intake before having their swallowing ability screened or assessed.²⁸ Similar widespread under monitoring and lack of treatment of fever, hyperglycaemia and swallow screening was reported more than a decade ago highlighting the suboptimal standard of stroke care and need for urgent behaviour change in Australian stroke services.²⁹ This instigated the Quality in Acute Stroke Care (QASC) randomised controlled trial (RCT) that developed standardised protocols to manage these three common acute stroke complications.^{30,31} The significance of the findings from this seminal Trial

instigated the development of a fifteen-year translational research program and is a key component of this thesis which is explained in detail in the following section.

1.2 Quality in Acute Stroke Care (QASC) Program of translational research

Established in 2005 with the seminal QASC RCT, the subsequent program of research that followed has influenced changes to policy, guidelines and clinical practice in Australia and internationally. The research conducted over the duration of this program consisted of two RCT's,^{31,32} three pre-test/post-test prospective studies,³³⁻³⁶ three process evaluation studies,³⁷⁻³⁹ studies exploring barriers and enablers to implementation,⁴⁰⁻⁴³ a data linkage study with the National Death Index to determine long-term all-cause mortality for QASC participants and a cross-sectional survey study.^{44,45} Translational research is regarded as a continuum of sometimes overlapping phases that represents a systematic progression of scientific discovery from basic research (T1/Phase 1) through clinical application (T2/Phase 2 and T3/Phase 3) to population-level health impact (T4/Phase 4).⁴⁶ Further details of the intervention studies from the QASC program of research (and the translational phase they relate to) are provided in this section with a brief synopsis of the aims, methods and outcomes for each outlined in Box 1. Their relevance to the background of this thesis is discussed in more detail in section 1.3.

Box 1 QASC Research program

Study	Aim	Method	Outcome
Quality in Acute Stroke Care (QASC) Trial³¹ 2005-2010 19 Stroke units (n=1696) NSW, Australia	To assess the effect of supported implementation of evidence-based treatment protocols for the management of fever, hyperglycaemia, and swallowing.	RCT Clinical protocols (to manage fever, hyperglycaemia and swallow) <u>Implementation Strategies:</u> Multidisciplinary workshops, barrier identification, opinion leaders, local adaptation, site champions, education, facilitation (site visits, telephone, and email support) reminders	15.7% more likely to be alive and independent at 90 days Improved SF-36 (physical health)
QASC Implementation Project (QASCIP)³³ 2013-2014 36 stroke services (n=2144) NSW, Australia	To assess the statewide scale-up of QASC intervention into all stroke units and services	Pre-test /post-test prospective study Clinical protocols (to manage fever, hyperglycaemia and swallow) *Same as QASC implementation strategies above	Significantly improved management of fever, hyperglycaemia and swallowing
Triage, treatment and transfer (T³) Trial³² 2013-2016 26 Emergency Departments (n=2242) NSW, ACT, VIC, QLD, Australia	To evaluate the effectiveness of an intervention to improve triage, treatment, and transfer for patients with acute stroke admitted to the emergency department	RCT Clinical protocols (to manage triage, treatment [thrombolysis, fever, hyperglycaemia and swallow] and prompt transfer to stroke unit *Same as QASC implementation strategies +state coordinators	No statistically significant differences in outcomes at 90 days (Death or dependency, health status [SF36] or 11 ED quality-of-care measures)
QASC Europe³⁵ 2017-2021 64 stroke services, 17 countries (n=6721) Europe	To determine real-world effectiveness of supported implementation of the FeSS Protocols across Europe.	Pre-test /post-test prospective study Clinical protocols (to manage fever, hyperglycaemia and swallow) *Same as QASC implementation strategies +1 audit cycle + country coordinators and remote facilitation	Significantly improved management of fever, hyperglycaemia and swallowing
QASC Germany³⁶ 2024 8 stroke units (n=1450) Germany	To evaluate the effects of nurse-led FeSS implementation on FeSS Protocol adherence in German stroke units	Pre-test /post-test prospective study Clinical protocols (to manage fever, hyperglycaemia and swallow) *Same as QASC Europe implementation strategies + country champions and remote facilitation	Statistically significant improvements in management of fever, hyperglycaemia and swallowing and shorter time to treatment.

·SF-36 Health Survey (Short Form), ED (Emergency Department), RCT (randomised controlled trial), NSW (New South Wales), ACT (Australian Capital Territory), VIC (Victoria), QLD (Queensland)

1.2.1 Translation of clinical research into patient care (T2/Phase 2): Quality in Acute Stroke Care (QASC) Trial

The seminal QASC Trial was an National Health and Medical Research Council (NHMRC) funded cluster RCT conducted in 19 stroke units in New South Wales (NSW) from July 2005-October 2010. The purpose was to evaluate the effect of a multifaceted implementation intervention to implement evidence-based stroke protocols on 90 day post stroke patient outcomes.³¹ Whilst their implementation required multidisciplinary collaboration, the protocols were specific to the nurse-initiated management of fever, hyperglycaemia (sugar) and swallowing (FeSS Protocols) for the first 72 hours after acute stroke unit admission. In the absence of standardised recommendations for the monitoring and treatment of these variables in the national stroke clinical practice guidelines at the time, a panel of clinical experts developed the FeSS Protocols with specific monitoring and treatment targets.⁴⁷ The aim of these protocols was to trigger prompt nursing assessment and bedside treatment for these three common post-stroke complications.³¹

Stroke units were randomised to receive support to implement the evidence-based FeSS Protocols, using evidence-based implementation science strategies.⁴⁸ These included multidisciplinary workshops with local opinion leaders for barrier identification,^{49,50} reinforcement of multidisciplinary teamwork⁵¹ and local adaptation.⁵² Additionally, a standardised interactive education program,^{53,54} the use of site champions,⁵⁰ site visits, telephone and email support as reminders⁵⁵ were also provided to the intervention stroke units. Those stroke units randomised to the control group received a copy of the national clinical guidelines for stroke, with no added support to implement them.³¹ More detail on the FeSS Protocols and evidence-based implementation strategies that made up the intervention used by the researchers in the QASC Trial are provided in Box 2.

Box 2. Quality in Acute Stroke Care Trial intervention

Clinical treatment protocols for FeSS management by nurses for first 72 hours of acute stroke unit (ASU) care: key elements

Fever

- Temperature monitored and charted every 4 h after admission to ASU for first 72 h.
- Temperature $\geq 37.5^{\circ}\text{C}$ treated with paracetamol (intravenous, per rectum, or oral), unless clinically contraindicated.

Sugar (hyperglycaemia)

- Formal glucose measured (venous blood not finger prick) on admission to hospital or admission to the ASU.
- Finger-prick blood glucose on admission to ASU.
- Finger-prick glucose every 1–6 h for first 72 h following ASU admission depending on previous blood glucose value.
- 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 for 6 h.
- If, at any time in first 48 h 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.

Swallowing

- Nurses underwent an education programme about dysphagia screening, which consisted of all nurses attending an in-service given by the speech pathologist using a DVD prepared specifically for this study.
- Nurses underwent a competency assessment before being able to screen patients, consisting of a pre-education and post-education written knowledge test, and a clinical competency test, completed on three patients and assessed by a speech pathologist.
- Patients were screened with the ASSIST tool by either a nurse who passed the competency test or a speech pathologist within 24 h of admission to ASU; the result of the screening was clearly documented in the patient's medical record by use of a sticker.
- Patients who failed the swallowing screening were referred to a speech pathologist for a swallowing assessment.

Site-based education and support

- Two multidisciplinary team-building workshops to identify local barriers and enablers to implement the FeSS nurse-initiated treatment protocols.
- Two site-based educational outreach meetings consisting of a standardised education programme about the FeSS treatment protocols delivered by the project officer (SD); Microsoft Powerpoint slides were left with the ASU nurse educator to be delivered to those who did not attend the meetings.
- Engagement of local stroke unit coordinators through support and feedback. The Project Officer (SD) visited each intervention ASU every 6 weeks, sent three monthly proactive emails to each site, and also instigated scheduled telephone follow-up every 3 months; all acted as reminders. She also responded to any site-based request for support if needed. Newsletters were sent out yearly.

ASU: Acute stroke unit; IV: Intravenous; PR: Per rectum; DVD: Digital video disc

Facilitated implementation of the multidisciplinary nurse-initiated FeSS Protocols to manage fever, hyperglycaemia and swallowing in stroke units was shown to reduce death and disability (15.7% adjusted absolute difference, number needed to treat 6.4) at 90 days post-stroke for patients in the QASC Trial.³¹ This finding was notable at the time for its clinical significance in relation to other available stroke treatments (e.g. aspirin, stroke unit care, thrombolysis within 4.5hours) that required much higher numbers needed to treat and absolute benefit of no more than 10%.³¹

Subsequent research conducted by the candidate (KC) prior to commencement of this thesis demonstrated these benefits were sustained, with over 20% of patients in the QASC intervention group more likely to be alive four years following their stroke⁴⁵. In Australia all death records are collated by the National Death Index and the Australian Institute of Health and Welfare links these to mortality codes from the Australian Bureau of Statistics.⁵⁶ This research was conducted as a data linkage study with the National Death Index, Australian Institute of Health and Welfare to determine long-term all-cause mortality for QASC participants. Median time for follow-up was 4.1 years (minimum 0.3 to maximum 70 months). Kaplan–Meier curves were generated to estimate the probability of survival and the log-rank test to compare crude survival by treatment group. Survival analysis was performed using Cox proportional hazard regression to compare time from hospital admission with stroke diagnosis to time of death between intervention and control groups. There was a small but clear divergence in survival curves by treatment group in the immediate post-trial period, which persisted over time (P value for log-rank test=0.05) (Figure 1). The regression analyses showed that those in the QASC intervention group, relative to control group, had improved survival of >20%. While unadjusted and adjusted hazard ratio benefits were similar, the difference was only statistically significant in the adjusted analyses (unadjusted hazard ratio [HR], 0.79; 95% confidence interval [CI], 0.58–1.07; $P=0.13$; adjusted HR, 0.77; 95% CI,

0.59–0.99; $P=0.045$). These results provided compelling evidence on the additional benefits of nurse-initiated multidisciplinary protocols for management of fever, hyperglycaemia, and swallowing dysfunction on longer-term mortality after discharge from stroke units.

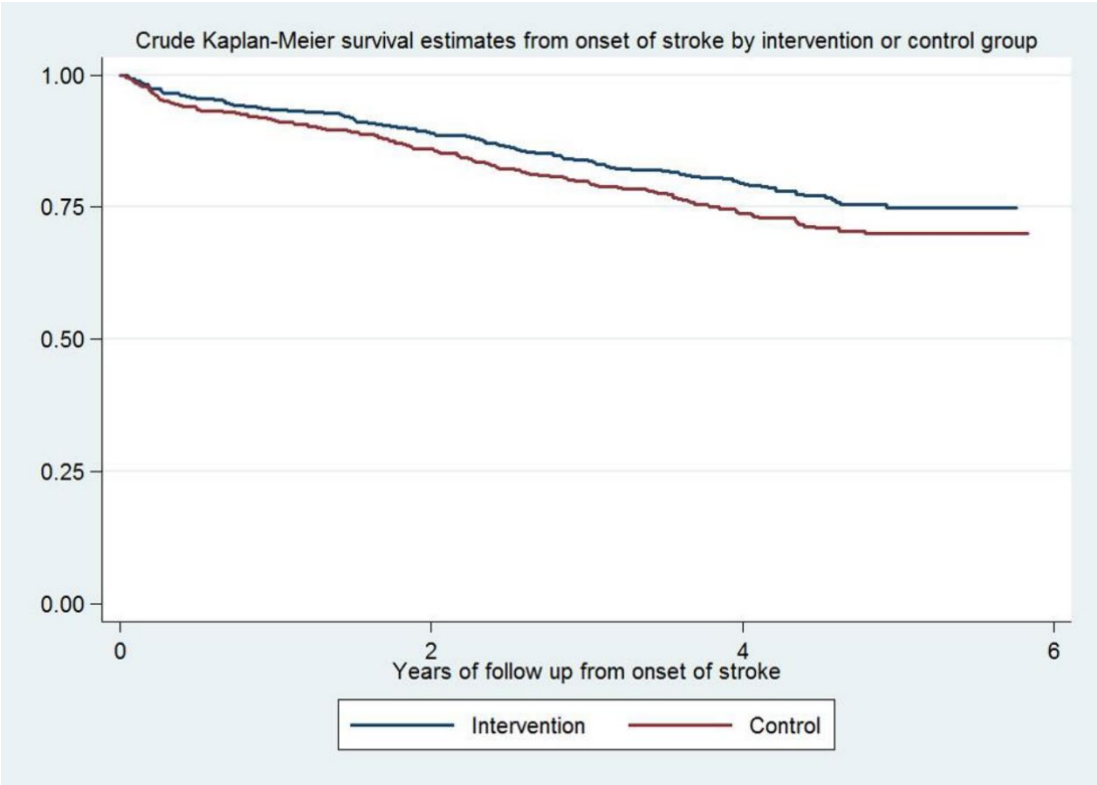


Figure 1. Kaplan–Meier survival estimates by treatment group

1.2.2 Translation of research into clinical practice (T3/Phase 3): Quality in Acute Stroke Care Implementation Project (QASCIP)

Scale up of the FeSS Protocols into all 36 NSW stroke services using those intervention elements demonstrated to be effective in the QASC trial, was evaluated from 2013-2014 using a pre-test/post-test prospective study design. The speed of this roll-out (eight months from intervention to completion of post implementation audit) was made possible by the collaboration with the National Stroke Foundation who included FeSS variables for the first time in their biannual national audit of acute stroke services and a collaboration with the NSW Agency for Clinical Innovation who provided sponsorship of the study.³³ Logistic regression analyses were undertaken to compare monitoring and treatment outcomes pre-and post-implementation. The proportions of patients receiving the three targeted clinical behaviours increased significantly: management of fever (pre: 69%; post: 78%; $p=0.003$), hyperglycaemia (pre: 23%; post: 34% $p=0.0085$) and swallowing (pre: 42%; post: 51%; $p=0.033$).³³

This study was novel for its time in that it was one of the few to successfully and systematically replicate methods from a positive implementation trial. The rapid rollout of the FeSS Protocols to all stroke services in NSW demonstrated that large-scale, evidence-based improvements in clinical care were achievable. The results, albeit statistically significant, also highlighted that there were still many patients not receiving evidence-based care for these serious post stroke complications (ie. only 35% patients in stroke units in NSW being appropriately managed for hyperglycaemia and fewer than half for swallow complications).

1.2.3 Translation of research into patient care and clinical practice (T2/Phase 2 and T3/Phase 3): Triage, Treatment and Transfer (T³) Trial

Scale up and spread of the FeSS Protocols into emergency departments (ED) and other states and territories in Australia was undertaken in the Triage, Treatment and Transfer (T³) cluster RCT (2013-2016).³² The investigators identified other variations in stroke ED management to target in addition to the suboptimal FeSS care processes demonstrated in QASCIP³³ and the national audit of acute stroke services 2013.⁵⁷ These included triage (30% patients with stroke being triaged incorrectly),⁵⁸ treatment (less than half of patients with stroke being assessed for thrombolysis, and only 7% of eligible patients receiving thrombolysis)⁵⁷ and transfer (median time from ED to stroke unit 7-11 hours (up to 20 hours)).^{37,59}

Twenty-six EDs in NSW, Victoria, Australian Capital Territory, and Queensland jurisdictions in Australia were randomised to receive the bundled T³ intervention or no support (control group). The intervention consisted of clinical protocols (to manage triage, treatment [thrombolysis, fever, hyperglycaemia and swallow] and prompt transfer to stroke unit). The same evidence-based implementation strategies as those previously demonstrated to be effective in stroke care settings (QASC and QASCIP studies) were utilised with the new addition of state or territory coordinators. Despite this, there were no significant differences in either the primary patient outcome of 90-day death or dependency; secondary patient 90-day outcomes of functional dependency or health status; or changes in ED clinical behaviour.^{32,60} A subsequent process evaluation determined that these neutral trial results were attributed to low intervention uptake and the context of competing demands of busy emergency departments, challenges also noted in other studies evaluating ED-based behaviour change interventions.^{32,61,62} Additionally, the senior nurses tasked with implementing change

and integrating the FeSS Protocols reported barriers that were relevant to their perceived professional boundaries in the context of low medical engagement and belief about the supporting evidence.³⁹

1.2.4 Translation of research into clinical practice (T3/Phase 3): QASC Europe and QASC Germany studies

International scale up and spread of the FeSS Protocols was evaluated in the QASC Europe (2017-2021) pre-test/post-test prospective study. A unique collaboration was formed with the European Stroke Organisation, the not-for-profit European Acute Networks Striving for Excellence in Stroke (Angels) Initiative (operating in European hospitals to optimise the quality of stroke treatment), and the Registry of Stroke Care Quality (RESQ). The study was coordinated remotely (by the research team in Australia) and used the same evidence-based implementation strategies as those previously demonstrated to be effective in stroke care settings (QASC and QASCIP studies). The FeSS Protocols were translated into thirteen languages and were delivered to local hospital champions by the Angels Initiative (non-medical) consultants who were able to support implementation strategies in the native language. A Project European Liaison Officer from the research team was also available to support the Angels Initiative consultants. Additionally, audit and feedback (hospitals were provided with their baseline audit results) and country champions were incorporated into the study design.³⁵

Statistically significant improvements for all three FeSS components were reported: fever elements (Pre: 17%, Post: 51%; Absolute difference 33%, 95% CI 30%, 37%; $p < 0.0001$); hyperglycaemia elements (Pre: 18%, Post: 52%; Absolute difference 34%; 95% CI 31%, 36%; $p < 0.0001$); swallowing elements (Pre: 39%, Post: 67%; Absolute

difference 29%, 95% CI 26%, 31%; $p < 0.0001$) and thus, in overall FeSS Protocol adherence (Pre: 3.4%, Post: 35%; Absolute difference 33%, 95% CI 24%, 42%; $p < 0.0001$).³⁵

QASC Germany (2024) was another international intervention study on a smaller scale. Translation of the FeSS Protocols into eight hospitals from the Interdisciplinary Neurovascular Network of Rhein-Main region was conducted using a pre-test/post-test prospective study design. Remote coordination (by the research team in Australia) and the same evidence-based implementation strategies as those used in QASC and QASCIP studies, were used with the addition of audit and feedback and country champion. Improvements were reported for overall FeSS adherence (Pre 20%, Post 28%; Adjusted difference in proportions (95% CI) 11%, (5.1%, 16%); $p < 0.001$), adherence to hyperglycaemia (Pre 43%, Post 55%; Adjusted difference 23%, (17%, 29%); $p < 0.001$) and swallowing (Pre 52%, Post 61%; Adjusted difference 11%, (5.2%, 17%); $p < 0.001$) but not fever protocol (Pre 76%, Post 78%; adjusted difference 1.5%, (-2.6%, 5.7%); $p = 0.474$). Improvements also were noted in administration of paracetamol (or other anti-pyretics) (Pre 29%, Post 59%; Adjusted difference 32%, (20%, 44%); $p < 0.001$); and insulin (Pre 41%, Post 60%; Adjusted difference 14%, (1.1%, 28%); $p < 0.034$) both within one hour, as well as in performing a swallow screen within 24hours of admission (Pre 65%, Post 74%; Adjusted difference 18% (8.8%, 26%); $p < 0.001$).³⁶

The translation of research into clinical practice in these global studies demonstrated that nurse-led, structured implementation of evidence-based protocols can improve the quality of stroke care even in diverse healthcare systems, likely transforming into improved patient outcomes, as shown in the original QASC study.³¹

1.2.5 Translation of research into population health (T4/Phase 4): Economic evaluation studies

External to the QASC program of translational research there have been two independent economic evaluations conducted in relation to use of the FeSS Protocols. This translation of research at the population level using economic evaluation methods assessed the cost-effectiveness of implementing evidence-based interventions at scale. These studies inform policy decisions by evaluating if interventions deliver value for money in diverse healthcare settings.⁶³ The first study, published in 2017, estimated that if 65% of eligible Australian stroke patients were managed using the FeSS Protocols over a 12 month period, there would be a saving of AUD \$281 million (gross).⁶⁴ The second study, published in 2021, estimated that over five years if the FeSS Protocols were implemented across the Australian stroke population this would prevent 1,154 deaths and yield an extra 876 years of life lived and 3,180 quality adjusted life years (QALYs). This would save the Australian healthcare system more than AUD \$65.2 million and AUD \$251.7 million in societal costs.⁶⁵

1.2.6 Translation of research into population health (T4/Phase 4): Clinical Practice Guideline and Policy changes

As a result of the seminal QASC Trial findings, a ‘Strong Recommendation’ to support use of the FeSS Protocols was included in the 2017 Australian Clinical Guidelines for Stroke Management namely: *‘All acute stroke services should implement standardised protocols to manage fever, glucose and swallowing difficulties in stroke patients’* (Middleton et al.).²² While information related to swallow processes has been included in national guidelines since 2007, recommendations related to the fever and hyperglycaemia protocols were new inclusions in this recommendation for a bundled care process to manage fever, hyperglycaemia and swallowing.²²

The strength of QASC Trial findings also prompted the inclusion of the FeSS variables for the purpose of auditing clinical practice in a national initiative designed to promote quality improvement in stroke care, namely the National Stroke Audit. In 2013, for the first time, fever and hyperglycaemia variables were incorporated (swallowing variables were already included). The National Stroke Audit for acute stroke services is a Stroke Foundation initiative that commenced in 2007. It is designed to report on adherence to recommendations outlined in the Clinical Guidelines for Stroke Management and the Australian Commission of Safety and Quality in Health Care's Acute Stroke Clinical Care Standard.⁶⁶ This voluntary audit cycle on clinical performance is conducted in acute stroke services biennially with good participation nationally. For example, acute stroke services participation rate in 2019 and 2021 was 76% & 79% of all eligible public services respectively,⁶⁷ which reflects 89% of all hospital admissions with stroke.

Retrospective audit data are collected in the Australian Stroke Data Tool (AuSDaT) which is a national harmonised online database platform enabling standardised and systematic data collection for multiple stroke data collection programs.⁶⁸ It is generally considered to be a passive form of audit given their retrospective nature, infrequency (acute stroke services alternate each year with stroke rehabilitation service) and delayed feedback loop associated with historical data.⁶⁹

1.3 Uptake of the FeSS Protocols over time

In 2017, adherence to the FeSS Protocols were evaluated across Australia using data from the National Acute Services Stroke Audit. While findings demonstrated some increase in uptake over a 4-year period (2013-2017), a significant evidence practice gap remained.⁷⁰ Fever, hyperglycaemia and swallow management were shown to be sub-optimal with only 41% of patients receiving all FeSS processes in 2017, and over half of those with fever, and three in

five with hyperglycaemia did not receive timely paracetamol and insulin, respectively.⁷⁰ The literature suggests that adherence to clinical practice guidelines after an intervention trial tends to decrease after one year.⁷¹ This is highly variable as in the aforementioned study greater uptake of the FeSS Protocols in hospitals that participated in the two original FeSS Intervention studies, QASC Trial and QASCIP, up to six years following the original trial were demonstrated.⁷⁰

This trend of sub-optimal adherence to clinical practice guidelines also has been noted for many stroke-related care processes that make up the Acute Stroke Clinical Care Standard indicators (e.g., access to stroke unit care, discharge anti-coagulation for atrial fibrillation, carer needs and training). Overall, when comparing audit years, there has been improvements in the uptake of each of these care standards. However, the persistent wide variation between regions has resulted in many of these indicators falling short of their achievable targets.²⁸

The transfer of knowledge, from those who produce the evidence in clinical research, to health professionals that need to implement this knowledge, is notoriously challenging for all conditions, including stroke. The substantial time lag from evidence generation to translation into routine clinical practice has been a persistent challenge for centuries.⁷² It is commonly cited that only 14% of research findings are ever integrated into everyday clinical settings, and this typically occurs over an average span of 17 years.⁷³ Alarming, this estimate is only based on 50% uptake and utilisation rate.⁴⁶ These figures highlight the ongoing systemic gap between knowledge generation and its practical application in healthcare delivery, emphasising the need for effective knowledge translation strategies. Clinician behaviour change and strategies for implementation of evidence-based care are discussed in further detail in this chapter in section 1.4.

Understanding the barriers to effective implementation is key to bridging the gap in translation of research into routine clinical practice and improving patient outcomes. Throughout the QASC program of translational research, barrier identification has been a key evidence-based implementation strategy that formed the basis of the multidisciplinary workshops.⁷⁴ Clinician reported barriers to using the FeSS Protocols have been used to inform each subsequent phase of the QASC Program of translational research and incorporated into the ongoing design and delivery of the intervention.⁴⁰⁻⁴³

In the seminal QASC Trial perceived barriers and enablers were collected prior to implementation of the FeSS Protocols during the multidisciplinary workshops. Post implementation an online survey was used to determine which, if any, had been actual barriers to FeSS protocol uptake.⁴³ Four main themes identified 22 barriers pre-implementation in relation to: (i) need for new policies; (ii) limited workforce (capacity); (iii) lack of equipment; and (iv) education and logistics of training staff. Of the 22 perceived barriers, only five were reported as actual barriers to implementation of the FeSS Protocols during the trial. These consisted of: (i) no previous use of insulin infusions; (ii) hyperglycaemic protocols could not be commenced without written orders; (iii) medical staff reluctance to use the ASSIST swallowing screening tool; (iv) poor level of engagement of medical staff; and (v) doctors' unawareness of the trial.⁴³ The study findings highlighted how many perceived barriers do not always eventuate as actual barriers to the implementation of new protocols and changes to workplace processes. Additionally, it also emphasised the value in providing this opportunity for the multidisciplinary team to work together to identify and overcome these potential barriers before implementation.⁷⁵

As identified in this study and subsequent exploration of barriers throughout the QASC program of translational research, resistance to treatment of hyperglycaemia has been consistently identified.^{39,41} Driving this has been the misconception regarding the safety of glycaemic management in stroke and the evidence supporting tight versus standard blood glucose level control.³⁹ The Glucose Insulin in Stroke (GIST) Trial conducted in stroke units in the United Kingdom showed no clinical benefit with an intensive insulin regime targeting a tight blood glucose level of 4-7 mmol/L.⁷⁶ Similarly, the Standard Treatment of Hyperglycaemia and Functional Outcome in Patients With Acute Ischemic Stroke (SHINE) Trial (conducted in high level care units able to manage intravenous insulin and stroke thrombolysis infusions) in the United States of America showed no clinical benefit with an intensive insulin regime targeting a tight blood glucose level of 4.4-7.2mmol/L.⁷⁷ The Intensive versus subcutaneous insulin in patients with hyperacute stroke (INSULINFARCT) Trial conducted in an intensive care unit in France, demonstrated no clinical benefit with an intensive insulin regime targeting a tight blood glucose level of 5.5-7mmol/L and an increase in infarct size.⁷⁸ Of note, all these trials were testing tight or intensive glucose control that were aiming to keep blood glucose levels below 7.2 mmol/L. All trials were negative showing no benefits for tight glycaemic control. However, evidence exists of the deleterious effect of uncontrolled glucose levels post stroke.⁷⁹ Consequently, international and national diabetes guidelines recommend managing glucose levels for all stroke patients to achieve and maintain blood glucose levels less than 10mmol/L.⁸⁰ Importantly, the same thresholds for treatment are recommended in myocardial infarction and for all hospitalised patients that are not critically unwell, highlighting these are national policies that are not specific to stroke patients only.^{80,81} The Australian Diabetes Society Guideline cites evidence from the seminal QASC Trial and the national Clinical Guidelines for Stroke Management to support their current recommendation for the management of major episodes of hyperglycaemia in acute stroke patients.⁸¹ Despite these clear recommendations, treatment for hyperglycaemia has been

particularly poor with less than a third of patients receiving recommended prompt treatment with insulin in QASC, QASCIP and T³ FeSS Intervention studies (14%, 27% and 13% of patients received insulin within one hour of major episode of hyperglycaemia post-intervention respectively).³¹⁻³³ Interestingly, this was not an issue in the international translation of these protocols who reported much higher proportions of patients treated promptly with insulin for hyperglycaemia in the QASC Europe and QASC Germany studies (75% and 60% of patients post-intervention respectively).³⁶ This contrast highlights the challenges with implementation fidelity of the FeSS Protocols and systemic clinical culture in Australian hospitals, however it also underscores what is potentially achievable.

1.4 Adherence versus sustainment

Outside of the FeSS Intervention studies (QASC Trial, QASCIP and T³) there has been **no systematic implementation of the FeSS Protocols across Australia.** The only data in relation to FeSS Protocol adherence have been derived from these studies and the management of FeSS complications from data collected in the biennial national acute stroke audits. The FeSS Intervention studies only included hospitals from the eastern states and territories of Australia (as other states were not eligible to participate), and not all hospitals that participated in these studies received the intervention due to randomisation within individual studies.

As sustainability is assessed after implementation has been established,^{35,82} this is not a primary focus of this thesis. However, the exploration of adherence to the FeSS Protocols across all hospitals nationwide will shed light on ‘sustainability’ in relation to whether it has occurred as a result of diffusion of the evidence over time. This concept is discussed further in section 1.6 of this chapter.

1.5 Clinician Behaviour Change and Implementation Science

Given the lack of nationwide systematic implementation of the FeSS Protocols, any serendipitous improvements in practice has been the result of passive dissemination such as the new guideline recommendation, the national acute stroke services passive audit and feedback cycles every second year, and dissemination of study results at national and international conferences and in scientific publications.⁸³ Historically, the untargeted distribution of published clinical practice guidelines (i.e. passive dissemination)⁸⁴ has been reported as ineffective when used in isolation to change clinical practice.⁸⁵ When compared to more passive approaches, active implementation and dissemination techniques, particularly multi-faceted strategies, have been shown to be more effective in driving changes in healthcare professional behaviour.⁸⁵ However, there is an argument that the significant costs and resources associated with some active implementation strategies, potentially outweigh the benefits of the clinical practice guideline being introduced.⁵⁵ Less expensive strategies that are simpler to implement, may also be more sustainable.⁸⁶ Recent research suggests that it is possible to achieve similar results with passive dissemination under certain conditions (i.e., in sites with moderate to high level of expertise and motivation, self-identified champions, and sufficient resources). More active dissemination efforts could then be reserved only for those sites where these conditions are absent.⁸⁴ The topic of clinician behaviour change and its relevance to the primary focus of this thesis is explored in further depth in section 1.5 below.

The complex issue of the translation of evidence into practice is not exclusive to the QASC Program of research or stroke populations. This is evidenced by consistent findings that approximately 40% of patients in hospital do not receive care that aligns with clinical practice guidelines for many of the most common medical conditions.^{87,88} The significant time lag after establishing efficacy of evidence-based interventions in health care, to translation into

clinical practice has driven the evolution of implementation science and research.⁸⁹ This branch of health related research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, to improve the quality and effectiveness of health services and care. It includes the study of influences on healthcare professional and organisational behaviour.⁹⁰ Implementation is part of the diffusion-dissemination-implementation continuum as the process of integrating new practices within a setting.⁹¹ Diffusion refers to the passive, informal and untargeted spread of new practices. Dissemination is the active deliberate spread of new practices to the target audience using formal planned strategies.⁹²

To translate the knowledge from evidence-based clinical practice guidelines into real world practice, behaviour change at both the organisational level and from the individual is required.⁹³ This challenge is notoriously difficult with active implementation and dissemination strategies (such as educational meetings / materials / outreach, local opinion leaders, computerised reminders) achieving widely variable success.⁹⁴ Another active implementation strategy, audit and feedback, is one of the most frequently used and studied implementation strategies for clinician behaviour change as evidenced by the systematic reviews on this topic.^{95,96} The most recent updated review evaluated 292 randomised controlled trials (RCTs) and the overall finding was a median effect size of 6.2% (Interquartile range [IQR] 4.1% to 8.2%) absolute increase in health care professionals' compliance with desired practice.⁹⁷ Similarly, a systematic review of the evidence for educational meetings and workshops reported a median effect size of 4.0% (IQR) 0.29% to 13.0%).⁹⁸ Although the evidence is now well established for the use of these implementation strategies, it is the wide range in effect size of many of these driving continued research in this area to understand why such variability exists.⁹⁴ The Cochrane systematic review of audit and

feedback has recently been updated.⁹⁷ Although the wide range in effect size has been reduced from the earlier review,⁹⁵ one quarter of the included studies in the updated review reported the use of audit and feedback was either not effective or the effect on professional practice was reduced.⁹⁷ This highlights the importance of context for audit and feedback as an implementation strategy. Establishing the determinants of effect size with behaviour change interventions is critical to knowledge translation.

Combining two or more implementation strategies is generally considered to be more effective than single strategies however, the evidence for this is uncertain.^{55,94} The use of multifaceted implementation strategies specific to evidence-based stroke care is discussed further in Chapter Two section 2.7.10.

Clinical guideline dissemination and implementation strategies targeting health professionals behaviour change have been the subject of many research studies over the decades⁹⁹ which now includes hundreds of systematic reviews and two Cochrane Effective Practice and Organisation of Care (EPOC) overviews of systematic reviews.^{100,101} With a growing body of literature demonstrating a positive association between the number of evidence-based care processes received in hospital and patient outcomes such as short^{102,103} and long-term survival,¹⁰⁴ greater functional outcome¹⁰³ and quality of life,¹⁰⁴ it is vital that future research is directed at resolving this vexatious health care issue.

1.6 Sustainability of evidence-based care

Sustainability is considered to be the final stage of the diffusion-dissemination-implementation continuum, referring to the ability to maintain the intervention (evidence-based care) over time.¹⁰⁵ Despite this, many studies evaluating the sustainability of evidence-based interventions in healthcare fail to define sustainability with sustainability periods either undefined or not long enough to truly understand if the intervention has been sustained.^{89,106} The implementation strategies discussed in the previous section to target individual and organisational behaviour change have demonstrated varying effectiveness in improving adherence to evidence-based care processes.^{55,97,98,107} Long term sustainability of these strategies remains unclear.

More than twenty years ago, an extensive systematic review of the literature conducted to develop the Conceptual Model for considering the Diffusion of Innovations in Health Service Delivery and Organisations,⁹¹ identified the near absence of empirical literature addressing the sustainability of innovations beyond initial implementation. Subsequently, there has been a great deal of research undertaken in this space,^{106,108-111} yet a widely endorsed definition of sustainability is yet to be established.^{111,112} Additionally, the inconsistent use of terminology often used interchangeably, has contributed to a lack of clarity in relation to sustainability concepts (i.e. sustainability, sustainment, maintenance, routinisation).^{82,112} The commonly cited definition of sustainability by Moore et al., is described as a process that occurs: (i) after a specific period of time; (ii) a program, clinical intervention, and/or implementation strategies continue to be delivered (iii) and/or individual behaviour change is maintained; (iv) the program and individual behaviour change may evolve or adapt while continuing to (v) produce benefits for individuals/systems.⁸² To reduce any ambiguity in relation to sustainability terms and concepts it is recommended that researchers specify the dimensions

of sustainability that their studies will address, and provide definitions that are in alignment with current sustainability literature.¹¹³ In alignment with Moore et al.'s definition,⁸² sustainability is referred to in this thesis as the continued delivery of the evidence-based FeSS Protocols (as measured by adherence as a sustainability outcome). Sustainment is referred to as the continued use of implementation strategies for the FeSS Protocols longer-term.^{108,114}

As noted earlier in this chapter, sustainability is typically evaluated once new knowledge and interventions have been successfully embedded into routine clinical practice.¹¹¹ In relation to 'sustainment' of the FeSS Protocols, no systematic sustainment activities have been conducted with any of the participating hospitals in the FeSS Intervention studies (QASC, QASCIP,T³).^{31,33} As the hospitals in the intervention groups from these studies represent the only available data on implementation, broader implementation efforts are unknown. In acknowledgement of this limitation, sustainability is not the primary focus of this thesis.

The time frame for measuring sustainability and sustainment are also not well-defined but there are recommendations in the literature that suggest sustainability should be assessed two or more years after implementation.^{108,115} A systematic review specific to sustainability of clinical practice guidelines included studies if they were at least one year post implementation.¹¹⁶ Although broader implementation efforts outside the FeSS Interventions studies are unknown, the timeline from the initial evidence supporting the FeSS Protocols (published 2011), to their inclusion in national stroke guidelines (2017), and the 15-year QASC translational research program, afforded the opportunity to assess diffusion and sustained use of the FeSS Protocols in real world clinical practice over a substantial time period. One study within this doctoral research program explores these longer-term outcomes.

Barriers and facilitators influencing the sustainability of hospital-based interventions were evaluated in a recent systematic review.¹¹⁷ Three key influences were identified that promote the long-term sustainability of innovation in hospital practice. These consist of having a clear accountability of roles and responsibilities; ensuring there is strong senior organisational leadership to support the intervention, and clinical champions advocating for use of the intervention. The most frequently reported barrier to sustainability was inadequate staff resourcing.¹¹⁷ Exploring similar constructs for sustainability in relation to hospitals' level of adherence to the FeSS Protocols over time is explored in the final study of this thesis. (Chapter 5). Critical end-user perspectives on individual and organisational factors perceived to influence adherence to FeSS Protocols are analysed in relation to their hospitals adherence as reported in the national acute stroke audits.

1.7 Significance of translation of research into the National Stroke Clinical Practice Guideline

The inclusion of the new guideline recommendation for use of the FeSS Protocols provided a unique opportunity to assess FeSS Protocol adherence beyond 2017 and the impact on improved care processes using National Acute Stroke Services audit data. Adherence to the evidence-based stroke clinical practice guideline serves as a natural history study of diffusion of this evidence into acute stroke care services nationally over time. The use of passive dissemination of a clinical practice guideline is complimented by data from hospitals exposed to active implementation strategies through participation in FeSS Intervention studies as part of the broader QASC program of translational research. This thesis contributes new knowledge to the field of clinician behaviour change and implementation science by its novel evaluation of longer term outcomes (as measured by adherence to FeSS Protocols) of both 'passive' dissemination and 'active' implementation strategies. Although passive dissemination

is deemed to be less effective when compared to more active implementation strategies,⁸⁵ the longer-term effectiveness of these active approaches remains unclear. The implementation science literature suggests there is often a decline in effectiveness (referred to as a ‘voltage drop’) of an intervention as it moves from controlled research settings (efficacy trials) to real-world practice (effectiveness and implementation).¹¹⁴ While this phenomenon is well documented, the extent of voltage drop is variable given an earlier study that demonstrated greater uptake of the FeSS Protocols in hospitals that participated in the two original FeSS Intervention studies, QASC Trial³¹ and QASCIP³³, up to six years following the original trial were demonstrated.⁷⁰ Evaluating the inclusion of the FeSS Protocols in the 2017 National stroke clinical practice guidelines provides a timely opportunity to assess their broader impact and the outcomes of a subsequent FeSS intervention study (T³ Trial)³² will also be incorporated.

The program of research presented in this thesis provides new insights into the longer-term outcomes of implementation strategies for a stroke clinical practice guideline and diffusion of evidence into acute stroke services nationally. Additionally, this is a long-term study of clinician behaviour change, that may have applicability for the implementation of other stroke (and non-stroke) clinical practice guidelines.

1.8 Thesis aim and research questions

The overarching aim of this thesis is to evaluate and explore diffusion of the FeSS Protocols for stroke in Australian hospitals, after their inclusion as recommended care in the 2017 National Acute Stroke Guidelines. National stroke data and front-line clinician perspectives have been used to assess adherence and factors that influence sustainment of implementation strategies for the FeSS Protocols.

The use of diverse research methods within this program provides a comprehensive approach to understanding the complex issue of translation of evidence into clinical practice. Underpinned by a critical realism paradigm, the program of research presented in this thesis was designed to answer the following questions:

1. Has adherence to the FeSS Protocols in Australian hospitals improved since their inclusion as a recommendation in the 2017 Australian Clinical Guidelines for Stroke Management as evidenced by National Stroke audit results of 2019 and 2021 when compared to National Stroke audit results of 2015 and 2017.
2. Does previous participation in the QASC, QASCIP or T³ FeSS Intervention studies increase adherence to the FeSS Protocols?
3. Does admission to a stroke unit rather than to a general medical ward increase adherence to the FeSS Protocols?
4. What strategies or interventions have been used to implement the FeSS Protocols and how do these compare for hospitals that participated in the FeSS Intervention studies and those that did not?
5. What are the perceived individual and organisational factors that influence FeSS clinical practice guideline adherence in i) hospitals with consistently low FeSS adherence composite scores, ii) hospitals with consistently high FeSS adherence composite scores and iii) hospitals with variable FeSS adherence composite scores?
6. Do the identified influential factors from hospitals with high, low and variable FeSS adherence composite scores map to factors from the Sustainability of

Innovation Framework and how do these factors influence sustained use of the FeSS Protocols in Australian hospitals?

1.9 Thesis structure

This thesis is divided into six chapters. It is presented as a Thesis with publication and contains two manuscripts presented in the same format as the thesis for the relevant chapters for ease of reading (one peer reviewed publication in the *International Journal of Nursing Studies Advances*, Q1 ranked journal, 2023 Journal Impact Factor 3.1 [Journal Citation Reports™ Clarivate, 2023]). The second manuscript is currently in press at the *Journal of Advanced Nursing*, Q1 ranked journal, 2023 Journal Impact Factor 3.8 [Journal Citation Reports™ Clarivate, 2023]). The published manuscript is provided as an appendix in the format that it appears online (Appendix I). As per publication requirements, the contribution of each author is clearly articulated within these manuscripts and the Statement of Authorship and Sources includes a declaration that the thesis is solely the candidate's work. The tables and figures are numbered consecutively in each chapter to also allow for ease of reading and a single reference list is included at the end of the thesis.

To provide a comprehensive understanding of the research topic within the broader context of existing literature regarding clinician adherence to acute stroke clinical practice guidelines, this thesis begins with a systematic-narrative hybrid review and synthesis of the literature in Chapter Two (Study One). Given the broad scope of the topic, the review provided an overview of systematic reviews and individual randomised controlled trials related to interventions designed to improve adherence to any stroke clinical practice guidelines, including any that were specific to the management of fever, hyperglycaemia and swallow complications post stroke. The

findings and gaps in knowledge identified from this review of the literature, informed the research questions and aims specific to each study in this doctoral research program. Although each study aim is addressed in separate studies, they are interconnected as they relate to the overarching aim and knowledge about implementation and sustained uptake of stroke clinical practice guidelines in acute hospital settings.

Chapter Three outlines the rationale behind the chosen research methods and methodology for the entire research program. As this is a thesis with publication, a brief description of these methods is also included in each manuscript, leading to some repetition. The chapter, however, discusses in more detail the methodological considerations of each study, specific to data collection and processes, data analysis and ethical conduct.

A pre-test/ post-test quantitative study using National stroke audit data is presented as a published manuscript in Chapter Four (Study Two). An evaluation of any improvement in use of the FeSS Protocols after the new ‘strong recommendation’ for their use as a clinical practice guideline, was critical to understanding the level of diffusion of the evidence for their use into acute hospital settings. The study design enabled more nuanced analysis to incorporate evaluation of additional significant factors (as identified in the literature) that may have influenced uptake of this clinical practice guideline.

A qualitative descriptive process evaluation of clinician perspectives of factors that influence sustained use of the FeSS Protocols, is also presented as a manuscript that has been accepted for publication and is currently in press in Chapter Five (Study Three).

Results from the pre-test/ post-test study in Chapter Four (Study Two) were used to

guide purposive sampling related to the identified factors that may have influenced uptake of this clinical practice guideline. Hospitals that had participated in three or more of the national acute stroke service audit cycles were stratified according to FeSS Protocol adherence, previous participation in a FeSS Intervention study and region (state) and remoteness, in acknowledgement of these factors reported to be associated with adherence in the pre-test/ post-test study Chapter Four. Including the perspectives of front-line stroke clinicians and end-users of the FeSS Protocols in this final study provided important data to comprehensively evaluate the quantitative results from Chapter Four and the key findings from the literature in Chapter Two.

The discussion and recommendations for future research, along with how this body of work contributes to the literature on this subject and the field of implementation science, are presented in the final Chapter Six. A synthesis of the overall results is presented that weaves the findings from individual studies to answer the overarching aim of the thesis. Strengths and limitations of the research are provided, and clinical and policy implications are discussed. The chapter concludes by providing a summary of recommendations for future research.

1.10 Summary

This chapter introduces the thesis topic: the use of the FeSS Protocols for stroke management in Australian hospitals. It outlines the critical importance of managing fever, hyperglycaemia, and swallowing complications in the acute stroke setting, and a comprehensive overview of the 15-year QASC program of translational research. Progress to date in implementing evidence-based FeSS Protocols in acute stroke care is reviewed, alongside a brief introduction to clinician behaviour change. The chapter also highlights the key research questions addressed in this thesis. Specifically, it explores

'passive' strategies (such as integration of the FeSS Protocols into national clinical guidelines and audit cycles) and the sustainment of *'active'* implementation strategies, including clinician-perceived factors influencing their continued use. Together, these investigations aim to contribute new insights to the broader field of stroke care and implementation science.

The next chapter presents a detailed review of the literature on clinician adherence to acute stroke clinical guidelines in acute hospital settings, particularly recommendations specific to the management of fever, hyperglycaemia and swallow complications post stroke.

CHAPTER TWO STUDY ONE: SYSTEMATIC- NARRATIVE HYBRID REVIEW AND SYNTHESIS OF THE LITERATURE

2.1 Overview

The purpose of this chapter is to situate the research within the broader context of the literature regarding clinician adherence to acute stroke clinical guidelines, particularly recommendations specific to the management of fever, hyperglycaemia and dysphagia complications post stroke.

Systematic-narrative hybrid reviews are increasingly being used for expansive research topics as they offer the flexibility to include diverse study designs while maintaining methodological rigour.^{118,119} A systematic review typically uses pre-specified eligibility criteria and explicit methods to search and appraise the literature to answer a narrowly focused research question.^{120,121} Narrative reviews offer a wider scope that can be more comprehensive as this flexibility allows coverage of a broader range of issues within a given topic.¹²¹ However, the less explicit methods can introduce bias and are not generally considered to have the scientific rigour of a systematic review as the methods are often poorly defined.¹²² For example, narrative reviews often lack a formal protocol with predefined search strategies, inclusion criteria, and quality appraisal methods, offering flexibility but less transparency and reproducibility.¹²³ A systematic-narrative hybrid review is an approach that incorporates elements of a systematic review (transparent description of the methods used to define search criteria) combined with a narrative approach to the synthesis of the literature.¹¹⁸ This form of literature review has been applied in various fields (education,¹²⁴ computing,¹²⁵ dentistry,¹²⁶ tourism,¹²⁷ social media)¹²⁸ and increasingly is being adopted in health care disciplines.^{118,119,129}

Previous work within the wider QASC program of translational research has shown that studies specific to fever, hyperglycaemia and dysphagia management are minimal, so the literature review topic was broadened to incorporate clinician adherence to *any* stroke clinical practice guideline. Although the seminal QASC Trial³¹ (where the evidence was established for use of the FeSS Protocols) was conducted in stroke units, subsequent studies to implement the FeSS Protocols were not restricted to this setting and also included smaller stroke services and emergency departments.^{18,19} A broader review of the literature was undertaken for this thesis that included all acute hospital settings and, hence, was not restricted to the stroke unit setting only. Evaluating the existing literature on interventions that improve hospital clinician adherence to stroke clinical practice guidelines outside of stroke units widened the scope and breadth of the literature review. In order to focus the research topic, quality improvement and non-randomised single studies were not included. However, given that almost half of published systematic reviews now include non-randomised studies,¹³⁰ systematic reviews that included mixed study designs were considered.

The comprehensive hybrid review approach integrates systematic review techniques and narrative synthesis which allows for the inclusion of a wide range of study designs that incorporate both quantitative and qualitative research. The methodological approach is presented based on a systematic-narrative hybrid review framework comprised of six essential components for reporting: (1) aims and research questions, (2) justification, (3) literature sources, (4) search parameters, (5) data cleaning and (6) information synthesis.¹¹⁸

2.2 Aim and research questions

The aim was to undertake a systematic-narrative hybrid review and synthesis of behaviour change interventions that improve hospital clinician adherence to any stroke clinical practice guideline highlighting those specific to fever, hyperglycaemia, and dysphagia management after stroke in adult patients. The research questions were as follows:

1. What behaviour change interventions improve in-hospital clinician adherence to any stroke clinical practice guideline after stroke in adult patients?
2. What behaviour change interventions improve clinician adherence to stroke clinical practice guidelines specific to the in-hospital management of fever, hyperglycaemia and dysphagia after stroke in adult patients?

2.3 Justification of Systematic-Narrative Hybrid Review

A systematic-narrative hybrid review method was chosen because it allows for a comprehensive and nuanced synthesis of both quantitative and qualitative findings.¹¹⁸ This approach is particularly suitable for complex topics like clinician behaviour change, where randomised controlled trials (RCTs) may not always capture the full scope of evidence. RCTs as primary studies provide the strongest levels of evidence and are most suited to meta-analysis in a systematic review.²³ However, not all research questions can be answered with a RCT study design, especially those that relate to the complex topic of clinician behaviour change in health care settings.²⁴

Interventions designed to improve clinician adherence to stroke clinical practice guidelines were evaluated using systematic review techniques to identify the literature.

Narrative methods were then used to synthesise the results. Given the complexity of this extensive topic, a hybrid method that allows a wide range of study designs to be included was deemed the most suitable. This approach leverages on the scientific rigour of systematic review methods and the comprehensiveness of a narrative synthesis that is able to incorporate study designs of significant variability.

2.4 Literature sources

The systematic-narrative hybrid review was limited to a pre-defined time period (1st January 2000 to 24th August 2024) to capture literature prior to the time the first FeSS Intervention study was conducted (QASC Trial 2005-2010) and during and after the other FeSS Intervention studies (QASCIP 2013-2014, T³ Trial 2013-2016). This provided relevant context to other interventions in the same time period.

The following electronic bibliographic databases were searched from 1st January 2000 to April 2022 and last updated on 24th August 2024: MEDLINE/PubMed, Cochrane, CINAHL, and EMBASE. Searches were conducted for keywords in the title or abstract combined with Medical Subject Heading (MeSH) terms or CINAHL Subject headings. The many variations of keywords combined with MeSH terms/CINAHL subject headings (and relevant sub-headings) used for the first broader search strategy were: ‘Adherence’, ‘Clinical practice guideline’, ‘Stroke’, ‘Nurse’ and ‘In hospital’ – See Appendix A. Searching of citations from identified studies was also used to supplement electronic searches. The dates of the last search for each database, the period searched, and the number of records retrieved for each database searched were recorded and all searches saved and rerun for updating before submission of the final thesis chapter.

A second search was conducted for each of the following keyword variations combined with MeSH terms/CINAHL subject headings (and relevant sub-headings) to obtain more information on studies specific to: 'Translational medical research', 'Quality assurance/improvement', 'Fever', 'Hyperglycaemia', and 'Dysphagia' (see Appendix A).

2.5 Search parameters

The reporting of this systematic-narrative hybrid review adhered to the Preferred Reporting items for Systematic Reviews and Meta-Analyses (PRISMA) statement¹³¹ (see Figure 1 for phases of this review process). The methodological criteria for studies that were included and excluded in the review are listed below:

Inclusion criteria

- Published systematic reviews of any study design that evaluated behaviour change interventions
- Randomised controlled trials that evaluated behaviour change interventions

Exclusion criteria

- Studies published before January 2000
- Papers written in languages other than English
- Non-randomised single studies (e.g., observational (cross sectional; prospective and retrospective cohorts), interrupted time series, controlled pre-test/post-test studies)

2.6 Setting

Inclusion criteria

- Studies conducted in acute care settings in any country.

Exclusion criteria

- Studies conducted in outpatient settings, nursing homes or residential aged care facilities, community or population-wide settings (such as public health campaigns), and those based in primary care, palliative care, or rehabilitation settings were excluded.

2.6.1 Patient and clinician inclusion and exclusion criteria

Inclusion criteria

- Hospital inpatients aged over 18 years with a diagnosis of ischaemic or haemorrhagic stroke
- Clinicians from any discipline, including nursing, medical, and allied health professionals.

Exclusion criteria

- Patients receiving palliative care were excluded.

2.7 Data cleaning

Stage 1: The titles and abstracts of all publications identified in the electronic databases were assessed and screened by a single reviewer (the PhD candidate) for relevance and appropriateness to the review aim. The use of a single reviewer is common for post-graduate student research and in rapid reviews.¹³²⁻¹³⁴ The titles and abstracts of articles in this screening process that were clearly not relevant were excluded.

Stage 2: The remaining publications were examined and assessed further regarding their eligibility after applying the inclusion and exclusion criteria. Publications not meeting the criteria were excluded (see Figure 1. PRISMA flow diagram). Full texts of

the remaining publications meeting the study selection criteria were collated, and the details summarised in an evidence table (Table 1).

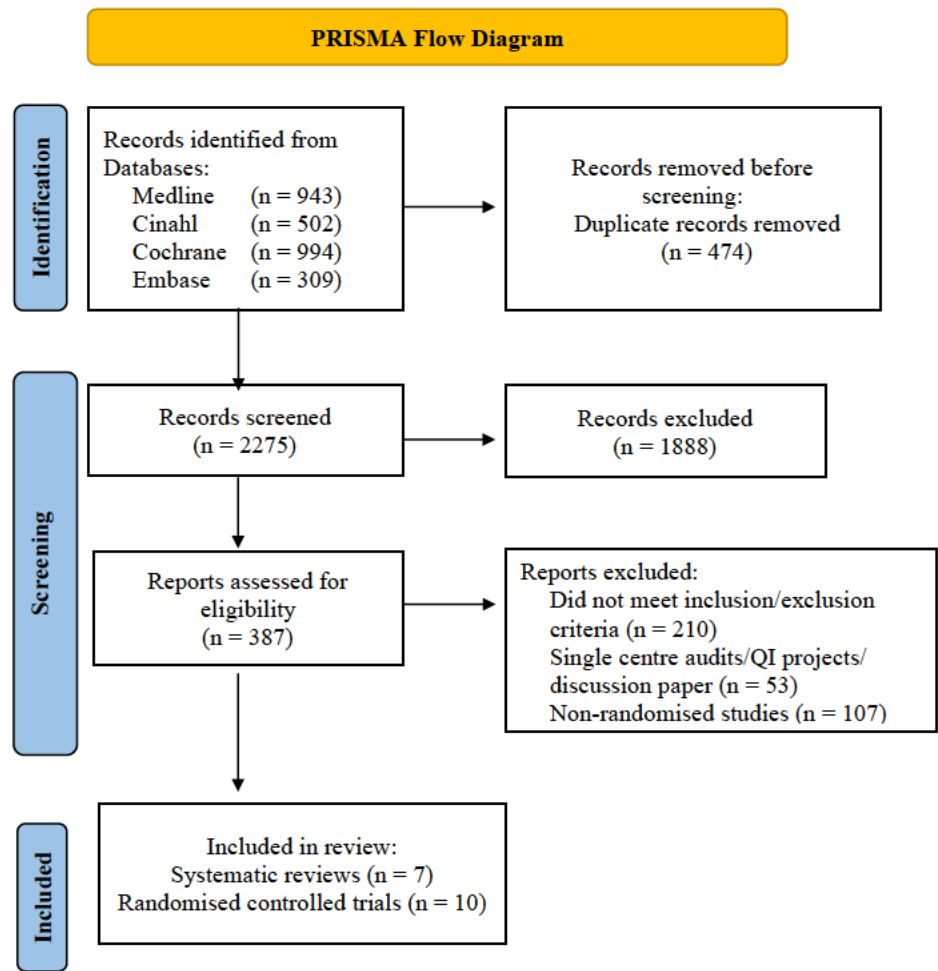


Figure 1. PRISMA Flow diagram

2.8 Information synthesis

The identified studies that met the criteria for inclusion in the systematic-narrative hybrid review were synthesised and analysed in three ways. Study characteristics were extracted and summarised in an evidence table (Table 1). The methodological quality of the studies was appraised using study design specific instruments (Table 2 and Table 3). Finally, analysis of the grouped behaviour change interventions was conducted using concept mapping as a narrative approach to illustrate and synthesise key themes (Table 4) and summarise both quantitative and qualitative findings.

2.8.1 Data extraction

The following data were extracted and summarised in an evidence table by the single reviewer: first author; year of publication; country/ study setting and population; study design; sample size; intervention details; and study outcomes (see Table 1). Full texts of the relevant papers were collated and stored.

2.8.2 Critical appraisal

The second version of A Measurement Tool to Assess Systematic Reviews (AMSTAR 2)¹³⁵ was used to critically appraise systematic reviews that included randomised or non-randomised studies of health care interventions. Overall confidence in the results of the review are presented as a rating as suggested by the creators of this tool (High=0 or 1 non-critical weakness; Moderate=>1 non-critical weakness; Low=1 critical flaw +/- non-critical weakness; or Critically low=>1 critical flaw +/- non-critical weakness)¹³⁵ (Table 2).

All individual RCTs were evaluated for risk of bias by a single reviewer (KC, PhD candidate) in Covidence¹³⁶ using the built in Cochrane Risk of Bias (RoB) template.¹³⁷ By using this collaborative software, the supervising team were able to review additional information to support the risk of bias judgement and adjudicate where required (Table 3).

2.8.3 Data analysis

The likelihood of heterogeneity in the included studies with regards to study design, intervention components and outcomes was considered in the *a priori* data synthesis protocol. If the included studies were sufficiently homogeneous, the data would have been pooled in a random-effects meta-analysis model and statistical heterogeneity assessed using the I^2 statistic.¹³⁸ However, given the considerable clinical and methodological heterogeneity in the included studies, a meta-analysis was not feasible. Hence, a narrative synthesis of all data was undertaken.

Data from the systematic reviews were tabulated, with a brief description of the included studies in Table 1 and the results of the critical appraisal presented in Table 2. Textual descriptions were also provided for the characteristics, findings, and discussion of the included studies. Reviews of the same intervention were grouped where possible.

Similarly, data from the included individual RCTs were analysed using this narrative synthesis approach, incorporating tabulation, textual descriptions and groupings where relevant¹³⁹ (Table 1, Box 1, Table 4).

2.9 Results

2.9.1 Study characteristics

The literature search yielded seven systematic reviews¹⁴⁰⁻¹⁴⁶ and ten individual RCTs^{31,62,147-153} relevant to the review aim. The seven systematic reviews included a total of 19 RCTs, 29 pre-test/post-test, four cross-sectional, three interrupted time series, 24 qualitative, one retrospective comparative, one quasi-randomised open label control, 13 quasi-experimental, and one mixed-methods studies, in their combined analysis of the best available evidence at the time of publication.

The studies were conducted in the following countries: United States of America,^{62,140,141,143,144,146,149} Australia,^{31,32,62,140,144,145,147-154} United Kingdom,¹⁴⁰⁻¹⁴⁶ China,^{145,153} Taiwan,^{144,146} Sweden,^{141,143} Netherlands,^{142,145} Italy,¹⁵¹ India,¹⁵² Ireland,¹⁴⁶ New Zealand,¹⁴⁶ Germany,¹⁴⁰ Austria,¹⁴⁰ Czech Republic,¹⁴⁰ France,^{140,148} Japan,¹⁴⁰ Norway,¹⁴⁰ Brazil,^{140,150} Argentina,¹⁵⁰ and Peru.¹⁵⁰ One RCT included patients diagnosed with transient ischaemic attack in addition to the acute stroke population in their study cohort.¹⁵⁰ One of the systematic reviews included pre-intervention and post-discharge care settings,¹⁴⁶ but only outcomes related to inpatient care were considered. Another two systematic reviews^{143,144} included subacute/stroke rehabilitation settings, again only outcomes relevant to the acute stroke setting were taken into consideration.

Four of the systematic reviews were focused on the evaluation of quality improvement interventions such as in-hospital care pathways,^{141,143} quality improvement collaboratives,¹⁴⁴ and advanced practice nurses as boundary spanners¹⁴⁶ which are commonly used in studies designed to improve adherence to generic stroke clinical

practice guidelines. The effect of multi-component interventions was evaluated in another systematic review on studies limited to stroke units.¹⁴⁵

More specific stroke clinical guidelines were evaluated in a systematic review of studies on the effect of simulation training on door-to-needle time for stroke thrombolysis.¹⁴⁰ The seventh systematic review¹⁴² focused on specific physiological aspects of acute stroke clinical practice guidelines. Other clinical intervention studies and reviews were excluded from the literature search results as the review aim was more relevant to behaviour change interventions that resulted in improved clinician adherence to clinical practice guidelines. However, this review was included as the methods for continuous physiological monitoring were deemed to be in direct alignment with the clinical practice guidelines for fever and hyperglycaemia, two of the complications of acute stroke under study.

Of the ten individual RCTs included in this narrative synthesis of the literature, seven used multiple behaviour change strategies simultaneously, to improve clinician adherence to stroke clinical practice guidelines. These included the use of local consensus processes (case management, roadmaps, barrier assessments, action plans) educational materials (checklists), educational meetings (workshops), audit and feedback, reminders, champions, facilitation, remote support and local opinion leaders. Two of the seven individual RCTs targeted improved adherence to generic stroke clinical practice guidelines and five focused on specific acute stroke clinical practice guidelines, namely improving thrombolysis screening and treatment rates, appropriate triage coding, management of fever, hyperglycaemia and dysphagia complications, and prompt transfer to a stroke unit.

2.9.2 Behaviour Change Interventions

The evidence table arising from this review highlights the behaviour change strategies, shown in bold in Box 1. A summary of the included studies, categorised by type of behaviour change technique, is outlined in more detail in Table 1. In order to address the research questions, the results were analysed using narrative synthesis of behaviour change interventions with concept mapping to illustrate key themes (Table 4).

Box 1. Behaviour change interventions designed to improve adherence to stroke clinical practice guidelines

- **Studies examining the effect of care pathways on adherence to stroke clinical practice guidelines** (n=2 systematic reviews that included: (i) n=3 RCT's, n=1 retrospective comparative study, n=11 pre-test/ post-test studies⁷⁰ and (ii) n=1 RCT, n=3 pre-test/ post-test studies, n=1 qualitative case study,⁶⁸ and n=1 RCT)¹⁵¹
- **Studies examining the effect of quality improvement collaboratives on adherence to stroke clinical practice guidelines** (n=1 systematic review that included: n=4 RCTs, n=4 cross-sectional, n=3 interrupted time series, n=4 pre-test/ post-test, n=2 qualitative studies)¹⁴⁴
- **Studies examining the effect of advanced practice nurses on adherence to stroke clinical practice guidelines** (n=1 systematic review that included: n=2 RCTs, n=13 quasi-experimental, n=1 mixed methods and n=2 qualitative studies)¹⁴⁶
- **Effect of simulation training on adherence to specific stroke clinical practice guidelines (thrombolysis use)** (n=1 systematic review that included: n=11 pre-test/ post-test and n=19 qualitative studies)¹⁴⁰
- **Studies examining the effect of continuous monitoring versus intermittent physiological monitoring on adherence to relevant clinical practice guidelines** (n=1 systematic review that included: n=2 RCTs, n=1 quasi-randomised open label control studies)¹⁴²
- **Studies examining the effect of audit and feedback on adherence to stroke clinical practice guidelines** (n=1 RCT)¹⁴⁹
- **Studies examining the effect of multi-component interventions on adherence to generic stroke clinical practice guidelines** (n=1 systematic review that included: n=7 RCTs,¹⁴⁵ and n=2 RCTs)^{147,150}
- **Studies examining the effect of multicomponent interventions on adherence to specific stroke clinical practice guideline** (n=5 RCTs)^{31,32,62,148,153}
- **Studies examining the effect of nurse led FeSS care bundle on adherence to specific stroke clinical practice guidelines (fever, hyperglycaemia and swallow protocols)** (n=1 RCT)¹⁵²

Table 1 Evidence Table by Behaviour Change Intervention

First Author (Year)	Country (Setting)	Study design (Sample)	Behaviour Change Intervention	Outcomes
<u>Effect of care pathways on adherence to stroke clinical practice guidelines</u>				
Kwan, J (2004)	USA, Sweden, UK Acute stroke and Stroke rehab	Cochrane Systematic Review x3 RCT's x1 retrospective comparative x11 pre-test/ post-test <i>(Total n= 4081 participants)</i>	Routine implementation of care pathways for acute stroke management or stroke rehab.	Insufficient evidence for routine implementation of care pathways for acute stroke management or stroke rehabilitation.
Allen, D (2008)	USA, Sweden, UK Acute stroke	Systematic review x1 RCT x3 pre-test/ post-test x1 qualitative case study <i>(Total n= 640 participants)</i>	Integrated Care Pathways: multidisciplinary (≥ 2) communication tool to improve quality and efficiency of evidence-based care	Evidence that Integrated Care Pathways (ICP) may support certain elements of service integration in the context of stroke care.
Panella, M (2012)	Italy Acute stroke (ischaemic only)	RCT (14 Hospitals) <i>(Total n= 476 participants)</i>	Training and development hospital specific clinical pathway that adhere to Italian clinical practice guidelines	Lower risk 7-day mortality and adverse functional outcomes (return to pre- stroke function) Improved adherence to evidence-based interventions and access to stroke unit and organised care No effect 30-day mortality

First Author (Year)	Country (Setting)	Study design (Sample)	Behaviour Change Intervention	Outcomes
<u>Effect of quality improvement collaboratives on adherence to stroke clinical practice guidelines</u>				
Lowther, H (2021)	USA, Netherlands, Taiwan, AUS, UK Acute stroke and Stroke rehab	Systematic review x4 RCTs x4 cross-sectional x3 interrupted time series x4 pre-test/ post-test x2 qualitative <i>(Total n=224 sites)</i>	Quality improvement collaboratives (core elements: (1) a specified topic; (2) clinical and QI experts working together; (3) multiple teams from multiple sites participating; (4) a model or framework for improvement with multiple tests of change; and (5) a series of structured collaborative activities in a given timeframe, involving learning sessions and visits from mentors and facilitators	Evidence around using Quality improvement collaboratives to achieve system-level change in stroke is equivocal.
<u>Effect of Advanced Practice Nurses on adherence to stroke clinical practice guidelines</u>				
Woo, B (2023)	USA, UK, Ireland, NZ, Taiwan Inpatient and/or outpatient stroke or TIA	Mixed-methods systematic review x2 RCT's x13 quasi-experimental x1 mixed-methods x2 qualitative <i>(Total n=18 hospitals, stroke centres, outpatient clinics, emergency departments)</i>	Advanced Practice nurses as boundary spanner across services and disciplines. Stroke code/rapid response Collaborative advanced practice nurse /Physician model of care Screening for Stroke/TIA and coordination of care	Reduced waiting times Stroke/TIA screening Shortened time to thrombolysis intervention No statistically significant difference in mortality, LOS, hospital readmissions, systolic blood pressure.

First Author (Year)	Country (Setting)	Study design (Sample)	Behaviour Change Intervention	Outcomes
<u>Effect of simulation training on adherence to specific stroke clinical practice guidelines (thrombolysis use)</u>				
Aljuwaisier, S (2024)	USA, Germany, AUS, UK, Austria, Brazil, Czech Republic, France, Japan, Norway	Systematic Review x11 pre-test, post-test simulation training x19 qualitative Hospitals, emergency departments, neurology department, stroke units, hospital simulation centres <i>(Total n=20,189 participants)</i>	Simulation training and the effects on door-to-needle time emergency stroke thrombolysis	Improved door to needle time stroke thrombolysis
<u>Effect of continuous monitoring versus intermittent physiological monitoring on adherence to relevant clinical practice guidelines</u>				
Ciccone, A (2013)	Italy, Netherlands, UK Acute stroke	Cochrane Systematic review x2 RCT x1 quasi-randomised open label control <i>(Total n=354 participants)</i>	Continuous versus intermittent physiological monitoring for acute stroke	Reduced death and disability at 3 months or discharge. Cardiac complications, fever and hypotension were detected significantly more often in participants who received continuous monitoring.
<u>Effect of audit and feedback on adherence to stroke clinical practice guidelines</u>				
Lakshminarayan, K (2010)	USA Acute Stroke Minnesota	RCT (multi-centre) 19 hospitals <i>(Total n= 1,210 participants)</i>	Audit and feedback delivered by opinion leaders. Targeted barriers to stroke care identified.	There was no definite intervention effect: both experimental and control hospitals showed significant secular trends with performance improvement.

First Author (Year)	Country (Setting)	Study design (Sample)	Behaviour Change Intervention	Outcomes
Effect of multi-component interventions on adherence to generic stroke clinical practice guidelines				
	AUS, UK, China, Netherlands Acute stroke units	Cochrane Systematic Review x7 RCT's <i>(Total n=129 hospitals, 42,489 acute stroke patients)</i>	Multifaceted intervention for the uptake of evidence-based recommendations in acute stroke settings	Uncertain if a multifaceted intervention improves adherence to evidence-based recommendations as certainty of evidence is very low.
Machline-Carrion, MJ (2019)	Brazil Argentina Peru Acute stroke, TIA	RCT (multi-centre) 36 hospitals <i>(Total n= 1624 participants)</i>	Multifaceted quality improvement intervention (case management, reminders, a roadmap and checklist for the therapeutic plan, educational materials, audit and feedback).	No significant increase in composite adherence score for evidence-based therapies in patients with AIS or TIA. However, when using an all-or-none approach, the intervention resulted in improved adherence to evidence-based therapies
Cadilhac,D (2022)	AUS Acute stroke	Stepped wedge partial randomisation 9 hospitals, 144 clinicians <i>(Total n=3147 participants)</i>	External quality improvement facilitation (workshops, remote support, routine monitoring via registry, audit and feedback, change champions, action plans)	Improved access stroke unit, discharge on antithrombotic meds, and issue of discharge plans.

First Author (Year)	Country (Setting)	Study design (Sample)	Behaviour Change Intervention	Outcomes
<u>Effect of multicomponent interventions on adherence to specific stroke clinical practice guidelines</u>				
Middleton, S (2011)	AUS Acute stroke Stroke Units	RCT (multi-centre) 19 hospitals <i>(Total n=1696 participants [687 pre- intervention and 1009 post- intervention])</i>	Clinical protocols, team building and educational workshops, barrier assessment, site champions, site visits, telephone and email support	Reduction in death and dependency Improved SF-36 (physical health)
Scott, PA (2013)	USA Acute stroke Hospitals Lower Peninsula of Michigan (not comprehensive stroke centers)	RCT (multi-centre) 12 matched hospital pairs <i>(n=745 of 40, 823 patients received t-PA)</i>	Multilevel, barrier assessment–interactive educational intervention (BA-IEI). Qualitative and quantitative assessment of barriers to alteplase use and ways to address the findings	No statistically significant increase alteplase use
Haesebaert, J (2018)	France Acute stroke Emergency departments	RCT (multicentre) 18 hospitals <i>(Total n= 691 participants)</i>	Multifaceted, interactive training program for emergency professionals. Train the trainer toolkit, site specific clinical pathway	Improved access to stroke thrombolysis No reduction intrahospital management times
Zhong, W (2022)	China Acute stroke	RCT (multicentre) 22 hospitals <i>(Total n=1634 participants)</i>	Multicomponent intervention Behaviour Change Wheel theory via teleconference (Persuasion, Environment reconstruction, Incentivization, Training, Education and Modelling)	Reduction door-to-needle- time stroke thrombolysis. Improved functional outcome (mRS 0-1)

First Author (Year)	Country (Setting)	Study design (Sample)	Behaviour Change Intervention	Outcomes
Middleton, S (2019)	AUS Acute stroke Hospitals with ED's, stroke units and thrombolysis protocols	RCT (multi-centre) 26 hospitals <i>(Total n=2242 participants [645 pre-intervention and 1597 post-intervention])</i>	Theory-informed, nurse-initiated, intervention: (1) workshops to identify barriers and solutions; (2) face-to-face, online, and written education; (3) national/local clinical pinion leaders; (4) email, telephone, and site visit follow-up.	No change patient outcomes (death or dependency) or clinician behaviour in the complex ED environment despite previous success in stroke units.
<u>Effect of nurse led FeSS care bundle on adherence to specific stroke clinical practice guideline (fever, hyperglycaemia and swallow protocols)</u>				
Sridhar, D (2024)	India Stroke unit	RCT (single centre) <i>(Total n=104 participants)</i>	Nurse-led care bundle, intervention wards trained in use protocols, data collection, champions	No difference 90-day mRS, Barthel Index Reduction in mortality

USA (United States of America), UK (United Kingdom), AUS (Australia), NZ (New Zealand), CPG (Clinical Practice Guideline), RCT (Randomised Controlled Trial), QI Quality Improvement, ED (Emergency Department) TIA (Transient Ischaemic Attack), AIS (Acute Ischaemic Stroke), mRS (Modified Rankin Scale), SF-36 (Short Form Survey), t-PA (thrombolysis)

2.9.3 Quality appraisal of systematic reviews

Of the seven systematic reviews, six included mixed study designs. The outcomes of critical appraisal of these reviews using AMSTAR 2¹³⁵ have been rated based on identification of critical domains (highlighted at items 2,4,7,9,11,13 and 15 in Table 2).

Only one of the two systematic reviews that evaluated stroke care pathways, was rated with high confidence in the results of the review.¹⁴³ As expected, the methodological rigour of this review from the Cochrane database of systematic reviews by Kwan and Sandercock¹⁴³ was sound with the exception of failure to report on the sources of funding for individual studies included in the review. Although this is defined as a non-critical weakness, it was a weakness identified in all six of the seven systematic reviews.^{140-144,146} Without this information it was not possible to determine if the studies were commercially or independently funded. (Commercially sponsored studies are reported to be subject to publication bias and findings that favour a sponsor's product).¹³⁵

In the second systematic review of stroke care pathways by Allen and Rixson,¹⁴¹ a low overall rating was based on the identification of five non-critical weaknesses. These included: (i) the lack of reported comparator, (ii) no mention of review authors performing study selection or (iii) data extraction in duplicate and (iv) no information provided on the source of funding for individual studies included in the review or (v) how funding or potential sources of conflict by the authors of the review were managed. There was also no explicit statement that the review methods were established prior to conduct of the review or that it had been registered.

The systematic review by Lowther et al.¹⁴⁴ that evaluated the evidence for stroke quality improvement collaboratives also received a low overall rating for the

confidence in the results of the review. This was due to the identification of one critical flaw for the failure of the authors to provide a list of the excluded studies. Although justification for exclusion is provided in the author's PRISMA flow diagram, a complete reference list for these excluded studies is not available. As mentioned earlier there was also a non-critical weakness identified as no information was provided on the source of funding for individual studies included in the review.

Similarly, the systematic review of studies examining the effect of advanced practice nurses on adherence to stroke clinical practice guidelines by Woo et al.¹⁴⁶ was also appraised as having low overall confidence for the same reasons. These consisted of the critical flaw of failure to provide a list of the excluded studies and non-critical weakness related to lack of information on the source of funding for individual studies included in the review. The PRISMA minimum requirements for reporting the overall number of records excluded and their reasons is insufficient without a complete table or appendix of each study excluded and the specific reason for this.

The systematic review by Aljuwaiser et al.¹⁴⁰ evaluated the effect of simulation training on adherence to stroke clinical practice guidelines (thrombolysis use). This review was rated as low overall confidence in the results due to the lack of an explicit statement that the methods for the review were established *a priori* and/or justification of any protocol deviations. Additionally, the non-critical weakness of lack of information on the source of funding for individual studies included in the review was also identified. Although the authors used the Cochrane Risk of Bias in Non-Randomised Studies of Interventions (ROBINS-I)¹⁵⁵ and the Medical Education Research Study Quality Instrument (MERSQI)¹⁵⁶ to assess for the risk of bias and quality of the included studies in their review, funding source for included studies is not included as a distinct item in either of these tools.

The sixth systematic review by Ciccone et al.¹⁴² evaluated the evidence for continuous monitoring versus intermittent physiological monitoring. This review received a high rating, as expected, given that it was identified from the Cochrane database of systematic reviews which is widely accepted and recognised internationally as gold standard for high-quality, trusted information. The only non-critical flaw identified was the lack of information regarding the sources of funding for individual studies included in the review.

The final review by Lynch et al.¹⁴⁵ from the Cochrane database of systematic reviews evaluated studies examining the effect of multi-component interventions on adherence to generic stroke clinical practice guidelines. A high overall rating was assigned to this review for the confidence in its findings given there were no critical flaws or non-critical weaknesses identified in any appraisal items.

2.9.4 Quality appraisal of RCTs

The ten individual RCTs that evaluated the effect of care pathways,¹⁵¹ audit and feedback¹⁴⁹ and multi-component interventions^{31,32,62,147,148,150,152,153} on adherence to stroke clinical practice guidelines were critiqued using the Cochrane Risk of Bias domains.¹³⁷ The overall results are summarised in Table 3. Although selection bias was low for all individual RCTs, six were at high risk of performance bias as it was not possible to blind clinicians to the intervention.^{31,62,151-153} However, none of these trials were at risk of detection bias as personnel performing data collection were blinded to the intervention.

Attrition bias was judged to be low risk for the majority (n=7) of individual RCTs. The study by Machline-Carrion et al.¹⁵⁰ reported that one hospital did not adhere to the intervention, but it was not clear how the outcome data from this site was dealt with. It did not appear to have been excluded from their analysis.¹⁵⁰ Another study by Zhong et al.¹⁵³ was potentially subject to attrition bias due to loss to follow-up. Although these numbers were disclosed and did not affect the primary outcome, this data was required for secondary outcomes. Adjustments during analysis to account for missing data for one secondary outcome was reported, but it was not clear if this had also been performed for other secondary outcomes. Potential for attrition bias was also noted for the study by Lakshminarayan et al.¹⁴⁹ who reported 24 hospitals who agreed to participate, yet only 19 were randomised. Two of the nine hospitals in the intervention arm subsequently withdrew from the trial.

Selective reporting was rated as low risk for most of the individual RCTs with the exception of two. The study by Zhong, et al.¹⁵³ provided limited detail on the sample of hospitals selected to participate. All participating hospitals were reported to be part of a stroke alliance group but no further information on what this alliance was, or how many hospitals were invited to participate but declined, were provided. There also appeared to be more tertiary hospitals with stroke units in the intervention group when compared to the control group but this was adjusted for in the analysis. The study by Haesebaert et al.¹⁴⁸ was noted to have changed the primary outcome after achieving a higher-than-expected statistical power. Selective reporting after observing the data is subject to bias given the potential to choose to report on favourable outcomes that support the authors hypothesis.¹⁵⁷

Other potential sources of bias for the included individual RCTs varied. The use of historical controls in the Lakshminarayan et al.¹⁴⁹ study made the study findings difficult to interpret. During the trial, several hospitals were also preparing for stroke unit certification which may have contributed to the non-significant findings. Other potential bias in the study by Cadilhac et al.¹⁴⁷ was related to the inclusion of hospitals that collected stroke registry data, many of which were non-urban hospitals. This limited meaningful comparisons to urban hospitals and those hospitals not motivated to collect registry data. The study by Scott et al.⁶² did not collect baseline characteristics pre-intervention, limiting their comparability with intervention cohort data. The study by Sridhar et al.¹⁵² also identified a large number of exclusions without enough details about which criteria potential participants didn't meet. This is important as one criterion was language based and therefore the end sample selection could be subject to bias. Additionally, the study sample reported an unusually high number of intracerebral haemorrhagic stroke types which accounted for 50% of the sample in both the intervention and control groups. Typically, this stroke type accounts for 11-22% of incident strokes⁴ indicating that the study findings may not be generalisable to other stroke populations.

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Table 2. Critical appraisal of systematic reviews using AMSTAR 2

	Kwan 2004	Allen 2008	Lowther 2021	Ciccone 2013	Lynch 2023	Woo 2023	Aljuwaiser 2024
1. Research questions/inclusion criteria address PICO	Yes	No comparator	Yes	Yes	Yes	Yes	Yes
2. Statement that methods established apriori and justification protocol deviations.	Yes	Partial Yes	Yes	Yes	Yes	Yes	No
3. Explanation study designs for inclusion	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4. Comprehensive literature search strategy	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5. Study selection in duplicate	Yes	No	Yes	Yes	Yes	Yes	Yes
6. Data extraction in duplicate	Yes	No	Yes	Yes	Yes	Yes	Yes
7. List excluded studies and justification	Yes	Yes	No	Yes	Yes	No	Yes
8. Enough detail included studies	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9. Adequate assessment RoB	Yes	Yes	Yes	Yes	Yes	Yes	Yes
10. Source of funding reported for studies	No	No	No	No	Yes	No	No
11. Appropriate statistical methods for meta-analysis	Yes	No meta-analysis	No meta-analysis	Yes	Yes	No meta-analysis	Yes
12. Impact of RoB on meta-analysis or other evidence synthesis	Yes	No meta-analysis	No meta-analysis	Yes	Yes	No meta-analysis	Yes
13. Account for RoB when interpreting results	Yes	Yes	Yes	Yes	Yes	Yes	Yes
14. Heterogeneity of results discussed	Yes	Yes	Yes	Yes	Yes	Yes	Yes
15. Publication bias discussed for quantitative synthesis results	Yes	No meta-analysis	Yes	Yes	Yes	No meta-analysis	Yes
16. Conflict of interest review funding	Yes	No	Yes	Yes	Yes	Yes	Yes
OVERALL RATING	HIGH	LOW	LOW	HIGH	HIGH	LOW	LOW

Egger M, Schneider M, Davey Smith G. Spurious precision? Meta-analysis of observational studies. BMJ. 1998 Jan 10;316(7125):140-4. doi: 10.1136/bmj.316.7125.140. PMID: 9462324; PMCID: PMC2665367.

Table 3. Quality Assessment of individual RCTs using Cochrane Risk of Bias Tool

	Random sequence generation (Selection bias)	Allocation concealment (Selection bias)	Blinding of participants and personnel (Performance bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other sources of bias
Panella 2012	Low	Low	High	Low	Low	Low	Low
Lakshminarayan 2010	Low	Low	Low	Low	High	Low	High
Machline-Carrion 2019	Low	Low	Low	Low	Unsure	Low	Low
Cadilhac 2022	Low	Low	Low	Low	Low	Low	High
Middleton 2011	Low	Low	High	Low	Low	Low	Low
Scott 2013	Low	Low	High	Low	Low	Low	High
Haesbaert 2017	Low	Low	Low	Low	Low	High	Low
Zhong 2022	Low	Low	High	Low	Unsure	Unsure	Low
Middleton 2019	Low	Low	High	Low	Low	Low	Low
Sridhar 2024	Low	Low	High	Low	Low	Low	High

Higgins, J. P., Altman, D. G., Gotzsche, P. C., Juni, P., Moher, D., Oxman, A. D., . . . Cochrane Statistical Methods, G. (2011). The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ*, 343, d5928. doi:10.1136/bmj.d5928

2.10 Narrative review and synthesis of behaviour change interventions

2.10.1 Effect of care pathways on adherence to stroke clinical practice guidelines

The effect of the routine use of care pathways was evaluated in the Cochrane systematic review of mixed study designs published by Kwan and Sandercock.¹⁴³ The authors defined a care pathway as: ‘a plan of care that: (1) involved two or more of the following aspects of care: assessment, investigation, diagnosis, or treatment; and (2) involved two or more disciplines (e.g., medical, nursing, physiotherapy, occupational therapy, speech and language therapy, dietician). Included in their analysis were three RCTs, one retrospective comparative and eleven pre-test/post-test studies (n=4081 patients).

Details of the implementation of the care pathways itself was limited in description. The pathway in isolation was listed as the intervention for seven of the 15 studies. Case management was also listed for two of the RCTs and two of the non-randomised studies and weekly multidisciplinary meetings was also reported for one of the RCTs and four of the non-randomised studies.

The control group for one of the RCTs and 11 of the non-randomised studies was undefined patient care (six of these were historical control periods). Same care (but no care pathway) was reported as the control for one RCT and one non-randomised study, and the lack of patient defined goals (outside of discharge) was used to define the control group for the remaining RCT.

The primary outcomes of death and dependency were not included in all studies as an outcome measure making the reliability of the results difficult to interpret. The three studies

(one randomised and two non-randomised) that included death reported no statistically significant difference between the care pathway and control groups. The two studies (one randomised and one non-randomised) that reported dependency at discharge found that patients in the care pathway group were significantly more dependent at discharge (WMD - 3.8, 95%CI -7.3 to -0.2, P = 0.04). However, the reporting of inpatient deaths in both studies were unclear so these findings are not reliable as they were possibly included in these figures on dependency at discharge. If discharge destination was used as a proxy in this circumstance (in the absence of an explicit measure of dependency) then these findings are not corroborated. Seven studies (one randomised and six non-randomised) reported a trend toward fewer patients discharged to institutional care in the care pathway group and no difference between the groups on discharge to home outcome. No significant differences between the groups were found for fever and pneumonia complications (of most relevance to the conditions under study in this doctoral thesis).

Kwan and Sandercock's¹⁴³ overall finding in this systematic review was that there was not enough evidence (based on patient outcomes of death and dependency) to justify the introduction of care pathways for the routine care of all patients with acute stroke. Improved performance in some processes for those in the care pathway group (e.g., first or second CT scan, CT scan<24hours) from non-randomised studies provide weak evidence in relation to the review aim of improved adherence to clinical practice guidelines.

In an attempt to explore these other outcomes further, a second systematic review on care pathways by Allen and Rixon¹⁴¹ differed in their overall objective which was to evaluate studies that had a specific focus on service integration. The authors definition of a care pathway was similar to the Kwan and Sandercock study in that it needed to be

in use by at least two different health professional disciplines but expressly stated that it must also be used as a communication tool between the professions.

Five studies were included in this review comprising one RCT, three pre-test/ post-test studies and one qualitative case study (n=640 participants). Four of these studies were also included in the earlier review.^{32,33,158-161} The evaluation of the effect of care pathways on service integration was grouped into broad domains of communication, role clarity, documentation, planning/goal planning, coordination, care costs, length of stay and interventions.

Concurring with the previous review, no statistically significant findings were found for death and dependency outcomes. There also were no statistically significant findings on length of stay or discharge destination. The occurrence of urinary tract infections as a complication of acute stroke was reported to be reduced as an effect of the care pathways, but the authors could not determine if this was a direct measure of 'service integration'.

Overall, Allen and Rixon¹⁴¹ found that care pathways in acute stroke can be effective in ensuring that patients receive relevant clinical interventions and/or assessments in a timely manner. However, it was not certain if this was because of the pathway or due to improved documentation. The authors concluded that there was some evidence that care pathways as an intervention may be effective in changing professional behaviours but only if there was a recognised problem in this area in the first place and only if the usual care pattern for this diagnosis was predictable (e.g., appropriate in acute stroke settings but not stroke rehabilitation settings).

Not included in either of these systematic reviews was a more recent multicentre individual RCT conducted in Italy by Panella et al.¹⁵¹ that evaluated the use of a site-specific clinical pathway in hospitals with stroke units. Seven hospitals were randomised to receive training in the use of clinical pathways for quality improvement and developed these over six months, another seven were randomised to the usual-care group (n=238 in each group). The clinical pathway was designed for use by multiple departments and professionals specifically: medical, allied health, pharmacy, psychology, nursing and support staff. The pathway was developed in accordance with Italian clinical practice guidelines for stroke, with defined hospital specific goals.

The primary outcome was 30-day mortality, secondary outcomes included 7-day mortality, length of stay, readmission rates, dependency levels, institutionalisation and complication rates. Quality of care was evaluated by adherence to the following process indicators: use of clinical protocol, CT/MRI and aspirin within 48hours of admission, swallow screen on day of admission, blood pressure assessment, ECG/eco-colour doppler within 24hours of admission, continuous monitoring within 48hours of admission, before discharge total assessment, use of discharge plan, use of Scottish Intercollegiate Guideline Network (SIGN) discharge plan, use of discharge summary and information pack, functional independence measure (FIM) before discharge and at three months. Organised care indicators were also evaluated: admission to stroke unit, admission to stroke unit within 24 hours until the end of in-hospital rehabilitation, use of case managers, use of stroke team, assessment of rehabilitation needs within 48hours of admission, patient needs assessment and planning for post-discharge services, three month follow up.

There was no statistically significant difference found for the primary outcome of 30-day mortality. However, in the adjusted model there was a significantly lower risk of 7-day mortality in the intervention group (OR=0.10; 95% CI 0.01 to 0.95) and a significantly higher probability of returning to pre-stroke function (OR=0.42; 95%CI 0.18 to 0.98). Overall, patients in the intervention group that were being cared for with a clinical pathway received higher levels of evidence-based processes of care and organisation of care indicators (statistically significant difference in 10 of 13 process indicators). This was also true for organised care indicators (all seven indicators reported a statistically significant difference). Included in these organised care indicators was access to stroke unit care which was significantly greater for the intervention group (OR=7.24; 95% CI 4.45 to 11.82). It is unclear if the improved adherence to the evidence-based process indicators and organised care indicators are attributable to use of the pathway or access to stroke unit care. There was also no measure of stroke severity, or the use of stroke thrombolysis included in the demographics when comparing the treatment arms. Both of these factors could create significant differences between the intervention and control groups. The study authors noted that the NIHSS (National Institutes of Health Stroke Scale) which could have been used to measure stroke severity at baseline, was still being validated. This raised more questions about the delay from study conduct to publication. The trial was conducted from 2005-2007 but the results weren't submitted for publication until January 2012 with no explanation for this.

When considering the findings from the systematic reviews, Kwan and Sandercock¹⁴³ found no justification for the introduction of care pathways for the routine care of all patients with acute stroke. However, a later systematic review by Allen and Rixon¹⁴¹ which used several of the same studies from the earlier review that met their inclusion

criteria, found that there is some evidence for the use of care pathways under certain conditions. When evaluating the evidence for interventions designed to improve adherence to stroke clinical practice guidelines these findings are important as they highlight the context of the current environment and conditions and how this may influence the usefulness of these interventions. The later multicentre individual RCT by Panella et al.¹⁵¹ which found improved outcomes for use of clinical pathways also reported a notable difference in access to stroke unit care. The context of this specialised environment may have influenced these findings.

2.10.2 Effect of stroke quality collaboratives on adherence to stroke clinical practice guidelines

The use of quality improvement collaboratives and their effect on system-level change in stroke (designed to improve adherence to stroke clinical practice guidelines) was evaluated in a systematic review by Lowther et al.¹⁴⁴ that included seventeen studies (four RCTs, four cross-sectional, three interrupted time series, four pre-test/ post-test and two qualitative) across 224 sites.

A quality improvement collaborative was defined by: (1) a specified topic; (2) clinical and quality improvement experts working together; (3) multiple teams from multiple sites participating; (4) a model or framework for improvement with multiple tests of change; and (5) a series of structured collaborative activities in a given timeframe, involving learning sessions and visits from mentors and facilitators. This review builds on previous reviews as was the first to use the Consolidated Framework for Implementation Research (CFIR)¹⁶² to explore the facilitators and barriers to using a quality improvement collaborative.

The authors approach to the heterogeneity in the trials and outcomes was to use a vote counting method. The outcomes were categorised according to process, patient or other. The studies were then categorised into groups based on the ratio of outcomes demonstrating positive directional change, either from baseline to end of the study or intervention versus control cohort comparison. Group (1) = positive directional change for all outcomes; Group (2) positive directional change for more than half of the outcomes; Group (3) positive directional change for half of the outcomes; Group (4) positive directional change for less than half of the outcomes; and Group (5) positive directional change for no outcomes.

A positive directional change of 50% to 100% was reported in all fourteen of seventeen studies that reported process outcomes (e.g., door-to-needle times, blood glucose testing). Of the seven studies that reported patient outcomes (e.g., mortality), three reported a positive directional change in 100% of outcomes, two reported a positive directional change in less than half of their patient outcomes and two reported no change. No change in other outcomes (e.g., staff engagement) was reported for five of the seven studies reporting on patient outcomes.

Facilitators were mapped to the relevant domains and constructs of the CFIR. Inter- and intraorganizational networking, feedback mechanisms, leadership engagement, and access to best practice examples were found to be key facilitators. Identified barriers included structural changes during the study period, lack of organisational support or prioritisation of quality improvement collaborative activities, and insufficient time and resources to participate in quality improvement collaborative activities.

The review findings of improved clinical processes in stroke care with the use of quality improvement collaboratives, but inability to effectively improve stroke patient outcomes was thought to potentially be due to the short-term nature of these initiatives. This finding is of importance when considering the review aim of what interventions improve adherence to clinical practice guidelines and over what time duration, they may need to be in place for to see any effect.

2.10.3 Effect of advanced practice nurses on adherence to stroke clinical practice guidelines

The use of advanced practice nurses and their impact on stroke care services and clinical and patient-reported outcomes was evaluated in a mixed-methods systematic review by Woo et al.¹⁴⁶ that included 18 studies: n=2 RCTs, n=13 quasi-experimental, n=1 mixed methods and n=2 qualitative. To meet criteria for advanced practice, nurses had to hold a Master's or Doctor of Nursing degree, and/or be a nurse practitioner or clinical nurse specialist.

As this specialist nursing position and responsibilities was not clearly defined, the authors also aimed to describe the practice patterns of advanced practice nurses and outcomes of advanced practice nurse stroke led services. Although this included outpatient services, for the purpose of this review only inpatient services and findings in relation to adherence to acute stroke clinical practice guidelines were considered. Of the 23 sites included, only two were outpatient clinics with the remainder being: hospitals, stroke centres and emergency departments. Three study populations included suspected transient ischaemic attack (TIA) patients, but these were not excluded from consideration for this review. The relevance of any improvement in adherence to this clinical practice guideline (screening for stroke in the emergency department) was thought to be of interest to this overall review aim given the potential applicability of using the same behaviour change strategy for stroke clinical practice

guidelines specific to fever, hyperglycaemia, and dysphagia management. The median sample size for each included study ranged from n=218 to n=282.

Practice patterns were defined as distinctive care delivery approaches employed by advanced practice nurses with specific focus on the role and tasks undertaken. Pre-intervention: the advanced practice nurse was reported to often act as the first responder for code stroke teams. Screening for stroke thrombolysis suitability and differentiating stroke from TIA to then initiate different treatment paths was tasked to advanced practice nurses, in addition to patient and family education and counselling. In-patient care: the advanced practice nurse was a valued member of a collaborative model required to coordinate care and communication within the multidisciplinary team in addition to patient and family education and counselling. This key coordination of evidence-based care for stroke patients was further defined as ‘boundary spanners’ across services and disciplines.¹⁶³ This included responsibility for data collection, data management and feedback, education and training and being the champion for stroke care. Specifically, advocating for improvements in existing processes.

None of the studies that included clinical outcomes (mortality, length of stay, hospital readmissions and systolic blood pressure) reported a statistically significant improvement in these outcomes. However, reduced waiting times for patients to be screened for stroke or TIA and shortened time to stroke thrombolysis treatment were identified. Advanced practice nurse involvement improved patient-reported outcomes in quality of life, medication adherence, lifestyle modifications, and overall satisfaction.

The review findings highlighted the improvement in stroke care attributable to the role of the advanced practice nurse, particularly in the pre-intervention phase to expedite time

critical treatment. The author's recommendation was for all institutions to integrate them into care in response to the growing stroke burden. This finding is significant when considering this review topic of strategies designed to improve hospital clinician adherence to stroke clinical practice guidelines. Clinical practice guidelines in relation to improving time to diagnosis and timing of critical acute stroke treatments are notoriously difficult to implement in emergency department settings.^{62,164} The role of the advanced practice nurse particularly as a boundary spanner across services and disciplines who manages data, education and communication is essential to support and improve in hospital processes. This role likely includes the prevention of acute stroke complications by improving adherence to clinical practice guidelines specific to fever, hyperglycaemia, and dysphagia management, which also need to commence in the emergency department.

2.10.4 Effect of simulation training on adherence to specific stroke clinical practice guidelines

The use of simulation training on door-to-needle time in the emergency thrombolysis of patients with ischaemic stroke was evaluated in a systematic review and meta-analysis published in 2024.¹⁴⁰ Eleven pre-test post-test studies and 19 qualitative studies were included (n =20,189 patients). Current local and international stroke guidelines advocate for the use of educational initiatives to improve outcomes in patients that present as emergencies with ischaemic stroke. Simulation training has been used in emergency departments for other time critical treatments,^{165,166} but its effects outside of single studies has not yet been evaluated in neurology presentations.

The primary outcome was door-to-needle time and secondary outcomes were improvement in acute stroke knowledge, 'feeling safe' in thrombolysis-related decision-making, self-perceived usefulness of simulation training and improvement in

communication. Meta-analysis reported a statistically significant mean difference of 15 minutes (95% CI: 8-21) in the reduction of door-to-needle time post simulation training. Statistically significant improvements were also noted for all secondary outcomes.

The heterogeneity of the included studies in this systematic review makes interpretation of the overall findings difficult. The simulation training itself varied considerably (use of hospital staff/mannequins/actors) as did the settings where the studies took place (emergency department /neurology department/classroom/stroke units). Additionally, the length of the intervention ranged from a one off 90-minute session to monthly training over two years. Furthermore, the quality of the included studies raised some issues. Although the studies had been critically assessed appropriately using ROBINS-I risk of bias tool for non-randomised studies, only one of the included studies was rated as low risk. Another two were rated as high overall risk of bias and the remainder were moderate, or no information provided to assess the risk of bias domains. Without funding details for the studies in the systematic review and meta-analysis, we could not assess potential publication bias. Commercially sponsored studies often favour their products. Lacking this information prevents evaluation of findings based on funding sources (e.g. commercial vs independent).

Simulation training and its effect on stroke thrombolysis is important when considered against this review topic of strategies designed to improve hospital clinician adherence to stroke clinical practice guidelines. Increasingly, simulation training is being used for varied emergency presentations (e.g. cardiac arrest and catheterisation),^{140,167} but is also a recommended strategy for training staff to translate evidence into practice.¹⁶⁸ Some of the improvements in secondary outcomes may have applicability for communication

between multidisciplinary teams, and improvement in acute stroke knowledge. This is relevant when translating evidence into practice and improving adherence to clinical practice guidelines for fever, hyperglycaemia and dysphagia management.

2.10.5 Effect of continuous monitoring versus intermittent physiological monitoring for acute stroke and the effect on adherence to relevant clinical practice guidelines.

The systematic review by Ciccone et al.¹⁴² consisted of two RCTs and one quasi-experimental study, focused on specific physiological aspects of acute stroke clinical practice guidelines. The author's aim was to understand the features of stroke units that make them so effective at reducing mortality and dependence.¹¹ More specifically, the intensity of physiological monitoring within this setting, and if any differences in monitoring intensity could explain the positive outcomes of care in stroke units. The stroke clinical practice guideline under study in this thesis recommends fever and hyperglycaemia to be monitored four times a day. Continuous monitoring as an intervention designed to improve adherence to this guideline recommendation warrants inclusion of this systematic review in this literature synthesis.

The definition of continuous monitoring (where the patient is connected to automatic equipment monitored by nursing staff) for inclusion in the review was that it had to be in use for a minimum of 12 hours within the first 72 hours of admission, and measure at least one physiological variable (blood pressure, pulse rate, respiration rate, oxygenation, heart rhythm, or body temperature). The same time/variable requirements were used to define non-continuous/intermittent physiological monitoring (where nurses use manual/portable equipment to measure). Two of the three included studies (two RCTs and one quasi-randomised open label control [n=354 participants]) also used blood glucose as a trigger. Primary outcomes were death and disability (modified

Rankin Scale (mRS) ≥ 3 or equivalent). Fever was in the list of complications that would be used as a surrogate outcome (as it triggered an intervention) and two of the studies included blood glucose level monitoring ($>7\text{mmol/L}$ ¹³ or $>10\text{mmol/L}$ ¹⁶⁹) in the list of variables to be monitored for complications related to immobility (anticipated consequence to the physical constraints of continuous monitoring).

In the pooled analysis, the authors reported that continuous monitoring significantly reduced the composite endpoint of death and disability at three months or discharge (OR 0.27, 95% CI 0.13 to 0.56). When looking at detection of fever, continuous monitoring was associated with a significant increase in the detection of fever (OR 2.17, 95% CI 1.27 to 3.70). Overall, they concluded that continuous monitoring improves attention to the change in physiological variables, which is one of the key features of the efficacy of stroke units.

The positive outcomes reported for use of continuous monitoring support the review aim of interventions that improve adherence to clinical practice guidelines so are of great interest.

2.10.6 Effect of audit and feedback on adherence to stroke clinical practice guidelines

Existing evidence for clinician behaviour change has demonstrated audit and feedback across multiple clinical conditions and inpatient and outpatient settings to be a key component to effect change in professional practice and healthcare outcomes. For the purpose of this systematic narrative hybrid review the Ivers et al.⁹⁵ seminal systematic review publication could not be included as only 36 of the 140 studies were conducted in an inpatient setting and only two were specific to a stroke population.⁹⁵ One of these stroke-specific studies was excluded as it was conducted in a subacute stroke setting

and the other individual RCT by Lakshminarayana et al.¹⁴⁹ is included in this systematic-narrative hybrid review.

The trial was conducted across nineteen hospitals and included n=1211 participants.¹⁴⁹ The authors evaluated the use of audit and customised feedback delivered by a local opinion leader in an acute stroke population. The primary outcome was compliance with guidelines for stroke as measured by adherence to ten quality indicators (none of these performance measures were specific to fever, hyperglycaemia, or dysphagia management).

In contrast to previous Cochrane systematic reviews that found audit and feedback generally leads to small effects (4.3% [IQR 0.5% to 16%]⁹⁵ and 5.0% [IQR +3% to +11%])⁹⁶ in professional practice under certain conditions (e.g. when baseline performance results are low); the authors of this study reported that there was no intervention effect. Of note, they found significant secular trends with performance improvement for both the intervention and control cohorts. At the time the trial was conducted there was a nationwide health service campaign to improve the quality of acute stroke care with the publication of new clinical practice guidelines and a stroke centre certification program. The authors acknowledge their findings may have been influenced by these factors and highlighted the issue with using historical controls in relation to this. Given the improvement in both cohorts the study outcomes are not definitive when considering audit and feedback as an intervention to improve adherence to stroke clinical practice guidelines.

2.10.7 Effect of multi-component interventions on adherence to generic stroke clinical practice guidelines

Evidence suggests that multiple strategies targeting different barriers to change are more likely to be effective than single interventions.⁹⁴ Therefore, many implementation

science studies are taking this approach. A review from the Cochrane database of systematic reviews from Lynch et al.¹⁴⁵ one primary multi-centre individual RCT by Machline-Carrion et al.¹⁵⁰ and another multicentre stepped-wedge partial randomisation trial by Cadilhac et al.¹⁴⁷ were used to evaluate the effect of multi-component interventions on adherence to generic stroke clinical practice guidelines.

The systematic review was published in 2023 and was limited to stroke unit settings, and RCT and cluster RCT trial designs only (n=7 RCTs, n=129 hospitals, 42,489 acute stroke patients). Implementation interventions were compared to no intervention or other interventions, for increasing adherence to evidence-based recommendations by health professionals working in acute stroke units. Secondary aims were to assess factors that may modify the effect of interventions and to determine if single or multifaceted strategies are more effective for increasing adherence to these evidence-based recommendations.

Interventions were targeted at enhancing adherence to evidence-based recommendations in acute stroke units and changing the behaviour of healthcare professionals, stroke services or both. Effective Practice and Organisation of Care (EPOC) taxonomy⁴⁸ was used to classify these further. These included educational outreach visits, establishing local consensus processes, interprofessional education in joint interactive learning, audit and feedback, and continuous quality improvement. Delivery arrangements included coordination of care and management of care processes.

Five trials compared a multifaceted implementation intervention to no intervention, and two trials compared one multifaceted implementation intervention to another

multifaceted implementation intervention. Meta-analysis was only conducted for multifaceted intervention versus no intervention. All studies reported quality of care outcomes (proportions of patients receiving evidence-based care).

The authors of this systematic review found that the certainty of evidence was very low when comparing multifaceted implementation intervention to no intervention in their meta-analysis of any change in adherence to evidence-based recommendations (RR 1.73, 95% CI 0.83-3.61). Moderate certainty of evidence was reported to support little or no evidence in the proportion of ischaemic stroke patients who received thrombolysis (RR 1.14, 95% CI 0.94-1.37) but a probable increase in the proportion of patients who receive a swallow screen within 24 hours of admission (RR 6.76, 95% CI 4.44-10.76). Moderate certainty of evidence was also reported to support little or no evidence for multifaceted implementation intervention in reducing the risk of death, disability or dependency, or length of stay compared to no intervention. For this reason, the authors concluded that overall, they were uncertain if multifaceted implementation intervention compared to no intervention improves adherence to evidence-based recommendations in acute stroke units.

Synthesis of the results in this systematic review was complex given the wide variation in outcome measures and interventions (e.g. 15 of 19 subcategories for implementation strategies and 2 of 5 subcategories for delivery arrangements in EPOC taxonomy).

Other limitations were in relation to the setting as stroke centres in America are not defined in the same way that stroke units are in many other countries^{145,170} so studies from this country were not included. Additionally, stroke units are generally only available in well-funded healthcare facilities which means the findings of this review are also not generalisable to many other low-income countries.¹⁷¹

Another two individual RCTs evaluated the use of multi-component interventions to improve adherence to generic stroke clinical practice guidelines: The Brazilian Intervention to Increase Evidence Usage in Practice (BRIDGE-Stroke)¹⁵⁰ [36 hospitals, 3 countries, n=1624 participants], and Shared Team Efforts Leading to Adherence Results (STELAR)¹⁴⁷ (9 hospitals, n=3147 participants). The intervention in BRIDGE-Stroke included case management, reminders, a roadmap and checklist for the therapeutic plan, educational materials, and periodic audit and feedback reports. The intervention in STELAR consisted of educational workshops, external improvement facilitators, and feedback of registry data (Australian Clinical Stroke Registry) to identify practice gaps, interprofessional education, barrier assessment and action plans, and change champions.

Both studies used an opportunity composite score as the primary outcome to measure compliance against key stroke performance measures. This was defined as the sum of performance measures achieved, divided by the total number of performance measures for which the patient was eligible. In the BRIDGE trial, in-hospital evidence-based therapies for patients with acute ischaemic stroke consisted of: early antithrombotic therapy, deep vein thrombosis prevention, rapid treatment with thrombolysis (≤ 60 minutes), dysphagia screening, rehabilitation assessment, antithrombotics/statins at discharge if indicated, anticoagulants if indicated, and smoking cessation education. Secondary outcomes included an all-or-none composite end point of performance measures, the individual process measure components of the composite end points, and clinical outcomes at 90 days after admission (stroke recurrence, death, and disability (mRS)).

In the STELAR trial, the opportunity composite score was the proportion of all required care provided to patients based on the performance measures included in each hospital's action plan. Secondary outcomes included the changes in adherence for all individual performance measure, including those not identified in the hospital specific action plans. Survival at 30 and 90 days, and disability (mRS) between 90-180 days were also included as secondary outcomes.

The primary outcome used to assess adherence to performance measures in the BRIDGE-Stroke trial showed no significant difference between the groups using a multicomponent intervention. However, there was a significant difference in the secondary outcome when using an all-or-none score (49.2% vs 25.2%; OR 2.59; 95%CI, 1.22-5.53; $p = 0.01$) The authors cited the inclusion of transient ischaemic attacks (TIAs) in addition to their ischaemic stroke population may have contributed to the non-significant findings by diluting their sample. Although TIAs only made up 11.7% ($n=190/1624$) of their study population, the sub-group analysis does support this finding with a notable improvement (but not statistically significant) in the composite measure scores when the sample only included the ischaemic stroke population. There was no difference between the groups for other secondary clinical outcomes at 90 days (stroke recurrence, death, and disability [mRS]).

The primary outcome findings for the STELAR trial showed that compared to the control phase, the median score for the composite outcome for the intervention phase was 17% greater for the indicators included in the hospitals' action plans (range 3% to 30%, $p = 0.016$) and overall, for all performance measures, 6% greater (range 3% to 10%, $p < 0.001$). Patients in the intervention phase more often received stroke unit care (odds ratio [OR] 1.39, 95% confidence interval [CI] 1.05–1.84), were discharged on antithrombotic medications (OR

1.87, 95% CI 1.50–2.33), and received a discharge care plan (OR 1.27, 95% CI 1.05–1.53).

Secondary patient outcomes were unchanged.

Although the systematic review and individual RCTs reported improvement in some evidence-based care processes, none of the studies were able to demonstrate any effect from the translation of these improvements on clinical outcomes such as mortality or disability. The authors of the BRIDGE and STELAR trials both suggested this was due to underpowered samples. The uncertainty from the systematic review also related to inconsistency in the results of the included studies. Much of the discrepancy in the results was due to study design flaws making the individual studies susceptible to bias which downgraded the overall systematic review evidence. This highlights that further research may be required with appropriately powered samples and study designs that are conducted under more rigorous conditions.

Additionally, the findings from these studies needs to be taken into careful consideration with the existing knowledge around quality improvement strategies and the small effect sizes commonly reported. Combining these strategies may not have the desired cumulative effect, but any improvement in adherence to evidence-based stroke clinical practice guidelines even if not statistically significant could potentially be of clinical significance.

2.10.8 Effect of multicomponent interventions on adherence to specific stroke clinical practice guideline

Five individual RCTs combined multiple quality improvement strategies as the intervention to improve adherence to more specific clinical practice guidelines for stroke. The Increasing Stroke Treatment Through Interventional Behavioural Change Tactics (INSTINCT) trial included a sample size of twelve matched hospitals that

treated 40,823 patients during the pre- and post- intervention periods of which 745 patients received t-PA (alteplase, thrombolysis).⁶² The multilevel, barrier assessment interactive educational intervention (BA-IEI) included: qualitative and quantitative assessment of barriers to alteplase use (to be addressed in the intervention phase when promoting clinical practice guidelines), development of local stroke champions/opinion leaders, continuing education, telephone support for treatment decisions, academic detailing and audit and feedback.

The investigators aimed to improve the proportion of ischaemic stroke patients who were treated with alteplase by targeting emergency departments for this behaviour change. While the results showed an improvement, it was not statistically or clinically significant (ITT: 89/7119 [1.25%] and 235/8419 (2.79%) vs control 99/7946 (1.25%) and 194/9222 (2.10%) [RR] 1.37, 95% CI 0.96–1.93; $p=0.08$). The target-population found a slightly larger increase in alteplase use in the intervention hospitals (59/5882 [1.00%] and 191/7288 [2.62%] vs control (65/5957 [1.09%] and 120/6989 [1.72%] [RR 1.68, 95% CI 1.09–2.57; $p=0.02$) but was still thought to be smaller than the effect to which the study was powered. During the years this trial was conducted (January 2005- December 2006, and January 2008- January 2010) there was a nationwide surge in treatment rates for thrombolysis.¹⁷² The authors acknowledged this secular trend and the heterogeneity of the response to the intervention that may indicate local conditions were a confounder to these results.

Another stepped wedge individual RCT conducted in 18 emergency departments (n=691 participants) by Haesbaert et al.¹⁴⁸ aimed to reduce in-hospital times and access to stroke thrombolysis. The multicomponent intervention consisted of a one-day training program for a physician and nurse from each hospital. These representatives took the package back to their respective teams and conducted the training (train the

trainer approach). Education on stroke recognition and diagnosis, and simulation packages for NIHSS scoring for physicians and FAST tool (Face, Arm, Speech, Time) training for nurses was conducted. Each team then developed a clinical pathway for the management of ischaemic stroke patients specific to their hospital (physician and nurse joined by their team neurologist and radiologist for this part of the training). The pathway was developed in accordance with the national French clinical practice guidelines but also contained key prompts and local information (e.g. phone numbers for imaging; location of stroke thrombolysis).

Primary outcomes consisted of in-hospital management times (e.g. door-to-needle time, door-to-imaging) and percentage of patients receiving thrombolysis. Secondary outcomes consisted of stroke complications, stroke recurrence, death and performance of FAST by nurses and NIHSS by physicians. The investigators were able to report a statistically significant increase in the proportion of patients treated with thrombolysis (OR 1.42, 95% CI, 1.01-2.01) and an improvement in imaging to stroke unit time (39 minutes vs 53 minutes, $P=0.03$). All other times (door-to-needle time, door to imaging, door to stroke unit) were non-significant.

When considering the outcomes of this trial, the authors hypothesised that the reason for improvement in one in-hospital time (imaging to stroke unit time) was because of the improved relationship with the emergency department from having participated in the training together. However, only one radiologist from the $n=18$ hospitals actually participated in the training. This lack of engagement and fidelity to the intervention may have contributed to the lack of improvement in any other in-hospital times. The median door to imaging time was 71.4 minutes for the control group and 79.8 minutes for the intervention group, falling well short of the recommended 25 minute door to

imaging clinical practice guideline.¹⁷³ As more than 90% of thrombolysis was administered in the stroke unit (door to stroke unit median time: 113 minutes in control group, 106.2 minutes in intervention group), this delay to imaging requires future concentrated efforts to reduce the door to needle time, This emphasizes the importance of conducting the trial and delivering the intervention as intended to achieve measurable outcomes.

The authors also stated they were only able to use the proportion of patients treated with thrombolysis as the primary outcome as they achieved a ‘higher-than-expected’ statistical power to do so. In the registered protocol, the proportion of patients thrombolysed was listed as a secondary outcome. If the results were published as per the pre-defined protocol this would have been reported as a secondary outcome, and they would have predominantly neutral results for all primary outcomes with the exception of imaging to stroke unit time. Changing the outcome after reviewing the data raises issues about bias and selective reporting.

An individual RCT by Zhong et al.¹⁵³ the Improving In hospital Stroke Service Utilization (MISSION trial) also evaluated a multicomponent intervention to shorten thrombolytic door-to-needle time. This study included ischaemic stroke patients receiving intravenous thrombolysis within four and half hours from symptom onset only. The intervention was based on six major components from the Behaviour Change Wheel¹⁷⁴ and was delivered via video conference monthly for a year. The Persuasion Environment reconstruction Incentivization Training Education Modelling intervention was compared to standard care plus stroke registry. Stroke knowledge training and education was provided in relation to rapid stroke diagnosis and assessment, and risk assessment for haemorrhage and complication management. Case studies, time tracking

and feedback, and champions were used to present examples of decreasing in-hospital delays. Incentives were provided with the development of an award based on the number of patients who received thrombolysis and the number with door-to-needle time ≤ 60 minutes. Standardised templates were included in electronic medical records to guide evidence-based performance measures.

Twenty-two hospitals (n=1634 participants) were recruited, and the primary outcome was door to needle time of ≤ 60 minutes. Secondary outcomes included door-to-needle time, onset to needle time, complications, mRS and death at discharge, and mRS at 90 days. A greater proportion of patients who received thrombolysis ≤ 60 minutes was reported for the intervention group when compared to the control group (82% compared to 73.3%; adjusted odds ratio 1.77, 95% CI 1.17-2.70). door-to-needle times was an average of 43 minutes versus 50 minutes (adjusted mean difference: -8.83, 95% CI -14.03—3.64; ICC 0.12, $p=0.001$). A greater proportion of patients in the intervention group were assessed as mRS 0-1 (favourable functional outcome) at 90 days but there were no other statistically significant secondary outcome differences.

Although more patients in the intervention arm were treated in a stroke unit, this was adjusted for in the analysis. Similarly, there was substantial missing data for both groups, but this was also addressed in the statistical methods. Sensitivity analysis also increased confidence in the overall results. The authors reported the delivery of the intervention remotely was a strength of the study and could potentially be used during the COVID-19 pandemic. The pandemic resulted in delayed stroke presentations (and a reduced number of presentations overall),¹⁷⁵ with substantial restructures to health care systems. Consequently, the findings from this individual RCT may not be generalisable to a markedly different pandemic stroke population and health service.

The multicomponent intervention used in the T³ (Triage, Treatment in the emergency department, and prompt Transfer to an acute stroke unit) Trial (26 hospitals, n=2242 patients) included: (1) workshops to identify barriers and solutions; (2) face-to-face, online, and written education; (3) national and local clinical opinion leaders and champions; and (4) email, telephone, and site visit follow-up. The investigators had previously demonstrated the effectiveness of this same multi-faceted intervention in the landmark QASC Trial to support implementation of nurse-led multidisciplinary clinical protocols to manage fever, hyperglycaemia, and swallow (dysphagia) in stroke units. The seminal QASC Trial consisting of 19 hospitals (n=10 intervention, n=9 control; 1696 patients), compared the effects of a multi-faceted intervention to the control group who received an abridged version of existing national stroke clinical guidelines only. Regardless of stroke severity, the intervention group were reported to be significantly less likely to be dead or dependent (mRS ≥ 2) at 90 days than the control group (adjusted absolute difference 15.7% [95% CI 5.8-25.4]). They also had improved Short Form Survey (SF-36) mean physical component summary scores (adjusted absolute difference 3.4 [95% CI 1.2-5.5]) and improved processes of care (reduced mean temperature and mean blood glucose).³¹

In the T³ Trial, fever, hyperglycaemia and swallow complications after stroke were targeted again, but this time in emergency department settings. In addition to these, they also targeted stroke clinical practice guidelines specific to Triage (recommendation for Australasian Triage Scale category 1 or 2); Treatment (improve screening for thrombolysis and subsequent treatment rates) and Transfer (prompt <4 hours stroke unit admission).

The primary outcome of death or dependency (mRS score of ≥ 2) at 90 days was not significant for the intervention group when compared to the control group. This was also true for the secondary outcomes and emergency department quality of care outcomes. The authors noted that thrombolysis rates were high in both groups, even higher than the nation's average at the time of publication. Similar to other studies that have reported difficulty achieving practice change in the very busy and challenging emergency department environment^{61,62,164} with many competing interests, it was noted that stroke patients may not be seen as a high priority for clinicians in this setting. Improving adherence to stroke clinical practice guidelines in this setting requires careful consideration.

2.10.9 Effect of nurse led FeSS care bundle on adherence to specific stroke clinical practice guideline

Similar to the QASC trial, a nurse-led care bundle to manage fever, sugar (hyperglycaemia) and swallowing was evaluated in a small single centre individual RCT in India (n=52 patients in each arm). However, in the QASC trial the bundled care protocols were part of a multi-faceted intervention that included several evidence-based implementation strategies as noted in section 2.10.8. In this trial the care bundle was portrayed as the singular intervention with minor adaptations to the protocols used in the QASC Trial. The FeSS bundle included 4hrly temperature and blood glucose level (BGL) monitoring for the first 72 hours. If a temperature $>37.5^{\circ}\text{C}$ was detected, paracetamol was to be administered within the hour and the patient monitored 2hrly with the physician alerted if the fever persisted. If a BGL greater than 11mmol/L was detected, sliding scale insulin was to be administered within one hour, and the physician was to be notified. Swallow screening was to be performed within 24 hours

of admission or before the first meal. If the patient failed the swallow screen, the physician was to be notified for subsequent speech pathologist assessment.

The control group received usual care: temperature monitoring once per shift (and as required), BGL measured in the emergency department then as directed by the physician. Oral intake was to commence after receiving instructions from the treating physician. Nurse champions were trained in use of the FeSS Protocol and data abstraction, and guidelines were displayed in the stroke wards. The primary outcomes were of mortality, disability (Barthel Index) and functional dependency (mRS) collected at 90 days. There were no statistically significant differences between the intervention and control groups for disability or functional dependency. However, a significant reduction in mortality was reported for the intervention group (RR 2.143 (95% CI 0.953-4.820)).

As discussed in the quality assessment and risk of bias section, more information is required from the authors of this study in relation to several key areas. In particular, clarification is required regarding the 220/334 patients screened that did not meet inclusion criteria. As one criterion was language based this would introduce selection bias before randomisation. Additionally, the large number of intracerebral haemorrhagic (ICH) stroke types (50%) means the sample for this study may not be comparable to other stroke populations (typically 11-22%). Evidence suggests that ICH patients may require longer evaluation periods to obtain more precise information about their long-term recovery. Therefore, using a 90 day endpoint to assess disability and functional dependency may be too early for this stroke sub-type.¹⁷⁶

The setting for this study was also unclear, in one section it was described as ‘the stroke care unit’ while in another section the setting was referred to as ‘respective stroke wards’. Further, in the table of baseline characteristics, Unit was listed as Emergency/Intensive Care Unit and Ward. A total of n=8/104 patients were allocated to the ward. There was also no data included in the table for treatment and monitoring variables. Although the authors described in the text that more intervention patients required insulin and paracetamol, there were no data available to confirm that they received this within the hour. In the discussion section, additional results were discussed, without a corresponding table reference to corroborate these findings.

When considering the reported findings of this study against the review aims of interventions that improve adherence to stroke clinical practice guidelines, this study provides weak evidence. There is insufficient information on the study design and methods making it difficult to replicate and highly susceptible to bias, thereby undermining confidence in the study findings. More importantly, without a more detailed results section, it is unclear if there was an improvement in adherence to the guidelines specific to fever, hyperglycaemia and dysphagia management after stroke in adult patients.

2.11 Discussion

The narrative synthesis of the body of evidence identified in this review incorporated the use of several recommended strategies¹³⁹ to analyse and draw conclusions when evaluating interventions that improve adherence to stroke clinical practice guidelines. These included tabulation for the evidence table (Table 1), grouped by the intervention (Box 1) and a textual description in the previous sections of this chapter (Section 2.10.1-2.10.9). A concept map¹³⁹ to identify similarities and/or differences and evaluate for potential relationships within and between the studies was used to visually translate

the data (Table 4). The next section discusses these key themes and overall assessment of the strength of the evidence available for drawing conclusions on the basis of this narrative synthesis.

Table 4 Narrative synthesis concept map

First Author (Year)	Publication Type	Adherence to clinical practice guidelines	Primary Outcomes	Secondary Outcomes	Theme 1 Improved processes that do not translate to clinical outcomes (all or some)	Theme 2 Study duration and the effect of time (e.g. secular trends)	Theme 3 Context (study setting) and quality of included studies (or study design)
<u>Care pathways</u>							
Kwan, J (2004)	SR	✓ Access to CT scans	✗ Mortality & dependency	✓ urinary tract infections ✓ readmissions ✓ neuroimaging ✗ patient satisfaction and quality of life	✓		✓
Allen, D (2008)	SR	✓ Timely assessments	✗ Service integration	Nil specified	✓		✓
Panella, M (2012)	RCT	✓ Evidence- based processes (10/13) ✓ Access to stroke unit	✗ 30day mortality	✓ Mortality (7 days) ✓ Return to pre-morbid dependency ✓ complication rates ✓ Swallow screen 24hrs	✓	✓	✓
<u>Quality improvement collaboratives</u>							
Lowther, H (2021)	SR	✓ Evidence- based processes (14/17) *BGL testing	Overall effectiveness, vote- counting method	✗ patient and other outcomes	✓	✓	✓
<u>Advanced Practice Nurses</u>							

✓ Outcome achieved, ✗ Did not achieve this outcome, ✓ Theme is relevant to this study, hrs (hours)

BGL (Blood glucose level), SR (Systematic review), RCT (Randomised controlled trial), CT (Computed tomography), LOS (Length of stay), SF 36 (36 item Short Form Health Survey), FAST (Face, Arm, Speech, Time), NIHSS (National Institute of Health Stroke Scale), ED (Emergency Department)

Table 4 Narrative synthesis concept map

First Author (Year)	Publication Type	Adherence to clinical practice guidelines	Primary Outcomes	Secondary Outcomes	Theme 1 Improved processes that do not translate to clinical outcomes (all or some)	Theme 2 Study duration and the effect of time (e.g. secular trends)	Theme 3 Context (study setting) and quality of included studies (or study design)
Woo,B (2023)	SR	✓ Stroke screening ✓ Time to thrombolysis	Convergent integrated approach	✗ Mortality, length of hospital stay, readmissions, systolic blood pressure	✓		
<u>Simulation training</u>							
Aljuwaisier, S (2024)	SR	✓ Door to needle time	✓ Door to needle time	n/a			✓
<u>Continuous physiological monitoring</u>							
Ciccone, A (2013)	SR	✓ Monitoring	✓ Mortality (discharge) and dependency (90 days)	✓ Detection of cardiac complications, fever and hypotension			✓
<u>Audit and feedback</u>							
Lakshminarayan, K (2010)	RCT	✗ Evidence- based processes	✗ Improvement in 10 quality indicators	n/a		✓	
<u>Multi-component interventions</u>							
Lynch,E (2023)	SR	✓ Swallow screen within 24hrs	✗ Quality of care (adherence to evidence-based recommendations)	✗ Patient outcomes, length of stay, resource or economic outcomes, health	✓		✓

✓ Outcome achieved, ✗ Did not achieve this outcome, ✓ Theme is relevant to this study, hrs (hours)

BGL (Blood glucose level), SR (Systematic review), RCT (Randomised controlled trial), CT (Computed tomography), LOS (Length of stay), SF 36 (36 item Short Form Health Survey), FAST (Face, Arm, Speech, Time), NIHSS (National Institute of Health Stroke Scale), ED (Emergency Department)

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First Author (Year)	Publication Type	Adherence to clinical practice guidelines	Primary Outcomes	Secondary Outcomes	Theme 1 Improved processes that do not translate to clinical outcomes (all or some)	Theme 2 Study duration and the effect of time (e.g. secular trends)	Theme 3 Context (study setting) and quality of included studies (or study design)
			Mortality and dependency (90 days)	professional knowledge			
Machline- Carrion, MJ (2019)	RCT	✓ Evidence- based processes ✓ thrombolysis rates	✗ Composite adherence score	✓ All or none composite score ✗ Patient outcomes	✓		
Cadilhac,D (2022)	RCT	✓ Access to stroke unit ✓ Discharge medications ✓ Discharge plans	✓ Composite indicators action plans	✓ Adherence to some individual indicators ✗ Patient outcomes	✓		✓
Middleton, S (2011)	RCT	✓ FeSS management	✓ Death or dependency (90 days) ✓ SF_36 (mean PCS) ✗ SF-36 (mean MCS) ✗ Barthel Index	✓ FeSS processes of care ✗ Aspiration pneumonia ✗ LOS			
Scott, PA (2013)	RCT	✗ Proportion treated with thrombolysis	✗ Change in thrombolysis use	Measurements of safety (reported separately)		✓	
Haesebaert, J (2018)	RCT	✓ Imaging to stroke unit time	✓ *Changed to proportion treated with thrombolysis	✗ Complications, death, ✓ FAST (nurses) ✓ NIHSS (physicians)			✓

✓ Outcome achieved, ✗ Did not achieve this outcome, ✓ Theme is relevant to this study, hrs (hours)

BGL (Blood glucose level), SR (Systematic review), RCT (Randomised controlled trial), CT (Computed tomography), LOS (Length of stay), SF 36 (36 item Short Form Health Survey), FAST (Face, Arm, Speech, Time), NIHSS (National Institute of Health Stroke Scale), ED (Emergency Department)

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First Author (Year)	Publication Type	Adherence to clinical practice guidelines	Primary Outcomes	Secondary Outcomes	Theme 1 Improved processes that do not translate to clinical outcomes (all or some)	Theme 2 Study duration and the effect of time (e.g. secular trends)	Theme 3 Context (study setting) and quality of included studies (or study design)
			X In hospital management times				
Zhong, W (2022)	RCT	✓ Door to needle time ✓ Proportion treated with thrombolysis	✓ Door to needle ≤60mins)	✓ Dependency (90 days) X Mortality and dependency (discharge)	✓		
Middleton, S (2019)	RCT	X Evidence- based processes	X Death or dependency	X Dependency, health status, ED quality of care		✓	✓
<u>Nurse led FeSS care bundle</u>							
Sridhar, D (2024)	RCT	✓ FeSS management	✓ Mortality (90 days) X Dependency (90 days)				✓

✓ Outcome achieved, **X** Did not achieve this outcome, ✓ Theme is relevant to this study, hrs (hours)

BGL (Blood glucose level), SR (Systematic review), RCT (Randomised controlled trial), CT (Computed tomography), LOS (Length of stay), SF 36 (36 item Short Form Health Survey), FAST (Face, Arm, Speech, Time), NIHSS (National Institute of Health Stroke Scale), ED (Emergency Department)

This systematic-narrative hybrid review of interventions designed to improve clinician adherence to clinical practice guidelines, has highlighted the difficulties with determining the effectiveness of implementation studies under controlled trial conditions. Many of the included studies reported positive trends, or improved processes of care. However, these did not often translate to improved patient outcomes when assessed using clinical endpoints of death and disability. In the absence of stronger RCT evidence, several of the reviews included lower-level study designs which limits generalisability of the results and overall interpretation. Other issues highlighted in this review were the effect of time. The use of historical controls and the wide variation in study duration were noted as factors that could affect study outcomes. Additionally, the settings in which the studies were conducted had the potential to impact the uptake of clinician adherence to stroke clinical practice guidelines.

The use of stroke care pathways was evaluated in one individual RCT¹⁵¹ and two systematic reviews (that included non-randomised observational studies in their analysis)^{141,143} The evaluation of this intervention, believed to promote organised, efficient, evidence-based multidisciplinary care was inconclusive based on the study outcomes examined in the reviews. However, the individual RCT reported both improved patient outcomes and adherence to evidence-based care processes.¹⁵¹ Improved access to stroke unit care was one of these evidence-based processes, so it is unclear if these findings are attributable to access to the stroke unit care setting or to use of the care pathway.

The Code Stroke alert system for coordination of response to acute stroke patients across health services has had great success in recent years. This critical pathway has been able to demonstrate improvements in thrombolysis screening, treatment rates, time

to treatment and also time to stroke unit¹⁷⁷⁻¹⁷⁹ all of which have been proven to improve patient outcomes.^{11,180} However, these improvements as key findings were not demonstrated in RCT study designs. The Code Stroke care pathway did not meet the definition for inclusion in either of the systematic reviews, possibly because of the pre-hospital focus or the requirement for the pathway to be used by multiple disciplines to meet criteria. Although the Code Stroke alert system and process is used by many hospitals, the shared care pathway for documentation may not be a requirement if the hospital specific code stroke process is followed. The success of this recognised Code Stroke type of care pathway to coordinate care though, has likely contributed to the widespread adoption of care pathways for in-hospital stroke management despite the seemingly lack of RCTs as ‘strong evidence’ for their use.

Contributing to the lack of ‘strong evidence’ for use of care pathways in stroke may be related to the choice of primary outcomes for this type of intervention. The use of clinical study end-points of death and disability to assess in-hospital care pathways may be incongruent with the overall purpose of these tools, which is the promotion of organised, efficient, evidence-based multidisciplinary care.¹⁵⁸ Evaluating the overall purpose and efficiency of these pathways may be better achieved by assessing improvements in processes of care and the type or amount of evidence-based care provided, and can still be used as the primary outcomes in an RCT study design.

Three of the included studies in the Kwan and Sandercock systematic review reported improved processes of care (CT scan<24 hours, aspirin<48 hours, medications on discharge)^{158,161,181} which is reflective of improvements in adherence to stroke clinical practice guidelines relative to these measures. However, all three studies were non-randomised and therefore, considered to be ‘weak evidence’. Allen and Rixson¹⁴¹ also concluded that there was some evidence that care pathways contributed to patients

receiving timely clinical interventions and/or assessments. However, the authors were unsure if this was due to improved documentation.¹⁴¹

Both of these reviews highlight the paucity of high-quality research evidence examining the effect of care pathways on clinician adherence to clinical practice guidelines. The findings from the individual RCT published after the two reviews highlighted further how the setting in which these care pathways are evaluated adds to the complexity of interpreting the value of their use. The ‘weak evidence’ for improved processes may be related to the choice of study outcomes and exacerbated by the mixed study designs. However, any improvement in performance even if considered weak evidence may have real clinical significance that shouldn’t be discounted on this basis.

The systematic review findings on the equivocal effect of stroke quality collaboratives is of interest, as all of the included studies reported positive process outcomes. Findings from the four individual RCTs included in the analysis showed increased adherence to stroke clinical practice guidelines^{61,154,164,182} specific to: improved thrombolysis rates, early rehabilitation, deep vein thrombosis prophylaxis and improved dysphagia screening rates. Unfortunately, these findings did not translate to improved patient outcomes which was hypothesised to be as a result of the short-term nature of these collaboratives. Given that study duration varied from six to 48 months between the included studies, further research is needed to determine the time required for the intervention’s effect to become apparent.

The Advanced Practice Nurses’ effect on adherence to stroke clinical practice guidelines did not improve short term patient outcomes but was able to shorten the time to diagnosis and assessment. With 1.9 million neurons lost every minute someone’s stroke is not

being treated,¹⁸³ the clinical importance of this finding should not be understated. The potential for brain salvage (by reducing time to treatment) and efficient use of limited hospital resources with expedited assessment and diagnosis of stroke may potentially have a cascading effect on detection and prevention of stroke sequelae (such as fever, hyperglycaemia and dysphagia).

The review highlighted the lack of clarity and standardisation of the Advanced Practice Nurse role and provides evidence of how they contribute to stroke care. Whilst other studies have reported that achieving behaviour change in the ED is notoriously difficult to achieve,^{61,164} the role of the Advanced Practice Nurse as the boundary spanner across stroke and emergency services could potentially shift this paradigm. Commonly, the Advanced Practice Nurses reported being responsible for data collection and management, and the use of data to educate and communicate to drive improvements in hospital processes across departments. With the use of learning health systems to drive quality improvement in stroke increasingly being recognised in the literature,¹⁸⁴ this role clarification further supports the Advanced Practice Nurse role in this process and the review recommendation for all hospitals to integrate this role in their teams.

Simulation training designed to improve thrombolysis door to needle time was challenging to interpret with confidence due to the quality of the non-randomised studies included in the review. The lack of funding details provided could not be disregarded when simulation training is often provided by an external company to the hospital. This educational method is being used increasingly in undergraduate courses^{185,186} and time critical emergency scenarios.^{165,166} The benefits of its utility specifically for communication between multidisciplinary teams in non-emergency settings is yet to be evaluated. Although relevant to the review topic of improving

adherence to stroke clinical practice guidelines, the use of simulation training would only be pertinent for those processes of care that are time critical (e.g. stroke thrombolysis).

The systematic review evaluating continuous versus intermittent physiological monitoring found significantly reduced endpoints of death and disability.¹⁴²

Furthermore, the review highlighted that the intensity or level of physiological monitoring may be a crucial element within stroke units contributing to positive patient outcomes. The intervention itself is associated with improved adherence to clinical practice guidelines. Specifically, those recommendations for the regular monitoring of physiological variables. The increased attention to any variance in these variables could be indicative of stroke sequelae allowing for early intervention and investigation.

However, the quasi-experimental study on continuous physiological monitoring accounted for 77% of the sample size (n=354), with group allocation based on bed availability. This likely reflects resource limitations in many hospitals, as continuous monitoring is typically for critical care beds. An economic evaluation is needed to compare the cost of continuous monitoring with its health and social benefits. The small sample size also suggests further research is required with a larger, more representative population.

As discussed earlier, seminal papers on audit and feedback^{95,96} were not included in this narrative synthesis of the literature as they did not meet the review inclusion criteria.

However, their substantial contribution to the body of evidence as a strategy for clinician behaviour change, and overall findings raises more questions about the wide variation shown in the interquartile range despite the modest effect size. The Cochrane review on audit and feedback has recently been updated and published after the conduct of this systematic-narrative hybrid review. The results demonstrate a slightly larger

effect size with smaller interquartile range (6.2%; 95% CI 4.1 to 8.2) however, a substantial number of studies in this review reported unchanged or worsened outcomes.⁹⁷ The cost of using this intervention to improve adherence to clinical practice guidelines would need to be considered carefully against the evidence for the expected effect size and the study setting and design.

The equivocal findings in the well-known PRISMM audit and feedback trial¹⁴⁹ included in this review that was specific to stroke, was thought to have been heavily influenced by secular trends at the time the study was conducted. This raises concerns regarding the use of historical controls for pre-intervention comparators. Also in this study, opinion leaders were used to deliver the feedback which is an intervention in itself. The control group also received audit and feedback in the form of a written report. Hence, it is unclear if the effect of audit and feedback was being evaluated in this study or the use of opinion leaders to deliver the feedback.

Using a combination of strategies for improving stroke clinical guideline adherence is not uncommon as seen in the large international series of BRIDGE trials,^{150,187} and the 20 year American Heart Association Get with the Guidelines stroke care quality improvement program.¹⁸⁸ The American stroke program and registry is designed as a collaborative learning model to improve the quality of inpatient care and patient outcomes by addressing individual hospital system level factors. The program has reported some major success, particularly in the first five years with improving adherence to clinical practice guidelines that continues to grow in participating hospitals and maintenance of high levels of compliance.¹⁸⁹ This success has been recognised in non-RCT settings¹⁹⁰ with the focus on the clinical significance of implementing evidence-based care. The programs' success has also been cited in the genesis of recent Australian national targets for stroke care.¹⁹¹

The individual RCTs^{147,150} and Cochrane systematic review¹⁴⁵ that used multicomponent strategies to target **generic** stroke clinical practice findings included in this review, reported conflicting overall findings. This could be due to the use of different outcome measures for the *a priori* definitions of primary versus secondary outcomes. However, overall, any improvements in processes of care did not often translate into improved patient outcomes. Although the authors of some of the individual RCTs acknowledged their studies were underpowered for these measures, this finding is not unusual in studies of implementation strategies. In a recent review of 86 systematic reviews of strategies designed to implement evidence into practice,¹⁹² few studies were able to demonstrate clear evidence for an improvement in patient outcomes. More recently, a systematic review of 204 studies of implementation strategies on nursing practice (predominantly multi-component), reported favourable outcomes for those studies that were ineligible for meta-analysis.¹⁹³ This incongruence in outcome measures was an additional contributor to the weak evidence reported in the Cochrane review¹⁴⁵ as not all studies could be included in the meta-analysis. While some studies showed a non-statistically significant trend towards an increase in improvement in adherence to clinical practice guidelines, further examination in relation to clinical significance even if not statistically significant is required.

Recent strong evidence from the wider QASC translational research program¹⁰² and another large RCT in an international stroke population,¹⁰³ demonstrates an association between the number of evidence-based care processes patients receive in hospital and improved patient outcomes of death and disability.^{102,103} These findings are corroborated by the Australian Clinical Stroke Registry that have also reported the number of evidence-based care processes received in hospital, translate to longer-term survival and improved quality of life outcomes.¹⁰⁴ Confirmation of this cumulative

effect of receiving evidence-based care processes must also be taken into consideration when assessing the evidence for outcomes of individual studies.

The landmark QASC Trial, which used multifaceted quality improvement strategies to target FeSS stroke clinical practice guidelines, is one of the few studies to demonstrate an improvement in processes that translated to better patient outcomes.³¹ The other individual RCTs that used multifaceted quality improvement strategies to target **specific** stroke clinical practice guidelines reported the inability of the intervention to improve clinical guideline adherence may likely be due to problems with the study setting rather than the intervention. Although these studies were conducted in acute stroke populations, the setting for delivery and assessment of thrombolysis was predominantly in emergency departments. Research in this complex environment is problematic.⁶¹ Interventions that have been found to work in stroke units have not demonstrated similar effects in emergency departments or improved thrombolysis treatment rates.³² Some of the proposed reasons for this lack of successful uptake are that stroke represents less than 1% of clinical presentations to emergency departments and emergency department staff have high turn overs.^{32,39} Further research is required to investigate alternative approaches to improve stroke clinical guideline adherence in this setting.

Deeper exploration on the influence of local context and settings is required to understand the wide variation in guideline adherence. Changing behaviour requires an understanding of the influences on behaviour in the context in which they occur.⁹³ The positive secular trends reported by several studies in this review have been attributed to major health care campaigns at the time the studies were conducted. This raises the question of the necessity of further studies on quality improvement if these campaigns will eventually lead to improved care and how intervention effect may be related to study duration. Reviews of stroke public educational interventions have been

inconclusive due to divergent campaign methods, study designs and scarcity of long term-studies.^{194,195} An Australian study of a stroke public educational intervention reported an increase in ambulance dispatches over a ten year period following a multimedia educational intervention (particularly in the month immediately after the campaign).¹⁹⁶ However, although the proportional increase was statistically significant, it was relatively small given the associated costs of producing these campaigns.

In summary, this systematic-narrative hybrid review of interventions designed to improve clinician adherence to stroke clinical practice guidelines, has highlighted three key themes that underscore the major issue of determining the effectiveness of implementation studies. These consist of the trend for improved adherence to clinical practice guidelines that do not translate to clinical patient outcomes. Suggested reasons for this are the choice of study endpoints, study duration and the effect of time (e.g. secular trends), context (study setting) and the quality of included studies, with lower-level study designs limiting the generalisability of the results and overall interpretation. Overall, the recommendations based on the body of evidence (and strength of the evidence if reported in source documents) for interventions designed to improve clinician adherence to stroke clinical practice guidelines are:

Care pathways: there is low to moderate evidence of improved adherence to stroke guidelines for the use of multidisciplinary care pathways. Their use is recommended if there is a recognised issue at baseline.

Quality improvement collaboratives: the evidence was reported as equivocal for this intervention. However, the clinical benefit of the improvement in adherence to stroke clinical practice guidelines warrants consideration.

Advanced Practice Nurses: the improvement in timely acute stroke assessment is likely attributable to the role of Advanced Practice Nurses as boundary spanners across services and disciplines that include the emergency department. Their use is recommended given how given the findings from this review that relate to context and how difficult it is to change behaviour for stroke care in emergency departments.

Simulation training: there is moderate evidence for improvement in time-critical therapies. Although the studies are non-randomized the positive outcomes supports its integration into clinical education and quality improvement initiatives. Further high-quality randomized controlled trials are warranted to strengthen the evidence base.

Continuous physiological monitoring: this intervention is recommended based on the positive primary outcome despite the low level evidence and high risk of bias related to the trial contributing most data to the primary outcome.

Audit and feedback: despite the neutral trial results of the study included in this review this intervention has been researched extensively enough to warrant support for its use as an intervention that yields modest improvements in improving adherence to clinical practice guidelines. This strategy should be considered in alignment with available resources and recommendations for effective feedback.

Multi-component interventions: multi-component interventions are likely to yield clinically significant improvements in care processes, even when not directly reflected in study endpoints. Their use requires careful consideration of contextual factors and the specific settings in which they are implemented.

Nurse-led care bundle: although the evidence included in this review was subject to a high risk of bias limiting its overall quality, the improvement in early mortality was significant. This strategy is recommended in view of existing evidence, despite low quality evidence analysed for this review.

2.12 Conclusions

This narrative synthesis of systematic reviews (of any study design) and individual RCTs of interventions designed to improve clinician adherence to stroke clinical practice guidelines has highlighted the difficulty getting evidence-based care into clinical practice. The overwhelming amount of lower-level evidence from observational studies on quality improvement interventions can be difficult to interpret with confidence. The inclusion of such studies in systematic reviews, due to the absence of stronger evidence, potentially contribute to the lack of clarity or definitive conclusions about interventions for improving clinician adherence to clinical practice guidelines. However, mounting evidence in relation to the benefits of the cumulative effect of receiving evidence-based processes of in-hospital care demands greater accountability from health care services. It is not acceptable for patients to receive care that is not evidence-based, and the variation in guideline adherence needs to be prioritised as an area for focused research efforts.

The results of this systematic-narrative hybrid review have been used to refine the research questions for the additional studies that make up this thesis, which are specific to the use of evidence-based FeSS Protocols in Australian hospitals. The use of passive dissemination of stroke clinical practice guidelines specific to fever, hyperglycaemia and dysphagia management was evaluated in a pre-test/post-test quantitative study of national stroke audit data in Chapter 4 (Study Two). A related qualitative descriptive process evaluation of stroke clinician perspectives of factors that influence adherence to the FeSS Protocols is explored in

Chapter 5 (Study Three). Rationale and justification for use of these study designs within the context of an implementation science framework is presented in the following chapter (Chapter 3: Research methods and methodology).

3.1 Overview

The purpose of this chapter is to outline the methods and methodology of this thesis and to highlight the rationale behind the chosen research approach to meet the objectives of the doctoral research program. The overarching aim of this thesis is to evaluate and explore diffusion of the FeSS Protocols for stroke in Australian hospitals, after their inclusion as recommended care in the 2017 National Acute Stroke Guidelines. National stroke data and front-line clinician perspectives have been used to assess adherence and factors that influence sustainment of implementation strategies for the FeSS Protocols. Specifically, the research was designed to answer the following questions:

1. Has adherence to the FeSS Protocols in Australian hospitals improved since their inclusion as a recommendation in the 2017 Australian Clinical Guidelines for Stroke Management as evidenced by National Stroke audit results of 2019 and 2021 when compared to National Stroke audit results of 2015 and 2017.
2. Does previous participation in the QASC, QASCIP or T³ FeSS Intervention studies increase adherence to the FeSS Protocols?
3. Does admission to a stroke unit rather than to a general medical ward increase adherence to the FeSS Protocols?
4. What strategies or interventions have been used to implement the FeSS Protocols and how do these compare for hospitals that participated in the FeSS Intervention studies and those that did not?

5. What are the perceived individual and organisational factors that influence FeSS clinical practice guideline adherence in i) hospitals with consistently low FeSS adherence composite scores, ii) hospitals with consistently high FeSS adherence composite scores and iii) hospitals with variable FeSS adherence composite scores?
6. Do the identified influential factors from hospitals with high, low and variable FeSS adherence composite scores map to factors from the Sustainability of Innovation Framework and how do these factors influence sustained use of the FeSS Protocols in Australian hospitals?

This Chapter begins with a description and rationale for the philosophical stance and design framework of the studies. Also presented is the rationale and justification for the use of a systematic-narrative hybrid review, pre-test/post-test quantitative study and a qualitative descriptive process evaluation within the context of an implementation science framework. The alignment of the research with the chosen conceptual frameworks (Conceptual Model for Diffusions of Innovations in Health Service Delivery and Organisations,⁹¹ and the Sustainability of Innovation)¹⁹⁷, used for the methodological approach to the qualitative descriptive process evaluation is also presented. Following this, an outline is provided regarding the research design specific to each study and the methods used for data analysis. Namely, multivariable mixed effects logistic regression for the quantitative pre-test/post-test study and inductive thematic analysis for the qualitative descriptive process evaluation study. The study settings and sampling techniques are discussed, along with details of the ethical considerations in the conduct of the research. The Chapter concludes with a summary of the strategies used to enhance the rigour of both studies.

3.2 Research philosophy: Critical realism

After reviewing potential research philosophies relevant to the overarching thesis aim and research questions, critical realism was identified as the most suitable. This philosophy supports the use of diverse research methods to comprehensively understand complex research questions. Critical realists advocate for the use of methods as dictated by the nature of the research question and phenomenon under study.¹⁹⁸ The research undertaken in this thesis consisted of the evaluation of a complex intervention which generated diverse research questions that required specific study designs to address these appropriately. The study designs comprised a systematic-narrative hybrid review of the literature, a pre-test/post-test quantitative study of national stroke data and a qualitative descriptive process evaluation of interviews with stroke specialist clinicians. The integration of mixed methods of research when appraising the relevant literature, including quantitative methods (to evaluate use of the FeSS Protocols after a new guideline recommendation for their use), and qualitative methods (to evaluate clinician perspectives of factors that influence adherence and sustainability of the FeSS Protocols) is in alignment with the research paradigm underpinning this thesis.

The origins of the relatively modern critical realism research paradigm were founded by the Indo-English philosopher Roy Bhaskar in the 1970s.^{199,200} This meta-theory (referring to broad perspectives or overarching theory of theories, specifically regarding the nature of reality)²⁰¹ has since been developed further by other social theorists, namely Margaret Archer²⁰² and Andrew Sayer,²⁰³ among others. Essentially, this research philosophy rejects the limitations of the more traditional positivism and constructionism paradigms but embraces the ontological position (view of reality)²⁰⁴ of realism and relative epistemological position (the study of knowledge)⁹ relevant to each

of these opposing philosophies.²⁰⁵ The positivist paradigm asserts that there is only one single reality to be understood, identified and measured.²⁰⁶ Positivism favours observable quantitative research, where research is designed using objective methods to test for scientific outcomes that can be measured and are generalisable.²⁰⁷ Critical realists accept the same realist ontological position of positivism and believe that reality is observable and exists independently of human knowledge.

However, critical realism also acknowledges that for experiments or events to occur, it is the interaction of several factors coming together under the right circumstances to causally generate these events.²⁰⁸ These factors include agency (beliefs, attitudes, and personal meaning), and contextual or structural factors (social norms, culture, geography, and environment).²⁰⁸ This relative epistemological position on how knowledge is viewed aligns more with constructionism and interpretivism paradigms. Both of these philosophies share a view of reality as subjective. Constructionists maintain that knowledge is produced through interactions between people.²⁰⁴ Interpretivist researchers see knowledge as socially constructed and created and attempt to understand meaning to a person or groups of people as motivation for their behaviour.²⁰⁴ These philosophies favour qualitative research that acknowledges findings will be more subjective as there can be multiple-constructed realities, and time and context can affect these, so findings are not always generalisable.²⁰⁷ A critical realist view of reality is broken into three stages: actual (events/actions that occur), the real (factors that cause these events), and the empirical (what is experienced/observed).^{208,209} A reductive reasoning process is then used to explain why these events occur.¹⁹⁸

This reasoning process begins with both deductive (using prior theory to test hypotheses) and inductive methods (creation of inferences from the data) but then uses a reductive process to create inferences or theory about underlying causal mechanisms which explain the observed experiences.^{198,205} When evaluating complex interventions in health care, a critical realist approach to examining all the available evidence (using the most appropriate methods of quantitative or qualitative design), attempts to explain "what is useful to whom and why."²¹⁰

The focus when looking for explanations (causal mechanisms) is on what the individual (or collective) can achieve (agency) in the social context in which they are operating (structures), and the relationship between the two concepts is interdependent.²⁰⁵ In order to answer the overarching research question of this thesis, the outcome of adherence to the FeSS Protocols is the observable reality. To answer the additional research questions and gain a more comprehensive understanding of the variance in this observed reality (e.g. FeSS Protocol adherence levels between hospitals), an assessment of the interaction between structure and agency was undertaken. The following contextual factors likely to influence FeSS Protocol adherence were considered. An evaluation of 'agency' (such as the beliefs, attitudes and personal meaning of implementation of the FeSS Protocols to the individual) and wider structural constraints to this process (the hospital as the governing body of policy/resources; historical, cultural and social influences, and socio-economic factors [e.g. metropolitan compared to regional settings]) was undertaken.

3.3 Research studies and methods

The study designs incorporated in this thesis comprised: a systematic-narrative hybrid review of the literature (on clinician adherence to stroke clinical practice guidelines); a pre-test/post-test quantitative study of adherence (using national stroke data), and a qualitative descriptive process evaluation of interviews with stroke specialist clinicians to understand FeSS Protocols adherence variability.

The systematic-narrative hybrid literature review highlighted the paucity in high quality evidence for interventions that improve clinician adherence to clinical practice guidelines, and the need for future research specific to the influence of local context. Subsequent study designs in this thesis were developed in response to this evidence gap that were specific to the clinical practice guidelines for the use of the FeSS Protocols in acute stroke hospital settings.

A combination of qualitative and quantitative research methods were used to address the overarching aim and research questions. The quantitative pre-test/post-test study design was used to evaluate the use of the FeSS Protocols for stroke in Australian hospitals. using national stroke data to answer the first three research questions:

1. Has adherence to the FeSS Protocols in Australian hospitals improved since their inclusion as a recommendation in the 2017 Australian Clinical Guidelines for Stroke Management as evidenced by National Stroke audit results of 2019 and 2021 when compared to National Stroke audit results of 2015 and 2017.
2. Does previous participation in the QASC, QASCIP or T³ FeSS Intervention studies increase adherence to the FeSS Protocols?

3. Does admission to a stroke unit rather than to a general medical ward increase adherence to the FeSS Protocols?

A more comprehensive understanding of these quantitative results was required to investigate factors that influenced clinicians' sustained adherence to the clinical practice guideline for use of the FeSS Protocols in real-world settings. A qualitative descriptive process evaluation was undertaken using semi-structured interviews with expert clinicians (from organisations that contribute to data to national stroke audits) to answer the additional research questions pertinent to this thesis:

4. What strategies or interventions have been used to implement the FeSS Protocols and how do these compare for hospitals that participated in the FeSS Intervention studies and those that did not?
5. What are the perceived individual and organisational factors that influence FeSS clinical practice guideline adherence in i) hospitals with consistently low FeSS adherence composite scores, ii) hospitals with consistently high FeSS adherence composite scores and iii) hospitals with variable FeSS adherence composite scores?
6. Do the identified influential factors from hospitals with high, low and variable FeSS adherence composite scores map to factors from the Sustainability of Innovation Framework and how do these factors influence sustained use of the FeSS Protocols in Australian hospitals?

3.3.1 Study One: Systematic-narrative hybrid review of the literature

Interventions designed to improve hospital clinician adherence to stroke clinical practice guidelines and those specific to fever, hyperglycaemia, and swallow management after stroke in adult patients.

To understand the overall research aim within the broader context of the literature regarding clinician adherence to acute stroke clinical guidelines, the first study undertaken in this thesis was a systematic-narrative hybrid review and synthesis of the literature. The aim was to evaluate the evidence for behaviour change interventions designed to improve hospital clinician adherence to any stroke clinical practice guideline, and those specific to fever, hyperglycaemia, and dysphagia management after stroke in adult patients.

To translate knowledge from evidence-based clinical practice guidelines into clinical practice, behaviour change at both the organisational level and from the individual is required. This is widely acknowledged as a very complex topic with interventions targeting behaviour change in health care under study for many years.⁹⁹ This extensive research now includes hundreds of systematic reviews and two Cochrane Effective Practice and Organisation of Care (EPOC) overviews of systematic reviews.^{100,101} A systematic-narrative hybrid review method was selected as it allows for a comprehensive synthesis of both quantitative and qualitative findings.¹¹⁸ This approach is particularly suitable for complex topics like clinician behaviour change, where randomised controlled trials (RCTs) may not always capture the full scope of evidence. RCTs as primary studies provide the strongest levels of evidence and are most suited to meta-analysis in a systematic review.²¹¹ However, not all research questions can be answered with an RCT study design, especially those that relate to the complex topic of clinician behaviour change in health care settings.²¹²

Systematic-narrative hybrid reviews are increasingly being used for expansive research topics as they offer the flexibility to include diverse study designs while maintaining methodological rigour.^{118,119} A systematic review typically uses pre-specified eligibility criteria and explicit methods to search and appraise the literature to answer a narrowly focused research question.^{120,121} Narrative reviews offer a wider scope that can be more comprehensive as this flexibility allows coverage of a wider range of issues within a given topic.¹²¹ However, the less explicit methods of a narrative review can introduce bias and are not generally considered to have the scientific rigour of a systematic review as the methods are often poorly defined.¹²²

Traditionally, systematic reviews combine the statistical results from separate RCTs to conduct a meta-analysis to synthesise their findings.¹²⁰ A narrative synthesis of findings is also now very common with the inclusion of non-randomised study designs in almost half of all systematic reviews which may not be suitable for meta-analysis.¹³⁵ The hybrid systematic-narrative approach incorporates elements of a systematic review that relate to the transparent reporting and description of the methods used to define search criteria; combined with a narrative approach to the review that includes broader research questions and a narrative synthesis of the literature.¹¹⁸

It was anticipated (based on the experience of the 15-year QASC Translational Research Program) that studies investigating adherence to fever, hyperglycaemia and swallowing management interventions in patients with stroke would be minimal, hence the search terms were broadened to include adherence to any stroke clinical practice guideline. Additionally, at the time of conducting the literature review, a search of the international prospective register of systematic reviews (PROSPERO) identified a Cochrane systematic review on a similar topic, namely interventions for the uptake of evidence-based recommendations in acute stroke

units.¹⁴⁵ This systematic review included studies undertaken in stroke units only, with a meta-analysis used to synthesise the evidence from randomised and cluster RCTs.¹⁴⁵

A broader review of the literature was undertaken for this thesis that included all acute hospital settings and was not restricted to stroke unit settings only. Although the seminal QASC Trial³¹ (where the evidence was established for use of the FeSS Protocols) was conducted in stroke units, subsequent studies to implement the FeSS Protocols were not restricted to these settings.^{32,33,35} Investigating their use outside of these speciality stroke units was expected to be a significant marker of diffusion and therefore, sustainability of this evidence-based practice in real-world settings. Evaluating the existing literature on interventions designed to improve hospital clinician adherence to stroke clinical practice guidelines outside of stroke units widened the scope and breadth of the literature review considerably. In view of this complex topic, a narrative review to synthesise and interpret the findings was considered to be the most suitable method.

Systematic methods were used to conduct a pre-determined procedure for a comprehensive search, screen, and selection of relevant literature (as detailed in Chapter Two). Critical appraisal and reporting methods that were predominantly textual were used to analyse the findings from the literature.¹²² This approach to a systematic review is designed to provide a descriptive summary to represent the findings.¹³⁹

The review incorporated mixed methods of research (individual RCTs and systematic reviews of RCTs as well as before and after, pre-test/post-test, observational, interrupted time series, qualitative, retrospective comparative, and quasi-randomised open label control studies). The inclusion of these studies which employ diverse research designs, is consistent with the critical realist philosophy underpinning this thesis. This approach acknowledges that the choice of research methods is dependent on the question driving the research. In the mixed

method systematic reviews, the non-RCT studies can provide critical insights into how contextual factors interact and potentially influence outcomes. Their inclusion was also anticipated to enhance the aforementioned Cochrane systematic review findings that only included RCTs or cluster RCTs.¹⁴⁵

Review aim

The aim was to undertake a systematic-narrative hybrid review and synthesis of behaviour change interventions designed to improve hospital clinician adherence to any stroke clinical practice guideline and those specific to fever, hyperglycaemia, and dysphagia management after stroke in adult patients.

Study selection

Chapter Two contains a more detailed report of the criteria for inclusion and exclusion of studies in this literature review. A summary of these are provided in the table below:

Table 1. Systematic-narrative hybrid literature review inclusion and exclusion criteria

Study inclusion criteria	Study exclusion criteria
Published systematic reviews of any study design that evaluate behaviour change interventions	Studies published before January 2000
RCTs that evaluate behaviour change interventions	Papers written in languages other than English
	Non-randomised single studies (e.g., observational [cross sectional; prospective and retrospective cohorts], interrupted time series, controlled before and after studies)
Settings inclusion criteria	Settings exclusion criteria
Acute care settings in any country	Outpatient setting
	Nursing home or residential aged care facilities
	Community/population wide setting (e.g. public health campaigns)
	Primary Care/Palliative care /Rehabilitation/settings
Patient and clinician inclusion criteria	Patient and clinician exclusion criteria
Hospital inpatients >18 years with ischaemic or haemorrhagic stroke diagnosis	Palliative care patients
Any discipline of clinicians (nursing, medical, allied health)	

Traditionally, RCTs as primary studies are considered to provide the strongest levels of evidence and are most suited to meta-analysis in a systematic review.²¹¹ However, not all research questions can be answered with an RCT study design, especially those that relate to the complex topic of clinician behaviour change in health care settings.²¹² Increasingly, this has been recognised with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement (used to guide the reporting of this review) recently updated to reflect this change and the inclusion of other non-RCT studies.²¹³ Any single studies of quality improvement or non-randomised studies were excluded. However, where they were included within a systematic review (almost half of published systematic reviews now include non-randomised studies of intervention effects),¹³⁵ they were incorporated. Individual RCTs and systematic reviews (of any study design) on interventions designed to improve hospital clinician adherence to generic stroke clinical practice guidelines, and those specific to fever,

hyperglycaemia and swallowing management after stroke in adult patients were included in the review.

The review question was defined using the Population, Intervention or exposure of interest, Comparator (if relevant) and study Outcomes (PICO)¹²⁰ mnemonic commonly used for evidence-based health services.

Box 1. PICO for systematic-narrative hybrid review and synthesis of the literature

Population: clinicians (nursing, medical or allied health)

Intervention or exposure of interest: stroke clinical practice guidelines

Comparator: standard stroke care

Outcome: adherence and/or compliance with stroke clinical practice guidelines

The review was limited to a twenty-four year publication time period to capture literature prior to the time the first FeSS Intervention study was conducted (QASC Trial 2005-2010) and during and after the other FeSS Intervention studies (QASCIP 2013-2014, T³ Trial 2013-2016). This provided relevant context to other interventions in the same time period. A more detailed protocol that defined the search terms, and inclusion and exclusion criteria was developed with the supervisory team before commencing the review (Study One, Chapter Two). Consultation with the Australian Catholic University's campus librarian was sought for peer review of the search strategy before finalising. The dates of the last search for each database, the period searched, and the number of records retrieved for each database searched were recorded, all searches saved, and alert systems created for updating the searches before submission of the final thesis chapter.²¹⁴

Data collection and analysis techniques

The titles and abstracts of all publications identified in the electronic databases were assessed and screened by a single reviewer (KC, PhD candidate) for relevance and appropriateness to the review aim. The remaining records were examined and assessed further regarding their eligibility after applying the inclusion and exclusion criteria. Articles not meeting the criteria were excluded and full texts of the remaining publications meeting study selection criteria were collated and stored, and the details summarised in an evidence table. Although it is generally considered best practice to have two reviewers conduct this process,²¹⁴ in some circumstances, the use of single reviewers is acceptable¹³² and has become increasingly common in rapid reviews.¹³³ Given the candidate's (KC) clinical background and familiarity with the topic, the supervisory team deemed my level of experience to be adequate to conduct the review independently with weekly meetings to supervise my progress and discuss decisions where required to develop the evidence table.

All individual RCTs were evaluated for risk of bias by a single reviewer (KC) in Covidence¹³⁶ using the gold standard built-in Cochrane Risk of Bias (RoB) template.¹³⁷ By using this collaborative software, the supervisory team were able to review additional information to support the risk of bias judgement and adjudicate where required. The second version of A Measurement Tool to Assess Systematic Reviews (AMSTAR 2)¹³⁵ was used to critically appraise systematic reviews that included randomised or non-randomised studies of health care interventions. This tool was chosen over the Risk Of Bias In Systematic reviews (ROBIS)²¹⁵ given that two of the systematic reviews included in the narrative synthesis of the literature did not include meta-analysis which the ROBIS tool is more suited to.²¹⁵

Given the considerable clinical and methodological heterogeneity in the included studies, a narrative synthesis of data was undertaken. Data from the systematic reviews were tabulated with a brief description of the included studies in an evidence table. Textual descriptions were then provided on the included study characteristics, findings, and discussion sections. Reviews of the same intervention were grouped where possible. Similarly, data from the included individual RCTs were also analysed using tabulation, textual descriptions and groupings where relevant.¹³⁹ Additionally, to assist with overall narrative synthesis of the findings, a concept map was used to visually translate the data and guide analysis.¹³⁹ This was achieved through identification of similarities and differences to evaluate for potential relationships within and between the studies to support overall conclusions. Recommended to convey both qualitative and quantitative results that include statistics and textual data, conceptually,²¹⁶ this approach highlighted common themes and concepts between the studies relevant to the review topic (Table 4, Chapter Two).

3.3.2. Study Two: A pre-test/post-test study examining adherence to a stroke clinical practice guideline for FeSS management post-stroke.

More detailed information on this study is presented in Chapter Four along with the published manuscript. The aim was to compare adherence to the FeSS Protocols pre- and post- the inclusion of a new ‘Strong Recommendation’ for their use in the Australian Clinical Guidelines for Stroke Management. Additional objectives were to determine if changes in FeSS Protocol adherence varied based on hospital prior participation in any treatment arm of a FeSS Intervention study or receiving treatment in a stroke unit; and to compare adherence to individual FeSS indicators across FeSS Intervention studies.

The quantitative study used a pre-test/post-test research design to analyse data from Australia’s stroke population at single points in time. This type of study does not randomly

assign participants but evaluates interventions by measuring outcomes before and after.²¹⁷ An RCT in this population would not have been feasible or appropriate given the evidence for use of the FeSS Protocols was already established.^{31,45} Withholding treatment that has been proven to significantly improve patient outcomes would have been unethical, and an example of research waste that occurs when previous evidence is not taken into account and research is replicated.²¹⁸

In this study, the retrospective clinical data from hospitals that participated in four cycles of the biennial Stroke Foundation Acute Services Stroke audit (2015, 2017, 2019 and 2021) were used to evaluate national FeSS Protocol adherence during the in-hospital stay for patients admitted to Australian hospitals with a stroke diagnosis. The Stroke Foundation is a registered charity that drives quality improvement by developing and maintaining clinical guidelines and coordinating national audits.²¹⁹ Established in 2007, the Stroke Foundation national audit program aims to measure hospitals' adherence to evidence-based practice recommendations as outlined in the Clinical Guidelines for Stroke Management.^{220,221} The methods for this audit program have been published in detail.^{220,221} Briefly, the audits include completion of a self-reported organisational survey by hospital clinicians that evaluate hospital adherence to the National Acute Stroke Services Framework^{222,223} (e.g. in-hospital stroke services and processes such as access to computerized tomography (CT) scan, acute therapies and stroke unit care). A retrospective clinical audit of approximately 40 consecutive cases per hospital is completed biennially (acute stroke services alternate each year with rehabilitation services). The in-hospital care provided is measured against evidence-based Clinical Guidelines for Stroke Management;²² and the Australian Commission of Safety and Quality in Health Care's Acute Stroke Clinical Care Standard⁶⁶ using metadata online registry (METEOR)²²⁴ compliant standard care indicators as outlined in the National Stroke Data Dictionary.²²⁵

The audit periods are retrospective and reflect admissions from June of the previous year. For example, the 2017 National Acute Services audit reflects patients with a diagnosis of stroke admitted to hospital from 1st June 2016 onwards. Auditors are trained in data abstraction and data entry into the Australian Stroke Data Tool (AuSDaT) platform, with inter-rater reliability cases provided from each site.²²¹ The AuSDaT is a national, online database platform that enables the standardised and systematic data collection for multiple stroke data collection programs.^{226,227} This Australia-wide audit of clinical practice in acute stroke hospital services is designed to promote quality improvements in stroke care. The results are fed back in a tailored report to hospitals for them to identify areas for improvement.

The Australian Institute of Health and Welfare (AIHW) use unlinked hospital and deaths data to provide a national estimate of annual stroke events.²²⁸ Although the Stroke Foundation audits are voluntary, they report high participation rates (89% of acute admissions for stroke in Australian hospitals).^{219,223,228} This is comparable to 90% of admitted strokes in the United Kingdom's mandatory stroke audit program.⁸ These figures confirm the representativeness of these data for assessing the quality of care in Australian hospitals for patients with acute stroke. Some hospitals use local databases and registries for quality monitoring. For example, hospitals are encouraged to contribute to the Safe Implementation of Treatments in Stroke (SITS) International Stroke Thrombolysis Register [ISTR])²²⁹ to monitor and compare acute stroke treatment outcomes. However, this data only covers a fraction of the Australian stroke population that are eligible for these treatments and participation is not mandatory. Similarly, local hospital databases lack a comparator and data variables may not be standardised to the National Stroke Data Dictionary²²⁵ which leaves them open to misinterpretation.

The Australian Stroke Clinical Registry (AuSCR) could one day be a suitable option as a comprehensive data source as they use the same standardised National Stroke Data Dictionary and the AuSDaT platform, however, their purpose is very different. The AuSCR is a Commonwealth led initiative in partnership with the Australian and State/Territory governments, together with the Australian Safety and Quality Commission and the Australian Institute of Health and Welfare (AIHW). The registry is designed to collect prospective, continuous stroke admission data, rather than the single point in time used for the cross-sectional design of the Stroke Foundation audits. As such, the variables collected have been rationalised to ease the burden of data collection for clinicians and this minimum dataset does not include FeSS variables. Just under half of the hospitals who participated in the 2021 Organisational Survey for the Stroke Foundation audit confirmed they were also collecting data in the AuSCR.²³⁰ At the time the study was conducted, these participation rates were not yet high enough for the AuSCR to be considered as an alternative data source for assessing the quality of care in Australian hospitals for patients with acute stroke. Only recently (July 2019) the FeSS variables were included as an optional dataset in this registry. In 2023 AuSCR reported that of the 65 hospitals that contributed data that year, 24 (37%) were electing to contribute data into the FeSS optional dataset²³¹ which is pleasing as indicates the interest from clinicians. However, recently, the Australian Stroke Clinical Registry (AuSCR) was awarded a new three-year \$1.5 million funding package under the Australian Government's National Clinical Quality Registry Program.²³² This funding is expected to enable national participation from all Australian stroke services allowing them to continuously contribute data and replace the biennial National Stroke cross-sectional audits.²³³ The implications of this are discussed further in Chapter Six (Discussion and Conclusion).

Sample

To be eligible for inclusion in this study, hospitals had to have participated in at least one Stroke Foundation audit cycle from each cohort: pre-guideline inclusion (using pooled sample of 2015 and 2017 audit cycles) and post-guideline inclusion (using pooled sample of 2019 and 2021 audit cycles). Without this, they would not have had an appropriate comparator period to assess if there had been any change in adherence to the FeSS Protocols in their hospital during these time periods. As participation in the Stroke Foundation audits is voluntary and relies on in-kind contributions from clinicians to collect and enter the data,²²⁰ this accounts for variation in the number of participating sites each year. For example, the corresponding audit cycle conducted during the COVID pandemic did not only see a concerning decline in acute stroke presentations to hospitals but also a reduction in the number of resources allocated to the inpatient stroke population.²³⁴ If hospitals do not have capacity to allocate staff resources to participate in the audit cycle, with a lack of funding to support this voluntary exercise, then they cannot always commit to participation in this biennial event. However, for the audit cycles in this study, the number of participating hospitals was similar (2015: n=112, 2017: n=117, 2019: n= 112, 2021: n= 104). Even though participating hospitals were lower during the 2021 cycle which coincided with the COVID pandemic, the 104 hospitals that contributed n=3892 patient records would still be considered representative of the quality of care for the Australian stroke population at this time.

In this study, there were 19 hospitals (700 patient records) excluded from the analysis as they had not completed an audit in at least one cycle from each cohort. Given the very large sample size of more than 7000 records in each time period (pre-guideline

inclusion 2015 and 2017 audit cycles) and (post-guideline inclusion 2019 and 2021) this was not expected to influence the outcomes. This number was also within the commonly used five percent parameter of ‘missing data’ which would limit any bias typically attributed to this.²³⁵⁻²³⁷

Data collection and analysis techniques

A condition of approval for the use of Stroke Foundation audit data was that it could only be accessed in the Monash Secure eResearch Platform (SeRP).²³⁸ This secure environment for sharing research data for collaboration and analysis is within the control and governance of the data custodian for the Stroke Foundation. A Monash virtual private network ‘Cisco anyConnect’ is required, there is no internet access available within the Safe Haven environment and a file in and file out approval process is used. Although the data were not identifiable at the patient level, they were identifiable by a hospital unique identifier. This was required to be able to match those hospitals that participated in previous FeSS Intervention studies.

When calculating the *a priori* sample size for adherence to the FeSS Protocols pre-guideline inclusion (using pooled sample of 2015 and 2017 audit cycles) and post-guideline inclusion (pooled sample of 2019 and 2021 audit cycles), an estimate of 130 hospitals with data entry of 40 stroke admissions for that cycle (n=5200 episodes of care) was used. Based on previous audit data of 90% adherence to the Fever Protocol (on the assumption that if a patient did not have a fever then they were treated as per FeSS Protocol),⁷⁰ this would be able to detect a 1.6 percentage point change in the proportion of patients receiving overall adherence to treatment processes between any two audit cycles with a power of 0.8 and type I error of 0.05. That is, there would be an 80% chance of detecting a real difference (power) while keeping the false positive rate at 5% (significance level).

Using this conservative estimate with the FeSS variable highest proportion of adherence instead of a FeSS variable with lower proportion of adherence (e.g. adherence to hyperglycaemia (Sugar) Protocols), facilitates the detection of a true difference, even if it is small. So even if the actual proportion in one group is at least 1.6 percentage points higher or lower we can be confident this estimate can identify a statistically significant difference. This is in keeping with the literature that a large sample size such as that used in this study, should be sufficient to obtain a standard Type I error as low as 0.05 or 0.01 and a power as high as 0.8 or 0.9.²³⁹

Additional benefits of having a large sample size enabled the use of logistic regression to be able to control for common confounders in this dataset. A confounder is a variable that can affect the outcome under study, so the results are ‘confounded’ or influenced by this relationship.²⁴⁰ Ideally, best practice is to address any confounding at the study design stage by randomisation.²⁴¹ As this was not an RCT, but a pre-test/post-test quantitative study, confounding was dealt with at the statistical analysis stage. A multi-variable model such as logistic regression is able to control for multiple confounders. The results can then be interpreted as an adjusted odds ratio because its value has been adjusted to control for other variables including confounders.²⁴⁰

The benefits of a multivariable mixed effects logistic regression model is that it can be used to evaluate both the effect of individual variables on the outcome of interest as an odds ratio and to analyse the association of multiple variables (and confounders) simultaneously.²⁴² In the multivariable mixed-effects logistic regression model for this study, the level as random intercept was defined as the hospital, and confounder variables that were adjusted for were: age, sex, treatment on a stroke unit, stroke type and stroke severity. These confounder variables

were selected because in stroke research, it is common to adjust for these vascular risk factors which can influence stroke outcomes.⁴⁸ Interaction terms were also included in the model to assess if there was a relationship between the new guideline inclusion and previous participation in a FeSS Intervention study; and if there was a relationship between the new guideline inclusion and receiving treatment on a stroke unit. This analysis assists with determining that any increase in adherence following the guideline inclusion was consistent across hospitals, regardless of their prior involvement in FeSS Intervention studies or stroke unit status.

Another reason for the choice of a multivariable mixed effects logistic regression model was because the primary outcome was binary. A composite score was derived as an overall process of care outcome that reflects adherence to all FeSS Protocol indicators as captured in the audit. Specifically, this summary measure is reported as the proportion of patients who received all six treatment elements of the FeSS Protocols among the eligible patients for these processes of care: prompt treatment of fever and/or hyperglycaemia; swallow screen or assessment before receiving oral food, fluids, or medication and, importantly, a swallow assessment if they failed a swallow screen. This measure of defect-free care has been used throughout the QASC Research Program,^{31-33,35,70} and to facilitate comparisons between the different studies. Criticisms of using a composite score is that often there are limited details in publications about how this score was derived.²⁴³ For complete transparency, the variables that made up the score were presented in textual and tabular format. Additionally, the individual components were also presented as a sub-analysis to compare outcomes over time and during the FeSS Intervention studies (Chapter Four). Although the individual components that make up the composite score are all related as care processes within the FeSS Protocols, the choice of these components was limited to use of the data that was readily at hand which is prone to 'availability bias'.²⁴³ The composite score in the seminal QASC study was derived from nine variables related to FeSS management.^{31,33} These same variables were included in

the 2013 National Stroke audit (acute services) however, two of these variables were removed (monitoring variables for temperature and hyperglycaemia) in subsequent audit years. The removal of these and other audit variables at this time reduced data entry by 25%.²⁴⁴ This coincided with the launch of the AuSDaT platform for data collection in 2015, designed to further reduce the burden of data entry and time for data collection on clinicians.²⁴⁴ The remaining variables were purposively selected to be used as standard indicators that align with the Acute Stroke Services Framework and Clinical Standards⁷⁰ and could be used in the future for spot audits (outside of the biennial acute services audit). However, this means that the true incidence of fever and hyperglycaemia can no longer be derived from the Stroke Foundation audit data as only the treatment of these complications is collected. This also impacts on the ability to compare overall composite scores between the studies and across the audit cycles before 2015.

The use of a binary composite outcome can also emphasise the process of care the patient failed to receive, without acknowledging that they may have received all other components that make up this composite score. In this study, the composite score is comprised of four swallowing variables out of a total of the six. The bundled nature of the FeSS Protocols means that it is not possible to separate the processes of care to show one being more important than the other, as we do not have the evidence to do so. Given four of the six variables are specific to swallowing, the weighting of the individual processes of care could be perceived to be biased towards swallow management. However, three of the four swallowing variables are dependent on the first variable response to a formal swallow screen actually taking place, for swallow management then to be measured. For this reason, it was important to present the individual FeSS variable results and explore the findings further. Overall, the simplicity of the composite outcome measure provides a general overview of FeSS management for stroke patients that enables some comparison with previous work and

composite outcomes that have been used throughout the QASC Research Program while acknowledging the above-mentioned limitations of using composite scores.

3.3.3 Study Three: Qualitative descriptive process evaluation using semi-structured interviews with purposively selected clinicians from hospitals with high, low and variable FeSS Protocol adherence

The systematic-narrative hybrid review (Study One) of interventions designed to improve hospital clinician adherence to stroke clinical practice guidelines highlighted gaps in knowledge and in the quality of existing literature specific to this topic. Previous research undertaken in the wider QASC Research Program have also demonstrated a wide variation in guideline adherence amongst intervention sites participating in the same trial.³¹⁻³³ In all three FeSS Intervention studies (QASC, QASCIP and T³), the influence of local context and setting on guideline compliance has been thought to contribute to these variations, and, as such has been identified as issues that warrant closer examination to better understand FeSS clinical practice guideline uptake variability.^{32,40,41,43}

The pre-test/post-test FeSS Adherence quantitative study (Study Two, Chapter Four) found some improvement in adherence to the FeSS Protocols following a new stroke clinical practice guideline and strong recommendation for their use. This improvement may have been augmented by participation in the national stroke audit cycles. All hospitals that contribute data to the biennial audit cycles receive external feedback as site-specific reports and hospitals are able to benchmark their performance against similar services across Australia.²²¹ Hence, a qualitative descriptive process evaluation study (Study Three) of hospitals that contributed audit data in the related quantitative study from 2015-2021 was conducted to identify other clinician and hospital-level factors that influence adherence to FeSS clinical practice guidelines (in addition to national audit and feedback cycles). The purpose of this

study was to build upon the findings of the previous studies in this thesis by exploring individual and organisational factors that influenced adherence and sustainability of the FeSS Protocols in Australian hospitals. In alignment with other evaluations of evidence-based interventions in health care, the benefits of a qualitative research design for a process evaluation study are the ability to collect data on potential determinants of sustainability (e.g., context) and participants' perspectives however, this design cannot solely measure mechanisms and outcomes of sustainability.⁸⁹ Conversely, this is also true with the limitations of the quantitative pre-test/post-test study design that was able to provide a measure of sustainability outcomes over time, but no data on sustainability determinants outside of audit variables or critical end-user insights. The inclusion of this third and final study facilitated a more comprehensive understanding of the research already conducted and addressed the remaining research questions relevant to the research program.

Understanding how organisational factors can impact evidence-based practice was highlighted as a priority topic for implementation science over a decade ago.⁹⁰ Some of the most commonly reported factors that influence implementation of evidence-based practice in healthcare settings consist of: organisational culture; leadership; networks and communication; resources; evaluation, monitoring and feedback; and champions.²⁴⁵ Understanding the inter-reaction and relationships between these factors is recommended.

Pre-intervention barriers and facilitators related to implementation have been explored previously in each of the FeSS Intervention studies.⁴⁰⁻⁴³ Cumulatively and over time, these findings have informed each subsequent study in the upscale and spread of the QASC translational research program.^{33,35} Whilst some similarities were found between the FeSS Intervention studies, the importance of close examination of barriers and facilitators specific to local settings and context is essential to explaining how or why certain outcomes have been

achieved.²⁴⁶ Understanding how these clinician and hospital-level barriers and enablers evolve over time has the potential to provide further insights given that many of the pre-intervention barriers can be perceived rather than actual, as highlighted in a study from the QASC Trial where most barriers were overcome by trial completion.⁴³

Process evaluations undertaken after the T³ Trial³⁹ and international translation of the FeSS Protocols in the QASC Europe project³⁸ identified readiness to change, role delineation, shared goals and team engagement as key factors influencing uptake of the FeSS Protocols. The importance of champions, as well as adaptability and communication to manage complexities were also highlighted. Evaluation of longer-term factors that hinder or facilitate implementation of the FeSS Protocols outside of clinical trial settings, warrant further consideration to strengthen understanding of adherence to clinical practice guidelines and the maintenance of implementation strategies over time. Equally, analysis of these same factors for those hospitals that did not participate in any of the FeSS Intervention studies will strengthen understanding of the spread of innovation by diffusion and dissemination longer-term. Analysis of FeSS Protocol adherence rates and implementation strategies (if any) from hospitals that have not had the exposure and external support that comes with participating in a clinical study is a novel study of the diffusion of evidence (or not) over time.

Process evaluations are an important aspect of implementation research, to understand the intervention process and factors associated with effective knowledge translation in a particular context.²⁴⁷ Commonly, process evaluations are conducted alongside clinical trials,²⁴⁸ in the evaluation of large scale quality improvement projects,²⁴⁹ the embedding and integration of clinical practice guidelines^{250,251} and in the scale-up of complex health interventions.²⁵² Now considered best practice to be undertaken alongside or soon after clinical trials, process evaluations typically focus on fidelity and quality of implementation,

clarification of causal mechanisms and identification of contextual factors associated with variation in outcomes.²⁴⁸ Evaluating how the intervention works, and how it interacts with the context in which it is implemented, contribution to system change, and how this evidence can be used to support decision making in the real world are now also recommended.²⁵³

Process evaluations after efforts to scale up health care innovations are less common. After establishing efficacy of the FeSS Protocols (2011),³¹ scale up of the FeSS Protocols included translational research (2013-2016),³³ inclusion in national guidelines (2017)²² and monitoring via biennial national stroke audits(2013 onwards).⁷⁰ To understand the quantitative study of FeSS Protocol adherence and uptake after the introduction of a new clinical practice guideline, a more comprehensive study design was required to further evaluate the important contextual individual and organisational factors identified by clinicians to have influenced uptake and sustainability of their use. A qualitative descriptive process evaluation study design (Study Three) using in-depth, individual semi-structured interviews, was undertaken to examine clinicians' perspectives of individual and organisational factors that influenced adherence and sustainability of the FeSS Protocols.

Semi-structured interviews generally begin with a predetermined set of open-ended questions, with other questions that then emerge from this dialogue.²⁵⁴ When undertaken individually, this eliminates the potential barrier of speaking in a more public focus group interview setting, enabling the researcher an opportunity to explore data further. The study was designed so neither the participant or the hospital would be identifiable when reporting the results. Given the confidential nature of the topic and study design, a focus group setting with participants from different hospitals would not have been appropriate. Rapport needs to be established quickly to gain trust and respect for the interviewee and the information he or she shares.²⁵⁴ Therefore, clarification at the start of the interview regarding confidentiality, and

how the data would be deidentified before analysis was provided to establish this rapport. Any perceived bias associated with the interviewer (KC PhD candidate) being a researcher attached to the QASC Research Program was potentially offset with an ‘introduction of self as a registered nurse also’ as a strategy to limit this perception.

Theoretical Frameworks

A theoretical underpinning is recommended best practice for interventional studies of behaviour change.²⁵⁵ The interview schedule was informed by the Conceptual Model for Considering the Determinants of Diffusion, Dissemination,⁹¹ and Implementation of Innovations in Health Service Delivery and Organisations.⁹¹ This framework was used to guide classification of the type of factors (otherwise known as barriers and facilitators) perceived to influence implementation outcomes. Understanding these influential factors on implementation of evidence-based care at various levels is an essential first step to facilitate the desired change with subsequent implementation success.⁷⁴

It was anticipated that there would be some hospitals that may not have engaged in any active implementation strategies to introduce the FeSS Protocols and/or did not participate in any of the FeSS Intervention studies. In addition to determinants of implementation, this framework also includes determinants of dissemination and diffusion (passive spread) of innovation in health service.⁹¹ This was especially relevant to hospitals that had not implemented any active implementation strategies for use of the FeSS Protocols. The Conceptual Model for Diffusions of Innovations in Health Service Delivery and Organisations was designed specifically for the health care sector and has been used in other health service implementation research to explore the factors influencing adherence to evidence-based practice and in analysis of diffusion in health care settings.²⁵⁶

The Normalisation Process Theory (NPT)²⁵⁷ and the Consolidated Framework for Implementation Research (CFIR)¹⁶² were also considered as alternative theoretical frameworks however, the NPT focus on the routine embedding of innovations may not address the early diffusion and dissemination phases as comprehensively as the conceptual model that delineates these stages. Similarly, the CFIR primarily focuses on the process of implementation which may not be relevant for those hospitals that have not participated in any of the FeSS Intervention studies or identified any formal implementation efforts. Under these circumstances the process of diffusion (or not) in this instance, of the evidence-based clinical practice guideline for the use of the FeSS Protocols were especially pertinent to probe.

The Sustainability of Innovation Framework¹⁹⁷ was also used to guide the interview schedule and for data analysis of concepts specific to sustainability. This framework is one of the eight recommended models, theories or frameworks to evaluate and interpret concepts of sustainability of evidence-based practices within acute care contexts.²⁵⁸ It was developed after an integrative review of the literature on sustainability of health service innovation that then also integrated the concepts of the Conceptual Model for Diffusions of Innovations in Health Service Delivery and Organisations⁹¹ and the Dynamic Sustainability Framework.¹¹⁴ The methodological uplift of using the Sustainability framework and the frameworks it was grounded in, enabled the development of a comprehensive interview schedule that probed participants in relation to the concepts of diffusion, dissemination and implementation. The data could then be analysed in accordance with the factors from the Sustainability Framework. This allowed a comparative analysis of responses based on FeSS Protocol adherence level and other stratification criteria. This in-depth evaluation of clinical practice guideline adherence and sustainability over a substantial timeline may inform future implementation strategies for evidence translation (See Chapter Five: Study Three for further detail).

Sample

Identification and analysis of individual and organisational factors that influence FeSS Protocol adherence, based on a hospitals' FeSS adherence performance ranking, is an efficient way to identify organisational variation and target the evidence-practice gap.²⁵⁹ Hospitals that participated in the National Acute Stroke Services audit in 2015, 2017, 2019 or 2021 were stratified to high, low or variable performance based on their mean FeSS adherence composite score (derived for each audit cycle in Study Two). Hospitals were ranked from highest to lowest adherence according to the overall mean FeSS composite score for each audit year (2015, 2017, 2019, 2021). Hospitals were then stratified into consistently high adherence ($\geq 25\%$ above the overall mean FeSS composite score for three or more audit cycles); consistently low adherence ($\geq 25\%$ below the overall mean FeSS composite score for three or more audit cycles) and variable adherence (one or more audit cycles in the low adherence threshold and one or more audit cycles in the high adherence threshold). The hospitals were then stratified by i) previous participation in any of the FeSS Intervention studies,^{31,33} and ii) according to region (state) and remoteness (Area based on the Accessibility and Remoteness Index of Australia [ARIA+]).²⁶⁰ The use of remoteness was a proxy for stroke units, as access to these is markedly lower in regional and remote areas compared to major city hospitals.¹⁰ Additionally, the QASC and QASCIP FeSS Intervention studies were conducted in one Australian state only. Purposeful selection from various Australian states and territories and the additional strata was to ensure representation of a broad range of hospitals to comprehensively explore any differences in factors identified for sustainability. (Figure 1)

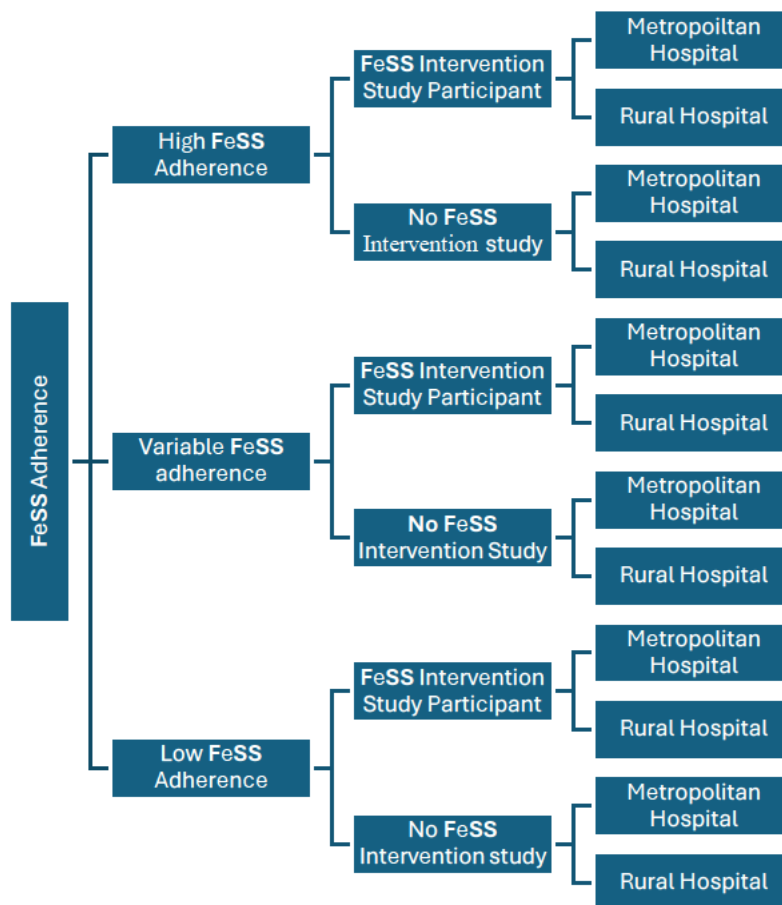


Figure 1. FeSS Protocol Adherence ranked sample and stratification by previous FeSS Intervention study participation and remoteness area (metropolitan/major cities or regional/rural).

Three hospitals were purposively selected from each of the FeSS Protocol adherence groups. This strategy of ‘extreme sampling’ is an efficient way to evaluate information rich exemplars of extremes of the variation in the target population.²⁶¹ Extreme sampling has also been used in a previous FeSS Intervention process evaluation study, but not over this many time points.³⁹ Those with variable adherence were included to provide insight on potential reasons for variation.

Participants were identified from professional stroke networks and the Stroke Foundation National audit cycles. Participating services and the names of those who contributed to data collection are acknowledged in the publicly available Stroke Foundation acute services audit

reports. In most circumstances this data collection role is performed by the Stroke Coordinator in those organisations. Although the title for this role varies greatly,²⁶² the typical Stroke Coordinator role is a specialist position (usually nursing), with several years' experience of directing or providing acute care for stroke patients.²⁶² These senior nursing clinicians were considered the most likely personnel to be directly involved in implementing new guidelines, and sufficiently knowledgeable regarding factors that may influence sustainment of these strategies after initial implementation. As the FeSS Protocols are designed to be nurse-initiated, Stroke Coordinators (or equivalent stroke clinician leader) were targeted from each of the nine hospitals. If there was no Stroke Coordinator (or equivalent stroke clinician leader), participation from the Nurse Unit Manager of the stroke unit or stroke service was sought. New employees of the hospital (less than six months) were considered unlikely to be sufficiently knowledgeable regarding the history of the spread of innovation (FeSS Protocols) in their organisation, so were excluded.

The Stroke Coordinator (or equivalent stroke clinician leader) for each of the nine hospitals' stroke unit or stroke service were invited via email to participate in semi-structured video-conference virtual interviews. If there was no response to this invite, a follow-up email was sent two weeks later with phone follow-up a week after this. During the interviews with Stroke Coordinators (or equivalent), snow-ball sampling recruitment technique was used. This method of recruitment is where the researcher asks the participant to connect them to other persons as potential participants.²⁶³ We aimed to interview a minimum of one person per hospital but also asked participants during the interviews if they were able to identify one other stroke clinician (from any discipline) who was involved with the implementation of the FeSS Protocols within their hospital and could offer additional insights. Including this additional perspective on individual and organisational factors perceived to influence use of the FeSS Protocols from within the same organisation was anticipated to strengthen the

integrity of the data source and broaden the generalisability of any findings in relation to the hospital.

Data collection

Interviews

Interviews were conducted and recorded via videoconference and teleconference (if the interviewee did not have access to video) using Microsoft Teams (version 24033.811.2723.2546). Conducting these interviews virtually rather than in person is acknowledged as a limitation (in regard to shortened responses and context).²⁶⁴ However, the vast distance between hospitals throughout Australia meant conducting the interviews in person was impractical. With no travel requirements, this virtual format was anticipated to increase the likelihood of participation. Interview recordings were downloaded, and transcriptions corrected and de-identified before analysis. The cost-saving of not having to pay and wait for professional transcription is a relatively new concept. Reviewing the transcripts within days of when the interview occurred afforded the opportunity to make any corrections and revisit the interview to consolidate early thoughts around analysis. In the event of any potential issues regarding reliability of the video and audio recordings, a backup transcription service was also used ([Otter AI](#)). This second transcription and recording was deleted as soon as the Microsoft Teams recording had been downloaded successfully and the transcription corrected and de-identified. A master participant list was created linking the codes to the participant details and stored separately from the interview data in accordance with standard practice.

Secondary interviews from clinicians within the same hospital were undertaken using the same procedure however, these were not always available either due to staff attrition (previous Stroke Coordinator [or equivalent] was no longer working within the

organisation) or the interviewee was not able to recommend a second person for interview. In this process evaluation study, there were a total of fourteen out of fifteen possible interviews conducted. A secondary interview participant at one hospital did not respond despite several email and telephone prompts after an initial agreement to participate.

Evidence from the literature suggests that a minimum of twelve interviews is sufficient to reflect a representative sample.²⁶⁵ Sample size was also guided by the concept of information power rather than a 'data saturation' point (where interviews continue until no new information is being discovered to answer the research question).²⁶⁶ In qualitative research information power can guide adequate sample size by considering the characteristics of the sample relevant to the study, potentially reducing the number of participants required.²⁶⁷ The model recommends five factors for consideration: study aim, sample specificity, use of established theory, quality of dialogue, and analysis strategy. Interaction between these factors will assist in determining an adequate sample. The use of purposive extreme sampling methods supported by established theory from two theoretical frameworks,^{91,197} was deemed to provide sufficient information power regarding recruitment numbers and dialogue quality for this qualitative descriptive process evaluation study.²⁶⁷

Interview Schedule

The interview schedule was developed in consultation with qualitative experts and supervisors from within the research team. Experience and familiarity with the interview process was obtained by testing these questions with the supervisory team. Specific feedback was sought on the interview technique, particularly prompts used to engage participants to elaborate on their first response answers and elicit further information and clarification of concepts presented by participants.

Semi-structured individual interview questions and prompts were guided by both the Conceptual Model for Diffusions of Innovations in Service Organizations⁹¹ and the Sustainability of Innovation Framework¹⁹⁷. Questions were specific to the exploration of individual and organisational factors that may influence clinician adherence to FeSS stroke clinical practice guidelines. The domains from these frameworks were used in the design of questions to prompt participants regarding the targeted behaviours relevant to the FeSS Protocols and any perceived barriers and facilitators identified by the participants (Appendix B Interview schedule mapped to Theoretical frameworks). Details on intervention strategies used to implement the FeSS Protocols were also collected. The interview schedule differed slightly for those hospitals that had not actively used any implementation strategies as they were only able to hypothesise on potential individual and organisational factors that may have influenced implementation. (Appendix B: Part C Interview schedule mapped to Theoretical frameworks).

Data analysis

De-identified transcripts were imported into NVivo software (version 12) to manage and organise the data. Analysis was conducted using inductive thematic analysis, but acknowledge previous findings from the broader QASC Research Program and familiarity with the theoretical frameworks used to guide the interview schedule, are likely to have informally influenced *a priori* deductive categories for coding. However a formal coding template was not included in the study design.

The coding process was conducted independently with close supervision and discussion with the supervisors. After becoming very familiar²⁶⁸ with the data transcripts from the

interviews, the first phase of analysis involved making sense of the data and using raw data to make some field notes (memos in NVivo). The text were then assigned descriptive code labels or terms.²⁶⁹ This first level of conventional coding effectively summarised sections of data into codes which after reviewing for any overlap were collapsed into a smaller number.²⁶⁹ The second level of coding consisted of interpreting this smaller number as categories and analysing for patterns and/or if any relationships existed between the coded categories and if this context generated any themes.²⁶⁹⁻²⁷¹ The resulting themes and sub-themes were then mapped to factors from the Sustainability of Innovation Framework¹⁹⁷ and the context considered in alignment with the research questions. Findings were compared and contrasted by FeSS Protocol adherence groups (consistently high, versus consistently low and variable). Previous participation in a FeSS Intervention study and geographical location were additional strata for consideration in the analysis. The themes (and sub-themes) are presented as the major findings of the study, with the data from multiple sources assigned to these categories then used as evidence for the theme.²⁶⁹

Strategies for scientific rigour

In addition to the pre-defined methods outlined in each study protocol some additional strategies were implemented to enhance the credibility of the findings under the headings below as recommended in the literature on this topic.^{272,273}

Trustworthiness: Recognition of the researchers' bias (both as an existing staff member within the wider QASC Research Program and as a stroke nurse clinician) was acknowledged and incorporated into the study design and how to approach interviews and analysis. Regular supervisor meetings allowed for these to be regularly reviewed. The transcripts were corrected in the qualitative study within a few days of the interview alongside revision of the video-conference recordings. This enabled accurate

data collection and promoted familiarity with the content. The transcripts and recordings were both available to revisit as required during analysis. The use of participant direct quotes were utilised as much as possible as evidence to support representativeness of the study findings.

Consistency/ Neutrality: The stages of data analysis for each study were presented to the supervisory team regularly and these documents have been preserved as an accurate record of this process (e.g. coding levels, relationship between categories, themes and sub-themes). Research expertise within the research team was able to be accessed outside of supervisory meetings as required.

Applicability: As much context as possible (without identifying participating sites) was provided within the study findings in the manuscript for publication to facilitate the transferability of these findings to similar settings and participants.

3.4 Ethical considerations

This thesis project adhered to the National Statement on Ethical Conduct in Human Research 2007 (updated 2018),²⁷⁴ the *National Statement on Ethical Conduct in Human Research (2023)* and the guidelines developed in accordance with the National Health and Medical Research Council (NHMRC) Act 1992. Co-authored by the NHMRC, the Australian Research Council and Universities Australia; these guidelines were created to protect research participants and guide the shared responsibilities of the researcher, and those providing ethical review.²⁷⁵ Also, in line with the standards as set out in the certification process for the international Good Clinical Practice certification (Appendix C) all data related to this thesis project have been stored, managed and archived in accordance with these guidelines and the relevant Human Research Ethics Committee (HREC) approved protocols.

The systematic-narrative hybrid review (Study One, Chapter Two) in this research program did not require HREC review as it involved the use of secondary data from published studies for which approval had already been granted. The protocol for Study Two (Chapter Four) and Study Three (Chapter Five) were registered on the Australia New Zealand Clinical Trials Registry (ANZCTR). These studies had to meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration to be accepted for registration in this international online registry (ACTRN 12623000445673) (Appendix D).

Institutional HREC review and approval of the pre-test/post-test analysis of Stroke Foundation audit data for Study Two (Chapter Four) was obtained from the Australian Catholic University HREC (2021-297N) (Appendix E). External approvals from the Stroke Foundation and Monash University (35037) as the data custodians, were also obtained before access to the data were provided (Appendix F). Individual patient consent was not required for this study as the data were not identifiable at the individual level, with summary data only reported.

The qualitative descriptive process evaluation Study Three (where the recruitment sample was derived from levels of adherence to the FeSS Protocols in Study Two) received institutional approval from St Vincents Hospital Sydney HREC (2023/ETH00446) as a low or negligible risk application (Appendix G). A separate site-specific application was reviewed and received research governance authorisation from this same institution where the research was conducted (2023/STE01065) (Appendix H). Although the data were de-identified before analysis and presentation of findings, individual participant consent was obtained for the in-depth semi-structured interviews. HREC approved participant information and consent forms

were provided with the invite to participate. These documents confirmed that participation was voluntary, and the published results would not be identifiable by hospital or person. Participants were not informed of their hospitals' FeSS Protocol adherence grouping however, they were aware of the purpose of the study.

All data that relate to this thesis are held securely in password protected files networked to the Nursing Research Institute on a password protected computer accessible only to investigators listed on the project team with computers stored in a locked restricted access office. No identifiable information provided during interviews were linked to individual participants. Voice-recordings from the interviews were permanently deleted once a transcript of voice recordings had been corrected and finalised. The transcripts were non-identifiable with all identifiers removed before analysis. No identifiable data was published or released. All study materials will be archived for fifteen years following publication in line with institutional and NHMRC requirements then disposed of in a confidential manner. This will include shredding of any hard copy data files and erasing all computer files including transcription files. The privacy and confidentiality of participants and their data were maintained by ensuring that no re-identifiable data has been stored or held by the student or research team at the conclusion of data collection and analysis. Any re-identifiable data following analysis was permanently deleted and results of the study have been presented in such a way that an individual's information cannot be identified. No individual participant data was reported.

3.5 Summary

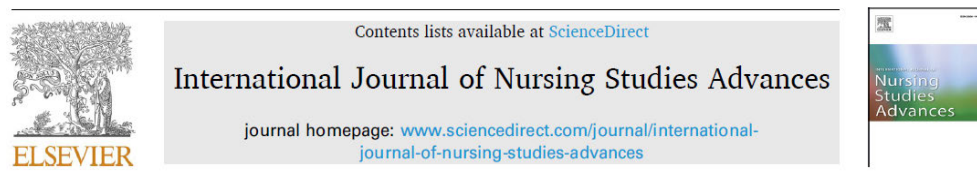
This chapter provided an overview of the methodological approaches that informed the design and conduct of the systematic-narrative hybrid literature review, the pre-test/post-test quantitative study and the qualitative descriptive process evaluation study. The underlying research philosophy of critical realism and the use of both quantitative

and qualitative methods were justified. The research aims and objectives of each study were accompanied by the methods designed to achieve these. For Study One (systematic-narrative hybrid literature review), methodological considerations were outlined to describe the development of the protocol, the type of literature review undertaken and the characteristics of the included studies. The relevant quality and risk of bias assessment tools and how the results were reported were also discussed. The methodological approach for the quantitative methods used in Study Two (pre-test/post-test quantitative study) was rationalised based on available access to the population level data and its contextual appropriateness. The study sample and statistical analysis plan were also discussed. Justification for the use of a qualitative descriptive process evaluation design (Study Three) to enrich the findings of the preceding Studies One and Two was outlined. This was based on hospitals' level of adherence to the FeSS Protocols across the Stroke Foundation's national audit cycles. The conceptual frameworks guiding the design and analysis of the findings of Study Three and the broader thesis were also discussed. Finally, the ethical considerations relevant to this body of research were delineated. The next chapter reports on the findings of Study Two.

CHAPTER FOUR STUDY TWO: PRE-TEST/POST-TEST EVALUATION OF THE USE OF FEVER, SUGAR AND SWALLOWING (FeSS) PROTOCOLS IN AUSTRALIAN HOSPITALS

The findings from this study have been published and are presented as a manuscript in section 4.2 of this chapter.

International Journal of Nursing Studies Advances 7 (2024) 100248



From ‘strong recommendation’ to practice: A pre-test post-test study examining adherence to stroke guidelines for fever, hyperglycaemia, and swallowing (FeSS) management post-stroke

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Coughlan K, Purvis T, Kilkenny MF, et al. From ‘strong recommendation’ to practice: A pre-test post-test study examining adherence to stroke guidelines for fever, hyperglycaemia, and swallowing (FeSS) management post-stroke. *International Journal of Nursing Studies Advances* 2024; 7: 100248. (Available online 23 October 2024)

4.1 Overview

The systematic-narrative hybrid review in Chapter Two highlighted the issues in improving clinician adherence to stroke clinical practice guidelines and the difficulty in translation of any improvements into clinical patient outcomes. Also highlighted in this review of the literature was that the QASC trial was one of the very few studies internationally to demonstrate reduced death and dependency using implementation science strategies to support the introduction of an evidence-based care bundle (FeSS Protocols).³¹ These results were fast tracked for publication in the Lancet and widely disseminated by the investigators locally and internationally (awarded the American

Heart Association Council on Cardiovascular and Stroke, *Stroke Article of the Year* 2012).²⁷⁶

Soon after, the QASC investigators partnered with the Australian New South Wales (NSW) Agency for Clinical Innovation, and 15 local health districts to conduct the QASC Implementation Project (QASCIP). This rapid state-wide translation of the FeSS Protocols into all 36 stroke services in NSW, resulted in significantly more patients receiving care according to the protocols.³³ Collaboration with the Stroke Foundation was critical to the rapid statewide roll-out, which enabled the FeSS indicators to be incorporated into national stroke audits for the first time in 2013. Additional impact was demonstrated with changes to the NSW Health directive for fever management policy which enabled nurses to administer paracetamol to stroke patients with a temperature of $>37.5^{\circ}\text{C}$ in line with the FeSS Protocols, previously not permissible until a patient's temperature was $>38^{\circ}\text{C}$.

The QASCIP team were subsequently awarded the NSW Premiers award, and the FeSS Protocols and associated resources were made freely available for end-users on the QASC website.²⁷⁶ Further scale up and spread of the FeSS Protocols in emergency departments was evaluated in the Triage, Treatment and Transfer (T³) cluster RCT (2013-2016). However, uptake by clinicians was limited resulting in neutral trial results.

Despite these concerted efforts to translate evidence into practice, a significant evidence-practice gap remained when adherence was evaluated nationally four years later.⁷⁰ Fever, hyperglycaemia and swallow management were shown to be sub-optimal with only 41% of patients receiving all FeSS processes in 2017, and over half of those

with fever and three in five with hyperglycaemia did not receive timely paracetamol and insulin, respectively.⁷⁰

In 2017, a 'Strong Recommendation' for use of the FeSS Protocols was included in the Australian Clinical Guidelines for Stroke Management, namely: '*All acute stroke services should implement standardised protocols to manage fever, glucose and swallowing difficulties in stroke patients (Middleton et al. 2011)*'.²² Swallow processes of care have been included in the clinical guidelines since 2007; however this was the first time recommendations related to fever and hyperglycaemia protocols were included.²² Consequently, there was a need to further assess protocol adherence beyond 2017 and the impact of the new guideline recommendations on reducing the evidence-practice gap using the National Acute Stroke Services audit data.

Outside of the FeSS Intervention studies (QASC, QASCIP and T³) there has been **no systematic implementation of the FeSS Protocols across Australia**. Any changes in practice would likely be due to passive dissemination, associated with the new guideline recommendation and the national acute stroke services passive audit and feedback cycles conducted every second year.

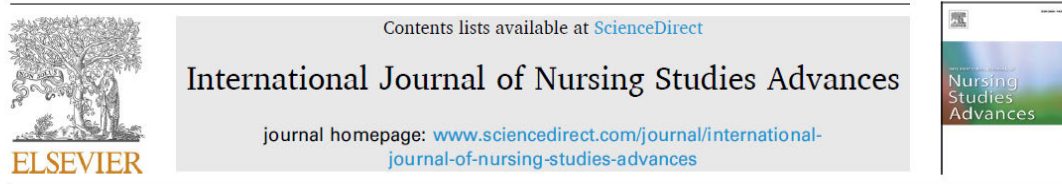
The purpose of this study was to evaluate adherence to the FeSS Protocols in Australian hospitals pre-and post-inclusion of this new strong recommendation in the clinical guidelines. Additionally, the study aimed to determine if adherence varied with prior participation in one of the FeSS Intervention studies (QASC, QASCIP or T³), or receiving treatment in a stroke unit. Given the considerable amount of time since the seminal QASC trial results were published, we also planned to compare this study's findings with those from the FeSS Intervention studies conducted over the 15-year

history of the wider research program. This substantial timeline also presented an opportunity to evaluate adherence to the FeSS Protocols in Australian hospitals at defined points in time as a measure of sustainability, an aspect directly aligned with the overarching aim of the thesis. These indicators of successful implementation and long-term integration of FeSS Protocols into routine stroke care provided valuable insight into the extent to which they have been embedded following their inclusion as recommended care in the 2017 National Acute Stroke Guidelines.

The findings of this study have been published and are presented in the following section. The version submitted to the journal is presented below as the final version accepted for publication. The pages have been renumbered for the thesis, but the manuscript is otherwise unchanged. Supplementary tables in the online version of the published paper are also provided. The published manuscript is provided as an appendix in the format that it appears online (Appendix I)

4.2 Publication: From ‘strong recommendation’ to practice: A pre-test post-test study examining adherence to stroke guidelines for fever, hyperglycaemia, and swallowing (FeSS) management post-stroke

International Journal of Nursing Studies Advances 7 (2024) 100248



From ‘strong recommendation’ to practice: A pre-test post-test study examining adherence to stroke guidelines for fever, hyperglycaemia, and swallowing (FeSS) management post-stroke

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TITLE

From ‘strong recommendation’ to practice: A pre-test post-test study examining adherence to Stroke Guidelines for Fever, Hyperglycaemia, and Swallowing (FeSS) management post-stroke.

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ABSTRACT

Background:

The Quality in Acute Stroke Care (QASC) Trial demonstrated that assistance to implement protocols to manage Fever, hyperglycaemia (Sugar) and Swallowing (FeSS) post-stroke reduced death and disability. In 2017, a ‘Strong Recommendation’ for use of FeSS Protocols was included in the Australian Clinical Guidelines for Stroke Management. We aimed to: i) compare adherence to FeSS Protocols pre- and post-guideline inclusion; ii) determine if adherence varied with prior participation in a treatment arm of a FeSS Intervention study, or receiving treatment in a stroke unit; and compare findings with our previous studies.

Methods:

Pre-test post-test study using Australian acute stroke service audit data comparing 2015/2017 (pre-guideline) versus 2019/2021 (post-guideline) adherence. Primary outcome was adherence to all six FeSS indicators (composite), with mixed-effects logistic regression adjusting for age, sex, stroke type and severity (ability to walk on admission), stroke unit care, hospital prior participation in a FeSS Intervention study, and correlation of outcomes within hospital. Additional analysis examined interaction effects.

Results:

Overall, 112 hospitals contributed data to ≥ 1 one Audit cycle for both periods (pre=7011, post=7195 cases); 42 hospitals had participated in any treatment arm of a FeSS Intervention study. Adherence to FeSS Protocols post-guideline increased (pre: composite measure 35% vs post: composite measure 40%, aOR:1.2 95%CI: 1.2, 1.3). Prior participation in a FeSS Intervention study (aOR:1.6, 95%CI: 1.2, 2.0) and stroke unit care (aOR 2.3, 95%CI: 2.0, 2.5) were independently associated with greater adherence to FeSS Protocols. There was no change in adherence over time based on prior participation in a FeSS Intervention study ($p=0.93$ interaction), or stroke unit care ($p=0.07$ interaction).

Conclusions:

There is evidence of improved adherence to FeSS Protocols following a ‘strong recommendation’ for their use in the Australian stroke guidelines. Change in adherence was similar independent of hospital prior participation in a FeSS Intervention study, or stroke unit care. However, maintenance of higher pre-guideline adherence for hospitals prior participation in a FeSS Intervention study suggests that research participation can facilitate greater guideline adherence; and confirms superior care received in stroke units. Nevertheless, less than half of Australian patients are being cared for according to the FeSS Protocols, providing impetus for additional strategies to increase uptake.

Trial registration: ACTRN 12623000445673. Registered 1 May 2023.

Keywords: stroke, guidelines, implementation, fever, hyperglycaemia, swallow, sustainability

Contributions to the literature

What is already known

- Inclusion in the national stroke clinical practice guidelines came several years after seminal trial results were published.
- Sustained practice change after clinical trial completion and efforts to upscale and disseminate results are rarely studied longer-term.

What this paper adds

- The overall improved adherence to FeSS Protocols following their inclusion in the guidelines is likely influenced by multiple factors.
- Sustained adoption of clinical guidelines in Australian hospitals is further enhanced by specialist stroke unit care and participation in implementation studies where external support is provided.
- This evaluation of a complex health intervention at the population level will assist with future implementation and dissemination efforts to maximise national adoption of FeSS Protocols

BACKGROUND

Facilitated implementation of a nurse-led intervention to manage **F**ever, hyperglycaemia (**S**ugar) and **S**wallowing (**FeSS** Protocols) in stroke units was shown to reduce death and disability (15.7% adjusted absolute difference) at 90 days post-stroke for patients in the cluster randomised Quality in Acute Stroke Care (QASC) Trial.³¹ This effect was sustained, with over 20% of patients more likely to be alive four years following their stroke (absolute risk reduction 5%).⁴⁵ Subsequent statewide scale-up of the protocols in the pre-test post-test Quality in Acute Stroke Care Implementation Project (QASCIP) during 2013-2014 demonstrated improvements in protocol adherence across New South Wales, Australia.³³ The effectiveness of the FeSS Protocols in the emergency department setting in the Triage, Treatment, and Transfer (T³) cluster randomised Trial was later evaluated between 2013 and 2016. However, uptake by clinicians within emergency departments was poor with no differences found between treatment and control groups in process measures or patient outcomes.³² In 2017, a 'Strong Recommendation' to support use of the FeSS Protocols was included in the Australian Clinical Guidelines for Stroke Management (hereafter referred to as the Stroke Guidelines) based on the QASC Trial results, namely: '*All acute stroke services should implement standardised protocols to manage fever, glucose and swallowing difficulties in stroke patients (Middleton et al. 2011)*'.²² Swallow processes of care have been included in the clinical guidelines since 2007; however this was the first time recommendations related to fever and hyperglycaemia protocols were included.²²

It is commonly cited that it takes 17 years on average for only 14% of new scientific discoveries to enter day-to-day clinical practice.^{73,277} Outside of the FeSS Intervention

studies (QASC, QASCIP and T³) that used multi-faceted implementation strategies (audit and feedback, clinical champions, barrier and enabler assessments, educational workshops and reminders) there has not been any systematic roll-out of the FeSS Protocols across Australia. Adherence to the FeSS Protocols has previously been evaluated using data from the National Stroke Audits (acute services) by Purvis et al. (2019) which demonstrated an increased uptake in their use over a 4-year period (2013-2017).⁷⁰ However, a significant evidence-practice gap remained with only 41% of patients receiving care in accordance with all FeSS Protocols in 2017. In that study, greater uptake of the FeSS Protocols was also reported for hospitals that participated in the two original FeSS Intervention studies, QASC and QASCIP, up to six years following the original trial.⁷⁰ This finding is in contrast to the literature that suggests adherence to clinical practice guidelines after an implementation research trial tends to decrease after one year.¹¹⁶

Historically, the distribution of untargeted publication of clinical practice guidelines (i.e. passive dissemination)⁸⁴ has been reported as ineffective at changing clinical practice when used in isolation.⁸⁵ The improvements in healthcare professional behaviour changes are reported to be more effective when more active implementation and dissemination techniques (especially multi-faceted strategies) are employed.⁸⁵ However, there is an argument that the significant costs and resources associated with some active implementation strategies (e.g. audit and feedback, educational meetings and outreach) potentially outweigh the benefits of the clinical practice guideline being introduced.⁵⁵ Less expensive strategies (e.g. dissemination educational materials and/or clinical practice guidelines) that are simpler to implement may also be more sustainable.⁸⁶

The inclusion of the new Stroke Guideline recommendation for use of the FeSS Protocols provided a unique opportunity to assess adherence to FeSS Protocols beyond 2017 and its impact on improved care delivery using the National Stroke audit (acute services) data.

We aimed to i) compare adherence to FeSS Protocols pre- and post-inclusion in Stroke Guidelines; ii) determine if changes in FeSS Protocol adherence varied based on a) hospital prior participation in any treatment arm of a FeSS Intervention study or b) receiving treatment in a stroke unit and; iii) compare adherence to individual FeSS indicators across FeSS Intervention studies.

METHODS

Study design and setting

A pre-test post-test study was undertaken using retrospective clinical data from hospitals that participated in the biennial Australian National Stroke Audit (acute services) comparing 2015 and 2017 audit years (pre-guideline); with 2019 and 2021 audit years (post-guideline).

Established in 2007, the Australian National Stroke Audit (herein referred to as the Audit) aims to measure hospitals' adherence to evidence-based practice recommendations as outlined in the Clinical Guidelines for Stroke Management.^{220,278}

The voluntary audit alternates between acute stroke services and inpatient rehabilitation services each year, and includes national representation (acute stroke services participation rate in 2019 and 2021: 76% & 79% of all eligible public services

respectively).^{28,223} Hospitals must admit approximately 50 patients with stroke annually to be eligible.

The National Stroke Audit program

The methods for the Audit program have been detailed elsewhere.^{220,278} Briefly, this involves:

i) completion of a self-reported organisational survey by hospital clinicians that evaluates hospital adherence to the National Acute Stroke Services Framework^{222,223} (e.g. in-hospital stroke services and processes such as access to CT, acute therapies and stroke unit care) and ii) a retrospective clinical audit of approximately 40 consecutive acute stroke cases per hospital (recently increased to 60 cases for 2023 Audit cycle).¹⁰ The in-hospital clinical care provided is measured against evidence-based Clinical Guidelines for Stroke Management;²² and the Australian Commission of Safety and Quality in Health Care's Acute Stroke Clinical Care Standard.²⁷⁹ The audit periods reflect all hospital admissions with stroke diagnosis from June of the previous year, for example, the 2017 Audit cycle reflects patient admissions with stroke from 1st June and discharged prior to 31st December 2016. Process of care indicators related to the management of fever, hyperglycaemia and swallowing during the in-hospital admission period for stroke have been included in the audit since 2013.

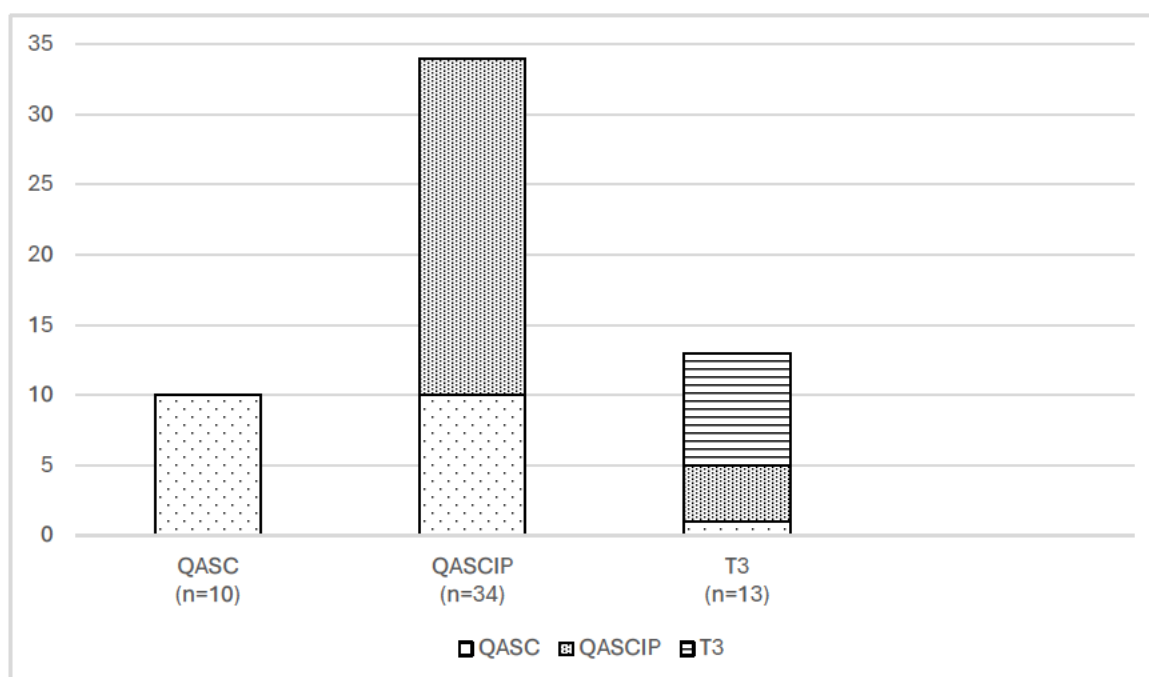
Auditors are trained in data abstraction and data entry into the Australian Stroke Data Tool (AuSDaT) platform, with inter-rater reliability cases provided from each site.²⁷⁸ The AuSDaT is a national, online database platform that enables the standardised and systematic data collection for multiple stroke data collection programs.^{226,227} This Australia-wide audit of clinical practice in acute stroke hospital services is designed to promote quality improvements in stroke care. The results are fed back in a tailored report to hospitals for them to identify areas for improvement.

Hospital and participant eligibility

Following approval processes, data were obtained from the Stroke Foundation for all Australian hospitals that participated in the 2015, 2017, 2019 and 2021 Audits. To be included in this analysis, hospitals had to have contributed data into at least one Audit cycle for both time periods (pre-guideline 2015 and/or 2017; and post-guideline 2019 and/or 2021). All patients with a primary diagnosis of stroke (ischaemic, haemorrhagic or undetermined) and aged ≥ 18 years were included. Patients who experienced a transient ischaemic attack (TIA) were excluded in addition to patients that were documented for palliative care measures (as this indicates the patient was not receiving curative treatments during their hospital admission, only pain relieving and comfort measures).

Data collection

The FeSS variables (Box 1) were extracted from audit data in addition to patient characteristics: age, sex, pre-morbid dependency level (modified Rankin scale[mRS]),²⁸⁰ prior risk factors, stroke type, and stroke severity (being able to walk independently on admission was used as a validated proxy for this measure).²⁸¹⁻²⁸³ Treatment with thrombolysis, receipt of care in a stroke unit, discharge dependency level (mRS) and discharge destination were collected with minimal hospital organisational characteristics (presence of a stroke unit, protocols to manage fever, and/or hyperglycaemia and/or swallow). Hospitals that had previously participated in any treatment arm of a FeSS Intervention study were defined as: the intervention hospitals in the Quality in Acute Stroke Care [QASC] randomised controlled trial,³¹ and/or the intervention hospitals in Triage, Treatment, and Transfer [T³] randomised controlled trial,³² and/or all hospitals in the Pre-Post QASC Implementation Project [QASCIP].³³ (Figure 1)



^a Intervention arm QASC 2005-2010 (Randomised Controlled Trial: Supported implementation FeSS Protocols in stroke units)
 All hospitals QASCIP 2013-2014 (Pre-Post Study: Supported implementation FeSS Protocols in all stroke services NSW)
 Intervention arm T³ 2013-2016 (Randomised Controlled Trial: Supported implementation FeSS Protocols in Emergency Departments)

Figure 1. Hospital participation in treatment arm of FeSS Intervention studies

Outcome measures

The outcome was an overall binary process of care adherence measure that reflected whether or not the patient received all six processes of care elements of the FeSS protocol assessed as part of the audit (composite measure) (Box 1). This measure of defect-free care used throughout the QASC research program^{31-33,35,70} was used to enable reliable comparisons with research that preceded the new Stroke Guideline inclusion.⁷⁰ Consistent with how Audit data have previously been reported, clinical impairments (e.g. ability to walk) were incorporated if the response was valid. However, for process of care indicators, not documented and unknown responses were assumed to be negative and included in the denominator.^{284,285}

Box 1. Adherence to FeSS Protocols composite measure comprised of six individual indicators**Fever**

- Paracetamol within one hour from first temperature equal to or greater than 37.5°C.

Sugar (Hyperglycaemia)

- Insulin within one hour from first blood glucose level (BGL) greater than 10mmol/L.

Swallowing

- A swallow screen, or swallow assessment by a speech pathologist within 24 hours.
- A swallow screen, or swallow assessment by speech pathologist before being given oral food or fluids.
- A swallow screen, or swallow assessment by speech pathologist before being given oral medications.

Statistical analysis

Patient sociodemographic and clinical characteristics, and hospital characteristics are presented for audit data obtained from pre (2015 / 2017) and post (2019 / 2021) Stroke Guideline inclusion. Mixed-effects logistic regression was undertaken to compare adherence to FeSS Protocols composite measure pre- versus post- Stroke Guideline inclusion, adjusting for age category (<65, 65-74, 75-84, 85+), sex, stroke type (haemorrhagic, ischaemic and undetermined) and severity (ability to walk on admission), hospital prior participation in a FeSS Intervention study, stroke unit care, and for correlation of outcomes within hospital. Regression models were also generated which included interaction terms (in addition to the previously specified covariates) to evaluate whether any pre-post Stroke Guideline inclusion changes in overall adherence to FeSS Protocols composite measure differed by: (i) hospital prior participation in any treatment arm of a FeSS Intervention study, and ii) treatment in a stroke unit and iii) each of these two factors.

The number and percentage of participants who had received each of the six FeSS indicators are reported for the pre- and post- Stroke Guideline inclusion samples. Mixed-effects logistic regression was undertaken to compare if any differences in these groups reached statistical significance using the previously specified covariates. Adjusted odds ratios (aOR) and 95% confidence intervals are reported from logistic regression models. Sensitivity analyses were undertaken comparing 2017 and with the last Audit cycle (2021) to determine if pooling data from the Audit cycles had an effect on the outcome.

To situate real-world clinical practice findings from the Audits, in the broader context of this study, the number and percentage of participants who had received each of the six FeSS indicators are ~~reported~~ displayed from the pre- and post- guideline Audit data compared to the post-intervention results from the FeSS Intervention studies (QASC 2010, QASCIP 2014, T³ 2016). Analyses was performed using Stata SE 15.0 (www.stata.com) and R statistical software.²⁸⁶

Ethics approval and consent to participate

Ethics approval for the study has been obtained from the Australian Catholic University Human Research Ethics Committee (2021-297N). External approvals from the Stroke Foundation and Monash University (35037) were also provided. Individual patient consent was not required for this study as the data were not identifiable at the individual level, with summary data reported. The protocol for this study was registered at the Australia New Zealand Clinical Trials registry on the 1 May 2023 (CTRN 12623000445673).

RESULTS

A total of 16,345 records from 131 hospitals were provided from the four Audit cycles. We excluded data from 19 hospitals (involving 2139 patient records (13%) since these hospitals had not contributed audit data for at least one cycle for either the pre-or post-guideline study periods. Patient records with the primary intent of treatment being palliative care or with a TIA diagnosis, were also excluded.

Therefore, 112 hospitals were included in the final dataset: pre-guideline (2015, 2017 pooled Audit cycle data [n=7011 patient records]), post-guideline (2019, 2021 pooled Audit cycle data [n=7195 patient records]) (Figure 2). Of these 112 hospitals, 42 had participated in the treatment arm of one or more FeSS Intervention studies QASC, QASCIP and/or T³(Figure 1).

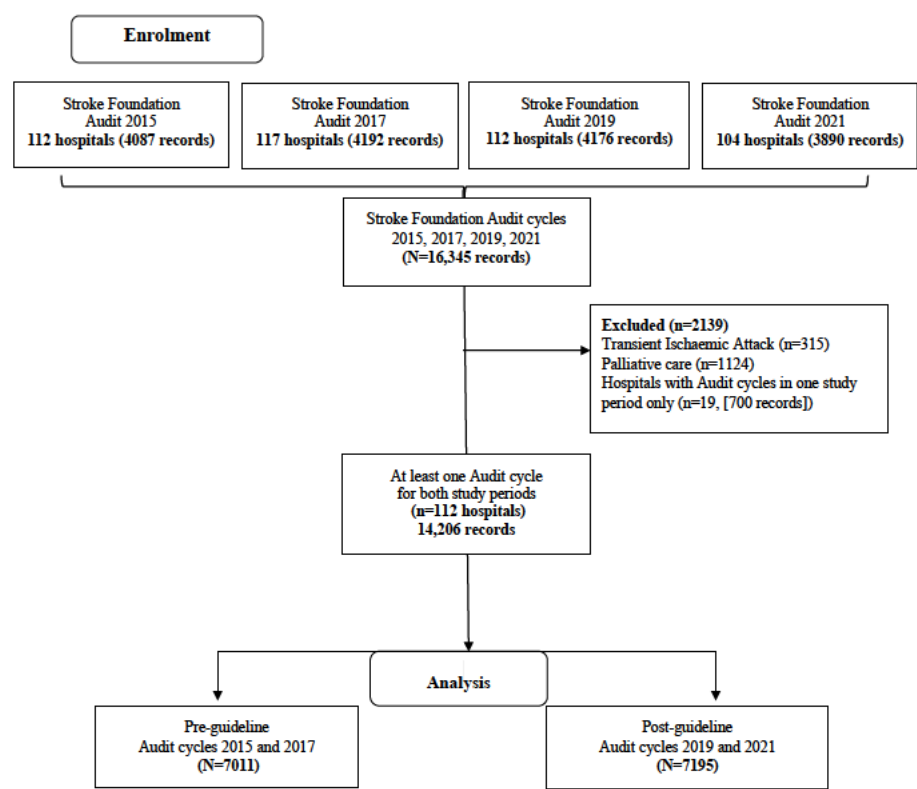


Figure2. FeSS Adherence flow diagram

Participant and hospital characteristics

Patient demographics were similar between the pre-guideline and post-guideline groups for age, sex and pre-morbid level of dependence (mRS 0-2) (Table 1). The post-guideline cohort had more ischaemic strokes (pre-guideline: 83%, post-guideline: 86%, $p < 0.001$), but fewer strokes that were classified as undetermined (pre-guideline: 6%, post-guideline: 3%, $p < 0.001$). These differences, while minor and clinically not significant, were likely due to neuroimaging advances and increased accessibility (e.g. change from clinical to tissue-based diagnosis for TIA's and mild strokes).

There was no difference between the pre-and post- Stroke Guideline inclusion groups for history of previous stroke, but there were more patients in the pre-guideline group with documented atrial fibrillation (pre-guideline: 27%; post-guideline 24%, $p < 0.001$) and ischaemic heart disease (pre-guideline: 27% post-guideline: 23%, $p < 0.001$).

Although comorbidities are associated with greater disability and increased stroke severity, the variables used to evaluate these characteristics showed no differences between the pre- and post-guideline groups: independence prior to stroke (mRS 0-2) and being able to walk on admission (validated stroke severity proxy).

Although more patients were screened for possible treatment with thrombolysis in the post-guideline group (pre-guideline: 42%, post-guideline: 59%, $p < 0.001$) there was no difference in the proportion of patients who subsequently received intravenous thrombolysis treatment between the pre- and post-guideline groups.

The small increase in the number of hospitals that reported a dedicated stroke unit was not statistically significant but may have contributed to the increased number of patients able to access stroke unit care (pre-guideline: 83%, post-guideline: 85%; p

=0.002). The marginal increase in the number of hospitals that reported the presence of locally agreed management (including assessment/monitoring) protocols for fever and hyperglycaemia after the guideline introduction also did not reach statistical significance (Table 1) but are an important indicator of organisational readiness: Fever Protocols pre-guideline:93%, post-guideline 96%; Sugar Protocols pre-guideline: 90%, post-guideline 94%.

Table 1: Patient characteristics pre- and post-guideline inclusion period

	Pre-guideline (N=7011) n (%)	Post-guideline (N=7195) n (%)	<i>p</i>-value^a
PATIENT CHARACTERISTICS			
Age <65 y	1796 (26%) ^b	1862 (26%)	0.186
Age 65-74 y	1732 (25%) ^b	1820 (25%)	
Age 75-84 y	2049 (29%) ^b	2152 (30%)	
Age ≥85 y	1426 (20%) ^b	1361 (19%)	
Sex, male	3969 (57%) ^b	4177 (58%) ^b	0.080
Independence prior to stroke (mRS 0-2)	5835 (83%)	6025 (84%)	0.411
Atrial fibrillation	1671 (27%) ^c	1624 (24%) ^d	<0.001
Previous Stroke	1476 (23%) ^c	1524 (22%) ^d	0.064
Ischaemic Heart Disease	1648 (27%) ^c	1560 (23%) ^d	<0.001
CLINICAL CHARACTERISTICS			
Ischaemic Stroke	5807 (83%)	6198 (86%)	<0.001
Haemorrhagic Stroke	775 (11%)	760 (11%)	0.346
Undetermined Stroke	429 (6%)	237 (3%)	<0.001
Walk independently on admission	3203 (47%) ^d	3215 (46%) ^d	0.146
Thrombolysis (ischaemic stroke)	583 (10%)	684 (11%)	0.076
Screened for thrombolysis	2931 (42%)	4242 (59%)	<0.001
Stroke unit care (if hospital had a stroke unit)	5037 (83%)	5332 (85%)	0.002
ORGANISATIONAL CHARACTERISTICS			
	Pre-guideline (N=112) n (%)	Post-guideline (N=112) n (%)	<i>p</i> value^a
Hospitals with a stroke unit	90/112 (80%)	94/112 (84%)	0.601
Hospital had Fever Protocols	104/112 (93%)	107/112 (96%)	0.569
Hospital had Sugar Protocols	101/112 (90%)	105/112 (94%)	0.462
Hospital had Swallow Protocols	110/112 (98%)	110/112 (98%)	1.0
^a chi-square test, mRS: Modified Rankin Scale; numbers may not add to total sample size due to missing values ^b <1% unknown/missing responses excluded ^c 11-12% unknown/missing responses excluded ^d 1-5% unknown/missing responses excluded ^e 6-10% unknown/missing responses excluded			

Overall adherence to FeSS Protocols post inclusion in Stroke Guidelines

As interaction terms were not statistically significant at the 5% level, $\alpha = 0.05$, (indicating that pre- to post- Stroke Guideline inclusion, changes in adherence to FeSS Protocols did not differ by hospital prior participation in the treatment arm of a FeSS Intervention study ($p = 0.93$) or treatment in a stroke unit ($p = 0.07$) (Supplemental Table 1), results are therefore presented for the main effects model only.

In the adjusted model, compared to the pre-guideline group, there was a significant improvement in overall adherence to FeSS Protocols for the post-guideline group: pre-guideline adherence to FeSS Protocols composite measure 2449/7011 (35%); post-guideline 2864/7195 (40%) aOR 1.2, 95% CI 1.2, 1.3, $p < 0.001$. (Table 2). Patients aged ≥ 85 years had statistically significant greater odds of being treated according to FeSS Protocols compared to younger age categories: aOR 1.3, 95% CI 1.1, 1.4, $p < 0.001$. However, patients with haemorrhagic stroke had lower odds of being treated according to the FeSS Protocols: aOR 0.74, 95% CI 0.66, 0.84, $p < 0.001$. Similar findings were noted for patients who were able to walk on admission (indicating a mild stroke presentation): aOR 0.81, 95% CI 0.75, 0.88, $p < 0.001$. (Table 2)

Adherence to FeSS Protocols and previous participation in a FeSS Intervention study

Overall, regression analyses demonstrated that patients who were cared for in hospitals that had previously participated in any treatment arm of a FeSS Intervention study had significantly greater odds of receiving care according to the FeSS Protocols (aOR 1.6,

95% CI 1.2, 2.0, $p < 0.001$) when compared to those cared for in hospitals that had not participated (or were not exposed to the intervention) in these studies (Table 2).

This is reflected in adherence to FeSS Protocols being higher both pre- and post-guidelines inclusion in hospitals that had participated in the treatment arm of a FeSS Intervention study (pre-guideline: exposed 40%, unexposed 31%, post-guideline: exposed 46%, unexposed 35%, $p < 0.001$). However, irrespective of exposure to treatment arm of a FeSS intervention, the change in adherence between pre- and post-guidelines was similar (p -value for interaction term $p = 0.93$) (Supplemental Table I).

Table 2: Logistic Regression Model: Factors associated with adherence to FeSS Protocols composite measure

	aOR ^b	95% CI	<i>p</i> -value
Post-guideline period ^a	1.2	1.2, 1.3	<0.001
Hospital participated in treatment arm FeSS Intervention study	1.6	1.2, 2.0	<0.001
Received stroke unit care	2.3	2.0, 2.5	<0.001
Age			
<65 y	ref		
65-74 y	1.1	0.97, 1.2	0.194
75-84 y	1.1	0.99, 1.2	0.090
≥85 y	1.3	1.1, 1.4	<0.001
Male	1.0	0.95, 1.1	0.450
Haemorrhagic stroke	0.74	0.66, 0.84	<0.001
Walk independently on admission	0.81	0.75, 0.88	<0.001

Reference is pre-guideline period; ^badjusted for factors listed in table including correlation of outcomes within hospital
aOR - adjusted odds ratio, CI - confidence interval

Adherence to FeSS Protocols and treatment on a stroke unit

Patients that received treatment in stroke units had double the odds of receiving care in accordance with FeSS Protocols (aOR 2.3, 95%CI: 2.0, 2.5, $p < 0.001$), compared to those who were not treated in a stroke unit regardless of the time period.(Table 2)

Similar levels of improvement over time was found for those treated on a stroke unit and for those treated outside of a stroke unit (pre-guideline: stroke unit care 40%, non-stroke unit care 21%, post-guideline: stroke unit care 44%, non-stroke unit care 27%, p -value for interaction term $p=0.07$). (Supplemental Table I). Results of the sensitivity analyses comparing 2017 and 2021 Audit cycles were consistent with the main results presented (Supplemental Table II).

Adherence to individual FeSS indicators post-inclusion in Stroke Guidelines

Comparison of adherence to the individual FeSS indicators pre -and post- guideline was variable (Table 3). There was no significant difference from pre-to post-guidelines in the increased proportion of patients who received prompt treatment with paracetamol for fever (pre-guideline: 53%, post-guideline: 50%). However, swallow screen within 24hours (pre-guideline: 68%, post-guideline: 75%; $p < 0.001$); swallow screen or assessment before oral food or fluids (pre-guideline: 60%, post-guideline: 65%; $p < 0.001$) and before oral medications (pre-guideline: 55%, post-guideline: 60%; $p < 0.001$) did show significant improvements. The odds of receiving prompt treatment with insulin for blood glucose level (BGL) $>10\text{mmol/l}$ post-Stroke Guideline inclusion were significantly lower (pre-guideline: 34%, post- guideline: 30%; $p=0.041$). (Table 3)

Table 3: Adherence to FeSS Protocols composite measure and individual FeSS indicators by pre-post guideline

	Pre-Guideline (N=7011)	Post-Guideline (N=7195)	aOR (95% CI)^a	p-value
Adherence to FeSS Protocols composite measure	2449 (35%)	2864 (40%)	1.2 (1.2, 1.3)	<0.001
1. Patient developed fever $\geq 37.5^{\circ}\text{C}$ within first 72 hours	778 (11%)	760 (11%)	0.94 (0.85, 1.1)	0.315
2. Paracetamol for the first elevated temperature administered within 1 hour	342 (53%) ^b	337 (50%) ^b	0.84 (0.66, 1.1)	0.147
3. Hyperglycaemia (first 48 hours of admission)	1211 (20%)	1336 (20%)	1.0 (0.95, 1.1)	0.452
4. Insulin administered within 1 hour of the first elevated finger-prick glucose (>10 mmol/L)	412 (34%)	404 (30%)	0.83 (0.69, 0.99)	0.041
5. Swallow screen or assessment within 24hrs	4000 (68%) ^c	4433 (75%) ^c	1.4 (1.3, 1.5)	<0.001
6. Swallow screen or assessment before oral food or fluids	4203 (60%)	4648 (65%)	1.2 (1.1, 1.3)	<0.001
7. Swallow screen or assessment before oral meds	3882 (55%)	4346 (60%)	1.2 (1.2, 1.3)	<0.001
8. Failed swallow screen and referred to Speech Pathologist	1,404 (97%)	1562 (96%)	0.81 (0.42, 1.6)	0.524

Not documented considered No, and included in denominator; aOR - adjusted odds ratio, CI – confidence interval, hrs (hours)

^aadjusted for stroke unit care, hospital prior participation in treatment arm of a FeSS Intervention study, age, sex, stroke type, stroke severity, including correlation of outcomes within hospital;

^bExcludes those already receiving regular paracetamol or where contraindicated

^cOnly cases with valid times included

Individual FeSS indicators compared to previous FeSS Intervention studies

Adherence to each of the individual FeSS indicators from the pre- and post- guideline

Audit data was informally compared to the post-intervention results from the FeSS

Intervention studies (QASC 2010, QASCIP 2014, T³ 2016) (Table 4). The overall

proportion of patients who were treated with paracetamol for fever, and insulin for

hyperglycaemia, has improved in clinical practice both before and after the guideline

recommendation when compared to each of the FeSS Intervention studies. In contrast,

adherence to the swallowing variables was generally better in the FeSS Intervention

studies. In the original QASC study, the proportion of patients who received a swallow screen or assessment within 24 hours (81%) was greater than either of the Audit groups (pre-guideline (68%), post-guideline (75%). Higher proportions of adherence to all swallowing variables were reported in the most recent FeSS Intervention study (T³) compared to both Audit groups. This was also true for three of the four swallowing variables in the QASCIP study, with the exception of the proportion of patients who received a swallow screen or assessment within 24 hours which was reported to be the same as post-guideline Audit data. We were unable to directly compare the composite measures from all the FeSS Intervention studies as these included monitoring variables for fever and hyperglycaemia which are no longer collected in the Audits after 2015.

Table 4: Post-intervention results for individual FeSS Intervention studies compared to pre-and post- Stroke Guideline inclusion Audit data

	QASC^a (2010)	QASCIP^a (2014)	T^{3a} (2016)	QASC Europe^{ac} (2021)	Pre- guideline (2015, 2017 Audit)	Post- guideline (2019, 2021 Audit)
Fever ($\geq 37.5^{\circ}\text{C}$)	17%	12%	4%	18%	11%	11%
Paracetamol within 1 hour for fever	18%	47%	6%	79%	53%	50%
Hyperglycaemia ($>10\text{mmol/L}$)	20% ^b	19%	13%	21%	20%	20%
Insulin within 1 hour for hyperglycaemia	14%	27%	10%	75%	34%	30%
Swallow screen/ assessment within 24 hours	81%	75%	81%	79%	68%	75%
Swallow screen/assessment before oral food or fluid	22%	68%	90%	82%	60%	65%
Swallow screen/assessment before oral medications	37%	62%	75%	82%	54%	59%
Swallow assessment if failed screen	78%	95%	91%	66%	86%	87%

^a Reference is post-intervention results; ^b $>11\text{mmol/L}$ in QASC Trial

^cQASC Europe 2017-2021 (Pre-Post International Study: Supported implementation FeSS Protocols in stroke services)³⁵

QASC 2005-2010 (Randomised Controlled Trial: Supported implementation FeSS Protocols in stroke units)³¹

QASCIP 2013-2014 (Pre-Post Study: Supported implementation FeSS Protocols in all stroke services NSW)

T³ 2013-2016 (Randomised Controlled Trial: Supported implementation FeSS Protocols in Emergency Departments)⁴

DISCUSSION

Overall, the findings of this study report two in five Australian stroke patients are being cared for in accordance with FeSS Protocols, despite a strong recommendation for their use in the Stroke Guidelines in 2017. There has been improvement in adherence to FeSS Protocols since this recommendation was made however, the higher adherence to FeSS Protocols pre-guideline for those hospitals that did participate in any treatment arm of the FeSS Intervention studies (QASC (2005-2010), QASCIP (2013-2014) or T³ (2013-2016) suggests that involvement in implementation research studies can enhance adherence to recommended care. Although there has been some improvement in adherence in non-stroke unit settings, patients treated in stroke units have double the odds of receiving care in accordance with FeSS Protocols.

Clinical practice guidelines are an essential source of current evidence-based recommendations for clinicians. Including research into national guidelines, although an accomplishment in itself, does not guarantee adherence. In the United States of America, the United Kingdom (UK) and Australia, patients receiving care according to clinical practice guidelines is widely acknowledged to be approximately 60%.³⁵ Guideline dissemination is generally considered to be a ‘passive’ implementation strategy when compared to more ‘active’ and often multi-faceted implementation strategies used in implementation research trials.⁸⁴ These varied approaches to getting evidence into practice (health professionals’ behaviour change) has been the subject of much research over the decades.⁹⁹⁻¹⁰¹ With a growing body of literature demonstrating a positive association between the number of evidence-based care processes received in hospital and patient outcomes^{102,103 104} it is vital that future research is directed towards guideline adoption.

The improvement in adherence to FeSS Protocols is not possible to attribute solely to inclusion of the new guideline recommendation. Although the promotion of this new recommendation may have contributed to the overall secular trend, it may also be due to participation in the Audit cycles itself. Audit and feedback is reported to have a modest effect size (median 4.3%); however, the range is widely variable (0.5-16%), dependent upon baseline performance and the conditions for feedback.³⁹

Coinciding with the new guideline recommendation for use of the FeSS Protocols in 2017, was the Stroke Foundation's partnership with Cochrane Australia to develop the world's first living Clinical Guidelines for Stroke Management in 2018.²⁸⁷ This dynamic model ensures new evidence relevant to the guideline topics is continually monitored and stroke evidence is updated as required to guide clinical practice and policy development.²⁸⁸ Although a recent evaluation of the introduction of this living Stroke Guidelines model reported a threefold increase in online access since their inception²⁸⁹ this is not indicative of active organisational implementation efforts.²⁹⁰

Previous participation in any treatment arm of the FeSS Intervention studies suggests that exposure to the multi-faceted implementation strategies used in these studies (audit and feedback, clinical champions, barrier and enabler assessments, educational workshops and reminders);^{31,33} provided greater implementation outcomes that are sustained long after the clinical trial is completed. All hospitals that participated in the QASC Trial were included in the subsequent FeSS Intervention study QASCIP, irrespective of the treatment group. This was essentially an additional 'dose' of the intervention for those hospitals in the intervention arm of the QASC Trial and/or likewise if they were in the intervention arm of the T³ Trial (Figure 1). Given the small

numbers, different study designs and timing of the interventions in these studies, any further statistical inferences about the potential added benefits of multiple study participation would be unreliable and require cautious interpretation. This repeated exposure to the FeSS Protocols and the implementation strategies may explain why our findings support those first reported by Purvis et al. (2019) who found that previous participation in a FeSS Intervention study was associated with improved adherence to the FeSS Protocols.⁷⁰ This is in contrast to the literature in relation to ‘voltage drop’ and ‘program drift’ that assumes the effect of an intervention decreases after a clinical trial as it moves into the dissemination and implementation research stages.^{114,258} Some decay effect is to be expected when assessing sustainability longer-term²⁹¹, however maintenance of and continued adherence to FeSS Protocols suggests that the external support (e.g. training, resources, performance feedback)³¹ to facilitate organizations to adopt these practices have been sustainable longer-term.²⁹² Although there was not an increase in the amount of change over time when compared to hospitals that did not participate in these studies (or were in the control arm), being in the treatment arm of any of the FeSS Intervention studies did result in a higher level of adherence pre-guideline that was upheld over time.

In general, research active hospitals produce better patient outcomes and quality of care.^{293,294} This may explain why those health services that elected to participate in the FeSS Intervention studies were more likely to adhere to clinical practice guidelines.²⁹⁵ The hospitals that participate in the Audits may likely also be quality-improvement/research ‘active’ with high voluntary participation rates reported each Audit cycle^{295,296} that suggest high motivation to improve care.

The evidence for stroke unit care and better patient outcomes is well established,²⁹⁷ yet the exact reasons why stroke units have this effect are still yet to be defined.⁷ The specialist multidisciplinary care and proactive prevention of common post stroke complications are among the many hypotheses for stroke unit effectiveness.²⁹⁷ Our study findings demonstrate adherence to FeSS Protocols is markedly lower for patients that do not receive treatment in a stroke unit. Ideally, every patient with stroke should be able to access stroke unit care however, this is not always practical in remote areas or smaller hospitals. We have previously reported that the FeSS Protocols can be implemented in non-stroke unit settings.³⁴ Understanding the barriers to implementation in these settings requires further investigation.

The FeSS Protocols and resources to implement have been freely available on the QASC research program website²⁷⁶ since the publication of the QASC trial results in 2011. Despite the concerted dissemination efforts of the trial results and inclusion in the national clinical guidelines for stroke management, the use of FeSS Protocols has not translated into everyday clinical practice for all Australian stroke patients.

The plateau in the uptake of FeSS Protocols and wide variation in practice is not unique to this stroke clinical practice guideline recommendation or country.^{28,32,164,298,299,300}

The supported implementation of FeSS Protocols by our team in the QASC Europe Study (2017-2021)³⁵ conducted in 64 hospitals in 17 countries, reported a very low baseline level of adherence to FeSS Protocols (3.4%) and whilst, following our facilitated implementation, this improved to 35% with an absolute difference of 33%, (95% CI: 24%, 42%), again, there is room for improved compliance. Of note, however, this more recent international comparison demonstrates higher levels of adherence (especially with prompt paracetamol or insulin administration) than previously

achieved in any Australian FeSS Intervention study suggesting that improvement in these areas are possible.

The most recent Cochrane systematic reviews to address the effectiveness of interventions for the uptake of evidence-based recommendations in both acute stroke settings¹⁴⁵ and stroke rehabilitations services³⁰¹ cited the small number of studies as the reason they were unable to determine if multi-faceted implementation strategies were more effective than no intervention. Our study adds to their call for additional research that evaluates the implementation of evidence-based clinical practice guidelines and strategies that support this.

Limitations related to this study were the retrospective design of the Audits and reliance on a one-time snapshot of approximately 40 cases per hospital at each cycle which may reduce the generalizability of the findings. The lack of randomization, voluntary participation and self-report is subject to reporting and/or response bias and some of the audit questions have changed over the cycle years which meant we were only able to include those variables that were collected in all cycles (e.g. risk factors for stroke).

The reliability of documentation in medical records and the assumption that if a process was not documented, it was not performed, needs to be acknowledged. In this study, older patients (≥ 85 years) had greater odds of receiving treatment in accordance with FeSS Protocols possibly related to the likelihood of co-morbidities that required closer monitoring. However, patients with haemorrhagic stroke had significantly lower odds of being treated according to the FeSS Protocols ~~as~~ even though this stroke subtype is generally considered to be the most severe with the highest morbidity and mortality rates.³⁰²

Although we excluded any patients who had been documented for palliative care, we cannot be sure that some of the haemorrhagic stroke admissions were missing this important documentation and were, in fact, being treated with palliative care measures. Similarly, for those patients who presented with mild stroke severity, the working diagnosis on admission may have been TIA which then progressed to stroke after further investigations and assessment during the course of their episode of care. Again, relying on documentation in the medical record may not capture this development accurately. However, we do know that it is common for this mild stroke population to be undertreated^{303,304} and discharged with unmet needs³⁰³ so this could also be yet another example of undertreatment.

The strengths of using the Audit data include the large sample size that is able to provide a robust and reliable overview of a cross-sectional snapshot of Australian acute stroke services and adherence to stroke clinical guidelines. Participation rates are high, 89% of acute admissions for stroke are to hospitals that participate in the Audit^{296,305} (comparable to 90% of admitted strokes in the UK mandatory stroke audit program).⁸

The use of this large dataset provides a more representative view of the wider Australian stroke population that includes both stroke unit and non-stroke unit care. As a measure of sustainability, the use of these data provide an estimate for the level of diffusion²⁹² for use of the FeSS Protocols outside of these specialist stroke units. Standardised training for data abstraction are provided for each Audit cycle and reliability cases are also reported which increase the confidence in use of this large dataset.²⁷⁸

Use of a composite outcome to assess adherence to the FeSS Protocols can be subject to limitations that relate to how missing data is handled, and the weighting of the individual FeSS indicators that make up this measure. To ensure consistency, missing data were handled in alignment with previous FeSS adherence research.^{31,33,35,60,70}

Although the individual components that make up the composite measure are all related as care processes within the FeSS Protocols, the choice of these components was subject to ‘availability bias’²⁴³ and the measures that were captured in the Stroke Foundation Audits. The Audits capture fever and hyperglycaemia treatment but not monitoring variables (which are collected in the FeSS Intervention studies).

Unfortunately, the nature of using a binary composite outcome can emphasise the process of care the patient failed to receive, without acknowledging that they may have received all other components that make up this composite measure. The bundled nature of the FeSS Protocols means that it is not possible to separate these processes out, as one being more important than the other, as we do not have the evidence to do so. However, we have presented the individual components that make up this measure to provide transparency in relation to where any overall shortcomings may be. These results suggest that the improvement in swallowing management may have driven the increase in overall adherence to FeSS Protocols. The simplicity of this outcome measure does provide an overview that enables appropriate comparison with previous work and composite outcomes that have been used throughout this research program.

CONCLUSIONS

This study provides new insights into the evaluation of the natural history and longer-term results of diffusion, dissemination, and implementation of stroke clinical practice

guidelines in Australian acute care hospitals. It has now been over a decade since the seminal QASC trial results were published and six years since the inclusion of a strong recommendation for their use in the Stroke Guidelines. Overall, adherence to FeSS Protocols has increased with a recommendation for their use in the guidelines (and audit and feedback associated with the Audits). However, with only two in five patients receiving this care, further efforts are still required to encourage more widespread adoption. As expected, stroke unit care was associated with increased adherence to FeSS Protocols that was sustained over time. The improvement in adherence to this clinical practice guideline was also increased and sustained over time for hospitals with previous exposure to the FeSS Protocols in any of the FeSS Intervention studies. This suggests that exposure to the more active implementation strategies and involvement in implementation research studies can enhance adherence to recommended care.

The significant costs and resources associated with these strategies could be offset by reserving these efforts for a more targeted delivery approach, where variation in practice has been identified. Future research is required in relation to how these sites are identified, and the levels of intervention required³⁰⁶ to improve uptake in use of the FeSS Protocols.

ABBREVIATIONS

ASSIST: Acute screening of swallow in stroke/TIA

AuSDaT: Australian Stroke Data Tool

BGL: Blood glucose level

EPOC: Cochrane Effective Practice and Organisation of Care

FeSS: Fever, Sugar, Swallow

HETI: Health Education and Training Institute

mRS: Modified Rankin Scale

QASC: Quality in Acute Stroke Care

QASCIP: Quality in Acute Stroke Care Implementation Project

T³: Triage, Treatment, and Transfer

TIA: Transient ischaemic attack

UK: United Kingdom

DECLARATIONS

Availability of data and materials

The data that support the findings of this study are available from the Stroke Foundation (Acute Audits) but restrictions apply to the availability of these data which were used under contract for the current study, and so are not publicly available. Data may be available from the authors upon reasonable request and with permission of the Stroke Foundation (Acute Audits).

Competing interests

KH (National Manager Stroke treatment, Stroke Foundation)

MK, MR, TP and DC are responsible for the independent and alloy analysis of National Stroke Audit data on behalf of the Stroke Foundation

MK (member of the Research Advisory Committee at the Stroke Foundation)

SM, CL, DC, SD, NWC, JG, CDE, EM, KC, OF, BM (Investigators QASC Research

Program: QASC QASCIP, T³ and QASC Europe Studies)

Funding

This study was funded by a National Health and Medical Research Council Investigator Grant (Grant ID: APP1196352) awarded to SM. It is also supported by a small grant from St. Vincent's Hospital Melbourne Research Endowment Fund (94653). KC is also supported by an Australian Government Research Training Program Scholarship. MK is supported by National Heart Foundation of Australia fellowship (105737). The funding bodies have no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Authors' contributions

KC and SM conceived the study, KC,TP,MFK,OF,SD,EM,BM, CDE, KH contributed significantly to the study design. KC, OF, SM, SD and BM prepared the first draft of the manuscript. TP, MFK, BM and CDE provided statistical expertise and conducted the primary statistical analyses with KC. MFK, KH, MR, TP and DAC provided national stroke audit data interpretation expertise. They were also responsible for data cleaning and provision of derived variables for analysis where available. KC, SM, TP, MFK, OF, SD, DAC, EM, BM, NWC, CL, JMG, CDE, MR, KH provided critical input and revised the manuscript draft. All authors read and approved the final version.

Acknowledgements

Hospitals that participate in the voluntary biennial Audit cycles that made this study possible.

Supplemental Table I: Change in adherence to FeSS Protocols composite measure pre-post-guideline by i) prior participation in any treatment arm of a FeSS Intervention study[#] and ii) treatment in a stroke unit

	Pre-guideline N=7011	Post-guideline N=7195	<i>p</i> -value ^{ab}
Hospital prior participation in any treatment arm of a FeSS Intervention study ^c	40%	46%	0.93
No prior participation in a FeSS Intervention study (or in control arm)	31%	35%	
^a p-value of interaction, ^b adjusted for stroke unit care, age, sex, stroke type, stroke severity, including correlation of outcomes within hospital; ^c Intervention arm QASC 2005-2010 (Randomised Controlled Trial: Supported implementation FeSS Protocols in stroke units) ³¹ All hospitals QASCIP 2013-2014 (Pre-Post Study: Supported implementation FeSS Protocols in all stroke services NSW) ³³ Intervention arm T ³ 2013-2016 (Randomised Controlled Trial: Supported implementation FeSS Protocols in Emergency Departments) ³²⁴			
	Pre-guideline N=7011	Post-guideline N=7195	<i>p</i> -value ^{ab}
Treatment in a stroke unit	40%	44%	0.07
Treatment outside of a stroke unit	21%	27%	

^a p-value of interaction, ^badjusted for hospital prior participation in treatment arm of a FeSS Intervention study, age, sex, stroke type, stroke severity including correlation of outcomes within hospital;

Supplemental Table II: Sensitivity analysis: Audit cycle 2017 compared to Audit cycle 2021 for adherence to FeSS Protocols composite outcome

	aOR^b	95% CI	p-value
2021 Audit cycle ^a	1.1	1.0, 1.3	0.016
Hospital participated/in treatment arm FeSS Intervention study	1.7	1.3, 2.1	<0.001
Treatment in a stroke unit	2.2	1.9, 2.5	<0.001
Age			
<65 y	ref		
65-74 y	1.1	0.9, 1.3	0.304
75-84 y	1.1	0.9, 1.3	0.270
≥85 y	1.2	1.1, 1.4	0.012
Male	1.0	0.9, 1.1	0.739
Haemorrhagic stroke	0.75	0.6, 0.9	0.001
Walk independently on admission	0.78	0.7, 0.9	<0.001

^aReference is 2017 Audit cycle; ^badjusted for factors listed in table, including correlation of outcomes within hospital;
aOR - adjusted odds ratio, CI – confidence interval

4.3 Summary

The inclusion of a new strong recommendation in the Australian national stroke clinical practice guidelines has resulted in a modest but significant improvement in FeSS Protocol adherence. The observed improvement of aOR 1.2 (i.e., a 20% increase in the odds of overall protocol adherence, with a 5% absolute increase in adherence (35% to 40%)), demonstrates the effect of this passive implementation strategy combined with biennial audit and feedback cycles. This effect size aligns with the lower end of the range typically seen in active implementation strategies (e.g. audit and feedback, educational outreach, opinion leaders).^{95,107,307} Importantly, this overall improvement was not driven by stroke unit care or a hospitals previous participation in a FeSS Intervention study (as indicated by the non-significant interaction terms). However, a higher proportion of patients received care in accordance with the FeSS Protocols in hospitals that participated in any treatment arm of the FeSS Intervention studies or if care was received in a stroke unit setting. These higher proportions were evident both pre and post the new clinical practice guideline recommendation (Supplement Table I). These findings suggest that while these factors did not independently drive the overall improvement, they were associated with better implementation of evidence-based care practices.

Additional variation in use of the FeSS Protocols was noted for patients aged ≥ 85 years who had statistically significant greater odds of being treated according to FeSS Protocols compared to younger age categories. Suggested reasons for this were the likelihood of co-morbidities in an older population that required closer monitoring. However, patients with haemorrhagic stroke had lower odds of being treated according to the FeSS Protocols, as did patients who were able to walk on admission (indicating a mild stroke presentation). These may be examples of undertreatment in these

populations which demonstrate a lack of understanding about appropriate use of the FeSS Protocols for all stroke types and stroke severity, or these findings could be attributable to the limitations inherent in medical record documentation.^{308,309}

Specifically, some patients with haemorrhagic stroke may have received palliative care, but if this was not explicitly documented, they would not have been excluded from the analysis. Similarly mild stroke presentations may have been initially admitted with a transient ischaemic diagnosis which was later revised to stroke following further investigations. Such diagnostic evolution is often difficult to capture accurately in retrospective medical record audits.

Whilst significant, the modest effect size observed in this study underscores a broader issue: although passive implementation strategies may yield incremental improvements, they are insufficient to close the evidence-practice gap. The findings indicate that fewer than half of stroke patients received care in alignment with all six FeSS indicators, regardless of whether they were treated in hospitals that participated in the treatment arm of the FeSS Intervention studies or if care was received in a stroke unit setting. Evidence suggests that patient outcomes will improve when a greater proportion of patients receive care aligned with best-practice guidelines. Additionally, there is mounting evidence that patients benefit from the cumulative effect of receiving evidence-based processes of in-hospital care.¹⁰²⁻¹⁰⁴ This highlights the need for greater accountability from health care services to both consumers and the wider population, particularly in terms of potential health care cost savings. Two independent economic evaluations have reported that if the FeSS Protocols were implemented in 65% of the eligible Australian population for one year, the total benefit would be AUD 281 million.³¹⁰ Another cost-effective analysis showed that over five years the protocols

could prevent 1,154 deaths and save AUD 65 million in healthcare costs and AUD 253 million in societal costs.⁶⁵

The plateau in overall adherence to the FeSS Protocols across defined points in time over a six year period (national stroke audit cycles 2015-2021) serves as a measure of sustainability. These data indicate that despite a significant but modest improvement over time, the protocols have not been fully embedded into routine clinical practice. This wide variation in practice following their endorsement as recommended care highlights the ongoing challenges in translating evidence-based guidelines into sustained practice change. It is unacceptable for patients to receive care that is not evidence-based. The variation in guideline adherence highlighted in stroke and other conditions internationally, has been prioritised as an area for focused research efforts.^{55,164,295,298-300,311} The next chapter explores this variance with critical end-user perspectives on individual and organisational factors that influence use of the FeSS Protocols.

CHAPTER FIVE QUALITATIVE DESCRIPTIVE PROCESS EVALUATION STUDY USING THE SUSTAINABILITY OF INNOVATION FRAMEWORK

5.1 Overview

This qualitative process evaluation study explored the perspectives of Stroke Coordinators on the individual and organisational factors influencing the sustained use of the Fever, Sugar (hyperglycaemia), and Swallow (FeSS) clinical practice guidelines in Australian hospitals. Despite a significant but modest improvement in adherence to these guidelines after the inclusion of a strong recommendation for use of the FeSS Protocols in the 2017 Australian Clinical Guidelines for Stroke Management, adherence remains suboptimal with substantial variability across hospitals.

The previous quantitative study of national audit data in Chapter Four highlighted the positive effects of stroke unit care and previous participation in a FeSS Intervention study on FeSS Protocol adherence. Patients treated in stroke units had more than double the odds of receiving care in accordance with the FeSS Protocols. Similarly, hospitals that had previously participated in the treatment arm of any of the FeSS Intervention studies (QASC, QASCIP, T³)³¹⁻³³ demonstrated higher adherence. The supplement data from the quantitative study (Table I) also showed higher FeSS Protocol adherence both pre-and post-guideline inclusion in these subgroups. However, the post- guideline inclusion figures indicated that a substantial proportion of patients with stroke in these subgroups were still not receiving care in accordance with the FeSS Protocols (stroke unit care: 44% vs non-stroke unit care: 27%; hospital prior participation in the treatment arm of a FeSS Intervention study: 46% vs no prior participation [or in control arm]: 35%). Notably, even among patients exposed to factors associated with higher adherence to the FeSS protocols (specialist stroke unit admission and hospitals with

prior participation in the treatment arm of a FeSS Intervention study), less than half of eligible patients received care in accordance with the protocols. This persistent gap suggests that additional, unmeasured factors may be contributing to the observed variance in care delivery.

The purpose of this study was to explore the drivers of this variance through a qualitative descriptive process evaluation. Using the same sample from the previous quantitative study in Chapter Four, the concept of sustainability was explored by evaluating data from the audit cycles to measure sustainability outcomes. The study design also incorporated a sustainability framework to guide the analysis and examine how implementation strategies have been maintained over time. The study focused on hospitals that participated in at least three national stroke audit cycles between 2015 and 2021, comparing those with consistently high adherence to the FeSS Protocols against those with low or variable adherence.

The manuscript reporting on the findings of this study has been accepted for publication and is currently in press with the *Journal of Advanced Nursing* (Q1 ranking, Journal Impact Factor 3.8). The final version submitted to the journal is presented below in its original form. The pages have been renumbered for the thesis, but the manuscript is otherwise unchanged.

5.2 Publication (in press): Stroke Coordinators' perspectives of factors influencing sustained use of Fever, Sugar (hyperglycaemia) and Swallow (FeSS) clinical practice guidelines: A process evaluation using the Sustainability of Innovation Framework.

TITLE

Stroke Coordinators' perspectives of factors influencing sustained use of Fever, Sugar (hyperglycaemia) and Swallow (FeSS) clinical practice guidelines: A process evaluation using the Sustainability of Innovation Framework.

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ABSTRACT

Aim:

To: i) examine Stroke Coordinators' perspectives of factors influencing sustained adherence to evidence-based protocols to manage Fever, Sugar (hyperglycaemia) and Swallow (FeSS) and ii) compare findings between hospitals with consistently high FeSS Protocol adherence versus those with consistently low or variable adherence.

Design:

Qualitative descriptive process evaluation using in-depth, individual semi-structured interviews.

Methods:

Hospitals that participated in ≥ 3 national stroke audit cycles were ranked by mean adherence to FeSS Protocols and stratified by consistently high, low and variable adherence. Three hospitals from each adherence strata were purposefully selected after further stratification by i) previous participation in a FeSS Intervention study; and ii) location (state; remoteness). Inductive thematic analysis was undertaken, with themes mapped to factors from the Framework to compare findings by adherence level and contextualise the findings in relation to sustainability.

Results:

Analysis of fourteen interviews identified two *themes* [and sub-themes] 1. *Stroke Coordinator as sustainability champions and boundary spanners* [maintenance of implementation strategies; fostering working relationships, communication and influence] mapped to workforce, organisational and innovation-specific factors. 2. *Hospital executive and middle management respect of stroke specialty* [designated area for stroke care; recognition of stroke specialist nursing skills; previous FeSS Intervention study participation] mapped to workforce and political factors. Key

differences by adherence groupings related to the Stroke Coordinator model, workplace configuration, and the impact of interdepartmental relationships and competing organisational directives.

Conclusion:

The Stroke Coordinator role was pivotal for sustained use of evidence-based FeSS Protocols for acute stroke care, driving multidisciplinary collaboration.

Impact/Implications:

Internationally, many patients do not receive evidence-based acute stroke care. Despite the proven benefits of the FeSS Protocols, consistent implementation remains a challenge. This study recognises the critical importance of a dedicated Stroke Coordinator for all acute stroke hospitals. Their advocacy for the use of evidence-based interventions is key to improving stroke outcomes.

Trial registration: ACTRN 12623000445673. Registered 1 May 2023.

Keywords: stroke, guidelines, implementation, fever, hyperglycaemia, swallow, sustainability

No Patient or Public Involvement: this study did not include patient or public involvement in its design, conduct, or reporting as it focused solely on the professional experiences of stroke care providers.

SUMMARY STATEMENT

- Previously collected quantitative data (to assess sustainability outcomes at multiple time points over a six-year period) were complemented by qualitative insights from end-users regarding sustainment of implementation strategies for the FeSS Protocols.
- Stroke Coordinators were identified as sustainability champions for use of the FeSS Protocols to maintain strategies and in fostering relationships across disciplines and departmental boundaries.
- Four factors from the Sustainability of Innovation Framework were identified for sustaining high adherence to the FeSS Protocols: Workforce (having more than one stroke champion), Organisational (effective working relationships, designated stroke speciality area and designated nursing staff), Innovation-specific (local adaptations) and Political (organisational agreement before implementation).

INTRODUCTION

Evidence-based recommendations for stroke care in hospitals are available to clinicians through practice guidelines.³¹² In 2017, a ‘Strong Recommendation’ to support use of standardised protocols to manage Fever, Sugar (hyperglycaemia) and Swallow (FeSS) difficulties in patients experiencing an acute stroke, was included in the Australian Clinical Guidelines for Stroke Management.²² Recommendations for the management of these common post-stroke complications are also included in international clinical practice guidelines.^{313,314} Despite the existence of this clinical practice guideline a recent national audit of in-hospital stroke care reported a persistent evidence practice gap. The recommended prompt treatment of fever and hyperglycaemia was reported to be lower than the previously conducted Audit cycle (2023:44% vs 2021:50%; 2023:27% vs:2021:29%) and 40% of patients were inappropriately given oral intake before a swallow screen or assessment had been performed.³¹⁵ Similar evidence-practice gaps in the management of these common acute stroke complications have also been reported internationally.^{35,36} The significant variability in adherence across hospitals highlights inconsistencies in the use of FeSS protocols, the underlying causes of which are poorly understood.

BACKGROUND

The Quality in Acute Stroke Care (QASC) Trial demonstrated a 15.7% reduction in death and disability following facilitated implementation of the FeSS Protocols,^{32,33} instigating the recommendation in national clinical practice guidelines. Subsequent state-wide scale-up of the FeSS Protocols into stroke units and stroke services throughout New South Wales, Australia, reported significant improvements in protocol uptake (The QASC Implementation study [QASCIP], 2013-2014).³³ Significant improvements were also demonstrated in the international upscale QASC Europe Study

(2017-2021) in 64 hospitals within 17 countries.³⁵ However, upscale into non-stroke specific settings in the Triage, Treatment, and Transfer (T³ Trial, 2013-2016) was not significant in the context of competing demands of busy emergency departments.³² The FeSS Intervention studies (QASC, QASCIP and T³) used active evidence-based, multifaceted implementation strategies (clinical champions, barrier and enabler assessments, educational workshops and reminders).³¹⁻³³ Beyond these studies there have been no nationwide active implementation efforts to introduce the nurse-led FeSS Protocols.

Passive implementation strategies⁸⁴ to scale-up this complex health innovation, consist of inclusion in national clinical practice guidelines and self-monitoring by voluntary participation in the biennial National Acute Stroke Audit and feedback cycles (hereinafter referred to as the Audit).^{22,221} FeSS variables have been included in the Audit from 2013 permitting standardised monitoring in Australian hospitals. This quality improvement initiative is designed to report on adherence to recommendations outlined for in-hospital acute care in national clinical guidelines for stroke management. Feedback is provided to hospitals as site-specific reports with the ability to benchmark their performance against similar services across Australia.²²¹

Despite these active and passive efforts over the last decade to scale up use of FeSS Protocols, consistent adherence remains suboptimal. Our recent study of FeSS Protocol adherence evaluated national audit data (2015-2021) after the strong recommendation for the use of these protocols was included in the National Clinical Guidelines for Stroke Management.³¹⁶ Although there had been some improvement, less than half of Australian patients were being cared for in accordance with these protocols. Additionally, a hospital's prior participation in the treatment arm of a FeSS

Intervention study, and/or stroke unit care were independently associated with greater adherence to FeSS Protocols.³¹⁶

It remains unclear why some hospitals consistently perform well in providing care in accordance with FeSS protocols while others do not. Sustainability has been identified as a research priority in implementation science¹⁰⁹ with growing recognition that strategies required for sustainability may differ from those used for initial implementation.^{317,318} Sustainability is defined as a process that occurs after a specific period of time whereby a program, clinical intervention, and/or implementation strategies continue to be delivered and/or individual behaviour change is maintained. The program and individual behaviour change may evolve or adapt while continuing to produce benefits for individuals/systems.⁸² Our previous published study has examined sustainability (the use of FeSS Protocols [clinical intervention] in Australian hospitals at defined points in time) and this study, undertaken as a process evaluation, is designed to examine sustainment (continued use of implementation strategies).¹⁰⁸

Aims:

We aimed to: (i) examine Stroke Coordinators' perspectives of organisational and individual factors influencing sustained adherence to FeSS Protocols in hospitals that participated in the 2015-2021 Audit cycles; and (ii) compare findings between hospitals with consistently high FeSS Protocol adherence versus those with consistently low or variable adherence.

METHODS

Study Design

This study adopted a qualitative descriptive process evaluation underpinned by a critical realist paradigm. Critical realism acknowledges that while an objective reality

exists, our understanding of it is shaped by social, cultural, and contextual influences.²⁰⁸ Process evaluations aim to understand the intervention process and factors associated with effective knowledge translation in a particular context.²⁴⁷ Previous process evaluations have accompanied FeSS Intervention studies,^{38,39} however the factors influencing strategies for sustaining use of FeSS Protocols outside of study conditions is yet to be explored. Qualitative methods are the most common method for process evaluation studies.²⁵² Qualitative descriptive research aims to discover and understand a phenomenon, process, or the perspectives of those involved. The focus is on describing rather than explaining, making it especially suitable for researching poorly understood areas.^{319,320} A qualitative descriptive process evaluation in Australian hospitals that participated in the 2015-2021 Audits using in-depth, individual semi-structured interviews with Stroke Coordinators was conducted to explore factors that influence FeSS Protocol adherence. The reporting of this study was guided by the COREQ (COnsolidated criteria for REporting Qualitative research) guidelines.³²¹

Setting

Eligibility

Australian hospitals that participated in three or more Audit cycles in 2015, 2017, 2019 or 2021. In general hospitals that had 50 or more stroke admissions each year were invited to participate in each Audit.

Sampling method

Hospitals were ranked based on their mean FeSS adherence composite score for each Audit cycle. The composite score is the proportion of patients who received all six treatment elements of the FeSS Protocols among the eligible patients for these processes of care: i) prompt treatment with paracetamol for fever; ii) prompt treatment with insulin for

hyperglycaemia; iii) swallow screen or assessment within 24hrs; iv) swallow screen or assessment before receiving oral food or fluids; v) swallow screen or assessment before receiving medication; and, vi) swallow assessment if they failed a swallow screen.³¹⁶

Hospitals were stratified into consistently high adherence ($\geq 25\%$ above the overall mean FeSS composite score for three or more Audit cycles); consistently low adherence ($\geq 25\%$ below the overall mean FeSS composite score for three or more Audit cycles) and variable adherence (one or more Audit cycles in the low adherence threshold and one or more Audit cycles in the high adherence threshold).

The hospitals were then stratified by i) previous participation in any of the FeSS Intervention studies³¹⁻³³, and ii) according to region (state) and remoteness (Area based on the Accessibility and Remoteness Index of Australia [ARIA+]).³²² The use of remoteness was a proxy for stroke units, as access to these is markedly lower in regional and remote areas compared to major city hospitals.³¹⁵ Additionally, the QASC and QASCIP FeSS Intervention studies were conducted in one Australian state only. Purposeful selection from various Australian States and Territories and the additional strata was to ensure representation of a broad range of hospitals to comprehensively explore any differences in factors identified for sustainability.

Three hospitals were purposively selected from each of the FeSS Protocol adherence groups. This strategy of 'extreme' sampling' is an efficient way to evaluate information rich exemplars of extremes of the variation in the target population.³²³ Hence, a hospital was ranked as 'consistently' high or low FeSS Protocol adherence using data from three or more of the four Audit cycles. Extreme sampling has also been used in a previous FeSS Intervention process evaluation study, but not over this many time points.³⁹ Those with

variable adherence were included to provide insight on potential reasons for variation. Sample size was guided by the concept of information power rather than data saturation. The premise of this method is that the more relevant information the sample holds, specific to the study aims, the lower amount of participants is needed.²⁶⁷ Purposive extreme sampling, supported by established theory from theoretical frameworks^{91,197} was expected to provide sufficient information power regarding recruitment numbers and dialogue quality.²⁶⁷

Clinician Eligibility

The Stroke Coordinator role is recognised globally as a specialist position (usually nursing), with several years' experience of directing or providing acute care for stroke patients.^{262,324} There are a wide range of alternative titles for this role (e.g. Clinical Nurse Consultant, Acute Stroke Nurse, Stroke Nurse Navigator) herein collectively referred to as Stroke Coordinators. Common responsibilities of this role consist of educating interdisciplinary staff and patients, demonstrating clinical leadership, and contributing to the development and implementation of protocols that promote standardised, evidence-based care.³²⁵ As FeSS Protocols are designed to be nurse-initiated, these senior nursing clinicians were considered the most likely personnel to be directly involved in implementing new guidelines, and sufficiently knowledgeable regarding factors that may influence sustainment of these strategies after initial implementation.

In hospitals who did not have a Stroke Coordinator, participation from the Nurse Unit Manager of the stroke unit or stroke service (or equivalent stroke clinician leader) was sought. We aimed to interview a minimum of one person per hospital but also asked participants during the interviews if they were able to identify one other stroke clinician

(from any discipline) who was involved with the implementation of FeSS Protocols within their hospital that could offer additional insights.

Clinician Exclusion Criteria

New employees of the hospital (less than six months) were excluded. In hospitals without a Stroke Coordinator, Nurse Unit Manager, (or equivalent stroke clinician leader) the hospital was excluded.

Recruitment

The publicly available Audit report includes the name of a site contact for each participating hospital. This person was contacted to obtain the name of the Stroke Coordinator (or equivalent stroke clinician leader) where this role was not filled by the named contact). The Stroke Coordinator (or equivalent stroke clinician leader) for each of the nine hospitals was invited via email to participate in a semi-structured video-conference interview. If there was no response to this invitation, a follow-up email was sent two weeks later with telephone follow-up a week after this. If participants were able to identify one other stroke clinician (from any discipline) who was involved with the implementation of FeSS Protocols within their hospital they provided the clinician's contact details.

Theoretical Framework and Interview Schedule

The Sustainability of Innovation Framework,¹⁹⁷ is one of the eight recommended models, theories or frameworks to evaluate and interpret concepts of sustainability of evidence-based practices within acute care contexts.²⁵⁸ Grounded in the conceptual Model for Considering the Determinants of Diffusion, Dissemination, and Implementation of Innovations in Health Service Delivery,⁹¹ and the Dynamic Sustainability Framework,¹¹⁴ this theoretical framework was deemed the most relevant

for focused analysis on sustained adherence. Semi-structured interview questions and prompts were guided by this framework and one of the more detailed models it was founded on (Supplement I).⁹¹ Individual factors and organisational factors influencing clinician adherence to FeSS Protocols were explored, and details on intervention strategies used to implement the protocols were also collected. The interview schedule differed slightly for those hospitals that reported that they had not actively used any implementation strategies as participants would then only be able to hypothesise on potential factors that influenced the decision not to implement (Supplement I).

Data Collection

Interviews were conducted and recorded via videoconference (Microsoft Teams, v25072.1611.3570.1995). Participants were not informed of their hospitals FeSS Protocol adherence grouping however, they were aware of the purpose of the study.

Data analysis

Transcripts were deidentified and imported into NVivo software (version 12). Participant demographics are presented using descriptive statistics. Analysis was conducted using inductive thematic analysis²⁷¹ with the theoretical frameworks used to guide the interview schedule. A formal coding template was not developed *a priori* as data were analysed inductively which involved iterative coding phases and theme refinement processes.²⁶⁹⁻²⁷¹ The coding process was conducted by one researcher with regular meetings with expert qualitative researchers within the team to reach consensus on emergent themes. Themes were mapped to factors from the Sustainability of Innovation Framework¹⁹⁷ to support deeper interpretation and contextual relevance. The factors in this Framework were derived from two other well established conceptual frameworks^{91,114} which were also consulted for further clarification as required. Comparative data analysis between hospitals based on their adherence was considered against the factors from the conceptual Framework and in alignment with the

research questions. Results are presented as themes constructed from sub-themes, and how these relate to factors identified in the literature to support sustainability from the Framework.

Ethical considerations

Ethics approval for the study was obtained from St Vincents Hospital Human Research Ethics Committee Sydney (2023/ETH00446) on the 20th April 2023. Participants provided written informed consent.

Rigor and reflexivity

Strategies were implemented to enhance trustworthiness, consistency, and applicability. Researcher bias was addressed by interviewer self-disclosure and regular team discussions during analysis. Transcripts were verified against video recordings to ensure accuracy and deepen data familiarity. Direct participant quotes supported representativeness, while systematic documentation of coding and theme development maintained analytical consistency. Qualitative expertise was available within the team, and contextual details were included to support the transferability of findings to similar clinical settings.^{272,273}

RESULTS

Of the 131 hospitals that participated across one or more of the Audit cycles, 109 had participated in three or more of these cycles. Fifty-two hospitals had participated in a FeSS Intervention study (QASC 2005-2010, QASCIP 2013-2014, T³ 2013-2016). Six hospitals were ranked with consistently high adherence and eight were ranked with consistently low adherence. Fourteen hospitals had variable adherence across the Audit cycles. All six hospitals ranked with consistently high adherence had stroke units and

five had previously participated in a FeSS Intervention study. Of the eight hospitals that were ranked with consistently low adherence, only two had a stroke unit and one had previously participated in a FeSS Intervention study. Five of the fourteen hospitals with variable adherence had previously participated in a FeSS intervention study and twelve had a stroke unit.

Three hospitals from each of the consistently high, consistently low adherence, and variable FeSS Protocol adherence were purposively selected after further stratification according to prior participation in a FeSS Intervention study and from geographically diverse areas where results in these groupings allowed (e.g. only one of eight hospitals in the consistently low adherence group had previously participated in a FeSS Intervention study but no longer had a stroke unit or Stroke Coordinator) (Figure 1). Given the risk of identification of hospitals in smaller States or Territories, the location is not presented however, interviews were conducted with Stroke Coordinators from all States and Territories except for one.

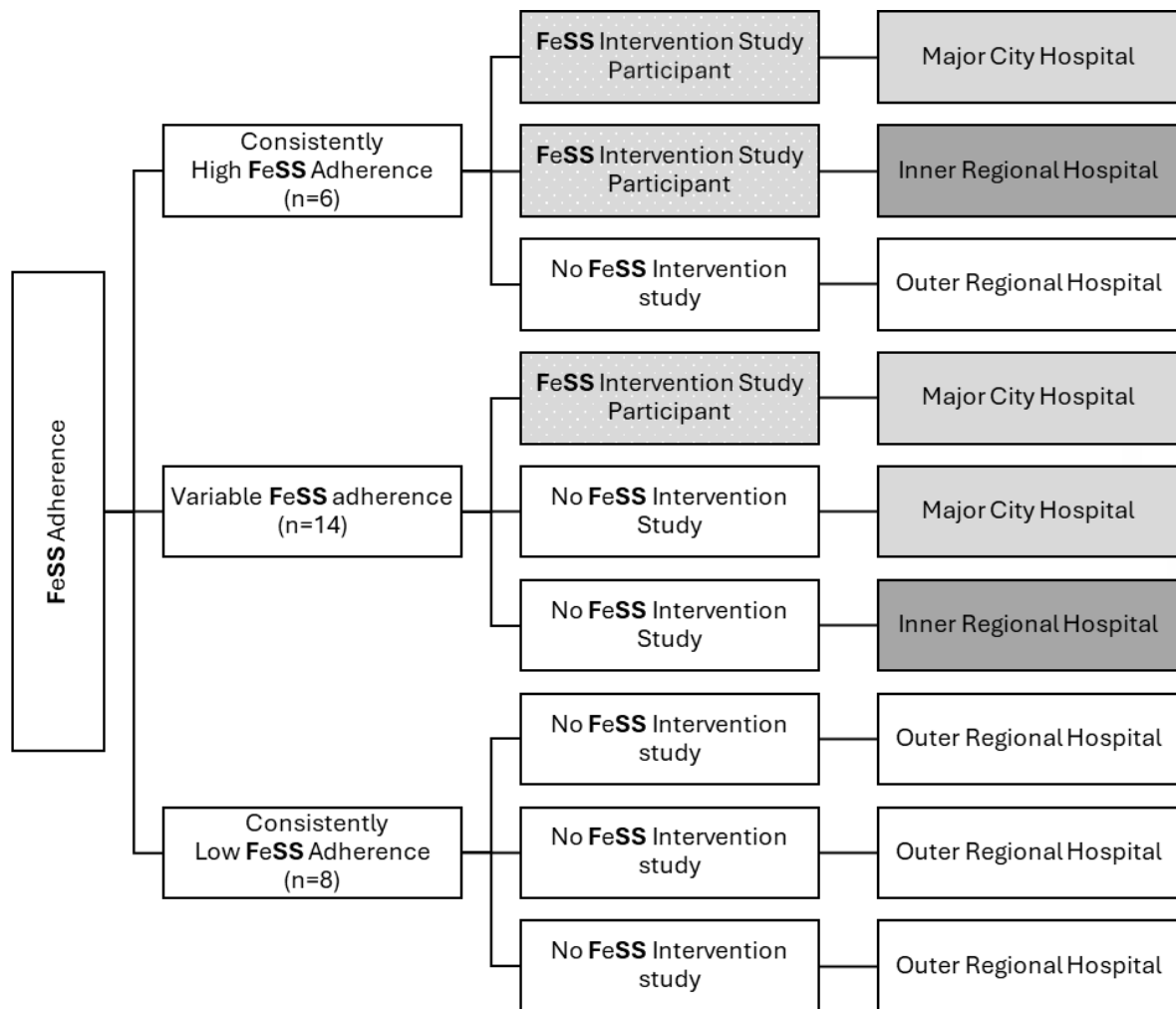


Figure 1. Study sample by FeSS Protocol adherence groups, previous FeSS Intervention study participation and location (remoteness).³²²

Participant characteristics

Six of the nine Stroke Coordinators identified an additional participant from their hospital. Of a possible 15 interviews, 14 were completed between September 2023 to January 2024 (one interview participant failed to respond after several follow-up attempts). The interviews ranged from 15 to 49 minutes in length, with a mean duration of 31 minutes. All were registered nurses excluding one occupational therapist and one stroke neurologist and 79% (n=11) of interview participants were female (Table 1). The median years of clinical experience was 21 (range 9-35) and median years in their current role was 7.5 (range 1.5-17).

Table1. Participant Characteristics

Health Profession	Gender	Years of clinical experience	Years in current role
Nursing	Female	31	17
*Nursing	Female	16	16
Nursing	Male	34	3
*Nursing	Female	35	7
Nursing	Female	24	8
Occupational Therapist	Female	10+	5
Nursing	Female	13	1.5
*Nursing	Female	20+	8
Nursing	Female	9	3
*Stroke Neurologist	Male	25	7
Nursing	Male	21	7
Nursing	Female	30	11
Nursing	Female	14	10
*Nursing	Female	16	16

*secondary interview participant

Major themes mapped to Sustainability of Innovation Framework

Two themes were constructed from several sub-themes and mapped to factors from the Framework. (Table 2). Participant quotes are used to illustrate the findings.

Table 2. Alignment of themes and sub-themes with factors from the Sustainability of Innovation Framework

Themes and sub themes	Sustainability of Innovation Framework factors
Stroke Coordinator as sustainability champions and boundary spanners • Maintenance of implementation strategies • Fostering working relationships • Communication and influence	• Workforce: (i) Employment models (i.e. a single staff member Stroke Coordinator model compared to a team of clinical champions) can influence the sustainment of implementation strategies. (ii) Working relationships require effective interpersonal skills by the Stroke Coordinator to act as a boundary spanner between departments/disciplines/organisations to foster network collaboration. • Organisational: (i) Implementation strategies were initiated and leveraged from existing systems. (ii) Sustainment of implementation strategies require ongoing maintenance to embed FeSS Protocols into clinical practice. (iii) Operational governance requires effective communication and maintenance of relationships with key stakeholders that share an understanding and value the use of FeSS Protocols. • Innovation-specific: (i) Site-specific adaptations of FeSS Protocols after initial implementation for optimisation in response to context, enable sustainability.
Hospital executive and middle management respect of stroke specialty • Designated area for stroke care • Recognition of stroke specialist nursing skills • Previous FeSS Intervention study participation	• Workforce: Hospital executive and middle management support and recognition of stroke expertise are required. This necessitates: (i) a designated area (e.g. stroke unit/service) where the FeSS Protocols align with the values and needs of the multidisciplinary team; and (ii) recognition that personal motivation, capacity, and competencies are different for stroke nursing compared to other speciality areas and levels of patient acuity. • Political: (i) a focused organisational approach before implementation of FeSS Protocols (e.g. agreement to participate in a FeSS Intervention study) enhances sustainability. (ii) It is important to be aware of other competing organisational directives before trying to implement an evidence-based intervention.

1. Stroke Coordinator as sustainability champions and boundary spanners

The Stroke Coordinator role was identified as the lead for initial implementation of FeSS Protocols, and for maintenance and sustainment of these strategies used in their individual stroke services. As senior stroke nurse leaders, they assumed responsibility for driving evidence-based practice and acted as a ‘boundary spanner’ to communicate across disciplines and departmental boundaries. This required the use of interpersonal skills to foster working relationships and coordinate organisational-level approaches to acute stroke care.

Sub-themes

1.1 Maintenance of implementation strategies

Education and training were common strategies employed for initial and ongoing implementation of FeSS Protocols into local stroke service processes and everyday clinical practice. A standardised document or care plan with organisational approval for use, specific to individual hospitals, was the predominant method to support these approaches. The names for these varied widely (policy, stroke care plan, pathway, checklist, protocol). Generally, this document was developed in line with the national clinical guidelines for acute stroke management that became a reference for use within the stroke service when requesting medical review and/or intervention:

“We have pretty good adherence to our swallowing, the fever and sugar only started probably with the FeSS protocols. We incorporated into our initial management in ED and then and into our stroke pathway in the ward.” [High Adherence 1]

“We have included the guidelines for FeSS Protocols into our governance for stroke unit care which can be easily accessed on the intranet.” [Variable Adherence 3]

Participants from hospitals with high FeSS Protocol adherence reported that these documents were used by nursing and medical staff to support care in accordance with FeSS recommendations:

“It’s on our intranet, if I put in stroke patient then all of the procedures, care paths, come up for you and you can pick it out. Every three years they get reviewed. FeSS has been added to the medical template in EMR.” [High Adherence 2]

“The junior doctors have a broad range of things they have to know in multiple patients...If we’ve got a stroke pathway and a framework, you can kind of say, well, here it is. And this is why we do it...they’re very open to it.” [High Adherence 1]

The existence of a multidisciplinary shared care pathway or document did not necessarily facilitate adherence as the Stroke Coordinator from a hospital with consistently low adherence also reported the use of a statewide stroke protocol designed for multidisciplinary and multiple departments to use:

“It follows the stroke key guidelines ... takes the doctors and the nursing staff through everything they have to do in that ED setting and then onto the acute ward and discharge planning [Low Adherence 1]

Leverage from an existing process to include FeSS Protocols into clinical practice was perceived positively in relation to the transparency and consistency of requirements for stroke care in all hospitals in the same region. However, upscaling of a local stroke protocol on a larger scale was perceived negatively by the Stroke Coordinator from a hospital with consistently low adherence due to the significant time delays associated with the increased levels of consultation required for any updates. In some circumstances, this meant the protocol was then unavailable during the consultation and review period:

“Having a district wide pathway meant we had to go through all that consultation. How can we actually just evolve what we’ve got instead of taking it away and saying no, you can’t use that anymore, and then we’ve got nothing for this period of time” [Low Adherence 2]

Similarly, frustration with broader organisational processes was described by the Stroke Coordinator from a low adherence hospital, in relation to their requirement to follow a generic protocol for all acute inpatient admissions in that region, rather than a stroke-specific protocol. There had been some recent success in negotiating approval for the use of a stroke thrombolysis and retrieval pathway, but a protocol specific to acute stroke management (for patients not eligible for stroke thrombolysis) was yet to be approved:

“It is only thrombolysis and early assessment, and the other part of the protocol is for all general medicine patients, but not specific for stroke.” [Low Adherence 3]

The need to de-implement outdated recommendations and update stroke pathways/protocols to manage service expansion (such as stroke telemedicine) or to maintain alignment with current national stroke clinical practice guidelines generated much discussion. For smaller stroke services, the evolution of the stroke telemedicine model was perceived positively, as protocols for this service were developed collaboratively with the larger and better resourced stroke hospitals. The Stroke Coordinator from a hospital with variable adherence described how the role itself evolved with this service:

“The Stroke Coordinator role is basically a new role for my organisation that has just came up when the Telestroke service has been implemented. We only started thrombolysis as part of the telestroke service implementation last year. Now with the new stroke pathway, they're just learning or starting to become aware of the FeSS protocol...” [Variable Adherence 3]

The incorporation and maintenance of these documents in electronic medical records (EMR) had varied perceptions. Being able to add FeSS Protocols to medical admission documentation templates, was perceived positively (as it facilitated a prompt for medical staff to prescribe care in relation to these protocols). However, the additional governance and approval processes in relation to this technology integration was perceived negatively as it was thought to contribute to significant time delays:

“We have a stroke patient acute procedure for non thrombolysed patients on our intranet. There is an electronic care plan developed for this, but we've never implemented because of the EMR delays. We keep hearing its coming, but it's never really happened.” [High Adherence 2]

Initially, the plan was to put it up in the EMR but this will take a very long time. As far as I'm aware, a lot of the stroke pathway forms are in paper form because it's easier to change it because of the quick change in Stroke Foundation guidelines.” [Low Adherence 2]

The Stroke Coordinator from a hospital with variable adherence described an update to their stroke pathway design that may have had a positive influence on their improved adherence. The revised design was aligned with national stroke clinical practice guidelines and now required documentation of compliance with this pathway for each nursing shift.

“FeSS was all sort of built into our pathway beforehand. Now there has to be some accountability that these things were done, for each shift.” [Variable Adherence 1]

The existence of a stroke unit to centralise acute stroke care was perceived to facilitate a cohesive approach to patient care, confirming alignment with shared goals of the organisation for evidence-based acute stroke care. The hospital-approved policies and protocols (adapted to include FeSS Protocols) were reported to be uniformly applied and regularly reviewed for currency with latest evidence. The relocation of a stroke unit was described as destabilising and how the absence of a stand-alone stroke unit impacted the Stroke Coordinators ability to reinforce and monitor compliance with stroke protocols:

“We've joined the whole Neurosciences ward as one and when that happened, we've had a fairly large turnover of staff. The stroke unit looked feral and old, but the systems, even though I thought they didn't work very well back then, I think they probably did because we were all in one area together.” [High Adherence 3]

“We don't have a stroke unit; protocols are not updated (the stroke pathway has not been updated since 2016). If they're not transferred out to a stroke unit, they can go basically anywhere...” [Low Adherence 2]

1.2 Fostering working relationships

The ability of the Stroke Coordinator to effectively maintain working relationships across departmental boundaries and disciplines were reported as being essential for sustained adherence to FeSS Protocols. Predominantly these were specific to the emergency department, speech pathology and medical colleagues:

“I would have to say I didn't get a lot of buy in or support from ED in regard to FeSS or time to imaging or any of those sorts of markers. And that's what's been a real challenge over the last couple of years ... I just got told by ED: I'm sorry it's not a priority.” [Low Adherence 1]

“So the swallow, it has been a problem because there is not always someone available in the stroke unit and in ED or in other medical wards to perform dysphagia screening. They are not trained to do it, and they have been always reluctant to be trained in swallow screening” [Low Adherence 3]

The relationship with the speech pathology department was identified as a positive influential factor for sustained adherence to FeSS Protocols, especially where there were shared arrangements for education and training, data collection and feedback. Another key relationship highlighted was with medical leadership and inconsistent support in relation to sustained adherence to FeSS Protocols. Frequently the Stroke Coordinator assumed some responsibility for orienting new and junior medical staff. However, if acute stroke management in accordance with FeSS Protocols was not reinforced by the medical leadership group, then sustainment of implementation strategies was difficult:

“I could kind of remind the doctors (we have a new one every six weeks). But then after hours, obviously there was no one there to prompt people. Our consultants obviously don't feel strongly about it” [High Adherence 3]

“My biggest issue would be the doctors not being aware, even though I give them orientation, the protocols and the consultants will say they're not aware. The doctors don't enforce our words.” [Variable Adherence 2]

The Neurology Advanced Trainee (three-year speciality fellowship post-basic physician training) was an exception to this finding, and was reported as someone who valued the evidence for the use of FeSS Protocols and supported their use:

“The neuro advanced trainees are very good, because they've come from other areas as well. So they'll give us some feedback too. If you say, what's the reasoning behind this? And they'll fill you in, on the latest research.” [High Adherence 1]

“Our advanced trainee at the moment is from XXXX, so they document, you know, as per FeSS Protocols.” [High Adherence 2]

1.3 Communication and influence

Data collection is a common task for most Stroke Coordinator roles²⁶² and widely reported in this study to be onerous. Those Stroke Coordinators that collected data for the Audit cycles reported to have also been responsible for communicating those results back to the multidisciplinary team. The Stroke Coordinator (from a hospital with consistently low FeSS Protocol adherence) who did not perform data collection for the Audit cycles was unaware of their hospital's participation, as the results had never been shared with the nursing staff:

“So, we've never done that [the acute Audit] on the ward, just the rehab Audit normally, I'm not sure who would collect that data because I've never done any.” [Low Adherence 3]

Participants were asked about any additional data collection (FeSS variables) outside of the Audit cycles, and if/how these results were communicated to the nursing staff and broader multi-disciplinary team. Additional data on FeSS variables was contributed into local databases and/or the Australian Stroke Clinical Registry (AuSCR) which has an optional dataset (as of July 2019) to collect continuous FeSS variables prospectively:

“We know where our gaps are because we do look at our AuSCR data a lot and that's why we signed on for the FeSS (optional dataset in AuSCR).” [Variable Adherence 3].

“I do monthly reports about the code stroke process to the medicine department and six monthly reports on adherence to the stroke protocol.” [Variable Adherence 2]

Strong links to professional networks were reported by Stroke Coordinators from hospitals with high and variable adherence as a factor perceived to enhance confidence

in advocating for adherence to FeSS Protocols in their stroke services. Some of these networks were region specific, and membership to a national stroke nursing network (the Australian Stroke Nurses Education Network (ASNEN) was also common. These forums were described as an opportunity to discuss common issues in relation to FeSS Protocol implementation and sustainability:

“We've talked about FeSS quite a lot and it's been something that we've tried to make a bit of a focus through some of the education that we've done as well. But certainly, I think the barriers are fairly similar across the board.” [Variable Adherence 1]

“You kind of need to go to these things (ASNEN stroke nurse leaders day) to learn that you're not just an utter failure.....you know, it's big to implement three protocols at one time.” [High Adherence 3]

Mapping to factors from the Sustainability of Innovation Framework

The first theme of the Stroke Coordinator as sustainability champions and ‘boundary spanners’ was constructed from sub-themes of maintenance of implementation strategies, fostering working relationships and communication and influence. Leverage and adaptation of hospital specific existing systems and tools by Stroke Coordinators to embed routine use of FeSS Protocols into clinical practice required ongoing maintenance for their sustained use. Underlying many of the reported issues were *Organisational factors*. Obtaining operational governance for these strategies was not a one-off process. As technology and the services offered by the hospital evolve, implementation strategies had to be flexible enough to accommodate these changes. Maintenance of interdepartmental relationships was identified by the Stroke Coordinators from hospitals with high adherence as essential to ensure the strategies in place for FeSS Protocols were not overlooked during any changes or upgrades within their service. Furthermore, those who were able to navigate the complexities of new technological innovations, such as telestroke and electronic medical records (EMR),

effectively leveraged these tools and new ways of working to incorporate FeSS Protocols to facilitate sustained adherence.

Although the protocols are designed to be nurse-led, they require endorsement from medical and speech therapy colleagues. Consideration of the Stroke Coordinator's interpersonal influence and ability to foster network collaboration with relevant stakeholders as the sustainability champion, highlights issues in relation to *Workforce Factors*. At the organisational level, the risk of a single Stroke Coordinator service model makes any implementation efforts vulnerable if this staff member is unavailable. In the absence of peers to share responsibilities of overcoming barriers to sustainment of implementation strategies, this critical staffing resource and strategies are compromised:

"We don't have anybody in the district who's got stroke experience, or a stroke champion or Clinical Nurse Specialist. So that lack of nursing expertise in stroke nursing is very difficult as well." [Low Adherence 2]

"I don't have anybody else; our Clinical Nurse Educators are largely not stroke, I bear the main load ...After hours, obviously there is no one there to prompt people. We had the protocols but obviously unless someone is there to push it, it didn't really happen." [High Adherence 3]

When considering this workforce factor for hospitals with variable adherence, an improvement in adherence may have coincided with the expansion of the single Stroke Coordinator role to a 24-hour model of care. Mitigating some of the risk associated with reliance on a single staff member Stroke Coordinator service model was also addressed by identifying stroke champions in other departments. These clinicians self-identified as having an interest in acute stroke care and were willing to learn about managing FeSS complications. This shared understanding facilitated their championing for the use of FeSS Protocols in their respective departments:

"I've created some ED and ICU stroke champions in those key stakeholder areas, some of them have fully completed the ASSIST (dysphagia screening tool) training and others are now doing it." [Variable Adherence 3]

“I think with the turnover of staff, get your champions actually working actively to help you so that it's not all dependent on the one senior nursing stroke lead.”
[Variable Adherence 1]

Innovation-specific factors for sustainability relate to the acceptability, quality and safety of the innovation to stakeholders. There were some reports of a lack of medical leadership to enforce the FeSS Protocols, particularly in relation to the use of insulin for treatment of hyperglycaemia. In response to the perceived risk or uncertainty, several adaptations to the FeSS Protocols to suit local context were in place (e.g. use of subcutaneous insulin instead of intravenous infusions and/or review by the endocrinology team).

2. Hospital executive and middle management respect of stroke specialty

The second theme was the essential principle of hospital executive and middle management support and respect for stroke as a distinct specialty area. The need for a designated area for stroke care and recognition of stroke specialist nursing skills were sub-themes fundamental to respect for the knowledge required to effectively manage and treat acute stroke patients. Previous FeSS Intervention study participation was another sub-theme pertinent to this topic as the benefits of a focused organisational agreement before attempts to implement FeSS Protocols became evident.

Sub-themes

2.1 Designated area for stroke care

Workplace configuration and the presence of a dedicated stroke unit featured prominently as a topic during interviews. Of the hospitals with consistently low FeSS Protocol adherence, only one was equipped with a stroke unit. The Stroke Coordinators from hospitals with high and variable adherence came from stroke units that operated independently as autonomous specialist departments:

“We've only got 5 beds and we're completely separate to the rest of the ward, so the nursing staff only work in the stroke unit. I think that the rest of the hospital has that respect for our unit. And they're very good at allowing us to manage the unit ourselves” [High Adherence 1]

However, constant negotiations required to reserve these beds for patients with stroke and to have stroke specialist staff assigned to their care was emphasised:

“Ringfencing of the beds is a daily challenge, to try and keep patients ‘cohorted’ together, I’ve been trying to have the roster ringfenced as well, so you have specific nurses in that acute space” [High Adherence 2]

The Stroke Coordinator from the only hospital with low FeSS Protocol adherence that had a stroke unit described the issues with inconsistent personnel for staffing (attributed to the hospitals location and transient population). Additionally, the patients in this stroke unit were not always managed by the neurology team unless they were the admitting team:

“The problem is that the patients are admitted under General Medicine so that is a different team of doctors every day that admit patients with stroke. This creates a bit of confusion, even if we lead the decisions, they are not immediately our responsibility.” [Low Adherence 3]

2.2 Recognition of stroke specialist nursing skills

Acknowledgement and recognition of the skills required to work in specialist stroke units varied between hospitals. Demonstration of competency was required by units with high and variable adherence compared to the one stroke unit with low adherence that was based on length of employment only:

“You can't work in our stroke bay, until you've done the transition program for stroke neurology and the telemetry package. No graduate nurses [work in this area] until it is their second year.” [High Adherence 2]

“Everyone who worked in the stroke unit had to have certain modules ticked off. They were given an orientation book that was very heavily FeSS influenced.” [Variable Adherence 1]

“New staff are not allowed into the stroke unit until they've been on the ward for over a year”. [Low Adherence 3]

There was significant discussion in relation to the stroke unit and other clinical specialities that shared the same workspace. Co-locating the acute stroke patients with sub-acute inpatient rehabilitation patients, was described as a contentious issue. It was suggested that combining the acuity levels diluted the specialist focus of the acute stroke unit, with continual negotiations required to maintain suitably qualified nurses to staff the stroke unit and protect existing nurse patient ratios:

“So it had its own FTE of staff who only worked in the stroke unit and that got degraded as everyone got mixed in. So, all the expertise within stroke got dispersed amongst the ward and it meant that you could have someone in the stroke unit who essentially had no experience working with acute stroke patients.”
[Variable Adherence 1]

It was also perceived that the change in acuity, resulted in a change in leadership. In the acute care setting, nurses were perceived to lead patient care. Whereas in the sub-acute setting, it was perceived that allied health were directing patient care:

“It might take 45mins to get someone dressed, showered and ready so they can attend their 10am physio session. But the nurse might then have their eye off the ball when someone is acutely deteriorating and is not able to respond in a timely manner. You lose that primary focus of the nurse leading the care to subacute focus where Allied Health direct the care.” [High Adherence 2]

Stroke Coordinators from hospitals with low adherence that did not have a stroke unit, managed patients with stroke on a mixed general medicine ward or the patients could be dispersed throughout the hospital to any bed with telemetry capacity. The mixed ward included both acute and sub-acute stroke patients. Although the nurse unit manager made every effort to keep the acute and sub-acute stroke patients at opposite ends of the shared ward, there was no delineation of staff or treatment phase specific protocols.

2.3 Previous FeSS Intervention study participation

Two of the hospitals with high FeSS Protocol adherence and one of the hospitals with variable adherence had previously participated in a FeSS Intervention study. None of the hospitals with low FeSS Protocol adherence had participated in any of the FeSS Intervention studies. When Stroke Coordinators were asked to recall the implementation strategies used during the studies, their responses were non-specific, or they couldn't remember:

"The designated clinical champions during that trial have continued, there was probably only myself and one of the other stroke nurses who is still here working. You sort of forget about it now because it's sort of just, you know, business as usual"
[High Adherence 1]

"I remember a lot of the training that happened particularly in the emergency department, I think there was a bit of uptake, particularly when it was happening and then it just died off again, because there weren't champions on the floor pushing that stuff." [Variable Adherence 1]

It wasn't clear if the limited clinician recall of the strategies used during these studies was indicative of the time that had passed since participating in the study and/or the successful embedding and normalisation of routine use of FeSS Protocols in their hospitals.

Mapping to factors from the Sustainability of Innovation Framework

Management support and recognition of the expertise required to care for the patients with acute stroke are important *Workforce Factors* for sustainability. The existence of a designated space within the organisation for management of this critical acute stroke period acknowledges the specialist skills required of staff who work in this space.

Similarly, having dedicated staff that have achieved the required competency in speciality skills to work in these environments is also a *Workforce factor* at the individual level that relates to their personal motivation, capacity, and competence.

Centralising the foci of professional knowledge facilitates assimilation of the

innovation as it is more likely to be consistent with the values and needs of the staff working there.⁹¹ Examples presented by Stroke Coordinators of potential threats to sustainment of implementation strategies include inconsistent staffing or high staff turnover, decline in morale (e.g. relocation of stroke unit), and staff attitudes and perceptions (mismatch of co-located clinical specialties).¹⁹⁷

Previous participation in a FeSS Intervention study is relevant to *Political factors* for sustainability. A focus on one particular policy or directive from the organisation at the early stage of implementation (such as agreement to participate in a clinical trial), can increase the chances of sustained implementation. To participate in one of the FeSS Intervention studies, agreement across the relevant departments would have been required for institutional and ethical approval before commencement. The additional time to negotiate these approvals prior to implementation, is likely to have positively influence sustained use of FeSS Protocols. The Stroke Coordinator from a hospital with low adherence also highlighted the importance of understanding other competing organisational directives before trying to implement the Protocols. The hospital did not have a specialist stroke unit or designated area for stroke patients. The Stroke Coordinator described some major resistance to implement any form of stroke pathway or protocol due to the competing national directive to immediately transfer patients out to a facility that did have a stroke unit:

“There's this big focus on making sure referrals were done, everyone would be spending all of their time ringing and faxing and you know my frustration then was but, in the meantime, let's just do some basic stuff.....I was repeatedly told you can't have a stroke pathway because you don't have a stroke service.” [Low Adherence 2]

This obviously becomes an issue if stroke unit beds at other hospitals are at capacity and the patient with stroke must remain on site in a non-specialist area with no pathway to guide recommended care in this acute period.

DISCUSSION

Despite the proven benefits of the evidence-based FeSS Protocols supported by a strong recommendation in clinical practice guidelines, their consistent application remains suboptimal. Understanding factors that contribute to clinical variation in acute stroke care is critical to improving adherence and ultimately patient outcomes. There are challenges in implementing and sustaining evidence-based care where different disciplines and departments are involved. Exploration of clinician perspectives of individual and organisational factors influencing sustained use of FeSS Protocols in Australian hospitals generated two themes constructed from six sub-themes. These mapped to four factors from the Sustainability of Innovation Framework. Theme 1: *Stroke Coordinator as sustainability champions and boundary spanners* [maintenance of implementation strategies; fostering working relationships, communication and influence] mapped to workforce, organisational and innovation-specific factors. Theme 2: *Hospital executive and middle management respect of stroke specialty* [designated area for stroke care; recognition of stroke specialist nursing skills; previous FeSS Intervention study participation] mapped to workforce and political factors. Stroke Coordinators from hospitals with consistently high adherence were from stroke units and were supported by other clinical champions. Hospitals with consistently low and variable adherence reported difficult interdepartmental working relationships and competing organisational directives.

The champion role is a powerful implementation strategy frequently used in research.⁹¹ The term is often used interchangeably with ‘opinion leader’ or ‘change agent’ despite the differences in these roles, contributing to lack of clarity about their effectiveness. Research usually focuses on the role of champions in relation to implementation rather than how the role continues or changes longer term, or in relation to sustainability.³²⁶

The Stroke Coordinator's role in implementation was expected given the leadership status of this senior nursing position. However, their informal role in sustainment of implementation strategies that included (but was not limited to): maintenance of hospital specific policies and protocol documents, education and training, coordination of data collection for Audits and other repositories, and the responsibility of delivering feedback of these Audit results to multiple disciplines and departments was a key finding. The Stroke Coordinator's interpersonal skills and ability to foster working relationships with other disciplines and departments are critical to their dual role of boundary spanner as cooperation from multiple stakeholders is required for sustained use of FeSS Protocols. Boundary spanning activities in an American study of advanced practice professionals (nurse practitioners and physician assistants) who act in stroke coordinator roles have also been credited for maintaining sustained engagement in acute stroke care.¹⁶³

FeSS Protocol adaptations to suit local context are consistent with literature on sustainability of healthcare innovation that sustained use of the FeSS Protocols as initially implemented is not a static event, but a process that must be continually negotiated among members of an organisation long after initial implementation.^{114,197} This type of continual improvement (adaptations) after initial implementation for optimisation in response to local context, enable sustainability.¹¹⁴ The Stroke Coordinator's leadership and collaboration skills can positively influence this process with effective communication channels to develop a shared understanding and values in relation to the use of FeSS Protocols. One example of these efforts is the feedback of Audit results across different departments and disciplines to drive engagement for the use of FeSS Protocols.

There is evidence of other nurse leader champions influence on the sustainability of best practice guidelines in hospitals for falls prevention, pressure ulcer prevention, and pain management.³²⁷ Champions are also included as a factor in the Integrated Sustainability Framework,¹¹³ and a recent systematic review of evidence-based intervention sustainability strategies.¹¹⁰ However, a more recent scoping review found the role and responsibilities of the champion were poorly defined.³²⁸ Similarly, despite national and international recommendations for a dedicated Stroke Coordinator position as an integral part of a hospitals stroke service,^{223,329} their role and scope of practice is often inconsistently defined.²⁶² This inconsistency is evident in one Stroke Coordinators lack of awareness of participation in the Audit in contrast to other Stroke Coordinators who led this quality improvement activity. Furthermore, it highlights that the Audit results were not shared with nursing staff which may hinder their engagement with evidence based care.

It is evident from this process evaluation that Stroke Coordinators cannot effect practice change alone. The use of a single staff member model, highlighted as a workforce factor for sustainability, may impact sustained use of FeSS Protocols. Having more than one Stroke Coordinator or designated stroke champions in other departments was identified as a contributing factor to successful sustainment of implementation strategies for the use of FeSS Protocols. The effectiveness of multiple champions compared to single champions has been recognised in implementation research³²⁶ and was also highlighted in the study of advanced practice professionals acting in stroke coordinator roles.¹⁶³

There were numerous strategies identified for embedding FeSS Protocols into site specific clinical practices, policies and processes. However, where patients with stroke

were not cared for in a designated area where care is centralised and managed by the multi-disciplinary team, protocols were seen as a guideline rather than mandatory. Similarly, the inclusion of acute and sub-acute stroke care in the same designated workspace was not viewed positively by interview participants, due to the lack of distinction in clinical areas. Stroke unit care remains the single most important recommendation in the national stroke guidelines.²²³ Overcoming this barrier requires management support and acknowledgement of the need for a distinct area with acute stroke care protocols, staffing ratios and the skillset required for staff to work in respective clinical areas.

Consistent with the literature on diffusion of innovations, the stroke units that were able to sustain consistently high FeSS Protocol adherence were stand-alone units with decentralised decision-making structures.^{91,330} The length of time a stroke unit had been established may account for some of the variation in FeSS Protocol adherence, however, investigating this was beyond the scope of this study. Regardless, international translation of FeSS Protocols in Europe (n= 64 hospitals, 17 countries) has demonstrated that the protocols can be successfully implemented by both stroke-unit and non-stroke-unit hospitals noting that establishment of dedicated stroke units are not always possible in smaller regional and remote hospitals.³⁴ A designated area for stroke patients, within a general or neurology ward has been demonstrated in other studies to maintain high standards of acute stroke care, particularly when using nursing ‘care bundles’ similar to the way the FeSS Protocols are packaged (three to five evidence-based interventions).³³¹ These examples highlight the instrumental role nurses can play in advancing stroke care through the use of nurse-led protocols. Maintaining high quality local services for patients with stroke unable to access stroke unit care has been identified as a challenge in this study and in the literature. Efforts are ongoing to

determine what elements of organised stroke care can be implemented to make the largest gain in these lower resourced settings.³³²

Strengths and limitations of the work

Strengths of this study include the use of end-user perspectives given that clinician acceptance has been identified as a key factor for sustainability.³³³ Furthermore, the choice of Stroke Coordinators as the most likely personnel to be sufficiently knowledgeable regarding factors that may influence adherence to FeSS Protocols is supported by the finding of a median of 7.5 years of service in this leadership role. Those participants with fewer years of service were able to nominate a secondary person for interview that had either filled this role before them or been directly involved with the implementation of FeSS Protocols in their hospital. The secondary interviews enhanced the reliability and applicability of the data obtained during the primary interviews and improved the generalisability of data in relation to the hospital.

Additional strengths consist of the purposive sampling design to efficiently analyse sustained adherence to FeSS Protocols and the extended time period over four Audit cycles that spanned a six-year period to explore sustainability. Sampling by adherence levels enabled focused data collection from participants who were able to provide valuable insights into their consistent ranking of high or low adherence across the Audit cycles. Additionally, the inclusion of hospitals with variable adherence to FeSS Protocols generated some understanding into why this inconsistency may have occurred. The substantial six year period for evaluation of an evidence based intervention at recommended multiple time points after scale-up is noteworthy, given the criticism of many studies attempts to evaluate sustainability at only one to two years post implementation.¹¹¹ Although we achieved representation from Stroke Coordinators across all Australian States and Territories with the exception of one, the

specialist nature of this clinical role and purposeful selection on other criteria may limit the representativeness of findings for other health professionals involved in stroke care.

Using a theoretical framework tailored to sustainability, and grounded in other established frameworks,^{330,114} facilitated a comprehensive understanding of the factors for sustainability. Although the data only mapped to four of the five factors that make up this framework, this was not considered a limitation. *Financial* factors were not identified as Stroke Coordinators are generally not tasked with departmental budget management. Similarly, authors of another study that used this framework to evaluate sustainability of Nurse Practitioners in Emergency Departments, also did not report findings that were relevant to this factor.³³⁴

Recommendations for further research

Future research on the national stroke unit accreditation which commenced in 2022, will be of interest to evaluate any impact this process may have on adherence to clinical practice guidelines.¹⁹¹ Additionally, there is a clinical trial underway in Australia and New Zealand that involves a multi-component implementation strategy using external remote facilitation to support healthcare teams in adopting FeSS Protocols.³⁰⁶ This approach may prove particularly beneficial for regional and remote areas and will direct future efforts in determining the amount of external support required to assist hospitals to implement FeSS Protocols.

Implications for policy and practice

The Stroke Coordinator is recognised for their role in ensuring coordinated, best-practice care,²²³ but their key role as sustainability champions has yet to be acknowledged in the literature. This finding is important not only for the sustained use of FeSS Protocols but also likely relevant to other stroke clinical practice guidelines. It

is recommended that all primary and comprehensive stroke services in Australia have a dedicated Stroke Coordinator role. Despite this, according to the 2023 national audit of acute stroke services (n=107 participating hospitals), only 70 of 86 (81%) services with stroke units and 11 of 21 (52%) services without a stroke unit reported having a dedicated Stroke Coordinator role.³¹⁵ Highlighting the value of this nursing leadership position by acknowledging their critical role in sustainability, strengthens the rationale for staffing of the Stroke Coordinator role in all stroke services.

CONCLUSION

This process evaluation after scale-up strategies to maximise nationwide use of FeSS Protocols, has identified several key factors for sustaining adherence to this clinical practice guideline. Importantly, it has recognised the pivotal role of the Stroke Coordinator in sustainment of implementation strategies enabled by their boundary spanning skills. The unique skillset of these stroke leaders should be acknowledged by health services to guide future implementation strategies to optimise in-hospital acute stroke care and improve patient outcomes.

ABBREVIATIONS

ASNEN: Australian Stroke Nurses Education Network

AuSCR: Australian Stroke Clinical Registry

FeSS: Fever, Sugar, Swallow

QASC: Quality in Acute Stroke Care

QASCIP: Quality in Acute Stroke Care Implementation Project

T³: Triage, Treatment, and Transfer

5.3 Summary

This study provided critical end-user insights into the factors that influence the sustained use of the FeSS clinical practice guidelines in acute stroke care. Considered alongside the sustainability outcomes measured across the audit cycles in the earlier quantitative study in Chapter Four, this study has highlighted additional factors that influence long term sustainment of implementation strategies that may account for variation in stroke care practices.

Guided by the Sustainability of Innovation Framework, the pivotal role of Stroke Coordinators as sustainability champions and boundary spanners who drive adherence through leadership, collaboration, and ongoing maintenance of implementation strategies was identified. This key workforce factor was one that had not been accounted for in the quantitative study, highlighting the value in the use of process evaluation qualitative research methods to uncover such insights. The use of advanced practice nurses to improve adherence to stroke clinical practice guidelines was previously identified in the literature review in Chapter Two. Specifically, their influence on timely acute stroke assessment was attributed to their boundary spanning skills in the emergency department. Again, the skills of advanced practice nurses (Stroke Coordinators) to drive engagement and evidence-based practice across services and disciplines have been noted in this study specific to acute stroke care settings. The importance of organisational support, designated stroke care areas, and recognition of stroke specialist nursing skills in fostering a culture of evidence-based practice were also identified as key factors that influence sustained adherence to the FeSS Protocols. Importantly, the study reveals that sustainability is not a passive outcome but an active, dynamic process requiring continuous adaptation, engagement, and institutional commitment. These insights offer valuable guidance for health services aiming to embed and sustain best-practice stroke care, particularly in settings with limited resources or structural challenges.

The next chapter summarises the findings from each study undertaken in this research program and considers them collectively in relation to the overarching research aim. It discusses the use of different research methods to evaluate the impact of the new evidence-based stroke clinical practice guideline and explores the diffusion of this evidence into acute stroke care services. Contributions to the field are highlighted, along with the strengths and limitations of the research, and recommendations for future work are outlined.

6.1 Overview

The use of Fever, hyperglycaemia (Sugar) and Swallowing (FeSS) Protocols for stroke in Australian hospitals, after their inclusion as recommended care in the 2017 National Acute Stroke Guidelines has been investigated in this doctoral research program. The thesis examined the current research evidence and was also a long-term study of clinician behaviour change and the natural history of diffusion, within the context of implementation of stroke clinical practice guidelines in Australian acute stroke care hospitals. Embedded within the translational Quality in Acute Stroke Care research program, this doctoral research was a unique opportunity to evaluate the sustainability of implementation strategies used in earlier FeSS Intervention studies³¹⁻³³ (i.e. clinical champions, barrier and enabler assessments, educational workshops and reminders), compared to the more passive implementation strategies,⁸⁴ such as dissemination of clinical practice guidelines and national audit and feedback cycles. The 2017 evidence-based stroke clinical practice guideline and the study of diffusion of this evidence into acute stroke care services, provides new insights into the longer-term sustainment of implementation strategies for stroke clinical practice guidelines.

The translation of research findings into clinical practice is commonly referred to as a pipeline from ‘bench to bedside’ and is broken down into distinct phases: T0 basic research (lab or bench based); T1 translation of basic research to humans; T2 translation to patients (bedside research); T3 translation to general practice care; and T4 translation of research to populations or communities.³³⁵ Implementation science is the study of methods and concepts to translate evidence-based clinical innovations in these later phases (T3-T4) into wider practice for public health impact.³³⁶ Many innovations do not make it into routine clinical practice and for those that do, there is a significant time lag between evidence generation of the interventions’

effectiveness and widespread uptake into clinical practice.³³⁶ Furthermore, the process of translating evidence into clinical practice is widely recognised as being notoriously difficult as it requires changing clinician behaviour.⁹⁴ Without successful implementation of the evidence, sustainability is unlikely. The process of *implementation* is the initial process of translating an innovation or evidence-based intervention into a setting or system,¹¹⁴ while *sustainability* is the extent to which it is maintained or normalised in routine practice within that setting or system.³³⁷

This thesis contributes to knowledge in the field of implementation science by its novel evaluation of the sustainability of FeSS Protocol adherence in relation to sustainment of implementation strategies longer-term. Additionally, it includes the critical perspective of front-line clinicians as the end-users of FeSS Protocols, regarding key factors that influence their sustained use. These include both individual factors (e.g. attributes of the innovation, social influence, values),³³⁰ and organisational factors (e.g. structure, culture, leadership, system readiness).³³⁰ Diverse research methods (a systematic-hybrid narrative review (Chapter Two), a quantitative pre-test/post-test study (Chapter Four) and a qualitative descriptive process evaluation (Chapter Five) have been used to comprehensively explore the complex topic of translation of an evidence-based intervention into widespread clinical practice. These methods are in accordance with the critical realism paradigm which advocates for the use of research methods relevant to the research question and phenomenon under study,¹⁹⁸ forming the foundation of this thesis.

The findings from each study undertaken in this research program are summarised in this chapter in relation to the overarching research aim. The first part of the chapter reviews the main findings of the research program and highlights their novel contributions to knowledge, mapped against each study aim. The strengths of the research are discussed, and the

limitations are also outlined and acknowledged. The chapter ends with a summary of recommendations for policy, clinical practice and research.

6.2 Study aims achieved

The overarching aim of this thesis is to evaluate and explore diffusion of the FeSS Protocols for stroke in Australian hospitals, after their inclusion as recommended care in the 2017 National Acute Stroke Guidelines. National stroke data and front-line clinician perspectives have been used to assess adherence and factors that influence sustainment of implementation strategies for the FeSS Protocols. The issues identified from the literature review in Chapter Two regarding adherence to stroke clinical practice guidelines informed the development of each research question, which are re-stated below:

1. Has adherence to the FeSS Protocols in Australian hospitals improved since their inclusion as a recommendation in the 2017 Australian Clinical Guidelines for Stroke Management as evidenced by National Stroke audit results of 2019 and 2021 when compared to National Stroke audit results of 2015 and 2017.
2. Does previous participation in the QASC, QASCIP or T³ FeSS Intervention studies increase adherence to the FeSS Protocols?
3. Does admission to a stroke unit rather than to a general medical ward increase adherence to the FeSS Protocols?
4. What strategies or interventions have been used to implement the FeSS Protocols and how do these compare for hospitals that participated in the FeSS Intervention studies and those that did not?

5. What are the perceived individual and organisational factors that influence FeSS clinical practice guideline adherence in i) hospitals with consistently low FeSS adherence composite scores, ii) hospitals with consistently high FeSS adherence composite scores and iii) hospitals with variable FeSS adherence composite scores?
6. Do the identified influential factors from hospitals with high, low and variable FeSS adherence composite scores map to factors from the Sustainability of Innovation Framework and how do these factors influence sustained use of the FeSS Protocols in Australian hospitals?

A quantitative pre-test/post-test study design was used to evaluate the use of the FeSS Protocols for stroke in Australian hospitals using national stroke data to address the first three research questions (Chapter Four). To gain a more comprehensive understanding of these study results, a qualitative process evaluation was conducted to investigate factors that influenced clinicians' sustained adherence to the clinical practice guideline for use of FeSS Protocols in real-world settings (Chapter Five). This study, using semi-structured interviews with expert clinicians from organisations that contribute to national stroke data, was designed to answer the remaining three research questions.

Specific aims were identified and addressed for each separate study that make up this thesis; however, they are interrelated, collectively contributing to the overarching aim and knowledge about implementation and sustained uptake of stroke clinical practice guidelines in acute hospital settings. Further detail regarding the main findings and key contributions to knowledge from each study is presented under their respective study sub-headings. A summary of these findings in relation to the individual study aims is also provided at the end of this section in Table 1.

6.2.1 Study One: Systematic narrative hybrid review and synthesis of the literature

The purpose of the first study was to situate the research within the broader context of current literature regarding clinician adherence to acute stroke clinical guidelines, particularly recommendations specific to the management of fever, hyperglycaemia and swallow complications post stroke. The aim was to undertake a systematic narrative hybrid review and synthesis of behaviour change interventions that improve hospital clinician adherence to any stroke clinical practice guideline, and those specific to fever, hyperglycaemia, and swallow management after stroke in adult patients. The findings informed the research questions and aims specific to each subsequent study in this doctoral research program.

The interventions investigated in the seven systematic reviews (total of 95 studies)¹⁴⁰⁻¹⁴⁶ and ten single RCTs^{32,62,147-153} designed to improve hospital clinician adherence to stroke clinical practice guidelines consisted of: in-hospital care pathways, quality improvement collaboratives, advanced practice nurses, simulation training, continuous physiological monitoring, audit and feedback, a nurse-led care bundle, and multicomponent interventions.

Collectively, the 105 total number of studies highlighted the lack of high-quality evidence for interventions designed to improve adherence to stroke clinical practice guidelines or those specific to fever, hyperglycaemia, and swallow management after stroke in adult patients. While improvements in processes were observed in relation to adherence to clinical practice guidelines, these did not often translate to improvements in clinical patient outcomes. Suggested reasons for this consist of the choice of study endpoints, study duration and the effect of time (e.g. secular trends), context (study setting), and the quality of included studies with lower-level study designs which limit the generalisability of the results and overall interpretation.

Notably, no studies meeting the inclusion criteria for the systematic-narrative hybrid review evaluated passive implementation strategies to improve adherence to stroke clinical practice guidelines. The identification of this evidence practice gap guided the design of Study Two in this doctoral program which evaluated the passive dissemination of a clinical practice guideline specific to fever, hyperglycaemia, and swallow management after stroke in adult patients. It is widely acknowledged within implementation science that contextual factors are critical to the uptake of any clinical innovation. The findings from Study One, particularly regarding context, informed the design of the subsequent studies in this doctoral program. Both Studies Two and Three provided an opportunity to incorporate further exploration of these contextual factors when assessing adherence to the FeSS Protocols and sustainability.

Contributions to knowledge

The systematic-narrative hybrid review as the first study undertaken in this doctoral research program, identified the paucity of high-quality evidence on implementation strategies to improve adherence to clinical practice guidelines. Although many studies reported an improvement in processes of care, the difficulty in the translation of these into improvements in patient clinical outcomes was a common theme.^{141,144-147,150,151,153,338} Insufficient study duration, timing (e.g. secular trends) and context were key factors identified as potentially contributing to uncertainty in the evidence. These findings contribute knowledge to the field of implementation science as they highlight the need for careful consideration when designing future studies and choosing study endpoints to evaluate the efficacy of the intervention under study.

The systematic-narrative hybrid review identified studies specific to active implementation strategies to improve adherence to stroke clinical practice guidelines, thereby highlighting the

lack of current evidence on passive implementation strategies. This was not unexpected given the evidence is well established for the superior effectiveness of active implementation strategies.^{84,85} Additionally, most studies now employ multi-faceted interventions and implementation planning processes to implement clinical practice guidelines³³⁹ making it difficult to study the effect of stand-alone passive implementation strategies. However, these findings contributed knowledge that was incorporated into the planning for subsequent studies in this thesis. For example, in the evaluation of national audit data in Study Two, the statistical analysis plan established *a priori*, was to compare hospitals that had previously participated in the treatment arm of a FeSS Intervention study (which used multiple active implementation strategies to implement FeSS Protocols) to those that had not or were in the control group for these studies. Additionally, contextual factors such as care received on a stroke unit, was incorporated into the design of Study Two to comprehensively evaluate how this affected adherence to the FeSS Protocols. The findings from the systematic-narrative hybrid review also contributed to knowledge when planning the design for Study Three. Many of the studies reviewed had cited short study duration and timing as a potential influence on study outcomes.^{32,62,144,149,151} Sample selection in study three was then determined by a hospital's adherence to FeSS Protocols at multiple defined time points over a substantial six-year period (biennial national stroke audit cycles 2015-2021). These data were then used to establish the natural history of FeSS Protocol adherence over time and if any patterns were evident (e.g. consistently high or low adherence to FeSS Protocols). A qualitative design was used for Study Three to explore further if there were other contextual factors perceived by stroke clinicians to influence sustained adherence to FeSS Protocols in addition to those already identified in the literature reviewed.^{32,140,142,145,147,148,151,152}

Collectively, the contributions to knowledge derived from this first study were predominantly in relation to the planning for subsequent studies in this thesis. This aligns with the

overarching aim of the research program, which was to situate the research within the broader context of current literature on this topic and identify gaps in evidence. A synthesis of behaviour change interventions that improve hospital clinician adherence to any stroke clinical practice guideline, and those specific to the FeSS Protocols were provided. The findings have informed the research questions, aims and design of studies specific to this doctoral research program and are of relevance to in hospital acute stroke care and the field of implementation science.

6.2.2 Study Two: From ‘strong recommendation’ to practice: A pre-test post-test study examining adherence to stroke guidelines for fever, hyperglycaemia, and swallowing (FeSS) management post-stroke

National Stroke audit data were used in Study Two to evaluate whether there had been improvements in the implementation of standardised protocols to manage fever, hyperglycaemia and swallowing difficulties (FeSS Protocols) in acute stroke patients after the new ‘strong recommendation’ for their use as a clinical practice guideline. The research questions incorporated factors identified from existing literature in Study One, with the aim of enriching data analysis and providing additional context to the results (e.g. care received on a stroke unit or if the hospital had been in the treatment arm of one of the FeSS Intervention studies). This study also provided an opportunity to review the FeSS indicators across a timeline of all the FeSS Intervention studies compared to real-world clinical practice National Stroke audit data.

Specifically, the aims were to: i) compare adherence to FeSS Protocols pre- and post-inclusion in Stroke Guidelines; ii) determine if changes in FeSS Protocol adherence varied based on a) hospital prior participation in any treatment arm of a FeSS Intervention study or

b) receiving treatment in a stroke unit and iii) compare adherence to individual FeSS indicators across FeSS Intervention studies.

When National Stroke audit data were compared between the two audit cycles preceding the new guideline recommendation (2015, 2017) to the audit cycles after the new recommendation (2019, 2021), there was evidence of improved adherence to FeSS Protocols. The improvement in adherence over time was similar for those hospitals that had previously participated in a treatment arm of any FeSS Intervention study when compared to those that had not. Similarly, this was also observed for those patients who received care in a stroke unit compared to those who did not. However, pre-guideline FeSS Protocol adherence was higher for hospitals that had previously participated in a treatment arm of any FeSS Intervention study (FeSS Protocol composite score 40% vs 31%, $p < 0.001$) and for patients who received care in a stroke unit (FeSS Protocol composite score 40% vs 21%, $p < 0.001$), which was sustained over time. These findings suggest that research participation can facilitate greater guideline adherence; and confirms the superior evidence-based care received in stroke units.

When evaluating the individual FeSS indicators across the FeSS Intervention studies and National Stroke audit cycles, the overall proportion of patients treated with paracetamol for fever, and insulin for hyperglycaemia, had improved in clinical practice. However, adherence to swallowing variables was generally better in the FeSS Intervention studies. An international comparator was included to provide a comprehensive overview from the QASC program of translational research. Interestingly, findings from the pre-test/post-test study of supported implementation of FeSS Protocols in Europe (64 hospitals, 17 countries)³⁵ showed the highest levels of adherence for prompt paracetamol or insulin administration, exceeding those previously achieved in any Australian FeSS Intervention study. This finding suggests that improvement in these areas are possible. However, it also underscores the critical and nuanced nature of context and local settings and how these factors can influence

implementation efforts. Building on the findings of Study One and Study Two, Study Three was designed as a comprehensive exploration into clinician perspectives of the contextual factors thought to influence uptake and sustained use of FeSS Protocols.

Contributions to knowledge

The research undertaken in the second study of this doctoral research program has confirmed existing evidence on the potential benefits of passive implementation strategies.³³⁹ A statistically significant improvement in adherence to the clinical practice guideline recommendation for use of the FeSS Protocols was demonstrated when the passive dissemination of clinical practice guidelines was combined with passive audit and feedback cycles (biennial National Stroke audits). However, it also contributed additional knowledge that supports the superior effectiveness of multi-faceted active implementation strategies⁸⁵ as evidenced by the greater odds of receiving care in accordance with the FeSS Protocols if you were cared for in a hospital that had participated in the treatment arm of a FeSS Intervention study.^{31-33 316} The multiple evidence-based active implementation strategies used in the FeSS Intervention studies combined with the external support that comes from participation in a clinical trial, has longer lasting benefits than the literature currently suggests. Although the change in adherence levels over time was not statistically different, hospitals that had previously participated in a FeSS Intervention study demonstrated higher levels of adherence pre-guideline implementation which was maintained over time. This new finding on the sustainment of implementation strategies is in contrast to existing literature on ‘voltage drop’¹¹⁴ which suggests that adherence to clinical practice guidelines decreases significantly after more than one year following implementation.¹¹⁶ This finding contributes new knowledge regarding the longer-term benefits of clinical trial participation, and underscores the importance of implementation planning and targeted strategies at the time of implementation for sustaining adherence to clinical practice guidelines.

The seminal QASC Trial is one of the few clinical trials to successfully demonstrate the effectiveness of implementation strategies in supporting clinicians to implement FeSS Protocols, leading to improved mortality and disability outcomes.³¹ The longer-term effects on mortality were still evident out to a median of four years later when the patients were followed up in a data linkage study with the National Death Index.⁴⁵ The identification of longer-term improved adherence to FeSS Protocols for hospitals that participated in the FeSS Intervention studies is likely augmented by the use of audit and feedback. The clinical significance lies in the increased number of patients who received evidence-based care in these hospitals and the resultant improvement in clinical patient outcomes that follow.

In addition, the findings contribute evidence on the value of specialist care received in a stroke unit. Patients with stroke that were cared for in these specialist units had twice the odds of receiving care in accordance with FeSS Protocols both pre- and post-inclusion of this new guideline recommendation.³¹⁶ The evidence for stroke unit care is well established as one of the strongest available for improving stroke patient outcomes irrespective of age, sex or stroke type.⁷ Study Two findings confirm how the expertise of the staff working in this specialty understand the evidence and are confident in providing gold standard care in line with current recommendations, using the integrated multi-disciplinary approach of stroke unit care.¹²

The contributions to existing and new knowledge derived from the second study in this program of research underscore the value of long-term evaluation and organisational support for targeted implementation strategies to achieve the widespread adoption of evidence-based practices in acute stroke care. The value of stroke unit care, and the long-term benefits of clinical research participation are key factors identified in efforts to optimise stroke care and improve patient outcomes.

6.2.3 Study Three: Stroke Coordinators' perspectives of factors influencing sustained use of Fever, Sugar (hyperglycaemia) and Swallow (FeSS) clinical practice guidelines: A process evaluation using the Sustainability of Innovation Framework.

The final study in this doctoral research program was a qualitative descriptive process evaluation. The purpose of this study was to examine stroke clinicians' perspectives of factors that influenced sustained adherence to FeSS Protocols. The study was inter-related with the earlier quantitative study (Chapter Four), as the sample was drawn from the same group of hospitals that contributed national acute stroke biennial audit data (2015, 2017, 2019, 2021) and aimed to address additional research questions in this thesis that were not suited to a quantitative study design. Typically, process evaluations are conducted alongside clinical trials,²⁴⁸ and to evaluate the scale-up of complex health interventions. Commonly, process evaluations involve qualitative interviews,^{252,340} to understand the interaction between interventions and context and how these affect outcomes. In this study, scale-up after establishing efficacy for the use of FeSS Protocols (2011)³¹ included translational research studies (QASCIP and T³ 2013-2016),^{32,33} inclusion in national clinical practice guidelines (2017),²² and monitoring through biennial national stroke audit and feedback cycles (from 2013 onwards).⁷⁰ As all hospitals in Study Two were exposed to the passive implementation strategies (inclusion in the national guidelines and audit cycles), this presented a unique opportunity to evaluate the sustainability of FeSS Protocols over a sufficient time period in Study Three. Additionally, using this same sample of hospitals facilitated the incorporation of a more comprehensive evaluation of contextual factors identified in the quantitative study as being independently associated with FeSS Protocol adherence (e.g. a hospital's previous FeSS Intervention study participation and stroke unit care). Although context is often referred to in terms of the setting or environment, it is also relevant to roles, interactions and multi-level relationships.³⁴¹

Hospitals that had contributed to at least three of the national stroke audit cycles were ranked based on their mean FeSS Protocol adherence composite score for each audit cycle. The ranked hospitals were stratified into adherence strata based on their adherence to FeSS Protocols over the audit cycles (consistently high, low and variable). Three hospitals were purposively selected from each adherence strata after consideration of additional stratification criteria: (i) previous participation in any of the FeSS Intervention studies³¹⁻³³, and ii) according to region (state) and remoteness (Area based on the Accessibility and Remoteness Index of Australia [ARIA+]).³²² The use of remoteness was a proxy for stroke units, as access to these is markedly lower in regional and remote areas compared to major city hospitals. Additionally, the QASC and QASCIP FeSS Intervention studies were conducted in one Australian state only. Purposeful selection from various Australian States and Territories and the additional strata (where possible) was to facilitate representation of a broad range of hospitals to comprehensively explore any differences in factors identified for sustainability.

The Sustainability of Innovation Framework³⁴² originated from the combined concepts of the Conceptual Model for Considering the Determinants of Diffusion, Dissemination and Implementation of Innovations in Health Service Delivery and Organisation,³³⁰ and the Dynamic Sustainability Framework.¹¹⁴ The interview schedule and prompts were guided by these frameworks in line with recommended best practice for process evaluation studies.^{252,343} Themes identified during inductive thematic analysis were mapped to factors from the Sustainability of Innovation Framework³⁴² to assess for patterns, gaps, or differences in participant responses and informed the analysis when considering sustainability of the FeSS Protocols.

Fourteen interviews were conducted with Stroke Coordinators from nine hospitals. Two *themes* [and sub-themes] mapped to four Framework factors. 1. *Stroke Coordinator as sustainability champions and boundary spanners* [maintenance of implementation strategies; fostering working relationships, communication and influence] mapped to workforce, organisational and innovation-specific factors. 2. *Hospital executive and middle management respect of stroke specialty* [designated area for stroke care; recognition of stroke specialist nursing skills; previous FeSS Intervention study participation] mapped to workforce and political factors.

Stroke Coordinators from hospitals with consistently high adherence were from stroke units and were supported by other clinical champions. Hospitals with consistently low and variable adherence reported difficult interdepartmental working relationships and competing organisational directives. The Stroke Coordinator role was pivotal for sustained use of evidence-based FeSS Protocols for acute stroke care, driving multidisciplinary collaboration. Stroke Coordinators were identified in this study as sustainability champions for the use of FeSS Protocols, due to their role in maintaining implementation strategies and fostering relationships across disciplines and departmental boundaries.

Exploration of the contextual factors within individual stroke services revealed a range of perceived influences on the sustainment of implementation strategies for the FeSS Protocols. These included both individual and organisational factors, many of which aligned with those identified in the literature as important for sustainability. Understanding these factors is essential to improving the sustainment of evidence-based care in acute stroke care settings.

Contributions to knowledge

Process evaluations after efforts to scale up health care innovations into population-level health systems and services are rarely studied long term.¹¹¹ The measurement of longer term adherence to FeSS Protocols at multiple time points over a six-year period provided an accurate depiction of hospitals' sustainment of adherence levels over time. The final process evaluation study in this doctoral research program contributed relevant knowledge to the overall thesis aim and the broader field of implementation science, particularly in the evaluation of complex health interventions longer-term.

The results of this study corroborated earlier findings of the related quantitative study, reinforcing the superior evidence-based care provided in stroke units and the longer-term benefits of hospitals' previous participation in a FeSS Intervention study. Of the 109 eligible hospitals, only six were able to sustain high adherence to FeSS Protocols for three or more audit cycles. All six hospitals had stroke units and five had previously participated in a FeSS Intervention study. Contrastingly, of the eight hospitals that were consistently ranked in the low adherence quantile for three or more audit cycles, only two had a stroke unit and the one hospital that had participated in a previous FeSS Intervention study no longer had a stroke unit or Stroke Coordinator. Although not a stated aim of the study, this convergence of evidence across studies in this research program further strengthened the validity and reliability of the findings.

Furthermore, identification of the Stroke Coordinator (or equivalent) as a potential determinant of sustained adherence to FeSS Protocols was a new finding not previously identified in the related quantitative study or other sustainability literature. Findings from this process evaluation highlighted that their role was pivotal as sustainability champions, through their advocacy and maintenance of earlier implementation

strategies. The Stroke Coordinators' success was largely determined by their 'boundary spanning' skills across disciplines, departments and organisations.

Referred to generically in this study as 'Stroke Coordinators' for ease of readability, it was noted that there were many variations of this title and responsibilities, consistent with other findings specific to this role in the literature.^{262,344} In Australia, this clinical leadership role in acute stroke is predominantly held by nurses but can also be assumed by an allied health clinician.²⁶² A proposed definition for nurse coordinator roles in 2010 was developed so that it is positioned within the Australian advanced practice nurse framework,^{344,345} however a recent survey of stroke coordinators in 2021 reported these roles remain undefined without a framework for practice that is specific to stroke.²⁶² The literature on the advanced practice nurse role was discussed in Study One and their impact on improved processes for other stroke clinical practice guidelines (e.g. rapid stroke/TIA screening, thrombolysis treatment times). This study has identified the Stroke Coordinators impact as a key factor in sustainment of adherence to FeSS Protocols. This finding is important not only for the sustained use of FeSS Protocols but also likely relevant to other stroke clinical practice guidelines. The Stroke Coordinator is recognised for their role in ensuring coordinated, best-practice care,²²³ but their key role as sustainability champions has yet to be acknowledged in the literature. It is recommended that all primary and comprehensive stroke services in Australia have a dedicated Stroke Coordinator role. Despite this, according to the 2023 national audit of acute stroke services (n=107 participating hospitals), only 70 of 86 (81%) services with stroke units and 11 of 21 (52%) services without a stroke unit reported having a dedicated Stroke Coordinator role. Highlighting the value of this nursing leadership position by acknowledging their critical role in sustainability, strengthens the rationale for staffing of the Stroke Coordinator role in all stroke services.

To our knowledge, this is the first study in acute stroke care to evaluate critical factors influencing sustained adherence to a stroke clinical practice guideline as identified by Stroke Coordinators (or equivalent) using the Sustainability of Innovation Framework. Published in 2015, this theoretical framework has been used in studies of nurse practitioners,^{334,346} and a longitudinal nursing study on the implementation of an acute pain protocol.³⁴⁷ However, this is the first time it has been tested in an acute stroke setting. Combined with purposive extreme sampling, the data obtained from end-users were analysed by factors already identified as being relevant to sustainability. This enabled focused and nuanced analysis to identify key differences based on hospitals' sustained adherence levels.

A summary of the individual study aims, and their corresponding main findings is presented in a table at the end of this section 6.2 (Table 1). This table provides a concise overview, allowing for comparison across the program highlighting key themes, outcomes, and methodological approaches.

Table 1. Summary of main findings from each study in this program

Study	Aims	Main findings
Study One	Undertake a systematic narrative hybrid review and synthesis of behaviour change interventions that improve hospital clinician adherence to any stroke clinical practice guideline, and those specific to fever, hyperglycaemia, and swallow management after stroke in adult patients.	• Interventions consisted of in-hospital care pathways, quality improvement collaboratives, advanced practice nurses, simulation training, continuous physiological monitoring, audit and feedback, a nurse-led care bundle, and multicomponent interventions. • There was a paucity in high quality evidence for interventions that improve clinician adherence to clinical practice guidelines. • The review highlighted the difficulties with translation of an improvement in processes into an improvement in clinical patient outcomes. • The effect of time was identified as a significant factor that can affect study outcomes (e.g. historical controls and study duration). • Study settings and local context were identified as major influential factors on uptake of stroke clinical practice guidelines. • There were no studies meeting inclusion criteria specific to passive implementation strategies that improve hospital clinician adherence to stroke clinical practice guidelines.
Study Two	i) Compare adherence to FeSS Protocols pre- and post- a ‘Strong Recommendation’ for their use in the Australian Clinical Guidelines for Stroke Management. ii) Determine if changes in FeSS Protocol adherence varied based on: (i) hospital prior participation in any treatment arm of a FeSS Intervention study or (ii) receiving treatment in a stroke unit.	• There was evidence of improved adherence to FeSS Protocols following a ‘strong recommendation’ for their use in the Australian stroke guidelines. • Maintenance of higher pre-guideline adherence was demonstrated for hospitals with prior participation in a FeSS Intervention study and patients cared for in stroke units. This suggests that research participation can facilitate greater guideline adherence; and confirms superior care received in stroke units.

	iii) Compare adherence to individual FeSS indicators across FeSS Intervention studies.	The overall proportion of patients treated with paracetamol for fever, and insulin for hyperglycaemia, has improved in clinical practice (audit cycles compared to FeSS Intervention studies). Adherence to swallowing variables was higher in QASCIP and T³ FeSS Intervention studies^{32,33} (compared to audit cycles).
Study Three	To identify from the viewpoint of stroke clinicians, individual and organisational factors perceived to have influenced uptake and sustained adherence to FeSS Protocols in Australian hospitals.	- Fourteen stroke co-ordinators from nine hospitals participated in semi-structured interviews. - Two major themes influenced sustained adherence: i) <i>Stroke Coordinators as sustainability champions and boundary spanners</i>; and ii) <i>Hospital executive and middle management respect of stroke specialty</i>. - Themes mapped to four factors from the sustainability framework³⁴² that identified key differences for sustaining adherence to FeSS Protocols: <i>Workforce</i> (the Stroke Coordinator model [single vs team of champions]) <i>Organisational</i> (working relationships, designated stroke speciality area and nursing staff) <i>Innovation-specific</i> (local adaptations) <i>Political</i> (organisation / district / national directives)

¹ Quality in Acute Stroke Care Implementation Project (QASCIP) 2013–2014 Pre-Post Study: Supported implementation FeSS Protocols in all stroke services NSW)

² Triage, treatment and transfer (T³) 2013–2016 Randomised Controlled Trial: Supported implementation FeSS Protocols in Emergency Departments)

³⁴² Sustainability of Innovation Framework

6.3 Strengths of the research program

The strengths of the individual studies undertaken as part of this doctoral research program have been highlighted in Chapters Two, Four and Five. This section elaborates on how these strengths are inter-related and how they collectively contribute to the strengths of the overall research program.

Key attributes of this doctoral research program and thesis are: i) its integration within the broader QASC program of translational research; ii) an inclusive review of relevant literature on any interventions that improve adherence to stroke clinical practice guidelines; iii) access to representative datasets from National Stroke audits; and iv) the inclusion of end-user perspectives in a process evaluation conducted outside of a time-limited clinical trial setting. These strengths discussed individually below, collectively provided a multifaceted exploration of adherence and sustainability of the FeSS Protocols over time, contributing new insights into the long-term evaluation of scale up of an evidence-based stroke clinical practice guideline and implementation science.

6.3.1 Integration within the broader QASC program of translational research

The advantages of being embedded within the broader QASC program of translational research are multi-factorial. This consisted of access to internationally renowned implementation science experts within the team,³⁴⁸ who led this work to obtain context and clarification where necessary,³⁴⁸ and to the rich historical sources of data and theory already established in the program of translational research since its inception. Most doctoral research programs are to be completed in three or four years, which limits what can be achieved in this short time frame. However, contributing new knowledge to an established body of work creates the opportunity to build on existing understanding, and minimise research waste and

expenditure to address the core issues effectively. Evaluation of the natural history of diffusion of evidence into practice over time alongside a translational research program that has embedded implementation science into each FeSS Intervention study design, is a rare opportunity. A recent systematic integrative review of sustainability of healthcare system improvements, programmes and interventions found that the majority of studies measured sustainability of a programme at one to two years after implementation.¹¹¹ This finding highlights the substantial and novel aspect of the timeline associated with this thesis. The seminal QASC Trial was conducted from 2005-2010 with efficacy results fast-tracked for publication in the Lancet in 2011.³¹ This research generated an additional thirteen peer reviewed publications and the trial was subsequently awarded multiple national and international accolades most notably, the American Heart Association Council on Cardiovascular Nursing 2012 Stroke Article of the Year (and also in 2023) and inclusion in the Faculty of 1000 Library-Top 2% of international articles (biology and medical research).³⁴⁸ Statewide scale-up of FeSS protocols into all stroke units in New South Wales (Australia) was conducted from 2013-2014 in the QASC Implementation Project,³³ and another multicentre randomised controlled trial (RCT) of FeSS Protocols into emergency departments in the T³ Trial from 2013-2016.³³ Internationally, FeSS Protocols have been translated into 18 countries and 72 hospitals in Europe (2017-2022).^{35,36} The results of the studies comprising the QASC program of translational research have been widely disseminated and published in high quality journals, ensuring the evidence-based use of FeSS Protocols for acute stroke remains topical locally and internationally. Yet, the evidence-practice gap still persists. The opportunity to evaluate the combination of these active translational research efforts alongside the effect of inclusion in national clinical practice guidelines (2017),²² and monitoring with biennial national stroke audit and feedback cycles (2013 onwards),⁷⁰ presents a comprehensive historical timeline of the diffusion-dissemination-implementation continuum. This thesis evaluates current findings in the context

of the wider QASC program of translational research program, which represents a unique strength of this work.

6.3.2 Inclusive review of relevant literature on any interventions that improve adherence to stroke clinical practice guidelines

A systematic-narrative hybrid review was undertaken in Study One (Chapter Two) of this doctoral research program to understand what interventions had been tested for clinical adherence to fever, sugar and swallow management and other stroke clinical practice guidelines. At the time of conducting the review, a Cochrane systematic review on a similar topic,¹⁴⁵ was identified in the international prospective register of systematic reviews (PROSPERO). This systematic review included a meta-analysis to synthesise the evidence from randomised and cluster randomised controlled trials and was restricted to stroke units. A Cochrane systematic review is typically considered the gold standard for summarising evidence-based literature.³⁴⁹ However, for the purpose of this thesis, the scope was broadened beyond stroke units and the strict criteria of a Cochrane review. A systematic-narrative hybrid review approach was used, allowing additional systematic reviews (of mixed study designs) to be incorporated and single RCT studies. This enabled a more comprehensive overview of interventions aimed at improving adherence to stroke clinical practice guidelines. The broader QASC research program has demonstrated locally³³ and internationally³⁴ that the FeSS Protocols can be used in non-stroke unit settings. The inclusion criteria for studies in the systematic-narrative hybrid review were not limited to stroke unit settings, allowing studies from countries such as the USA, where a stroke unit is defined differently from many countries,¹⁴⁵ to be included.

The Cochrane review was inconclusive on the effects of implementation interventions on adherence to evidence-based recommendations in acute stroke units because the certainty of evidence was very low.¹⁴⁵ This finding provided further impetus for a more inclusive

type of review, consistent with the research paradigm (critical realism) underpinning this thesis. This paradigm supports the use of diverse research methods, where necessary, to answer the questions driving the research.¹⁹⁸ Almost half of systematic reviews now include non-randomised studies of intervention effects.¹³⁵ The incorporation of these study designs acknowledges the important contribution they make in relation to the overarching aim of the systematic-narrative hybrid review. The literature recognises the underuse of RCTs in implementation science.³⁵⁰ This relates to longstanding debate about the suitability of stringent RCT criteria which do not accurately reflect the complexities of real-world implementation settings.³⁵¹ This debate is evolving with increasing recognition and use of pragmatic implementation science trial designs that depict real-world context.³⁵² The mixed methods research (if included in a systematic review) identified in the systematic-narrative hybrid review undertaken as part of this thesis is accompanied by an appropriate risk of bias assessment¹³⁵ and the findings are discussed in relation to other RCTs of the same intervention (Chapter Two). The review provided a comprehensive overview of all research relevant to the broad review topic of improving clinician adherence to any stroke clinical practice guideline.

6.3.3. Use of representative datasets from National Stroke audits

The systematic-narrative hybrid review in Study One (Chapter Two) highlighted the challenges in implementation research of translating improvements in processes of care into clinical patient outcomes. This finding guided the design of Study Two (Chapter Four) which analysed National Stroke audit data to report on improvements in FeSS processes of care as the primary outcome, rather than clinical patient outcomes already established in the seminal QASC Trial³¹ more than a decade ago. Access to these audit data is a notable strength of this research program in relation to its size and representativeness. Although prospective, continuous stroke data such as that collected

in the Australian Stroke Clinical Registry (AuSCR) is scientifically more robust when compared to retrospective cross-sectional audit data, the participation rates for AuSCR are not yet as representative²³⁰ as those of the National Stroke audits. There are over six hundred hospital facilities in Australia,²²⁸ but many do not manage acute stroke, or are very small hospitals and clinics that manage less than twenty strokes per year. For the National Stroke audit, only hospitals that manage greater than 50 stroke admissions each year are invited to participate.^{295,315} In the most recent audit, there were 107 hospitals that participated.³¹⁵ The AuSCR does not exclude hospitals based on stroke admission numbers, but in 2023 only 65 hospitals across seven states and territories entered data into the registry.²³¹ Hospitals from the Northern Territory do not participate and only one hospital (paediatric) in NSW contributed data.²³¹ Of these 65 hospitals, 24 (37%) hospitals were voluntarily contributing data to the optional FeSS dataset.²³¹ This additional dataset has been available since July 2019 and contains variables relevant to fever and sugar (hyperglycaemia). The minimum dataset in AuSCR collects swallow screening and assessment variables only.³⁵³

Currently the National Stroke audit contains data reflective of 89% of all acute stroke admissions in Australia. These voluntary, non-funded audit participation rates are commendable when compared to other mandatory audit programs such as the Stroke Sentinel National Audit Programme in the UK that reportedly captures 90% of admitted strokes in that country. The use of the extensive National Stroke audit dataset in this thesis provides the only available representative overview of the Australian in hospital acute stroke population that includes both stroke unit and non-stroke unit care.

Investigating the use of FeSS Protocols outside of speciality stroke units is a significant marker of diffusion of the evidence for their use and sustainability in real-world clinical settings over time.

6.3.4 Use of end-user perspectives in a process evaluation conducted outside of a time-limited clinical trial setting

Including the perspectives of end-users in Study Three provided a deeper understanding of the quantitative results from Study Two and the findings from the systematic-narrative hybrid review in Study One. Comprehensive exploration of the overarching aim of this thesis was achieved through the collection of qualitative data that was specific to a hospital's adherence level to FeSS Protocols. National Stroke audit data across the years 2015-2021 was used to determine these adherence levels. The assessment of individual and organisational factors influencing sustained use of FeSS Protocols as reported by hospitals with varying FeSS Protocol adherence levels, provided critical insights into this complex topic. Clinician acceptance has been identified in the literature as a key factor for sustainability. The inclusion of Stroke Coordinators (or equivalent) perspectives as the end-users of FeSS Protocols was critically important to identify potential issues with clinician acceptance of the FeSS Protocols. The substantial years of clinical experience (median 21, range 9-35) further strengthened the justification of their selection as the primary interview participants as the most likely to have knowledge on the use of FeSS Protocols in their respective organisations.

The use of qualitative research methods using semi-structured interviews was also considered an important strength of this doctoral research program because of the opportunity to ask additional questions that were not pre-determined. This adaptability allows for the emergence of unanticipated insights and themes, enriching the data and enhancing its relevance to real-world contexts.³⁵⁴ Surveying a large group of clinicians was considered as an alternative, but the use of purposeful extreme sampling was regarded as superior in terms of efficiency in determining key differences between participant responses. Semi-structured interviews with a small sample of participants from hospitals representing each strata (i.e. consistently high, low and variable FeSS

Protocol adherence across the audit years 2015-221), provided the opportunity to clarify and explore responses further in an interview setting. In contrast, pre-planned closed-ended survey questions do not have this flexibility and is also limited in open-ended survey questions.³⁵⁵

The conduct of this process evaluation outside of a time-limited clinical trial was an additional novel strength of this study. Most commonly, process evaluations are conducted alongside or soon after a clinical trial to understand the implementation process and why an intervention did or did not work.²⁴⁸ Previous process evaluations conducted as part of the broader QASC program of translational research were conducted during or soon after the FeSS Intervention studies were completed.^{38,39} The focus of the process evaluation in Study Three was on the sustainment of implementation strategies longer-term, rather than short term implementation outcomes. This approach provided critical insights into the practical implications of the longer-term requirements of maintaining adherence to the FeSS Protocols and other stroke clinical practice guidelines as told from the perspective of end-users.

Collectively, the strengths of this doctoral research program (integration within the broader QASC program of translational research program, a comprehensive review of relevant literature, use of large representative datasets, and the inclusion of end-user perspectives in a long-term, real-world process evaluation) provided a robust understanding of FeSS Protocol adherence and sustainability over time, significantly contributing to the field of implementation science in stroke care.

6.4 Limitations of the research program

Similar to section 6.3 Strengths of the research program; the limitations of the individual studies undertaken as part of this doctoral research program have been highlighted in the relevant Chapters Two, Four and Five. This section outlines the constraints of the research

program as a whole, including the methodological limitations of the findings in the systematic-narrative hybrid review, the use of secondary data, potential for selection bias, and their possible impact on study outcomes.

6.4.1 Methodological limitations of the findings in the systematic-narrative hybrid review

The findings from the systematic-narrative hybrid review in Study One (Chapter Two) on interventions designed to improve hospital clinician adherence to any stroke clinical practice guideline, and those specific to fever, hyperglycaemia, and swallow management after stroke in adult patients, was limited by a lack of high-quality evidence. The inclusion of lower-level study designs in some of the included systematic reviews^{140,145,141,143} could be attributed to the lack of certainty in the evidence which limited the generalisability of the results and overall interpretation. Additionally, many of the single RCTs did not achieve their primary outcomes.^{32,62,141,143,145,149-151} It is standard practice to examine secondary outcomes to better understand the characteristics of treatment effects. However, if the primary outcome (on which the study was designed) is not statistically significant, no definitive conclusions should be drawn from secondary outcomes due to the increased risk of type I error (false positive) when testing multiple outcomes.³⁵⁶ Although, the study results should be considered as a whole, the primary outcome is the key measure on which an intervention's efficacy is evaluated. Interpreting the findings of the systematic-narrative hybrid review was made more complex by the limitations and/or the potential bias of lower level study designs included in some of the systematic reviews. These issues also restricted the overall narrative analysis and synthesis.

6.4.2 Use of secondary data

Secondary data were used for two of the studies in this doctoral research program. This method addresses new questions from a dataset previously gathered for a different primary

study. Criticisms of this method are that the researcher has no control over the variables already collected or the primary study design.

In Study Two (Chapter Four), National Stroke audit data were used to conduct a pre-test/post-test quantitative study examining adherence to stroke guidelines for fever, hyperglycaemia, and swallowing (FeSS) management post-stroke. Process of care indicators related to the management of fever, hyperglycaemia and swallowing during the in-hospital admission period for stroke have been included in the audit since 2013. These data were also used in Study Three (Chapter Five) to derive the sample of hospitals selected to be interviewed for the process evaluation study. The data collected in the audits are intended to report on adherence to the recommendations outlined in the Clinical Guidelines, as well as indicators from the Australian Stroke Coalition (ASC) agreed data framework and the Australian Council on Healthcare Standards (ACHS). In 2015, the data were reviewed, and a number of elements were removed in a bid to reduce the data entry burden for clinicians. This resulted in a 25% reduction in data entry which included the removal of FeSS monitoring variables (specifically, how often the temperature and blood glucose levels were measured and recorded). Hence, the FeSS variables used from 2015 onwards in this secondary source of data were subject to ‘availability bias’,²⁴³ as only the treatment variables for fever and hyperglycaemia were collected (that is, whether the patient received prompt treatment for fever and/or hyperglycaemia). This prevents any direct composite score comparisons between the National Stroke audit data and the FeSS Intervention studies. As discussed in Chapters Three and Four, a binary composite measure has been consistently used across the broader QASC program of translational research to present results. To maintain consistency with the broader research program, this approach has been used again to present the quantitative results in this thesis. However, formal comparisons between the quantitative study results from this program and the FeSS Intervention studies were not possible due to differences in

the variables comprising the composite outcome. Additionally, variations in the FeSS Intervention study designs further limited comparative analysis (e.g. some studies were RCTs, and others were pre-test/post-test study design).

Despite these limitations, the secondary data source used in this research program offers significant advantages by being the only nationally representative dataset available and is cost-effective. The prohibitive costs and resources to undertake primary data collection would not have been feasible for the purpose of this doctoral research program. Additionally, the statistical support the data custodians were able to provide in managing the longitudinal data ensured the data were adequately analysed and consistent with how previous audit data have been presented. Furthermore, programmed logic checks are conducted on the audit data to maximise the accuracy of data collected, and three to five cases are independently validated by a second auditor further increasing reliability of the data.

6.4.3 Potential for selection bias

The voluntary nature of participation in the national audits (Study Two in Chapter Four) and in the interviews (Study Three in Chapter Five) introduced the potential for selection bias, as those who volunteer to participate may be different from those who do not (systematic error). This bias was offset by the representativeness of national audit data in relation to the target population which was highlighted as a strength in Section 6.3 (the audit data is indicative of 89% of all acute stroke admissions in Australia and comparable to mandatory international audit programs).⁸ The Stroke Coordinators who agreed to be interviewed for the process evaluation in Study Three (Chapter Five) did not self-select as the hospitals were purposefully selected (based on their hospital's FeSS Protocol adherence over three or more audit cycles and other strata). The use of secondary interviews was intended as a form of corroboration of data sources to help mitigate any potential bias.

Despite the methodological limitations outlined, these were carefully considered and addressed in the design of the doctoral research program. The findings from this thesis provide a valuable contribution to both the wider QASC program of translational research and the broader field of sustainability of implementation strategies for improving adherence to clinical practice guidelines for stroke care.

6.5 Recommendations

The use of FeSS Protocols for stroke in Australian hospitals, after their inclusion as recommended care in the 2017 National Acute Stroke Guidelines has been investigated in this doctoral research program. Embedded within the wider QASC program of translational research, this thesis provided a unique opportunity to study the diffusion of this evidence into acute stroke care services and to evaluate the sustainability of implementation strategies used in earlier FeSS Intervention studies in real-world clinical practice longer-term. This doctoral research program has provided critical new insights into the need for hospital support in the implementation of clinical practice guidelines.

Based on the findings of this doctoral research program, which contribute to the body of knowledge on clinician behaviour change and the sustainability of both active and passive implementation strategies, recommendations for policy, clinical practice and future research are proposed in relation to organisational, individual, and system level actions required. A brief discussion of each recommendation is provided, and a summary of the recommendations are presented at the end of this section in Table 2.

6.5.1 Policy (*Systems level*)

Recently, the Australian Stroke Clinical Registry (AuSCR) was awarded a new three-year \$1.5 million funding package under the Australian Government's National Clinical Quality Registry Program. The registry program is a Commonwealth led initiative in partnership with the Australian and State/Territory governments, together with the Australian Safety and Quality Commission and the Australian Institute of Health and Welfare (AIHW). This funding for the AuSCR, recognised as a clinical priority in Australian healthcare, is expected to enable national participation from all Australian stroke services allowing them to continuously enter data into the registry, thereby replacing the biennial National Stroke cross-sectional audits.²³³ As the expert advisory panel and committee work towards finalising the minimum reporting variables, it is essential that the FeSS variables are included in the registry and made mandatory for hospitals to collect, to promote ongoing monitoring of adherence. As highlighted in this thesis, when the use of clinical practice guidelines is supported with an active implementation strategy such as audit and feedback, there are improvements in adherence to FeSS Protocols. This is supported by the meta-analysis of 292 trials from the most recent Cochrane review on audit and feedback in healthcare, which reported a 6.2% improvement in compliance with professional practice (95% CI 4.1 to 8.2) and an adjusted odds ratio of 1.47 (95% CI 1.31 to 1.64).^{97,316}

Additionally, it would be beneficial to include both FeSS monitoring and treatment variables in the AuSCR to capture data on these common complications in Australian patients who experience stroke. Data on the monitoring of temperature for fever and blood glucose level for hyperglycaemia are currently not included in the minimum reporting variables for the National Stroke audits. Although data on the presence of fever and hyperglycaemia are collected, the true denominator is unknown. Without mandatory and systematic monitoring of these common post stroke complications, they may be missed or only identified incidentally.

Furthermore, it would also be beneficial to consider including FeSS monitoring and treatment variables in the Australian Commission of Quality and Safety in Health Care, Acute Stroke Clinical Care Standards so they could continue to inform quality acute stroke care. The standards were last updated in 2019 and a revision is expected in 2026.³⁵⁷ Clinical care standards are concise, evidence-based statements that define the essential components of high-quality care for specific conditions or procedures. These differ to clinical practice guidelines which provide comprehensive recommendations to guide clinical decision-making across a wide range of scenarios.⁶⁶

Mandatory monitoring of FeSS variables in the AuSCR and the Acute Stroke Clinical Care Standards also provides opportunities to identify variations in practice (low FeSS Protocol adherence) so that hospitals could implement targeted implementation support and strategies. This doctoral research program has highlighted how critical support, such as that received by participating in a FeSS Intervention study, is to the implementation of FeSS Protocols and sustained adherence to the protocols over time. With national participation in the AuSCR to monitor these variables, a quality improvement learning health system⁸² package could be developed to be delivered by individual hospital quality improvement teams. A learning health system is a continuous learning approach that integrates existing evidence and real-world data to inform clinical decision making. The broader Australian Stroke Learning Health System has been used as an exemplar case study, demonstrating how this framework can deliver clinical benefits. Further refinements to this data-driven learning model could support the development of an implementation and education package for sites identified as having variation in practice. This package would contain strategies and resources for quality improvement (similar to the resources already publicly available on the QASC website) to be implemented by individual hospital quality improvement teams.

In addition to the improved patient outcomes demonstrated in the original QASC Trial, that is the 15.7% reduction in death and dependency at 90 days post stroke,³¹ and longer-term reduction in mortality out to four years,³¹ two independent economic evaluations have also reported significant cost savings to the Australian healthcare system if FeSS Protocols were used.^{65,310} However, with only 2 in 5 patients receiving care in accordance with FeSS Protocols in Australian hospitals, there is a clear need to intensify efforts to implement these protocols. Continued efforts to promote the adoption of FeSS Protocols at the systems level are essential in achieving the full potential of these benefits and improving the quality of stroke care in Australia.

6.5.2 Clinical Practice (*Individual and organisational levels*)

In view of the findings from the studies in this thesis, there is a need for ongoing education and reminders regarding the importance of managing fever, hyperglycaemia and swallow swallowing in patients following a stroke. The FeSS Protocols should be prioritised and incorporated into stroke service local protocols and policies irrespective of their stroke unit status. The wider QASC translational research program has demonstrated that these protocols can be implemented outside of stroke speciality units³⁴ when admission to a stroke unit is not possible. Although the protocols are designed to be nurse-led, it is imperative they are endorsed and approved for use by the multidisciplinary team for effective implementation. In Study Three (Chapter Five), Stroke Coordinators (or equivalent) described how support from other disciplines could be both an enabler and a barrier (if this support was not forthcoming) to FeSS Protocol implementation. Engaging other related disciplines, such as speech pathology and medical leads, to review and approve the integration of FeSS Protocols into local protocols and policy promotes adherence longer-term. These organisational level approved documents can then be used as a resource to reinforce the importance of adherence to FeSS management principles. Local protocols and policies may require minor adaptations

to suit local context, which is acceptable as long as the core concepts of the intervention remain unchanged³³⁰ for example, some Stroke Coordinators in Study Three (Chapter Five) reported an endocrinology referral was required before commencing an insulin infusion). Adaptations of this nature, made to suit the local context and circumstances, are believed to promote sustainability.¹¹⁴ The evidence base and supporting resources for FeSS Protocols should be included in the orientation of new hospital staff, particularly junior medical staff that rotate frequently. For existing staff, ongoing education and reminders on the importance of adherence to FeSS Protocols could be included into scheduled activities such as annual competency assessments (e.g. dysphagia screening).

Monitoring of ongoing research is required to ensure FeSS Protocols align with best practices and the latest evidence. As the FeSS Protocols are included as a recommendation in the national stroke clinical guidelines, new evidence is continually monitored and reviewed as part of the world's first living clinical guidelines model. The Stroke Foundation partnered with Cochrane Australia to develop this model in 2018.^{288,289} This ensures new evidence relevant to stroke is continually monitored and the guidelines are updated as required to guide clinical practice and policy development.

6.5.3 Reporting (*Systems level*)

In addition to FeSS variables being included in the mandatory minimum reporting requirements for the AuSCR, further reporting recommendations are proposed. These consist of having FeSS variables and performance indicators continue to be available as a clinical dashboard for reporting variables within the AuSCR platform. Since 2023, clinicians are able to visualise summary data via interactive dashboards for some stroke quality indicators. These near real-time results reflect hospital-specific data, and importantly allow for benchmarking against national standards.³⁵⁸ FeSS variables have recently been included in these dashboards, for hospitals that contribute to this optional dataset in the AuSCR.³⁵³ Despite the growing

popularity of clinical dashboards, the evidence for their use is mixed.^{359,360} This relates to the way they are used (e.g. constant screen saver view compared to clinician choice to access the information)³⁶⁰ and the quality of the information presented.³⁶¹ Nonetheless, these live reports signal to clinicians that FeSS variables are a quality care metric and an important component of stroke patient care. Hence, they should remain available to clinicians in the AuSCR.

Another reporting recommendation at the systems level, is for adherence to FeSS Protocols to be incentivised through a rewards program. There are two quality stroke service reward programs available in Australia. The World Stroke Organisation Acute Networks StrivinG for ExceLLence in Stroke (ANGELS) Awards are designed to acknowledge and honour teams and individuals committed to stroke practice and to establish a culture of continued monitoring.⁸³ Hospitals in Australia that capture treatment data in a pre-approved registry or database can participate in this program based on global benchmarks for best-practice stroke care. The Australian Stroke Coalition Quality Stroke Service Awards is another incentive-based rewards program that recognises excellence in hospital acute stroke care. This program is more comprehensive than the ANGELS Awards and assesses performance against the Australian Acute Stroke Clinical Care Standards⁶⁶ using national audit and registry data. The appeal of rewards programs is wide-reaching, from clinicians through to hospital executives and consumers. In Australia, all public and private hospitals must be accredited under the National Safety and Quality Health Service (NSQHS) Standards. The regular accreditation cycles are a quality assurance mechanism to ensure that appropriate systems are in place to meet expected standards of safety and quality, and in some cases are linked to funding. Monitoring the quality of stroke care provided and participation in a rewards program that recognises this is one way for hospitals to demonstrate their alignment with NSQHS standards. The Acute Stroke Clinical Care Standard was designed to align with many of the NSQHS Standards which health service organisations are evaluated against.⁶⁶ Having the

FeSS variables incorporated into the Acute Stroke Clinical Care Standard would allow hospitals to streamline care processes, reduce variation, and enhance clinical governance and performance monitoring. Additionally, a rewards program incentivises and highlights to clinicians the importance of this component of stroke patient care.

Embedding the FeSS variables in the mandatory minimum reporting requirements in the AuSCR alongside their inclusion in the dashboards, the national acute stroke clinical care standards, and an incentive-based rewards program has the potential to improve adherence to FeSS Protocols by emphasising their importance as a quality of care metric.

6.5.4 Future Research (*Organisational level*)

There are several recommendations for future research that have been identified based on the findings of this doctoral research program.

1. Uptake of optional AuSCR FeSS dataset and its association with adherence to FeSS Protocols over time.

The first future research priority is to evaluate the existing AuSCR data, specifically the uptake of the optional FeSS dataset and its association with adherence to FeSS Protocols over time. This optional dataset has been available since July 2019. Possible research questions that could be addressed using this existing data source include:

- i) Do hospitals that enter FeSS data in AuSCR demonstrate better adherence to FeSS Protocols in the historical National Stroke audit data compared with hospitals that do not enter these data?

- ii) Does entry of FeSS data in AuSCR improve adherence to FeSS Protocols over time?

This future research will be of significant interest to the Australian stroke research community given the transition from the National Stroke audits (used for the last twenty years) to national data collection in the AuSCR.²⁸⁵ It may also have broader implications for other clinical registries in the National Clinical Quality Registry Program. There is growing evidence of the association between the number of in-hospital processes of care that a patient receives and improved patient outcomes.¹⁰²⁻¹⁰⁴ Of interest will be whether hospitals already collecting data in the registry demonstrate higher adherence to FeSS Protocols and/or if adherence to FeSS Protocols improves over time.

Study Design and Methods

The research questions can be addressed with a cross-sectional observational study design. Specifically, analysis would include testing for (i) any correlation with the composite score derived in the corresponding 2019 and 2021 National Stroke audit cycles and (ii) time series analysis to test for change in adherence to FeSS Protocols over time. A different composite score would need to be derived for the latter part of this analysis based on the FeSS processes captured in the AuSCR which include some monitoring variables not collected in the National Stroke audits.

2. Using AuSCR data to identify variance in FeSS Protocol adherence and develop targeted implementation support.

Future research using the national AuSCR platform to capture FeSS data is recommended to identify low adherence to FeSS Protocols and develop a targeted intervention to address this variation. The significant costs and resources required for conducting large translational research studies on FeSS Protocol implementation could be optimised by focusing efforts on hospitals where low adherence to FeSS Protocols has been identified. Poor baseline levels or variation in practice has been identified as a condition most conducive to active implementations strategies such as audit and feedback.⁹⁵

Study Design and Methods

The data source for this future research will be scientifically more robust as the data are collected prospectively. A prospective pre-test/post-test study design could be used to i) identify variation in practice (low FeSS Protocol adherence, ii) evaluate uptake of the offer for targeted intervention and iii) undertake a post-test evaluation to compare hospitals that accepted the intervention to their own pre-test baseline performance, as well as to hospitals that did not take up the offer of targeted intervention.

A consideration for future research and methods for analysis is the use of an opportunity composite score in addition to a binary composite score. An opportunity composite score is calculated as the number of times a required process was performed against the total number of instances in which care processes were required. The binary composite score used consistently across the QASC program of translational research, is calculated as the number of patients who received all required care processes against the total number of patients eligible for care processes. Using both scores would enable tracking of incremental

improvements as well as overall adherence to FeSS Protocols. This additional level of detail would help clinicians identify if there are specific aspects to the complex implementation of FeSS Protocols that may require more focused attention. This example of providing very specific feedback, rather than general feedback, is also supported in the literature as a key strategy for optimising effective audit and feedback.

The findings from the original QASC Trial demonstrated that when nurses were supported to implement FeSS Protocols, this translated to significantly improved patient outcomes.³¹ These findings are strengthened by the results from this doctoral research program, which has also identified additional longer-term benefits from participating in the treatment arm of any of the FeSS Intervention studies in the QASC program of translational research. To build on these findings, further research is required to determine the dose of targeted support required for FeSS Protocol implementation. The intensity of external remote facilitation to support Australian and New Zealand stroke units and stroke services to implement FeSS Protocols is currently being evaluated in a multi-country cluster RCT, the QASC Australasia Trial. The outcomes of this trial are expected to provide valuable insights that could potentially reduce evidence-implementation costs and resources and improve clinical practices. These findings will have meaningful clinical importance both locally and internationally. A process evaluation will be conducted as part of this trial's design to examine the contextual factors influencing intervention uptake. Identification of clinicians' views regarding factors that influence uptake of the FeSS Protocols in metropolitan, rural and remote hospitals will be critical to the wider QASC program of translational research. The clinicians' perspectives will inform plans for the development of an implementation package to support further implementation scale up and spread both locally and internationally.

3. Evaluating the management of fever and hyperglycaemia, with the incorporation of both FeSS monitoring and treatment variables as mandated data items within AuSCR.

Details are still emerging regarding the transition from biennial Stroke Foundation National Stroke audits to the new methodological approach for collecting continuous prospective national stroke data in the AuSCR. Despite the audits and AuSCR both using standardised variables from the National Stroke Data Dictionary collected in the Australian Stroke Data Tool, their datasets and programs are quite different. Only hospitals with greater than 50 stroke admissions each year are invited to participate in the National Stroke audit. In the most recent 2023 cycle, there were 107 hospitals that participated. In comparison, the AuSCR includes smaller hospitals (with no minimum annual stroke admissions) and in 2023 reported data contributions from 65 hospitals across seven states and territories. Of these, 24 (37%) hospitals were voluntarily contributing data to the optional FeSS dataset. This is a positive result and reflects the clinicians' interest in this variable set. FeSS monitoring variables were removed from the National Stroke audit after 2013 to reduce the data entry burden on clinicians. It is imperative that both FeSS monitoring and treatment variables are reinstated in the finalised mandatory minimum dataset for the national stroke registry. The evidence for these nursing quality of care indicators was derived from the QASC RCT, which established a bundled care approach based on three protocols (Fever, Sugar and Swallow Protocols). This is one of the few nursing-led interventions demonstrated to improve patient outcomes, reducing 90 day morbidity and mortality³¹ and longer-term morbidity.⁴⁵ Inclusion of these variables in the AuSCR would facilitate their ongoing evaluation and monitoring in association with patient outcomes. Although the variables specific to swallow are currently included in the minimum dataset for AuSCR, there are no variables for monitoring or treating fever and hyperglycaemia (these are only captured in the optional AuSCR FeSS dataset). While this aligns with common variables collected in other stroke registries globally,³⁶² there is no

evidence to suggest that the findings observed in the QASC Trial were specifically associated with the swallow protocol of the bundled FeSS Protocols intervention. The evidence of effectiveness was for all three FeSS Protocols. The incidence rates for fever and hyperglycaemia^{17,18} are as common as swallow complications,²⁰ with equally serious consequences for patient outcomes.^{363,364} Hence, it is essential that all FeSS variables are included in the future mandatory minimum reporting dataset to be used in the AuSCR, particularly as the evidence from the original QASC Trial is for the bundled intervention (ie fever, hyperglycaemia and swallowing). This will not only enable the monitoring of adherence to these evidence-based quality of care indicators but also provide important data of how effectively these common stroke complications are managed in the Australian stroke population.

Study Design and Methods

At the systems level, evaluating the management of common stroke complications such as fever, hyperglycaemia and swallow, could be undertaken using prospective national registry data, provided both monitoring and treatment FeSS variables are included in the mandatory minimum dataset. It would also be of interest to determine whether fever, hyperglycaemia and swallowing complication rates are higher compared to those previously reported in the retrospective National Audits that only included the FeSS treatment variables. To achieve this a pre-test/post-test study using historical National Audit data compared to prospective AuSCR data would be required.

A summary of each recommendation discussed in this section is presented in Table 2. This table consolidates the key points, with an overview of the proposed actions, and application of the findings outlined in this thesis and preceding discussion.

Table 2 Summary of recommendations for adherence to the FeSS Protocols in Australian acute stroke services

Topic	Recommendation
Policy (<i>Systems level</i>)	1. FeSS monitoring and treatment variables should be included in the mandatory minimum reporting variables to be collected in AuSCR and the ACSQHC Acute Stroke Clinical Care Standard. 2. Hospitals with variations in adherence to FeSS Protocols to be offered targeted implementation support and strategies. This could be developed as a quality improvement learning health system¹⁸⁴ package to be delivered by individual hospitals/regions by quality improvement teams.
Clinical Practice (<i>Individual and organisational levels</i>)	1. Ongoing education of stroke clinicians should be conducted for orientation of new personnel by stroke leaders of all disciplines on the evidence base for and the importance of the use of FeSS Protocols. This could also be incorporated into annual competency assessments (e.g. dysphagia screening) for existing staff. FeSS Protocols should be incorporated into local protocols and policies. 2. Monitoring of current research best practices and update FeSS Protocols as required if new evidence emerges.
Reporting (<i>Systems level</i>)	1. Early dashboard development and reporting to continue to be available for clinicians to view real-time results as collected in Australian Stroke Clinical Registry. 2. Adherence to FeSS Protocols incentivised in a recognised rewards program for stroke care quality.
Future Research (<i>Organisational level</i>) Evaluation of uptake of optional Australian Stroke Clinical Registry FeSS dataset and its association with adherence to FeSS Protocols over time.	Study Design and Methods 1. Cross-sectional observational study using existing data of hospitals that contribute data to the optional FeSS dataset in the Australian Stroke Clinical Registry. Testing for (i) association with corresponding FeSS composite score derived in relevant National Stroke audit cycles and (ii) if adherence to FeSS Protocols has improved since data collection commenced using continuous data collection in Australian Stroke Clinical Registry.

Future Research <i>(Organisational level)</i> Evaluation of FeSS Protocol adherence using Australian Stroke Clinical Registry data to identify low adherence and offer levels of targeted implementation support.	Study Design and Methods 2. i) Prospective study to identify low FeSS Protocol adherence and evaluate uptake of targeted intervention. ii) Targeted intervention ‘doses’ will be informed by results of QASC Australasia Trial which is testing the level of facilitation support required to implement FeSS Protocols.³⁰⁶
<i>(Systems level)</i> Evaluation of the management of fever and hyperglycaemia with the inclusion of both FeSS monitoring and treatment variables in the AuSCR <i>(Collection of these variables are currently optional in AuSCR).</i>	3. Pre-test/post-test study using historical National Audit data compared to prospective AuSCR data to evaluate if monitoring for fever and hyperglycaemia in the first 72hours is associated with any differences in reported complication rates and their management in all acute stroke services.

6.6 Summary and conclusions

Inclusion of a 'strong recommendation' for all acute stroke services to implement FeSS Protocols in the 2017 national stroke clinical practice guidelines occurred several years after the seminal QASC Trial results were published in 2011 for the management of fever, hyperglycaemia and swallow complications. This doctoral research program evaluated the diffusion of the FeSS Protocols for stroke in Australian hospitals. National stroke data was used to evaluate adherence to FeSS Protocols as a measure of sustainability outcomes. Front-line clinician perspectives of factors that influence adherence to the FeSS Protocols were used to assess sustainment of implementation strategies. Additionally, the long-term outcomes of exposure to the active implementation strategies employed in earlier FeSS Intervention studies (QASC, QASCIP and T³ studies) were compared to those resulting from passive dissemination of clinical practice guidelines and biennial national audit participation. The evidence-based stroke clinical practice guideline specific to implementing the FeSS Protocols, and the study of diffusion of this evidence into acute stroke care services, provides new insights into the longer-term outcomes of implementation strategies for stroke clinical practice guidelines.

For this doctoral research program, quantitative national stroke audit data and qualitative interview data from senior stroke clinicians were obtained, collated, analysed and evaluated to comprehensively examine the use of FeSS Protocols in Australian hospitals. The overall research findings have provided valuable insights and new knowledge to better understand clinician behaviour change. They also substantiate existing evidence on passive dissemination and highlight the value of specialised stroke unit care. Importantly, this doctoral research program contributes new knowledge regarding the need to support hospitals in implementing clinical practice guidelines, and the long-term outcomes of both passive and active implementation strategies and evidence on the value of Stroke Co-ordinators.

The process of changing clinician behaviour and translating evidence into clinical practice is widely recognised as being challenging. This novel program of research examines the history of a fifteen year translational research program to actively disseminate, upscale and spread implementation of the evidence-based FeSS Protocols into everyday clinical practice. The adoption of a critical realist lens to explore the complex process of translating evidence into clinical practice facilitated the identification of underlying mechanisms and contextual conditions that contributed to sustainability of the FeSS Protocols. Deeper insights into how and why evidence-based interventions succeed or fail in clinical practice, have provided valuable learnings that may be applicable to other clinical practice guidelines nationally and internationally.

The transition to a new methodological approach for collecting representative national stroke registry data makes the research undertaken in this thesis particularly timely. It establishes a baseline for future comparisons and supports efforts to have FeSS variables included in the minimum mandatory reporting dataset. Dissemination of the research findings from the studies included in this doctoral research program have been presented at national and international conferences (Appendix J). The published manuscripts from this body of work, together with collaboration with the Stroke Foundation and the data custodians at AuSCR and AuSDaT, will inform the stroke community of recommendations to improve adherence to FeSS Protocols in Australian hospitals. It is hoped that the recommendations made in this thesis, based on the evidence from the research undertaken, can be instituted to support future implementation and dissemination efforts to maximise national adoption of FeSS Protocols. The patient outcomes and significant economic benefits of in-hospital acute stroke care that aligns with FeSS Protocols justifies the need to continue to advocate for their use and undertake ongoing translational research in this area. Furthermore, the relevance of the

findings from this thesis and their potential applicability to other clinical practice guidelines, contributes valuable evidence to the literature on clinical practice change and sustainability.

In conclusion, this doctoral research program highlights that while some clinically significant improvements have been made in adherence to FeSS Protocols, ongoing efforts are required at the organisational, system and individual levels given that only two in five patients currently receive this care.

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APPENDICES

Appendix A Literature review search strategy matrix

Search 1. Any stroke clinical practice guidelines

Key word (Title, Abstract)	MeSH
Adherence OR compliance OR behaviour change OR care processes OR implement OR application OR adoption	'Guideline adherence/standards' OR 'Treatment adherence and compliance' OR 'Compliance' OR 'Behaviour' OR 'Change management' OR 'Outcome assessment and process assessment, health care/Methods/Organization and admin/standards' OR 'Nursing Process/standards' OR 'Implementation science' OR 'Health plan implementation/method/Organization and admin standards'
Clinical practice guideline OR Clinical practice management OR protocol OR policies OR guideline OR guideline adherence OR practice guideline OR recommendation OR best practice OR care pathway	'Practice guidelines as topic/standards' OR 'Guidelines as topic' OR 'Early medical intervention' OR 'Guideline adherence/standards' OR 'Clinical protocols/standards' OR 'Standing orders' OR 'Evidence Based Practice /Instrumentation/Methods/standards ' OR 'Evidence Based Nursing/methods/standards' OR 'Professional practice/standards' OR 'Professional practice gaps'
Stroke OR ischemic stroke OR intracerebral hemorrhage OR hemorrhagic stroke OR poststroke OR cerebral vascular OR infarct OR cerebrovascular infarct	'Ischemic Stroke/Complications/Diet therapy/Drug therapy/Epidemiology/Mortality/Nursing/Prevention and control' OR 'Hemorrhagic Stroke/ Complications/Diet Therapy/Drug therapy/Epidemiology/Mortality/Nursing/Prevention and control' OR 'Stroke/ Complications/Diet Therapy/Drug therapy/Epidemiology/Mortality/Nursing/Prevention and control' OR 'Cerebral Infarction/ Complications/Diet Therapy/Drug therapy/Epidemiology/Mortality/Nursing/Prevention and control'
Nurse OR Nursing OR Clinician OR Practitioner OR Health professional OR Allied health OR Physicians	'Nursing/instrumentation/methods/standards' OR 'Evidence based nursing /methods/standards' OR 'Evidence based practice/ instrumentation/methods/standards' OR 'Evidence based medicine/ instrumentation /methods/standards' OR 'Health personnel/standards' OR 'Allied Health personnel/standards' OR 'Professional autonomy' OR 'Professional role' OR 'Physicians' OR 'Physician-Nurse relations'
Inhospital OR acute care OR Hospital units OR Patient care team	'Inpatients' OR 'episode of care'

Search 2. Additional keywords combined with MeSH terms to be run individually with search 1 results

Key word (Title, Abstract)	MeSH
Translational medical research	'Translational research- bio medical /instrumentation/Methods/Organisation and Admin/Standards' OR 'Health Services Research/ Methods/Organisation and Admin/Standards'
Quality assurance OR Quality improvement OR Quality initiative OR Quality plan OR Quality program OR Quality review OR Quality audit	'Quality Assurance-Health care/ Methods/Organisation and Admin/Standards'
Fever OR Temperature OR Hyperthermia OR Pyrexia	'Fever/Complications/Drug therapy /Classification/Diagnosis/Etiology/Mortality/Nursing/Prevention and control') OR 'Hot temperature' OR 'Body temperature'
Hyperglycaemia OR Glucose	'Hyperglycaemia/complications/diet therapy/ drug therapy/etiology/immunology/metabolism/mortality/nursing/prevention and control'
Dysphagia OR swallowing OR swallowing disorders OR aspiration OR deglutition OR deglutition disorders OR oropharyngeal	'Deglutition disorders/complications/diagnosis/etiology/mortality/nursing/physiopathology/prevention and control'

Questions mapped to <i>components</i> Greenhalgh et al, (2004) Conceptual Model for Diffusions of Innovations in Health Service Delivery and Organisations ¹
Questions mapped to <i>factors</i> Fox et al, (2015) Sustainability of Innovation framework ²

Interview Guide: Stroke Coordinator /Stroke Clinicians**Aim:**

To identify Stroke Coordinator /Stroke Clinicians views on the factors that may have influenced the introduction, implementation and embedding of clinical protocols for the management of Fever, Sugar (hyperglycaemia) and Swallow

conducting interviews with Stroke Clinicians directly involved in acute stroke care and who are knowledgeable about the use of **FeSS** Protocols in their hospital.

***Choose relevant Option A or B**

Option A: You have been selected for this interview because of your role as Stroke Coordinator at (*insert name of hospital*). As such, we anticipate that you will be able to give an informed perspective about your role and on factors that you think may have influenced the introduction of and uptake and sustainability of the **FeSS** Protocols.

Option B: You have been identified through our interview with your hospital's Stroke Coordinator as a stroke clinician (XXXX insert discipline and/or role if known) at (*insert name of hospital*) who may be able to give an informed perspective about factors that you think may have influenced the introduction of and uptake and sustainability of clinical protocols for the management of Fever, Sugar (hyperglycaemia) and Swallow (**FeSS**) complications after stroke in your stroke service. This includes whether they were actually implemented at your hospital, or only partially implemented, and/or implemented but then discontinued.

Recording instructions

If you are agreeable, I will take notes and record the interview so that I don't miss any details and can carry on an attentive conversation with you. All interviews are confidential, and recordings and transcripts of the interview will be anonymised and you and your hospital will not be identified in any publication.

Do you have any questions?

Consent form instructions

Check that the interviewee has read the participant information sheet and read and signed consent forms. They keep a copy and the researcher keeps a copy as well.

PART A**1. Role of interviewee**

1.1 Clinical designation of interviewee at time of interview _____

1.2 Length of service within organisation _____

1.3 Years clinical experience and brief background (how long have they worked in stroke specialty)

1.4 Did your hospital implement clinical protocols for the management of Fever, Sugar (hyperglycaemia) and Swallow (**FeSS**) complications after stroke? _____

***If No (or don't know) got to PART C**

1.5 Have you been involved in any way in implementing **FeSS** Protocols at any point? Y/N?

*If Yes what was your role exactly (e.g. education, distributing materials, obtaining resources, utilising them in clinical practice etc)

1.6. Can you recall the time period that you were involved in implementation?
(*Need the year at least to be able to document how long after implementation the interview is taking place)

PART B

Implementation (*sites not enrolled in FeSS Intervention study)

2.1 What efforts have been made to introduce the **FeSS** Protocols in your stroke service? (e.g. in-service education, added to stroke pathway, signs up in work space). If yes to education sessions- are these revisited often during in-service calendar year? Part of new staff training?

Implementation and routinisation (human resource issues, team based training, funding)

Political factors (staff involvement in implementation and decision making)

2.2. Were you able to try out different aspects of the **FeSS** Protocols before or during their introduction (i.e. was it broken down into stages or all at once)?

The Innovation (Trialability, Reinvention, complexity)

Organisational factors (Refining of innovation)

2.3 Are there any modified versions of any of the Fever, Sugar, Swallow Protocols in use? (e.g. different insulin regime, only monitor for day of admission not full 72hrs)-

The Innovation (Reinvention, risk)

Organisational factors (Refining of innovation)

2.4 Was implementation of the **FeSS** Protocols led by a specific health discipline? (e.g. nursing/medical/speech)

Adoption by individuals (Context-specific psychological antecedents, the adoption decision)

Diffusion and dissemination (Champions)

Workforce factors (single staff member model, staff attrition, inadequate staffing)

Financial factors (funding)

Political factors (staff involvement in implementation and decision making)

2.5 What were the feelings of the stroke service team in general about the introduction/training in the use of the protocols? Was everyone included in the training? Was/is there enough training? What methods were used? (*Probe: Was/is there any concerns from stroke team towards any aspect of adopting the **FeSS** Protocols? What are these concerns? Internal, external factors)

System readiness for innovation (Power balances [support and advocacy; peer opinion leader (Communication and influence)
Assimilation by the system (the assimilation)
Diffusion and dissemination (Network structure, Opinion leaders)
Implementation and routinisation (intraorganizational communication, human resource issues, team-based training, funding)
Workforce factors (communication and networking strategies)

- 2.6.1 Were management supportive of the FeSS Protocols and implementation process? (e.g. supervisors/ heads of department for nursing/medical/allied health/speech pathology).
 (Probe for any suggestion of a ‘hands on approach’?e.g. vocal support for their use at MDT meetings, attendance at training)

System Antecedents for innovation (Structural determinants of innovativeness [slack resources]; Receptive context to change [leadership and vision/ good managerial relations]) System readiness for innovation (Dedicated time and resources)
Diffusion and dissemination (Opinion leaders)
Implementation and routinisation (leadership and management)
Financial factors (funding)
Workforce factors (inadequate staffing)
Political factors (upper management and organisational support)

- 2.7 Are use of the **FeSS** Protocols formalised (e.g. part of the EMR or stroke care pathway, policy) or informal (e.g. everyone just knows that you have to monitor for fever, sugar, swallow complications but it’s not documented as part of their predicted care plan)?

(*Probe for details for each variable specifically (fever, sugar, swallow. Are there designated roles when implementing the **FeSS** Protocols (e.g. is everyone competent in performing swallow screens, are they completely nurse led)?

The Innovation (compatibility)
System antecedents for innovation (Absorptive capacity for new knowledge “learning organisation culture”)
Assimilation by the system
Implementation and routinisation (leadership and management)
Political factors (policy)

- 2.8 What do you think have been the barriers and/or enablers to the introduction of the FeSS Protocols in your stroke service? (*Probe for resolved and intractable and each protocol specifically [fever, sugar, swallow])

Barriers:

Enablers:

- 2.9 What do you think, if anything, could have helped to resolve the intractable barriers/promote the enablers ? (*Probes/prompts barriers raised in FeSS Intervention

studies e.g. medical team buy in, no medical champion? Beliefs in evidence, outside scope of practice, resources [training, workload, equipment, time, budget]

Barriers:

Enablers:

3.0 Do you think the **FeSS** Protocols are simple and easy to implement?

(*Prompt: Do you think the FeSS Protocols are easy to teach or show new staff? When seeking advice about use of the FeSS Protocols who would you normally direct these queries to? What processes do they have to train staff new to the ward about FeSS? (e,g orientation module, on the job training, competency to be completed with educators?)

The Innovation (compatibility, complexity, task issues, knowledge to use it)

Innovation-specific factors (acceptability, quality)

Implementation process

3.1 When considering use of the **FeSS** Protocols in clinical practice do you think communication regarding their use amongst the multi-disciplinary team was/is effective?

(*Prompts: Stroke team responsive to treatment of fever, sugar, swallow complications, topic for discussion in team meetings, communication to new staff and reminders to existing staff)

System Antecedents for Innovation (absorptive capacity for new knowledge [enablement of knowledge sharing via internal networks])

Implementation and routinisation (intraorganizational communication)

Organisational factors (communication, meetings teamwork)

3.2 Is there a process for any kind of feedback in relation to the use of the **FeSS** Protocols? (*Prompts: internal performance audits [AuSCR optional dataset for **FeSS**], Stroke Foundation audit results, feedback from speech department, Endocrinology referrals, are they referred to in MDT meetings)?

(*Probe: What are the expectations within your organisation in regard to use of the FeSS Protocols? Are there reprimands if the protocol is not followed/acknowledgement when they are used correctly? From whom)?

System Antecedents for Innovation (Receptive context to change [high quality data capture])

System readiness for innovation (Monitoring feedback, support and advocacy, capacity to evaluate the innovation)

Adoption by individuals (concerns in established users)

Implementation and routinisation (feedback)

Innovation-specific factors (evaluation measures)

Workforce factors (quality monitoring and feedback)

Innovation

- 4.1 What do you think or see are the benefits of the **FeSS** Protocols? (*PROBE: Have they had any impact on referral volume etc, Do you think the evidence is clear about the value of them for improving patient care and outcomes?)

The Innovation (relative advantage)

Innovation-specific factors (acceptability, quality)

- 4.2 Are there any risks to the patient or staff that you can think of in relation to the FeSS Protocols? If so do these outweigh the benefits for their use? (e.g. hypoglycaemia, acting outside scope of practice)

The Innovation (risk)

System Readiness for Innovation (innovation-system fit, assessment of implications)

Innovation-specific factors (safety)

- 4.3 How do the **FeSS** Protocols fit within your hospital's normal ward routine (e.g. vital sign scheduling)? (*Probe: If their use has discontinued is it due to this or would they require significant ward level changes to accommodate use of the protocols; if so, what kind of changes?).

System readiness for Innovation (Innovation-system fit)

The Innovation (compatibility)

Implementation and routinisation

Workforce factors (processes in place to support and evaluate)

- 4.4 When considering your stroke service, is there an emphasis on evidence-based care (e.g. getting clinical guidelines into clinical practice, removing outdated practices).

System antecedents for innovation (Absorptive capacity for new knowledge "learning organisation culture")

Innovation specific factors (support/barriers to the innovation)

Political factors (staff involvement in implementation and decision making)

- 4.5 Do you think there is an awareness of the strong recommendation for use of **FeSS** Protocols in the National Clinical Guidelines for Stroke Management?

Diffusion and dissemination (Boundary spanner)

Political factors (staff involvement in implementation and decision making)

- 4.6 What about nurse-led projects in your stroke service? Are they common? Can you provide some examples?

System antecedents for innovation (structural determinants of innovativeness [slack resources, absorptive capacity for new knowledge])

Political factors (staff involvement in implementation and decision making)

Communication and influence

- 5.1 Are you aware of other stroke services experience in implementing **FeSS** Protocols? Are they a topic likely to be discussed at professional group meetings? (e.g. ASNEN, Stroke Society Australasia)

Diffusion and dissemination (Homophily, Opinion leaders, champions, boundary spanners)

The Outer Context: Interorganisational networks and collaboration (Informal interorganisational networks)

Organisation factors (networking external organisations)

- 5.2 Were there any changes in the organisation at any point that may have had a positive or negative impact upon the implementation of the protocols? (*Probe for sustainability)

Assimilation by the system

Workforce factors (staff role changes)

Organisational factors (alignment, staff involvement)

Innovation-specific factors (fluidity, adaptability)

Final thoughts and comments

Is there anything else that you would like to add? Recommendations to others that are planning to implement the FeSS Protocols in their hospitals?

Thank you for your valuable time and input

PART B

Implementation (*sites enrolled in FeSS Intervention study)

- 2.1 Do you recall what strategies were used during the XXXX study to introduce and implement the FeSS protocols? (e.g. was there a clinical champion, meetings with opinion leaders, education sessions)

Linkage among components of the model (Role of the change agency)

Political factors (staff involvement in implementation and decision making)

- 2.2 Did these same strategies continue after trial completion. (e.g. clinical champion, education for new staff, spot auditing).

Linkage among components of the model (Role of the change agency)

Political factors (staff involvement in implementation and decision making)

- 2.3 Have there been additional efforts or strategies to embed the **FeSS** Protocols in your stroke service (either during or after the FeSS intervention study?) [e.g. education sessions- are these revisited often during in-service calendar year? Part of new staff training, added to stroke pathway, signs up in work space, does FeSS belong to nurse leaders portfolio?] What processes do they have to train staff new to the ward about FeSS? (e.g orientation module, on the job training, competency to be completed with educators?)

System antecedents for innovation (Absorptive capacity for new knowledge “learning organisation culture”)

Political factors (staff involvement in implementation and decision making)

- 2.4. Were you able to try out different aspects of the FeSS Protocols before or during their introduction (i.e. was it broken down into stages or all at once)?

- 2.5 Are there any modified versions of any of the Fever, Sugar, Swallow protocols in use? (e.g. different insulin regime, only monitor for day of admission not full 72hrs- maybe better suited to your workplace?)

- 2.6 Was implementation of the **FeSS** Protocols led by a specific health discipline (e.g. nursing/medical/speech)?

- 2.7 What were the feelings of the stroke service team in general about the introduction/training in the use of the protocols? Was everyone included in the training? Was/is there enough training? What methods were used? (*Probe: Was/is there any concerns from stroke team towards any aspect of adopting the FeSS protocols? What are these concerns? Internal, external factors)

- 2.8 Were management supportive of the FeSS Protocols and implementation process (e.g. supervisors/ heads of department for nursing/medical/allied health/speech pathology). (Probe for any suggestion of a ‘hands on approach’?e.g. vocal support for their use at MDT meetings, attendance at training)

- 2.9 Are use of the **FeSS** Protocols formalised (e.g. part of the EMR or stroke care pathway, policy) or informal (e.g. everyone just knows that you have to monitor for fever, sugar, swallow complications but it's not documented as part of their predicted care plan)? (*Probe for details for each variable specifically (fever, sugar, swallow. Are there designated roles when implementing the **FeSS** Protocols (e.g. is everyone competent in performing swallow screens, are they completely nurse led)?
- 3.0 What do you think have been the barriers and/or enablers to the introduction of the FeSS Protocols in your stroke service? (Probe for resolved and intractable and each protocol specifically [fever, sugar, swallow])

Barriers:

Enablers:

- 3.1 What do you think, if anything, could have helped to resolve these intractable barriers/promote the enablers ? (*Probes/prompts barriers raised in FeSS Intervention studies e.g. medical team buy in, no medical champion? Beliefs in evidence, outside scope of practice, resources [training, workload, equipment, time, budget]

Barriers:

Enablers:

- 3.2 Do you think the **FeSS** Protocols are simple and easy to implement? (*Prompt: Do you think the FeSS Protocols are easy to teach or show new staff? When seeking advice about use of the FeSS Protocols who would you normally direct these queries to? What processes do they have to train staff new to the ward about FeSS? (e,g orientation module, on the job training, competency to be completed with educators?)

(*Prompt: Do you think the FeSS Protocols are easy to teach or show new staff? When seeking advice about use of the FeSS Protocols who would you normally direct these queries to?

Implementation process

- 4.1 When considering use of the **FeSS** Protocols in clinical practice do you think communication regarding their use amongst the multi-disciplinary team was/is effective? (*Prompts: Stroke team responsive to treatment of fever, sugar, swallow complications, topic for discussion in team meetings, communication to new staff and reminders to existing staff)
- 4.2 Is there a process for any kind of feedback in relation to the use of the **FeSS** Protocols?

(*Prompts: internal performance audits [AuSCR optional dataset for **FeSS**], Stroke Foundation audit results, feedback from speech department, Endocrinology referrals, are they referred to in MDT meetings)?

(*Probe: What are the expectations within your organisation in regards to use of the FeSS Protocols? Audit results? Are there reprimands if the protocol is not followed/Acknowledgement when they are used correctly? From whom)?

Innovation

- 5.1 What do you think or see are the benefits of the **FeSS** Protocols?
(*PROBE: Have they had any impact on referral volume etc, Do you think the evidence is clear about the value of them for improving patient care and outcomes?)
- 5.2 Are there any risks to the patient or staff that you can think of in relation to the FeSS Protocols? If so do these outweigh the benefits for their use? (e.g. hypoglycaemia, acting outside scope of practice)
- 5.3 How do the **FeSS** Protocols fit within your hospital's normal ward routine (e.g. vital sign scheduling)? (*Probe: If their use has discontinued is it due to this or would they/did they require significant ward level changes to accommodate use of the protocols)
- 5.4 When considering your stroke service, is there an emphasis on evidence-based care (e.g. getting clinical guidelines into clinical practice, removing outdated practices).
- 5.5 Do you think there is an awareness of the strong recommendation for use of **FeSS** Protocols in the National Clinical Guidelines for Stroke Management?)
- 5.6 What about nurse-led projects in your stroke service? Are they common? Can you provide some examples?

Communication and influence

- 6.1 Are you aware of other stroke services experience in implementing **FeSS** Protocols? Are they a topic likely to be discussed at professional group meetings? (e.g. ASNEN, Stroke Society of Australasia)
- 6.2 Were there any changes in the organisation at any point that may have had a positive or negative impact upon the implementation of the protocols? (*Probe for sustainability)

Final thoughts and comments

Is there anything else that you would like to add? Recommendations to others that are planning to implement the FeSS Protocols in their hospitals?

Thank you for your valuable time and input

PART C

For hospitals that answered that there had been **NO attempts or they **don't know** of any attempts to implement clinical protocols for the management of Fever, Sugar (hyperglycaemia) and Swallow (**FeSS**) complications after stroke*

2.1 What do you think have been the barriers to the introduction of **FeSS** Protocols in your stroke service? (*Probe for resolved and intractable and each protocol specifically [fever, sugar, swallow])

2.2 What do you think, if anything, could have helped to resolve these intractable barriers/promote the enablers? (*Probes/prompts barriers raised in FeSS Intervention studies e.g. medical team buy in, no medical champion? Beliefs in evidence, outside scope of practice, resources [training, workload, equipment, time, budget]

2.3 Are you aware if the idea of introducing the FeSS Protocols has ever been revisited?

2.4 Have you been able to try out any aspect of the FeSS Protocols (e.g. only the fever or only the swallow screening)?

2.5 Are there any modified versions of any of the Fever, Sugar, Swallow protocols in use? (e.g. different insulin regime, only monitor for day of admission not full 72hrs).

2.6 Are you aware of any input from management regarding the use of protocols for the management of fever, sugar or swallow complications after stroke?

System Antecedents for innovation (Structural determinants of innovativeness [slack resources]; Receptive context to change [leadership and vision/ good managerial relations]) System readiness for innovation (Dedicated time and resources)
Diffusion and dissemination (Opinion leaders)
Implementation and routinisation (leadership and management)
Financial factors (funding)
Workforce factors (inadequate staffing)
Political factors (upper management and organisational support)

2.7 What do you think or see are the benefits of the FeSS Protocols? (*PROBE: Do you think the evidence is clear about the value of them for improving patient care and outcomes?)

2.8 Are there any risks to the patient or staff that you can think of in relation to the FeSS Protocols? If so do these outweigh the benefits for their use? (e.g. hypoglycaemia, acting outside scope of practice)

2.9 If you are aware of the FeSS Protocols, do you think they are simple and would be easy to implement? Who would you direct any queries to regarding their use? (e.g. another health service? professional network)

- 3.0 Do you receive any feedback regarding your hospitals performance in the national audit reports? If so, do you recall any feedback in relation to FeSS and how your service performs in this area generally? (*Prompts :Does your service conduct internal performance audits or contribute to a stroke registry?)

System Antecedents for Innovation (Receptive context to change [high quality data capture])

System readiness for innovation (Monitoring feedback, support and advocacy, capacity to evaluate the innovation)

Adoption by individuals (concerns in established users)

Implementation and routinisation (feedback)

Innovation-specific factors (evaluation measures)

Workforce factors (quality monitoring and feedback)

- 3.1 How would the FeSS Protocols fit within your hospital's normal ward routine (e.g. vital sign scheduling)? (*Probe: would they require significant ward level changes to accommodate use of the protocols)
- 3.2 When considering your stroke service, is there an emphasis on evidence-based care (e.g. getting clinical guidelines into clinical practice, removing outdated practices).
- 3.3 Do you think there is an awareness of the strong recommendation for use of FeSS Protocols in the National Clinical Guidelines for Stroke Management?)
- 3.4 What about nurse-led projects in your stroke service? Are they common? Can you provide some examples?

Communication and influence

- 4.1 Are you aware of other stroke services experience in implementing FeSS Protocols? Are they something likely to be discussed at professional group meetings? (e.g. ASNEN, Stroke Society)
- 4.2 Were there any changes in the organisation at any point that may have had a positive or negative impact upon the implementation of FeSS Protocols? (*Probe for sustainability)

Final thoughts and comments

Is there anything else that you would like to add? Recommendations to others that are planning to implement the FeSS Protocols in their hospitals?

Thank you for your valuable time and input

1. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. *The Milbank Quarterly* 2004; **82**(4): 581-629.
2. Fox A, Gardner G, Osborne S. A theoretical framework to support research of health service innovation. *Australian Health Review* 2015; **39**(1): 70.



This is to certify that

Kelly Coughlan

Has successfully completed

Maridulu Budyari Gumat: Good Clinical Practice Refresher V2.0

"This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors"

Issued: 2023-06-09

ghrd7uryep

Protocol Registration

From: info@anzctr.org.au <info@anzctr.org.au>
Sent: Monday, 1 May 2023 1:30 PM
To: Kelly Coughlan <Kelly.Coughlan@acu.edu.au>
Cc: Sandy Middleton <Sandy.Middleton@acu.edu.au>
Subject: Your ACTRN (registration number): ACTRN12623000445673

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Dear Kelly Coughlan and Sandy Middleton ,

Re: Fever, Hyperglycaemia (Sugar), Swallow (FeSS) Protocols use in Australian hospitals. Analysis of national stroke data and clinician perspectives of critical factors that influence their use.

Thank you for submitting the above trial for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12623000445673

Web address of your trial: <https://www.anzctr.org.au/ACTRN12623000445673.aspx>
Date submitted: 14/04/2023 1:55:18 PM
Date registered: 1/05/2023 1:30:28 PM
Registered by: Kelly Coughlan
Principal Investigator: Sandy Middleton

If you have already obtained Ethics approval for your trial, please send a copy of at least one Ethics Committee approval letter to info@anzctr.org.au or by fax to (+61 2) 9565 1863, attention to ANZCTR.

Note that updates should be made to the registration record as soon as any trial information changes or new information becomes available. Updates can be made at any time and the quality and accuracy of the information provided is the responsibility of the trial's primary sponsor or their representative (the registrant). For instructions on how to update please see <https://www.anzctr.org.au/Support/HowToUpdate.aspx>.

Please also note that the original data lodged at the time of trial registration and the tracked history of any changes made as updates will remain publicly available on the ANZCTR website.

The ANZCTR is recognised as an ICMJE acceptable registry (<http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>) and a Primary Registry in the WHO registry network (<https://www.who.int/ictrp/network/primary/en/index.html>).

If you have any enquiries please send a message to info@anzctr.org.au or telephone +61 2 9562 5333.

Kind regards,
ANZCTR Staff
T: +61 2 9562 5333
F: +61 2 9565 1863
E: info@anzctr.org.au
W: www.ANZCTR.org.au



From: Leanne Stirling <Leanne.Stirling@acu.edu.au> on behalf of Res Ethics <Res.Ethics@acu.edu.au>

Sent: Wednesday, 1 December 2021 12:59 PM

To: Kelly Coughlan <Kelly.Coughlan@acu.edu.au>

Cc: Res Ethics <Res.Ethics@acu.edu.au>; Sandy Middleton <Sandy.Middleton@acu.edu.au>; Oyebola Fasugba <Oyebola.Fasugba@acu.edu.au>; Simeon Dale <Simeon.Dale@acu.edu.au>; Liz McInnes <Liz.McInnes@acu.edu.au>

Subject: [2021-297N] - Ethics application approved!

Dear Applicant,

Chief Investigator: Ms Kelly Coughlan

Professor Elizabeth McInnes, Professor Sandy Middleton, Ms Simeon Dale, Bola Fasugba, Benjamin McElduff

Ethics Register Number: 2021-297N

Project Title: Fever, Hyperglycaemia (Sugar), Swallow (FeSS) clinical guidelines adherence: analysis of national audit data and stroke registry data.

Date Approved: 01/12/2021

End Date: 31/12/2023

This is to certify that the above human ethics [application](#) for access to non-identifiable data has been reviewed by the Australian Catholic University Human Research Ethics Committee (ACU HREC). The HREC notes that the project will be using previously collected non-identifiable data which can be exempt from review according to the National Statement on Ethical Conduct in Human Research (NHMRC 2007) section 5.1.22 and 5.1.23.

The Australian Catholic University notes that permission to access the de-identified data will be submitted by an application to the data custodians AuSCR and AuSDaT research committees after receipt of ACU HREC, to analyse the de-identified data for the purpose of research and that the data will be viewed in a non-identifiable format, and the permission/approval will be forwarded to ACU HREC.

Researchers must immediately report to the HREC any matter that might affect the ethical acceptability of the protocol such as changes to the protocol, unforeseen circumstances or adverse effects on participants.

For our record-keeping purposes, we deem that this activity will be in progress until 31/12/2023, unless we hear from you to the contrary. It will then be classified as completed.

Please do not hesitate to contact the office if you have any queries.

We wish you every success with your research.

Kind regards,

Leanne Stirling

on behalf of ACU HREC Chair, Assoc Prof. Michael Baker

Research Ethics Officer | Research Services | Office of the Deputy Vice-Chancellor (Research)

Australian Catholic University

T: +61 2 9739 2646 E: res.ethics@acu.edu.au

THIS IS AN AUTOMATICALLY GENERATED RESEARCHMASTER EMAIL



4th July 2022

Ms Kelly Coughlin
St Vincent's Hospital Sydney,
St Vincent's Hospital Melbourne
and Australian Catholic University

Dear Ms Coughlin,

Re: **Fever, Hyperglycaemia (Sugar), Swallow (FeSS) clinical guidelines adherence: analysis of national audit data and stroke registry data**

Thank you for submitting the above project for review by the AuSCR Research Task Group. The Research Task Group and the AuSCR Management Committee have assessed your proposal and we are pleased to advise that the project has been approved.

To cover the costs of the administrative processes including the checking of your documents and providing support for the submission at each stage for the review process, we require upfront payment of the Project Submission fee of \$1,300 ex GST. Once the project has been completed, this fee will be deducted from the total price and the balance will be invoiced.

The Master Services Agreement will also need to be signed by your institution and the Florey to ensure all work undertaken and responsibilities are clear and documented. This document replaces the superseded Data Access Agreement.

Any major changes to your project requirements will have to be submitted to the AuSCR Research Task Group for further review and approval.

Please liaise with Adele Gibbs (adele.gibbs@florey.edu.au), to progress access to AuSCR data for this project.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'D. Cadilhac', is written above the printed name.

Professor Dominique Cadilhac
AuSCR Data Custodian

Project Consortium:

The Florey Institute of Neuroscience and Mental Health, Stroke Foundation,
The George Institute for Global Health and Stroke Society of Australasia

From: no_reply@regis.health.nsw.gov.au <no_reply@regis.health.nsw.gov.au>
Sent: Thursday, 20 April 2023 1:25 PM
To: Sandy Middleton <Sandy.Middleton@acu.edu.au>
Cc: Kelly Coughlan <Kelly.Coughlan@acu.edu.au>; svhs.research@svha.org.au
<svhs.research@svha.org.au>
Subject: 2023/ETH00446: Application HREA - Approved

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Date of Decision Notification: 20 Apr

2023 Dear Professor Sandy Middleton,
Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2023/ETH00446: Fever, Sugar (hyperglycaemia) and Swallow (FeSS) adherence: A qualitative analysis of critical factors that influence clinician adherence to FeSS clinical practice guidelines for stroke.
This Application was reviewed as a Low or negligible risk review pathway and was initially considered by the St Vincent's Hospital Human Research Ethics Committee at its meeting held on 19 April 2023.
The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was APPROVED.

This email constitutes ethical and scientific approval only.
This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.

This project has been Approved to be conducted at the following sites:

- St Vincent's Hospital Sydney

The following documentation was reviewed and is included in this approval:

- FeSS Adherence Qualitative Study Protocol V1 31stMarch 2023
- Participant Information Letter V1 31stMarch 2023
- Consent Form V1 31stMarch 2023
- Recruitment email V1 31stMarch 2023
- Interview Guide V1 31stMarch 2023

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.02

Date: 20 Apr 2023

The approval is for a period of 5 years from the date of this e-mail (20 Apr

2023) The Coordinating Principal Investigator will:

- provide the HREC with an annual report and the final report when the project is completed at all sites. This will be through the submission of a milestone in REGIS.
- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect. This will be through a notification of an amendment in REGIS
- will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.

Submission of annual progress/final reports (milestone), amendments and safety reports should be done through the forms provided in REGIS. Guidance on these processes can be found on the [REGIS website](#).

It is noted that the St Vincent's Hospital Human Research Ethics Committee is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2007 (NHMRC).

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this study with you throughout the project lifecycle.

Regards,

Monica Logan
monica.logan@svha.org.au
[g.au](#)
Research Office | St Vincent's Health
Network svhs.research@svha.org.au |
[Website link](#)



From: no_reply@regis.health.nsw.gov.au <no_reply@regis.health.nsw.gov.au>
Sent: Thursday, 31 August 2023 9:50 AM
To: Sandy Middleton
<Sandy.Middleton@acu.edu.au> **Cc:** Kelly
Coughlan <Kelly.Coughlan@acu.edu.au> **Subject:**
2023/STE01065: SSA - Authorised

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Date of Decision Notification: 31 Aug
2023 Low or negligible risk review
pathway

Dear Professor Sandy Middleton,

Thank you for submitting the following Site Specific Assessment (SSA) for governance review;
2023/STE01065: Fever, Sugar (hyperglycaemia) and Swallow (FeSS) adherence: A qualitative analysis of critical factors that influence clinician adherence to FeSS clinical practice guidelines for stroke.

The Application has been reviewed by the Chief Executive/Delegate who has determined the application has been AUTHORISED to begin at this site:

St Vincent's Health Sydney

The following documentation is included in this authorisation:

- 2023ETH00446 FeSS Adherence Qualitative Study Protocol V1 31st March 2023
- 2023ETH00446 FeSS Adherence Interview Participant Information Letter_V1 31stMarch2023
- 2023ETH00446 FeSS Adherence Interview Consent Form_V1 31st March 2023
- 2023ETH00446 FeSS Adherence recruitment email_V1_31stMarch2023
- 2023ETH00446 FeSS Adherence Interview guide V1 31st March 2023
- 2023 ETH00446 Lead HREC SVH approval_FeSS Adherence Qual study 20 Apr 2023

[Application Documents](#) (Please note : Due to security reasons, this link will only be active for 14 days. The approved documents are also available to download from forms section of this project in REGIS)

The Site Specific Assessment reviewed/authorised is:

Version: 1.03

Date: 29 Aug 2023

Site authorisation with cease on the date of HREA expiry

20/04/2028. The Principal Investigator will:

- Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the lead HREC for review, are provided to the office through REGIS.
- Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project, are to be submitted to this office, via REGIS.
- The appropriate documentation must be submitted for authorisation before any external researcher is authorised to conduct research procedures at this site.

We wish you all the best with the study and remind you that any changes to the application and safety reports will need

to be submitted via REGIS and acknowledged prior to implementation.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below.

Kind Regards

Nik Maiolo

Research

Officer

St Vincent's Hospital Sydney Research Office | St Vincent's Health Network |
Translational Research Centre | 97-105 Boundary Street | Darlinghurst | NSW
2010 | Phone: +612 8382 4960

Email: nikolas.maiolo@svha.org.au SVHS.Research@svha.org.au |

Website: <https://svhs.org.au/home/research-education/research-office>

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Appendix I

Statement of contributions to jointly published work

Thesis output – Papers included in the thesis

Study two (Chapter Four)-published

1. **Coughlan K**, Purvis T, Kilkenny MF, Cadilhac DA, Fasugba O, Dale S, Hill K, Reyneke M, McInnes E, McElduff B, Grimshaw JM, Cheung NW, Levi C, D'Este C, Middleton S.

From ‘strong recommendation’ to practice: A pre-test post-test study examining adherence to stroke guidelines for fever, hyperglycaemia, and swallowing (FeSS) management post-stroke.

International Journal of Nursing Studies Advances 2024; 7: 100248.

(Available online 23 October 2024) Q1 ranked journal, 2023 Journal Impact Factor 3.1

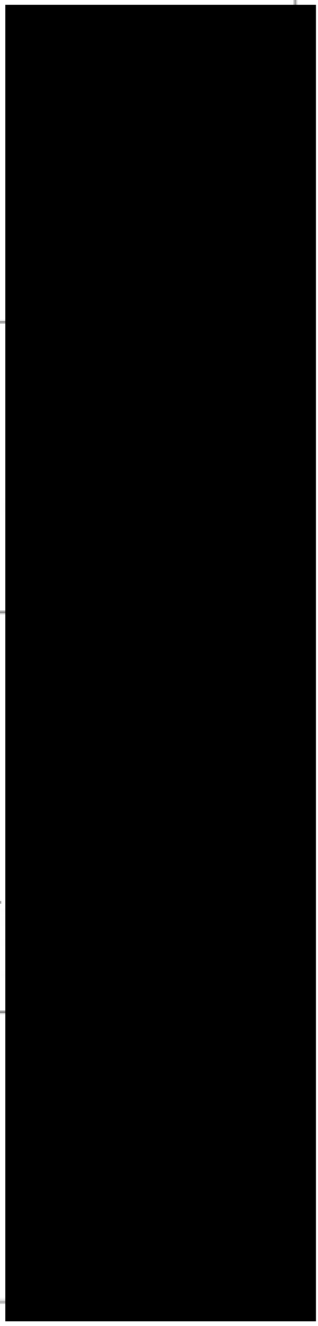
[Journal Citation Reports™ Clarivate, 2023])

Images of the PDF copy of this published article are included after the **Statement of contributions to jointly published work**. The article is published as Open Access and use of this article in this manner is permissible under the Creative Commons Attribution (CC BY 4.0) license, as displayed on the first page (“This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>)”).

Statement of contributions to jointly published work

Coughlan K, Purvis T, Kilkenny MF, Cadilhac DA, Fasugba O, Dale S, Hill K, Reyneke M, McInnes E, McElduff B, Grimshaw JM, Cheung NW, Levi C, D'Este C, Middleton S. From 'strong recommendation' to practice: A pre-test post-test study examining adherence to stroke guidelines for fever, hyperglycaemia, and swallowing (FeSS) management post-stroke. *International Journal of Nursing Studies Advances* 2024; 7: 100248.
(Available online 23 October 2024)

All authors acknowledge their contribution to the above published paper is as outlined in the table below as evidenced by their signature.

Authors	Actual contribution	(%)	Authors signature
Kelly Coughlan (PhD candidate)	Conceptualisation of research aims and study design Formal analysis of study data Writing original draft, review and editing subsequent drafts Visualisation, preparation and presentation of published work Project administration of research activity planning and execution	51	
Sandy Middleton	Chief Investigator QASC Program of translational research Conceptualisation of research aims and study design Primary academic supervisor Oversight of research activity planning and execution Manuscript revisions	9	
Oyebola Fasugba	Investigator QASC Program of translational research Conceptualisation of research aims and study design Academic Co-supervisor Oversight of research activity planning and execution Manuscript revisions	7	
Tara Purvis	Statistical expertise and conducted the primary statistical analyses with the candidate Manuscript revisions	7	
Simeon Dale	Investigator QASC Program of translational research Conceptualisation of research aims and study design Member Research Advisory Group Supervision of research activity planning and execution Manuscript revisions	5	

Elizabeth McInnes	Investigator QASC Program of translational research Conceptualisation of research aims and study design Academic Co-supervisor (Jan 2022-Sep 2024) Oversight of research activity planning and execution Manuscript revisions	5
Catherine D'Este	Investigator QASC Program of translational research Statistical expertise and conducted the primary statistical analyses with the candidate Manuscript revisions	5
Kelvin Hill	Conceptualisation of research aims and study design End-user academic supervisor Manuscript revisions	2
Monique F Kilkenny	Statistical expertise and National stroke audit data interpretation expertise Manuscript revisions	2
Dominique A Cadilhac	Investigator QASC Program of translational research Member Research Advisory Group Manuscript revisions	2
Ben McElduff	Statistical expertise and conducted the primary statistical analyses with the candidate	1
Jeremy M Grimshaw	Investigator QASC Program of translational research Manuscript revisions	1
N Wah Cheung	Investigator QASC Program of translational research Manuscript revisions	1
Chris Levi	Investigator QASC Program of translational research Manuscript revisions	1
Megan Reyneke	National stroke audit data retrieval Manuscript revisions	1



Contents lists available at ScienceDirect

International Journal of Nursing Studies Advances

journal homepage: www.sciencedirect.com/journal/international-journal-of-nursing-studies-advances

From 'strong recommendation' to practice: A pre-test post-test study examining adherence to stroke guidelines for fever, hyperglycaemia, and swallowing (FeSS) management post-stroke

Kelly Coughlan^{a,b}, Tara Purvis^c, Monique F. Kilkenny^{c,d}, Dominique A. Cadilhac^{d,e}, Oyebola Fasugba^{a,b}, Simeon Dale^{a,b}, Kelvin Hill^e, Megan Reyneke^c, Elizabeth McInnes^{a,b}, Benjamin McElduff^{a,b}, Jeremy M. Grimshaw^f, N Wah Cheung^g, Christopher Levi^h, Catherine D'Este^{i,j}, Sandy Middleton^{a,b,*}

^a Nursing Research Institute, St Vincent's Health Network Sydney, St Vincent's Hospital Melbourne and Australian Catholic University, Level 5, deLacy Building, 390 Victoria Street, Darlinghurst, NSW 2010, Australia

^b School of Nursing, Midwifery and Paramedicine, Australian Catholic University, 33 Berry Street, North Sydney, NSW 2060, Australia

^c Stroke and Ageing Research, School of Clinical Sciences, Monash University, Monash Medical Centre, Block E, Level 5, 246 Clayton Rd, Clayton, VIC 3168, Australia

^d Stroke Theme, The Florey Institute of Neuroscience and Mental Health, University of Melbourne, 245 Burgundy Street, Heidelberg, VIC 3084, Australia

^e Stroke Foundation, Level 7/461 Bourke St, Melbourne, VIC 3000, Australia

^f Ottawa Health Research Institute, Ottawa Hospital - General Campus, Centre for Practice-Changing Research (CPCR); and University of Ottawa, 501 Smyth Box 511, Ottawa, ON K1H 8L6, Canada

^g Centre for Diabetes and Endocrinology Research, Westmead Hospital and University of Sydney, Hawkesbury Road, Westmead, NSW 2145, Australia

^h John Hunter Hospital, University of Newcastle, Lookout Rd, New Lambton Heights, NSW 2305, Australia

ⁱ Sax Institute, Level 3/30C Wentworth St, Glebe, NSW 2037, Australia

^j School of Medicine and Public Health, College of Health, Medicine and Wellbeing, University of Newcastle, Newcastle, NSW, Australia

ARTICLE INFO

Keywords:

Stroke
Guidelines
Implementation
Fever
Hyperglycaemia
Swallow
Sustainability

ABSTRACT

Background: The Quality in Acute Stroke Care (QASC) Trial demonstrated that assistance to implement protocols to manage Fever, hyperglycaemia (Sugar) and Swallowing (FeSS) post-stroke reduced death and disability. In 2017, a 'Strong Recommendation' for use of FeSS Protocols was included in the Australian Clinical Guidelines for Stroke Management. We aimed to: i) compare adherence to FeSS Protocols pre- and post-guideline inclusion; ii) determine if adherence varied with prior participation in a treatment arm of a FeSS Intervention study, or receiving treatment in a stroke unit; and compare findings with our previous studies.

Abbreviations: ASSIST, acute screening of swallow in stroke/TIA; AuSDaT, Australian stroke data tool; BGL, blood glucose level; EPOC, cochrane effective practice and organisation of care; FeSS, fever, sugar, swallow; HETI, health education and training institute; mRS, modified rankin scale; QASC, quality in acute stroke care; QASCIP, quality in acute stroke care implementation project; T³, triage, treatment, and transfer; TIA, transient ischaemic attack; UK, United Kingdom.

Trial registration: ACTRN 12,623,000,445,673. Registered 1 May 2023.

* Corresponding author at: Nursing Research Institute, St Vincent's Health Network Sydney, St Vincent's Hospital Melbourne & Australian Catholic University, Level 5, deLacy Building, St. Vincent's Hospital, 390 Victoria Street, Darlinghurst, NSW 2010, Australia.

E-mail address: sandy.middleton@acu.edu.au (S. Middleton).

<https://doi.org/10.1016/j.ijnsa.2024.100248>

Received 31 July 2024; Received in revised form 3 October 2024; Accepted 12 October 2024

Available online 23 October 2024

2666-142X/© 2024 The Author(s). Published by Elsevier Ltd. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Methods: Pre-test post-test study using Australian acute stroke service audit data comparing 2015/2017 (pre-guideline) versus 2019/2021 (post-guideline) adherence. Primary outcome was adherence to all six FeSS indicators (composite), with mixed-effects logistic regression adjusting for age, sex, stroke type and severity (ability to walk on admission), stroke unit care, hospital prior participation in a FeSS Intervention study, and correlation of outcomes within hospital. Additional analysis examined interaction effects.

Results: Overall, 112 hospitals contributed data to ≥ 1 one Audit cycle for both periods (pre=7011, post=7195 cases); 42 hospitals had participated in any treatment arm of a FeSS Intervention study. Adherence to FeSS Protocols post-guideline increased (pre: composite measure 35% vs post: composite measure 40 %, aOR:1.2 95 %CI: 1.2, 1.3). Prior participation in a FeSS Intervention study (aOR:1.6, 95 %CI: 1.2, 2.0) and stroke unit care (aOR 2.3, 95 %CI: 2.0, 2.5) were independently associated with greater adherence to FeSS Protocols. There was no change in adherence over time based on prior participation in a FeSS Intervention study ($p = 0.93$ interaction), or stroke unit care ($p = 0.07$ interaction).

Conclusions: There is evidence of improved adherence to FeSS Protocols following a 'strong recommendation' for their use in the Australian stroke guidelines. Change in adherence was similar independent of hospital prior participation in a FeSS Intervention study, or stroke unit care. However, maintenance of higher pre-guideline adherence for hospitals prior participation in a FeSS Intervention study suggests that research participation can facilitate greater guideline adherence; and confirms superior care received in stroke units. Nevertheless, less than half of Australian patients are being cared for according to the FeSS Protocols, providing impetus for additional strategies to increase uptake.

Contributions to the literature

What is already known

Inclusion in the national stroke clinical practice guidelines came several years after seminal trial results were published. Sustained practice change after clinical trial completion and efforts to upscale and disseminate results are rarely studied longer term.

What this paper adds

The overall improved adherence to FeSS Protocols following their inclusion in the guidelines is likely influenced by multiple factors.

Sustained adoption of clinical guidelines in Australian hospitals is further enhanced by specialist stroke unit care and participation in implementation studies where external support is provided.

This evaluation of a complex health intervention at the population level will assist with future implementation and dissemination efforts to maximise national adoption of FeSS Protocols

1. Background

Facilitated implementation of a nurse-led intervention to manage Fever, hyperglycaemia (Sugar) and Swallowing (FeSS Protocols) in stroke units was shown to reduce death and disability (15.7 % adjusted absolute difference) at 90 days post-stroke for patients in the cluster randomised Quality in Acute Stroke Care (QASC) Trial (Middleton et al., 2011). This effect was sustained, with over 20 % of patients more likely to be alive four years following their stroke (absolute risk reduction 5 %) (Middleton et al., 2017). Subsequent statewide scale-up of the protocols in the pre-test post-test Quality in Acute Stroke Care Implementation Project (QASCIP) during 2013–2014 demonstrated improvements in protocol adherence across New South Wales, Australia (Middleton et al., 2016). The effectiveness of the FeSS Protocols in the emergency department setting in the Triage, Treatment, and Transfer (T³) cluster randomised Trial was later evaluated between 2013 and 2016. However, uptake by clinicians within emergency departments was poor with no differences found between treatment and control groups in process measures or patient outcomes (Middleton et al., 2019).

In 2017, a 'Strong Recommendation' to support use of the FeSS Protocols was included in the Australian Clinical Guidelines for Stroke Management (hereafter referred to as the Stroke Guidelines) based on the QASC Trial results, namely: 'All acute stroke services should implement standardised protocols to manage fever, glucose and swallowing difficulties in stroke patients (Middleton et al., 2011)' (National Stroke Foundation. Clinical Guidelines for Stroke Management, 2017). Swallow processes of care have been included in the clinical guidelines since 2007; however this was the first time recommendations related to fever and hyperglycaemia protocols were included.⁵

It is commonly cited that it takes 17 years on average for only 14 % of new scientific discoveries to enter day-to-day clinical practice (Morris et al., 2011; Balas and Boren, 2000). Outside of the FeSS Intervention studies (QASC, QASCI and T³) that used multi-faceted implementation strategies (audit and feedback, clinical champions, barrier and enabler assessments, educational workshops and reminders) there has not been any systematic roll-out of the FeSS Protocols across Australia. Adherence to the FeSS Protocols has previously been evaluated using data from the National Stroke Audits (acute services) by Purvis et al. (2019) which demonstrated an increased uptake in their use over a 4-year period (2013–2017) (Purvis et al., 2019). However, a significant evidence-practice gap remained with only 41 % of patients receiving care in accordance with all FeSS Protocols in 2017. In that study, greater uptake of the FeSS Protocols was also reported for hospitals that participated in the two original FeSS Intervention studies, QASC and QASCI, up to six years following the original trial (Purvis et al., 2019). This finding is in contrast to the literature that suggests adherence to clinical practice guidelines after an implementation research trial tends to decrease after one year (Ament et al., 2015).

Historically, the distribution of untargeted publication of clinical practice guidelines (i.e. passive dissemination) (Vedel et al., 2018) has been reported as ineffective at changing clinical practice when used in isolation (Prior et al., 2008). The improvements in healthcare professional behaviour changes are reported to be more effective when more active implementation and dissemination techniques (especially multi-faceted strategies) are employed (Prior et al., 2008). However, there is an argument that the significant costs and resources associated with some active implementation strategies (e.g. audit and feedback, educational meetings and outreach) potentially outweigh the benefits of the clinical practice guideline being introduced (Grimshaw et al., 2004). Less expensive strategies (e.g. dissemination educational materials and/or clinical practice guidelines) that are simpler to implement may also be more sustainable (Squires et al., 2014).

The inclusion of the new Stroke Guideline recommendation for use of the FeSS Protocols provided a unique opportunity to assess adherence to FeSS Protocols beyond 2017 and its impact on improved care delivery using the National Stroke audit (acute services) data.

We aimed to i) compare adherence to FeSS Protocols pre- and post-inclusion in Stroke Guidelines; ii) determine if changes in FeSS Protocol adherence varied based on a) hospital prior participation in any treatment arm of a FeSS Intervention study or b) receiving treatment in a stroke unit and; iii) compare adherence to individual FeSS indicators across FeSS Intervention studies.

2. Methods

2.1. Study design and setting

A pre-test post-test study was undertaken using retrospective clinical data from hospitals that participated in the biennial Australian National Stroke Audit (acute services) comparing 2015 and 2017 audit years (pre-guideline); with 2019 and 2021 audit years (post-guideline).

Established in 2007, the Australian National Stroke Audit (herein referred to as the Audit) aims to measure hospitals' adherence to evidence-based practice recommendations as outlined in the Clinical Guidelines for Stroke Management (Stroke Foundation, 2020; Harris et al., 2010). The voluntary audit alternates between acute stroke services and inpatient rehabilitation services each year, and includes national representation (acute stroke services participation rate in 2019 and 2021: 76 % & 79 % of all eligible public services respectively) (Stroke Foundation 2019, Stroke Foundation, 2021). Hospitals must admit approximately 50 patients with stroke annually to be eligible.

2.2. The national stroke audit program

The methods for the Audit program have been detailed elsewhere (Stroke Foundation, 2020; Harris et al., 2010). Briefly, this involves: i) completion of a self-reported organisational survey by hospital clinicians that evaluates hospital adherence to the National Acute Stroke Services Framework (Stroke Foundation. National Acute Stroke Services Framework, 2019; National Stroke Foundation. National Acute Stroke Services Framework, 2015) (e.g. in-hospital stroke services and processes such as access to CT, acute therapies and stroke unit care) and ii) a retrospective clinical audit of approximately 40 consecutive acute stroke cases per hospital (recently increased to 60 cases for 2023 Audit cycle) (Stroke Foundation 2023). The in-hospital clinical care provided is measured against evidence-based Clinical Guidelines for Stroke Management (National Stroke Foundation. Clinical Guidelines for Stroke Management, 2017); and the Australian Commission of Safety and Quality in Health Care's Acute Stroke Clinical Care Standard (ACSQHC, 2019). The audit periods reflect all hospital admissions with stroke diagnosis from June of the previous year, for example, the 2017 Audit cycle reflects patient admissions with stroke from 1st June and discharged prior to 31st December 2016. Process of care indicators related to the management of fever, hyperglycaemia and swallowing during the in-hospital admission period for stroke have been included in the audit since 2013.

Auditors are trained in data abstraction and data entry into the Australian Stroke Data Tool (AuSDaT) platform, with inter-rater reliability cases provided from each site (Stroke Foundation, 2020). The AuSDaT is a national, online database platform that enables the standardised and systematic data collection for multiple stroke data collection programs (Australian Stroke Coalition, 2023; Ryan et al., 2022). This Australia-wide audit of clinical practice in acute stroke hospital services is designed to promote quality improvements in stroke care. The results are fed back in a tailored report to hospitals for them to identify areas for improvement.

2.3. Hospital and participant eligibility

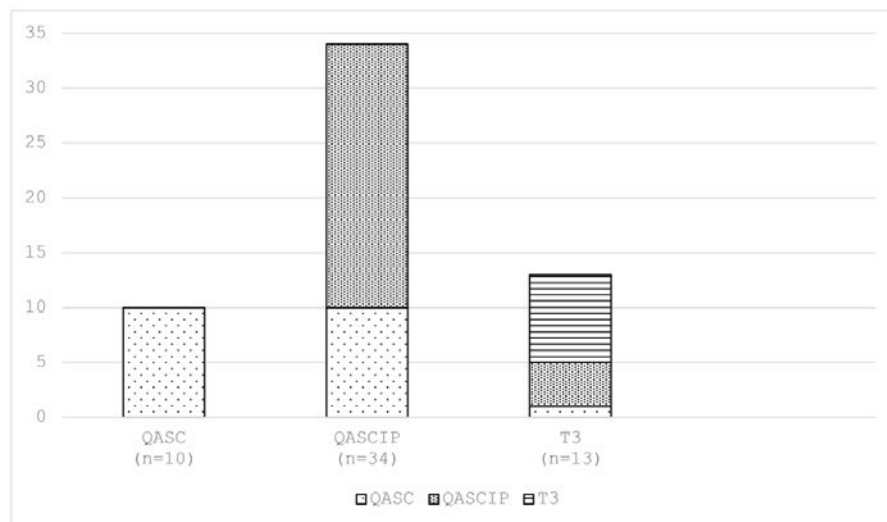
Following approval processes, data were obtained from the Stroke Foundation for all Australian hospitals that participated in the 2015, 2017, 2019 and 2021 Audits. To be included in this analysis, hospitals had to have contributed data into at least one Audit cycle for both time periods (pre-guideline 2015 and/or 2017; and post-guideline 2019 and/or 2021). All patients with a primary diagnosis of stroke (ischaemic, haemorrhagic or undetermined) and aged ≥ 18 years were included. Patients who experienced a transient ischaemic attack (TIA) were excluded in addition to patients that were documented for palliative care measures (as this indicates the patient was not receiving curative treatments during their hospital admission, only pain relieving and comfort measures).

2.4. Data collection

The FeSS variables (Box 1) were extracted from audit data in addition to patient characteristics: age, sex, pre-morbid dependency level (modified Rankin scale[mRS]) (Banks and Marotta, 2007), prior risk factors, stroke type, and stroke severity (being able to walk independently on admission was used as a validated proxy for this measure) (Cadilhac et al., 2019; Counsell et al., 2002; Kilkenny et al., 2020). Treatment with thrombolysis, receipt of care in a stroke unit, discharge dependency level (mRS) and discharge destination were collected with minimal hospital organisational characteristics (presence of a stroke unit, protocols to manage fever, and/or hyperglycaemia and/or swallow). Hospitals that had previously participated in any treatment arm of a FeSS Intervention study were defined as: the intervention hospitals in the Quality in Acute Stroke Care [QASC] randomised controlled trial; and/or the intervention hospitals in Triage, Treatment, and Transfer [T³] randomised controlled trial (Middleton et al., 2019), and/or all hospitals in the Pre-Post QASC Implementation Project [QASCIP] (Middleton et al., 2016) (Fig. 1).

2.5. Outcome measures

The outcome was an overall binary process of care adherence measure that reflected whether or not the patient received all six processes of care elements of the FeSS protocol assessed as part of the audit (composite measure) (Box. 1). This measure of defect-free care used throughout the QASC research program (Middleton et al., 2011, 2016, 2019; Purvis et al., 2019; Middleton et al., 2022) was used to enable reliable comparisons with research that preceded the new Stroke Guideline inclusion. Consistent with how Audit data have previously been reported, clinical impairments (e.g. ability to walk) were incorporated if the response was valid. However, for process of care indicators, not documented and unknown responses were assumed to be negative and included in the denominator (Cadilhac et al., 2019; Purvis et al., 2023).



* Intervention arm QASC 2005-2010 (Randomised Controlled Trial: Supported implementation FeSS Protocols in stroke units)¹

All hospitals QASCIP 2013-2014 (Pre-Post Study: Supported implementation FeSS Protocols in all stroke services NSW)²

Intervention arm T³ 2013-2016 (Randomised Controlled Trial: Supported implementation FeSS Protocols in Emergency Departments)⁴

Fig. 1. Hospital participation in treatment arm of FeSS Intervention studies.

Fever

- Paracetamol within one hour from first temperature equal to or greater than 37.5°C.

Sugar (Hyperglycaemia)

- Insulin within one hour from first blood glucose level (BGL) greater than 10mmol/L.

Swallowing

- A swallow screen, or swallow assessment by a speech pathologist within 24 hours.
- A swallow screen, or swallow assessment by speech pathologist before being given oral food or fluids.
- A swallow screen, or swallow assessment by speech pathologist before being given oral medications.
- A swallow assessment by speech pathologist if failed swallow screen.

Box. 1. Adherence to FeSS Protocols composite measure comprised of six individual indicators.

2.6. Statistical analysis

Patient sociodemographic and clinical characteristics, and hospital characteristics are presented for audit data obtained from pre (2015 / 2017) and post (2019 / 2021) Stroke Guideline inclusion.

Mixed-effects logistic regression was undertaken to compare adherence to FeSS Protocols composite measure pre- versus post-Stroke Guideline inclusion, adjusting for age category (<65, 65–74, 75–84, 85+), sex, stroke type (haemorrhagic, ischaemic and undetermined) and severity (ability to walk on admission), hospital prior participation in a FeSS Intervention study, stroke unit care, and for correlation of outcomes within hospital. Regression models were also generated which included interaction terms (in addition to the previously specified covariates) to evaluate whether any pre-post Stroke Guideline inclusion changes in overall adherence to FeSS Protocols composite measure differed by: (i) hospital prior participation in any treatment arm of a FeSS Intervention study, and (ii) treatment in a stroke unit and (iii) each of these two factors.

The number and percentage of participants who had received each of the six FeSS indicators are reported for the pre- and post-Stroke Guideline inclusion samples. Mixed-effects logistic regression was undertaken to compare if any differences in these groups reached statistical significance using the previously specified covariates. Adjusted odds ratios (aOR) and 95 % confidence intervals are reported from logistic regression models. Sensitivity analyses were undertaken comparing 2017 and with the last Audit cycle (2021) to determine if pooling data from the Audit cycles had an effect on the outcome.

To situate real-world clinical practice findings from the Audits, in the broader context of this study, the number and percentage of participants who had received each of the six FeSS indicators are reported displayed from the pre- and post- guideline Audit data compared to the post-intervention results from the FeSS Intervention studies (QASC 2010, QASCIP 2014, T3 2016). Analyses were performed using Stata SE 15.0 (www.stata.com) and R statistical software (R Core Team, 2023).

2.7. Ethics approval and consent to participate

Ethics approval for the study has been obtained from the Australian Catholic University Human Research Ethics Committee (2021–297 N). External approvals from the Stroke Foundation and Monash University (35037) were also provided. Individual patient consent was not required for this study as the data were not identifiable at the individual level, with summary data reported. The protocol for this study was registered at the Australia New Zealand Clinical Trials registry on the 1 May 2023 (CTRN 12623000445673).

3. Results

A total of 16,345 records from 131 hospitals were provided from the four Audit cycles. We excluded data from 19 hospitals (involving 2139 patient records (13 %)) since these hospitals had not contributed audit data for at least one cycle for either the pre- or post-guideline study periods. Patient records with the primary intent of treatment being palliative care or with a TIA diagnosis, were also excluded.

Therefore, 112 hospitals were included in the final dataset: pre-guideline (2015, 2017 pooled Audit cycle data [$n = 7011$ patient records]), post-guideline (2019, 2021 pooled Audit cycle data [$n = 7195$ patient records]) (Fig. 2). Of these 112 hospitals, 42 had participated in the treatment arm of one or more FeSS Intervention studies QASC, QASCIP and/or T³ (Fig. 1).

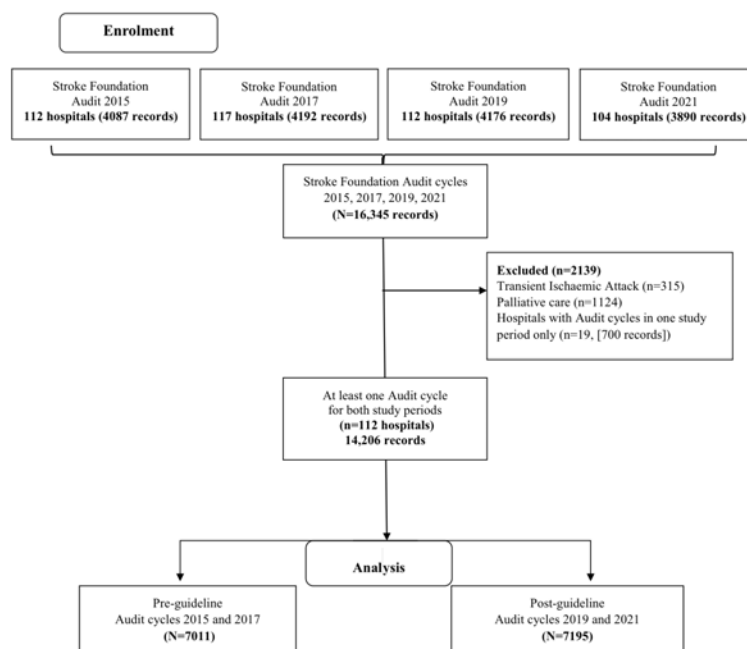


Fig. 2. FeSS Adherence flow diagram.

3.1. Participant and hospital characteristics

Patient demographics were similar between the pre-guideline and post-guideline groups for age, sex and pre-morbid level of dependence (mRS 0–2) (Table 1). The post-guideline cohort had more ischaemic strokes (pre-guideline: 83 %, post-guideline: 86 %, $p < 0.001$), but fewer strokes that were classified as undetermined (pre-guideline: 6 %, post-guideline: 3 %, $p < 0.001$). These differences, while minor and clinically not significant, were likely due to neuroimaging advances and increased accessibility (e.g. change from clinical to tissue-based diagnosis for TIA's and mild strokes).

There was no difference between the pre-and post-Stroke Guideline inclusion groups for history of previous stroke, but there were more patients in the pre-guideline group with documented atrial fibrillation (pre-guideline: 27 %; post-guideline 24 %, $p < 0.001$) and ischaemic heart disease (pre-guideline: 27 % post-guideline: 23 %, $p < 0.001$). Although comorbidities are associated with greater disability and increased stroke severity, the variables used to evaluate these characteristics showed no differences between the pre- and post-guideline groups: independence prior to stroke (mRS 0–2) and being able to walk on admission (validated stroke severity proxy).

Although more patients were screened for possible treatment with thrombolysis in the post-guideline group (pre-guideline: 42 %, post-guideline: 59 %, $p < 0.001$) there was no difference in the proportion of patients who subsequently received intravenous thrombolysis treatment between the pre- and post-guideline groups.

The small increase in the number of hospitals that reported a dedicated stroke unit was not statistically significant but may have contributed to the increased number of patients able to access stroke unit care (pre-guideline: 83 %, post-guideline: 85 %; $p = 0.002$). The marginal increase in the number of hospitals that reported the presence of locally agreed management (including assessment/monitoring) protocols for fever and hyperglycaemia after the guideline introduction also did not reach statistical significance (Table 1) but are an important indicator of organisational readiness: Fever Protocols pre-guideline:93 %, post-guideline 96 %; Sugar Protocols pre-guideline: 90 %, post-guideline 94 %.

3.2. Overall adherence to FeSS Protocols post inclusion in Stroke Guidelines

As interaction terms were not statistically significant at the 5 % level, $\alpha = 0.05$, (indicating that pre- to post-Stroke Guideline

Table 1
Patient characteristics pre- and post-guideline inclusion period.

	Pre-guideline (N = 7011) n (%)	Post-guideline (N = 7195) n (%)	p-value ^a
PATIENT CHARACTERISTICS			
Age <65 y	1796 (26 %) ^b	1862 (26 %)	0.186
Age 65–74 y	1732 (25 %) ^b	1820 (25 %)	
Age 75–84 y	2049 (29 %) ^b	2152 (30 %)	
Age ≥85 y	1426 (20 %) ^b	1361 (19 %)	
Sex, male	3969 (57 %) ^b	4177 (58 %) ^b	0.080
Independence prior to stroke (mRS 0–2)	5835 (83 %)	6025 (84 %)	0.411
Atrial fibrillation	1671 (27 %) ^c	1624 (24 %) ^d	<0.001
Previous Stroke	1476 (23 %) ^c	1524 (22 %) ^d	0.064
Ischaemic Heart Disease	1648 (27 %) ^c	1560 (23 %) ^d	<0.001
CLINICAL CHARACTERISTICS			
Ischaemic Stroke	5807 (83 %)	6198 (86 %)	<0.001
Haemorrhagic Stroke	775 (11 %)	760 (11 %)	0.346
Undetermined Stroke	429 (6 %) ^c	237 (3 %)	<0.001
Walk independently on admission	3203 (47 %) ^d	3215 (46 %) ^d	0.146
Thrombolysis (ischaemic stroke)	583 (10 %)	684 (11 %)	0.076
Screened for thrombolysis	2931 (42 %)	4242 (59 %)	<0.001
Stroke unit care (if hospital had a stroke unit)	5037 (83 %)	5332 (85 %)	0.002
ORGANISATIONAL CHARACTERISTICS			
	Pre-guideline (N = 112) n (%)	Post-guideline (N = 112) n (%)	p value ^a
Hospitals with a stroke unit	90/112 (80 %)	94/112 (84 %)	0.601
Hospital had Fever Protocols	104/112 (93 %)	107/112 (96 %)	0.569
Hospital had Sugar Protocols	101/112 (90 %)	105/112 (94 %)	0.462
Hospital had Swallow Protocols	110/112 (98 %)	110/112 (98 %)	1.0

^a chi-square test, mRS: Modified Rankin Scale; numbers may not add to total sample size due to missing values

^b <1 % unknown/missing responses excluded

^c 11–12 % unknown/missing responses excluded.

^d 1–5 % unknown/missing responses excluded.

^e 6–10 % unknown/missing responses excluded.

inclusion, changes in adherence to FeSS Protocols did not differ by hospital prior participation in the treatment arm of a FeSS Intervention study ($p = 0.93$) or treatment in a stroke unit ($p = 0.07$) (Supplemental Table 1), results are therefore presented for the main effects model only.

In the adjusted model, compared to the pre-guideline group, there was a significant improvement in overall adherence to FeSS Protocols for the post-guideline group: pre-guideline adherence to FeSS Protocols composite measure 2449/7011 (35 %); post-guideline 2864/7195 (40 %) aOR 1.2, 95 % CI 1.2, 1.3, $p < 0.001$ (Table 2). Patients aged ≥ 85 years had statistically significant greater odds of being treated according to FeSS Protocols compared to younger age categories: aOR 1.3, 95 % CI 1.1, 1.4, $p < 0.001$. However, patients with haemorrhagic stroke had lower odds of being treated according to the FeSS Protocols: aOR 0.74, 95 % CI 0.66, 0.84, $p < 0.001$. Similar findings were noted for patients who were able to walk on admission (indicating a mild stroke presentation): aOR 0.81, 95 % CI 0.75, 0.88, $p < 0.001$ (Table 2).

3.3. Adherence to FeSS Protocols and previous participation in a FeSS Intervention study

Overall, regression analyses demonstrated that patients who were cared for in hospitals that had previously participated in any treatment arm of a FeSS Intervention study had significantly greater odds of receiving care according to FeSS Protocols (aOR 1.6, 95 % CI 1.2, 2.0, $p < 0.001$) when compared to those cared for in hospitals that had not participated (or were not exposed to the intervention) in these studies (Table 2).

This is reflected in adherence to FeSS Protocols being higher both pre- and post-guidelines inclusion in hospitals that had participated in the treatment arm of a FeSS Intervention study (pre-guideline: exposed 40 %, unexposed 31 %, post-guideline: exposed 46 %, unexposed 35 %, $p < 0.001$). However, irrespective of exposure to treatment arm of a FeSS intervention, the change in adherence between pre- and post-guidelines was similar (p -value for interaction term $p = 0.93$) (Supplemental Table 1).

3.4. Adherence to FeSS Protocols and treatment on a stroke unit

Patients that received treatment in stroke units had double the odds of receiving care in accordance with FeSS Protocols (aOR 2.3, 95 % CI: 2.0, 2.5, $p < 0.001$), compared to those who were not treated in a stroke unit regardless of the time period (Table 2). Similar levels of improvement over time was found for those treated on a stroke unit and for those treated outside of a stroke unit (pre-guideline: stroke unit care 40 %, non-stroke unit care 21 %, post-guideline: stroke unit care 44 %, non-stroke unit care 27 %, p -value for interaction term $p = 0.07$). (Supplemental Table 1). Results of the sensitivity analyses comparing 2017 and 2021 Audit cycles were consistent with the main results presented (Supplemental Table II).

3.5. Adherence to individual FeSS indicators post-inclusion in Stroke Guidelines

Comparison of adherence to the individual FeSS indicators pre- and post- guideline was variable (Table 3). There was no significant difference from pre- to post-guidelines in the increased proportion of patients who received prompt treatment with paracetamol for fever (pre-guideline: 53 %, post-guideline: 50 %). However, swallow screen within 24 hrs (pre-guideline: 68 %, post-guideline: 75 %; $p < 0.001$); swallow screen or assessment before oral food or fluids (pre-guideline: 60 %, post-guideline: 65 %; $p < 0.001$) and before oral medications (pre-guideline: 55 %, post-guideline: 60 %; $p < 0.001$) did show significant improvements. Prompt treatment with insulin for blood glucose level (BGL) >10 mmol/l post-Stroke Guideline inclusion was significantly lower (pre-guideline: 34 %, post-guideline: 30 %; $p = 0.041$) (Table 3).

3.6. Individual FeSS indicators compared to previous FeSS Intervention studies

Adherence to each of the individual FeSS indicators from the pre- and post- guideline Audit data was informally compared to the

Table 2
Logistic Regression Model: Factors associated with adherence to FeSS Protocols composite measure.

	aOR ^a	95 % CI	p-value
Post-guideline period ^a	1.2	1.2, 1.3	<0.001
Hospital participated in treatment arm FeSS Intervention study	1.6	1.2, 2.0	<0.001
Received stroke unit care	2.3	2.0, 2.5	<0.001
Age	ref		
<65 y	1.1	0.97, 1.2	0.194
65–74 y	1.1	0.99, 1.2	0.090
75–84 y	1.3	1.1, 1.4	<0.001
≥ 85 y	1.0	0.95, 1.1	0.450
Male	0.74	0.66, 0.84	<0.001
Haemorrhagic stroke	0.81	0.75, 0.88	<0.001
Walk independently on admission			

^a Reference is pre-guideline period.

^b adjusted for factors listed in table including correlation of outcomes within hospital

aOR - adjusted odds ratio, CI - confidence interval.

Table 3

Adherence to FeSS Protocols composite measure and individual FeSS indicators by pre-post guideline.

	Pre-Guideline (N = 7011)	Post-Guideline (N = 7195)	aOR (95 % CI) ^a	p-value
Adherence to FeSS Protocols composite measure	2449 (35 %)	2864 (40 %)	1.2 (1.2, 1.3)	<0.001
1. Patient developed fever ≥ 37.5 °C within first 72 h	778 (11 %)	760 (11 %)	0.94 (0.85, 1.1)	0.315
2. Paracetamol for the first elevated temperature administered within 1 h	342 (53 %) ^b	337 (50 %) ^b	0.84 (0.66, 1.1)	0.147
3. Hyperglycaemia (first 48 h of admission)	1211 (20 %)	1336 (20 %)	1.0 (0.95, 1.1)	0.452
4. Insulin administered within 1 hour of the first elevated finger-prick glucose (>10 mmol/L)	412 (34 %)	404 (30 %)	0.83 (0.69, 0.99)	0.041
5. Swallow screen or assessment within 24hrs	4000 (68 %) ^c	4433 (75 %) ^c	1.4 (1.3, 1.5)	<0.001
6. Swallow screen or assessment before oral food or fluids	4203 (60 %)	4648 (65 %)	1.2 (1.1, 1.3)	<0.001
7. Swallow screen or assessment before oral meds	3882 (55 %)	4346 (60 %)	1.2 (1.2, 1.3)	<0.001
8. Failed swallow screen and referred to Speech Pathologist	1404 (97 %)	1562 (96 %)	0.81 (0.42, 1.6)	0.524

Not documented considered No, and included in denominator; aOR - adjusted odds ratio, CI - confidence interval.

^a adjusted for stroke unit care, hospital prior participation in treatment arm of a FeSS Intervention study, age, sex, stroke type, stroke severity, including correlation of outcomes within hospital.^b Excludes those already receiving regular paracetamol or where contraindicated.^c Only cases with valid times included.

post-intervention results from the FeSS Intervention studies (QASC 2010, QASCIP 2014, T³ 2016) (Table 4). The overall proportion of patients who were treated with paracetamol for fever, and insulin for hyperglycaemia, has improved in clinical practice both before and after the guideline recommendation when compared to each of the FeSS Intervention studies. In contrast, adherence to the swallowing variables was generally better in the FeSS Intervention studies. In the original QASC study, the proportion of patients who received a swallow screen or assessment within 24 h (81 %) was greater than either of the Audit groups (pre-guideline (68 %), post-guideline (75 %)). Higher proportions of adherence to all swallowing variables were reported in the most recent FeSS Intervention study (T³) compared to both Audit groups. This was also true for three of the four swallowing variables in the QASCIP study, with the exception of the proportion of patients who received a swallow screen or assessment within 24 h which was reported to be the same as post-guideline Audit data. We were unable to directly compare the composite measures from all the FeSS Intervention studies as these included monitoring variables for fever and hyperglycaemia which are no longer collected in the Audits after 2015.

4. Discussion

Overall, the findings of this study report two in five Australian stroke patients are being cared for in accordance with FeSS

Table 4

Post-intervention results for individual FeSS Intervention studies compared to pre-and post-Stroke Guideline inclusion Audit data.

	QASC ^a (2010)	QASCIP ^b (2014)	T ^{3a} (2016)	QASC Europe ^{a,c} (2021)	Pre-guideline (2015, 2017 Audit)	Post-guideline (2019, 2021 Audit)
Fever (≥ 37.5 °C)	17 %	12 %	4 %	18 %	11 %	11 %
Paracetamol within 1 h for fever	18 %	47 %	6 %	79 %	53 %	50 %
Hyperglycaemia (>10 mmol/L)	20 % ^b	19 %	13 %	21 %	20 %	20 %
Insulin within 1 hour for hyperglycaemia	14 %	27 %	10 %	75 %	34 %	30 %
Swallow screen/ assessment within 24 h	81 %	75 %	81 %	79 %	68 %	75 %
Swallow screen/assessment before oral food or fluid	22 %	68 %	90 %	82 %	60 %	65 %
Swallow screen/assessment before oral medications	37 %	62 %	75 %	82 %	54 %	59 %
Swallow assessment if failed screen	78 %	95 %	91 %	66 %	86 %	87 %

^a Reference is post-intervention results.^b >11 mmol/L in QASC Trial.^c QASC Europe 2017–2021 (Pre-Post International Study: Supported implementation FeSS Protocols in stroke services)²⁸QASC 2005–2010 (Randomised Controlled Trial: Supported implementation FeSS Protocols in stroke units)¹QASCIP 2013–2014 (Pre-Post Study: Supported implementation FeSS Protocols in all stroke services NSW)³T³ 2013–2016 (Randomised Controlled Trial: Supported implementation FeSS Protocols in Emergency Departments)⁴.

Protocols, despite a strong recommendation for their use in the Stroke Guidelines in 2017. There has been improvement in adherence to FeSS Protocols since this recommendation was made however, the higher adherence to FeSS Protocols pre-guideline for those hospitals that did participate in any treatment arm of the FeSS Intervention studies (QASC (2005–2010), QASCIP (2013–2014) or T³ (2013–2016) suggests that involvement in implementation research studies can enhance adherence to recommended care. Although there has been some improvement in adherence in non-stroke unit settings, patients treated in stroke units have double the odds of receiving care in accordance with FeSS Protocols.

Clinical practice guidelines are an essential source of current evidence-based recommendations for clinicians. Including research into national guidelines, although an accomplishment in itself, does not guarantee adherence. In the United States of America, the United Kingdom (UK) and Australia, patients receiving care according to clinical practice guidelines is widely acknowledged to be approximately 60 % (Braithwaite et al., 2020). Guideline dissemination is generally considered to be a 'passive' implementation strategy when compared to more 'active' and often multi-faceted implementation strategies used in implementation research trials (Vedel et al., 2018). These varied approaches to getting evidence into practice (health professionals' behaviour change) has been the subject of much research over the decades (Grimshaw et al., 2006; Bero et al., 1998; Grimshaw et al., 2001). With a growing body of literature demonstrating a positive association between the number of evidence-based care processes received in hospital and patient outcomes (Middleton et al., 2019; Muñoz Venturelli et al., 2019; Cadilhac et al., 2017) it is vital that future research is directed towards guideline adoption.

The improvement in adherence to FeSS Protocols is not possible to attribute solely to inclusion of the new guideline recommendation. Although the promotion of this new recommendation may have contributed to the overall secular trend, it may also be due to participation in the Audit cycles itself. Audit and feedback is reported to have a modest effect size (median 4.3 %); however, the range is widely variable (0.5–16 %), dependent upon baseline performance and the conditions for feedback (Stroke Foundation, 2018).

Coinciding with the new guideline recommendation for use of the FeSS Protocols in 2017, was the Stroke Foundation's partnership with Cochrane Australia to develop the world's first living Clinical Guidelines for Stroke Management in 2018 (Stroke Foundation 2018). This dynamic model ensures new evidence relevant to the guideline topics is continually monitored and stroke evidence is updated as required to guide clinical practice and policy development (English et al., 2022). Although a recent evaluation of the introduction of this living Stroke Guidelines model reported a threefold increase in online access since their inception (Wiles et al., 2024) this is not indicative of active organisational implementation efforts (Straus et al., 2013).

Previous participation in any treatment arm of the FeSS Intervention studies suggests that exposure to the multi-faceted implementation strategies used in these studies (audit and feedback, clinical champions, barrier and enabler assessments, educational workshops and reminders) (Middleton et al., 2011, 2016); provided greater implementation outcomes that are sustained long after the clinical trial is completed. All hospitals that participated in the QASC Trial were included in the subsequent FeSS Intervention study QASCIP, irrespective of the treatment group. This was essentially an additional 'dose' of the intervention for those hospitals in the intervention arm of the QASC Trial and/or likewise if they were in the intervention arm of the T³ Trial (Fig. 1). Given the small numbers, different study designs and timing of the interventions in these studies, any further statistical inferences about the potential added benefits of multiple study participation would be unreliable and require cautious interpretation. This repeated exposure to the FeSS Protocols and the implementation strategies may explain why our findings support those first reported by Purvis et al. (2019) who found that previous participation in a FeSS Intervention study was associated with improved adherence to the FeSS Protocols (Purvis et al., 2019). This is in contrast to the literature in relation to 'voltage drop' and 'program drift' that assumes the effect of an intervention decreases after a clinical trial as it moves into the dissemination and implementation research stages (Chambers et al., 2013; Nadalin Penno et al., 2019). Some decay effect is to be expected when assessing sustainability longer term (Cadilhac et al., 2017), however maintenance of and continued adherence to FeSS Protocols suggests that the external support (e.g. training, resources, performance feedback) (Middleton et al., 2011, 2016, 2019) to facilitate organizations to adopt these practices have been sustainable longer term (Francis et al., 2016). Although there was not an increase in the amount of change over time when compared to hospitals that did not participate in these studies (or were in the control arm), being in the treatment arm of any of the FeSS Intervention studies did result in a higher level of adherence pre-guideline that was upheld over time.

In general, research active hospitals produce better patient outcomes and quality of care (Australian Academy of Health and Medical Sciences, 2022; Purvis et al., 2016). This may explain why those health services that elected to participate in the FeSS Intervention studies were more likely to adhere to clinical practice guidelines (Stroke Foundation, 2021). The hospitals that participate in the Audits may likely also be quality-improvement/ research 'active' with high voluntary participation rates reported each Audit cycle (Stroke Foundation, 2019, 2021) that suggest high motivation to improve care.

The evidence for stroke unit care and better patient outcomes is well established (Langhorne P DM, 1998), yet the exact reasons why stroke units have this effect are still yet to be defined (Langhorne and Ramachandra, 2020). The specialist multidisciplinary care and proactive prevention of common post stroke complications are among the many hypotheses for stroke unit effectiveness (Langhorne P DM, 1998). Our study findings demonstrate adherence to FeSS Protocols is markedly lower for patients that do not receive treatment in a stroke unit. Ideally, every patient with stroke should be able to access stroke unit care however, this is not always practical in remote areas or smaller hospitals. We have previously reported that the FeSS Protocols can be implemented in non-stroke unit settings (Ding et al., 2024). Understanding the barriers to implementation in these settings requires further investigation.

The FeSS Protocols and resources to implement have been freely available on the QASC research program website (Australian Catholic University, 2024) since the publication of the QASC trial results in 2011. Despite the concerted dissemination efforts of the trial results and inclusion in the national clinical guidelines for stroke management, the use of FeSS Protocols has not translated into everyday clinical practice for all Australian stroke patients.

The plateau in the uptake of FeSS Protocols and wide variation in practice is not unique to this stroke clinical practice guideline

recommendation or country (Middleton et al., 2019; Stroke Foundation, 2021; Levi et al., 2020; European Stroke Initiative Executive Committee et al., 2003; Adams et al., 2007; Intercollegiate Stroke Working Party, 2012). The supported implementation of FeSS Protocols by our team in the QASC Europe Study (2017–2021) (Middleton and McElduff, 2022) conducted in 64 hospitals in 17 countries, reported a very low baseline level of adherence to FeSS Protocols (3.4 %) and whilst, following our facilitated implementation, this improved to 35 % with an absolute difference of 33 %, (95 % CI: 24 %, 42 %), again, there is room for improved compliance. Of note, however, this more recent international comparison demonstrates higher levels of adherence (especially with prompt paracetamol or insulin administration) than previously achieved in any Australian FeSS Intervention study suggesting that improvement in these areas are possible.

The most recent Cochrane systematic reviews to address the effectiveness of interventions for the uptake of evidence-based recommendations in both acute stroke settings (Lynch et al., 2023) and stroke rehabilitations services (Cahill et al., 2020) cited the small number of studies as the reason they were unable to determine if multi-faceted implementation strategies were more effective than no intervention. Our study adds to their call for additional research that evaluates the implementation of evidence-based clinical practice guidelines and strategies that support this.

Limitations related to this study were the retrospective design of the Audits and reliance on a one-time snapshot of approximately 40 cases per hospital at each cycle which may reduce the generalizability of the findings. The lack of randomization, voluntary participation and self-report is subject to reporting and/or response bias and some of the audit questions have changed over the cycle years which meant we were only able to include those variables that were collected in all cycles (e.g. risk factors for stroke).

The reliability of documentation in medical records and the assumption that if a process was not documented, it was not performed, needs to be acknowledged. In this study, older patients (≥ 85 years) had greater odds of receiving treatment in accordance with FeSS Protocols possibly related to the likelihood of co-morbidities that required closer monitoring. However, patients with haemorrhagic stroke had significantly lower odds of being treated according to the FeSS Protocols even though this stroke subtype is generally considered to be the most severe with the highest morbidity and mortality rates (Woo et al., 2022).

Although we excluded any patients who had been documented for palliative care, we cannot be sure that some of the haemorrhagic stroke admissions were missing this important documentation and were, in fact, being treated with palliative care measures.

Similarly, for those patients who presented with mild stroke severity, the working diagnosis on admission may have been TIA which then progressed to stroke after further investigations and assessment during the course of their episode of care. Again, relying on documentation in the medical record may not capture this development accurately. However, we do know that it is common for this mild stroke population to be undertreated (Finch et al., 2017; Gong et al., 2022) and discharged with unmet needs (Finch et al., 2017) so this could also be yet another example of undertreatment.

The strengths of using the Audit data include the large sample size that is able to provide a robust and reliable overview of a cross-sectional snapshot of Australian acute stroke services and adherence to stroke clinical guidelines. Participation rates are high, 89 % of acute admissions for stroke are to hospitals that participate in the Audit (Stroke Foundation, 2019; AIHW, 2021) (comparable to 90 % of admitted strokes in the UK mandatory stroke audit program) (SSNAP, 2023).

The use of this large dataset provides a more representative view of the wider Australian stroke population that includes both stroke unit and non-stroke unit care. As a measure of sustainability, the use of these data provide an estimate for the level of diffusion (Francis et al., 2016) for use of the FeSS Protocols outside of these specialist stroke units. Standardised training for data abstraction are provided for each Audit cycle and reliability cases are also reported which increase the confidence in use of this large dataset (Stroke Foundation, 2020).

Use of a composite outcome to assess adherence to the FeSS Protocols can be subject to limitations that relate to how missing data is handled, and the weighting of the individual FeSS indicators that make up this measure. To ensure consistency, missing data were handled in alignment with previous FeSS adherence research (Middleton et al., 2011, 2016, 2015; Purvis et al., 2019; Middleton and McElduff, 2022).

Although the individual components that make up the composite measure are all related as care processes within the FeSS Protocols, the choice of these components was subject to 'availability bias' (Barclay et al., 2019) and the measures that were captured in the Stroke Foundation Audits. The Audits capture fever and hyperglycaemia treatment but not monitoring variables (which are collected in the FeSS Intervention studies). Unfortunately, the nature of using a binary composite outcome can emphasise the process of care the patient failed to receive, without acknowledging that they may have received all other components that make up this composite measure. The bundled nature of the FeSS Protocols means that it is not possible to separate these processes out, as one being more important than the other, as we do not have the evidence to do so. However, we have presented the individual components that make up this measure to provide transparency in relation to where any overall shortcomings may be. These results suggest that the improvement in swallowing management may have driven the increase in overall adherence to FeSS Protocols. The simplicity of this outcome measure does provide an overview that enables appropriate comparison with previous work and composite outcomes that have been used throughout this research program.

5. Conclusions

This study provides new insights into the evaluation of the natural history and longer-term results of diffusion, dissemination, and implementation of stroke clinical practice guidelines in Australian acute care hospitals. It has now been over a decade since the seminal QASC trial results were published and six years since the inclusion of a strong recommendation for their use in the Stroke Guidelines. Overall, adherence to FeSS Protocols has increased with a recommendation for their use in the guidelines (and audit and feedback associated with the Audits). However, with only two in five patients receiving this care, further efforts are still required to encourage

more widespread adoption. As expected, stroke unit care was associated with increased adherence to FeSS Protocols that was sustained over time. The improvement in adherence to this clinical practice guideline was also increased and sustained over time for hospitals with previous exposure to the FeSS Protocols in any of the FeSS Intervention studies. This suggests that exposure to the more active implementation strategies and involvement in implementation research studies can enhance adherence to recommended care.

The significant costs and resources associated with these strategies could be offset by reserving these efforts for a more targeted delivery approach, where variation in practice has been identified. Future research is required in relation to how these sites are identified, and the levels of intervention required (Fasugba et al., 2023) to improve uptake in use of the FeSS Protocols.

Declarations

Availability of data and materials

The data that support the findings of this study are available from the Stroke Foundation (Acute Audits) but restrictions apply to the availability of these data which were used under contract for the current study, and so are not publicly available. Data may be available from the authors upon reasonable request and with permission of the Stroke Foundation (Acute Audits).

CRediT authorship contribution statement

Kelly Coughlan: Conceptualization, Methodology, Software, Formal analysis, Data curation, Writing – original draft, Writing – review & editing, Visualization, Project administration, Funding acquisition. **Tara Purvis:** Conceptualization, Methodology, Software, Formal analysis, Resources, Data curation, Visualization, Writing – review & editing. **Monique F. Kilkenny:** Conceptualization, Methodology, Software, Formal analysis, Resources, Data curation, Visualization, Writing – review & editing. **Dominique A. Cadilhac:** Methodology, Resources, Writing – review & editing. **Oyebola Fasugba:** Conceptualization, Methodology, Visualization, Writing – review & editing, Supervision. **Simeon Dale:** Conceptualization, Methodology, Visualization, Writing – review & editing, Supervision. **Kelvin Hill:** Conceptualization, Methodology, Resources, Writing – review & editing, Supervision. **Megan Reyneke:** Resources, Writing – review & editing. **Elizabeth McInnes:** Conceptualization, Writing – review & editing, Supervision. **Benjamin McElduff:** Conceptualization, Methodology, Software, Formal analysis, Data curation, Writing – review & editing. **Jeremy M. Grimshaw:** Writing – review & editing. **N Wah Cheung:** Writing – review & editing. **Christopher Levi:** Writing – review & editing. **Catherine D'Este:** Conceptualization, Methodology, Software, Formal analysis, Data curation, Writing – review & editing, Visualization. **Sandy Middleton:** Conceptualization, Methodology, Resources, Writing – original draft, Writing – review & editing, Visualization, Supervision, Funding acquisition.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Professor Sandy Middleton reports financial support was provided by National Health and Medical Research Council Investigator Grant. Kelly Coughlan reports financial support was provided by Australian Government Research Training Program Scholarship. Monique Kilkenny reports financial support was provided by National Heart Foundation of Australia fellowship. Kelly Coughlan reports financial support was provided by St Vincent's Hospital (Melbourne) Limited. Kelvin Hill reports a relationship with Stroke Foundation Australia that includes: employment. Co-author Monique Kilkenny is a member of the Research Advisory Committee at Stroke Foundation Australia Co-authors Monique Kilkenny, Megan Reyneke, Tara Purvis and Dominique Cadilhac are responsible for the independent and alloy analysis of National Stroke Audit data on behalf of the Stroke Foundation Corresponding author and co-authors Sandy Middleton, Christopher Levi, Dominique Cadilhac, Simeon Dale, N Wah Cheung, Jeremy Grimshaw, Cate D'Este, Elizabeth McInnes, Kelly Coughlan, Oyebola Fasugba, are investigators for the QASC Research Program (QASC QASCIPT3 and QASC Europe Studies)

If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

Hospitals that participate in the voluntary biennial Audit cycles that made this study possible.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.ijnnsa.2024.100248](https://doi.org/10.1016/j.ijnnsa.2024.100248).

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Study three (Chapter Five)-accepted for publication and currently in press (approval letter included after the Statement of contributions to jointly published work)

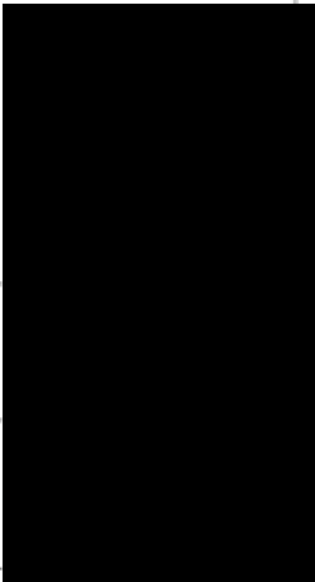
2. **Coughlan K**, Fasugba O, Dale S, Hill K, Cadilhac DA, Middleton S, McInnes E. (2025) Stroke Coordinators' perspectives of factors influencing sustained use of Fever, Sugar (hyperglycaemia) and Swallow (FeSS) clinical practice guidelines: A process evaluation using the Sustainability of Innovation Framework. *Journal of Advanced Nursing* Q1 ranked journal, 2023 Journal Impact Factor 3.8 [Journal Citation Reports™ Clarivate, 2023]).

Statement of contributions to jointly published work

Coughlan K, Fasugba O, Dale S, Hill K, Cadilhac DA, Middleton S, McInnes E. Stroke Coordinators' perspectives of factors influencing sustained use of Fever, Sugar (hyperglycaemia) and Swallow (FeSS) clinical practice guidelines: A process evaluation using the Sustainability of Innovation Framework. *Journal of Advanced Nursing*

All authors acknowledge their contribution to the above published paper is as outlined in the table below as evidenced by their signature.

Authors	Actual contribution	(%)	Authors signature
Kelly Coughlan (PhD candidate)	Conceptualisation of research aims and study design Formal analysis of study data Writing original draft, review and editing subsequent drafts Visualisation, preparation and presentation of published work Project administration of research activity planning and execution	58	
Sandy Middleton	Chief Investigator QASC Program of translational research Conceptualisation of research aims and study design Primary academic supervisor Oversight of research activity planning and execution Manuscript revisions	10	
Elizabeth McInnes	Investigator QASC Program of translational research Conceptualisation of research aims and study design Academic Co-supervisor (Jan 2022-Sep 2024) Oversight of research activity planning and execution Manuscript revisions	10	
Oyebola Fasugba	Investigator QASC Program of translational research Conceptualisation of research aims and study design Academic Co-supervisor Oversight of research activity planning and execution Manuscript revisions	8	

Simeon Dale	Investigator QASC Program of translational research Conceptualisation of research aims and study design Member Research Advisory Group Supervision of research activity planning and execution Manuscript revisions	8	
Dominique A Cadilhac	Investigator QASC Program of translational research Manuscript revisions	5	
Kelvin Hill	Conceptualisation of research aims and study design End-user academic supervisor Manuscript revisions	1	

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12-Jul-2025

Dear Professor Middleton:

It is a pleasure to provisionally accept your manuscript Stroke Coordinators' perspectives on sustaining use of Fever, Sugar (hyperglycaemia) and Swallow (FeSS) Protocols. Process evaluation using a Sustainability Framework for publication in Journal of Advanced Nursing. The comments of the reviewer(s) who reviewed your manuscript are included at the foot of this letter.

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Editor Comments to Author:

Editor

Comments to the Author:

Thank you for engaging in the ongoing review process, your paper has now been accepted for publication. Congratulations.

Conference presentations 2022			
Type	Date	Title	Setting
Oral presentation	3rd August 2022	<i>The role of stroke nurse country coordinators in the Quality in Acute Stroke Care (QASC) Europe evidence translation project: Results from a process evaluation.</i>	2022 St. Vincents Hospital Melbourne Research Week Aikenhead Centre for Medical Discovery (ACMD)
Oral presentation	18th-19 th August 2022	<i>The role of stroke nurse country coordinators in the Quality in Acute Stroke Care (QASC) Europe evidence translation project: results from a process evaluation.</i>	Smart Strokes Conference, Sydney
Symposium session (1 of 3 presenters)	1 st Dec 2022	<i>Clinician behaviour change and the Quality in Acute Stroke Care (QASC) translational research program. From evidence-based trial results to nurse-led practice change: Factors influencing the upscale of QASC nationally and internationally.</i>	Health Services Research Conference 2022, Sydney
Other			
Guest Lecture Nursing Undergraduate Program (1 hour)	4 th October 2022	<i>Getting Evidence into Practice</i>	Notre Dame University, Sydney Campus
Brief oral presentation	October 2022	<i>QASC Australia & FeSS Adherence Study</i>	AuSCR contributors session 10th Annual National Stroke Quality Improvement Workshop
Brief oral presentation	6 th September 2022	<i>FeSS Adherence Study Overview</i>	Mary Mackillop Institute Health Research Australian Catholic University

Activities	
Nursing Representative, St Vincents Hospital Melbourne Aikenhead Centre for Medical Discovery (ACMD) 2022 Research Week	Active Research Week committee member: • Input into program planning and nursing representation. • Abstract marking and selection. • Sourcing session judges Lead role in organizing Nursing and Allied Health Symposium (planning abstract session/presenters/judging and Nursing keynote speaker)
NRI and Allied Health Collaboration - Research Seminar Program	Chair -February Session 2022 Navigating the ethics process @ St Vincent's Hospital Melbourne Chair-June Session 2022 Grant Writing 101 – Tips for Success
NRI_SVHM Nursing Research Interest Group	Co-Chair 6 weekly meetings Feedback to group re SVHM Research Week planning Recruitment and marketing in relation to this group
Chair Abstract Session Smart Strokes Conference Sydney 18 Th August 2022	Abstract Session Five: Life After Stroke Co-Chair with Ian Meade
Working Party member National Stroke Foundation Clinical Guidelines 2015-ongoing	Nursing member since 2015 and world first Living Stroke Guidelines project 2018-2021

Conference presentations 2023			
Oral presentation Junior Investigator session and Opening ceremony session	7th August 2023	<i>Does a 'Strong recommendation' within a clinical practice guideline change clinician behaviour? National uptake of Fever, hyperglycaemia (Sugar) and Swallowing (FeSS) management following stroke.</i>	2023 St. Vincents Hospital Melbourne Research Week. Aikenhead Centre for Medical Discovery (ACMD) <u>*Top scoring nursing abstract selected to present in person at Opening ceremony session</u>
Oral presentation	23rd August 2023	<i>Does a 'Strong recommendation' within a clinical practice guideline change clinician behaviour? National uptake of Fever, hyperglycaemia (Sugar) and Swallowing (FeSS) management following stroke.</i>	Stroke 2023 (Joint Annual Scientific meeting of the Stroke Society of Australasia (SSA) and Smart Strokes) Melbourne
Oral presentation	10 th November 2023	<i>Do clinical practice guidelines change clinician behaviour? Management of post stroke Fever, hyperglycaemia (Sugar) and Swallowing (FeSS) after their inclusion in national stroke clinical practice guidelines.</i>	Australian Neuroscience Nursing Association Conference, Fremantle
Other			
Oral presentation	July 2023	<i>Does a 'Strong recommendation' within a clinical practice guideline change clinician behaviour? National uptake of fever, hyperglycaemia and swallowing management following stroke</i>	AMR Seminar program St Vincents Sydney and SVHM
Activities			
St Vincents Hospital Melbourne, Aikenhead Centre for Medical Discovery (ACMD) 2023 Research Week	Nursing Representative, ACMD Research Week committee member Input into program planning and nursing representation Abstract marking and selection Sourcing session judges		

St Vincents Hospital Melbourne, Aikenhead Centre for Medical Discovery (ACMD) 2023 Research Week	Joint Coordinator Nursing and Allied Health Symposium (Program design, management in-person and virtual attendance, lighting abstract session /judging/Nursing keynote speaker)
NRI and Allied Health Collaboration Research Seminar Program 2023	Joint Seminar Program Coordinator
NRI_SVHM Nursing Research Interest Group 2023	Co-Chair 6 weekly meetings Feedback to group re SVHM Research Week planning Recruitment and marketing in relation to this group
Working Party member National Stroke Foundation Clinical Guidelines 2015-ongoing	Nursing member since 2015 and world first Living Stroke Guidelines project 2018-2021

Conference Presentations 2024			
Oral presentation Junior Investigator session	1-4 August 2024	<i>Factors influencing sustained use of Fever, Hyperglycaemia (Sugar) and Swallow (FeSS) Protocols for stroke: findings from a qualitative study of real-world implementation.</i>	2024 St. Vincents Hospital Melbourne Research Week. Aikenhead Centre for Medical Discovery (ACMD)
Oral presentation	29th-30 th August 2024	<i>Factors influencing sustained use of Fever, Hyperglycaemia (Sugar) and Swallow (FeSS) Protocols for stroke: findings from a qualitative study of real-world implementation.</i>	Smart Strokes Conference, Sydney *ASNEN Outstanding Nursing Abstract (scientific committee)
Oral presentation	25th-28 th September 2024	<i>Bridging borders for the use of evidence-based protocols for Fever, Hyperglycaemia (Sugar) and Swallow (FeSS) and clinical practice: Findings from a qualitative study of factors influencing their sustained use.</i>	Asia-Pacific Stroke Conference (Combined Australia and New Zealand Stroke Organisation Conference) Adelaide
Other			
Oral presentation	June 19 th 2024	<i>Fever, Sugar (hyperglycaemia) and Swallow (FeSS) adherence: A qualitative analysis of critical factors that influence clinician adherence to FeSS clinical practice guidelines for stroke</i>	AMR Seminar program St Vincents Sydney and SVHM
Activities			
Working Party member National Stroke Foundation Clinical Guidelines 2015-ongoing	Nursing member since 2015 and world first Living Stroke Guidelines project 2018-2021		
Scientific committee member Smart Strokes Conference, Sydney	Abstract marking and selection		

Conference Presentations 2025			
Upcoming oral presentation	22-25 July =	<i>Clinician Perspectives on Factors Influencing the Sustained Use of Fever, Hyperglycaemia, and Swallow Protocols in Stroke Treatment.</i>	World Federation of Neuroscience Nurses 2025 Congress, Darwin
Activities			
Working Party member National Stroke Foundation Clinical Guidelines 2015-ongoing	Nursing member since 2015 and world first Living Stroke Guidelines project 2018-2021		
Scientific committee member Australia and New Zealand Stroke Organisation (ANZSO) Conference, Hobart	Abstract marking and selection		
Scientific committee member Smart Strokes Conference, Newcastle	Abstract marking and selection		

Journal publications external to candidature and relevant to thesis topic

1. Middleton. S, Dale. S, McElduff. B, **Coughlan. K**, McInnes. E, Mikulik. R, Fischer. T, Van der Merwe. J, Cadilhac. D, D'Este. C, Levi. C, Grimshaw.J, Grecu.A, Quinn.C, Cheung.NW, Koláčná.T, Medukhanova.S, Menendez.E, Salselas.S, Messchendorp.G, Cassier-Woidasky.AK, Skrzypek-Czerko.M, Slavat-Plana.M, Urso.A, Pfeilschifter.W and on behalf of the QASC Europe Steering and Implementation Committees. Translation of nurse-initiated protocols to manage fever, hyperglycaemia and swallowing following stroke across Europe (QASC Europe): A pre-test/post-test implementation study. *European Stroke Journal*. 2022;0(0). doi:10.1177/23969873221126027
2. Rihari-Thomas J, Whittam S, Goncharov L, Slade D, McElduff B, Pritchard T, McMahon J, Coventry A, **Coughlan K**, Steadward Y, Taylor J, Thornton A, Riddell K, Tuqiri K, Oleson K, Dahm M, Chien L, Kelly P, McInnes E, Middleton S. Assessment and Communication exCELlence for safe patient outcomes (ACCELERATE): Trial Protocol. *Collegian*. Volume 29, Issue 5,2022,Pages 799-805,ISSN 1322-7696, doi.org/10.1016/j.colegn.2022.06.006
3. Middleton, S., Dale, S., McElduff, B., **Coughlan, K.**, McInnes, E., Mikulik, R., Fischer, T., Van der Merwe, J., Cadilhac, D., D'Este, C., Levi, C., Grimshaw, J. M., Grecu, A., Quinn, C., Cheung, N. W., Koláčná, T., Medukhanova, S., Sanjuan Menendez, E., Salselas, S., & Messchendorp, G. (2022). Translation of nurse-initiated protocols to manage fever, hyperglycaemia and swallowing following stroke across Europe (QASC Europe): A pre-test/post-test implementation study. *European Stroke Journal*. <https://doi.org/10.1177/23969873221126027>
4. Middleton S, Dale S, McElduff B, **Coughlan K**, McInnes E, Mikulik R, Fischer T, van der Merwe J, Cadilhac DA, D'Este C, Levi C, Grimshaw J, Grecu A, Quinn C, Cheung N, Koláčná T, Medukhanova S, Sanjuan E, Salselas S, Messchendor G, Cassier-Woidasky AK, Skrzypec-Czerko M, Slavat-Plana M, Urso A, Pfeilschifter W. Translation of nurse-initiated protocols to manage fever, hyperglycaemia, and swallowing following stroke across Europe (QASC Europe): a prospective pre-test/post-test implementation study. *European Stroke Journal*. 2023; 8:132-147. <https://doi.org/10.1177/23969873221126027>
CVSN Stroke Article of the Year Award 2023
5. Fasugba O, Dale S, McInnes E, Cadilhac DA, Noetel M, **Coughlan K**, McElduff B, Kim J, Langley T, Cheung W, Hill K, Pollnow V, Page K, Sanjuan E, Neal E, Griffith S, Christie LJ, Slark J, Ranta, Levi C, Grimshaw J, Middleton S. Evaluating remote facilitation intensity for multi-national translation of nurse-initiated stroke protocols (QASC Australasia): A protocol for a cluster randomised controlled trial. *Implementation Science*. 2023; 18:2. <https://doi.org/10.1186/s13012-023-01260-9>
6. Fasugba O, Sedani R, Mikulik R, Dale S, Vařecha M, **Coughlan K**, McElduff B, McInnes E, Hladíková S, Cadilhac DA, Middleton S. How registry data are used to inform activities for stroke care quality improvement across 55 countries: A cross-sectional survey of Registry of Stroke Care Quality (RES-Q) hospitals. *Eur J Neurol*.2023;00:1-14. doi:10.1111/ene.16024

7. Ding R, Betihavas V, McElduff B, Dale S, **Coughlan K**, McInnes E, Middleton S & Fasugba O. Fever, Hyperglycaemia and Swallowing Management in Stroke Unit and Non-stroke Unit European Hospitals: A QASC Europe Substudy. *Journal of Neuroscience Nursing*, Accepted 31 October 2023
8. McInnes E, Dale S, Bagot K, **Coughlan K**, Grimshaw J, Pfeilschifter W, Cadilhac DA, Fischer T, van der Merwe J, QASC Europe Steering Committee, QASC Europe Implementation Committee and Middleton S. The Quality in Acute Stroke Care (QASC) global scale-up using a cascading facilitation framework: a qualitative process evaluation. *BMC Health Services*. 2024;144
9. Cassier-Woidasky A-K, Middleton S, Dale S, **Coughlan K**, D'Este C, McInnes E, et al. Quality in Acute Stroke Care (QASC) Germany: improving efficiency in stroke care with nurse-initiated FeSS-protocols. *Neurological Research and Practice*. 2024;6(1):48.
10. Fasugba O, Cheng H, Dale S, **Coughlan K**, McInnes E, Cadilhac DA, et al. Finding the right dose: a scoping review examining facilitation as an implementation strategy for evidence-based stroke care. *Implementation Science*. 2025;20(1):4.