

Paramedic response to acute stroke/TIA

A population-based study of current practice and outcomes

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Abstract

Stroke is a major cause of death and disability. Recent changes in the treatment and care of stroke and transient ischaemic attack (TIA) patients have improved survival and quality of life. However, these therapies are strictly time-dependent, with improved outcomes for early-arriving patients, while late-arriving patients are excluded from some forms of treatment.

The overarching aim of this thesis is to explore the paramedic care of acute stroke/TIA patients, through an investigation of the utilisation of the emergency medical services (EMS) as the first medical contact, current EMS practice and patient-focused outcomes.

This population-based study links clinical and operational data from the EMS, with patient data from hospital medical records, to explore whether there is a relationship between paramedic care and patient outcomes in acute stroke/TIA. The observational study adopts a quantitative approach and includes records from 2,524 stroke/TIA cases.

Sixty-four percent of patients in this study, had their first medical contact with a paramedic rather than with a primary care doctor or Emergency Department staff. Four factors were associated with initial contact with an EMS paramedic: increasing patient age, the presence of signs at onset that were recognisable with a FAST test, a final diagnosis of intracerebral haemorrhage compared to TIA and other sub-classifications compared to lacunar circulation infarct.

Paramedics recognised 70 percent of stroke/TIA cases. Six factors were associated with non-recognition of stroke/TIA by paramedics. These factors were: a dispatch code other than stroke, absence of a patient or familial history of stroke/TIA, severity described as minor compared to more severe presentations, absence of a documented FAST assessment, a final diagnosis of intracerebral haemorrhage or ischaemic stroke compared to TIA and a classification of posterior compared to lacunar circulation infarction.

Among ischaemic stroke patients, first medical contact with an EMS paramedic was associated with a shorter onset-to-door delay compared to initial contact with a primary care doctor. Thrombolysis rates were higher among ischaemic stroke patients when the paramedic recognised the event. Mortality was higher, and functional independence and quality of life scores were lower among EMS patients than those using other prehospital pathways. These poorer patient outcomes were associated with greater dependency prior

to stroke onset or a more severe stroke among this group of patients. However, despite greater severity at baseline in the EMS group, there was no difference between the two groups in the proportion who improved to achieve independent functioning at 28 days.

This study identifies a need for increased public awareness of the importance of contacting the EMS in cases of suspected stroke/TIA and of the risk of stroke among younger age groups. Paramedics need to be educated about atypical stroke symptoms and the necessity of screening a wider range of patients in order to improve recognition of stroke/TIA cases. The importance of arriving at a stroke centre as early as possible to maximise the benefits of treatment, rather than within four hours, should be emphasised. Finally, paramedicine as a nascent healthcare profession, should be actively engaged in research collaborations that support evidence-based practice.

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Attestation of authorship

“I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.”

Signature:

Date:

30 August 2017

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Chapter 1 INTRODUCTION

Stroke is the second leading cause of death and disability worldwide (GBD 2015 DALYs and HALE Collaborators, 2016; GBD 2015 Mortality and Causes of Death Collaborators, 2016). In New Zealand, cerebrovascular disease is the third leading cause of mortality, and accounted for 2,612 deaths in 2012 (Ministry of Health, 2015). However, mortality figures underestimate the burden of stroke, as they do not register the effects of on-going disability, which stroke survivors live with. At least half of people who survive a stroke with a residual deficit, require ongoing assistance with activities of daily living (Feigin et al., 2010).

Stroke, and disability after stroke, cause substantial hardship to individuals and their families. Stroke also incurs a significant cost to the New Zealand Health System. A study using 2007 values estimated the average cost of initial hospitalisation for stroke was NZ\$15,811, with annual direct costs to the nation of NZ\$450 million (Brown, 2009). These costs were projected to increase to \$700 million by 2015. This calculation does not include indirect costs, such as years of lost productivity due to inability to continue in employment, or reduction in workforce engagement by family members, in order to care for a relative disabled by stroke. The intangible costs of changes that may persist after a stroke, such as loss of speech, personality changes and dementia, are notoriously difficult to measure and were similarly excluded from this estimation of the cost of stroke.

The burden of stroke is increasing globally and nationally. Worldwide, the number of people suffering their first stroke, dying from stroke and the number of disability-adjusted life years lost, have all increased greatly over the last 25 years (Krishnamurthi et al., 2013). This is attributable to a sharp rise in stroke in low-income countries and an ageing population structure in middle and high-income countries. Projections suggest that the burden of stroke in New Zealand will continue to increase, in line with international trends (Feigin et al., 2015). Overall, a greater number of people are living with the effects of stroke, despite a steady decrease in incidence and mortality rates in recent decades. This paradox is explained by the interaction of three factors: stroke is more common among older people and improvements in stroke survival have occurred in combination with New Zealand's ageing population structure (Jackson, 2007; Tobias, Cheung, Carter, Anderson, & Feigin, 2007).

Stroke is a medical emergency and treatment is time-critical. Recent advances in treatment have improved patient outcomes, but these are strictly time-dependent. Better outcomes are achieved with earlier access to medical services (Saver et al., 2013) and some treatment is restricted to patients who arrive at hospital within a narrow therapeutic window. Both prehospital and in-hospital delays limit eligibility to certain potentially life-saving treatment. Significant advances have been made in recognising and reducing delays within hospital processes (Meretoja et al., 2012; Meretoja et al., 2013). However, less progress has been made in identifying prehospital delays and establishing the contribution that EMS paramedics can make to increasing access to timely stroke care.

Overview of stroke/TIA

Stroke is a brain dysfunction originating in disease of the blood vessels which supply the brain. The World Health Organisation defines stroke as “rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin” (Aho et al., 1980, p. 114). Increasingly, pathological and management diagnoses of stroke, are based on imaging and calculations of the amount of salvageable penumbra (Montalvo, Siket, Jayaraman, Yaghi, & Silver, 2016). The signs and symptoms of stroke are caused by an interruption of the blood supply to the tissues of the brain preventing delivery of essential oxygen and nutrients and removal of toxic metabolic products. This disruption to the circulation may be caused by either occlusion of the vessel, due to a lesion or clot, or haemorrhage as a consequence of vessel rupture (Porth & Matfin, 2009). The three broad sub-classifications: ischaemic stroke, intracerebral haemorrhage, and subarachnoid haemorrhage, reflect this pathophysiology. In an ischaemic stroke, obstruction of the blood vessel causes the distal tissues initially to become hypoxic and then, as time progresses, to infarct. Surrounding the core of dead cells, is a penumbra of poorly perfused cells that are salvageable, if recanalization can restore adequate circulation within a time-critical window. In haemorrhagic strokes the primary problem is disruption of the circulation due to bleeding into the brain tissues, rather than an obstruction of the vessel lumen. Subarachnoid haemorrhages occur when a ruptured cerebral aneurysm causes bleeding under the arachnoid membrane, that in turn compresses the brain and may lead to further complications. Treatment is aimed at stopping the haemorrhage and limiting the adverse effects on the cerebral tissue.

Of the three stroke types, ischaemic strokes are the most common. However, relative proportions vary between populations. For instance, data from the United States of America has reported that 87% of all strokes are ischaemic, 10% intracerebral haemorrhages and 3% subarachnoid haemorrhages (Go et al., 2013), whereas in Japan the respective proportions of 68%, 23% and 8% have been observed (Iguchi et al., 2013).

A further method of classifying stroke are the Oxfordshire Community Stroke Project (OCSP) criteria, (Bamford, Sandercock, Dennis, Burn, & Warlow, 1991). Based on presenting signs and symptoms, strokes are categorised as either total anterior, partial anterior, posterior or lacunar circulation infarctions. These relate to the blood supply of the affected territory. Total anterior strokes are recognisable by the presence of higher dysfunction (such as aphasia or visuospatial deficit) in conjunction with both hemianopia and hemiplegia or hemisensory loss. Partial anterior strokes are identified by presentation with some but not all of the signs and symptoms of total anterior infarcts. Posterior events are diagnosed by cranial nerve palsy with contralateral hemiparesis or sensory loss, or bilateral signs, cerebellar dysfunction or isolated hemianopia. Lacunar infarcts affect the smaller arteries deeper within the brain and are characterised by motor or sensory signs of stroke, or ataxic hemiparesis in the absence of higher dysfunction.

An acute cerebrovascular event is classified as a transient ischaemic attack (TIA) when the signs of stroke last less than 24 hours, and neuroimaging investigations exclude bleeding in the brain. However, in the majority of TIA cases symptoms last for less than an hour. Furthermore, on imaging, and particularly magnetic resonance imaging, as many as 60% of TIA patients have acute ischaemic lesions that meet the diagnostic criteria of stroke (Lee et al., 2017). For these reasons, TIA events should routinely be included in stroke studies. TIA and ischaemic stroke are frequently studied together, as ischaemic syndromes (The European Stroke Organisation [ESO] Executive Committee and the ESO Writing Committee, 2008). For paramedics, examining the patient during the first 24 hours, the signs and symptoms of a TIA may be indistinguishable from those of a stroke. However, if these later resolve, the event will have a final diagnosis of a TIA. Similarly, stroke symptoms may be mild or fluctuate, leading to a premature and incorrect diagnosis of TIA. Therefore, stroke and TIA should be studied together in the prehospital setting.

Five innovations in the last 25 years have radically changed acute stroke treatment. These are stroke units, thrombolysis for ischaemic stroke, endovascular clot retrieval, antithrombotic therapy and hemicraniectomy. Prior to the 1990's, stroke was treated

palliatively, using “cares and comforts”. With the development and introduction of new therapeutic approaches, stroke became a treatable medical emergency.

Specialist stroke services were pioneered in the 1990s. They coordinate a multidisciplinary team to provide more intensive stroke management than would be received on a general ward (Langhorne & on behalf of the Stroke Unit Trialists' Collaboration, 2014). Admission to a stroke unit, has been shown to reduce stroke mortality and improve functional outcomes in patients of all ages, by 30% (Saposnik et al., 2009). Admission within three hours of symptom onset, is associated with reduced disability at three months, compared with admission after three hours (Silvestrelli et al., 2006).

Thrombolysis for ischaemic strokes was introduced following publication of the findings from the National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group (1995) (NINDS) trial. Advances in brain imaging technology had enabled neurologists to differentiate between ischaemic strokes, with the potential to benefit from thrombolysis and those caused by a primary intracerebral haemorrhage. However, to achieve these benefits the thrombolytic agent, tissue-type plasminogen activator (alteplase), must be administered within four and a half hours of symptom onset, with earlier thrombolysis producing better outcomes (Saver, 2006; Wardlaw, Murray, Berge, & Del Zoppo, 2009). Beyond this window, intravenous administration of thrombolytic agents can worsen outcomes by precipitating an intracerebral haemorrhage (Wardlaw et al., 2012). More recently, a meta-analysis pooling the data from nine trials verified that administration of alteplase reduces mortality and improves functional outcomes across age groups and symptom severity (Emberson et al., 2014).

A recent meta-analysis of five randomised trials supported the efficacy of endovascular clot retrieval for large vessel occlusion and its superiority to thrombolysis in these cases (Goyal et al., 2016). Treatment was associated with higher rates of functional independence among survivors and a reduction in patients living with severe disability, compared to patients who received thrombolytic therapy. While current guidelines specify that endovascular clot retrieval treatment must be initiated within six hours from symptom onset, there is evidence that supports extending this window to seven, and possibly eight, hours (Saver et al., 2016).

Antithrombotic therapy is effective in preventing ischaemic stroke events and is indicated once brain imaging has been completed (Phan, Sanders, & Srikanth, 2013). Antiplatelet

and anticoagulant drugs can reduce the risk of recurrent strokes and avoid stroke in TIA patients.

The highly invasive decompressive hemicraniectomy procedure, has been successfully used in malignant middle cerebral artery infarction. This intervention temporarily removes a bone flap to avoid a secondary injury, due to cerebral oedema. Pooled results from three trials, in patients under 60 years of age, revealed a 50% absolute risk reduction of death and improved functional outcomes (Vahedi, 2009).

A range of further innovations are currently being trialled in the prehospital setting including diagnostic trans-cranial ultrasound, neuroprotective strategies, differentiation of ischaemic and haemorrhagic stroke using blood markers (Yperzeele et al., 2014), paramedic transport direct to the imaging unit (Flynn et al., 2017), prehospital recognition of large vessel occlusion and mobile stroke units. These last two have the potential to directly impact on timely revascularisation.

Screening tools have been developed to aid the paramedic in recognising large vessel occlusions. These include the Rapid Arterial Occlusion Evaluation (Perez de la Ossa et al., 2014), and the Los Angeles Motor Scale (Nazliel et al., 2008). Untreated, this type of stroke, is associated with a very poor outcome. However, recognition in the field increases timely access to endovascular thrombectomy by allowing the paramedic to bypass the nearest stroke hospital and proceed directly to a specialist neurovascular interventional centre. Mobile stroke units are ambulances equipped with imaging, laboratory and telecommunication equipment. They are crewed by specialist staff and are able to diagnose stroke and commence reperfusion therapy in the community. Since their first deployment in 2008, mobile stroke units have been established at over 20 sites internationally. However, questions remain on the safety of patients and the risk of adverse events, the clinical efficacy as measured by independence post-stroke, whether they are better suited to urban or rural settings, and the cost-effectiveness compared to in-hospital thrombolysis (Fassbender et al., 2017).

The concepts of a “brain attack” and a “stroke chain of survival”, already familiar from cardiac disease, have been developed to convey the time-critical nature of stroke treatment (Pepe, Zachariah, Sayre, Floccare, & Recovery Writing, 1998). The “time is brain” model quantifies the damage sustained; during a large vessel ischaemic stroke neurons die at the rate of 1.9 million per minute with 13.8 billion synapses and 12km of axonal fibres lost (Saver, 2006). Even small reductions in the delay to thrombolysis can

produce significant benefits for the patient. For every minute of reduction in the onset-to-treatment time, the thrombolysed patient can on average potentially gain 1.8 days of healthy life (Meretoja et al., 2014). Although thrombolysis for ischaemic stroke has been the main driver of time-critical stroke care, patients with intracerebral or subarachnoid haemorrhages also benefit from early medical attention. Treatment options may include interventions to stop bleeding, reverse anti-coagulation, control blood pressure and access lifesaving treatment, including early aneurysm clipping/coiling in aneurysmal subarachnoid haemorrhage surgery (Audebert, Saver, Starkman, Lees, & Endres, 2013).

Despite the strong evidence of improved functional outcomes and favourable cost-effectiveness ratios (Tan Tanny et al., 2013), low rates of thrombolysis are reported internationally. In New Zealand, the national registry reported 6.4% of 2,796 ischaemic stroke patients were thrombolysed during the first six months of 2015 (Joshi et al., 2016). This represents a substantial improvement on the 3% observed in a 2008 audit (Stroke Foundation of New Zealand, 2010) and is comparable with the 2015 Australian rate of 7% (National Stroke Foundation, 2015). However, it is less than the 9.1% achieved in England in 2011 (B. Bray et al., 2013). Substantially higher rates, from 20% to 40%, have been demonstrated during trials (Abdullah, Smith, Biddinger, Kalenderian, & Schwamm, 2009; O'Brien et al., 2012; Quain et al., 2008; Wojner-Alexandrov, Alexandrov, Rodriguez, Persse, & Grotta, 2005). Although, time from onset is a key criterion for thrombolysis eligibility, patients may be excluded for other reasons such as pregnancy, or being at high risk for major haemorrhagic complications.

The low rate of thrombolysis and the narrow therapeutic window for administration of alteplase, has focused attention on delay as a barrier to treatment. A major effort has been to streamline hospital processes through the reorganisation of stroke services, in order to decrease door-to-needle times. The American Stroke Association guidelines state that alteplase should be administered within 60 minutes of arrival at hospital (Jauch et al., 2013). However, this recommendation has been criticised for creating a weak target at the expense of encouraging earlier thrombolysis (Michel, 2016). Three initiatives, introduced in Helsinki and replicated in Melbourne, demonstrate the feasibility of a door-to-needle delay of less than 30 minutes (Meretoja et al., 2012; Meretoja et al., 2013). In the "Helsinki Model", the stroke team is notified and meets the ambulance on arrival to assess the patient. The patient bypasses the hospital Emergency Department and instead proceeds directly to computed tomography or magnetic resonance imaging while still on the ambulance stretcher. Thrombolysis is initiated immediately on confirmation of the

diagnosis and while still in the imaging area. The reorganisation of hospital processes has reduced door-to-needle times and the challenge to increasing thrombolysis eligibility now lies in the prehospital phase.

Prehospital delay contributes to the progression of neurological damage in acute stroke. Delay also limits access to treatment since patients must arrive within the first three and a half or four hours from onset (depending on local guidelines) to be considered eligible for thrombolysis. In people with known time of stroke onset, prehospital delay can be split into two components; the patient-attributable delay from symptom onset until medical assistance is sought and the system-related delay from the request for help until arrival at hospital.

First, the patient, or his or her advocate, must identify the need for medical aid. “Decision delay” has been described as a complex process mediating recognition, interpretation and negotiation (Moloczij, McPherson, Smith, & Kayes, 2008). Extended delay may occur if the patient is asleep at symptom onset or is alone and incapacitated so that they are unable to summon assistance. Other people may wait to see whether their symptoms improve spontaneously. Once the decision is made to seek help, there are three choices: calling the EMS (Emergency Medical Service), contacting a primary care doctor or presenting at the Emergency Department of a hospital. When surveyed on what action they would take if a stroke was suspected, more people indicate that they would call an ambulance, than actually do when confronted with a real stroke event (Carroll, Hobart, Fox, Teare, & Gibson, 2004; Hsia et al., 2011). Reasons that stroke patients provide for not calling an ambulance include feeling that their condition was not severe enough, or concern that the service was overworked (Moloczij et al., 2008). Public education campaigns aim to reduce the duration of patient-attributable delay, by increasing recognition of stroke and knowledge of appropriate responses. Success with these initiatives, has been demonstrated (Wolters, Paul, Li, Rothwell, & on behalf of the Oxford Vascular Study, 2015). Typically the campaign message will incorporate an aid to recognition that can be easily used by the public. One such aid is the Face-Arms-Speech tool, known as the “FAST test”.

The FAST screening tool was developed in Newcastle, England in the late 1990’s by a team led by Professor Gary Ford (Snow, 2013). Informed by other prototype instruments, their aim was to produce a quick test that, in combination with other assessments, would support paramedic recognition of stroke (Harbison et al., 2003). The tool evaluates

whether the patient has facial weakness, arm weakness or speech disturbance with each element incorporated in the memorable mnemonic. An abnormal response in any one of the three factors returns a positive test result for suspected stroke. The “T” is a prompt for paramedics to record the onset time. The simplicity of this test makes it ideal as an aid for stroke recognition by the public. Here the message is adjusted with the ‘T’ advising that it is “time to get help”, thus conveying the need for urgency. The FAST tool has featured in public health education campaigns in New Zealand, Australia the United Kingdom and the United States of America (Wolters et al., 2015).

The second phase of prehospital delay, begins with seeking medical assistance and continues until arrival at hospital. At this juncture, the length of delay is influenced by the chosen prehospital pathway and system-related impediments impacting on arrival at hospital. This stage of the patient’s prehospital journey, and in particular the role of the EMS paramedic, is the focus of this thesis.

Professional significance

Paramedicine is a profession within the healthcare sector focused on providing unscheduled healthcare to patients in a variety of community and clinical settings. A rapid paradigm change has seen paramedicine transform from a primarily transportation role, to an emergency speciality requiring a wide range of clinical and decision-making skills (Simpson, 2013). Despite increasing professionalism and moves towards registration as healthcare practitioners with tertiary education a requirement for entry into the profession, the paramedicine research culture is under-developed and hindered by a lack of capacity (Tunnage, 2014). To the best of my knowledge, this thesis represents the first doctoral study investigating paramedic care and patient outcomes in New Zealand. This lack of a strong research culture in paramedicine has contributed to a dearth of evidence on the prehospital care of stroke patients in this country.

Aims and objectives of this study

The aim of this thesis is to explore the proposition that:

For acute stroke and transient ischaemic attack (TIA) patients, the application of best-practice paramedic Emergency Medical Service (EMS) care, compared to initial contact with a non-EMS healthcare professional or EMS care that does not meet the standard, is associated with better management (earlier arrival at hospital and higher

rates of thrombolysis for ischaemic stroke) and improved health outcomes measures at 28 days post-stroke.

In order to investigate this proposition it is necessary to address the following three objectives:

- to identify how people access emergency medical assistance in cases of acute stroke and TIA in New Zealand,
- to evaluate the quality of care delivered by paramedics to patients suffering an acute stroke or TIA, and
- to explore whether first medical contact with the EMS and the quality of paramedic care provided are associated with improved measures of key process indicators and health-related patient outcomes.

Design

The study links EMS data from the paramedic-completed patient report form (PRF) and operational archives, with information collected from hospital clinical records during a population-based study. This enables identification of the patient pathway to hospital, measurement of the quality of paramedic stroke/TIA care and investigation of the relationship of these factors with patient outcomes.

Originality

Three original contributions to the current knowledge arise from this study:

- this is one of the largest population-level studies of acute stroke/TIA care in the prehospital setting internationally and includes variables that have not been examined previously,
- it is one of very few studies worldwide to apply population-based research methods to evaluate paramedic care, and
- it is the first study to explore the association between paramedic care and patient outcomes in New Zealand and introduces patient outcome variables that are novel in this field.

The study identifies cases from the fourth Auckland Regional Community Stroke study (ARCOS IV) and sources some data from that investigation. However, the paramedic perspective, methodology and addition of detailed EMS data from both the patient report

and the computerised activity log, are unique. The study was conceptualised by the doctoral candidate. The study design, development of tools, data collection, data analysis and interpretation of results, are the work of the author. The study has been conducted at the Auckland University of Technology under the supervision of Dr Rita Krishnamurthi, the co-director of the ARCOS IV study, Professor Valery Feigin, Principal Investigator of ARCOS IV and Director of the National Institute for Stroke and Applied Neurosciences Research Institute and Dr Andrew Swain, Medical Director of Wellington Free Ambulance and Associate Professor of Paramedicine.

Given its impact, stroke is a crucial area for health research worldwide. However, compared with cancer and coronary heart disease, stroke research is grossly underfunded in the United Kingdom and the United States of America (Luengo-Fernandez, Leal, & Gray, 2012; Rothwell, 2001) and there is no reason to expect that the New Zealand situation is different. In New Zealand, stroke has previously been identified as a target area for action by the Ministry of Health (2011).

Overview of thesis structure

Chapter One identifies the importance of this study in the context of an increasing global burden of stroke/TIA and its significance to the nascent profession of paramedicine. The aims and design of the study are summarised.

Chapter Two presents a review of the literature to place the study within the current research knowledge. This chapter appraises publications related to the specific topics within this study. Those topics are: identifying the first medical contact in stroke/TIA, assessing the quality of paramedic stroke care, and examining for associations between paramedic care and patient outcomes

Chapter Three introduces the study methodology, and provides a detailed description of all elements of the methods employed in the PhD study. This includes a review of the development of the database that is used for all subsequent analyses within this study. The linkage of the data sources and investigations into the quality of the overall database, are reported. This is necessary as the scale of the data set is such that it cannot be reproduced within the thesis.

Chapter Four reports the results of the study. The proportions of patients using each of the prehospital referral pathways are identified, along with potential predictors of EMS use. The quality of the EMS care provided and potential predictors of non-recognition of

Chapter 1. Introduction

stroke by paramedics are presented. Finally, the findings from the investigation into the association between paramedic care and patient outcomes are described.

Chapter Five discusses the findings from this study in relation to the overall research question and in relation to previously published literature in a similar topic area. The strengths, limitations and implications of the study are discussed and recommendations for future research are provided.

Chapter Six provides the final conclusion to the study.

Chapter 2 LITERATURE REVIEW

As established in Chapter 1, the aim of this thesis is to determine whether, for acute stroke and TIA patients, the application of best-practice paramedic EMS care, compared to initial contact with a non-EMS healthcare professional or EMS care that does not meet the standard, is associated with better case management and improved health outcomes measures.

This chapter examines the published literature on prehospital stroke and TIA care, to establish the current knowledge relating to the acute community care of this patient group. The review focuses on original peer-reviewed research publications although other materials, such as reports from non-governmental organisations and industry, were also sourced. This chapter is presented in three sections. It commences with a focused examination of the current literature on prehospital pathways from the community to hospital, in acute stroke/TIA and the factors that may predict whether a paramedic is the first medical contact. The subsequent section appraises investigations that measure the quality of paramedic care. This includes the sensitivity of paramedic diagnosis, factors that predict non-recognition and measures of the overall care delivered. The final section of this chapter evaluates studies that explore associations between paramedic care and patient outcomes.

2.1 Method of the literature review

A focused review was undertaken for each of the three sections within this chapter. The reviews adopted a structured search process. It was not the intention to combine the results into a meta-analysis, as it was anticipated that heterogeneity of the study settings, design and quality would prohibit this. Rather, a narrative approach was planned. The electronic databases CINAHL Plus with Full Text via EBSCO, PubMed via EBSCO, and Scopus were searched up to 12th May 2017. One reviewer (the author) undertook the search and study selection.

The search strategies are presented in Appendix A. These used keywords, medical subject headings (MeSH) terms and Boolean operators. Searching was limited to English language publications that reported results of original research studies. A limit of publication after December 1995 was imposed. This restricted the literature reviewed to post-date publication of the findings from the NINDS trial. The NINDS trial was the first

to support thrombolysis for acute ischaemic stroke, and this led to a reconceptualisation of the condition as a medical emergency (Snow, 2013). The literature review was limited to peer-reviewed papers with full text available. Abstracts and letters were excluded, due to insufficient detail of the methods used. Additional publications were identified from reference lists in review papers. Online searching for relevant grey literature, such as documents from government and non-governmental organisations, was conducted.

The titles and abstracts of all papers identified through this process were screened for relevance. Full texts of all potentially relevant papers were retrieved and reviewed. The study quality was evaluated by assessing elements of the study design. The electronic search strategies were saved and re-run to provide updates of recently published material.

Through a review of the literature, this chapter identifies gaps in the knowledge of prehospital stroke and TIA care.

2.2 First medical contact

2.2.1 Rationale and methods of the literature review

The aim of this review was to evaluate the literature that describes the referral pathways by which stroke/TIA patients reach hospital. The first objective was to report the proportion of patients using each prehospital pathway: EMS, primary care doctor or Emergency Department. The second objective was to identify factors that predict use of the EMS as the first medical contact. The rationale for this review is that because the overall research hypothesis compares patient outcomes by referral route, it is necessary to understand the proportions and factors relating to use of EMS as first medical contact. Understanding the utilisation of prehospital pathways at a population level, can guide health care planning and inform public education initiatives to increase eligibility to time-critical treatments.

The literature search was conducted as described in section 2.1. Retrospective designs were excluded because they are more prone to selection bias and missing information than studies with a prospective design. (Hennekens & Buring, 1987).

2.2.2 Proportion of cases by first medical contact

Twelve studies were identified that specified the proportion of stroke/TIA patients whose initial contact was with either a paramedic, primary care doctor or Emergency Department staff (Table 1). The studies used varying categories to describe the initial medical contact

and, in some instances, groups were aggregated by the author of this thesis to align the reporting of results within the review. For example, referrals by road ambulance crew and air rescue services were combined (Agyeman et al., 2006), as were phone calls and face-to-face consultations with primary care doctors (Faiz, Sundseth, Thommessen, & Ronning, 2013).

Five of the studies were conducted in Europe (Agyeman et al., 2006; Faiz et al., 2013; Geffner, Soriano, Perez, Vilar, & Rodriguez, 2012; Lahr et al., 2014; Rossnagel et al., 2004) and four in the United Kingdom (Harbison et al., 2003; Harraf et al., 2002; Salisbury, Banks, Footitt, Winner, & Reynolds, 1998; Wolters et al., 2015). Of the remaining studies, two originated from the United States of America (Kleindorfer et al., 2006; Rosamond, Gorton, Hinn, Hohenhaus, & Morris, 1998) and one from Japan (Yoneda, Morib, Ueharaa, Yamadaa, & Tabuchia, 2001). Cases were enrolled from as early as mid-1995 and most recently in 2013. All studies used a cross-sectional design, although Wolters et al. (2015) incorporated an analysis before and after a public education initiative.

Heterogeneity was apparent in many aspects of the study conduct. Sample sizes ranged between 152 and 3,814 cases, although the majority included less than 500 cases and only two studied more than 1,000 cases. Investigations set in a single centre (either a stroke unit or an Emergency Department) predominated and only three studies used population-level data. As previously noted, categories of medical contact varied. Inclusion criteria based on diagnostic criteria and stroke sub-groups were inconsistent. Five studies included patients with suspected strokes, irrespective of the final discharge diagnosis, and all but one of the seven studies that used confirmed diagnosis, excluded sub-arachnoid haemorrhages.

There was considerable variation between the 12 studies in the proportions of patients using each prehospital pathway. A primary care doctor was the most frequent initial contact in seven studies and an EMS paramedic in five. A paramedic was the least accessed healthcare professional in two studies, (Geffner et al., 2012; Rosamond et al., 1998).

There was wide variation in the proportion of stroke/TIA patients, whose first medical contact was with the EMS. This ranged from a maximum of 71.0% of patients to as few as 17.1%. There was no clearly observable temporal association with EMS use. Low rates of EMS utilisation were recorded in both earlier (Rosamond et al., 1998) and more

Table 1. Summary of papers reporting first medical contact (FMC) in stroke or TIA

Study ID	Location	Sites	n	Enrolment dates	Cases Included	First Medical Contact (%)				
						EMS	PCD	ED	Other	
Agyeman 2006	Switzerland	1 SU	615	Jan 2000 - Dec 2003	IS, TIA	17.1 ^a	37.9 ^a	7.5	37.6 ^b	
Faiz 2013	Norway	1 SU	440	Apr 2008 - Apr 2009	IS, TIA, PICH	52.5	46.2 ^a	1.4		
Geffner 2012	Spain	1 SU	388	Feb 2007 - Feb 2008	IS, TIA, PICH	18.0	48.3	28.3		
Harbison 2003	UK	1 SU	487	Feb 2000 - Jul 2000	suspected stroke	37.0	44.0	n/a	19.0 ^b	
Harrar 2002	UK, Dublin	22 hospitals	736	Not stated; 4 weeks	suspected stroke	43.0	50.0 ^a	7.0		
Kleindorfer 2006	USA	population	3,814	Jan 1999 - Dec 1999	IS, TIA, PICH	38.8	2.7	37.2	7.4 ^c	
Lahr 2014	Netherlands	13 hospitals	1,811	Feb 2010 - Aug 2010	suspected stroke	31.2	54.8 ^a	11.3	1.6 ^c	
Rosamond 1998	USA	1 ED	152	Jul 1995 - Mar 1996	suspected stroke	28.3	33.6	31.6 ^a	4.0	
Rossmagel 2004	Germany	4 hospitals	558	Aug 2000 - Jul 2001	suspected stroke	49.0	25.0 ^a	16.0	10.0	
Salisbury 1998	UK	population	152	Jan 1997 - Jun 1997	IS, PICH	41.0	56.0	3.0		
Wolters 2015	pre post	UK	population	416	Apr 2002 - Apr 2009	IS, TIA, PICH, SAH	55.5	41.8	1.7	1.0
				252	Apr 2009 - Mar 2013		71.0	22.4	3.7	2.8
Yoneda 2001	Japan	1 SU	254	Jan 1998 - Jun 1999	IS, TIA	31.0	22.0	28.0	19.0 ^{b,c}	

Notes. ED = Emergency Department; EMS = emergency medical services; IS = ischaemic stroke; PCD = primary care doctor; PICH = primary intracerebral haemorrhage; SAH = subarachnoid haemorrhage; SU = stroke unit; TIA = transient ischaemic attack; UK = United Kingdom; USA = United States of America.

^a calculated from data presented; ^b transfers from another hospital; ^c in-patient at stroke onset

recent studies (Geffner et al., 2012). Similarly, it was not possible to identify a relationship between prehospital pathway and the study location. However, within the United Kingdom, a trend of increasing use of EMS as first medical contact over time seemed plausible.

Studies that were conducted in stroke units often included patients transferred from secondary hospitals, without specifying the prehospital pathway (Agyeman et al., 2006; Harbison et al., 2003; Yoneda et al., 2001). Presumably this reflected the perspective of the researcher, as transport mode is easier to identify from hospital records than determining the FMC and avoids the need to link cases with the EMS database. While expedient, this approach does not provide insight into the referral pathway chosen by the stroke patient (or his or her advocate) and represents a missed opportunity to identify prehospital delay.

Collectively, the studies reviewed did not reveal any clear patterns of referral by the three prehospital pathways. This review highlights that relatively little is known about how patients access emergency assistance in acute stroke and TIA.

2.2.3 Predictors of initial contact with Emergency Medical Service (EMS)

The second objective of this section of the literature review was to identify patient factors predicting first contact with an EMS paramedic in stroke/TIA. Two of the 12 studies identified in the preceding section addressed this topic. In a further analysis of their data, Faiz, Sundseth, Thommessen, and Rønning (2014) reported that patients with National Institute of Health Stroke Scale (NIHSS) scores representing moderate and severe symptoms, were significantly more likely than patients with milder symptoms, to have initial contact with a paramedic. They did not observe any association between first medical contact with the EMS and any of the other variables tested: age, gender, type of cerebrovascular event (stroke/TIA), presence of risk factors (hypertension, hypercholesterolemia, atrial fibrillation) or history of previous cerebrovascular or heart disease. A surprising finding was that initial contact with a paramedic was not greater among patients who had suffered a previous stroke/TIA, compared to those for whom it was a first event (Geffner et al., 2012). Difficulties with changing patient behaviour, were suggested as a reason for this result.

These findings contrast with those of Adeoye et al. (2009). Their population-based study analysed data from 3,949 cases from the Greater Cincinnati/Northern Kentucky Stroke

Study. Their study was designed to measure trends in stroke incidence and population differences in risk factors. They found that FMC with EMS (compared with non-EMS) was associated not only with higher NIHSS severity scores, but also with increasing age, haemorrhagic compared to ischaemic stroke, and onset at work rather than in the home.

Other studies have examined whether patient factors predict the mode of transportation to hospital. Increasing patient age and greater severity at onset have been associated with transportation to hospital by ambulance in acute stroke events (Ekundayo et al., 2013; C. I. Price et al., 2013; Rosamond et al., 1998; Schroeder, Rosamond, Morris, Evenson, & Hinn, 2000). Transportation by ambulance was linked with haemorrhagic rather than ischaemic stroke in the DASH II study (Schroeder et al., 2000). The evidence on the association between ethnicity and transportation mode is more equivocal. Some researchers from the United States of America reported that African-Americans and people from ethnic minorities, were less likely to use ambulance transportation (Ekundayo et al., 2013; Lacy, Suh, Bueno, & Kostis, 2001). However, other studies found “Blacks used 911 as frequently as Whites” (Kothari, Jauch, et al., 1999, p. 6) or that “Non-whites were statistically more likely to arrive via EMS than Whites” (Engelstein, Margulies, & Jeret, 2000, p. 259). However, these studies did not differentiate between patients who accessed medical care from the EMS and those who first contacted a primary care doctor.

Distinguishing between EMS as the first medical contact, rather than the transport mode is pivotal to understanding prehospital delay. The first medical contact determines the steps in the referral route to hospital where delays may occur. Stroke patients who consult a primary care doctor can be delayed by waiting for the doctor to return the call, or for an appointment or a house call (Mosley, Nicol, Donnan, & Dewey, 2011). Patients who self-present at an Emergency Department may arrive by either private or public transport. Using non-EMS transport modes has been associated with beliefs that the condition was not serious and that self-transport would be faster (Phelps, Rodriguez, Passanante, Dresden, & Kriza, 2002). It has also been linked to a lack of health insurance in the United States of America that suggests cost is a factor in deciding not to contact EMS (Ekundayo et al., 2013). However, in addition to the risk the patient is exposed to, should his or her condition decline on route, delays at hospital are caused by registration and triaging which are avoided in ambulance transportation (Morris, Rosamond, Madden, Schultz, & Hamilton, 2000).

2.2.4 New Zealand situation

Published accounts of the New Zealand prehospital pathway in stroke and TIA are scarce and only four studies were located (Bay et al., 2015; Fink, 2005; Stroke Foundation of New Zealand, 2010; Thorne, Wong, & McGonigal, 2012). None of these studies differentiated between EMS utilisation as FMC versus mode of transport.

The only national level data was gathered in an audit of stroke patients admitted, treated and discharged by the 21 District Health Boards between 1 June and 31 December 2008 (Stroke Foundation of New Zealand, 2010). The audit found that 77% of the 754 included patients, were transported by ambulance. However, the proportion who had first consulted with a primary care doctor was not stated. Two smaller studies identified that 72% of 61 patients referred to a stroke thrombolysis service (Fink, 2005) and 100% of 32 patients treated with alteplase (Thorne et al., 2012), arrived at hospital by ambulance. A survey of public knowledge reported that respondents who had a history of stroke or exposure through their work or family, were more likely to identify the need for emergency medical assistance than those with no personal experience of stroke (Bay et al., 2015).

2.2.5 Summary

Much uncertainty still exists in the literature as to how stroke/TIA patients access urgent medical care and the proportions of patients whose first medical contact is with an EMS paramedic, a primary care doctor or Emergency Department staff. It is unclear which factors predict first contact with the EMS in stroke/TIA. Despite the importance of early access to specialist stroke services, there are no studies reporting the proportion of stroke/TIA patients using each of the three prehospital pathways in New Zealand. Published studies are limited to reporting EMS use as the mode of transportation to hospital.

2.3 Quality of paramedic care

2.3.1 Rationale and methods of the literature review

The second literature review appraises the current knowledge on the standard of stroke/TIA care provided by the EMS paramedic. There were three specific objectives: to report the paramedic diagnostic sensitivity for stroke/TIA when using the FAST

instrument in clinical practice, to identify factors associated with EMS non-recognition of stroke/TIA and to describe methods for measuring the quality of paramedic care.

The research proposition compares patient outcomes based on the quality of paramedic care. Paramedic recognition of stroke is vital for patients to receive the most appropriate care for their condition (Sheppard et al., 2015). In this study, recognition of stroke/TIA is used as one measure of the standard of paramedic care. Published studies of stroke diagnosis, will provide a benchmark for the current analysis and insight into factors potentially predicting paramedic non-recognition of stroke/TIA. Reviewing approaches to evaluating EMS care, will inform further measures of the quality of stroke/TIA care delivered by paramedics.

Stroke is sometimes difficult to recognise. Strokes and TIA have been described as chameleons, because their symptoms may be mistaken for other disorders such as vertigo and visual disturbances (Fernandes, Whiteley, Hart, & Al-Shahi Salman, 2013). On the other hand, certain conditions, such as hypoglycaemia and seizures, can mimic the symptoms of stroke and lead to a false positive stroke diagnosis. In response, screening tools have been designed to support the recognition of stroke in the prehospital setting.

The 2010 New Zealand Stroke Guidelines recommend that paramedics use a stroke screening tool. Numerous pre-hospital stroke-screening tools have been developed and tested. Four that are widely used are the FAST instrument (Harbison et al., 2003), the Cincinnati Prehospital Stroke Scale (CPSS) (Kothari, Hall, Brott, & Broderick, 1997), the Melbourne Ambulance Stroke Screen (MASS) (J. E. Bray et al., 2005) and the Recognition of Stroke in the Emergency Room (ROSIER) tool (Nor et al., 2005). All four tools assess facial droop, arm weakness and speech disturbance in the physical examination. However, the method of assessment can vary between tools. For example, the CPSS requires the patient to repeat a set phrase whereas the FAST uses conversational speech during the overall patient contact. In addition to the shared elements, the MASS adds evaluation of grip strength whereas the ROSIER includes leg weakness and visual field testing components. The MASS and ROSIER also consider patient history factors of seizure activity and blood glucose testing, although acceptable blood glucose levels differ. The MASS alone, considers the patient's age.

Although the relative efficacy of these screening tools is a topic of considerable debate (Brandler, Sharma, Sinert, & Levine, 2014; J. E. Bray et al., 2005; Purrucker et al., 2015; Rudd, Buck, Ford, & Price, 2016), it is not the focus of the current study. This review

focuses exclusively on use of the FAST instrument. As described in Chapter 1 the FAST message is frequently incorporated into public education campaigns. It is also widely used as a screening tool by EMS providers in the United Kingdom, Europe (Fassbender et al., 2013) and Ireland (Feeney et al., 2016). The tool was adopted in the clinical practice guidelines for New Zealand paramedics in October, 2011 (National Ambulance Sector Clinical Working Group, 2011).

This review focuses on the sensitivity of the FAST instrument as a measure of the quality of paramedic care. The value of a screening tool can be measured in several ways. These are described in detail in the Methods chapter (section 3.10.2). However, many stroke experts argue that high sensitivity is the most important attribute of a prehospital stroke screening tool, as it reduces missed diagnoses thereby increasing access to hospital assessment and treatment (Harbison et al., 2003; Meretoja & Kaste, 2012; Sheppard et al., 2015; Smith, Corry, Fazackerley, & Isaacs, 1999). While false positive paramedic diagnoses of stroke potentially create a burden for the hospital system, this needs to be weighed against the costs to the individual and society of missing a case of stroke.

A second assessment of the quality of paramedic care that will be used in this study is compliance with prehospital clinical practice guidelines. Clinical quality indicators are a method of measuring the quality of clinical performance. They report on standardised measures of patient care and case management typically identified from evidence-based sources such as guidelines. For example, the National Health Service in the United Kingdom requires EMS providers to submit monthly reports on their performance against prescribed standards. For suspected stroke cases, providers report the proportion of patients who received appropriate care and the proportion who were potentially eligible for thrombolysis and arrived at a stroke unit within one hour. Clinical quality indicators were introduced into the New Zealand EMS sector in 2015 (Dicker, 2016).

A search of the literature followed the procedure previously outlined in section 2.1. Studies of the sensitivity of the FAST screening tool, needed to fulfil two additional requirements. These were to present sensitivity findings derived from EMS paramedics assessing adult suspected stroke patients in normal practice, (rather than under experimental conditions) and to report the proportion of patients with a confirmed diagnosis of stroke/TIA that the paramedic diagnosed correctly. Studies that only reported the positive predictive value of the paramedic diagnosis were not included.

2.3.2 Sensitivity of paramedic diagnosis using the FAST tool

Five original studies were found that reported on paramedic diagnostic sensitivity, based on the FAST tool (Table 2) and two reviews (Brandler et al., 2014; Rudd et al., 2016). Two of the studies reported high values for diagnostic sensitivity of 95% and 97% (Bergs, Sabbe, & Moons, 2010; Fothergill, Williams, Edwards, Russell, & Gompertz, 2013), two reported low values of 52% and 54% (Nor et al., 2005; Williams et al., 2017). The remaining study reported a sensitivity of 79% (Harbison et al., 2003). Discordance between the reported sensitivity values may be due to differences in the provision of EMS services, temporal effects or aspects of study design.

The structure and provision of EMS systems varies considerably between different locations and countries. In many parts of Europe, including Austria, France, Finland, Germany, Poland and Russia, a doctor or other healthcare professional is frequently part of the EMS crew (Fassbender et al., 2013; Roudsari et al., 2007). Variations of this model, include a doctor in the control room to assess patients by phone (Casolla et al., 2012) and Emergency Department nurses with specialist training, crewing the ambulance (Bergs et al., 2010). Other countries, including New Zealand, Australia, the United States of America and the United Kingdom, use an advanced life support system. This is characterised by a high level of paramedic education and a complex skill set. In this system, doctors only work on helicopter emergency medical systems (Dick, 2003) or under special circumstances such as prolonged entrapment (Roudsari et al., 2007). In basic life support systems, the level of EMS education is lower, the skill set is limited and the emphasis is on rapid evacuation to a medical facility. This system operates in rural and remote areas of New Zealand and is common in middle-income countries. In low-income countries, there may be no organised EMS system and people must make their own way to hospital. The validity of generalising results between EMS systems that use different organisational models, is uncertain. For example, findings may not be transferable if the education and clinical practice of EMS crew who are qualified nurses and doctors, is not equivalent to the knowledge and experience of paramedics working in advanced life support systems. Among the reviewed studies, Belgian ambulances crewed by Emergency Department nurses (Bergs et al., 2010) reported comparable sensitivity to paramedics in the United Kingdom advanced life support system (Fothergill et al., 2013).

Table 2. Summary of papers reporting sensitivity of EMS diagnosis using FAST tool

Study ID	Location	Setting	Enrolment dates	FAST criteria; (age in years)	Reference standard	n	Age <i>M</i> (years)	Male %	Sensitivity [CI]
Bergs 2010	Belgium	1 ED	Dec 2005-Apr 2006	neurological condition; (≥ 18)	ED discharge diagnosis	31	77	61	95% [85-100]
Fothergill 2013	UK	1 hospital	Jan 2010-Mar 2011	suspected stroke; (> 18)	senior stroke consultant diagnosis	295	65	53	97% [93-99]
Harbison 2003	UK	1 SU	Feb 2000-Jul 2000	suspected stroke; (> 18)	stroke physician /consultant diagnosis	487	72	48	79%
Nor 2005	UK	1 SU	Nov 2002-Jul 2003	suspected stroke; (> 18)	stroke physician /consultant diagnosis	49	70	49	54%
Williams 2017	Australia	1 EMS	Jul 2012-Jun 2014	suspected stroke; (≥ 45)	ED discharge diagnosis	2,217	80	49	52% [50.0, 54.5]

Notes. ED = Emergency Department; EMS = emergency medical service; FAST = Face-Arms-Speech test; ID = identifier; SU = stroke unit; UK = United Kingdom.

Another possible cause of differences in the reported sensitivity may be temporal changes. Two studies set in the United Kingdom showed increasing sensitivity over time (Fothergill et al., 2013; Harbison et al., 2003). This could reflect an improvement in paramedic education; the first paramedicine degree course in the United Kingdom was granted approval by the United Kingdom Health and Care Professions Council in 2003. However, the intervening lower sensitivity reported by Nor et al. (2005) does not support this explanation.

It is more likely that aspects of the study designs account for variation in the reported sensitivity of the FAST instrument. In two investigations (Bergs et al., 2010; Nor et al., 2005) the sample included less than 50 patients. Small sample sizes increase the impact of chance occurrences on the observed results. Another important difference in design was the definition of a positive result from a FAST assessment. The tool was developed so that a positive FAST test result is assigned if any one of the three assessments is abnormal, whereas a negative score is assigned only after all three criteria have been tested and found to be normal (Harbison et al., 2003). One study used a local protocol that required an abnormal finding for at least two of the three FAST criteria for a test result to be positive for stroke (Williams et al., 2017). This more exigent requirement could lead to a lower rate of positive cases.

Differences between the studies in the inclusion criteria were also noted. Four of the five included studies required the paramedic to screen the patient, only if a stroke was suspected. However, Bergs et al. (2010) specified 12 circumstances where the patient was to be assessed for stroke. These included generalised presentations, such as “acute neurological event without clear origin, altered level of consciousness” (Bergs et al., 2010, p. 3). The broader requirement would increase the frequency of assessments and could potentially result in the identification of stroke/TIA events that were not suspected by the EMS crew. Other differences in the conduct of the studies were only enrolling patients aged 45 years or older (Williams et al., 2017), using retrospective case ascertainment (Williams et al., 2017), and using the Emergency Department, rather than neurologist diagnosis, as the reference standard (Bergs et al., 2010; Williams et al., 2017). A further difficulty was in the treatment of cases with a false-negative screen who were not transported to the study centre (Fothergill et al., 2013; Harbison et al., 2003). In these circumstances, false-negative cases would be under-reported, inflating the estimate of sensitivity.

Collectively, these studies show that the diagnostic sensitivity of the FAST test, when used by paramedics to recognise stroke, is uncertain. However, in all the studies reviewed, design features challenged the robustness of the findings. Establishing the sensitivity of paramedic stroke/TIA diagnosis will become increasingly important. For example, the introduction of “hub-and-spokes” models of care delivery will require the paramedic to decide whether to by-pass the closest hospital, in favour of a distant but specialist stroke service (Moynihan, Davis, Pereira, Cloud, & Markus, 2010). There is currently no published research quantifying the sensitivity of paramedic recognition of stroke in New Zealand.

2.3.3 Predictors of non-recognition of stroke

There is an extremely limited body of literature that is concerned with identifying factors associated with paramedic non-recognition of stroke/TIA. Non-recognition has been associated with the absence of motor signs, with increased stroke severity and to cases where the paramedic did not document an assessment with a stroke recognition tool (Gropen et al., 2014). Paramedics are more likely to identify strokes in patients who present with clinical signs that are recognisable by a FAST screen, compared to patients with subtle or nonspecific symptoms (Brandler et al., 2015). However, both these studies acknowledge that their results were based on a relatively small sample of patients and used a retrospective study design. The robustness of their statistical approach is questionable, as using an extremely low case to variable ratio, is inadvisable (Bagley, White, & Golomb, 2001; Ottenbacher, Ottenbacher, Tooth, & Ostir, 2004).

The FAST tool is limited to examining the patient for facial palsy, altered motor functioning of the arm and abnormal speech. However, testing of these three elements may not identify mild or severe strokes, atypical presentations or those affecting only the posterior circulation (Kothari et al., 1997). Extremes of severity at presentation influence paramedic recognition of stroke; both mild and severe strokes may be unidentified in the prehospital setting (Gropen et al., 2014; Kidwell, Starkman, Eckstein, Weems, & Saver, 2000). Patients reporting general symptoms, such as malaise and headache, are less likely to be recognised as a stroke case by paramedics than patients with more typical signs of stroke (Brandler et al., 2015). On the other hand, patients with an altered level of consciousness or severe impairment, may be unable to undertake a FAST assessment. In these cases, the paramedic response is to treat the life-threatening conditions and a working diagnosis may not be established.

During the early development of stroke tools, it was noted that motor signs were the element with the greatest reliability between raters (Kothari, Pancioli, Liu, Brott, & Broderick, 1999). Absence of motor signs has been associated with non-recognition (Gropen et al., 2014).

Posterior strokes are difficult to diagnose, even when using comprehensive stroke tools that were designed for in-hospital assessment (Purrucker et al., 2015; Studnek, Asimos, Dodds, & Swanson, 2013; Whiteley, Wardlaw, Dennis, & Sandercock, 2011) and even by doctors (Nor et al., 2004). Among patients whose FMC is with the EMS, a higher proportion of anterior circulation infarcts and a lower proportion of posterior and lacunar infarcts, has been reported, compared with primary care doctor referrals and Emergency Department presentations (Harbison et al., 2003). The rate of posterior infarcts among EMS referrals has also been described as lower than the population prevalence (Nor et al., 2004). The authors proposed that a greater severity of signs and symptoms in anterior strokes had prompted the patient or advocate to seek assistance from the EMS.

Additional assessments for leg weakness and disturbances of vision, perception, balance and coordination would increase the thoroughness of prehospital stroke screening (Gropen et al., 2014; Harbison et al., 2003). However, these would come at a cost to the speed and simplicity of the FAST tool. More importantly, non-recognition of stroke was associated with an absence of documentation of a stroke tool assessment on the paramedic's report (Gropen et al., 2014). The absence of documentation is likely to reflect a lack of screening for stroke, that results in the event being unrecognised by the paramedic.

2.3.4 Quality of care

While performance indicators are an established means to measure and support improvement in the quality of in-hospital stroke care (Kapral et al., 2004; Salhi et al., 2014), their introduction to the prehospital setting is a recent innovation. Previously, EMS effectiveness was measured exclusively by response time criteria, such as New Zealand Standard 8156:2008 (Standards New Zealand, 2008). This standard specifies that 80% of emergency calls will have an ambulance locate within 10 minutes in an urban setting, 16 minutes for rural and 30 minutes for remote rural areas. However, response time has been criticised as a poor gauge of performance, because it does not provide a patient-centred measure of care and the link to improved survival is weak (L. Price, 2006). The challenge for paramedicine has been to develop methods that reliably report the

quality of patient care, and to determine those aspects of paramedic intervention that are associated with better patient outcomes (Shapiro, 2000; Snooks et al., 2008). Clinical quality indicators provide a more relevant and patient-focused measure of care than response time performance. They can also be used to support clinical improvement through prompts and feedback to clinical staff and to increase opportunities for clinical engagement through education initiatives and research collaborations within and between organisations (Siriwardena et al., 2014).

Reviewing current practice against evidence-based guidelines can drive service improvement (Bowling, 2009). Table 3 summarises the recommendations from international guidelines on the EMS care of acute stroke patients. Unlike the European guidelines, which recommend first medical contact with the EMS, the 2010 New Zealand guidelines (Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010), give no guidance on where the public should seek medical assistance. Furthermore, no New Zealand evidence was used to support the prehospital guidelines, presumably because none was available.

Table 3. Comparison of international guidelines for prehospital acute stroke care

Recommendations	SFNZ^a	ASA^b	ESO^c	RCP^d
Paramedic education programmes	-	✓	✓	✓
EMS as FMC	-	✓	✓	-
High priority designation	✓	-	✓	✓
Specific time-based targets	-	✓	-	✓
Stroke screening tool	✓	✓	✓	✓
Blood glucose	-	✓	-	✓
Onset time documented	-	✓	-	-
Notification	✓	✓	✓	✓
Transport highest priority	-	✓	✓	-
By-pass to specialist centre		✓	✓	✓
Rural/remote helicopter transfers		✓	✓	
Transfers prioritised	✓	✓	-	✓

Notes. ^a Stroke Foundation of New Zealand and New Zealand Guidelines Group (2010); ^b American Stroke Association (Jauch et al., 2013); ^c The ESO Executive Committee and the ESO Writing Committee,(2008); ^d Royal College of Physicians (Intercollegiate Stroke Working Party, 2012).

These guidelines identified a lack of evidence on the prehospital management of stroke patients (Intercollegiate Stroke Working Party, 2012), or a low grade of evidence (Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010; The ESO Executive Committee and the ESO Writing Committee, 2008). This reflects the international lack of robust research to inform evidence-based paramedic practice.

As described in section 2.3.1, clinical quality indicators are developed from these evidence-based guidelines. Piloting of a range of EMS clinical indicators began in the United Kingdom in 2008, with national registry data collection commencing two years later (Siriwardena et al., 2010; Siriwardena et al., 2014). The first New Zealand audit of national EMS clinical performance in stroke was published in 2016 (Dicker). Table 4 presents a comparison of the composition and performance on three clinical performance bundles to report the quality of EMS stroke care (Dicker, 2016; Oostema, Nasiri, Chassee, & Reeves, 2014; Siriwardena et al., 2014). A direct comparison between the results reported was not appropriate due to differences in the study designs. Findings from the New Zealand report are reviewed in section 2.3.5.

Table 4. Comparison of clinical quality indicators for prehospital acute stroke care

Clinical quality indicator	NZ^a (%)	USA^b (%)	UK^c (%)
Stroke scale recorded	36	78.5	✓
Onset time documented	84	68.3	-
Blood glucose recorded	82	86.0	✓
Blood pressure recorded	99	-	✓
Notification	53	56.5	✓
Highest dispatch priority	-	82.8	-
Transported highest priority	-	55.4	-
Response time ≤ 8 minutes	-	65.6	-
On-scene time ≤ 15 minutes	-	46.8	-
Onset-to-hospital time ≤ 3.5 hours	66	-	-
Alarm-to-hospital time ≤ 60 minutes	-	-	63.8 ^d

Notes. NZ = New Zealand; USA = United States of America; UK = United Kingdom

^a Dicker (2016) ^b Oostema et al. (2014), ^c Siriwardena et al. (2014) ^d NHS England (2013)

Assessment with a stroke tool, blood glucose monitoring and advance notification, were common to all three clinical quality indicator profiles. This reflects broad acceptance of the need to identify stroke, exclude hypoglycaemia, which can mimic stroke, and to enable the receiving hospital to prepare resources including imaging equipment and specialist stroke staff, to facilitate the rapid assessment and treatment of the patient. Oostema et al. (2014) did not specify blood pressure measurement; presumably this would be recorded during the secondary survey. Documenting an accurate onset time was included in two clinical quality indicator profiles. Failure by paramedics to record an exact, rather than a relative time (such as “this morning”), and to differentiate between a known onset time, when the patient was “last known well” and when the symptoms were recognised have been observed (Curfman et al., 2014; Spokoiny et al., 2015). Paramedics also tend to underestimate the last known well time in cases when the patient wakes with stroke symptoms (Curfman et al., 2014).

The dispatch and transportation priority level were only included in the quality indicators developed in the United States of America. The priority assigned to the case at dispatch determines whether the ambulance responds “under lights and siren” or travels with the normal traffic flow. It also influences how long the job may be queued before being assigned, the order in which cases are allocated if resources are in high demand, whether a fully crewed ambulance or a single crewed response vehicle is dispatched, and the level of crew qualification (e.g. basic or advanced life support). It has been estimated that half of suspected stroke patients have a high priority dispatch (Puolakka, Väyrynen, Erkkilä, & Kuisma, 2016; Wireklint Sundström, Herlitz, Hansson, & Brink, 2015). High priority dispatch has been associated with increased rates of thrombolysis (Berglund et al., 2012). However, the evidence supporting high priority transportation to the hospital is weak, with one study reporting significant reductions in prehospital and in-hospital delay (Vidale et al., 2016) while another found no benefit (Berglund et al., 2012). High priority transportation to hospital has not been regular practice in New Zealand, as the increased risk for the crew, patient and other road users must be balanced against the uncertain time benefits. High priority transport to hospital has been recently mandated in New Zealand for stroke cases where time saving is anticipated to be clinically significant.

While time-based standards remain in all three clinical quality indicator profiles (Table 4), they have evolved from a simple response time indicator to clinically relevant measures linked to treatment eligibility. The total EMS contact time can be divided into four intervals: from receipt of the emergency call or “alarm” until ambulance dispatch

(queuing), from dispatch to arrival with the patient (response), from arrival to departure from the scene (on-scene) and from departure until hospital arrival (transport). The on-scene interval accounts for over 40% of the total EMS contact time but is potentially modifiable by the paramedic (Schwartz, Dreyer, Murugiah, & Ranasinghe, 2016; Simonsen et al., 2014). In one study, only 26.7% of cases had a scene time of 15 minutes or less when the stroke was unrecognised, compared with 53.2% when the stroke was recognised by the EMS (Oostema et al., 2014). Furthermore, Patel et al. (2013) reported a reduction in on-scene time of 2.2 minutes by introducing a scene time protocol. Using a simulation model, Lahr, van der Zee, Vroomen, Luijckx, and Buskens (2013) estimated that a 1.4% increase in the thrombolysis rate could be achieved by reducing the on-scene time.

The National Health Service of the United Kingdom reports on the proportion of FAST positive patients potentially eligible for stroke thrombolysis that arrive at a hyperacute stroke unit within 60 minutes from the emergency call (NHS England, 2013). In April 2011, across the 12 English Ambulance Trusts, values for completion ranged from 46.6% to 90.9% with a national average of 66.3%. One year later in April 2012, the comparative figures were 48.9 to 82.8% and 63.8%. The most recently published available are October 2016 and the comparative figures were 39.9% to 62.6% and a nationwide average of 51.7%.

2.3.5 New Zealand situation

The St John New Zealand 2016 national audit of EMS clinical performance, retrospectively reviewed completion of six clinical tasks (Table 4) for 460 suspected stroke cases over a one-month period (Dicker, 2016). Compliance with the reporting of onset time, blood glucose level and blood pressure, was high. Two-thirds of patients with a recorded onset time arrived within three and a half hours of symptom onset. Advance notification was made to the hospital for half of the cases and a stroke scale score was recorded for one third of patients.

2.3.6 Summary

The literature review has revealed a lack of robust evidence on the diagnostic sensitivity of paramedics using the FAST instrument, a comparative absence of research exploring factors associated with paramedic non-recognition of stroke, a paucity of research on the

care delivered to stroke patients by EMS paramedics and an overall dearth of prehospital research to inform guideline recommendations.

2.4 Patient outcomes and paramedic care in ischaemic stroke

2.4.1 Rationale and methods of the literature review

Within this thesis, outcome measures are used to compare the effect of the interventions identified in the proposition. This third and final section of the literature review examines and assesses the current knowledge on the relationship between initial paramedic contact, the quality of paramedic care and key process indicators of the management of stroke cases and health-related patient outcomes. The measures used to investigate these relationships are: 1) the duration of the prehospital delay, 2) the rate of thrombolysis administration in ischaemic stroke and 3) health-related outcomes measured by mortality and scores on the modified Rankin Scale and the EuroQol EQ-5D. The stroke-specific modified Rankin Scale and the generic EQ-5D are used to explore independence, functional ability and quality of life; outcomes that matter to stroke patients and their families. These three measures are inter-twined as shorter delay from onset until hospital arrival increases access to, and the potential to benefit from, thrombolysis, which in turn improves patient health-related outcomes.

The literature review drew on publications identified during the search for studies investigating the first medical contact (section 2.2) and made additional searches using key terms. The search strategy is shown in Appendix A.

2.4.2 Onset-to-door delay

The onset-to-door delay is the interval from the time of symptom onset until arrival at the hospital door. It is a key process measure in the context of stroke as a medical emergency. This is exemplified by, but not limited to, the four and a half hour constraint on the administration of alteplase. Admission to a stroke unit within three hours, even without thrombolysis, is associated with improved NIHSS scores and functional outcomes compared to later arrival (Silvestrelli et al., 2006). Systematic reviews and computer simulation studies agree that focusing on prehospital factors has the greatest potential to increase access to acute stroke treatment (Evenson, Foraker, Morris, & Rosamond, 2009; Fassbender et al., 2013; Lahr et al., 2014). Decreasing prehospital delay, increases both the number of patients who arrive within the time-critical therapeutic window and the

volume who arrive earlier, before the full potential of the neurological damage has been realised. Quantifying the onset-to-door delay enables local EMS providers and stroke service networks to benchmark prehospital performance against international standards and provides a baseline for continuing improvement.

Determining an accurate time of stroke onset is problematic particularly if the patient was asleep at the time, or alone and experienced symptoms that precluded giving a clear history. In contrast to the clinician's need to establish therapeutic eligibility, the researcher's definition of stroke onset time is informed by the aims of the study. Studies exploring the accessibility of treatment will mirror clinical eligibility criteria whereas investigations describing patient-attributable delay in summoning assistance, may use the time that the patient was found with symptoms. The effect of onset definition on study inclusion was demonstrated by Salisbury et al. (1998). They reported that an exact time was known for 55% of identified cases. Broadening the onset definition to include a last known well time included 84% and extending it to "discovered with symptoms", captured 94% of cases in the analysis.

Excluding large proportions of the sample population from the analysis, due to missing onset times, risks introducing bias and limiting the strength of the findings. To avoid this outcome, other researchers have imputed onset times, often based on the information available. However, the values ascribed are selected by the individual researcher so that "morning" can be designated as 8am, in one study (Kothari, Jauch, et al., 1999) and 9am in another (Fogelholm, Murros, Rissanen, & Ilmavirta, 1996). Applying the time the patient was found or imputing the time both risk systematically misestimating the onset-to-door delay.

Imaging procedures and treatment protocols continue to evolve rapidly. New evidence supports late thrombectomy in cases where the severity of the patient's presentation is disproportionately greater than expected from the imaging report (Nogueira et al., 2017). EMS paramedics can support clinical decision-making by reporting onset time aligned with therapeutic eligibility criteria; that is, the time of onset if known, or the time the patient was last known well, with the time of awakening in cases where onset occurred during sleep.

First medical contact and onset-to-door delay

Studies that attempted to quantify the relationship between initial medical contact and onset-to-door delay were scarce. As previously discussed, many studies define EMS usage as the mode of transport rather than as the first point of contact. While these display a strong effect in favour of transport by ambulance, they do not measure the potential benefit of initial contact with EMS in stroke and TIA.

Six of the studies previously identified in the FMC literature review (Table 1) extended their analysis to calculate the difference in onset-to-door time by the FMC referral route (Agyeman et al., 2006; Geffner et al., 2012; Harraf et al., 2002; Rossnagel et al., 2004; Salisbury et al., 1998; Yoneda et al., 2001). Their findings are summarised in Table 5.

The findings reported by the six studies were unanimous; onset-to-door time was always less when the first medical contact was with a paramedic. The shortest reported median EMS onset-to-door time was 75 minutes (Rossnagel et al., 2004) and the longest was 123 minutes (Harraf et al., 2002). This compared to a range from 224 to 650 minutes when the FMC was a primary care doctor (Agyeman et al., 2006; Rossnagel et al., 2004) and 174 to 285 minutes for Emergency Department staff (Agyeman et al., 2006; Geffner et al., 2012). It was apparent from studies that reported a measure of variance, that the onset-to-door distribution was skewed to the right, due to late-arriving cases (Geffner et al., 2012; Harraf et al., 2002).

Earlier studies (Agyeman et al., 2006; Rossnagel et al., 2004; Salisbury et al., 1998) often, but not always (Harraf et al., 2002), reported much shorter median onset-to-door delays for FMC with EMS than the most recent study (Geffner et al., 2012). This is at odds with the trend of decreasing prehospital delay (Evenson et al., 2009). However, the discrepancy is likely to be explained by the earlier studies preferring an onset definition of time of symptom recognition. This definition would systematically underestimate the delay in comparison to studies using the criteria of the time that the patient was last known to be well (Geffner et al., 2012; Harraf et al., 2002).

Table 5. Summary of papers reporting onset-to-door time by first medical contact

Study ID (Location)	<i>n</i>	Onset time definition	Onset-to-door			
			First medical contact	<i>Mdn</i> (min)		
Agyeman, 2006 (Switzerland)	615	Symptom recognition	EMS	80		
			Helicopter	93		
			PCD	224		
			Emergency doctor	175		
			ED	174		
			Transfer ^a	195		
Rossnagel, 2004 (Germany)	452	Symptom recognition	EMS ^b	75		
			PCD ^b	650		
			Phoned PCD ^b	375		
			ED ^b	200		
			Other ^b	400		
Salisbury, 1998 (UK)	153	Symptom recognition	EMS	77		
			PCD	282		
			ED	229		
			First medical contact	<i>Mdn</i> [IQR]		
Geffner, 2012 (Spain)	388	Last known well	EMS	117 [64, 460]		
			PCD	546 [145, 1,313]		
			ED	285 [73, 969]		
			First medical contact	<i>Mdn</i> [range]		
Harrarf, 2002 (UK, Dublin)	736	Last known well, imputation	EMS	123[47, 432]		
			PCD	432 [125, 1,237]		
			ED	not reported		
			Proportion arrived (%)			
				≤ 6 hr	6-24hr	1-7 day
Yoneda, 2001 (Japan)	254	Last known well	EMS	55	25	5
			PCD	16	26	28
			ED	18	30	40
			Other ^{a,c}	12	19	27

Notes. ED = Emergency Department; EMS = emergency medical service; ID = identifier; PCD = primary care doctor; UK = United Kingdom.

^a transfers from other hospitals to specialist stroke unit; ^b times estimated from diagram; ^c in-hospital cases.

Another method of presenting prehospital delay has been to report the percentage arriving within specified time limits. The time intervals of interest are aligned with guidance on stroke management and goals for in-hospital processes. This approach also demonstrated that higher proportions of early-arriving patients had initial contact with the EMS compared to other prehospital pathways (Yoneda et al., 2001).

Other differences related to location and design, may have contributed to variation between studies in the duration of the onset delay. The organisation of EMS systems varied between locations. In Germany, Spain and Switzerland, doctor-led advanced life support delivery predominated (Agyeman et al., 2006; Geffner et al., 2012; Rossnagel et al., 2004). In the United Kingdom and Ireland advanced life support systems were favoured (Harraf et al., 2002; Salisbury et al., 1998). In Japan a basic life support model, with limited advanced skills, prevailed (Yoneda et al., 2001). Categories of FMC varied between studies, such as phoning versus consulting with a primary care doctor (Rossnagel et al., 2004), consulting with an emergency doctor versus a primary care doctor and sub-classification by EMS ambulance versus EMS helicopter (Agyeman et al., 2006). The study perspective also affected reporting, with investigations set in stroke units including inter-hospital transfers (Agyeman et al., 2006; Yoneda et al., 2001). This obscured the initial referral pathway from the community to the first hospital.

Recognition and onset-to-door delay

The effect of paramedic recognition on the onset-to-door delay is not well understood. Population level data has suggested that paramedic contact may account for two-thirds of the onset-to-door interval in cases where the FMC is with the EMS (Wolters et al., 2015). In this case, even small time-savings would have the potential to increase patient eligibility for, and ability to benefit from, treatment. A trend of marginally longer on-scene delay but shorter transport times with paramedic recognition of stroke, has been described but did not reach statistical significance (Abboud et al., 2016). However, as no significant difference in the overall EMS contact time was observed, it is unlikely that a paramedic clinical impression of stroke would have affected the onset-to-door interval.

Studies reporting the association between specific paramedic interventions and the duration of the onset-to-door time, were also rare. Modifications to EMS procedures were typically introduced as part of a wider programme of changes to hospital processes known as a “Code Stroke” (Gladstone et al., 2009; Meretoja et al., 2013; O’Brien et al., 2012; Vidale et al., 2016). Evidence from combined initiatives was contradictory, with trends

of both decreasing (Meretoja et al., 2013; O'Brien et al., 2012) and increasing (Abdullah et al., 2009; Belvís et al., 2005; Casolla et al., 2012; Vidale et al., 2016) onset-to-door times reported. However, even among studies where the median onset-to-door time increased, delays from onset-to-treatment were briefer. For example, Vidale et al. (2016) studied the effects of a public education campaign and staff training initiatives in conjunction with advance notification by the EMS and introduction of a hospital Code Stroke response. They reported a non-significant 14 minute increase in prehospital delay but a statistically significant 29 minute decrease in the onset-to-needle time and an increase in the number of patients receiving thrombolysis. Enhancement of care transitions has been observed to decrease in-hospital delay to specialist review, imaging and treatment (Abboud et al., 2016; Belvís et al., 2005; Meretoja et al., 2013; Mosley et al., 2007; Sheppard et al., 2015).

2.4.3 Thrombolysis rates

Although other therapeutic interventions have demonstrated benefit in acute stroke, thrombolysis for ischaemic stroke has been the driver for reducing prehospital delay. Paramedic contact with the patient, is for a relatively short duration, but occurs at a critical phase and can facilitate prioritisation of the stroke patient at the receiving hospital. This literature review investigates whether the higher proportion of early-arriving patients observed in the EMS prehospital pathway, translates to a higher rate of thrombolysis for ischaemic stroke in the same patient group. Although this may seem intuitive, unexpected factors, such as a higher prevalence of pre-stroke dependency or excluding criteria, could confound this result. This is followed by an examination of the literature linking rates of thrombolysis to EMS stroke care interventions.

First medical contact and thrombolysis rates

Failure by patients and their advocates to call the EMS as soon as a stroke is suspected, may be the greatest barrier to thrombolysis (California Acute Stroke Pilot Registry (CASPR) investigators, 2005). Higher rates of thrombolysis have been reported for patients who arrived at the stroke unit by “emergency ambulance”, compared with arrival by other transport modes (C. I. Price et al., 2013). Higher proportions of patients transported by ambulance (60.8%) arrived within three hours of onset, compared to patients transported by non-EMS modes (40.0%), and this translated into thrombolysis rates of 24.7% and 12.8% respectively (Ekundayo et al., 2013). Among patients who were treated with alteplase, the majority (72%) arrived by ambulance (Vidale et al., 2016).

For patients whose FMC was with a primary care doctor, the prehospital delay often exceeded limits for thrombolysis and excluded them from treatment (Wolters et al., 2015).

However, with the exception of Wolters et al. (2015), these studies all reported EMS usage as the mode of transport rather than as the first medical contact. There remains a lack of evidence quantifying the impact on thrombolysis of alternative referral pathways by EMS, primary care doctor and Emergency Department. Given that the rate of thrombolysis is low, a large sample is necessary to detect a statistically significant difference between the FMC groups, making a population study a suitable methodological approach.

Recognition and thrombolysis rates

The influence of paramedic care on thrombolysis rates were frequently reported within the context of introducing a Code Stroke in a single hospital setting. These typically included a number of prehospital changes including high prioritisation of suspected stroke calls, use of a stroke tool, a bypass protocol and advance notification in combination with in-hospital education and reorganisation of services. Studies reporting on the introduction of a Code Stroke, found that rates of thrombolysis increased in comparison to previous rates (Kim et al., 2009; Lindsberg et al., 2006; O'Brien et al., 2012; Vidale et al., 2016) or locally reported rates (Meretoja et al., 2012).

Early recognition of stroke by paramedics, is vital to facilitate access to treatment. Use of a prehospital stroke assessment instrument may support recognition and promote thrombolytic therapy. A cluster randomised control trial in Italy that introduced the Cincinnati Pre-hospital Stroke Scale (CPSS) to EMS paramedics, showed significant increases in the frequency of administration of alteplase (De Luca et al., 2009). However, this intervention was combined with educating Emergency Department staff in the use of the NIHSS. In a small retrospective study, ischaemic stroke patients whose condition was recognised by EMS paramedics, had a significantly higher rate of thrombolysis than those whose stroke was not recognised by paramedics (Abboud et al., 2016). This effect was independent of age, symptom severity and duration and irrespective of advance notification to the receiving Emergency Department. In contrast, use of the Kurashiki Prehospital Stroke Scale (KPSS) in a Japanese EMS system, was not associated with an increase in the rate of thrombolysis (Iguchi, Kimura, Watanabe, Shibasaki, & Aoki,

2011). No studies were found that investigated the effect on the thrombolysis rate of introducing the FAST screening tool to paramedic practice.

2.4.4 Health-related outcomes

The relationship between paramedic care and health-related patient outcomes such as level of independent functioning, quality of life and mortality, remain unexplored. The impact of prehospital care on process measures, such as access to thrombolysis, is heavily mediated by hospital systems and care. This includes access to acute, specialist and general medical services and contact with a range of allied services, including physiotherapy, speech and language therapy, occupational therapy and rehabilitation. It follows that the contribution of prehospital care to long-term patient outcome measures, will be attenuated by the patient's overall experience in the healthcare system (Oostema et al., 2014).

Higher mortality in stroke, is associated with transportation by ambulance (C. I. Price et al., 2013; Romano et al., 2016). The same studies found that patients who arrived by ambulance had significantly greater disability at discharge, were less likely to be independent and were more likely to be discharged into institutional care. However, patients transported by ambulance had a higher level of pre-stroke dependence (C. I. Price et al., 2013), and more severe symptoms at onset (Turan et al., 2005), compared with patients who were not transported by EMS. Worse health status at baseline could account for the poorer outcomes observed in the EMS patient group, across various health-related measures.

Limited evidence supports an association between co-ordinated prehospital and in-hospital stroke care and improved health-related outcomes, independent of the patient's presentation at onset. Patients conveyed directly to a specialist centre under a Code Stroke protocol, were more likely to be functionally independent at discharge than patients who did not by-pass the community hospitals, after adjusting for the increased severity of the EMS group at baseline (Perez de la Ossa et al., 2008). No studies were located that compared patients' quality of life scores using a generic instrument, such as the EQ-5D, by the stroke patient's first medical contact.

2.4.5 New Zealand situation

Despite a thorough search of the literature, no studies presenting the onset-to-door interval by FMC in New Zealand were found. The first nationwide audit of acute stroke

services in New Zealand was conducted over three months in 2009 (Stroke Foundation of New Zealand, 2010). The study found that among 772 stroke patients arriving from the community, and for whom an onset time could be determined, 33% arrived within three hours and 38% had arrived by four and a half hours from onset.

No studies were located that reported on the association between paramedic care and patient outcomes. One study observed a decrease in stroke-related deaths in Auckland over a 20 year period and attributed enhanced in-hospital stroke care practice as a major contributor to this improvement. (Carter, Anderson, Hackett, Barber, & Bonita, 2006). However, in this study, the investigators defined first medical contact as seeking attention from either a primary care doctor or at an Emergency Department; paramedics were not included. Consequently, the effects of initial EMS contact and paramedic care were not visible in this analysis.

2.4.6 Summary

Overall, these studies highlight the need for a greater understanding of the association between paramedic care and both case management processes and patient health-related outcomes. A strong trend emerged of shorter prehospital delay, when the initial contact was with the EMS compared to other prehospital pathways. Comparisons of the duration of onset-to-door delay were difficult, due to the lack of a standard definition of onset time.

2.5 Summary of the literature review

In conclusion, while the research literature supports the use of EMS as the FMC in acute stroke/TIA, much uncertainty still exists about the proportion of people who access care by this pathway. The generalisability of research findings between different countries is uncertain, due to varying structures and organisation of healthcare systems and very little is known about what factors predict first medical contact with EMS in acute stroke/TIA. Furthermore, researchers frequently fail to distinguish between the uses of EMS as the first medical contact, compared with the mode of transport. In New Zealand there is no published data describing the relative proportions of stroke patients who have their first medical contact with the EMS, a primary care doctor and Emergency Department staff.

There is a lack of robust research exploring the quality of paramedic care. Results from previously published studies on the sensitivity of paramedic diagnosis of stroke/TIA using the FAST assessment tool, are inconsistent and it is still unknown what factors are

associated with non-recognition of stroke/TIA by paramedics. To date, there has been very little quantitative analysis of the quality of paramedic care provided to stroke/TIA patients, using measures that are aligned with recommendations from the clinical guidance. Weak study designs, including single sites, retrospective case ascertainment and small sample sizes, are a common feature. Earlier studies have focused on time-based measures and industry reporting is restricted to cases of suspected stroke. The literature also demonstrates extremely limited reporting of the relationship between paramedic care and case management indicators and patient-centred outcomes that describe functional independence and quality of life. Very few studies have investigated in any systematic manner the association between paramedic recognition of stroke and the administration of a thrombolytic agent.

Overall, there appears to be a relatively small body of literature that is concerned with paramedic practice in the care of acute stroke and TIA patients. The current study is therefore essential to address this gap in the knowledge. It will use a population-based approach to investigate the prehospital pathway, examine the quality of paramedic care and explore outcomes for patients with a diagnosed stroke/TIA event. The current study will for the first time report from a paramedic perspective, on the prehospital care of patients who were subsequently diagnosed with stroke or TIA in New Zealand. This information, which is currently unobtainable, has the potential to inform local prehospital stroke initiatives and extend the international knowledge on this topic. One example, is targeted public education initiatives aimed at increasing access to time-critical specialist stroke interventions through appropriate prehospital pathways.

It is anticipated that the findings from this study will make an important contribution to the understanding of paramedic stroke/TIA recognition. In particular, it will shed new light on the sensitivity of the paramedic working diagnosis using the FAST assessment tool and provide new insights into factors that predict non-recognition of stroke/TIA. A better understanding of prehospital stroke recognition can be used to inform education curriculums and clinical guidelines for paramedics to increase diagnostic sensitivity. This has the potential to improve the access to appropriate in-hospital care for stroke and TIA patients. The use of clinical indicators to report on the quality of care delivered by paramedics is a comparatively recent development in the prehospital setting. Using population level data, this study will report on the care delivered to all stroke/TIA cases and to those that were recognised by the paramedic.

Chapter 2. Literature Review

This study provides a substantial opportunity to advance the understanding of the relationship between paramedic care and patient outcomes. In particular, the investigation will offer important insights into the relationship between paramedic care and access to time-critical treatment, functional outcome and quality of life after stroke. This study makes a major contribution towards establishing robust research-based evidence, to support the development of knowledge in the field of paramedic stroke/TIA care.

Chapter 3 METHODS

The chapter commences with a statement of the research aims and objectives. After reflecting on the methodology and perspective of the study, the design, setting, participants, and variables are described. Attention then turns to the data sources, potential sources of bias and the study size. Finally, the handling of the quantitative variables in the analyses and the statistical methods are explained. The structure of the chapter follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (Vandenbroucke et al., 2007; von Elm et al., 2008) and is also informed by the Standards of Reporting of Neurological Disorders (STROND) checklist (Bennett et al., 2015). These guidelines were constructed to increase thoroughness and precision in the reporting of studies.

3.1 Aim and objectives

The aim of this thesis is to explore the proposition that:

For acute stroke and transient ischaemic attack (TIA) patients, the application of best-practice paramedic Emergency Medical Service (EMS) care, compared to initial contact with a non-EMS healthcare professional or EMS care that does not meet the standard, is associated with better management (earlier arrival at hospital and higher rates of thrombolysis for ischaemic stroke) and improved health outcomes measures at 28 days post-stroke.

The thesis proposition follows the Population-Intervention-Comparator-Outcome structure of framing clinical questions to support evidence-based medicine (Richardson, Wilson, Nishikawa, & Hayward, 1995). In this enquiry, acute stroke and TIA patients comprise the study population. Two intervention and comparator relationships are considered. Firstly, initial medical contact with the EMS is compared to a non-EMS prehospital pathway. Secondly, best practice paramedic care is compared with a lesser standard of paramedic care, determined by stroke recognition and adherence to clinical guidelines. The outcomes of interest measure case management, mortality and health-related outcomes of independent functioning and quality of life at 28 days after the stroke/TIA event.

In order to investigate this proposition it is necessary to address the following objectives:

1. to identify how people access emergency medical assistance in cases of acute stroke and TIA in New Zealand, and whether any patient factors predict the first medical contact
2. to evaluate the quality of care delivered by paramedics to patients suffering an acute stroke or TIA by determining the paramedic diagnostic sensitivity, factors that predict non-recognition of stroke/TIA, and adherence to the clinical guidelines
3. to explore whether first medical contact with the EMS and the quality of paramedic care provided are associated with improved measures of case management and health-related patient outcomes. Outcomes measured are: delay from stroke onset to arrival at hospital door, thrombolysis rates for ischaemic stroke, mortality, functional outcome (measured by the modified Rankin Scale) and quality of life (measured by the EQ-5D).

All three objectives rely upon the integrity of the data set that was constructed from the paramedic patient report and the database that was created by combining EMS clinical and operational data with hospital-sourced data. Therefore, it was essential to establish the reliability of the combined data set before proceeding with the analyses.

3.2 Methodology and perspective

The methodological approach of any study informs the appropriate methods to answer the research question and guides the perspective of the study analysis. This study is conducted using scientific methods and a quantitative statistical approach. Population-level data and statistical analysis are used to explore the research propositions. Epidemiology has been criticised for taking a positivistic perspective within the western biomedical model. The contention is, that this results in a focus on causative factors and individual responsibility while ignoring the social context of health determinants (Moon, Gould, & Colleagues, 2000). These criticisms can be addressed by emphasising the context in which the study is located and interpreting statistical associations with care.

Randomised controlled trials are often regarded as the most robust form of evidence (Moon et al., 2000). However, some research can only be answered by non-experimental, epidemiological studies as it would be unethical to randomise patients to experimental groups (Feigin & Howard, 2008). Similarly, while qualitative approaches provide insight into experiences of a small group of patients, as with a randomised controlled trial, they

cannot describe frequency and patterns of service use, to inform health service planning (Feigin & Howard, 2008). Clinical review is often the only method to answer critical questions on service provision, uptake and quality (Ellis et al., 2013; Feigin & Howard, 2008; Sinnott, 2015). Research is distinguished from audit activity by its purpose and power to enhance and change current practice (Bowling, 2009). These factors make a population approach appropriate for this study.

In medical research, the role of the researcher and their values and beliefs are frequently invisible and are assumed to have no bearing upon the investigation. However, the selection of the research method is determined by the researcher's beliefs as well as the topic of investigation and the research question (Grant & Giddings, 2002). The current study is informed by the researcher's experiences of working in the health sector as an intensive care paramedic and educator, registered nurse and health economics researcher. This is a study conducted from a paramedicine perspective in the context of a nascent healthcare profession. The lack of research capacity within the discipline of paramedicine, has hindered the development of scientific investigations led from within the profession. This occurs in combination with a lack of stroke and TIA research (Luengo-Fernandez et al., 2012). In this setting, scientific enquiry into the paramedic care of stroke and TIA patients is a priority.

3.3 Study Design

The study used a cross-sectional observational design, to examine the prehospital phase of acute stroke and TIA, with particular emphasis on the paramedic care of patients. This was achieved through chart review of paramedic-completed PRF.

The study forms an extension to the fourth Auckland Regional Community Stroke (ARCOS IV) population study. Full details of the ARCOS IV methods have been published (Krishnamurthi et al., 2014) but a brief overview is provided here. ARCOS IV is a prospective population-based stroke incidence and outcomes research project for measuring and reducing stroke burden in New Zealand. The programme has run for over 35 years with the first ARCOS investigation undertaken between 1981-2 and subsequent population surveys in 1991-92 and 2002-03. ARCOS IV commenced on 1 March 2011 and continued to locate and register all incident TIA and stroke events for the 12 months until 29 February 2012. Cases were included if the patient was aged 16 years or older and was normally resident in the study area. Multiple overlapping sources and "hot" and

“cold-pursuit” methods were used to achieve thorough case ascertainment. Hospital admissions were checked daily and discharge records and outpatient clinics weekly. Private hospitals, rest homes, and community health services were reviewed monthly and primary care doctors’ clinics quarterly. Annual checks were made of the Ministry of Health national database of all stroke admissions and of coroner’s reports, autopsy records and death certificates.

The current study was added to the ARCOS IV umbrella of projects after the ARCOS IV design was finalised and data collection had commenced. Stroke and TIA cases were identified from ARCOS IV records and the paramedic-completed PRF were located and reviewed, to provide the additional data required for this study. Although the cases were identified prospectively in the ARCOS IV study, collection of the PRF occurred retrospectively. However, deterioration of data quality due to decay of recall was not a concern as the PRF provided a written record completed at the time of the event. The resulting database contains variables which detail the clinical care for stroke and TIA cases that were cared for by paramedics. By linking ambulance callouts to the EMS computer-aided-dispatch system, operational data was able to be included. The statistical analysis of the EMS clinical and operational data, combined with hospital-sourced patient information collected in the ARCOS IV study, created a unique opportunity to explore the prehospital phase of acute stroke care at a population level.

3.4 Setting

The study is set in the Auckland province in New Zealand. Auckland is the largest city in New Zealand and is centred on a narrow isthmus which separates two harbours, the Waitemata and the Manukau (Appendix B). The city is surrounded by rural environs and several permanently inhabited islands. The ARCOS IV study used the same geographical area as the previous ARCOS studies to support comparisons, despite some changes to the local government boundaries in 2010. In mid-2012 the population of the greater Auckland region was 1,507,600 residents (Statistics New Zealand, 2013) with two-thirds of inhabitants aged 16 years or older.

In New Zealand, acute stroke and TIA care is provided by the public health system which is free to all citizens. Planning and provision of health services, is managed by District Health Boards (Ministry of Health, n.d.). There are three District Health Boards in the

Auckland region and in 2012 their individual populations were estimated to be between 450,000 and 550,000 (Appendix B) each.

At the time of the study four major hospitals provided Emergency Department, radiology and neurology services including thrombolysis for ischaemic stroke and specialist stroke unit care. In the south and east of the region, Counties-Manukau District Health Board supplied services from Middlemore Hospital, for a predominantly urban-dwelling population but also for rural communities up to 90 km from the hospital. To the north and west, the largest District Health Board, Waitemata, co-ordinated services from two locations: North Shore and Waitakere Hospitals. Like Counties-Manukau, most inhabitants lived in urban areas but the catchment included settlements 90km from either hospital. In the centre of the province, Auckland District Health Board delivered services from Auckland City Hospital. This was the only hospital in the greater region providing endovascular clot retrieval. Although most of the 450,000 inhabitants of this catchment area lived within a 20 km radius of the hospital, it included Waiheke and Great Barrier Islands, where medical evacuation is only by helicopter, fixed wing aircraft or boat.

The study considered three possible referral routes from the community location where the stroke or TIA commenced, to the four tertiary hospitals providing specialist care. Care could be accessed by, or on behalf of, the patient by calling the EMS, consulting either in person or by phone with a primary care doctor or presenting at the Emergency Department of a hospital. These will be described in turn.

In New Zealand, the public can summon urgent medical aid by using the 111 emergency services phone number. In the greater Auckland region, St John is the sole EMS provider. Nationally, St John provides emergency medical cover for 90% of the population covering 97% of the country's geographical area (St John New Zealand, n.d.). EMS providers are not part of the Department of Health and the two providers, the Order of St John and Wellington Free Ambulance, are both registered charities. Partial funding of the services is received through contracts with District Health Boards and the Ministry of Health. In most areas of New Zealand ambulance users are charged a fee for medical callouts. The standard cost of an emergency call out in 2017 is \$98 (St John New Zealand, 2016).

The New Zealand EMS system, is a mix of 52% fulltime career paramedics working from basic to advanced life support levels, 24% part time and casual staff and 24% volunteer first responders, who tend to be located in rural regions and work at a basic life support

level (Beck et al., 2016). In the absence of regulation of paramedicine as a health care profession, a doctor employed as a Medical Director or Advisor by the EMS provider, grants EMS staff authority to practice within a specific scope of practice (Tunnage, Swain, & Waters, 2015). This scope of practice defines the specific interventions and medicines which individual personnel can administer to a patient. At the time of the study, scopes of practice were divided into three areas: basic, intermediate and advanced life support. The stroke/TIA care stipulated in the clinical practice guidelines current at the time, (National Ambulance Sector Clinical Working Group, 2011) was all designated within the basic life support scope of practice and so applied to all levels of practice. Therefore, in this thesis, the term “paramedic” is used generically to represent an EMS healthcare professional, rather than to signify a particular level of education and practice.

The second prehospital referral pathway, is through contacting a primary care doctor. This may be the patient’s general practitioner or a doctor working at a private accident and emergency centre. For the purposes of this thesis, all doctors practising general medicine in the community will be referred to as primary care doctors. Charges vary between practices, but patients enrolled at a practice are subsidised by government funding and generally pay half the fee of a casual patient. Typical charges in 2017 for an adult consultation on a medical problem are \$42.50 for an enrolled patient and \$85 for a casual patient (Henderson Medical Centre, n.d.).

Finally, patients may present at the Emergency Department of a public hospital. In this case, their initial medical contact is most likely to be with the triaging nurse. In New Zealand, healthcare in public hospitals is provided free to all at the point of delivery. Payment is sought at a later date, from individuals who are ineligible for funded medical care.

3.5 Participants

The current study examined all new stroke and TIA cases during the 1 March 2011 to 29 February 2012 study period that were identified by the ARCOS IV investigators. Incidence studies, such as ARCOS IV, measure the number of new events that develop in a population during a specific time interval, irrespective of whether it was an individual patient’s first ever stroke or TIA or a recurrence (Hennekens & Buring, 1987). Where a patient had a TIA and a stroke, both were considered to be incident events and were recorded. However, if the patient had a second TIA or stroke during the 12 months of the

study, it was recorded as a complication of the initial event and fewer details of the case were collected from the hospital medical records.

As previously described in section 3.3, the ARCOS IV study collected de-identified demographic and clinical information from multiple sources for all new stroke and TIA events that occurred during the study period. Patients, or their proxies, were also invited to enrol in the full ARCOS IV study. Patients who consented to participate in the outcomes study had a baseline interview with an ARCOS IV research assistant within two weeks of their stroke or TIA and their medical records were reviewed. Follow-up of consented patients occurred at 28 days, 6-months and 12-months after their event. For patients who did not consent to the full study, medical notes were reviewed at baseline only (Krishnamurthi et al., 2014). ARCOS IV follow-up finished on 28 February 2013, 12 months after the final enrolment into the study. Data collection for the PRF database commenced in October 2014 and was completed by 30 June 2015.

Stroke and TIA were defined using the World Health Organisation definitions. As previously described, stroke is differentiated from TIA by the duration of clinical signs that persist for more than 24 hours or result in death (Aho et al., 1980, p. 114). Ischaemic stroke, primary intracerebral haemorrhage and subarachnoid haemorrhage were included, whereas cases detected by neuroimaging, in the absence of clinical signs and symptoms, were not included. TIA is defined as “an acute loss of focal cerebral or ocular function with symptoms lasting less than 24 hours and which after adequate investigation, were presumed to be due to embolic or thrombotic vascular disease” (Hankey, Slattery, & Warlow, 1991, p. 801). Including TIA cases was particularly important in the current study, as paramedics may witness signs before they resolve.

ARCOS IV included incident strokes and TIA during the study period if the patient was a resident in the Auckland region and aged 16 years or older. Patients were included irrespective of whether they were admitted to a hospital. A diagnostic review committee comprised of three stroke neurologists and a stroke physician, considered the clinical findings, imaging results and the patients' medical notes, to confirm the stroke/TIA diagnosis for each case. The committee's diagnosis included pathological typing as ischaemic stroke, intracerebral haemorrhage or subarachnoid haemorrhage (Krishnamurthi et al., 2014). Stroke sub-classification was applied using the OCSP system (Bamford et al., 1991). As described in Chapter 1 this uses the patient's presenting

signs to group strokes/TIA as total anterior, partial anterior, lacunar, or posterior circulation infarctions.

The current study imposed four additional exclusion criteria: 1) in-patient stroke events; 2) patients who did not attend at any hospital 3) patients who presented at a hospital outside the Auckland study area; and 4) patients whose symptoms commenced while they were, by chance, in the presence of a healthcare professional. The rationale for the first two exclusions, was that there would be no referral pathway to hospital. For the third criteria, collecting EMS data from outside the region, was logistically unfeasible. Finally, cases where the patient was already with a healthcare professional presumably did not require the patient, or his or her lay, advocate to make a choice on how to seek assistance.

3.6 Data sources

Data was obtained from three sources. First, variables originating from the ARCOS IV database covered a range of demographic, social, clinical and health-related measures. Data in the ARCOS IV database was either transcribed from the patient's hospital medical records or collected during interviewing by ARCOS IV research assistants. Second, variables measuring the paramedic care of the patient were abstracted from the paramedic-completed PRF, by the author of this thesis. Finally, variables recording operational performance were sourced from the EMS computer-generated activity log. The source of each variable is shown in Appendix C. This section will describe in detail how data was sourced from the PRF and the computer-aided-dispatch system.

To collect data related to the paramedic care of the patient, the PRF for the event first had to be located. At the time of the study, the EMS provider used a paper-based system that required the paramedic to complete a handwritten case report form in triplicate (Appendix D). The top copy of the report was given to the receiving healthcare professional as part of the transition of care. The EMS provider retained the other copies for administrative use, including clinical audit and account generation before archiving them securely off-site.

Initially it was planned to obtain the PRF from the patient's hospital medical record, held by the District Health Boards. However, it became apparent that the three District Health Boards had different processes and conditions for accessing data. In particular, one intended to impose a substantial fee to access the records. Consequently, data collection was undertaken using the records held by the EMS provider.

Data collection for EMS variables was undertaken when the ARCOS IV record indicated that the patient had been transported to hospital by ambulance. This included cases where either a paramedic or a primary care doctor was the first medical contact. Data collection was also attempted for cases where transport mode data was missing from the ARCOS IV record. No additional data was collected for patients who reached hospital by a transport mode other than EMS; only variables obtained from the ARCOS IV database were available for these cases.

Searching the EMS archives was anticipated to be labour-intensive. It was estimated that approximately 100,000 PRF were generated during the 12-month ARCOS IV study period (Henderson, 2015; P. Wyawahare, personal communication, December 14, 2015). As the PRF were filed by date only, all these forms needed to be recalled from off-site storage and reviewed in order to locate those stroke and TIA cases identified by the ARCOS IV study (Appendix D).

Six patient identifiers, common to both the ambulance PRF and the ARCOS IV record, were used to match cases. These were: the patient's name (encoded), date of birth and sex and the date, time and hospital attended. Any discrepancies in the match were investigated by referring back to the original hard-copy ARCOS IV data collection files and to the Ministry of Health national database records of all stroke admissions. Electronically scanned copies of the PRF, with all patient and crew details redacted and the linking ARCOS IV identification number inserted, were stored in secure files. Data was entered into a spreadsheet (Excel v.7, Microsoft Corporation, Redmond, USA).

Based on the experiences of other investigators in locating EMS records (section 3.13), the target was to match 85% of eligible cases. A late difficulty was encountered when the achieved find rate for the PRF was observed to be lower than this target. However, following-up on missing forms by searching for the hospital-held record, was now feasible due to the reduced cost of requesting a smaller number of files. Final data collection was completed on-site at the three District Health Boards.

In addition to granting access to archived paper copies of PRF for the study period, the EMS provider made available additional data collected by the computer-aided-dispatch system. This system generates a time log of key activities, commencing from the moment the call is picked up in the Communications Centre and finishing when the job is closed by the emergency medical dispatcher.

The PRF database was linked to the EMS computer-aided-dispatch system data, using the unique master incident number. This number is automatically assigned when the EMS provider answers the call and it is also recorded on the PRF. This code number, in combination with key time identifiers, enabled identification of the corresponding computer record and facilitated linkage with operational information. Once the link was established, key operational data points relevant to the study could be added to the PRF data base for use in the analysis.

3.7 Variables

The variables used in the analyses, the source they were obtained from and a brief definition are listed in Appendix C. Variables described demographic, social, clinical, paramedic care quality indicator, EMS operational and outcomes data.

Demographic variables

The patient's age on the date of the event was calculated from the date of birth, which was sourced from both the PRF and the ARCOS IV data. Age was divided into four categories for analyses, to address the left skewed age distribution and to align with reporting from the ARCOS studies. These groups were 15 to 64, 65 to 74, 75 to 84, and 85 years and older. The sex of the patient was treated as binary; male or female.

Ethnicity data was recorded using Statistics New Zealand Level 1 codes with Ministry of Health prioritised output protocols applied if multiple responses were recorded (Ministry of Health, 2004). This system ascribes one ethnicity, based on policy importance, in the sequence of Māori, Pasifika, Asian, Other and New Zealand European. However, during analyses, insufficient numbers in some groups made statistical tests invalid and required categories to be combined (Pallant, 2013). Collapsing the ethnicity variable into a binary variable determined by identification with an ethnic minority enabled this effect to be examined. This approach has previously been used to identify differences in EMS utilisation among ethnic minorities (Addo et al., 2012; Adeoye et al., 2009; Carter et al., 2006). Furthermore, the binary variable also reflected the predominance of New Zealand Europeans in the paramedic workforce with 80% of fulltime staff identifying with this ethnicity and 74% of volunteers (Morrison & Tunnage, 2014). This was particularly important for the analysis of factors predicting paramedic recognition of stroke/TIA. While greater precision in ethnicity is desirable, this approach enabled exploration of the

effect of belonging, or not belonging, to the ethnic group that is dominant among New Zealand paramedics.

Social variables

The place of abode was categorised as either a private residence, or a retirement village, or a rest home, which included private hospitals and boarding houses. An online geocoding tool was used to apply New Zealand Deprivation Index scores to the street address of the abode prior to de-identification of the PRF (Statistics New Zealand, n.d.). The New Zealand Deprivation Index combines census data including household income, home and car ownership, employment, and qualifications to produce a score from 1 to 10 where 1 represents the 10% of areas with the least deprived scores (Atkinson, Salmond, & Crampton, 2014). Scores were dichotomised into a binary variable with scores of 1 to 5 representing areas of lower deprivation and 6 to 10 representing higher deprivation. New Zealand Deprivation Index scores were only available for cases where the patient was transported by ambulance. Employment status was recorded at three levels as: non-manual, manual or non-participating with the latter category including unemployment and retirement. Living alone was treated as a binary variable.

Clinical variables

Three types of first medical contact were identified: attention from a paramedic via the EMS system, phoning or consulting in person with a primary care doctor and assessment at a hospital Emergency Department. Phone contact with a community-based doctor was combined with face-to face consultations, even if the patient subsequently called the EMS, because the duration of delay was unable to be determined. Failure by doctor's receptionists and health line advisors to refer callers describing stroke signs and symptoms to the EMS, has been reported (Jarrell, Davis, Coyner, Crocco, & Whiteman, 2011; Jarrell, Tadros, Whiteman, Crocco, & Davis, 2007; Mellor et al., 2015). In one study, nearly a third of callers to a primary care practice reporting stroke signs, were advised by the receptionist to consult the doctor later in the day if their symptoms had not resolved (Jarrell et al., 2011).

The presence or absence of FAST signs at onset (facial or arm weakness and speech disturbances), was obtained from ARCOS IV records. This variable was used to indicate whether a member of the public using the FAST tool would have been able to recognise the stroke.

Experience of stroke was defined as a history of a previous stroke or TIA either in the patient or in a close blood relative. This information was obtained during an interview with the patient, or from their medical records, by the ARCOS IV research assistant as part of the baseline data collection.

A final diagnosis of either TIA, subarachnoid haemorrhage, primary intracerebral haemorrhage or ischaemic stroke, was determined by the ARCOS IV diagnostic review committee based on information obtained from the patient's case notes and medical records. The clinical subtype of events was classified using OCSF definitions of either total or partial anterior, posterior or lacunar circulation infarction (Bamford et al., 1991). The paramedic working diagnosis was recorded using the ProQA™ Advanced Medical Priority Dispatch System (AMPDS version 12, Salt Lake City, Utah) radio code recorded on the patient report form. This system of EMS call-handling and dispatch is described in the subsequent section on operational data.

The Glasgow Coma Score that was recorded by the paramedic, was transcribed from the PRF. The scale is presented in Appendix E. Paramedics frequently record at least two Glasgow Coma Scores during the patient contact and the lower or lowest score was used in the database to account for patients with a fluctuating condition. In the analysis, Glasgow Coma Scores were dichotomized and classified as low, if a score of 8 points or less was recorded (Addo et al., 2012; Carter et al., 2006; Jennet & Teasdale, 1977).

The patient status code is a subjective assessment of the patient severity that is assigned by the paramedic. There are no published studies comparing status code values to validated severity scales. However, there is limited support for its ability to predict whether the patient's condition will result in a hospital admission (Swain, 2016). Notes from the clinical practice guidelines on applying status codes are presented in Appendix F (National Ambulance Sector Clinical Working Group, 2011). Stroke with a level of consciousness greater than nine is classified as status two, signifying a potential threat to life. Status three is applied to TIA, indicating that the condition is unlikely to pose a threat to the patient's life. Paramedics record an initial status code early in the patient contact and a second on arrival at hospital. Only the latter score, reflecting the patient's condition on arrival at hospital, after stabilisation by the paramedic, was included. In this study, a status one patient is described as critical, status two as serious, status three as moderate and status four as minor.

The NIHSS is a stroke-specific instrument with 15 items which takes five to eight minutes to administer (Bowling, 2001). It includes assessment of the patient's level of consciousness, vision, facial paresis, motor function in all limbs and speech. A score of 1 indicates mild stroke symptoms and the maximum score of 42 represents a severe stroke resulting in death. A trained stroke specialist nurse or physician usually undertakes this clinical assessment. In the ARCOS IV study, the trained research assistant either recorded the NIHSS score from the medical records or assessed the patient. However, completion of this field was extremely low at approximately 10% of cases. Therefore, this variable was not included in any analyses.

The ARCOS IV study also recorded whether or not the patient had been thrombolysed with alteplase.

Paramedic care quality indicators

The quality of paramedic care was assessed by completion of seven key tasks identified from the international guidelines previously presented (Table 3). The definition of these performance measures and the criteria that were applied are described in Table 6.

In accordance with standard operating procedures, a maximum likelihood strategy was adopted so that tasks not recorded on the PRF were presumed not to have been completed (Gearing, Main, Barber, & Ickowicz, 2006). In line with previous studies, completion of a FAST test (Appendix G) was defined as either recording a positive finding in any one element, or negative results in all three items, or documentation that attempts to complete the task were unsuccessful (Fothergill et al., 2013; Harbison et al., 2003; Lindsberg et al., 2006; Wolters et al., 2015). If none of these three criteria were met, it was determined that a FAST assessment had not been undertaken by the paramedic. The FAST assessment described in the clinical practice guidelines included an additional assessment for abnormal gait. This was not included in the analysis due to a low rate of completion. The effects of the two definitions of onset time and the two criteria for advance notification, as shown in Table 6, were explored in the analyses.

Table 6. Clinical quality indicator definitions for current study

Performance measure	Definition and Criteria
FAST assessment of <ul style="list-style-type: none"> - face for new onset of unilateral weakness - arms for new onset of unilateral weakness or drift, and - speech for new onset of abnormal speech including slurring of words and difficulty or inability to name objects. 	Proportion of patients assessed using FAST tool and recorded as either <ul style="list-style-type: none"> - positive with at least one abnormal element documented, or - negative with all three elements documented as normal, or - unable, or declined to complete the assessment.
Onset time (Any definition)	Proportion of report forms with any attempt to record a time including unknown, wake-up time.
Onset time (Last known well)	Proportion of report forms with onset time recorded as known or last known well.
Blood glucose level recorded	Proportion of patients with either a blood glucose level recorded or that declined testing.
Blood pressure recorded	Proportion of patients with either a blood pressure recorded or that declined testing.
Notification (Exclude minor and moderate)	Proportion of cases documenting advance notification to the receiving hospital unless the patient was Status 3 or 4 or transmission failure.
Notification (Overall)	Proportion of cases documenting advance notification to the receiving hospital or transmission failure.
On-scene \leq 20 minutes	Proportion of cases where interval from arrival on-scene until depart to hospital was less than or equal to 20 minutes.
Alarm-to-door \leq 60 minutes	Proportion of cases where interval from initial call to EMS until arrival at hospital was less than or equal to 60 minutes.

Notes. All data was obtained from the paramedic completed patient report form except for the two time indicators that came from the computer-assisted dispatch record.

Operational data

The priority assigned to the responding ambulance was obtained from the computer-aided-dispatch system. For a priority one response, the ambulance travels under lights and siren requesting the right-of-way from other road-users. In contrast, for a priority two response, the ambulance travels with the normal traffic flow and observes all regulations. In priority three and lower dispatch levels, the emergency medical dispatcher may queue the response, allowing other calls to take precedence for the next available ambulance dispatch.

The emergency medical dispatcher's impression of the nature of the call was obtained from the ProQA™ Advanced Medical Priority Dispatch System (AMPDS version 12, Salt Lake City, Utah) radio codes. AMPDS is used internationally to support EMS providers through an integrated call handling and dispatch system. Emergency call handling is standardised through scripted algorithms based on the caller's responses. The stroke protocol is used if the caller either identifies the problem as a stroke or reports sudden onset of problems with speech, unilateral weakness, numbness or paralysis, balance or coordination, vision or severe headache. In cases of suspected stroke, the call-handler script includes questions to assess facial palsy, arm movement and speech based on the FAST tool. AMPDS assists EMS providers by prioritising calls and allocating resources on the basis of the assessed urgency. The call-handler's impression of the chief complaint is conveyed to the responding ambulance crew at the time of case assignment through a dispatch radio code which is also recorded in the computer-aided dispatch system. This system was the source of the emergency medical dispatcher code variable that was included in this study.

Transport mode was defined as either by ambulance, including helicopter or any other medical evacuation coordinated by the EMS, or non-ambulance, which comprised private vehicle, taxi and public transportation means of arrival at hospital.

Outcomes

Onset-to-door was measured as the duration of the delay between the onset time and arrival at hospital. Only cases where the reliability of the onset time measure could be cross-checked against the ambulance dispatch time were included in analyses. Patient mortality data was provided from the ARCOS IV study. Two measures of health-related outcome were also sourced from the ARCOS IV study with data collected from consenting participants at baseline and at 28 days after the stroke/TIA.

The first health-related outcome was functional independence, as measured by modified Rankin Scale scores. The modified Rankin Scale is a brief and widely used stroke-specific instrument that summarises an individual's functional independence and level of disability after stroke (Bowling, 2001). The patient is scored between zero, representing no symptoms, and six if the patient is deceased. The ARCOS IV survey pages used to collect this data are shown in Appendix H.

The second health-related outcome was quality of life, as measured using the EuroQol EQ-5D. This is a non-disease-specific health survey tool (Bowling, 2005; van Reenen & Janssen, 2015). The tool surveys the patient across five dimensions and in a visual analogue scale which summarises self-rated health. From these responses, either a descriptive health profile can be generated or a single value for health status. The ARCOS IV study used the modified EQ-5D-3L version, which limits responses across the five dimensions to three levels (no problem, some problem, extreme problem). The ARCOS IV survey pages used to collect this data are shown in Appendix I.

3.8 Addressing potential bias

Population studies such as ARCOS IV, have the advantage of presenting the least biased reflection of stroke incidence and outcomes within their communities. In contrast, clinical trials, such as Barsan et al. (1993), are prone to selection bias which limits the generalisability of results, since the subjects are unlikely to represent the wider stroke population. Furthermore, because the ARCOS IV study had ethical approval to use de-identified patient data at baseline, potential bias from requiring patients to consent-in was not encountered (Kho, Duffett, Willison, Cook, & Brouwers, 2009). However the ARCOS IV did require participant consent for enrolment in the outcomes study. This has the potential to introduce a bias towards including patients with better outcomes since patients with more severe presentations, and their next-of-kin, are less likely to participate in medical research (Kho et al., 2009).

To avoid introducing bias during construction of the database and linkage of the data sets, strict processes and quality checks were followed. These are described in detail and the results reported in section 3.12.

3.9 Study size

As cases were identified from the ARCOS IV population-based incidence study, the sample size was determined by the number of new cases recorded in the Auckland region during the 12-month observation period. All cases that met the study eligibility criteria, described in section 3.5, were included.

3.10 Statistical methods

This section describes the methods of the analyses. A description of the methods used to assess the reliability of the database is presented in section 3.12. All statistical analyses were performed using Statistical Package for Social Sciences (SPSS) version 23 software (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp). Alpha (type 1 error) was set at 0.05 unless otherwise specified. Rules for management of missing data were determined in advance to avoid non-response bias (Gearing et al., 2006). The statistical analyses were the work of the author with statistical support from Professor Chris Frampton (Appendix J).

3.10.1 First medical contact

This study focused on two analyses; quantifying proportions of cases using each of the first medical contact alternatives and determining patient factors that were potentially predictive of initial contact with the EMS in stroke or TIA. All cases where the FMC could be established were included in this study.

Identification of first medical contact

The frequency of initial medical contact with either EMS paramedic, primary care doctor or Emergency Department staff was calculated. The frequency of utilisation of ambulance and non-ambulance modes of transportation to hospital were also reported. Patient characteristics were compared according to whether or not their initial contact was with an EMS paramedic.

Predictive factors for first medical contact

Factors potentially predictive of a first medical contact with the EMS in stroke/TIA, were identified from theoretical models. Demographic, social and clinical variables were included. Patient-level covariates examined were age, sex, ethnicity, abode, employment status, living alone, stroke experience from previous patient or close relative event, presence of FAST signs at onset, final diagnosis and OCSP stroke classification. Statistical associations between all variables were inspected using Pearson's chi-square tests of independence. Unadjusted odds ratios were calculated from the cross tabulations between the dependent variable and potential predictors. The odds of FMC with EMS were compared to FMC with non-EMS, with one level within each variable used as the reference value.

While an unadjusted odds ratio considers the association between the dependent variable and one predictor variable, it does not take account of any confounding with other explanatory variables. Consequently, the unadjusted odds ratio may inflate the true effect of the variable on the outcome, due to confounding with other factors (Barton & Peat, 2014). In contrast, adjusted odds ratios control for the effects of all other predictors. STROBE guidelines for statistical reporting, require that both unadjusted and adjusted odds ratios results be presented (Vandenbroucke et al., 2007).

Adjusted odds ratios were computed using multivariate binary logistic regression analysis. Prior to analysis, the data was inspected in relation to the assumptions of binary logistic regression (Barton & Peat, 2014; Tabachnick & Fidell, 2014). These assumptions require that the sample is representative of the population it relates to and is of sufficient size to support the model. It is also assumes that a stable relationship between the outcome and explanatory variables existed during the study period, and all important explanatory variables are included, but are not highly collinear (Barton & Peat, 2014; Tabachnick & Fidell, 2014). A statistical regression approach was appropriate given that the variables were selected based on prior knowledge of the subject, analysis was conducted to identify predictive variables and the sample was sufficiently large to ensure an adequate ratio of events per explanatory variable (Steyerberg, Eijkemans, & Habbema, 1999; Tabachnick & Fidell, 2014).

Variables that were significant ($P < 0.05$) in the bivariate analyses were included in the analysis, provided that data was available for at least 85% of cases and they were not strongly collinear. These exclusions were required as missing data reduces the power of the regression analysis and collinearity between explanatory variables violates the assumptions of logistic regression analysis (Tabachnick & Fidell, 2014). Variables were entered into a forward inclusion stepwise model at a significance level of 0.05. The same variables were entered into a backward elimination stepwise model and the results derived from the two methods, were compared for convergence of selected variables in the model. Finally, direct logistic regression analysis, using a single model, evaluated the contribution of those variables identified as significant from the forward and backward stepwise models in the statistical regressions. These were expressed as adjusted odds ratios with 95% confidence interval.

3.10.2 Quality of paramedic care

The quality of paramedic care was evaluated in three analyses: firstly the sensitivity of paramedic diagnosis, secondly factors predicting paramedic non-recognition of stroke/TIA and thirdly completeness and timeliness of the EMS care delivered to the patient. Inclusion in these analyses was limited to those cases where the stroke/TIA patient’s first medical contact was with an EMS paramedic. Descriptive statistics characterising the study sample were tabulated.

Sensitivity of paramedic stroke recognition

Paramedic recognition of stroke/TIA, as a measure of the quality of care, was explored by calculating the diagnostic sensitivity. Sensitivity is one measure of the validity of a screening test. It is defined as the probability of having a positive screening test result if the disease is actually present (Hennekens & Buring, 1987). In this analysis the paramedic working diagnosis was considered as a “screening test” for stroke or TIA and the final diagnosis determined by the ARCOS IV review committee, was the “gold standard”. The sensitivity of the paramedic working diagnosis in ascertaining the true “disease” status of a patient, is the proportion of all stroke and TIA cases in the study that were correctly recognised by the paramedic (Figure 1). Unlike other measures of test validity, the sensitivity does not change with the prevalence of the disease in the population being tested and is unaffected by the specificity of the screening test (Hennekens & Buring, 1987).

		<i>Gold Standard</i>			
		ARCOS IV review panel diagnosis			
<i>Screening Test</i>		Stroke/TIA	Other		
		Paramedic Working Diagnosis	Stroke/TIA		
		Other	False Negative (FN)	True Negative (TN)	<i>Negative Predictive Value</i> = TN/(TN+FN)
		<i>Sensitivity</i> = TP/(TP+FN)		<i>Specificity</i> = TN/(TN+FP)	

Figure 1. Calculation of measures of validity for screening tests

Depending on the study design, specificity and positive and negative predictive values of the paramedic working diagnosis can also be estimated (Figure 1). Calculation of these measures was not feasible in this study, for the following reasons. Incidence studies, such as ARCOS IV, focus on new stroke and TIA events during the study period and the data collected on recurrent events is typically less comprehensive. If paramedic working diagnoses of recurrent events were incorrectly classified as false positive diagnoses, it could result in systematic errors in the estimation of the sensitivity, specificity and positive predictive values. Furthermore, in order to identify true negative cases, all PRF from the 12-month study period would need to be reviewed. Ideally, the paramedic's diagnosis of a non-stroke or non-TIA condition would then be compared to the gold standard of the hospital discharge diagnosis. This would have required following up on at least 100,000 EMS patient contacts, which was beyond the resources of the current study.

The sensitivity of the call taker's clinical impression was calculated as the proportion of all stroke and TIA events that were assigned a ProQA™ AMPDS code of 28 CVA by the emergency medical dispatcher. This is the code used for suspected stroke and TIA events during ambulance dispatch. As in the analysis of paramedic diagnostic sensitivity, this analysis used the final discharge diagnosis as the gold standard comparator.

In New Zealand, paramedic clinical practice guidelines are updated and reissued every three years. New guidelines were released in October 2011, during the ARCOS IV study period of 1 March 2011 to 29 February 2012 (National Ambulance Sector Clinical Working Group, 2011). However, these were introduced sequentially around the country in conjunction with training presentations, with adoption completed by 31 March 2012. The Auckland region was one of the last areas to implement the new procedures, although the exact date was unable to be determined (T. Bradley, personal communication, September 20, 2016). Whereas the 2009-11 clinical practice guidelines did not provide any references to stroke or TIA, the 2011-13 guidelines introduced the FAST tool (Appendix G) and specific directions on the assignment of patient status in stroke and TIA (Appendix F). This "natural experiment" created a unique opportunity to assess the impact of changes to the clinical practice guidelines on paramedic practice. To investigate the effect of the introduction of the 2011-13 guidelines, the data was divided into two groups based on an event date of 1 October 2011. Pearson's Chi-square tests for independence were used to compare the proportions of correct paramedic diagnoses and FAST assessments undertaken between the two time periods.

Predictive factors for non-recognition

Factors potentially predictive of paramedic non-recognition of stroke/TIA were identified from theoretical models. Demographic, social, clinical and operational variables were included. Patient-level covariates examined were age, sex, ethnicity, employment status, living arrangements, deprivation, stroke experience, presence of FAST signs at onset, final diagnosis, OCSP classification, Glasgow Coma Score, ambulance severity status code, FAST assessment, emergency medical dispatcher code and dispatch priority.

The analysis followed the same statistical method as described in detail in section 3.10.1. Briefly, before analysis, the data was scrutinised with respect to the assumptions of logistic regression (Barton & Peat, 2014; Tabachnick & Fidell, 2014). Statistical associations between all variables were explored, baseline characteristics were compared according to whether or not the paramedic diagnosed the stroke/TIA and unadjusted odds ratios calculated. Adjusted odds ratios were then computed using binary logistic regression analysis. Variables were included in the analysis provided that data was available for at least 85% of cases and they were not strongly collinear. A forward stepwise approach was used to identify factors in the model and a backward stepwise model was examined for convergence. Factors included in these models were entered into a single model and the individual contribution of each of the variables was expressed as an adjusted odds ratio with 95% confidence interval.

Completeness and timeliness of care

The overall proportional adherence to each quality measure was calculated with 95% confidence intervals (Barton & Peat, 2014). Pearson's Chi-square tests for independence were used to compare paramedic reporting on the key tasks and the overall care bundle between cases recognised and unrecognised by paramedics.

The median EMS contact duration for the on-scene interval and from alarm-to-door were reported overall and by paramedic recognition versus non-recognition of the stroke/TIA. Chi-square tests were used to compare whether any difference between the survival curves of recognised and unrecognised cases was statistically significant. Kaplan-Meier survival analysis was undertaken to explore the relationship between paramedic stroke/TIA recognition on both of these intervals. The Kaplan-Meier survival method assumes a clearly defined start point and precise measurement of time. If this assumption is not met, for example by bias in the estimation of onset time, then the survival analysis will be unreliable (Barton & Peat, 2014). As previously discussed in section 2.4.2, onset

time in stroke is notoriously difficult to establish. In this study, strict standards for the identification of the onset time were imposed to increase accuracy. In the analysis of on-scene time, the outcome variable was defined as departing the scene to hospital, with explanatory variables of time (in minutes) and grouping by paramedic recognition versus non-recognition of the stroke/TIA. Similarly, in the analysis of the alarm-to-door interval, the outcome variable was defined as arrival at hospital, and the same explanatory variables of time and paramedic recognition were used. Survival curves were plotted to show the cumulative proportion of patients who had still not left the scene or had not arrived at hospital at a specific time.

3.10.3 Case management and patient outcome measures

The association between paramedic care and patient outcomes was explored through five analyses. These compared key time, treatment, mortality, functional and quality of life outcomes by the first medical contact and paramedic recognition of the event. This study was limited to those cases where the ARCOS IV review panel determined that the patient had suffered an ischaemic stroke event and the initial medical contact was known. Baseline characteristics of the study sample were presented.

Onset to door time

The interval from symptom onset to arrival at the hospital door was calculated for patients when a symptom onset time could be determined but capped at a maximum of 24 hours. To maintain data quality, only those cases where the time of the call to the EMS was available from the computer-aided-dispatch system, and did not precede the onset time, were included. This limited inclusion to cases transported by ambulance. The influence of two factors on the duration of the onset-to-door delay was explored; 1) the effect of FMC with either an EMS paramedic or a primary care doctor and 2) the effect of the quality of care as measured by whether the paramedic diagnosed the stroke or not. Median onset-to-door interval times, with interquartile range, were reported overall, by first medical contact and by paramedic diagnostic groups. Groups were compared using the Chi-square test. Kaplan-Meier survival analysis was undertaken as described in the analysis of the quality of paramedic care (section 3.10.2). The outcome variable was binary and defined as arrival at hospital. Explanatory variables were time (in minutes), and grouping by either initial contact or paramedic diagnosis. Survival curves were plotted to show the cumulative proportion of patients who had still not arrived at hospital from the community at a specific time. For key onset-to-door intervals, the proportions

of patients who had arrived at hospital was reported. The reported intervals were selected for their clinical relevance and for comparison with previously published studies and guidelines criteria.

Thrombolysis rates

The study population was limited to ischaemic stroke patients for whom thrombolysis status data was available. The rate of thrombolysis was calculated over all strokes, including cases where the onset time could not be determined. This is in accordance with the New Zealand national reporting requirements (A. Davis, personal communication, February 25, 2016).

The first analysis investigated the association between the referral route and thrombolysis. The thrombolysis status of patients who saw a paramedic first and those who did not was compared using Pearson's Chi-square test for independence. Unadjusted odds ratios for receiving thrombolysis based on initial contact with the EMS were calculated from cross tabulations. To investigate possible confounding between the initial contact and onset-to-door delay, this analysis was repeated for only those patients who arrived at hospital within three and a half hours of symptom onset. Among thrombolysed patients, the proportion arriving by each prehospital pathway was reported.

The second analysis examined the association between paramedic recognition of stroke (as a measure of the quality of paramedic care) and thrombolysis. Only cases where first medical contact was with an EMS paramedic were included. Patients' thrombolysis status was compared according to whether or not the stroke was recognised, using Pearson's Chi-square test for independence. Unadjusted odds ratios for receiving thrombolysis based on the paramedic recognition of the stroke were calculated from cross tabulations.

Mortality and health-related outcomes

The number of cases where the patient did not survive to follow-up at 12-months post – stroke was reported by first medical contact group.

Data on functional outcomes was only collected from those patients who consented to participate in the full ARCOS IV study. Follow-up was undertaken at three time points; at 28 days, 6 months and 12 months after the event. However, only the data collected at 28 days after the event was used in this analysis. This short follow-up interval was chosen

in order to limit the effects of co-morbidities and a longer rehabilitation period on the outcome measures. This differs to the practice of most clinical trials that report on stroke outcome measures at 90 days in order to allow greater stabilisation of the patient's condition. A descriptive rather than a statistical approach was used, due to an inability to adequately control for the patient's pre-morbid state, severity at onset and administration of alteplase.

Functional outcomes

Functional outcome was measured using the modified Rankin Scale. Patients with a score of 6, representing death, were excluded. In the first analysis, the proportions of patients with a score within each category, from 0 to 5, were graphed to compare baseline and 28-day follow-up scores by the initial medical contact grouping. Secondly, for those patients that were functionally dependent at baseline (score of 3-5), the 28-day follow-up score was presented graphically by first medical contact group.

Functional outcome was further explored by dichotomizing the modified Rankin scores into two groups with scores of 0-2, representing functional independence and scores of 3-5 indicating dependence (Saver & Gornbein, 2009). Using paired data, the change from baseline, in the proportion of cases where the patient was independent at 28-days, was compared between EMS and non-EMS groups. Pearson's Chi-squared test of independence was used to determine whether the difference in the proportion of change over time between the two groups was statistically significant.

Quality of life outcomes

Quality of life was explored using dichotomised scores from the EQ-5D-3L. The three levels of responses were divided into two groups based on whether or not the patient reported any problems (van Reenen & Janssen, 2015). Scores for each of the five dimensions were dichotomised and displayed graphically by the FMC group. The EQ-5D visual analogue scale data was plotted to show the mean percentage score by FMC.

3.11 Ethical considerations

The conduct of this study followed the principles of good clinical practice in order to protect the participants and to report accurate and reliable results (ICH Expert Working Group, 1996).

The confidentiality of all participants was protected. De-identified electronic copies of the PRF were used for data abstraction and stored securely. De-identified and coded paper copies of the PRF have been stored securely, and will be archived securely by the National Institute for Stroke and Applied Neurosciences, Auckland University of Technology.

The electronic database for the analysis contained only variables required for the analysis and the ARCOS IV study number for each patient. It did not contain any patient identifiable data. The database was constructed using SPSS and located on at least three distinct and secure (password protected) locations. The linking of the PRF audit database with the ARCOS IV study database, was justified as part of high-quality health care delivery and research with the potential to benefit the public.

3.11.1 Consent

Consent was not obtained from participants for the following reasons. The study used retrospective collection of data equivalent with an audit of the care provided by EMS paramedics. There was no contact with patients or additional data collection from patients. The patient record was de-identified and coded with the ARCOS IV registration number. The study was undertaken at a population level and included data from a large number of stroke and TIA cases which was aggregated and reported as summary statistics. Consequently, the research carried minimal risk to individual patients and the benefits from the research for high-quality health care delivery and outcome analysis justified any potential risk of harm associated with not seeking consent. In addition, due to both the age and quantity of the records it would have been difficult in practice to obtain consent.

The ARCOS IV study had ethical approval to obtain de-identified data for all stroke/TIA cases from patient medical records. This information included demographic data, medical history and co-morbidities, event history, diagnosis, hospitalisation, quality of care data and serious adverse events.

3.11.2 Ethical approval

Initial advice indicated that the current study could be added as an extension to the existing ARCOS IV ethical approval granted by the Northern X Regional Ethics Committee of the Health and Disability Ethics Committee (Approval number NTX/090/10) and the Auckland University of Technology Ethics Committee. As described in section 3.6, the actual data collection process varied from the original plan.

During notification of these changes, the Health and Disability Ethics Committee (HDEC) requested that a new application for ethical approval be submitted. Ethical reviews are summarised in Table 7 and copies of permissions and locality authorisations are presented in Appendix K.

Table 7. Summary of ethical approval

Date	Authority	Activity
15 March 2013	HDEC	Confirmation that an amendment to include the PhD study was not required
23 April 2013	AUtec	Amendment approved to include PhD study
12 March 2014	St John	Approval of research study
15 June 2014	HDEC	Approval of full application 14/NTB/66
26 June 2014	AUtec	Approval of full application 14/202

Notes. AUtec = Auckland University of Technology Ethics Committee; HDEC = Health and Disability Ethics Committee.

3.11.3 Consultation

Consultation has been undertaken with key stakeholders to ensure that the study focus is aligned with the research priorities they have identified.

St John, the major provider of prehospital emergency health care in New Zealand, has endorsed the study. The study is aligned with St John’s commitment to improving prehospital healthcare in New Zealand and the need to establish research evidence to support clinical practice. Particular analyses within the study have been designed to be compatible with St John reporting, in order to provide a baseline to compare with future measures of service delivery.

The study proposal was reviewed at the Kawa Whakaruruhau Māori Research meeting on 20 June 2013. Kawa Whakaruruhau is a Māori advisory committee within the School of Clinical Sciences, at the Auckland University of Technology.

The Northern Region Stroke Network Group and the Auckland Region Stroke Interest Group are networks of clinicians specialising in provision of stroke services in the greater Auckland Region. The study protocol has been presented in these forums.

3.12 Description of the data

In this thesis, the research proposition is explored through three inter-related studies of the first medical contact, the quality of care and case management and patient health-related outcomes, using an extensive collection of data. Confidence in the findings is contingent upon the integrity of the database. The large scale of the study prohibits inclusion of the raw data and complete analyses within the thesis document. Therefore, this section reports on the development of the combined database with a specific focus on establishing the quality of the data set.

Linking EMS data with other medical records is challenging. This study required three separate sources of data to be linked; the PRF data, computer-aided-dispatch system data and the ARCOS IV data set. There are numerous reasons why it might not be possible to link a case across all three databases. For example, the paper copy of the PRF could have been misfiled or lost and hospital records may have been unavailable. Information may have been incorrectly or illegibly recorded on either the PRF or the ARCOS IV files making it impossible to match records.

EMS studies frequently report difficulties with linking prehospital and in-hospital patient records. Recent studies have reported matching of approximately two-thirds of EMS cases to hospital data (Abboud et al., 2016; Mears et al., 2010). One study reported a near perfect rate of 98.9% (Oostema et al., 2014). However, this was in a small data set of 188 cases and their high rate of linkage are an exception. Linking of patient reports and operational data within the same EMS system can also be problematic with one industry report describing a match of 78% (Dicker, 2016). A “lack of coordination” between EMS providers and hospitals has been proposed as one cause (Institute of Medicine, 2006, p. 1082) and other researchers have observed that data collection is complicated when more than one hospital is included (Abboud et al., 2016). In New Zealand the EMS is structurally disconnected from the hospital system in comparison to the United Kingdom, where it is part of the National Health Service.

This chapter follows the sequence of steps that was used to construct the database. After examining the case selection process, the linkage of the three data sources is appraised. Quality checks are then presented and finally, demographic and clinical characteristics of the cases included in the data set are summarised.

For consistency, a single researcher (the author of this thesis) undertook the collection of data almost exclusively. Two supervised novice researchers assisted for a combined total of ten days as part of a research experience. The author completed data entry for all cases across all variables. For a sample of PRF, a paid research assistant completed double data entry to enable quality checks, as described later in this section.

Database quality was addressed by careful planning during the design phase, to ensure alignment between the research questions and the data fields. Adherence to the principles of high quality data review was maintained in both the process and construction of study tools. Prior to commencement of data entry, a chart abstraction protocol was developed with clear guidance on the conduct of the review process.

Data abstraction is a review process that reduces an entire record to only the information required to answer a specific question. Potential problems in establishing a high quality database from medical record review have been well described (Allison et al., 2000; Gearing et al., 2006; Mi, Collins, Lerner, Losina, & Katz, 2013; To, Estrabillo, Wang, & Cicutto, 2008; Verma, 2009). In particular, data quality can be compromised by an unclear research question, insufficient definition of variables, a poorly designed data template, and entry and interpretation errors by the abstractor (Allison et al., 2000).

Transferring elements of the medical record to a template, creates a risk of data entry errors. A custom formatted spreadsheet (Excel v.7, Microsoft Corporation, Redmond, USA) was developed as a template. The entry order of variable data followed the layout of the PRF. To increase accuracy, the formatting made use of several in-built functions. In particular, “data validation” limited responses to a pre-specified drop-down list and “conditional formatting” of cells highlighted values outside the expected range for immediate review. Abstractors used highlighting on the active row to avoid line errors while entering data. Reference data from different sources was added using “VLookup” to avoid data entry error. Computational cells establishing the duration of ambulance contact and the onset to door time were used to identify time entry errors. For example, where the ambulance contact spanned midnight, if two different dates were not specified the abstractor would be alerted by the computational error to review the file.

The protocol identified the intention of each variable, the location on the PRF of the data point, acceptable synonyms and appropriate coding of responses. Free text responses were avoided and precise definitions of the set responses were established and refined in the early stage of the data collection process, to lessen the risk of interpretation errors.

Where possible, definitions were aligned with previously published studies and industry standards. Composite indicators that merged variables were avoided. For example, date of birth was collected in preference to age, and key times were recorded rather than interval durations. Clear instructions for coding negative findings and missing data were provided. The data-abstraction manual specified that data should be entered as it appeared on the PRF without any interpretation unless the variable specifically required a judgement to be made. Sixteen items were extracted from each PRF and the source of each data point is shown in Appendix D.

The number of cases excluded from the current study was reported as a proportion of eligible cases. Similarly, the number of cases that were linked with a PRF and the number that were subsequently matched to the computer-aided-dispatch system were reported as proportions of the cases included from the ARCOS IV database.

Two methods were used to test the data reliability; inter-rater reliability and concordance between the three data sets. Firstly, inter-rater reliability was assessed using the kappa statistic to establish the consistency of data abstraction from the paramedic clinical record. Random number generation was used to select a sample of 210 PRF, representing 12% of the 1,811 cases where PRF were collected. This sample size would enable the detection of a kappa statistic over the value 0.70 with 90% power at an alpha level of 0.05 (Sim & Wright, 2005).

A research assistant abstracted data for six variables from the sample of PRF with a target of 95% agreement (Allison et al., 2000). The six variables were: first medical contact, paramedic diagnosis of stroke/TIA, combined face, arms and speech components of the FAST assessment, blood pressure, blood glucose level and notification to the receiving hospital. The research assistant was selected on the basis of computer literacy, familiarity with medical terminology and experience using the PRF. Thorough training included an overview of the study, introduction of the study protocol, demonstrations and practice with real cases and signing of a patient confidentiality agreement. Double data abstraction enabled review of typographical data entry errors and variation in the interpretation of data entered. Inter-rater reliability was measured using the kappa statistic (Allison et al., 2000; To et al., 2008).

The kappa statistic measures the reliability between two raters for binary and nominal scales after allowing for agreement due to chance (Barton & Peat, 2014; Pallant, 2013). A kappa value of zero implies that agreement is due to chance and a negative value

suggests less agreement than would be expected by chance. One weakness of this statistic is that the value increases with the prevalence of the positive value (Pallant, 2013). Therefore, the proportion of positive responses for each rater was reported (Sim & Wright, 2005) and 95% confidence intervals were constructed from the standard error (SE) using the formula $p \pm (SE \times 1.96)$ (Barton & Peat, 2014, p. 259). The kappa statistic was interpreted using the algorithm of Landis and Koch (1977). Values greater than 0.80 represented almost perfect agreement, 0.61 to 0.80 represented substantial agreement, 0.41 to 0.60 represented moderate agreement and below 0.40 signified fair or slight agreement.

Secondly, to explore concordance between the three data sources, the values of variables that were recorded independently in more than one data set, were compared. For the binary variable of sex of the patient, it was possible to use the kappa value as described above. For ordered and continuous data, weighted kappa must be used to reflect varying levels of concordance between the two sources. However, the SPSS software package does not calculate estimates of weighted kappa (Barton & Peat, 2014). Date strings were of particular interest as they are prone to transcription and illegibility errors. Comparisons between date strings from different data sources were expressed using a reliability coefficient. This was calculated as the number of actual agreements between data sources as a proportion of the number of possible agreements (Salkind, 2014). Higher values of the reliability coefficient indicated higher levels of agreement.

Prior to commencement of analyses, the database was screened for errors. A standard approach was employed to query outliers using range and distribution (Pallant, 2013). As a further quality check, for those cases transported by ambulance, the date of symptom onset time recorded in ARCOS IV, was compared with the time that the call was made to the ambulance service. This enabled a logic check that symptom onset was before the call for assistance to the EMS. Where an unexpected value was encountered, the PRF was re-examined to confirm accuracy or correct any error and the ARCOS IV hardcopy files were reviewed.

The initial analysis described the demographic characteristics and clinical features of the population. Specifically, the age, sex and ethnicity of patients and the stroke sub-category. Categorical (nominal) variables, such as sex and ordinal variables, such as age in groups, were summarised using frequencies and percentages. Continuous variables

such as age were summarised using means, standard deviations, medians, quartiles and range (Pallant, 2013).

3.12.1 Included cases

During the 2011-2012 ARCOS IV study, 2,911 cases of stroke and TIA events were identified in the Greater Auckland region. Of these 2,911 eligible cases, 2,524 (86.7%) met the study criteria and were included in the analysis (Figure 2). The majority of the 387 cases were excluded for one of two reasons. Either the patient suffered the stroke/TIA in hospital during an admission for an unrelated health problem (43.4%) or the patient did not present at a hospital at all (42.9%). A further 10.1% of patients were not in the greater Auckland region when their stroke/TIA commenced and attended a hospital outside this region. Finally, a few patients (3.6%) were in the presence of a healthcare professional when their symptoms commenced. This included people who were accompanying a sick relative to their general practitioner, attending clinics, or working in primary or secondary care as a healthcare professional at the time of symptom onset.

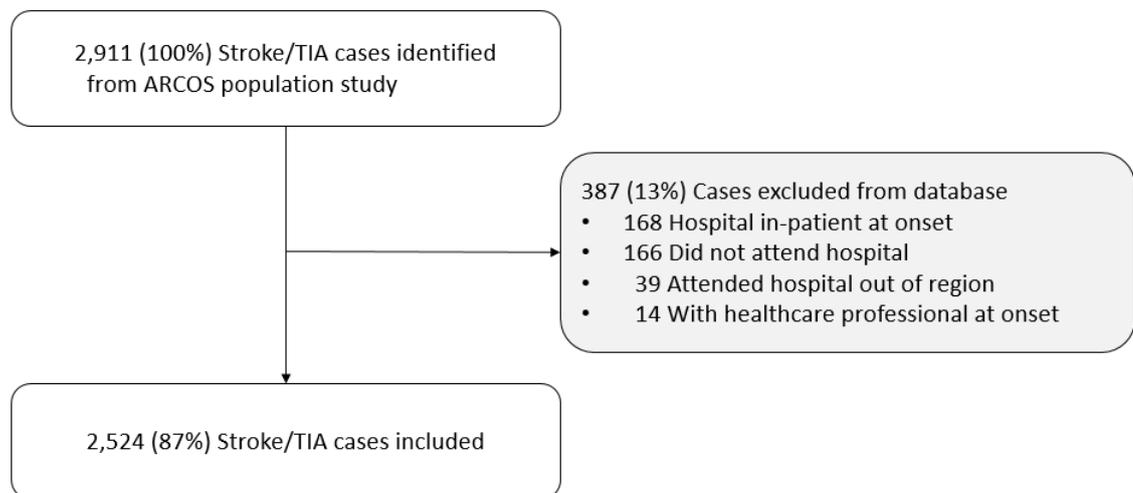


Figure 2. Flow chart of identification of cases included in the study

The study inclusion criteria were aligned with the aims of the enquiry and informed by the literature. In this study, 13.3% of the 2,911 cases were excluded because the patient's referral route did not include the option of initially accessing prehospital care from the EMS system within the study area.

Population level studies of paramedic care of acute stroke and TIA patients are rare. Opportunities to compare the proportion of cases excluded in the current study to those

in previously published research are limited to two studies arising from the Greater Cincinnati/Northern Kentucky Stroke Study. One study of EMS utilisation used similar criteria to the current study (Adeoye et al., 2009). The researchers excluded 9% of the 3,949 confirmed stroke/TIA cases because the patient was in-hospital, out of the study area, with another healthcare practitioner or at an unknown location at the time of onset. In contrast, 74.4% of 3,814 cases were excluded in an investigation of prehospital delay and socioeconomic status (Kleindorfer et al., 2006). This high exclusion rate was a consequence of the narrowly defined study criteria. The authors only included cases if the patient had their stroke/TIA at a private dwelling, accessed assistance through the EMS, and complete time records were available. However, exclusion of a large proportion of subjects from a study introduces the risk of selection bias.

The proportion of cases excluded in the current study was consistent with the limited published data available and supported the integrity of the analyses.

3.12.2 Data linkage

Data linkage between the three sources (the PRF, computer-aided-dispatch system and the ARCOS IV data set) was conducted in two phases as planned. In the first step, the paramedic report was connected to the population study. The ARCOS IV study had identified that in 393 (15.6%) of the 2,524 included events, the patient used public or private transport to reach hospital. In the remaining 2,131 (84.4%) cases, either the patient was conveyed to hospital by ambulance or transport mode data was missing (Figure 3).

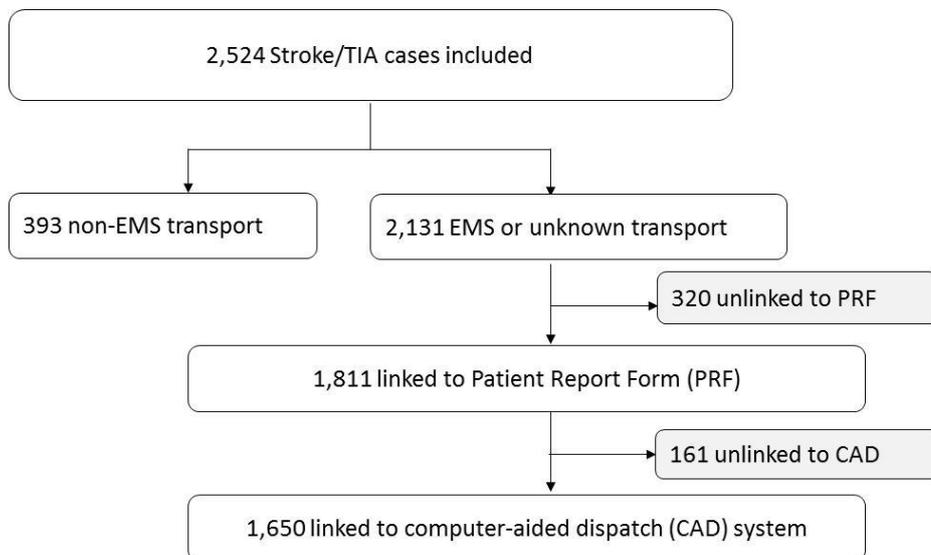


Figure 3. Flow chart of results of linkage between three data sources

By checking shared data elements, a paramedic-completed PRF was paired to 1,811 of the 2,131 cases (85.0%) where the transport mode was either unknown or known to be by ambulance. Matched cases were then linked to the ARCOS IV database of variables to be used in the analysis.

Of the 1,811 cases where a PRF was located for the ARCOS IV record, the paramedic-completed clinical report was also matched to the EMS computer-aided-dispatch system for 1,650 (91.1%) events. For these cases, both EMS clinical and operational data was available. Data linkage across the three databases was achieved for 77.4% of the 2,131 cases.

In this study, it was necessary to join three databases to be able to examine the paramedic care of the stroke or TIA patient from the first call for assistance, during the prehospital contact and onward to his or her hospital treatment. Missing records and inaccurate or illegible documentation account for an inability to locate a corresponding PRF for some of the 15.0% of unmatched cases. However, it is highly likely that a number of the patients with unmatched records reached hospital by non-EMS transport. In these cases, attempts to link the EMS and ARCOS IV records would be unsuccessful as no EMS contact occurred.

In summary, despite joining patient records from three distinct sources, this study achieved a high proportion of linked cases that compares favourably with previous studies (Adeoye et al., 2009; Mears et al., 2010). Furthermore, the proportion of the total cases that were included in this study was consistent with, or substantially better than, other population-based EMS studies (Adeoye et al., 2009; Kleindorfer et al., 2006). These results support the integrity of the database for use in the subsequent analyses.

3.12.3 Data reliability

Data reliability was explored using measures of inter-rater reliability and concordance of variable values between the three data sources.

The reliability of the data abstracted from the PRF, was evaluated using the kappa statistic to measure the agreement between a sample of data values abstracted and entered independently, by two raters. Analysis of double data entry was undertaken for six binary variables over 12% of the sample. Inter-rater concordance across all measured variables was strong (Table 8). For five variables (first medical contact, paramedic diagnosis, blood glucose level, blood pressure, and notification of the receiving hospital) the kappa

value was between 0.81 and 1.00. According to Landis and Koch (1977) this range represents almost perfect agreement between the two raters. There was substantial agreement between raters as to whether the paramedic had conducted a FAST assessment (excluding the onset time element) of the patient, as evidenced by the kappa value of .74 (Landis & Koch, 1977).

Table 8. Inter-rater reliability measured by kappa values over 8% of included cases

Variable	n	% of positive values		Proportion in agreement	Kappa	Kappa (95% CI)	P
		Rater 1	Rater 2				
First medical contact	210	80.0	80.5	.98	.92	(.86, .99)	<.001
Paramedic diagnosis	209	70.3	68.9	.99	.97	(.93, 1.00)	<.001
FAST assessment	210	78.6	76.2	.91	.74	(.63, .85)	<.001
Blood glucose	210	70.0	69.5	.99	.97	(.93, 1.00)	<.001
Blood pressure	210	99.5	99.5	1.00	1.00	(1.00, 1.00)	<.001
Notification	108	59.3	57.4	.93	.84	(.74, .94)	<.001

Notes. FAST = Face-Arms-Speech test

To explore the concordance across the three data sources, the values of those variables that were present in multiple data sets were compared. Near perfect agreement ($\kappa = 0.98$, 95% CI: 0.96, 1.00) was observed in a sample of 464 values for patient sex recorded in the PRF database and the ARCOS IV database (Table 9). Using the same two databases, the proportion of agreement for the documented date of birth was calculated for 1,676 cases where both values were available. The inter-rater reliability coefficient of .97 demonstrated strong reliability (Salkind, 2014). Fifty-eight cases with a difference in the date of birth were checked against National Health Index data. In most cases ($n=54$) this was due to illegibility of the handwritten paramedic report. Transcription errors in the ARCOS IV database accounted for the four remaining cases. The proportion of agreement for the documented date of the stroke/TIA event was determined between the ARCOS IV and the computer-aided-dispatch databases for 1,657 cases. The inter-rater reliability coefficient exhibited lower agreement (.83) than for date of birth.

Table 9. Inter-database reliability measured by kappa values and reliability coefficient

Data Sources Variable	n	% of positive values		Proportion in agreement	Kappa (95% CI)	P
		PRF	ARCOS IV			
PRF-ARCOS IV						
Sex	464	50.9	50.9	.99	.98 (.96, 1.00)	<.001
	n	Disagreements	Agreements	Reliability coefficient	(95% CI)	
PRF-ARCOS IV						
Date of birth	1,676		58	1,618	.97 (.96, .97)	
ARCOS IV-CAD						
Onset date	1,657		284	1,373	.83 (.81, .85)	

Notes. PRF = patient report form; ARCOS IV = 4th Auckland Regional Community Stroke Study

Preliminary screening of the ARCOS IV database, revealed that onset time data was missing more often from cases where the FMC was not with an EMS paramedic. The reliability of the onset time could only be tested for cases where the patient was conveyed to hospital by ambulance. For these cases, subtracting the onset time recorded in the ARCOS IV study from the EMS computer-generated log of call times yielded the patient-related delay. When the onset-to-alarm duration was a negative value, it implied that symptom onset time had occurred after the emergency call was placed.

Strong inter-rater agreement confirmed the robustness of the database constructed by abstracting information from the paramedic-completed report form. Strict protocols had governed the data abstraction process. The highest agreement between the raters was observed for recording of the blood pressure and blood glucose level. Of note, these are routine and objective measures and both had a dedicated entry field on the report form. In contrast, variables with the least agreement, (recording of the FAST assessment and notification to the hospital) did not have a specific data entry field on the patient report. Reporting results of the FAST assessment in free text, led to inadequate and incomplete recording that required a more subjective interpretation by the two raters. The high concordance between raters for the paramedic diagnosis is likely to reflect the precise study criteria that required the stroke/TIA to be either named or coded as the patient's chief complaint.

As with the inter-rater reliability checks, higher agreement was observed between the databases for less complex variables. The number of disagreements was lower for the

recording of patient sex compared with date of birth. As a longer data string, date of birth was subject to transcription errors and, at times, illegibility of the handwritten PRF led to confusion between numerals. This greater potential for transcription errors also applied to recording of the onset time. Discordance between the ARCOS IV and PRF records in nearly one fifth of cases was problematic and data that was clearly in dispute with computer-generated operational times, was excluded. Due to concerns about the accuracy of the onset time and the inability to cross check with another source, it was decided that cases where patients were transported privately would not be included in the analysis of onset time.

Few studies report measures of data integrity in studies of EMS stroke/TIA care. Those that have addressed the reliability of their data set, either justified why they believed it was unnecessary in their study (Brandler et al., 2015) or only described in-hospital variables (Oostema et al., 2014). In the current study, robust design and processes were used to ensure a high quality data set and to address the potential risk of errors. Rigorous checks established confidence in the quality of data abstraction from original documentation and the linkage between data sources. This confirms the suitability of the combined database as the basis for investigation into the paramedic care of stroke/TIA patients.

3.12.4 Characteristics

The characteristics of the study subjects are summarised in Table 10. Demographic data describing the patient age, sex and ethnicity was available for all 2,524 cases. The mean age was 71.4 years (SD: 14.7) and the median was 74 years with a range from 19 to 103 years. Therefore, the distribution of ages was left skewed. Nearly half of all strokes and TIA (47.9%) were observed among people aged 75 years and older. Women accounted for slightly more than half (51.8%) of the sample. Applying the New Zealand Department of Health prioritised ethnicity classification protocol (Ministry of Health, 2004), the majority of patients identified themselves as New Zealand Europeans (57.2%).

For most cases, a final diagnosis and sub-classification using the OCSP criteria were also available. The majority of events had an ischaemic aetiology (86.1%). For events that had an OCSP classification, lacunar locations were the most frequent (31.5%) whereas posterior loci were the least common (20.2%).

Table 10. Overall characteristics of included cases (n=2,524)

Characteristic	Cases (n)	%
Age		
<i>Mdn</i> (years) [IQR]	74 [62,83]	n/a
15-64	744	29.5
65-74	565	22.4
75-84	704	27.9
>84	511	20.2
Sex		
Female	1,307	51.8
Ethnicity		
New Zealand European	1443	57.2
Māori	151	6.0
Pasifika	271	10.7
Asian	194	7.7
Other	465	18.4
Diagnosis ^a		
transient ischaemic attack	636	25.4
subarachnoid haemorrhage	86	3.4
primary intracerebral haemorrhage	261	10.4
ischaemic stroke	1,520	60.7
OCSP classification ^b		
lacunar	694	31.5
posterior	445	20.2
partial anterior	646	29.4
total anterior	416	18.9

Notes. OCSP = Oxford Community Stroke Project.

^a = 2,503. ^b = 2,201.

The age and sex of the study population were similar to the Greater Cincinnati/Northern Kentucky Stroke Study (Adeoye et al., 2009). In both studies the median age was 74 years and women comprised over half of the cases. The ethnic diversity was greater in Auckland with 42.8% of people identifying with an ethnicity other than New Zealand European compared with 17.1% who identified with an ethnicity other than “White” in the previous population-based study (Adeoye et al., 2009, p. 7). This may reflect differences between the studies in the way that people who identified with multiple ethnicities were coded in the database. However, a more likely explanation is that it

represents the greater ethnic diversity of Auckland's population compared to that of Kentucky, in the United States of America. Māori appear under-represented in the overall ARCOS IV study, with the observed proportion of cases (6%) less than the general population proportion of 16%. One possible explanation for this is the confounding effect of age (Sandiford, Selak, & Ghafel, 2016); the Māori population profile is more youthful than that of New Zealand Europeans. The proportions of the final stroke/TIA diagnoses were similar between this study and the population-based study by Adeoye et al. (2009), with ischaemic stroke accounting for at least 60% and TIA for one quarter of cases, in both studies.

3.13 Study boundaries

The focus of this study is on the EMS, and data collection was only undertaken for adult patients who had a contact with the EMS, either as the first medical contact or as the means of transport to hospital.

The study is concentrated on paramedic care. The role of the wider EMS system, including the role of call-takers and emergency medical dispatchers, was only investigated in relation to paramedic care.

While a number of stroke assessment tools have either been trialled or are in use in the prehospital setting, this study is only concerned with the use of the FAST stroke screening tool.

3.14 Summary

This study adopted a methodology that is congruent with both the context in which the study is located and the research proposition that it explores. A population-based approach was appropriate to explore first medical contact in acute stroke/TIA and to assess the quality and contribution of paramedic care to health outcomes within the overall New Zealand healthcare system. Detailed methods, informed by the work of other researchers in this field have been developed to guide and support the study. This study is situated within the context of a nascent research environment within the discipline of paramedicine in New Zealand.

Chapter 4 RESULTS

4.1 First medical contact

Of the 2,524 stroke and TIA events that occurred during the study period and met the inclusion criteria, this analysis included 2,204 (87.3%) cases where the patient's first medical contact was identified. The remaining 12.7% of cases were excluded because it was not possible to establish the initial contact. Baseline demographic, social and clinical characteristics are presented in Table 11.

Demographic data was available for all cases. The median age of the stroke and TIA patients was 72 years and ranged from 19 to 103 years (data not shown). Age is reported in four age groups. Female patients accounted for 51.8% of the sample. The majority of patients identified with a New Zealand European ethnicity (58.8%).

Social characteristics, describing the patient's abode, whether they lived alone and their employment status, were available for many but not all cases. The majority of patients lived in private accommodation (79.1%) and with other people (76.8%). Most people were not participating in the labour force because they were either retired or unemployed (77.3%).

Clinical information was generally available. Most patients had signs of stroke at onset that were recognisable by a member of the public using the FAST tool (85.3%). Nearly half the patients (43.5%) reported an experience of previous stroke or TIA, either for themselves, or among their immediate relatives. Ischaemic aetiologies were high with over 60% of events classified as an ischaemic stroke at discharge and a further 24% as TIA. OCSP classifications were completed for ischaemic events. Lacunar and partial anterior circulation classifications accounted for 30% each with the remainder split evenly between total anterior and posterior circulation events.

Table 11. Characteristics of cases included in analyses of first medical contact (n = 2,204)

Demographic Characteristics			Social Characteristics			Clinical Characteristics		
	n	%		n	%		n	%
Age ^a			Abode ^b			FAST signs at onset ^e		
15-64	605	27.5	Private	1,066	79.1	Yes	1,796	85.3
65-74	481	21.8	Retirement village	120	8.9	Stroke experience ^f		
75-84	637	28.9	Rest home	162	12.0	Yes	958	43.5
>84	481	21.8	Employment status ^c			Final diagnosis ^g		
Sex ^a			Manual	153	8.4	transient ischaemic attack	517	23.7
Female	1141	51.8	Non-manual	262	14.3	subarachnoid haemorrhage	74	3.4
Ethnicity ^a			Non-participating	1,416	77.3	primary intracerebral haemorrhage	245	11.2
NZ European	1,296	58.8	Living alone ^d			ischaemic stroke	1,347	61.7
Māori	126	5.7	Yes	463	23.2	OCSF classification ^h		
Pasifika	222	10.1				lacunar	576	29.9
Asian	162	7.4				posterior	378	19.6
Other	398	18.1				partial anterior	569	29.5
						total anterior	403	20.9

Notes. FAST = Face-Speech-Arms test; NZ = New Zealand; OCSF = Oxford Community Stroke Project

^a n = 2,204. ^b n = 1,348. ^c n = 1,831. ^d n = 1,998. ^e n = 2,105. ^f n = 2,193. ^g n = 2,183. ^h n = 1,926.

4.1.1 Analysis of first medical contact

Among the 2,204 cases included in this analysis, 64.0% of patients had their first medical contact during the stroke or TIA event with an EMS crew (Figure 4).

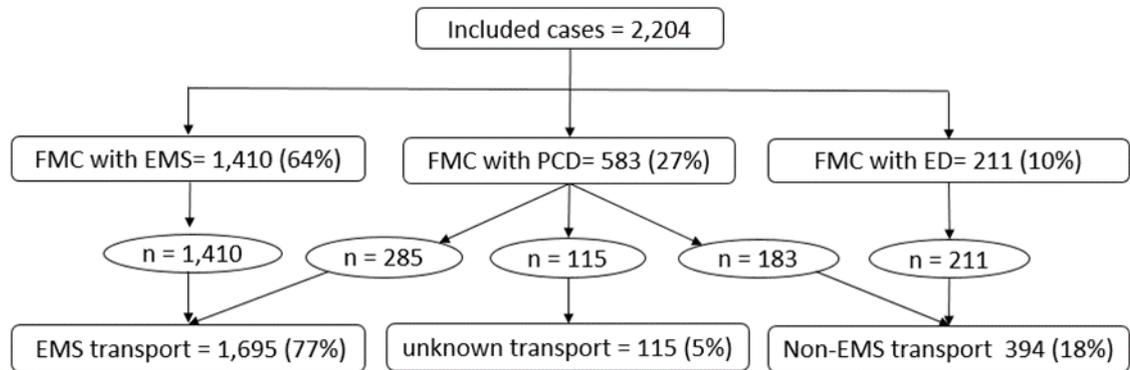


Figure 4. Flow chart of first medical contact and transport mode in acute stroke/TIA

A further 26.5% consulted a primary care doctor and most of these were face-to-face consultations. In 29 cases (1.3%) the receptionist at the primary care practice advised the caller to hang-up and contact the EMS urgently. The final 9.6% of cases presented to a hospital Emergency Department.

The mode of transport was determined in 2,089 of included cases (94.7%) with 1,695 (76.9%) conveyed by ambulance and the remaining 17.8% travelling by public or private transport.

4.1.2 Predictors of first medical contact with the EMS in acute stroke/TIA

The analysis commenced with a review of the available demographic, clinical and presenting features which might be associated with EMS as FMC. NIHSS scores were unavailable for 89% cases and were not considered for analysis. For two more variables, (employment status and abode) data was missing for more than 15% of cases. On this basis, these variables were excluded from the analysis. Both of these variables were also collinear with age. Correlations between other potential predictor variables (using phi coefficient or Cramer's V) did not suggest strong associations using Cohen's criteria as reported by (Pallant, 2013).

Inspection of the data in relation to the assumptions of logistic regression was undertaken before analysis (Barton & Peat, 2014; Tabachnick & Fidell, 2014). Due to the population study method and sample of over 2,000 cases, the data was assumed to be representative

and of sufficient size to support the model. As there were no public education campaigns on stroke/TIA during the study period, nor any changes to service delivery, the relationship between the dependent and explanatory variables was presumed to be stable. A relevant set of predictor variables was available for the analysis, highly collinear variables were removed and the data rigorously checked for accuracy. Given these circumstances, use of a logistic regression method was appropriate to determine the independent contribution of potential predictor variables to FMC with EMS.

The unadjusted odds ratios calculated from the frequency data are presented in Table 12. Univariate analyses using Pearson's chi-square tests suggested that FMC with EMS was associated with age, living alone, FAST signs at onset, final diagnosis and OCSP classification. There was no significant association between FMC with the EMS and the patient's sex, identifying as a New Zealand European or having a previous experience of stroke themselves or among close relatives.

The five variables identified from the unadjusted odds ratios as significantly associated with EMS as the initial contact were entered into two statistical logistic regression models. Both the forward and backward stepwise models met the Hosmer-Lemeshow Goodness of Fit Test criterion. This tests how well the model fits the data, with a significance value less than 0.05 implying a poor fit (Pallant, 2013). Four variables, age, FAST signs at onset, final diagnosis and OCSP classification were included in both models. It is of interest to note, that while the "living alone" variable was statistically significant in the bivariate analysis with FMC, it was not included in the final model. A Chi-square test for independence indicated a small to moderate association between living alone and age, ($\chi^2_3 = 105.73$, $p < 0.001$, Cramer's $V = .23$) using Cohen's criteria as described by (Pallant, 2013). This underlines the necessity of calculating an adjusted odds ratio, which considers the interactions between explanatory variables, rather than relying on the unadjusted odds ratio.

Table 12. Factors associated with first medical contact with EMS (UOR)

	EMS		non-EMS		χ^2	<i>P</i>	UOR
	n	%	n	%			
Total	1,410	64.0	794	36.0			
Age ^a					82.45	<0.001	
15-64	313	51.7	292	48.3			1.00
65-74	289	60.1	192	39.9			1.40
75-84	440	69.1	197	30.9			2.08
>84	368	76.5	113	23.5			3.04
Sex ^a					1.05	0.31	
Male	668	62.8	395	37.2			1.00
Female	742	65.0	399	35.0			1.10
NZ European ^a					0.01	0.97	
No	580	63.9	328	36.1			1.00
Yes	830	64.0	466	36.0			1.01
Living alone ^b					5.88	0.02	
No	947	61.7	588	38.3			1.00
Yes	315	68.0	148	32.0			1.32
FAST signs at onset ^c					11.59	0.001	
No	167	54.0	142	46.0			1.00
Yes	1155	64.3	640	35.7			1.53
Stroke experience ^d					2.72	0.09	
No	809	65.5	426	34.5			1.00
Yes	594	62.0	364	38.0			0.86
Final diagnosis ^e					75.34	<0.001	
TIA	278	53.8	239	46.2			1.00
SAH	55	74.3	19	25.7			2.49
PICH	209	85.3	36	14.7			4.99
IS	853	63.3	494	36.7			1.48
OCSP classification ^f					159.04	<0.001	
lacunar	295	51.2	281	48.8			1.00
posterior	220	58.2	158	41.8			1.33
partial anterior	362	63.6	207	36.4			1.67
total anterior	360	89.3	43	10.7			7.97

Notes. significant p-values are shown in boldface. EMS = emergency medical services; IS = ischaemic stroke; NZ = New Zealand; OCSP = Oxford Community Stroke Project; PICH = primary intracerebral haemorrhage; SAH = subarachnoid haemorrhage; TIA = transient ischaemic attack; UOR = unadjusted odds ratio.

^a n=2,204. ^b n=1,998. ^c n=2,104. ^d n=2,193. ^e n=2,183. ^f n=1,926.

The four variables (age, FAST signs at onset, final diagnosis and OCSF classification) were entered into the final model to determine the contribution of each in explaining whether the initial healthcare contact was with the EMS. Due to missing values, 378 cases were excluded. No data imputation was undertaken leaving 1,826 cases available for analysis. The full model containing the four predictors was statistically significant, ($\chi^2_{10} = 254.07, p < 0.001$). This indicates that the model was able to differentiate those cases where the FMC was with the EMS from others, where another healthcare professional was seen first. All four independent variables made a statistically significant contribution to the model: age, FAST signs at onset, final diagnosis and OCSF classification.

The adjusted odds ratios and 95% confidence intervals are presented in Table 13.

Table 13. Factors associated with first medical contact with EMS (AOR)

	<i>B</i>	<i>SE</i>	Wald	<i>P</i>	AOR	95% CI
Age			76.10	<0.001		
15-64					1.00	
65-74	0.47	0.14	10.61		1.60	[1.21, 2.11]
75-84	0.93	0.14	46.47		2.54	[1.94, 3.33]
>84	1.22	0.16	62.11		3.38	[2.48, 4.60]
FAST signs at onset			12.77	<0.001		
No					1.00	
Yes	0.60	0.17			1.82	[1.31, 2.54]
Final diagnosis			20.23	<0.001		
TIA					1.00	
SAH	0.30	0.78	0.17		1.35	[0.30, 6.18]
PICH	1.10	0.25	19.91		3.01	[1.84, 4.91]
IS	0.14	0.13	1.08		1.15	[0.89, 1.49]
OCSF classification			66.76	<0.001		
lacunar					1.00	
posterior	0.43	0.15	7.37		1.54	[1.14, 2.08]
partial anterior	0.38	0.13	9.53		1.47	[1.15, 1.88]
total anterior	1.64	0.20	67.17		5.13	[3.46, 7.60]

Notes. AOR = adjusted odds ratio; IS = ischaemic stroke; OCSF = Oxford Community Stroke Project; PICH = primary intracerebral haemorrhage; SAH = subarachnoid haemorrhage; TIA = transient ischaemic attack.

A strong effect was noted of increasing FMC with EMS at older levels of age. The adjusted odds ratios using the youngest group (15-64) as the reference group, increased with increasing age cohorts from 1.60 for the 65-74 group to 3.38 for the oldest group, those aged 85 years or older.

Patients with signs of stroke at onset that were recognisable using the FAST test, were significantly more likely to have their FMC with EMS paramedics than patients who did not have FAST signs (AOR, 1.82; 95% CI, 1.31, 2.54; $P < 0.001$).

Final diagnosis was also a predictor of EMS contact. For patients subsequently diagnosed with a primary intracerebral haemorrhage, the odds that the initial contact was an EMS paramedic was treble that among TIA patients (AOR, 3.01; 95% CI, 1.84, 4.91; $P < 0.001$). The wider confidence interval reflects the smaller proportion (11.2%) of primary intracerebral haemorrhages. No significant effect was observed for either ischaemic stroke or subarachnoid haemorrhage as evidenced by the confidence intervals overlapping 1.0.

The strongest association with initial contact with an EMS paramedic was the total anterior classification compared with lacunar, within the OCSP variable (AOR, 5.13; 95% CI, 3.46, 7.60; $P < 0.001$). Within the OCSP variable, posterior (AOR, 1.54; 95% CI, 1.14, 2.08; $P = 0.005$) and partial anterior (AOR, 1.47; 95% CI, 1.15, 1.88; $P = 0.002$) classifications were also significantly associated with FMC with EMS compared with lacunar circulation infarction.

4.2 Quality of paramedic care

This study included the 1,410 cases where the patient's first medical contact was with the EMS (Figure 4). In one case the paramedic's clinical impression was not recorded and so the analysis was conducted on the remaining 1,409 cases. Demographic, social, clinical and operational baseline characteristics are presented in Table 14.

In summary, the 1,409 cases have the following characteristics. Demographic data was available for all patients. The median age was 74.3 years with a range from 20 to 100. More patients were female (52.6%) than male, and the majority identified as New Zealand Europeans (58.8%).

Table 14. Characteristics of cases included in analyses of quality of paramedic care (n=1,409)

Characteristic	n	%	Characteristic	n	%
Demographic			Stroke experience ^g		
Age ^a			Yes	594	42.4
15-64	312	22.1	Final diagnosis ^h		
65-74	289	20.5	TIA	278	19.9
75-84	440	31.2	SAH	55	3.9
>84	368	26.1	PICH	209	15.0
Sex ^a			IS	852	61.1
Female	741	52.6	OCSP classification ⁱ		
Ethnicity ^a			lacunar	295	23.9
NZ European	829	58.8	posterior	220	17.8
Māori	73	5.2	partial anterior	362	29.3
Pasifika	156	11.1	total anterior	359	29.0
Asian	104	7.4	GCS low ^j		
Other	247	17.5	Yes	138	9.8
Social			Status ^k		
Abode ^b			Minor	20	1.4
Private	603	75.3	Moderate	539	38.4
Retirement Village	85	10.6	Serious	689	49.1
Rest home	113	14.1	Critical	156	11.1
Deprivation ^c			FAST assessment ^a		
More deprived	653	49.4	No test	336	23.8
Employment status ^d			Negative	84	6.0
Manual	78	6.8	Positive	820	58.2
Non-Manual	115	10.0	Excluded	169	12.0
Non-participating	958	83.2	Operational		
Living alone ^e			EMD code (stroke) ^l		
Yes	315	25.0	Yes	596	43.4
Clinical			Priority ^l		
FAST signs at onset ^f			P1	1,161	84.6
Yes	1,155	87.4	P2	182	13.3
			P3	30	2.2

Notes. EMD = emergency medical dispatcher; FAST = Face-Arms-Speech test; GCS = Glasgow Coma Score; IS = ischaemic stroke; NZ = New Zealand; OCSP = Oxford Community Stroke Project; PICH = primary intracerebral haemorrhage; P1 = priority one, lights and siren; P2 = priority two, normal traffic flow; P3 = other priorities; SAH = subarachnoid haemorrhage; TIA = transient ischaemic attack.

^a n = 1,409. ^b n = 801. ^c n = 1,323. ^d n = 1,151. ^e n = 1,261. ^f n = 1,322. ^g n = 1,402. ^h n = 1,394. ⁱ n = 1,236. ^j n = 1,406. ^k n = 1,404. ^l n = 1,373.

Four factors measured the social circumstances of the patients. Data on the type of abode was missing in nearly half of all cases but where it was recorded, a private dwelling was most frequent (75.3%). Deprivation scores, derived from the New Zealand Deprivation Index, were available for 94% of cases and were equally divided between the higher and lower levels of deprivation. Of the 82% of cases with a known employment status, over 80% of patients were not participating in the workforce, due to either retirement or unemployment. Data describing the living arrangements of patients was available in 90% of cases and one quarter of these people lived alone.

Clinical characteristics of patients whose first contact was with the EMS, were evaluated by seven variables. At the onset of their stroke or TIA event, most patients (87.4%) experienced signs or symptoms that would have been recognisable to a member of the public using the FAST tool. Less than half the patients (42.4%) reported a history of stroke or TIA themselves or among their immediate relatives. Final diagnoses were available for 88% of cases with the majority being ischaemic events (61.1% ischaemic stroke and 19.9% TIA). Among the remaining haemorrhagic strokes, 15.0% were classified as primary intracerebral and 3.9% as subarachnoid events. OCSP classification identified each of total anterior and partial anterior strokes in approximately 30% of cases, lacunar in 24.0% with posterior infarcts the least common at 17.8%. Less than 10% of patients had a Glasgow Coma Score of less than 9 recorded by the EMS crew. In most cases, the patient's status was recorded as serious (49.1%) or moderate (38.4%). Almost a quarter of patients did not have a FAST assessment recorded by the EMS crew.

Finally, two EMS operational factors were reported. In 43.4% of cases, the emergency medical dispatcher assigned a code for a suspected stroke or TIA to the ambulance response. In the majority of cases (84.6%), the ambulance was assigned an urgent priority enabling them to respond under lights and siren. In the case of multiple vehicle assignments to the call, only the priority of the ambulance that first assessed the patient was reported.

4.2.1 Sensitivity of paramedic recognition

The sensitivity of paramedic recognition of stroke/TIA was calculated as the percentage of all final diagnosis stroke and TIA events. The final diagnosis, as determined by the ARCOS IV diagnosis review committee, was used as the gold standard for comparison. Both a final diagnosis and a paramedic working diagnosis were available for 1,409 cases. A paramedic working diagnosis of either, stroke or TIA was accepted as evidence of

recognition in the analysis (Table 15). Overall, paramedics recognised that the patient was having either a stroke or TIA event in 979 of the 1,409 cases resulting in a diagnostic sensitivity of 69.5%.

The sensitivity of paramedic recognition, as the exact working diagnosis, was also computed. Paramedics correctly identified 61 cases of 278 TIA events, resulting in paramedic sensitivity of 21.9% for an exact diagnosis of TIA. If the paramedic diagnostic criterion were expanded to include the additional 86 cases with a joint diagnosis of stroke/TIA, the sensitivity of TIA diagnosis increased to 52.9%. Similarly, there was a paramedic diagnosis of stroke for 533 cases of the 1,131 with a final diagnosis of stroke, producing a sensitivity of 47.1%, which increased to 64.2% if the 193 combined stroke/TIA diagnoses were added. Overall, these results indicate a low degree of agreement between an exact paramedic working diagnosis of stroke or TIA and the final diagnosis.

Table 15. Sensitivity of paramedic working diagnosis of stroke/TIA

Paramedic diagnosis	Final diagnosis		
	TIA	Stroke	Total
TIA	61	48	109
Stroke/TIA	86	193	279
Stroke	58	533	591
non-stroke/TIA	73	357	430
Total	278	1,131	1,409

Notes. TIA = transient ischaemic attack.

The range of working diagnoses that were coded by the paramedics are presented in Figure 5. Four non-stroke classifications accounted for about a quarter of the paramedic clinical impressions. These were: unwell, unconscious, headache and falls. The remaining 5% of cases, shown as “other” in Figure 5, were described by 16 different working diagnoses. Seizures, a common stroke mimic, accounted for less than 1% of the working diagnoses.

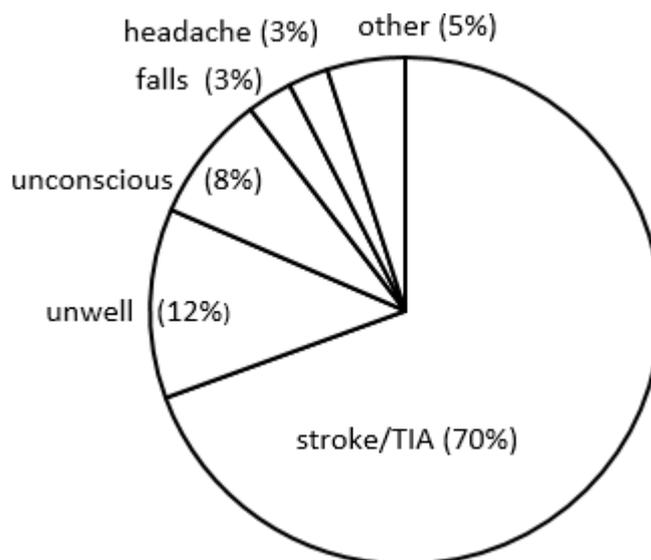


Figure 5. Paramedic working diagnoses for 1,409 cases with a final diagnosis of stroke/TIA

The dispatch code applied by the emergency medical dispatcher was available for 1,359 cases (Table 16). Of these, 595 cases were assigned a dispatch code identifying the call as a possible stroke/TIA case. This equates to a sensitivity of 43.8%.

Table 16. Sensitivity of emergency medical dispatcher code assignment

Emergency medical dispatcher code	Final diagnosis		
	TIA	Stroke	TOTAL
Stroke/TIA	162	433	595
Other	110	654	764
TOTAL	272	1,087	1,359

Notes. TIA = transient ischaemic attack.

The effect on paramedic diagnostic sensitivity of the introduction of new clinical practice guidelines for stroke and TIA during the study period was tested. As established above, the paramedic diagnostic sensitivity for recognition of stroke/TIA events across the one-year study period was 69.5%. Before the update, paramedic diagnostic sensitivity was 68.1%, increasing to 71.5% after the introduction of specific stroke guidelines (data not shown). A Pearson's chi-square test for independence indicated that the proportion of correct diagnoses was similar in each time period ($\chi^2_{1,} = 1.76, p = .18$). There was no significant association between introduction of the new guidelines and recognition of stroke and TIA by paramedics.

Further investigations were conducted to determine whether there was a statistical association between introduction of the new guidelines and either the number of FAST assessments undertaken by paramedics, or the proportion of positive scores of the FAST tests. Prior to the introduction of the new guidelines, 77% of cases had a FAST assessment documented by the paramedic compared with 75% after their introduction (data not shown). This small difference between the two periods, in the proportion of cases with a documented FAST assessment, was not statistically significant ($\chi^2_1 = .61$, $p = .44$). Likewise, there was no significant difference in the proportion of FAST assessments with a positive result documented before (57.4%) and after (59.4%) the guideline change ($\chi^2_1 = 4.06$, $p = .26$) (data not shown).

4.2.2 Predictors of non-recognition of stroke/TIA by paramedics

Prior to analysis, variables were reviewed. NIHSS scores were unavailable for 91% of cases and were not considered for analysis. For two variables, employment status and abode, data was missing for more than 15% of cases. On this basis, these variables were excluded from the analysis. Unadjusted and adjusted odds ratios were estimated to identify predictors of paramedic non-recognition of stroke/TIA cases from 16 variables. The unadjusted odds ratios were calculated from the frequency data and are presented in Table 17. These univariate analyses suggested significant relationships between non-recognition of stroke/TIA and 10 putative predictor variables.

One demographic factor, ethnicity other than New Zealand European, was associated with non-recognition of the stroke/TIA by the paramedic. All seven clinical factors were significantly associated with non-recognition by the paramedic. These were, an absence of FAST signs at onset, no experience of stroke in the patient or family, a final diagnosis of stroke compared to TIA, all other OCSF sub-classifications compared to lacunar infarction, a low prehospital Glasgow Coma Score, status severity assessed as minor and absence of a documented FAST assessment on the PRF, irrespective of the score. EMS operational factors related to non-recognition were, a dispatch code other than stroke and assignment of a less urgent response priority.

Table 17. Factors associated with paramedic non-recognition of stroke/TIA (UOR)

	Recognised		Unrecognised		χ^2	<i>P</i>	UOR
	n	%	n	%			
Total (n = 1,409)	979	69.5	430	30.5			
Demographic							
Age ^a					6.57	0.09	
15-64	204	65.2	108	34.5			1.00
65-74	207	71.6	82	28.4			0.75
75-84	321	73.0	119	27.0			0.70
>84	247	67.1	121	32.9			0.93
Sex ^a					0.39	0.50	
Male	470	70.4	198	29.6			1.00
Female	509	68.7	232	31.3			1.08
NZ European ^a					4.73	0.03	
No	384	66.2	196	33.8			1.00
Yes	595	71.8	234	28.2			0.77
Social							
Abode ^b					2.59	0.27	
Private	454	75.3	149	24.7			1.00
Retirement village	62	72.9	23	27.1			1.13
Rest home	77	68.1	36	31.9			1.42
Deprivation ^c					3.46	0.06	
Less deprived	480	71.6	190	28.4			1.00
More deprived	436	66.8	217	33.2			1.26
Employment status ^d					1.68	0.43	
Manual	52	66.7	26	33.3			1.00
Non-Manual	76	66.1	39	33.9			1.03
Non-participating	680	71.0	278	29.0			0.82
Living alone ^e					2.96	0.07	
No	678	71.7	268	28.3			1.00
Yes	209	66.3	106	33.7			1.28
Clinical							
FAST signs at onset ^f					156.56	<0.001	
No	51	30.5	116	69.5			1.00
Yes	896	77.6	259	22.4			0.13
Stroke experience ^g					10.67	0.001	
No	533	66.0	275	34.0			1.00
Yes	441	74.2	153	25.8			0.67

	Recognised		Unrecognised		χ^2	<i>P</i>	UOR
	n	%	n	%			
Final diagnosis ^h					52.88	<0.001	
TIA	205	73.7	73	26.3			1.00
SAH	16	29.1	39	70.9			6.85
PICH	134	64.1	75	35.9			1.57
IS	622	73.0	230	27.0			1.04
OCSP classification ⁱ					118.28	<0.001	
lacunar	239	81.0	56	19.0			1.00
posterior	97	44.1	123	55.9			5.41
partial anterior	300	82.9	62	17.1			0.88
total anterior	248	69.1	111	30.9			1.91
GCS low ^j					28.68	<0.001	
No	910	71.8	358	28.2			1.00
Yes	68	49.3	70	50.7			2.62
Status severity ^k					154.29	<0.001	
Minor	6	30	14	70			1.00
Moderate	302	56	237	44			0.34
Serious	583	84.6	106	15.4			0.08
Critical	83	53.2	73	46.8			0.38
FAST assessment ^a					586.97	<0.001	
No test	89	26.5	247	73.5			1.00
Negative	43	51.2	41	48.8			0.34
Positive	771	94.0	49	6.0			0.02
Excluded	76	45.0	93	55.0			0.44
Operational							
EMD code (stroke) ^l					187.54	0.001	
No	421	54.2	356	45.8			1.00
Yes	529	88.8	67	11.2			0.15
Priority ^l					13.90	0.001	
P1 - lights and siren	822	70.8	339	29.2			1.00
P2 – normal traffic	115	63.2	67	36.8			1.41
P3 – other	13	43.3	17	56.7			3.17

Notes. significant *p*-values in boldface. EMD = emergency medical dispatcher; FAST = Face-Arms-Speech test; GCS = Glasgow Coma Score; IS = ischaemic stroke; OCSP = Oxford Community Stroke Project; PICH = primary intracerebral haemorrhage; SAH = subarachnoid haemorrhage; TIA = transient ischaemic attack; UOR = unadjusted odds ratio.

^a n = 1,409. ^b n = 801. ^c n = 1,323. ^d n = 1,151. ^e n = 1,261. ^f n = 1,322. ^g n = 1,402. ^h n = 1,394. ⁱ n = 1,236. ^j n = 1,406. ^k n = 1,404. ^l n = 1,373.

Binary logistic regression analysis was used to calculate adjusted odds ratios to determine the independent associations between the putative predictors and the non-recognition of stroke/TIA (Table 18). This followed the same process describe in section 4.1.2. The assumptions of binary logistic regression were met for the following reasons (Barton & Peat, 2014). The study population was large and no sampling was undertaken. Although clinical practice guidelines were updated during the study period, no change in the proportion of cases assessed by the FAST tool, or the sensitivity of paramedic diagnosis was observed. A relevant set of explanatory variables was used; the variables were not highly collinear. Two variables, employment status and abode, were excluded from the analysis due to the amount of missing data.

The 10 variables identified from the unadjusted odds ratios as significantly associated with paramedic non-recognition of stroke/TIA were entered into the forward and backward logistic regression models. The models both identified the same six variables: final diagnosis, experience of stroke, OCSP classification, emergency medical dispatcher code, FAST assessment and patient status. These were entered into a direct logistic regression model to optimise the sample size for this model and to determine the individual and independent contributions in explaining whether the stroke/TIA event was unrecognised.

Missing data excluded 229 cases from the final logistic regression analysis. No data imputation was undertaken leaving 1,180 cases available for analysis. The full model containing the six predictors was statistically significant ($\chi^2_{14} = 685.73, p < 0.001$) which means that the model was able to differentiate between those cases where the EMS paramedic did or did not recognise the event as a stroke or TIA.

The logistic regression analysis indicated that paramedic non-recognition of stroke was associated with six factors: stroke experience, final diagnosis, OCSP sub-classification, an emergency medical dispatcher coding of stroke, FAST assessment and patient severity status. The adjusted odds ratios and 95% confidence intervals are presented in Table 18.

Table 18. Factors associated with paramedic non-recognition of stroke/TIA (AOR)

Variable	<i>B</i>	<i>SE</i>	Wald	<i>P</i>	AOR	95% CI
Stroke experience				0.001		
No					1.00	
Yes	-0.67	0.20	10.95		0.51	[0.34, 0.76]
Final Diagnosis			9.80	0.02		
TIA					1.00	
SAH	0.81	0.93	0.77		2.26	[0.37, 13.90]
PICH	0.98	0.39	6.42		2.66	[1.25, 5.69]
IS	0.94	0.30	9.60		2.57	[1.41, 4.66]
OCSP classification			13.47	0.004		
lacunar					1.00	
posterior	0.88	0.31	8.14		2.41	[1.32, 4.41]
partial anterior	-0.09	0.30	0.08		0.92	[0.51, 1.66]
total anterior	0.45	0.33	1.87		1.57	[0.82, 3.00]
Status severity			21.13	<0.001		
Minor					1.00	
Moderate	-1.62	0.77	4.47		0.20	[0.04, 0.89]
Serious	-2.58	0.78	10.87		0.08	[0.02, 0.35]
Critical	-2.60	0.85	9.33		0.07	[0.01, 0.39]
FAST assessment			206.23	<0.001		
No test					1.00	
Negative	-0.98	0.35	7.88		0.38	[0.19, 0.75]
Positive	-3.83	0.28	192.20		0.02	[0.01, 0.04]
Exclude	-1.41	0.38	14.06		0.24	[0.12, 0.51]
EMD code (stroke)				<0.001		
No					1.00	
Yes	-1.90	0.24	64.40		0.15	[0.09, 0.24]

Notes. AOR = adjusted odds ratio; EMD = emergency medical dispatcher; FAST = Face-Arms-Speech test; IS = ischaemic stroke; OCSP = Oxford Community Stroke Project; PICH = primary intracerebral haemorrhage; SAH = subarachnoid haemorrhage; TIA = transient ischaemic attack.

In contrast to patients who did not report a personal or family experience of stroke or TIA, paramedics were twice as likely to recognise a stroke/TIA if the patient reported a history of these events for themselves or among close relatives (AOR, 0.51; 95% CI, 0.34, 0.76; $P= 0.001$). This effect is significant as evidenced by the 95% confidence intervals not overlapping 1.0.

Adjusted odds ratio for both intracerebral haemorrhages and ischaemic stroke were more than 2.5 greater than that for TIA for non-recognition of the acute cerebrovascular event. This result indicates that these patient groups were less likely to be recognised by a paramedic than TIA patients, after controlling for other factors in the model. There was no significant finding for the subarachnoid haemorrhage group. However, the number of subarachnoid haemorrhage cases was considerably less than all other final diagnosis groups.

A patient with an OCSF classification indicating a posterior infarction was more than twice as likely to have their stroke unrecognised than a patient with a lacunar infarct (AOR 2.41). There was no significant finding for either the total or partial anterior circulation infarction groups.

Non-recognition of stroke was also significantly associated with the paramedic's subjective assessment of the severity of the patient's condition. Compared to those patients classed by the paramedic, as of minor severity, patients with a status of moderate (AOR 0.20), serious (AOR 0.08) or critical (AOR 0.07) were all more likely to have their stroke/TIA event recognised.

Compared with patients who did not have a FAST assessment documented, patients with a positive FAST assessment result (AOR 0.02), a negative FAST result (AOR 0.38) or who were excluded from a FAST assessment (AOR 0.24), were all significantly more likely to have their condition recognised by the paramedic as a stroke/TIA.

One operational factor was significantly associated with paramedic non-recognition of stroke/TIA; the code assigned to the call by the emergency medical dispatcher. In cases where the code indicated a possible stroke, the paramedic was more likely to recognise the condition than those with a non-stroke dispatch code, after controlling for all other variables in the model (AOR, 0.15; 95% CI, 0.09, 0.24; $P < 0.001$).

No significant associations were found between the dependent variable and the demographic explanatory variables, although there is some suggestion ($p < 0.10$) that ethnicity may play some role here. Likewise, none of the social factors were associated with paramedic recognition of the event. The only two clinical variables that were excluded from the model were moderately collinear with other explanatory variables. FAST signs at onset was moderately collinear with final diagnosis, and low Glasgow

Coma Score was also moderately collinear with final diagnosis and OCSF sub-classification.

4.2.3 Quality of care measures

The quality of care as measured by adherence to the clinical practice guidelines, was variable. A FAST assessment was attempted in just over three quarters of all cases (Table 19). Two criteria were used to assess the recording of the onset time. When any reference to a timeframe was allowed, including the time the patient awoke with symptoms, or recording that the onset time was unknown, adherence was high (85.7%). However, when onset was defined as the known time or the time the patient was last known well, far fewer cases (59.2%) were compliant with this measure of clinical quality. Assessment of blood pressure had high adherence at 99.9%, but monitoring of the blood glucose level to exclude hypoglycaemia was lower at 80.1%.

Two criteria were used to report documentation that the receiving hospital was notified in advance of arrival. Overall, advance notification was given for one third (35.6%) of stroke/TIA events. The second analysis required that the hospital be alerted if the patient status was critical or severe (Status 1 or 2). Using this standard, notification was made or attempted in 58.2% of cases. For one third of stroke/TIA patients assessed by the attending paramedic to be critical, and more than 40% classified as severe, the report form indicated that no advance notification was given (data not shown). On-scene time was within 20 minutes in two-thirds (64.7%) of cases and the total contact time, from the initial call until arrival at hospital, was within one hour in three quarters (74.0%) of all events.

The total adherence to the clinical quality indicators was reported, for patients that the paramedic classified as of serious or critical severity. This was calculated as the proportion of cases where the care that the patient received met the standard for all seven performance criteria. For this measure, cases were compliant with the guidelines if an onset time was recorded as known or last known well. Advance notification was only required for cases with a critical or serious severity status. Where data was missing, the standard was assumed to have not been met. Data from the paramedic case report indicated that in approximately one-third of cases (32.6%) the patient received care adhering to every standard of best-care.

Table 19. Compliance with clinical quality indicators

Clinical Quality Indicator	% All cases	[95% CI]	% Recognised	[95% CI]	% Unrecognised	[95% CI]	χ^2	<i>P</i>
	<i>n</i> 1,409		979		430			
Face-Arms-Speech test assessment recorded	76.2	[74.0, 78.4]	90.9	[89.1, 92.7]	42.6	[37.9, 47.3]	381.96	<0.001
Onset time (any definition)	85.7	[83.9, 87.5]	91.8	[90.1, 93.5]	71.6	[67.3, 75.9]	128.80	<0.001
Onset time (last known well)	59.2	[56.6, 61.8]	64.4	[61.4, 67.4]	47.4	[42.7, 52.1]	34.67	<0.001
Blood glucose level recorded	80.1	[78.0, 82.2]	80.9	[78.4, 83.4]	78.1	[74.2, 82.0]	1.26	0.26
Blood pressure recorded	99.9	[99.8, 1.00]	100.0	[100.0, 100.0]	99.8	[99.3, 1.003]	0.18	0.67
	<i>n</i> 1,407		977		430			
Advance notification (all cases)	35.6	[33.1, 38.1]	41	[37.9, 44.1]	23.3	[19.3, 27.3]	86.49	<0.001
	<i>n</i> 859		674		185			
Advance notification (critical and serious only)	58.2	[54.9, 61.5]	59.3	[55.6, 63.0]	54.1	[46.9, 61.3]	1.46	0.23
	<i>n</i> 1,373		950		423			
On-scene \leq 20 minutes	64.6	[62.1, 67.1]	68.7	[65.8, 71.6]	55.3	[50.6, 60.0]	22.46	<0.001
Total contact time \leq 60 minutes	73.90	[71.6, 76.2]	74.2	[71.4, 77.0]	73.3	[69.1, 77.5]	0.09	0.77
	<i>n</i> 844		665		179			
Total clinical quality indicator adherence	32.6	[29.4, 35.8]	36.4	[32.7, 40.1]	18.4	[12.7, 24.1]	72.81	<0.001

Notes. significant *p*-values in boldface.

Performance on clinical quality measures was compared, based on whether or not the case was recognised as a stroke/TIA by the attending paramedic (Table 19). Documented delivery of care was statistically significantly better in recognised than unrecognised stroke/TIA cases for performance of a FAST test, recording of onset time, overall advance notification rates, an on-scene time of 20 minutes or less and total clinical quality indicator adherence. However, when the requirement to notify the hospital was limited to critical and serious cases, there was no significant difference between the two groups. Likewise, there was no significant difference in rates of recording blood pressure and blood glucose level between the two groups.

On-scene time

Turning to the time-based indicators, distributions of the two time-based performance measures were assessed for normality. Histograms of the on-scene and total contact time variables revealed right-skewed distributions and Kolmogorov-Smirnov test significance *P*-values of less than 0.001 indicated violation of the assumption of normality.

The overall median on-scene interval was 18 minutes (IQR: 17.5, 18.5). For recognised cases, the median time on-scene was 17 minutes (IQR: 16.5, 17.6) compared with 19 minutes (IQR: 18.2, 19.8) for unrecognised cases. A significantly greater proportion of cases recognised by the paramedic as a stroke or TIA, had an on-scene delay of 20 minutes or less compared to unrecognised cases ($\chi^2_1 = 22.46, p < .001$).

Kaplan-Meier survival curves plotted the function of departure for hospital by time on-scene (Figure 6). From this curve the proportion of patients still waiting to depart the scene can be established. At 20 minutes after the crew arrived on location, 31% of cases recognised as stroke/TIA and 45% of those unrecognised had not departed for hospital.

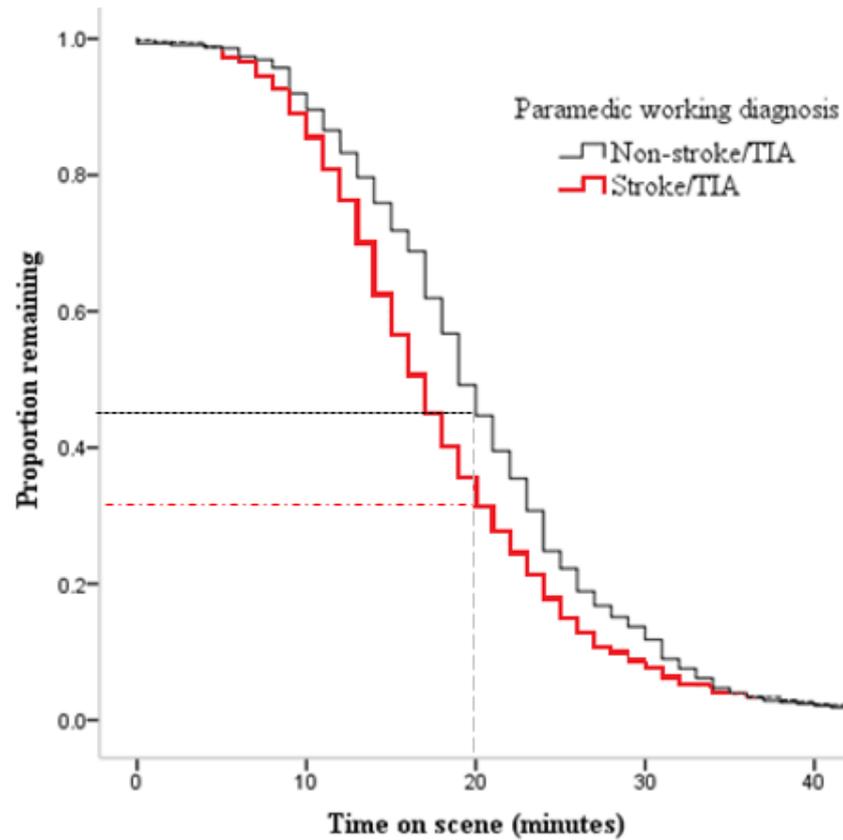


Figure 6. Duration of on-scene interval by paramedic recognition of stroke/TIA

Total EMS contact time

The effect of paramedic diagnosis of stroke/TIA on total contact time, from the call to the EMS until arrival at hospital, was investigated. Median values were again reported due to the right-skewed distribution.

The overall median contact time, from alarm until arrival at hospital, was 48 minutes (IQR: 47.0, 49.0). This compared to 48 minutes (IQR: 46.7, 49.3) for recognised stroke/TIA and 50 minutes (IQR: 48.5, 51.5) for unrecognised events.

There was no significant difference between recognised and unrecognised events in the proportion of cases with a call-to-door interval within one hour ($\chi^2_1 = 0.09$; $p = .77$).

One hour after the call was placed to the EMS, more than a quarter of both the recognised and unrecognised stroke/TIA cases had not arrived at hospital (Figure 7).

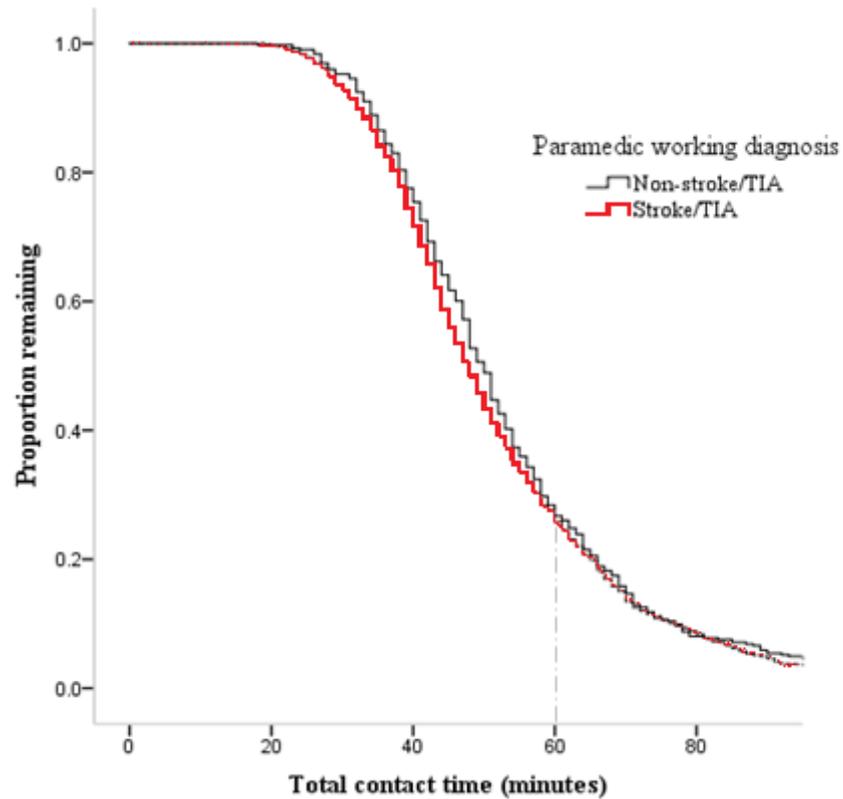


Figure 7. Duration of total contact time by paramedic recognition of stroke/TIA event

Finally, the median on-scene interval was calculated as a proportion of the median EMS contact duration from alarm until arrival at hospital. The time on-scene represented 38% of the total EMS contact time.

4.3 Case management and patient outcome measures

From the database of 2,524 cases, 1,520 ischaemic stroke events were identified (Figure 8). The first medical contact was unknown in 173 (11%) of cases and these were excluded. Of the remaining 1,347 cases, almost two thirds (63.3%) had a first contact with the EMS.

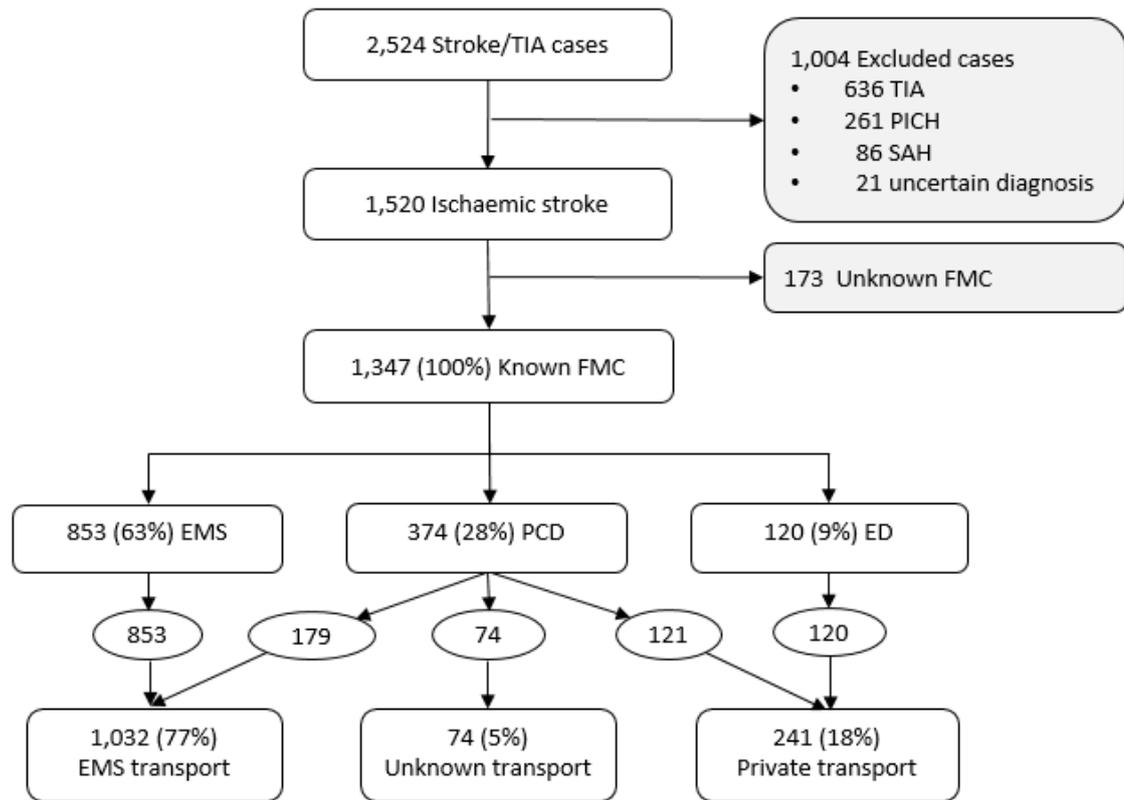


Figure 8. Flow chart of cases included in outcomes study

Characteristics of the sample of 1,347 cases are presented in Table 20. Demographic data was available for all patients. The median age was 76 years and ranged from 19 to 103. Fewer patients were female (49.5%) than male, and the majority identified as New Zealand Europeans (58.9%).

An OCSF sub-classification was recorded for all cases. The most frequently identified sub-classification was partial anterior (31.3%), followed by lacunar (27.8%), posterior (21.3%) and total anterior (18.0%) territory strokes. In a small proportion of cases (1.6%) the OCSF sub-classification was unconfirmed. All of these patients had died soon after their stroke event.

Data recording whether or not the patient had been thrombolysed was available for 1,262 cases and in 6.4% of these cases alteplase was administered. Mortality data was available for all cases and one quarter of patients died.

Table 20. Characteristics of cases included in analyses of outcomes (n = 1,347)

Characteristic	Cases (n)	%
Age		
15-64	330	24.5
65-74	307	22.8
75-84	396	29.4
>84	314	23.3
Sex		
Female	667	49.5
Ethnicity		
NZ European	794	58.9
Māori	83	6.2
Pasifika	145	10.8
Asian	90	6.7
Other	235	17.4
OCSP classification		
lacunar	375	27.8
posterior	287	21.3
partial anterior	421	31.3
total anterior	242	18.0
uncertain	22	1.6
Thrombolysis ^a		
administered	81	6.4
Mortality		
participant died	337	25.0

Notes. NZ = New Zealand; OCSP = Oxford Community Stroke Project.

^a n = 1,262

4.3.1 Onset-to-door delay

Only the 1,032 patients who were transported by the EMS and whose record was linked to the computer-aided-dispatch database were included in this analysis. This enabled the onset time to be checked against the computer-aided-dispatch record of the time that the call was received. If the call time preceded the onset time the case was excluded. The exact onset time or a last known well time was available for 718 (69.6%) of cases. The majority of these had an initial contact with the EMS, although 13% consulted a primary care doctor first. The remaining cases either had no onset time recorded or recorded the time that the patient woke, or was found, with symptoms.

Examination of the onset-to-door data revealed that the interval durations were not normally distributed, but were right-skewed. Consequently, median, rather than mean, values were reported. The overall median onset-to-door duration for the 718 included cases was 127 minutes [IQR: 68, 333]. The cumulative proportion that had arrived at hospital within key time frames was derived from the Kaplan-Meier survival analysis (Table 21). More than two thirds of ambulance-transported patients arrived within the 4-hour, time-critical window that enabled them to be assessed for thrombolytic therapy.

Table 21. Patients arriving at hospital within key times (ambulance transported only)

Onset-to-door delay	≤ 3 hr	≤ 3½ hr	≤ 4 hr	≤ 4½ hr	≤ 6 hr
Number at hospital	427	464	488	506	552
(%)	(59.5)	(64.6)	(68.0)	(70.5)	(77.0)

Onset-to-door delay by first medical contact

When a paramedic was the first medical contact, the median onset-to-door interval was shorter than cases when a primary care doctor was consulted and the patient was subsequently transported to hospital by ambulance (Table 22). The Log Rank test confirmed that the difference in the onset-to-door delay between the two groups was statistically significant, ($\chi^2_1 = 31.14, p < .001$).

Table 22. Median [IQR] onset-to-door interval by first medical contact

Variable	n	onset-to-door (min)		onset-to-alarm (min)		alarm-to-door (min)	
		Mdn	[IQR]	Mdn	[IQR]	Mdn	[IQR]
First medical contact	718		p < .001		p < .001		p = .34
EMS	627	107	[65, 272]	58	[14, 207]	49	[40, 61]
PCD	91	318	[151, 642]	271	[117, 584]	50	[39, 62]

Notes. EMS = emergency medical service; onset-to-door = interval from symptom onset until arrival at hospital door; onset-to-alarm = interval from symptom onset until EMS called; alarm-to-door = interval from call to EMS until arrival at hospital door; PCD = primary care doctor.

In a further analysis, the onset-to-door delay was divided into two intervals at the moment that the call was made to the EMS, either directly by the patient/advocate or by the primary care doctor to transport the patient to hospital. This separated the delay that was attributable to the patient and the doctor, from the delay caused within the EMS system. The interval from symptom onset until the EMS was called, was significantly shorter in

the EMS group at 58 minutes compared to 271 minutes in the community doctor referral pathway (Log rank: $\chi^2_1 = 32.25$, $p < .001$). For EMS cases, the median delay of 58 minutes from onset to alarm represented 54.2% of the total 107-minute prehospital interval. Among the group consulting with a primary care doctor, the median delay of 271 minutes from symptom onset until calling the EMS to arrange transport accounted for 85.2% of the total 318-minute prehospital delay. In comparison, there was no significant difference in the “EMS-attributable” alarm to door times of 49 and 50 minutes by first medical contact grouping (Log rank: $\chi^2_1 = .92$, $p = .34$).

The results from the analysis by first medical contact, are presented in a Kaplan-Meier curve (Figure 9). This displays the cumulative proportion of patients that had not arrived at hospital up to six hours after symptom onset. The proportion of cases that had arrived at hospital at any specified time, can be calculated by subtracting the value from 100%. From the survival curve, at three hours from symptom onset, 64% of EMS patients and 26% of patients using the primary care doctor pathway, had arrived at hospital. These proportions increased to 69% and 33% respectively at three and a half hours. By the four-hour arrival limit for thrombolysis eligibility, 73% of EMS patients had reached hospital, compared to only half this proportion in the doctors’ group. Six hours from symptom onset, 80% of patients who initially contacted the EMS, but only 53% who had consulted with a primary care doctor, were at hospital. Among patients who arrived within the first three hours from onset, 95% were seen first by a paramedic; at six hours this proportion was 91%.

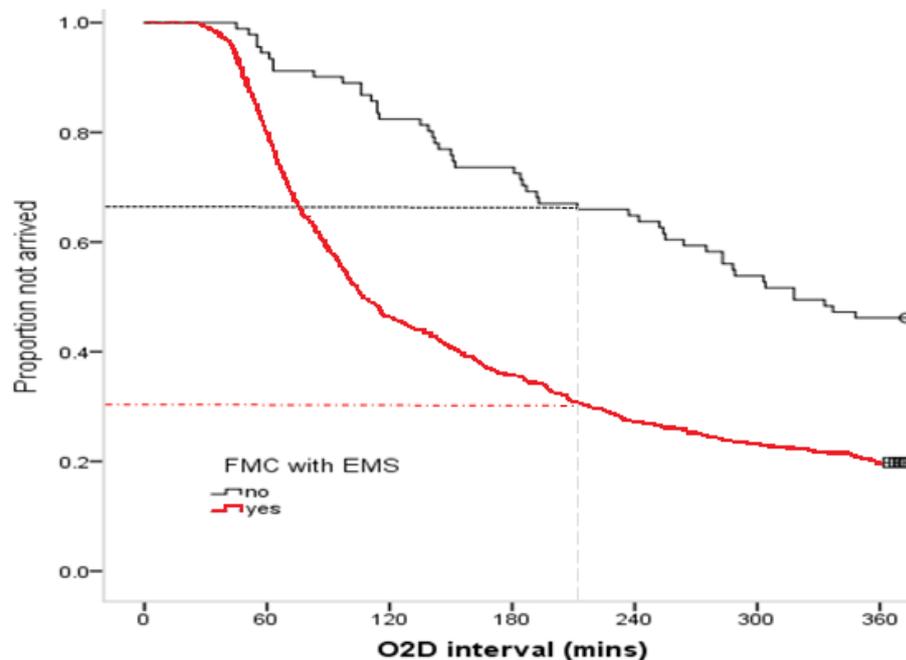


Figure 9. Duration of onset-to-door (O2D) interval by first medical contact

Onset-to-door delay by paramedic recognition of the stroke/TIA

As noted at the start of this section, in 87% of cases where a clinically relevant onset time was established, the patient's FMC was with an EMS paramedic. There was no statistically significant difference between the onset-to-door interval, when the paramedic recognised the stroke (median = 107 minutes), compared with when it was undiagnosed (median = 110) (Log Rank test: $\chi^2_1 = .07$, $p = .79$) (Table 23). Similarly, there was no statistically significant difference between recognised and unrecognised cases in either the onset-to-alarm interval or the total EMS alarm-to-door contact duration (Table 23).

Table 23. Median [IQR] onset-to-door interval by paramedic diagnosis

Variable	n	onset-to-door (min)		onset-to-alarm (min)		alarm-to-door (min)	
		<i>Mdn</i>	[IQR]	<i>Mdn</i>	[IQR]	<i>Mdn</i>	[IQR]
Paramedic diagnosis	627						
stroke/TIA	493	107	[64, 261]	58	[14, 200]	48	[39, 61]
non-stroke/TIA	134	110	[68, 325]	56	[15, 285]	51	[42, 62]

Notes. Onset-to-door = interval from symptom onset until arrival at hospital door; onset-to-alarm = interval from symptom onset until EMS called; alarm-to-door = interval from call to EMS until arrival at hospital door; TIA = transient ischaemic attack.

The absence of an effect for a paramedic working diagnosis of stroke on the duration of the onset-to-door interval, is illustrated in a survival plot (Figure 10).

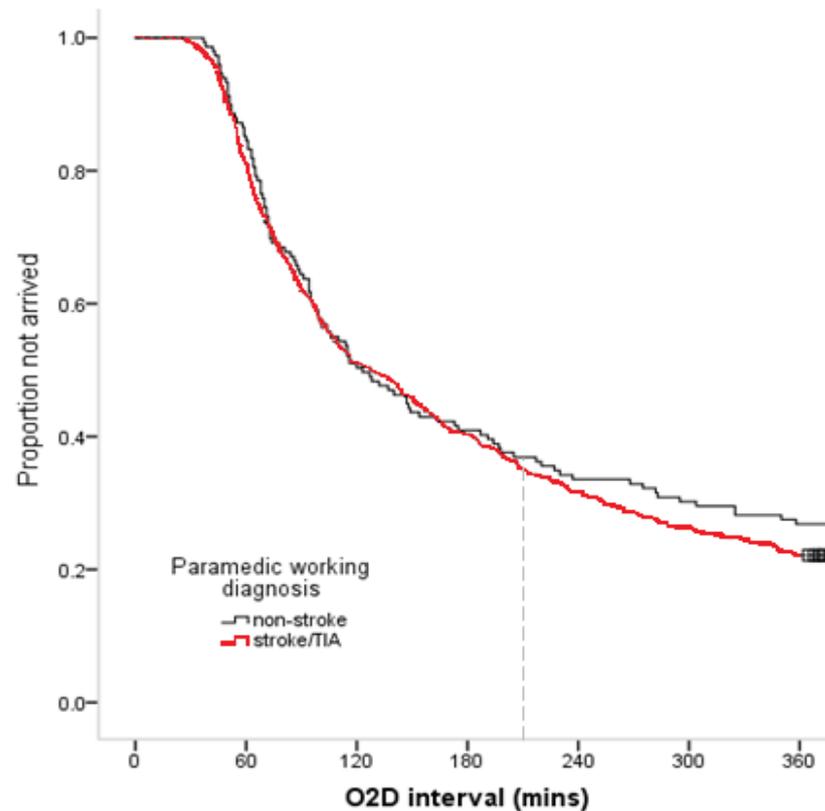


Figure 10. Duration of onset-to-door (O2D) interval by paramedic working diagnosis

4.3.2 Thrombolysis rates

Of the 1,347 ischaemic stroke cases with a known FMC (Figure 8), this study analysed the data for 1,262 events where it was possible to determine whether or not a thrombolytic agent had been administered to the patient. The patient was thrombolysed in 81 cases, yielding a rate of 6.4%.

First medical contact and thrombolysis

The association between the FMC and thrombolysis was examined for the 1,262 ischaemic stroke cases where data was available.

Of these 1,262 included cases, 792 (62.8%) had an initial contact with the EMS, 359 (28.4%) consulted a primary care doctor and 111 (8.8%) presented at an Emergency Department (Table 24). Among patients whose FMC was with the EMS, 8.7% were thrombolysed compared to 2.6% when the FMC was a primary care doctor or Emergency Department staff ($\chi^2_1 = 17.62, p < 0.001$). Patients who were seen initially by the EMS, had an unadjusted odds ratio of receiving alteplase that was 3.6 times greater than patients

who accessed medical assistance from either a community-based doctor or the Emergency Department.

Table 24. Association between first medical contact with EMS and thrombolysis

Thrombolysis	yes		no		χ^2	<i>P</i>	UOR
	n	(%)	n	(%)			
All cases ^a					17.62	<.001	
FMC non-EMS	12	(2.6)	458	(97.4)			1.0
FMC with EMS	69	(8.7)	723	(91.3)			3.6
Early arrival ^{b, c}					0.29	.59	
FMC non-EMS	3	(10.0)	27	(90.0)			1.0
FMC with EMS	62	(15.5)	339	(84.5)			1.7

Notes. significant *p*-values are shown in in boldface. EMS = emergency medical service; FMC = first medical contact; UOR = unadjusted odds ratio;

^a n = 1,262. ^b n = 431. ^c < 3 ½ hours from onset-to-door

The analysis was repeated for early-arriving cases with an onset-to-door interval of less than three and half hours. This only included patients who were transported by the EMS, although their FMC was with either a paramedic or a primary care doctor. Data on alteplase administration status was available for 431 of the 464 early-arriving cases. There was no significant association between first contact with EMS (15.5%), compared to non-EMS (10.0%), and thrombolysis, among early-arriving patients, ($\chi^2_1 = 0.29$, *p* = .59).

Review of the 81 thrombolysed cases revealed that first medical contact was with a paramedic in 69 (85.2%) cases, a primary care doctor in eight (9.9%) and an Emergency Department staff member in four (4.9%). In these same cases, 75 patients (92.6%) were transported by ambulance and six (7.4%) arrived at hospital by public or private transport.

Paramedic recognition and thrombolysis

The association between the paramedic recognition of stroke and thrombolysis was examined for the 792 cases where the patient's initial contact was with the EMS. Paramedics recognised the stroke in 577 of these cases (72.8%) (Table 25). In the remaining 215 cases (27.2%) the condition remained unrecognised in the prehospital setting. There was a significant association between recognition of the stroke by the paramedic (10.7 %), compared to non-recognition (3.3%), and administration of alteplase ($\chi^2_1 = 10.16$, *p* = .001). When the stroke was recognised by the paramedic, the patient

had an unadjusted odds ratio of being thrombolysed that was 3.6 times greater than patients whose stroke went undiagnosed (Table 25).

Table 25. Association between paramedic recognition of stroke and thrombolysis

Thrombolysis	yes		no		χ^2	<i>p</i>	UOR
	n	(%)	n	(%)			
Paramedic stroke recognition					10.16	= .001	
Unrecognised	7	(3.3)	208	(96.7)			1.0
Recognised	62	(10.7)	515	(89.3)			3.6

Notes. Significant *p*-values are shown in in boldface. UOR = unadjusted odds ratio

4.3.3 Health-related outcomes

Mortality rates

Mortality data was available for all 1,520 ischaemic stroke cases. Patient death was the outcome in 361 events (23.8%). Of these, the FMC was with the EMS in 76.7% of cases, with non-EMS in 16.6% of cases and unknown in 6.6%.

Functional outcome

From the 1,347 ischaemic stroke cases with a known FMC (Figure 8), analysis of health-related outcomes was limited to the 631 (46.8%) patients who consented to participate in the full ARCOS IV study. Of the 631 consented participants, 258 participants completed a modified Rankin Scale assessment at both baseline and at the 28-day follow-up. This group was comprised of 147 patients who had their FMC with EMS and 111 patients whose FMC was not with the EMS.

Figure 11 and Figure 12 compare modified Rankin Scale scores at baseline and 28 days, by FMC group, to show the shift in functioning between the two measurements. It is apparent that at baseline, a greater proportion (53.1%) of the 147 EMS patients had scores of 3 to 5 indicating moderate to severe disability and dependence in comparison to the 111 patients in the non-EMS group (35.1%). At the 28-day follow-up, both groups showed an increase in the proportion of patients with scores of 0 to 2 indicating functional independence. Among the EMS group the proportion of modified Rankin scores between 0 and 2 increased from 46.9% at baseline to 55.8% at 28 days. For the non-EMS patients, scores of 0 to 2 increased from 64.9% of the group at baseline to 78.3% at 28 days. This represented a 119% increase in the proportion of EMS patients that were functionally

independent one month after their stroke and 120% increase among non-EMS patients over the same period. The difference between these proportions was not statistically significant ($\chi^2_1 = 5.35, p = .07$).

Results for 117 patients with greater disability (scores of 3 to 5) at the baseline assessment, were investigated further and described. Precisely two thirds of these patients had their initial contact with an EMS paramedic and the remaining third either consulted a primary care doctor or presented to the Emergency Department. A greater proportion of modified Rankin scores of 4 or 5, representing more severe disability (scores of 4 or 5) was observed among the EMS group compared to patients whose FMC was not with the EMS (Figure 13 and Figure 14). At the 28-day follow-up, 32.0% of the EMS group of patients and 43.6% of the non-EMS group had improved scores of between 0 and 2, representing functional independence. The difference between these proportions was not statistically significant ($\chi^2_1 = 1.05, p = .31$).

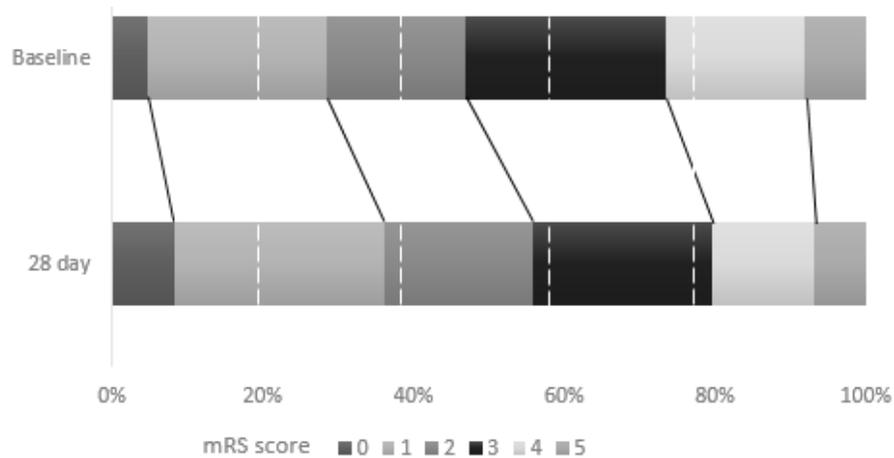


Figure 11. Modified Rankin Scale shift at 28 days: EMS patients

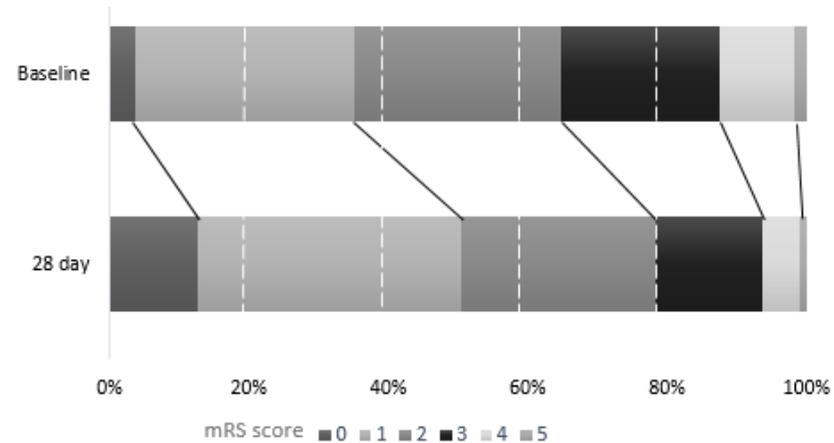


Figure 12. Modified Rankin Scale shift at 28 days: non-EMS patients

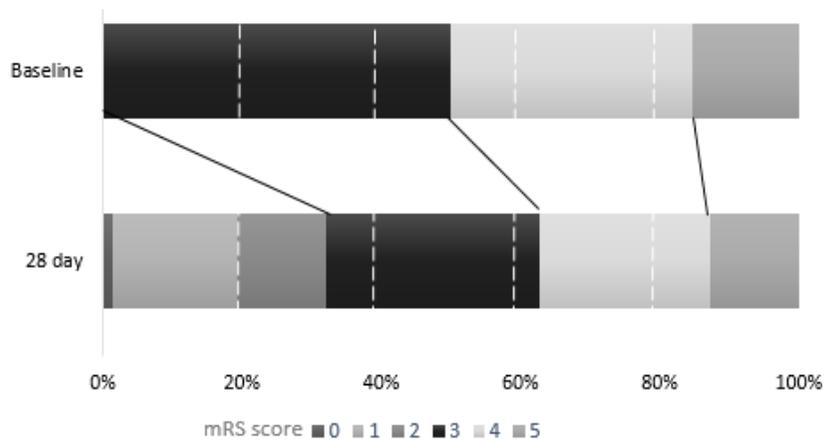


Figure 13. Modified Rankin Scale shift at 28 days: EMS patients dependent at baseline

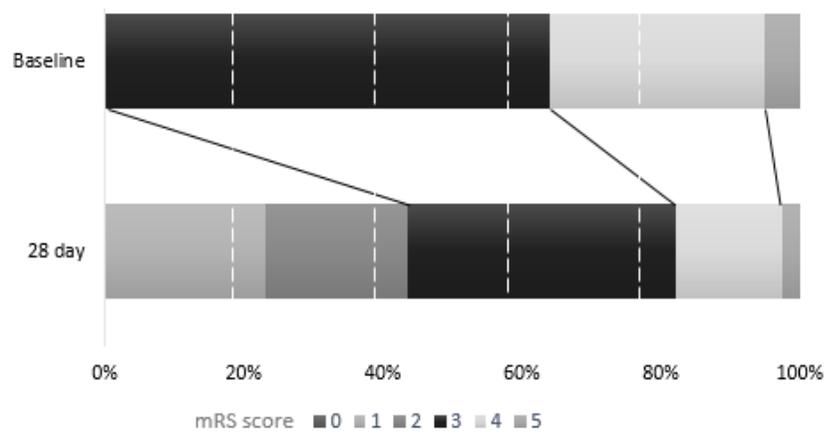


Figure 14. Modified Rankin Scale shift at 28 days: non-EMS patients dependent at baseline

Quality of life

The EQ-5D questionnaire required participants to answer five questions and complete the visual analogue scale by scoring their self-assessed health on the assessment day using a 100-point scale. The response completion rate varied between questions, even at the same assessment time. In the analysis, all results were aggregated and reported. For the 631 consented participants, the lowest proportion of responses to any question was the visual analogue scale at baseline and the highest proportion of responses were to mobility and self-care questions at 28 days (data not shown).

At baseline, participants reported the most problems in three dimensions: mobilising, caring for themselves and carrying out their usual activities (Figure 15). Problems with pain or discomfort and anxiety or depression were reported less often. Generally, EMS patients acknowledged more problems, although the frequency of reporting on pain was equal between groups and the EMS group had lower levels of anxiety. Median visual analogue scale scores, reflecting the patient's overall self-reported health state were the same for both groups at 70 out of a possible 100.

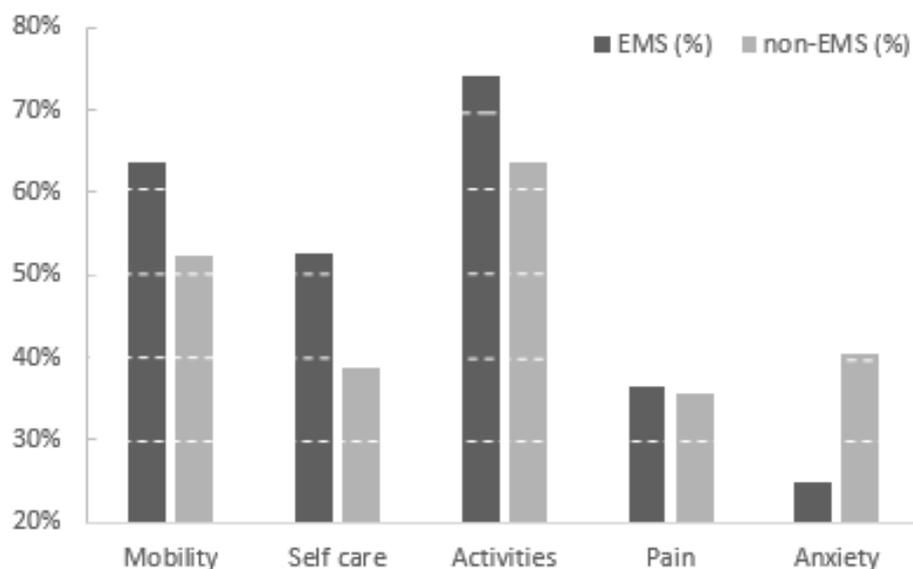


Figure 15. EQ-5D at baseline: Proportion of participants reporting a problem

At the 28-day follow-up, both groups of participants reported decreases in the frequency of problems with mobility, caring for themselves and their usual activities, than at baseline (Figure 16). However, the level of reporting problems with pain or discomfort had increased for both groups. Problems with anxiety or depression increased from

baseline in the EMS groups and decreased in the non-EMS group. Overall, a higher proportion of EMS patients reported problems than non-EMS patients. The median visual analogue scale scores increased to 75 points for the EMS patients, and to 80 points for the non-EMS group, indicating improved self-reported health status.

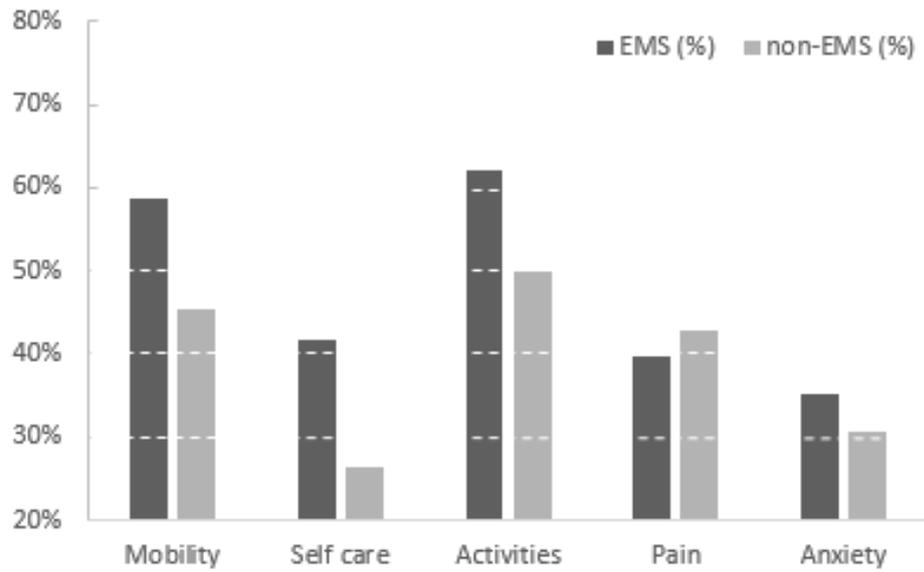


Figure 16. EQ-5D at 28 days: Proportion of participants reporting a problem

Chapter 5 DISCUSSION

This section explores the key findings from the analyses, in relation to the original research questions and in the context of the existing literature. The strengths and limitations of this study, and the significance and relevance of the findings including the implications for practice and directions for future research, will also be addressed.

5.1 First medical contact

The first objective of this analysis was to establish how stroke/TIA patients access emergency medical assistance in New Zealand, by quantifying the use of prehospital referral routes. The second objective was to identify whether any patient-related factors predicted initial contact with an EMS paramedic compared to non-EMS referral pathways.

5.1.1 First medical contact with EMS

In this study, 64% of acute stroke/TIA patients had their initial contact with an EMS paramedic. Among the same group of patients, 77% were conveyed to hospital by ambulance. The difference in proportion between the two definitions of EMS use is explained by patients who consulted a primary care doctor first, but subsequently used the EMS as their mode of transport to hospital. This finding identifies that one third of all stroke/TIA patients sought medical care through less time-efficient prehospital pathways. Furthermore, the results reveal that using transport mode in research studies to characterise prehospital care, overestimates the proportion of appropriate EMS utilisation in stroke/TIA. One in six patients arriving at hospital by ambulance, had consulted a community-based doctor initially. This is the first time that the prehospital pathway of stroke/TIA patients in New Zealand has been characterised.

In this study, the proportion of stroke/TIA cases whose first medical contact was with the EMS, was a higher proportion than is generally described in the literature. In the review presented in section 2.2.2, 11 of the 12 published studies reported a lower rate of first contact with the EMS. The comparatively high rate of initial contact with EMS that was observed in the current study, may represent true variation in utilisation. It is also possible that variation between their findings is due to differences in the purpose and methods of the studies. These will be now be examined.

The organisation of the healthcare system, impacts on patient access, including the choice of referral route, through mechanisms such as direct costs. The health system in the United Kingdom is funded from general taxation and EMS care is free at point of access, whereas in the United States of America the funding model is predominately one of private health insurance. Three studies located in the United Kingdom, and conducted in close succession, (Harbison et al., 2003; Harraf et al., 2002; Salisbury et al., 1998) showed similar proportions of initial contact with the EMS supporting this premise. Likewise, two studies based in the United States of America showed moderate agreement on the proportion of first contact with the EMS (Kleindorfer et al., 2006; Rosamond et al., 1998) In New Zealand, direct charges for an emergency ambulance contact, might be expected to have an inhibitory effect on the use of the EMS. However, the observed rate in this study was higher than most of the United Kingdom studies, where ambulance care is free to the consumer. This may be explained by the ability in New Zealand to offset the cost, if the patient has private insurance, belongs to an ambulance subscriber scheme or is eligible for additional state assistance with medical costs. Unfortunately, economic effects were not able to be explored in this study as Deprivation Index scores were only available for patients who were transported to hospital by ambulance.

One outlying result amongst the United Kingdom studies, was the more recent study by Wolters et al. (2015), which reported the highest published rate of first medical contact with the EMS. Their finding could reflect evolving public awareness of advances in stroke treatment and the need for an urgent response. However, differences in patterns of accessing emergency healthcare in stroke/TIA are not explained simply by changes over time. The two lowest rates were observed in data collected between January 2000 to December 2003 (Agyeman et al., 2006) and February 2007 to February 2008 (Geffner et al., 2012). Higher rates were reported both earlier (Salisbury et al., 1998) and later (Faiz et al., 2013), than these two studies. Even data collection contemporaneous with the current study, reported a rate of FMC with EMS that was less than half that reported here (Lahr et al., 2014). Wolters et al. (2015) described a significant increase in rates of EMS as the first medical contact from 56% to 71% after a public education campaign. As no public stroke education campaigns were carried out in New Zealand concurrent with the data collection phase of the present study, public education is unlikely to be a reason for the comparatively high rate of 64%.

The study setting and conduct varied between published studies. Whereas the current study was population-based, six studies were conducted in a single stroke unit or

Emergency Department and with a smaller sample size (Agyeman et al., 2006; Faiz et al., 2013; Geffner et al., 2012; Harbison et al., 2003; Rosamond et al., 1998; Yoneda et al., 2001). In three of these studies, the investigators included a substantial proportion of inter-hospital transfers to their tertiary centre as a separate admission route, without providing details of the initial prehospital pathway (Agyeman et al., 2006; Harbison et al., 2003; Yoneda et al., 2001). Even so, for all three studies, combining the transferred cases with those known to have a FMC with the EMS, still produced an estimate well below the 64% of the current study.

Inclusion criteria based on diagnostic groups, differed between the studies. For example five studies included suspected stroke but not TIA (Harbison et al., 2003; Harraf et al., 2002; Lahr et al., 2014; Rosamond et al., 1998; Rossnagel et al., 2004). This could potentially increase the proportion of cases initially seen by a paramedic if TIA cases were more likely to present to a primary care doctor. Despite this, the current study included TIA, and all types of stroke, and yet reported higher rates of EMS as FMC than studies that excluded TIA.

The comparatively higher rate of FMC with EMS observed in this study, is attributed to the complex interplay of differences in the location, setting and conduct of the studies. It is clear that generalisation of previously published results to the New Zealand situation is unreliable. Furthermore, while the reported rate of FMC with the EMS in this study is comparatively high, in absolute terms the finding that one in three stroke/TIA patients are not using this prehospital pathway, is concerning.

Turning to the use of the EMS as a mode of transport, the finding from this study, that 76.9% of stroke and TIA patients use the EMS as their mode of transport to hospital, is equivalent to the 76.7% reported in the 2008 New Zealand audit (Stroke Foundation of New Zealand, 2010). This concurrence establishes that there was no change in the rate of ambulance use as the mode of transportation to hospital, in the four years between the nationwide audit and data collection for the ARCOS IV study. However, the current study highlights that the use of the mode of transport as a proxy measure for first medical contact, is unreliable and clearly overestimates EMS use in acute stroke/TIA. The preference for reporting EMS utilisation as the mode of transport, rather than first medical contact, may reflect either the greater ease of its capture by the hospital-based researcher, or a failure to distinguish between the two measures of EMS utilisation. Measuring the mode of transport fails to analyse referral pathways from the community to hospital in

acute stroke and TIA. This risks confounding the results, if patients who are transported by ambulance after seeing their primary care doctor, are included in the FMC with EMS group. This distinction is important in studies of delay, as reporting by transport mode overestimates the proportion of stroke/TIA patients using an efficacious prehospital pathway. The need for collaboration with paramedic researchers is highlighted.

5.1.2 Predictors of first medical contact with EMS

Analysis of demographic, social and clinical variables in a New Zealand stroke/TIA population identified four factors predicting FMC with EMS. Increasing age, the presence of FAST signs at onset, a final diagnosis of intracerebral haemorrhage compared to TIA and all other OCSF classifications compared to lacunar circulation infarction, were significantly associated with initial contact with a paramedic. Although including the patient sex improved the accuracy of the logistic regression model, it was not independently significant. Ethnicity, living arrangements, employment and stroke experience were not associated with FMC with EMS in this study.

As a patient's age increased, the odds ratio of having initial contact with an EMS paramedic, continued to rise in comparison to the youngest group of patients. This may reflect reduced transport options that acts as a barrier to presenting at a primary care clinic or an ED. Another possible explanation is that due to a greater need for assistance because of higher dependency, older patients are more likely to have a caregiver to call the EMS on their behalf (Adeoye et al., 2009). Furthermore, the signs and symptoms of stroke may be less recognised among younger age groups if the public believes stroke to be exclusively a condition of old age. This would result in lower activation of EMS and greater use of the less urgent pathways of consulting a community doctor or presenting at an Emergency Department in the youngest age band. The finding of greater use of paramedics as the initial contact with increasing age, is consistent with other studies (Adeoye et al., 2009; Ekundayo et al., 2013; Gache, Couralet, Nitenberg, Leleu, & Minvielle, 2013; Kleindorfer et al., 2006).

The higher odds ratio for first contact with the EMS in cases when the patient had positive FAST test signs at onset, is encouraging. A possible explanation for this is that education campaigns that raise public awareness of stroke are influencing decisions on where to seek medical help in a suspected stroke/TIA event. Despite thorough searching, no other studies were located that explored the effect of the presence of FAST signs and symptoms at onset on accessing medical assistance.

Among patients with a final diagnosis of a primary intracerebral haemorrhage the odds ratio for initial contact with EMS, was three times that of TIA patients. This relationship may be explained by a more severe presentation in this patient group, prompting an urgent response from bystanders. The result is congruent with previous findings on haemorrhagic stroke that the severity and type of symptom, such as an intense headache, may encourage calling the EMS (Adeoye et al., 2009). Surprisingly, a diagnosis of subarachnoid haemorrhage did not predict ambulance use in this study, despite a characteristic of sudden and severe onset. In this instance, the absence of a statistically significant association may be due to the small number of subarachnoid haemorrhage cases. There was no significant difference in the odds ratios predicting first medical contact with the EMS between TIA and ischaemic stroke cases, and this may possibly be explained by their similar presentation in the hyperacute phase.

Patients with OCSF classifications of total anterior, partial anterior or posterior circulation infarcts were all more likely to have their initial clinical contact with the EMS than were patients with lacunar characteristics. This is likely to be explained by the presentation of the patient. The FAST tool assesses anterior territory infarction (Brandler et al., 2015; Kothari et al., 1997) increasing the likelihood that total and partial anterior circulation infarcts are recognised. Compared to total and partial anterior and even posterior infarcts, lacunar territory strokes are described by vaguer signs and symptoms, such as limb weakness, clumsiness, sensory impairment or numbness. These may be less recognisable to the public and less likely to prompt either the patient or an advocate to seek urgent care from the EMS. An important finding in this study is that close to 20% of stroke/TIA events attended by the EMS, were subsequently classified as posterior circulation infarcts, reflecting the incidence rate over all cases. This finding is contrary to that of Nor et al. (2004), who reported that only 5% of EMS stroke/TIA referrals were classified as posterior territory infarcts. They concluded that there was a lower proportions of posterior stroke cases among EMS cases. However, as their study was set in a stroke unit, it is more likely that this reflected prehospital and Emergency Department misdiagnoses and non-referral to their unit rather than a low rate among the EMS group. The finding that patients with total anterior circulation infarction had a five-fold greater odds ratio of initial contact with the EMS compared to lacunar infarction patients is likely to reflect the greater severity at onset reducing decision delay. No other studies were found that included OCSF classification as a factor predicting first medical contact with the EMS.

Even when no significant association was found between an explanatory variable and FMC with EMS, the lack of relationship is of interest. Patient sex was not a significant predictor of EMS use in the current study. This is congruent with published studies of FMC in acute stroke and TIA that have found no relationship with patient sex (Adeoye et al., 2009; Gache et al., 2013; Kleindorfer et al., 2006).

In this study, patient ethnicity was not significantly associated with the first healthcare professional contact in either the univariate analysis, or the logistic regression analysis. Published findings describing the effect of patient ethnicity on utilisation of EMS as FMC are equivocal (Adeoye et al., 2009; Ekundayo et al., 2013; Kleindorfer et al., 2006). This may reflect the mediating effect of other factors such as socio-economic status and education. It also suggests the difficulty of generalising findings on ethnicity and EMS usage between study locations. In the current study, measures describing the patient's place of residence and employment status were excluded due to high levels of missing data. The third social measure, living alone, was statistically significant in the univariate analysis. However, this result is likely to have been caused by confounding with age and no relationship was indicated by the adjusted odds ratio.

Disappointingly, previous experience of a stroke or TIA in either the patient or a close relative, did not increase the likelihood of contacting the EMS first. One possible explanation for this phenomenon is that patients and their families are not receiving adequate education on how to react in future suspected stroke and TIA events. This result is consistent with previous findings from other countries (Ekundayo et al., 2013; Geffner et al., 2012). The result from a survey of a sample of the general Auckland population, that experience of stroke increased the likelihood of recognising the need for urgent assistance (Bay et al., 2015), did not translate into actions in the current study. This reinforces the reported gap between intention and actual behaviour (Carroll et al., 2004; Hsia et al., 2011) and highlights the important role of population-based studies.

Knowledge of patient factors that predict use of EMS as the first medical contact, can inform strategies that have the potential to improve access to treatment in acute stroke/TIA. The findings from this study identify a need to increase public awareness of the importance of accessing urgent care through the EMS, and of the risk of acute cerebrovascular events across the age spectrum. The findings support public education campaigns using the FAST message and suggest a potential benefit for targeted education of stroke/TIA patients and their families on how to access help.

5.2 Quality of paramedic care

This analysis examined the quality of care delivered to stroke and TIA patients when a paramedic was the patient's first medical contact. The first objective was to report the sensitivity of the paramedic diagnosis as a measure of the quality of care. The second objective was to identify factors that predicted non-recognition of the stroke/TIA, by the paramedic. The third objective was to use clinical indicators to measure the standard of care delivered in relation to the guidelines for prehospital stroke care.

Population studies of prehospital care are rare. Analysing data for over 1,410 cases makes this study one of the largest internationally to examine the care delivered by paramedics to stroke/TIA patients. The large sample increases the robustness of the findings and generalisability of the study findings.

5.2.1 Recognition of stroke/TIA by paramedics

Paramedic recognition of stroke and TIA events is critical. Patients whose condition is unrecognised in the prehospital setting do not benefit from an enhanced care transition and streamlined in-hospital processes through an established stroke pathway. For the first time, this study reports the sensitivity of the working diagnosis by New Zealand paramedics for a large sample of patients with a diagnosis of stroke/TIA that was confirmed by neurological review.

Paramedics recorded a working diagnosis of stroke or TIA in 69.5% of the cases they encountered. In cases where the paramedic specified that the event was a stroke and not a TIA, their clinical impression was correct in less than half of cases. Similarly, the sensitivity of an exact paramedic diagnosis of TIA was only 21.9%. This finding underlines the inappropriateness of attempting to distinguish between stroke and TIA, particularly in the hyperacute phase before the signs and symptoms of TIA have resolved. Furthermore, TIA is a risk factor for stroke and requires urgent specialist review (Lee et al., 2017). Early initiation of treatment, including anti-thrombotic drugs, may prevent a stroke from occurring. Given the difficulty of differentiating between TIA and fluctuating signs of stroke in the prehospital setting, the value of paramedics attempting to do so is highly questionable. Recognition of an acute cerebrovascular event is a more realistic and appropriate goal.

Among the 30.5% of cases where the paramedic did not recognise either a stroke or a TIA, a working diagnoses of unconscious or unwell was recorded for two out of three

patients. While paramedics were not expected to diagnose stroke in somebody who was in a coma, the more generalised impression of unwell may represent a lost opportunity to recognise the acute cerebrovascular event. Eighteen other clinical impressions were used to describe the remaining 10.5% of unrecognised cases. These included common stroke chameleons such as headaches and seizures and possible complications of the stroke/TIA such as falls and more rarely, traffic accidents. Screening of these patients using a stroke assessment tool, may have assisted the paramedic to identify the underlying stroke/TIA. Using a stroke tool to identify stroke, rather than to confirm the impression in a suspected case, may increase paramedic diagnostic sensitivity (Brandler et al., 2015). In addition, the misdiagnosis of isolated disturbances of vision and balance highlights the need for recognition by paramedics of a wider range of stroke symptoms, such as those associated with posterior circulation infarction.

Addition of the FAST stroke screening tool to the clinical practice guidelines did not significantly increase paramedic diagnostic sensitivity, the number of FAST assessments undertaken or the proportion of positive test results. One explanation may be that the guidelines had not been fully adopted during the ARCOS IV study period. Although the update was released in October, the associated training was not completed until March 2012, coinciding with the end of enrolment in the ARCOS IV study. Another explanation for the lack of observed change in behaviour may have been that paramedics had already adopted the FAST assessment and the guidelines were catching up with actual practice.

The sensitivity value observed in this study, corroborates previous results observed by Harbison et al. (2003). The results are contrary to the lower rates of recognition reported by Nor et al. (2004) and Williams et al. (2017) and do not support the higher rates described by Bergs et al. (2010) and Fothergill et al. (2013). The findings of the current study are supported by the robustness of the population-based, multi-centre approach and large sample size. In comparison, the generally smaller sample size and single-centre setting of the other studies limit the strength of their findings. The current study also used greater rigour in the design by including patients from the age of 16, using a diagnosis confirmed by a review panel as the gold standard and applying the FAST instrument as designed with the criteria of one abnormal response to generate a positive test score.

These findings provide a baseline for the sensitivity of paramedic recognition of stroke/TIA in Auckland. The applicability to other locations within New Zealand is expected to be high. The generalisability of the results to other countries is anticipated to

be appropriate when the organisation and structure of the EMS system are similar, with an advanced life support system level of practice and an equivalent standard of paramedic education.

5.2.2 Predictors of paramedic stroke/TIA non-recognition

Analysis of demographic, social, clinical and operational variables in a New Zealand stroke/TIA population identified six factors associated with non-recognition of the stroke/TIA by the paramedic. These factors were: the absence of a patient or familial history of stroke/TIA, a final diagnosis of intracerebral haemorrhage or ischaemic stroke compared to TIA, an OCSF classification of posterior circulation infarction compared to lacunar infarction, severity described as minor compared to more severe presentations, absence of a documented FAST assessment, and a dispatch code other than stroke.

Paramedics were significantly less likely to recognise the event as a stroke or TIA when there was no history of stroke/TIA, in either the patient or close blood relative, compared to patients with a personal or familial history. This is consistent with a previous stroke/TIA diagnosis, or a familial history of the same, signalling an increased risk to the paramedic and lowering his or her diagnostic threshold.

Patients with a final diagnosis of ischaemic stroke or a primary intracerebral haemorrhage were less likely to be diagnosed by the paramedic, compared to TIA cases. This finding was unanticipated as TIA are commonly thought of as milder events compared to stroke and therefore, would be expected to be less recognised. One possible explanation is that the paramedic attended the TIA patient in the hyperacute phase, when the signs and symptoms were more florid. However, this should result in similar predictability between TIA and ischaemic stroke. Instead, it seems possible that the greater likelihood of recognition may be due to the ability of the TIA patient, as their signs and symptoms resolve, to give a history that supports a correct working diagnosis. Obtaining a good history of the event is a key factor in stroke/TIA recognition. In contrast, stroke patients with ongoing cerebral infarction are less able to report the very symptoms that would prompt a paramedic to form an impression of stroke. In the review of the ambulance report forms, some patients were described as “poor historians” or “uncooperative”. This provides anecdotal support to the conjecture that the inability of stroke patients to communicate effectively, was not always comprehended by the attending paramedic as a sign of stroke. While Brandler et al. (2015) observed that TIA and primary intracerebral haemorrhage were as likely to be recognised by paramedics as ischaemic stroke, the

possibility that TIA events might be more recognisable than strokes, appears to be a novel finding. No literature was found that proposed that a final diagnosis of either ischaemic or haemorrhagic stroke, compared to TIA, predicted non-recognition by paramedics.

Patients that were determined on review to have had a posterior circulation infarction, were more than twice as likely to have been unrecognised by paramedics in the prehospital setting, than patients with lacunar infarction. Identification rates for events subsequently classified as partial and total anterior circulation infarctions, were not statistically significantly different from lacunar strokes. This finding was not unexpected as atypical presentations, such as isolated disorders of vision, balance, perception and coordination, are known to complicate the recognition of posterior stroke. Furthermore, the elements of the FAST instrument, all test for signs and symptoms associated with total and partial anterior strokes. This result is consistent with the theory that simple stroke assessment tools, including the FAST tool, which assess facial and arm weakness and speech disturbance, are more sensitive to disturbance in the anterior circulation than the posterior (Brandler et al., 2015; Harbison et al., 2003). For the first time, this study provides strong evidence, at a population-level, to support the assumptions that posterior stroke is a predictor of non-recognition of stroke/TIA by paramedics. However, the findings of the current study do not support previous research that found posterior territory events comprised a small proportion of stroke/TIA presenting to the EMS. Whereas Nor et al. (2004) reported that only 5% of 217 stroke/TIA cases referred by paramedics to an acute stroke unit were posterior events, this study identified 17.8% of posterior stroke among the 1,409 cases. This finding highlights the importance of improving paramedic diagnosis of cases involving the posterior territory, which account for one in every five stroke cases encountered by paramedics. Improved paramedic education and assessment tools to better assess patients with this type of event are clearly indicated.

Patients assessed by a paramedic as having a minor severity status, were less likely to have their stroke recognised compared to patients with moderate, serious or critical severity. Failure to recognise a mild stroke can have major consequences for the patient if late deterioration results in exclusion from time-critical treatments. This result is congruent with the finding that paramedics are less likely to diagnose very mild strokes with a low NIHSS score (0-1) (Gropen et al., 2014). In the same study, paramedic recognition was also observed to be low in patients with more severe strokes, with an NIHSS score above 12. One explanation is that subtle stroke/TIA signs are missed in

mild presentations and in severe cases when the patient may be unconscious. A similar trend was noted in the current study with the highest odds of recognition among those patients assigned a moderate severity status. This consistent finding was observed despite differing measures of severity used in the two studies. The current study used a subjective paramedic impression of general severity (Appendix F). The correlation between this subjective assessment of status and validated measures of severity (such as the NIHSS) has not been established. Of note, in the current study, nearly one third of all recognised stroke/TIA were assigned a moderate severity despite the guidelines that were current at the time, identifying stroke as a condition of serious status (National Ambulance Sector Clinical Working Group, 2011). This raises the question of whether the urgency of stroke/TIA is adequately understood by paramedics.

Absence of paramedic documentation of a stroke scale assessment, also predicted non-diagnosis of stroke/TIA. Cases without a documented FAST assessment were significantly less likely to be recognised compared to cases with a test recorded, even when a negative result was scored, or the test was unable to be completed due to the patient's condition. A negative test result in the presence of a strong history of the event may lead to an impression of a TIA with resolved signs. This study presumed that in cases where a FAST test was not reported, an assessment had not been undertaken. Another possible explanation is that paramedics are less likely to record negative test findings. Even so, more than half of all patients whose condition was unrecognised by paramedics, did not have a documented FAST assessment. This result corroborates the observation by Gropen et al. (2014), that the odds ratio of stroke or TIA identification increased 12 times when an EMS stroke assessment was documented. The current study extends their result, which was observed among 310 cases, to a much larger sample, with a wider range of variables and greater statistical robustness. Even cases with negative results and incomplete assessments, were more likely to be recognised as stroke/TIA than cases that did not report a FAST test. This supports the argument of Brandler et al. (2015) that paramedics are using the FAST tool to confirm a suspected stroke diagnosis, rather than to screen patients before a clinical impression has been formed. These results emphasise the importance of using FAST as a tool to screen out possible stroke or TIA cases. For example, in cases where the patient is presenting after a fall or with confusion or general malaise, a FAST assessment may identify stroke as the cause of the symptoms. Similarly, the inability to provide a clear history, should signal potential neurological changes to the paramedic and the need to assess the patient more fully with a stroke tool.

If stroke screening is only used to confirm suspected cases, the opportunity to recognise a chameleon stroke or TIA event is lost. That a quarter of patients who were untested with the FAST tool were still diagnosed with a suspected stroke or TIA, suggests obvious signs of stroke and under-reporting of the test in the paramedic case report. Paramedics need to be aware of the importance of documenting the baseline results of a stroke assessment in sufficient detail to allow subsequent comparison by other healthcare professionals. This is particularly important in cases where clinical signs are fluctuating or resolving.

Cases coded by the emergency medical dispatcher as other than stroke were less likely to be recognised by paramedics than those coded as a stroke event. Presumably in these cases, information obtained during the emergency call suggested a strong presentation with recognisable signs of stroke. However, the dispatcher's coding of stroke may gain diagnostic momentum and influence the paramedic's clinical impression. Potentially, this could influence the rate of false positive working diagnoses of stroke/TIA; a topic which was outside the limits of the current study.

None of the demographic or social factors were significantly associated with paramedic non-recognition of stroke or TIA. However, there was some suggestion that the binary ethnicity variable had an effect that did not reach the threshold for statistical significance. The trend suggested that stroke and TIA may not be as well recognised among patients identifying with any ethnicity other than New Zealand European, compared to those only identifying as New Zealand Europeans. This could be usefully explored in future research. The clinical variable of a low Glasgow Coma Score was not predictive of paramedic recognition. It is likely that critical patients would be coded with a clinical impression of unknown or unconscious, as in many cases their inability to respond would exclude them from a FAST screen.

Recognition of stroke or TIA, is an important measure of the quality of care delivered by paramedics to this patient group. Identification of factors that predict stroke and TIA cases that paramedics are less likely to recognise, can be used to inform educational initiatives, to potentially improve this rate. This may include additional criteria to assist with recognition of posterior and lacunar infarctions such as dysarthria, ataxia and disturbances of balance and vision including, diplopia and nystagmus. In unconscious patients, this could extend to assessment of plegia, the Babinski reflex and external rotation of the affected foot in addition to pupillary response. For cases with a subtle

presentation, teaching the significance of sensory loss, balance and visual changes, and dysphagia may also increase recognition. In patients with a severe presentation, screening for large vessel occlusion may increase timely arrival at an endovascular centre. These could be prompted by addition of specific fields in the electronic PRF.

5.2.3 Quality of care measures

The standard of care delivered to stroke/TIA patients was assessed by seven measures of clinical performance that were identified from local and international guidelines (Dicker, 2016; NHS England, 2013; Oostema et al., 2014; Siriwardena et al., 2014). These were documentation of a blood pressure, blood glucose level, FAST assessment, onset time, advance notification, an on-scene time of 20 minutes or less and a total EMS contact time of 60 minutes or less.

Completion of blood pressure recording was close to 100% and compliance with blood glucose measurement was relatively high. These results are most likely to reflect the routine nature of these observations. Blood pressure is recorded during virtually every EMS callout. The clinical practice guidelines require blood glucose testing for many patients, including those with an altered level of consciousness, or who are unwell for no apparent reason, and to eliminate hypoglycaemia in cases of suspected stroke (National Ambulance Sector Clinical Working Group, 2011). There was no significant difference in completion rates between recognised and unrecognised cases of stroke/TIA for either measure.

In contrast, compliance with a FAST assessment was lower. Unsurprisingly, a FAST result was recorded significantly less often among unrecognised cases compared to recognised cases. This adds support to the finding from a previous smaller study (Gropen et al., 2014). It is also consistent with FAST assessment being used to confirm suspected strokes, rather than to screen for an underlying stroke, when the presenting signs and symptoms were vague. Undertaking a FAST assessment for patients with complaints such as headaches and falls, has the potential to increase the sensitivity of paramedic recognition by identifying cases not initially suspected by the paramedic to be stroke/TIA events. This was possibly a factor in the high sensitivity for stroke/TIA recognition reported by Bergs et al. (2010).

Documentation of symptom onset time, the fourth element of the FAST test, was reviewed separately. When any definition of onset time was included, completion of this

field exceeded that of the combined face, arms and speech components of the FAST tool. A possible explanation for this is that, as with the blood pressure, paramedics routinely document onset time in medical and injury callouts, and there is a dedicated field on the PRF. When the definition of onset time was limited to the clinically relevant last known well time, compliance decreased substantially. Although onset time was recorded more often when strokes and TIA were recognised, reporting of clinically relevant times remained low. As previously discussed, onset time can be difficult to establish, particularly if the patient wakes or is discovered with symptoms. Even in these cases, it is often possible for the paramedic to record details that would assist the neurologist. However, in many instances, the PRF recorded an imprecise onset time such as “at dinner” or “this evening”. Failure by paramedics to record a clinically relevant onset time, suggests a lack of insight into their influence on in-hospital processes and the potential impact on the patient’s access to early neurological evaluation and specialist care that extends to all types of stroke and TIA (Saver, 2006).

When advance notification to the receiving hospital was measured as a proportion of all stroke/TIA events, compliance was low, at one third of cases. This reflects the practice of only alerting the Emergency Department for patients assessed by the paramedic to have a high acuity. When compliance was recalculated to only include patients classified by the paramedic as critical or serious, compliance increased to near 60%. It is concerning that 40% of patients, determined by the paramedic to have a higher acuity presentation, arrived at hospital without notification. There are several possible explanations for this result. The low rate may reflect under-reporting due to incomplete documentation by the paramedic. This can be exacerbated by the high cognitive load of managing a seriously unwell patient or time pressures such as being cued for another call-out during the patient hand-over. An alternative possibility is that, although the patient’s condition was serious, the paramedic chose not to notify the hospital as, due to high pre-existing dependency or comorbidities, the patient was unlikely to be a candidate for thrombolytic therapy. Even so, it would be anticipated that the Emergency Department would appreciate notification to plan the management of an acutely unwell patient with complex needs. A further explanation could be that the care provided did not meet the standard of best-practice.

Among those patients with a more severe clinical impression, there was no difference in the rate of notification between cases that were recognised by the paramedic compared to those that were unrecognised. This lack of distinction implies that the severity of the condition, rather than a working diagnosis of stroke, prompted the paramedic to alert the

Emergency Department. For unstable patients, the paramedic's priority is to manage life-threatening conditions and a working diagnosis may not be established in the prehospital setting.

Advance notification was unanimously supported across international guidelines on prehospital care (Intercollegiate Stroke Working Party, 2012; Jauch et al., 2013; Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010; The ESO Executive Committee and the ESO Writing Committee, 2008). Notification contributes to reducing the door-to-needle time, by prioritising the stroke patient's pathway through hospital processes (Fassbender et al., 2013; Sheppard et al., 2015). Furthermore, the potential to benefit from thrombolysis is strongly associated with early administration of alteplase (Saver, 2006). Rates of notification may potentially be influenced by local practice. For example, over-diagnosis by paramedics may lead to a negative response amongst Emergency Department staff which then discourages paramedics from notifying stroke cases. While frequent notification calls can disrupt the workflow of the Emergency Department, this must be balanced against the costs of failing to treat a time-critical patient and the ability of the stroke team to quickly triage-out false positive cases.

The final two measures of clinical performance were time-based. On-scene intervals were of a significantly shorter duration when the paramedic recognised the stroke/TIA compared to when he or she did not. This supports the theory that on-scene delays are modifiable, to some degree and were reduced when the stroke/TIA was recognised. On-scene delays were typically extended by patient complexity or difficult of egress. In this study, examination of the outlying cases revealed that examples of extreme delays at the scene were often due to the inability of the vehicle on-scene to transport the patient. This included bariatric patients requiring a specialist vehicle to be responded and patients at island locations necessitating further transport arrangements for evacuation by air or sea.

In this study, one quarter of stroke and TIA patients had not arrived at hospital within one hour of the initial call for help. The duration of the total contact time with the EMS, from alarm until arrival at hospital, was prolonged in those cases previously identified where the paramedic needed to arrange specialist transport from the scene. Another factor that extended the total contact time was a remote location, incurring greater travelling times to the scene and from the scene to the hospital. Strategies to reduce these delays could include more frequent and earlier activation of the helicopter, particularly in distant locations where there is strong evidence of a stroke diagnosis during the initial call, or

higher urgency of transport to hospital, by travelling under lights and siren. A third factor that may have contributed to EMS-attributable delay was the number of vehicles assigned to the case. The assignment of multiple vehicles can occur where the case is initially assigned a lower priority and the responding ambulance is then redirected to a higher priority call, or where a crew is sent to assess the patient but will require back-up, to transport. Addressing this cause of delay may require a systems-level approach including increased training for call-takers and emergency medical dispatchers and greater EMS resources. These are all important issues for future research. This study found no difference between the total contact time for recognised and unrecognised cases, suggesting the influence of factors other than on-scene time.

Given that all the patients in this study were discharged with either a stroke or TIA diagnosis, it was disappointing to find that only a third were delivered care that met the clinical quality indicator across all seven dimensions. This emphasises the need for regular auditing that engages with clinical staff as a means to improve the quality of EMS stroke care. These methods, in conjunction with collaboration across organisations have been shown to improve feedback to paramedics and to develop the opportunity to learn from specific cases (Patel et al., 2013; Siriwardena et al., 2014).

The ability to compare the findings on paramedic stroke care observed in this study with others, is limited by the paucity of reporting on measures of paramedic stroke care. Overall, these results were consistent with those of Oostema et al. (2014) and extend the findings from a small group of 186 ischaemic stroke patients in the United States of America to a larger group including all stroke types and TIA. The two studies reported on five equivalent measures. Completion rates for blood glucose testing and the stroke scale assessment were over 75% in both studies. The level of compliance for recording of onset time, using the last known well criterion, was lower in the current study at 59.2%, compared to 68.3%. Similar rates of advance notification (58.2%-56.5%) were observed, if it is assumed that this was only expected to be completed for high acuity patients. Compliance with the on-scene interval was higher in the current study at 64.6% compared to 46.8%. However, Oostema et al. (2014) set a standard of 15 minutes or less on-scene and in the current study only 38.7% of cases would have meet this more stringent criterion. Both studies found higher compliance with use of a stroke tool, recording of last known well time, and a limited on-scene delay when the paramedic recognised the stroke/TIA compared with when it was undiagnosed. This supports the premise that on-scene time is modifiable (Simonsen et al., 2014) and is contrary to reports of an

association between recognition and longer on-scene times (Abboud et al., 2016). In the current study, the median on-scene interval of 18.0 minutes fell within the range reported by previous investigators of 15 minutes (Schwartz et al., 2016) to 21 minutes (Puolakka et al., 2016). Oostema et al. (2014) also reported a significant increase in advance notification when the stroke was identified, although this was not corroborated by the current study.

Unlike the current study and that by Oostema et al. (2014), which included cases on the basis of the final diagnosis, the industry audit (Dicker, 2016) investigated adherence to the guidelines in cases where the paramedic suspected a stroke. Despite this difference, the rates of blood pressure and blood glucose monitoring were close to identical in the two studies, reflecting the standard nature of these assessments. However, the rate of FAST assessments for all cases in the current study was more than double the industry report and even higher among recognised cases. This variation is most likely explained by differences in the methods of the two studies. This study followed the standard FAST criteria of one abnormal element for a positive FAST result and three normal elements for a negative test result (Fothergill et al., 2013; Harbison et al., 2003). In comparison, the industry report required all three assessments within the FAST instrument to be recorded in order for a case to be compliant with the clinical practice guidelines. Rates of reporting for onset time were comparable between this study and the industry audit, at 84.0% and 85.7% if any attempt to document the time was allowed. However, when the clinically appropriate criterion of reporting a last known well time was applied, this study found a much lower rate of 59.2%. The rates of advance notification were similar at 53.0% and 58.2%, if only higher acuity cases were considered.

The proportion of cases that arrived at hospital within 60 minutes from the call to the EMS was compared with contemporaneous reporting from the National Health Service in England. At 73.9%, the proportion of cases in the current study with a call-to-door time of one hour or less was higher than the overall national proportion of 63.8% in 2012 (NHS England, 2013). However, due to the substantial regional variation between reporting from the 12 participating English Ambulance Trusts, these results should be interpreted with caution.

No significant difference in the total EMS contact time was observed between cases in this study based on whether or not the paramedic recognised the stroke. This suggests the influence of other EMS-related factors such as the assigned priority, queuing,

reassignment and the effect of distance on response and transport times. Further research in this area is indicated. Extending the endpoints to include in-hospital process measures, such as medical assessment or imaging, may reveal further benefits of prehospital recognition. As with the on-scene interval, data for the duration of the total EMS contact time is more easily captured within EMS systems than other quality indicators.

In this study, the median total contact time of 48 minutes was longer than reports in the literature. These ranged from 36 minutes (Schwartz et al., 2016) to 41 minutes (Simonsen et al., 2014) although both authors reported wider interquartile ranges due to smaller sample sizes. However, the proportion of the total contact time which was spent on-scene was lower. In the current study, on-scene time represented 38% of the total contact time, whereas other studies observed proportions of 41% (Schwartz et al., 2016) and 44% (Simonsen et al., 2014). These comparisons suggest that distances travelled in the New Zealand setting may be longer in contrast to international studies.

This study set out to establish the quality of care delivered by paramedics to stroke and TIA patients, as measured by the ability to correctly recognise the patient's condition, and to provide care aligned with evidence-based guidelines for best-practice. While acknowledging the complexity of managing patients in the out-of-hospital setting within the limited resources available to the EMS paramedic, this study has identified that there are opportunities to improve the care delivered to stroke patients.

5.3 Case management and patient outcome measures

Prehospital contact with the EMS is for a brief but critical period within the entire patient journey. The considerably longer interaction with the hospital system, and the treatment received throughout the entire admission, mediates and attenuates the relationship between paramedic care and patient outcomes (Oostema et al., 2014). Consequently, the focus is on identifying how EMS practice can decrease prehospital delay and, by facilitating hospital processes, increase access to treatments such as thrombolysis which are in turn associated with better patient outcomes.

5.3.1 Onset-to-door delay

This study identified that among ischaemic stroke patients transported to hospital by ambulance, 59.5% had arrived within three hours of onset and 70.5% at four hours and a half hours. These figures are encouraging as they suggest that a sizeable proportion of

stroke patients are arriving within the time-critical window for thrombolysis. However, the proportions observed in this study were far greater than the 33% at three hours and 39% at four and a half hours, reported from the 2008 New Zealand audit (Stroke Foundation of New Zealand, 2010). There are several possible reasons for this result. The current analysis did not include patients who arrived by public and private transport. As these patients have longer prehospital delay, the results from the current study will overestimate the proportion of early-arriving patients among all cases. It is also possible that more patients had to travel further to reach hospital in the national audit, compared to patients living in the greater Auckland region in this study. Finally, it is possible that public awareness of stroke treatments has increased over time and more patients are now arriving sooner at hospital. There is still clearly room for improvement if the number of stroke patients arriving at hospital in time to be assessed for thrombolysis eligibility is to increase.

The most recent update of the EMS clinical practice guidelines (National Ambulance Sector Clinical Working Group, 2016), extended prioritisation of transport for stroke patients by 30 minutes. Immediate transport and advance notification is now indicated for patients who can reach a specialist stroke centre within four hours. In this data set, the effect of increasing the onset-to-door criterion from three and half hours could have facilitated an additional 24 patients to be assessed for eligibility for thrombolytic therapy. Increasing the number of early-arriving patients will support an improvement in patient outcomes. The effects of initial contact with the EMS and of paramedic recognition of stroke on the onset-to-door delay, are considered in the following sections.

First medical contact

In the current study, an exact or last known well onset time was established for 53.3% of cases. In the remainder, patients either woke or were found with signs of stroke or else the time was not documented in a useful way, or at all. This proportion is consistent with previous studies (Faiz et al., 2013; Salisbury et al., 1998). This study analysed data for a larger sample than all but one of the published studies identified by the literature review. The current analysis quantified the effect of consulting a primary care doctor for stroke/TIA in New Zealand. When a doctor was contacted initially, the median onset-to-door time of 318 minutes was nearly three times longer compared to cases where first contact was with the EMS. These results were congruent with the findings of other

studies that also used the last known well definition of onset time (Geffner et al., 2012; Harraf et al., 2002).

In the current study, scrutiny of the alarm-to-door interval revealed that the difference in the prehospital delay between the two prehospital pathways was not attributable to the EMS. The median alarm-to-door interval was not significantly different for patients whose initial contact was with an EMS paramedic compared to those who consulted a primary care doctor. However, in the EMS group, the interval from onset-to-alarm represented 54.2% of the overall onset-to-door delay whereas among the doctor group this proportion was 85.2%. In comparison, the onset-to-alarm delay in the United Kingdom among patients initially seen by a paramedic has been observed to account for 31% of the onset-to-door time (Wolters et al., 2015). This suggests that in New Zealand, the decision delay when using the EMS as the first medical contact may be longer than in the United Kingdom.

In cases where the FMC was with a primary care doctor, the longer onset-to-door delay was entirely attributable to patient-related delays in seeking help and the delaying effect of consulting with a doctor. One explanation for patients choosing a community-based doctor as the FMC is related to the severity at onset (Harbison et al., 2003). When the stroke onset is associated with profound signs, such as aphasia or loss of consciousness, bystanders are less likely to “wait and see” if the patient improves and more likely to seek emergency assistance. This is consistent with the association observed in this study between OCSF classifications of total and partial anterior circulation infarction, compared to lacunar, and initial contact with a paramedic. Conversely, with a more mild presentation, care may be accessed less urgently by consulting a primary care doctor or transporting the patient to an Emergency Department. Therefore, patients with more severe strokes arrive at hospital sooner (Harbison et al., 2003; Silvestrelli et al., 2006).

The findings from this study support other investigations that have found that initial contact with the EMS is associated with a shorter onset-to-door time. The median onset-to-door time of 107 minutes for initial contact with the EMS is comparable to other studies which used a last known well definition of onset time (Geffner et al., 2012; Harraf et al., 2002). However, this median onset-to-door interval represents an additional 30 minutes of prehospital delay compared to the 72 minute median onset-to-door delay among patients treated with alteplase as reported in the New Zealand Thrombolysis Register

(Joshi et al., 2016). These findings underscore the importance of educating the public on the need for urgent medical assistance, sourced from the EMS, in acute stroke/TIA.

Paramedic recognition

No significant difference was observed in the overall onset-to-door interval between cases where the paramedic recognised the stroke, compared to when it was unrecognised. This was unsurprising given that although recognition of stroke increased the proportion with an on-scene time ≤ 20 minutes, it did not translate to a greater proportion of cases with a total contact interval of an hour or less. While small reductions in the scene time may seem inconsequential compared to the overall onset-to-alarm delay, the time is brain concept is a useful reminder that every second is valuable (Meretoja et al., 2014; Saver, 2006).

Using arrival at hospital as the endpoint may be premature and underestimate the beneficial effects of paramedic care in increasing access to treatment. It may be more appropriate to look at the effect of paramedic recognition at time points beyond the prehospital phase to observe the benefits of recognition. Paramedic recognition has been associated with reduced delay to medical assessment and imaging, facilitating access to time critical treatment in stroke (Abboud et al., 2016; Sheppard et al., 2015).

5.3.2 Thrombolysis rates

This study reported a thrombolysis rate of 6.4% among all ischaemic stroke patients. This is identical to the national rate for New Zealand in 2015 as reported by Joshi et al. (2016).

Administration of alteplase was significantly associated with the patient having initial contact with a paramedic rather than another healthcare professional. However, this result did not control for other factors, most notably for the length of the delay from symptom onset until hospital arrival. Thrombolysis is only indicated where the time from symptom onset to administration of the drug is less than four and a half hours. Outside of this interval, the risk of precipitating an intracerebral haemorrhage outweighs the potential benefits of treatment. The maximum onset-to-door interval has recently been extended to four hours to reflect improved hospital processes (National Ambulance Sector Clinical Working Group, 2016). However, at the time of data collection for this study, guidelines advised that patients should arrive at hospital within three and half hours in order to be considered for thrombolysis. This study has confirmed a strong relationship between a shorter onset-to-door interval and FMC with the EMS. When the analysis of thrombolysis

by FMC was limited to patients who arrived at hospital within three and half hours from symptom onset, no significant difference was found between patients whose FMC was with an EMS paramedic and a primary care doctor. This result is evidence that the higher rates of thrombolysis observed among patients whose FMC was with a paramedic rather than a community-based doctor is associated to the facilitation of access to timely specialist stroke care.

Recognition of the stroke by the paramedic was significantly associated with the patient receiving thrombolytic therapy. In conjunction with the finding that a FAST assessment by the paramedic supports stroke recognition (section 4.2.2), this provides strong support to the thesis proposition that paramedic care can facilitate access to treatment that improves patient outcomes in stroke.

Few studies have reported on patient outcomes in stroke in relation to paramedic care. In this study, thrombolysis rates of 8.7% among patients seen first by an EMS paramedic contrasted starkly with 2.6% in patients who used an alternative initial medical contact. This pattern of results is consistent with previous findings although the proportions observed in this study were lower. In two studies reporting on EMS use as the mode of transport, thrombolysis rates in ambulance transported cases versus other transport modes were 11% and 4% respectively, in the United Kingdom (C. I. Price et al., 2013) and 24.7% and 12.8% in the United States of America (Ekundayo et al., 2013). The difference in the magnitude of the results most likely reflects a higher overall thrombolysis rate; England achieved a rate of 9.1% in 2011 (B. Bray et al., 2013) compared with a rate of 6.4% in this study. Furthermore, Ekundayo et al. (2013) limited their analysis of the thrombolysis rate to patients with an onset-to-door time of two hours or less. In another study that did not find an association between prehospital care and administration of alteplase, the authors suspected that their analysis was underpowered due to a sample size of only 188 ischaemic stroke cases (Oostema et al., 2014). As the rate of thrombolysis is low, a large sample, such as that provided by a population-level approach, is required to reach statistical significance in sub-group analyses. Differences between the studies, in the definition of EMS use, may have contributed to variation in the results. For example, the finding in the present study that 85.2% of thrombolysed cases had a first contact with the EMS exceeds the 72% reported in a study where EMS contact was defined as the mode of transport (Vidale et al., 2016). This appears to be the first study to identify a greater rate of thrombolysis when EMS use is defined as the patient's first medical contact rather than the mode of transport.

The finding that paramedic recognition of stroke was associated with thrombolysis corroborates the results of an earlier study (Abboud et al., 2016), but in a larger sample. It does not support the finding by Iguchi et al. (2011) of no effect. Furthermore, the use of a prospective case ascertainment design in the current study achieved a higher rate of data linkage between EMS and hospital records than the 61.0% reported by Abboud et al. (2016) reducing the possible effects of selection bias. Whereas unreliable documentation prohibited them from determining whether a stroke tool had been used, the present study has been able to extend the knowledge to show the connection between paramedic recognition and assessment with a stroke instrument.

Overall, these findings support the research proposition. For the first time, the findings show that stroke recognition, assisted by the FAST tool, is associated with a higher rate of thrombolysis in ischaemic stroke than when the stroke is unrecognised by the paramedic.

5.3.3 Health-related outcomes

Mortality rates

A higher rate of death was observed when the patient's FMC was with an EMS paramedic. The most likely explanation for this phenomenon is a more critical presentation at onset, prompting the patient or his/her advocate to call the EMS, rather than accessing care through the less urgent routes of a primary care doctor consultation or presenting at an Emergency Department. However, due to the lack of data measuring severity with a validated tool in the ARCOS IV study, (stroke severity was only measured in those who consented to a full follow-up) this theory cannot be tested. The finding is consistent with the literature (C. I. Price et al., 2013; Romano et al., 2016).

Functional outcomes

At 28 days after their stroke, patients who had an initial contact with the EMS were less likely to report a modified Rankin score indicating a good functional outcome (score \leq 2), compared to those patients who had a non-EMS first medical contact. However, at baseline the EMS group also had a smaller proportion of patients (46.9%) with good function than the non-EMS group (64.9%). This trend persisted when only those patients with greater dependency at baseline (score \geq 3) were considered. These results are consistent with previous findings that patients with greater pre-existing dependence or

symptom severity at onset are more likely to contact the EMS than use other prehospital pathways (C. I. Price et al., 2013; Turan et al., 2005).

The proportion of cases with a modified Rankin Scale shift to 0-2 at 28-days was similar for EMS and non-EMS groups. This suggests that initial contact with an EMS paramedic improves disability outcomes because despite a greater severity at baseline in the EMS group there was no difference between the two groups in the proportion who improved to achieve independent functioning at 28-days.

Quality of life

At baseline, EMS patients generally reported more problems compared to the non-EMS group in the EQ-5D questionnaire, but visual analogue scores were the same for the two groups. The dimensions across which patients reported the most problems, mobility, self-care and usual activities were aligned with the modified Rankin Scale outcome descriptions. In combination with the modified Rankin Scale results, these reinforce the picture of greater severity among the EMS group. At the 28-day follow-up, both groups of patients reported fewer problems across these three dimensions, although levels of reporting on pain and anxiety had increased. There are a number of possible explanations for the overall improved scores at 28-days. For example, improvement in function, adaptation to their condition or rehabilitation therapy could all result in improved scores. These results reflect the ambiguities and tenuousness in trying to link patient health-related outcomes to prehospital care. Reporting of the association between EMS care and indicators of timely in-hospital case management may convey more useful information.

In summary, case management process measures showed strong support for the thesis proposition that initial contact with an EMS paramedic, compared to a non-EMS healthcare professional, is associated with better management. By contrast, patient health-related outcomes seemed less encouraging. However, the poorer scores for independence and quality of life and the greater mortality in the EMS group, is most likely to be explained by the greater severity of their condition at onset. Furthermore, a note of caution is due here because of the requirement for participants to consent into the ARCOS IV study of outcomes. Patients with more severe presentations, and their next-of-kin, are less likely to engage with medical research (Kho et al., 2009) introducing the risk of selection bias. In this study, less than half of ischaemic stroke patients consented to participate in the full ARCOS IV study and less than half of these completed the 28-day

follow-up. This could lead to an overestimation of functional outcome. Despite thorough searching, no comparable studies were located in the literature.

5.4 Summary of main findings

Sixty-four percent of patients had their first medical contact with an EMS paramedic, while a further 27% contacted a primary care doctor and 10% presented at a hospital Emergency Department. Patients who contacted the EMS initially were older, more likely to report FAST signs at onset, more likely to have a final diagnosis of primary intracerebral stroke and to have anterior or posterior territory infarction rather than a lacunar stroke.

The paramedic recognised the stroke/TIA event in 70% of cases. Non-recognition of a stroke/TIA event was associated with final diagnoses of primary intracerebral and ischaemic stroke compared to TIA, an OCSF classification of posterior circulation infarction compared to a lacunar infarct, absence of a documented FAST screening test or assessment of the patient's severity status as mild. Paramedics were more likely to recognise the stroke/TIA when the patient or family reported a history of stroke or when the dispatch code was stroke. Completion rates varied between quality indicators. When the event was recognised by the paramedic, the patient was more likely to have a documented FAST assessment and onset time, and an on-scene delay of 20 minutes or less. The paramedic was also more likely to notify the hospital in advance when the stroke was recognised. However, this effect did not persist if inclusion was limited to patients that were assessed to have greater severity. The duration of the total EMS contact interval, from the emergency call until arrival at hospital, did not differ between recognised and unrecognised cases.

Among ischaemic stroke patients who were transported to hospital by ambulance, the onset-to-door interval was significantly shorter if the first medical contact was with a paramedic and not a primary care doctor. There was no difference in the onset-to-door interval between cases that were recognised by the paramedic and those that were unrecognised. While patients were more likely to be administered a thrombolytic agent, if their first contact was with a paramedic and not a community-based doctor, this effect did not persist when the analysis was limited to cases arriving in the first three and half hours from onset. For patients whose first contact was with the EMS, recognition of the stroke was associated with a higher unadjusted odds ratio of treatment with alteplase. In

this group of ischaemic stroke patients, health-related outcomes were poorer among patients whose first medical contact was with a paramedic compared with a primary care doctor. These less favourable outcomes included higher mortality rates, less functional independence and poorer quality of life scores 28 days after the stroke/TIA as measured respectively by the modified Rankin Scale and EQ-5D instruments. However, baseline modified Rankin Scale and EQ-5D scores were also lower among the EMS group compared to the doctor group and this is likely to reflect greater stroke severity and greater pre-stroke dependence among patients who initially saw a paramedic.

Overall, for stroke and TIA patients, first medical contact with an EMS paramedic, compared to a primary care doctor or Emergency Department staff, was associated with earlier arrival at hospital. Recognition of the stroke by the paramedic, as a measure of care, was associated with higher rates of thrombolysis. While mortality, and 28-day functional and quality of life outcomes were poorer among the EMS group, these patients also appeared to have greater impairment at baseline.

5.5 Strengths

This study is characterised by its robust design and rigorous methods of data collection and diagnostic criteria. Population-based approaches that include data from a large number of cases are extremely rare in the prehospital field. Prospective case ascertainment from multiple centres and for a large cohort of stroke/TIA cases was achieved through collaboration with the ARCOS IV project. Whereas chance events may reach statistical significance when a low number of cases are included, the reliability of findings is greatly enhanced in a large sample such as this, which lessens the chance of bias, due to data missing in a non-random way.

Although the work was undertaken by a single researcher, rigorous testing of the reliability of the database was undertaken. Double-entry of data for a sample of cases by a research assistant, enabled testing to establish the reliability of abstraction and data entry. Sourcing the original paper PRF was onerous and missing records were inevitable. Despite this, 84.9% of cases were matched between the paramedic and hospital records (from the ARCOS IV study). This rate is high in comparison with other EMS studies. The introduction of electronic PRF in 2015 (AKLD region in February 2016), is anticipated to greatly reduce the burden of data collection for future EMS studies.

Another strength is that the study included cases based on a diagnosis of stroke/TIA that was made by a neurological review committee. This enabled the exploration of confirmed false negative cases, in order to increase the understanding of which factors are predictive of non-diagnosis by paramedics. Examination of these cases is not possible in studies where inclusion is based on the paramedic's clinical impression of a suspected stroke.

A unique feature and major strength of the current study is that it is conducted from a paramedic perspective. The absence of a paramedic viewpoint was apparent in numerous studies that defined ambulance utilisation as the mode of transportation, or ignored EMS contact entirely. These approaches failed to reflect acute care in the prehospital setting accurately. As a new healthcare profession, the discipline of paramedicine is critically under-researched. The current study highlights the importance of developing a research culture within paramedicine to support evidence-based practice and to present the paramedic perspective within research collaborations.

The degree of generalisability of these results is dependent on the extent to which the Auckland region is representative of other New Zealand locations and international settings. The greater Auckland region includes rural areas and inhabited islands with difficult access (Appendix B) that may mimic EMS response to rural and remote areas in other parts of the country. Auckland is a multicultural city and this will increase the generalisability of the findings to other populations with diverse demographic profiles. A further factor to consider is the profile of the EMS workforce. The generalisability of the findings is expected to be greater in locations with a similar advanced life support level of provision. Results may be different in settings with a predominantly basic life support or doctor-led advanced life support service delivery model.

5.6 Limitations

In this study, it was not possible to determine the specificity of paramedic diagnosis because false positive cases, where the paramedic incorrectly suspected a stroke/TIA, were not determined. There were two reasons for this. Firstly, because ARCOS IV was an incidence study, recurrent events were treated as a complication and less data was recorded, making it difficult to identify these cases. Secondly, the additional volume of data and resources required to confirm the final discharge diagnosis, was beyond the capacity of the current study. However, this was deemed to be a minor issue, as sensitivity is the most important measure of paramedic diagnostic ability.

It is possible that the study did not identify cases where a paramedic inappropriately decided that the patient could remain at home. This would have increased the onset-to-door delay until the patient was subsequently transported by a second crew or by a non-EMS mode. However, it is anticipated that these cases will be rare and it is extremely unlikely that they would affect the results in such a large sample.

Incomplete documentation on the PRF could result in under-reporting of paramedic completion of care activities that were captured in the clinical quality indicators. An example of this would be failure to record on the PRF that the receiving hospital was notified prior to arrival. Similarly, the paramedic may have attended a fall and used this coding, despite recognising that the fall was caused by a loss of balance secondary to an acute stroke. Documentation is an important way that healthcare professionals communicate between different settings and across time to ensure continuity of care. Consequently, standard operating procedures assume that actions that are undocumented were not undertaken, and this position was adopted in this study.

One limitation of the study is the lack of a measure of stroke severity. While NIHSS scores were collected, the large amount of missing data precluded using this variable in the analyses. This issue was addressed within the study by using proxy measures of severity including the paramedic-reported patient severity status and the Glasgow Coma Score. As previously noted, the patient status is a subjective assessment made by the paramedic based on his or her experience and clinical judgment, but it is not a validated instrument. The Glasgow Coma Score and patient status were available for most ambulance-transported patients and were included in the analysis to identify predictors of paramedic non-recognition of stroke. The Glasgow Coma Scale has been used as a measure of stroke severity in other studies (Addo et al., 2012; Carter et al., 2006). However, it was not possible to compare the severity of patients across the prehospital pathways when the patient was not transported by ambulance. Similar issues were encountered in interpreting the influence of social factors due to inadequate data on income and education level.

Another limitation of the study is that some cases were excluded from analyses due to missing information. This introduces the risk of selection bias if patients who were excluded from the study varied systematically in some way from those who were included. For example, there is a potential for bias in the outcomes study, if non-English speaking patients and those with more severe strokes were less likely to consent to follow-

up. This was anticipated by the ARCOS IV investigators who ensured that research assistants included speakers of different languages and encouraged the use of family members as patient proxies. The proportion of the total cases that were excluded in this analysis is equivalent with other studies. As previously noted, ethical approval allowed data collection at baseline without obtaining individual consent. However, the participants' consent was required for the follow-up study of patient outcomes. As described in section 3.8, this creates a potential bias towards including patients with better outcomes. Furthermore, the analysis of change between repeated measures of modified Rankin Scale and EQ-5D scores was limited to consenting patients who completed testing at both baseline and 28 days. This led to a smaller sample size in the analyses of health-related outcomes of functional independence and quality of life.

A further cause of bias is confounding by other factors. This was addressed by including a broad range of variables in the study design. Alternative statistical approaches such as discriminant analysis could have been used and these may have led to a different result.

5.7 Recommendations for future research

There are still many unanswered questions arising from this study and future research on the paramedic response to acute stroke/TIA is strongly recommended. These are highly topical in the context of initiatives such as bypassing hospitals that provide stroke thrombolysis to access endovascular thrombectomy at specialist centres in cases of suspected large vessel occlusion (Zhao et al., 2017). These decisions will rely on a high standard of paramedic stroke care. Further studies on strategies to reduce prehospital delay, increase paramedic diagnostic sensitivity and enhance care transitions would all be fruitful areas for investigation.

Further research is needed to explore community awareness of the need to respond urgently by calling the EMS, in cases of suspected stroke. Establishing the efficacy of public education campaigns (such as the 2017 national FAST public education television campaign) and complementary strategies to improve the initial response in the community would be worthwhile.

The findings from this study have demonstrated that considerably more work needs to be done on improving paramedic stroke recognition. This could include examining the effect of screening patients complaining of falls, with a stroke tool. As previously noted, the possible association between the patient's ethnicity and non-recognition of stroke is

an intriguing issue which could be explored in future research. There is also a need to develop evidence-based tools or education that improve recognition in patients with signs and symptoms that are not recognisable by the FAST tool. This includes recognition of stroke symptoms in unconscious patients, of posterior circulation infarction and among patients with subtle signs and symptoms. Some preliminary work has been done in this area.

This study identified a comparatively longer overall contact time compared to international investigations. More research is required to better understand the effect of distance on the total EMS contact interval and the possible role of telemedicine. This is of particular importance for rural and remote areas of the country. Further studies could assess the effect of dispatch priority and multiple vehicle assignment on the delay to reaching the patient and high priority transportation to hospital including utilisation of helicopters for rapid transfer direct to neuro-interventional centres and specialist stroke units. The potential role of ambulance-based mobile stroke units in acute stroke management in New Zealand has not been examined.

Further work should be undertaken to investigate the effect of advance notification to the receiving hospital. The effect of the greater emphasis in the latest Clinical Practice Guidelines update on providing advance notification (National Ambulance Sector Clinical Working Group, 2016) could be examined by replicating this study. This may show an increase from the relatively low rates observed in this study where the guidelines current at the time did not include advice to notify the receiving hospital. It would be useful to explore the effect of advance notification on the transition from prehospital to in-hospital care by measuring the delay from arrival at the hospital door until brain imaging. While this has been studied in other locations, the generalisability of the results to the New Zealand healthcare setting is uncertain.

In the context of rapidly evolving stroke care, paramedics need to identify their contribution to increasing access to life-saving treatments. Furthermore, for paramedicine to advance as a healthcare profession, it must develop greater involvement in research collaborations. EMS systems play an important role in patient care and it is critical that research includes a paramedicine perspective. There is a clear need to develop capacity within this nascent profession to facilitate robust studies which examine outcomes of importance to stroke/TIA patients and their families.

5.8 Implications for practice

Stroke is a priority area, due to the high burden of stroke mortality and disability and the increasing proportion of the population at risk. EMS systems need to respond to the challenges of rapidly evolving treatments and reorganisation of service delivery, to improve patient access to time-critical care.

The public needs to be aware that stroke is a medical emergency that requires an EMS response. There is also a potential for primary care doctors to contribute to reduced prehospital delay, through improved screening of calls. Public education campaigns have demonstrated improvement in the accessing of acute stroke/TIA medical care from EMS providers (Wolters et al., 2015). In this study, the analysis of factors predicting the prehospital pathway in stroke identified possible opportunities for improved public education on stroke. For example, this study found that having a personal experience of stroke/TIA, or stroke/TIA among close relatives, did not increase the likelihood that a patient would contact the EMS for acute stroke care. To address this, during stroke admissions, patients and their families should learn how to respond to future events. The results also demonstrated lower use of EMS among younger stroke patients. Although the risk of stroke/TIA increases with age, education initiatives are needed to increase public awareness that stroke/TIA can occur at any age.

Paramedics need to understand how their care of stroke and TIA patients impacts on access to time-critical treatments and to patient outcomes. Paramedics should record their findings clearly and in a way that allows other healthcare professionals assessing the patient later to make direct comparisons. The importance of a well-documented assessment with a stroke tool in determining whether the patient's symptoms are improving, worsening or fluctuating, should not be under-estimated. Particularly valuable is reporting of the onset time which must be absolute, not relative, and identified as either known, last known well, or unknown. Tools can be designed to support improved reporting. Designating specific fields for key activities acts as an aide memoire and electronic reporting can utilise forcing functions to encourage paramedic compliance with guidelines. For example, a stroke assessment could be required after a fall if the patient meets pre-specified criteria for being at a higher risk of stroke.

Stroke assessment instruments should be used more widely as a screening tool rather than only to confirm the clinical impression of stroke. This could include cases where the patient presents with confusion, general malaise, dizziness, hypertension, a suspected new

onset of atrial fibrillation, a headache or after a fall. Paramedics should be aware of the greater risk of failing to recognise stroke/TIA among patients with a more mild presentation. Paramedics also need to be aware of other signs and symptoms of stroke/TIA that are not identified by a FAST assessment. Educational curricula should include assessment for signs and symptoms associated with posterior territory infarction, given that 20% of strokes attended by paramedics in this study met this sub-classification. Paramedics should not try to differentiate between TIA and stroke as the diagnostic sensitivity for an exact diagnosis is low in the prehospital setting. Furthermore, all acute cerebrovascular events should be urgently assessed by a specialist because early treatment of TIA reduces the risk of a stroke developing.

As previously noted, paramedics should be aware of the significance of advance notification in facilitating prioritised in-hospital treatment. Rates of advance notification need to increase in synergy with optimised hospital Code Stroke initiatives, to reduce delay and improve access to time-critical treatments. This precedent has already been established in the care of acute coronary syndromes with pathways for direct access to catheter laboratories for primary coronary angioplasty.

At a higher level, clinical quality audit should be linked to evidence-based practice and be an opportunity for staff to learn and improve performance. Paramedicine as a healthcare profession must engage with research and investigators in the field of stroke should seek collaborations with paramedic researchers to incorporate a paramedic perspective of the care of acute stroke/TIA patients.

Chapter 6 CONCLUSION

This thesis represents the first population-level study of prehospital care of stroke/TIA patients in New Zealand. The study adopted a uniquely paramedic perspective and employed observational methods and a quantitative approach to explore whether paramedic care is associated with better management and improved patient health-related outcome measures for stroke and TIA patients. The three main objectives were as follows.

The first objective was to identify how people access medical assistance in acute stroke/TIA and to establish the factors associated with initial contact with an EMS paramedic. Overall, 64% of stroke/TIA patients had an initial contact with a paramedic, compared to 27% who consulted a primary care doctor and 10% who presented to an Emergency Department. The study identified four factors associated with initial contact with an EMS paramedic: increasing patient age, the presence of signs at onset that were recognisable with a FAST test, a final diagnosis of primary intracerebral haemorrhage compared to TIA and all other OCSF classifications compared to lacunar circulation infarct. Although these findings represent a high rate of first medical contact with the EMS compared to international studies, they reveal that there is room for further improvement in accessing urgent care for stroke/TIA. Establishing the FMC in acute stroke/TIA characterises patterns of service use and provides a measure of public stroke knowledge. This can identify potential opportunities to reduce delay in accessing specialist care, inform health services planning and guide public education strategies. For the first time, onset presentation with signs recognisable by a FAST assessment and subsequent OCSF classification have been demonstrated to be associated with initial contact with an EMS paramedic. An original contribution has been to establish that defining EMS use as the mode of transport, rather than as the FMC, substantially overestimates the proportion of acute stroke/TIA patients accessing care through an urgent prehospital pathway. This knowledge should be considered in the design of studies that include the prehospital phase of stroke/TIA care.

The second objective was to evaluate the quality of paramedic care in acute stroke/TIA by measuring the sensitivity of paramedic diagnosis of the event, identifying factors associated with non-recognition and evaluating the compliance of care with evidence-based guidelines. In this study, the sensitivity of the paramedic working diagnosis of stroke/TIA was 70%. Non-recognition of stroke/TIA by paramedics was associated with

six factors: a dispatch code other than stroke, absence of a patient or familial history of stroke/TIA, severity described as minor compared to more severe presentations, absence of a documented FAST assessment, a final diagnosis of intracerebral haemorrhage or ischaemic stroke compared to TIA, and an OCSP classification of posterior circulation infarction compared to lacunar infarction. Observations from this investigation suggest that clinical indicators are a useful approach for assessing the quality of care provided by paramedics. Adherence to clinical guidelines for the management of stroke/TIA, was greater when the paramedic recognised the event. However, there is room for improvement in the care delivered to stroke/TIA patients in order to meet the standard recommended by international guidelines. To the best of the author's knowledge, this is the largest international study to establish the sensitivity of paramedic diagnosis of stroke/TIA using the FAST tool. The findings clarify the conflicting results from previous studies on the sensitivity of the FAST instrument in the paramedic recognition of stroke/TIA. The contribution of this study, to the understanding of factors associated with paramedic non-recognition of stroke/TIA could be used to inform the design of effective education programmes for paramedics, in the context of time-critical treatments and the evolving management of this patient group.

The final objective, was to explore the association between the FMC, the quality of EMS care and case management indicators as well as patient outcomes among ischaemic stroke events. This work contributes to the existing knowledge by confirming that delay from stroke onset to arrival at the hospital door is shorter when the initial contact is with an EMS paramedic compared to a community-based doctor. One of the significant findings to emerge is that ischaemic stroke patients are more likely to be thrombolysed if the paramedic recognises their condition, compared to when it is undiagnosed in the prehospital setting. Among ischaemic stroke cases, patient outcomes were poorer for those whose FMC was with a paramedic, compared to a primary care doctor or Emergency Department staff. Initial contact with the EMS was associated with higher mortality, greater functional dependence scores and lower quality of life measures. However, baseline scores suggest that these poorer outcomes are related to a higher frequency in the EMS group of severe presentation at onset and pre-stroke dependence. Despite this, the proportion of patients who improved from baseline to be able to function independently by the 28 day follow-up, was the same for EMS and non-EMS groups.

In summary, the findings in relation to the research proposition were mixed. In this study, paramedic care was associated with better management of stroke/TIA. Initial contact

with an EMS paramedic, compared to a primary care doctor or Emergency Department staff, was associated with earlier arrival at hospital, and a greater proportion of patients potentially eligible for, and treated with, thrombolytic therapy. Recognition of stroke by the paramedic, was strongly associated with a documented stroke assessment, and an improved odds ratio for thrombolytic therapy compared to patients whose stroke was undetected. However, the results do not support the proposition that paramedic care is associated with improved patient health-related outcome measures in stroke/TIA. This finding is most likely to be due to differences in the severity of the stroke and the pre-existing health status of the patient.

Finally this study and its new insights into paramedic practice, highlight the importance of researchers from within the discipline of paramedicine collaborating in clinical investigations that will inform evidence-based practice to improve patient outcomes.

GLOSSARY of Terms

Abbreviation	Term
AMPDS	Advanced Medical Priority Dispatch System
AOR	adjusted odds ratio
ARCOS IV	Fourth Auckland Regional Community Stroke study
CI	confidence interval
ED	Emergency Department (of hospital)
EMS	Emergency Medical Service
EQ-5D	EuroQol EQ-5D instrument
FAST	Face-Arms-Speech test
FMC	first medical contact
IQR	interquartile range
Mdn	median
NIHSS	National Institute of Health Stroke Scale
NINDS	National Institute of Neurological Disorders and Stroke
OCSP	Oxford Community Stroke Project
PRF	patient report form
SPSS	Statistical Package for Social Sciences
TIA	transient ischaemic attack
UOR	unadjusted odds ratio

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Appendix A. Search strategy for literature review

Example shown for Medline via EBSCO

Line	Search term	Theme
1	stroke /	
2	"transient ischemic attack" /	stroke/TIA
3	1 OR 2	
4	ambulance	
5	EMS	
6	"emergency medical service*"	EMS
7	paramedic*	
8	prehospital	
9	pre-hospital	
10	4 OR 5 OR 6 OR 7 OR 8	
11	"first medical contact"	
12	"first contact*"	first medical
13	"initial contact"	contact
14	refer*	
15	delay*	
16	11 OR 12 OR 13 OR 14 OR 15	
17	recogni*	
18	identif*	
19	diagnos*	
20	accura*	recognition
21	sensitivity)	
22	17 OR 18 OR 19 OR 20 OR 21	
23	FAST	
24	"F.A.S.T."	
25	"face, arm*, speech"	
26	23 OR 24 OR 25	
27	22 AND 26	
28	thromboly*	
29	fibrinoly*	
30	recanali*	thrombolysis
31	revascular*	
32	tPA	
33	t-PA	
34	rt-PA	

Appendices

35	alteplase	
35	"tissue plasminogen activator"	
36	28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35	
37	3 AND 10 AND 16	First medical contact
38	Limit 37 to English language	in stroke and TIA
39	3 AND 10 AND 27	Paramedic recognition
40	Limit 39 to English language	of stroke/TIA
41	3 AND 10 AND 35	Paramedic care and
42	Limit 41 to English language	thrombolysis

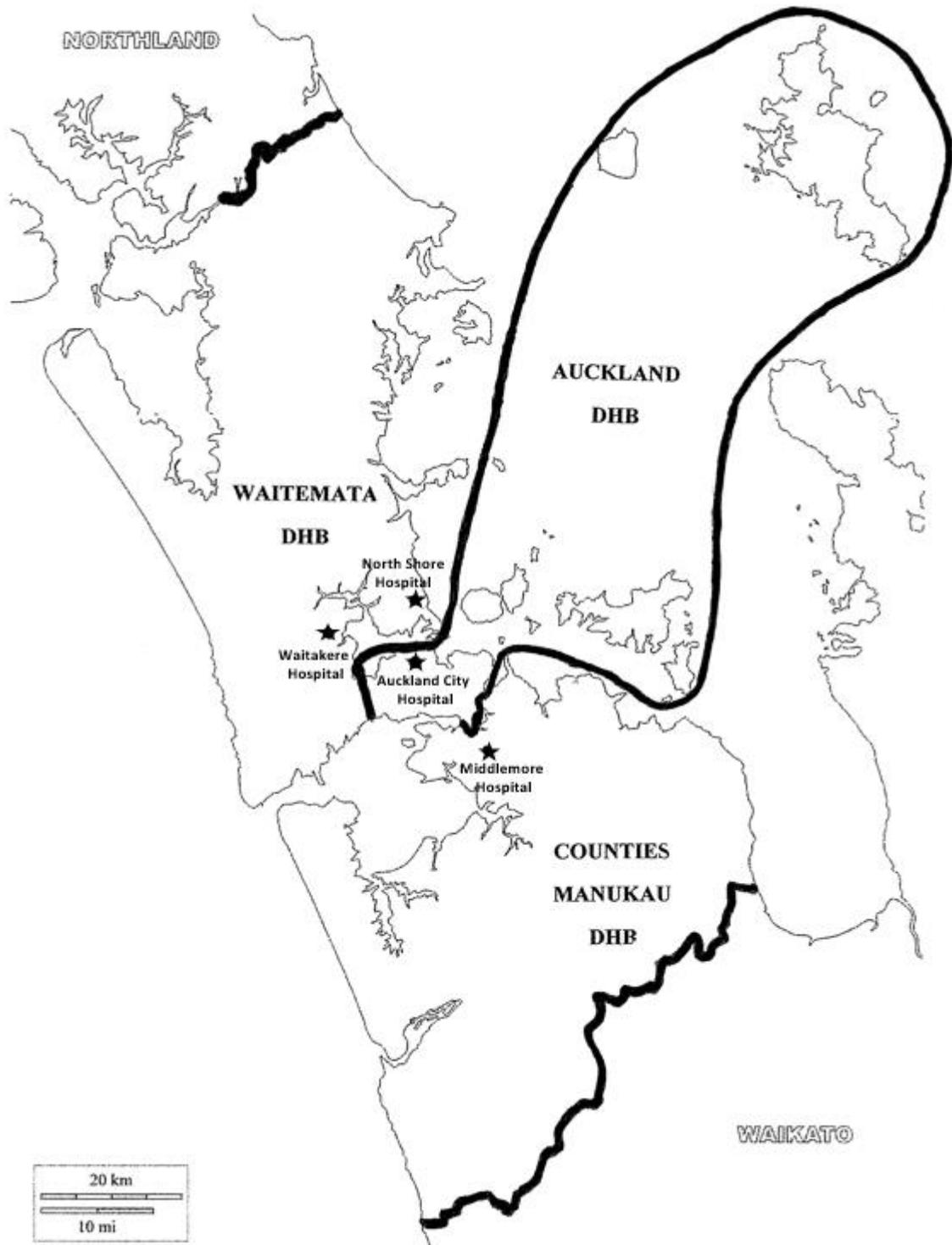
/ = medical subject heading (MESH)

* = any ending

" " = search phrase

Appendix B. Map of the study region

The greater Auckland region showing the boundaries of the three District Health Boards (DHB). Auckland is geographically smaller than both Waitemata and Counties Manukau. However, it is more densely populated and the catchment area includes several permanently occupied islands. The locations of the four hospitals are marked with a star.



Appendix C. Quantitative variables and source

Variable	Description (values)	Source
Demographic		
Age	date of birth to date of event	PRF; ARCOS IV
Sex	binary (male; female)	PRF; ARCOS IV
Ethnicity	Level 1 New Zealand census categories (New Zealand European; Māori; Pasifika; Asian; Other)	ARCOS IV
Social		
Abode	(private residence; retirement village; rest home)	ARCOS IV
Deprivation Index	Geo-coded to residence (1 = least; 10 = most)	PRF
Employment status	(manual; non-manual; non-participating)	ARCOS IV
Living alone	(alone; with others)	ARCOS IV
Clinical		
FAST signs at onset	recognisable by FAST assessment (yes; no)	ARCOS IV
Final diagnosis	determined by ARCOS IV review panel (ischaemic stroke; primary intracerebral haemorrhage; subarachnoid haemorrhage; transient ischaemic attack)	ARCOS IV
OCSF classification	(total anterior; partial anterior; posterior and lacunar circulation infarctions)	ARCOS IV
Stroke experience	history of stroke in patient or close relative (yes; no)	ARCOS IV
Glasgow Coma Score	recorded by paramedic (15 = conscious; orientated; 3 = unconscious, no response)	PRF
Status	subjective impression by paramedic (critical; serious; moderate; minor)	PRF
NIHSS score	stroke severity (1 = minor stroke; 42 = death)	ARCOS IV
Care quality indicators		
Paramedic diagnosis	Paramedic clinical impression	PRF
FAST assessment	paramedic documented FAST result (negative; positive; excluded)	PRF
Onset time	paramedic documented onset time	PRF
Onset definition	paramedic documented (exact; last known well; other)	PRF

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Variable	Description (values)	Source
Blood glucose	recorded by paramedic (yes; no)	PRF
Blood pressure	recorded by paramedic (yes; no)	PRF
Notification	Advance notification to receiving hospital (yes; no)	PRF
On-scene	interval from arrival on-scene to departure to hospital	PRF/CAD
Alarm-to-door	interval from emergency call pick-up until arrival at hospital	PRF/CAD
Operational		
Priority response	Ambulance dispatch priority (P1 = highest priority; P2 = immediate; P3 = other)	CAD
Emergency medical dispatcher code	Dispatch code assigned by emergency medical dispatcher	CAD
First medical contact	first contact with healthcare professional (paramedic; phoned or consulted a primary care doctor; Emergency Department staff)	PRF; ARCOS IV
Transport mode	mode of transportation to hospital (ambulance; non-ambulance)	ARCOS IV
Outcomes		
Onset-to-door	onset time to arrival at hospital	PRF; ARCOS IV
Thrombolysed	alteplase administered to patient (yes; no)	ARCOS IV
Died	patient died during the study period (yes; no)	ARCOS IV
modified Rankin Scale	functional outcomes (0 = no symptoms; 5 = severe disability)	ARCOS IV
EQ-5D-3L	quality of life score (no problems; some problems; extreme problems)	ARCOS IV

Notes: ARCOS IV = 4th Auckland Regional Community Stroke Study; CAD = computer-aided dispatch; ED = emergency department; FAST = Face-Arms-Speech test.

Appendices

The PRF were recalled from secure off-site storage. Each carton contained three folders that contained the PRF for one day. The patient report forms were filed only by date.



The contents of one folder, ready for review. This represents 1/366th of the PRF that were reviewed. It is estimated that over 100,000 forms were physically reviewed in order to identify the PRF for cases included in the study; enough to cover a football field (1.32 acres).



Appendix E. Glasgow Coma Score

Glasgow Coma Score, from the 2011 clinical practice guidelines update. (Pocket edition shown.)

6.3 ADULT/CHILD GLASGOW COMA SCORE

Best eye opening (E)

Spontaneously	4
To voice	3
To pain	2
None	1

Best verbal response (V)

Orientated	5
Mildly confused	4
Very confused	3
Moans or grunts	2
None	1

Best motor response (M)

Obeys commands	6
Localises pain	5
Withdraws from pain	4
Flexion	3
Extension	2
None	1

Do not estimate GCS 'at a glance'; individually assess and score each component. The motor score is the most important part of the GCS. During generalised seizures score the GCS as 3. If the patient is staring blankly ahead ('the thousand metre stare') score the eye component as 1.

National Ambulance Sector Clinical Working Group (2011)

Appendix F. Emergency Medical Service status codes

Severity status codes, from the 2011 clinical practice guidelines update. (Pocket edition shown.)

6.15 STATUS CODES

Status	Condition	Triage tag colour
Status zero	Dead	Black/white
Status one	Immediate threat to life	Red
Status two	Potential threat to life	Orange/yellow
Status three	Unlikely threat to life	Green
Status four	No threat to life	Green

- Status codes are a numerical means of describing an estimate of the severity of a patient's condition.
- They are qualitative, require clinical judgement and are allocated to a patient after taking into account their illness or injuries, their vital signs and the potential threat to their life.
- They are not altered by the mechanism of injury, the physical environment, e.g. trapped or not trapped, or the age of the patient.
- The examples below are not an exhaustive list, but are indicative only.

Examples

- **Status one:** obstructed airway or airway needing intervention, severe stridor, severe respiratory distress, shock unresponsive to fluid loading, multisystem trauma with abnormal vital signs, cardiac arrest or post cardiac arrest, cardiogenic shock, anterior ST elevation myocardial infarction on 12 lead ECG, status epilepticus, coma with GCS ≤ 9 .
- **Status two:** moderate stridor, moderate respiratory distress, shock responsive to fluid loading, multisystem trauma with normal or near normal vital signs, multiple long bone fractures, inferior ST elevation myocardial infarction on 12 lead ECG, myocardial ischaemia unrelieved (or not significantly relieved) by nitrates alone, abnormal level of consciousness with GCS 10-13, stroke.
- **Status three:** mild stridor, mild respiratory distress, isolated SVT with no other symptoms, myocardial ischaemia relieved (or mostly relieved) by nitrates alone, isolated long bone fractures (including compound fractures), loss of consciousness with normal or near normal (GCS 14 or 15) recovery, transient ischaemic attack.
- **Status four:** isolated minor fractures, isolated hand injuries, strains and sprains, lacerations with controlled bleeding.

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National Ambulance Sector Clinical Working Group (2011)

Appendix G. Clinical practice guidelines for stroke (2011-2013)

Stroke guidance from the 2011 clinical practice guidelines update. (Pocket edition shown.)

MISCELLANEOUS
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6.4 STROKE AND TIA

Stroke

The FAST assessment
Use this for assessing a conscious patient with a possible stroke

FACE:	Look for new onset of unilateral facial weakness. Ask the patient to smile and show all of their teeth/gums.
ARM:	Look for new onset of unilateral arm or leg weakness: <ul style="list-style-type: none"> • Ask the patient to raise their arms (to 90 degrees from the body) with their palms facing upward. Then ask them to close their eyes and hold their arms there for 5 seconds while you count aloud. Look for one arm that drifts downwards. • Ask the patient to walk. Look for abnormal gait.
SPEECH:	Look for new onset of abnormal speech: <ul style="list-style-type: none"> • Ask the patient to repeat a sentence. Look for slurring of words. • Show the patient several common objects and ask them to name them. Look for difficulty or inability to name objects.
TIME:	Note the time of onset of symptoms. This is defined as the time that the patient was last seen to be normal . If the patient has woken up with the signs or symptoms, then the time of onset of symptoms is the time that the patient went to sleep.

Patients with new onset of abnormalities as detected by the FAST assessment are having a stroke until proven otherwise.

- Measure blood glucose and treat accordingly.
- Transport to hospital without delay.
- In general, transport to hospital should be by road. Consider discussing the possibility of transport by helicopter (with the intensive care paramedic on the clinical desk within the EACC or with a Medical Advisor if:
 - a) The patient is aged under 70 years of age **and**
 - b) The patient has significant signs of weakness **and**
 - c) The patient can reach hospital within 3.5 hours of the onset of symptoms **and**
 - d) Helicopter transport will save more than 1 hour compared to road transport.

Appendix H. Modified Rankin Scale

The modified Rankin Scale tool as it appeared in the ARCOS IV study data collection form.



2.0 Modified Rankin Scale

SCORE	DESCRIPTION
<input type="radio"/> 0	No symptoms at all
<input type="radio"/> 1	No significant disability despite symptoms; able to carry out all usual duties and activities
<input type="radio"/> 2	Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance,
<input type="radio"/> 3	Moderate disability; requiring some help, but able to walk without assistance
<input type="radio"/> 4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
<input type="radio"/> 5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
<input type="radio"/> 6	Dead

2.1 MRS Score

Appendix I. EQ-5D instrument

The EQ-5D tool as it appeared in the ARCOS IV study data collection form.

2.0 EQ-5D

Instructions: By placing one tick only in each question, please indicate which statements best describe your health today

2.1 Mobility (tick one only)

- I have no problems walking about
- I have some problems walking about
- I am confined to bed

2.2 Self-Care (tick one only)

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

2.3 Usual Activities (e.g. work, study, housework, family or leisure activities) (tick one only)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

2.4 Pain/Discomfort (tick one only)

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

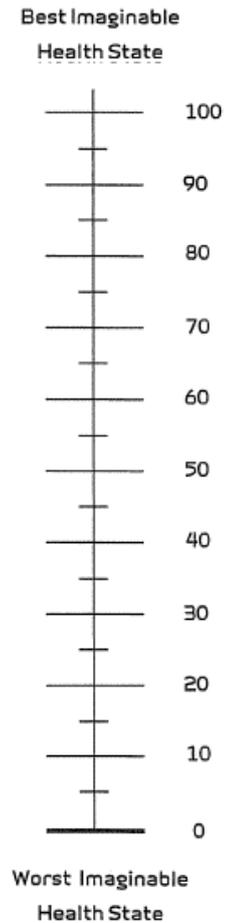
2.5 Anxiety/Depression (tick one only)

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



(Office Use only)

2.6 Health state score

Appendix J. Contribution of Professor C. Frampton to the thesis



Chris Frampton BSc (Hons), PhD
45 Beveridge St
Christchurch 8013, New Zealand
Mobile: 027 272-9378
E-mail: statistecol@xtra.co.nz

16th February, 2017.

Invoice to:

Bronwyn Tunnage
HRC Clinical Research Training Fellow PhD Candidate
National Institute for Stroke & Applied Neurosciences
Faculty of Health & Environmental Sciences
Auckland University of Technology

Invoice relating to:

- 1) Review statistical approaches and results for PhD Study '*Paramedic response to acute stroke: investigating current practice and outcomes*'. Includes advice on statistical strategy and reviewing SPSS output files and summary results tables generated from these outputs. (5 hours)

10th August, 2017.

Invoice to:

Bronwyn Tunnage
HRC Clinical Research Training Fellow PhD Candidate
National Institute for Stroke & Applied Neurosciences
Faculty of Health & Environmental Sciences
Auckland University of Technology

Invoice relating to:

- 1) Review statistical results, presentation and interpretation for PhD Study '*Paramedic response to acute stroke: investigating current practice and outcomes*'. (4 hours)

Appendix K. Ethical approval



Health and Disability Ethics Committees
Ministry of Health
C/- MEDSAFE, Level 6, Deloitte House
10 Brandon Street
PO Box 5013
Wellington
6011

hdec@moh.govt.nz

16 June 2014

Ms Bronwyn Tunnage



Dear Ms Tunnage

Re:	Ethics ref:	14/NTB/66
	Study title:	Paramedic response to acute stroke; investigating current practice and outcomes.

I am pleased to advise that this application has been approved by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at a *given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 16 June 2015.

Participant access to ACC

The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or

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distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Mrs Raewyn Sporle
Chairperson
Northern B Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendices

Appendix A Documents submitted

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI	May 2014	19 May 2014
Evidence of scientific review: St John Authorisation for study	1	12 March 2014
Evidence of scientific review: HRC - Letter of Notification of HRC Career Development Award	Colour	11 November 2013
Protocol: Study Protocol	2	12 May 2014
Evidence of scientific review: PG Review 2: by Dr Daniel Shepherd	1	13 May 2014
Evidence of scientific review: PG Review 1: by Associate Professor Paula Kersten.	1	09 May 2014
Application		

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Appendix B Statement of compliance and list of members

Statement of compliance

The Northern B Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Raewyn Sporie	Lay (the law)	01/07/2012	01/07/2015
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Mrs Kate O'Connor	Non-lay (other)	01/07/2012	01/07/2015
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2014
Ms Kerin Thompson	Non-lay (intervention studies)	01/07/2012	01/07/2015

<http://www.ethics.health.govt.nz>

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26 June 2014

Rita Krishnamurthi
Faculty of Health and Environmental Sciences

Dear Rita

Re Ethics Application: **14/202 Paramedic response to acute stroke; investigating current practice and outcomes.**

Thank you for providing evidence as requested, and satisfying the point raised.

I am pleased to confirm that the Chair and I have approved your ethics application for three years until 25 June 2017.

As part of the ethics approval process, you are required to submit the following to AUTECS:

- A brief annual progress report using form EA2, which is available online through <http://www.aut.ac.nz/researchethics>. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 25 June 2017;
- A brief report on the status of the project using form EA3, which is available online through <http://www.aut.ac.nz/researchethics>. This report is to be submitted either when the approval expires on 25 June 2017 or on completion of the project.

It is a condition of approval that AUTECS is notified of any adverse events or if the research does not commence. AUTECS approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

AUTECS grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to obtain this. If your research is undertaken within a jurisdiction outside New Zealand, you will need to make the arrangements necessary to meet the legal and ethical requirements that apply there.

To enable us to provide you with efficient service, please use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

All the very best with your research,

A handwritten signature in black ink, appearing to read 'K O'Connor', is positioned above the typed name.

Kate O'Connor
Executive Secretary
Auckland University of Technology Ethics Committee

Cc: Bronwyn Tunnage

Auckland University of Technology Ethics Committee

WA505F Level 5 WA Building City Campus

Private Bag 92006 Auckland 1142 Ph: +64-9-921-9999 ext 8316 email ethics@aut.ac.nz

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Authorisation report

Study ref:	14/NTB/66
Study title:	Paramedic response to acute stroke.
Status:	Application decision given - Decision: decision of "approved" 15/06/2014 23:40:00

This authorisation report was generated by Ms Bronwyn Tunnage on 01 Jun 2017 at 05:34 PM

Authoriser Type	Authoriser	Authoriser Position Title	On Behalf of (Institution/Company)	Date and time	Lead Investigator(s) at locality	Site Name (if different from Institution)	Authorisation Type
Co-ordinating Investigator	Bronwyn Tunnage			19 May 2014, 04:09 PM			
Other Investigator	Prof. Valery Feigin			19 May 2014, 04:32 PM			
Other Investigator	Rita Krishnamurthi			20 May 2014, 09:36 AM	Valery Feigin		
Primary Contact Person	Bronwyn Tunnage			19 May 2014, 04:10 PM			
Locality	St John, Bridget Dicker			20 May 2014, 09:38 AM			
Locality	Waitemata DHB			30 Apr 2015, 10:25 AM			
Locality	Auckland District Health Board			14 May 2015, 01:06 PM	Bronwyn Tunnage		
Locality	SHamshad Karatela			11 Jun 2015, 02:02 PM			

Electronic Authorisations History

Date	Authoriser Type	Action
11 Jun 2015, 02:02 PM	Locality	Authorisation given by Dr Shamshad Karatela
11 Jun 2015, 02:01 PM	Locality	Request for authorisation accepted by Dr Shamshad Karatela
11 Jun 2015, 01:59 PM	Locality	Request for authorisation sent by Ms Bronwyn Tunnage to Dr Shamshad Karatela
14 May 2015, 01:06 PM	Locality	Authorisation given by Research Office Auckland District Health Board ADHB
14 May 2015, 01:03 PM	Locality	Request for authorisation accepted by Research Office Auckland District Health Board ADHB
13 May 2015, 11:36 AM	Locality	Request for authorisation sent by Ms Bronwyn Tunnage to Research Office Auckland District Health Board ADHB
30 Apr 2015, 10:25 AM	Locality	Authorisation given by Waitemata District Health Board
30 Apr 2015, 10:18 AM	Locality	Request for authorisation accepted by Waitemata District Health Board
29 Apr 2015, 10:51 AM	Locality	Request for authorisation sent by Ms Bronwyn Tunnage to Waitemata District Health Board
20 May 2014, 09:38 AM	Locality	Authorisation given by Dr Bridget Dicker
20 May 2014, 09:36 AM	Other Investigator	Authorisation given by Dr Rita Krishnamurthi
20 May 2014, 08:37 AM	Locality	Request for authorisation accepted by Dr Bridget Dicker
19 May 2014, 04:32 PM	Other Investigator	Authorisation given by Professor Valery Feigin
19 May 2014, 04:31 PM	Other Investigator	Request for authorisation accepted by Professor Valery Feigin
19 May 2014, 04:21 PM	Other Investigator	Request for authorisation sent by Ms Bronwyn Tunnage to Professor Valery Feigin
19 May 2014, 04:21 PM	Other Investigator	Request for authorisation accepted by Dr Rita Krishnamurthi
19 May 2014, 04:19 PM	Other Investigator	Request for authorisation sent by Ms Bronwyn Tunnage to Dr Rita Krishnamurthi
19 May 2014, 04:16 PM	Locality	Request for authorisation sent by Ms Bronwyn Tunnage to Dr Bridget Dicker
19 May 2014, 04:10 PM	Primary Contact Person	Authorisation given by Ms Bronwyn Tunnage
19 May 2014, 04:09 PM	Co-ordinating Investigator	Authorisation given by Ms Bronwyn Tunnage
19 May 2014, 04:08 PM	Co-ordinating Investigator	Authorisation invalidated by data change
18 May 2014, 06:26 PM	Co-ordinating Investigator	Authorisation given by Ms Bronwyn Tunnage