

Fluid intake, hydration and health status of inpatients with and without dysphagia following stroke

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Abstract

Dysphagia, a common consequence of stroke, compromises an individual's ability to drink fluids and prescription of thickened fluids, a common strategy for reducing aspiration risk, may further exacerbate the risk of dehydration. To date few studies have investigated the impact of fluid intake on the outcomes of hydration and fluid–related health outcomes of individuals with dysphagia.

This thesis uniquely describes the fluid intake, hydration and health status of hospital inpatients with dysphagia post-stroke who are reliant on thickened fluids. A randomised control trial (RCT) was conducted to determine whether water protocols improve these outcomes compared with thickened fluids alone. Simultaneously, a cohort study was conducted with individuals *without* dysphagia to determine whether stroke related comorbidities or institutional factors have an impact on fluid intake, hydration status and health outcomes. Three background studies were conducted to provide additional context; i) incidence of stroke and comorbidities in South Australian hospitals; ii) a retrospective medical record audit of consumption of thickened fluids by patients with dysphagia post-stroke in South Australian hospitals; and iii) a survey of Australian health professionals about their practices for providing thickened fluids and measuring consumption and hydration of patients with dysphagia.

Unexpectedly, participants with dysphagia randomised to the water protocol group in the RCT did not drink any more than those on thickened fluids only, both groups consuming on average 1103ml per day. They typically drank 300ml of water per day but off-set this by consuming less of the thickened fluids offered. Those on the water protocol had an improving trajectory of hydration, faster resolution of their dysphagia for thin fluids and fewer adverse health outcomes than those on thickened fluids only, although none of these differences between groups were significant. No participants in either group developed pneumonia. The findings suggest that patients with dysphagia, with similar demographic and stroke characteristics as the present sample, could be safely trialled on a water protocol as a potential avenue for improving hydration. Combined findings from the RCT and cohort study indicated that individuals *with* dysphagia in inpatient rehabilitation drank significantly less on average per day (1103ml, representing 46% of their calculated fluid requirement) than those *without* dysphagia (1504ml, representing 67% of their calculated requirement). Collectively, 71% of the participants *with* dysphagia in the RCT had urea/creatinine results which classified them as dehydrated compared with 40% of those *without* dysphagia in the cohort study. They also had a significantly greater number of adverse health outcomes of dehydration, urinary tract infection and constipation (43%) compared with those *without* dysphagia (16%). The findings confirm that dysphagia is a major risk factor for dehydration. However, even individuals *without* dysphagia had suboptimal fluid intake and hydration compared with healthy adults living in the community and factors such as greater dependency, restricted mobility and older age had a significant impact on their fluid intake and hydration.

In light of the findings, wide-ranging strategies for improving hydration are discussed which focus on patients with dysphagia but could be applicable to *all* patients hospitalised post-stroke. Recommendations for clinical practice and development of clinical guidelines are highlighted along with specific areas where further high quality research is needed.

Declaration by the Author

This thesis is composed of my original work. I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Joanne Murray

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My speech pathology colleagues, Dr Anna Correll, Maree Creevy and Melissa Saliba, were there with me at the very beginning. They helped me to search for evidence of better practice and realising its scarcity, helped to conceptualise a study to provide answers. And so the journey began.

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Publications Arising from this Thesis

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Murray, J., Doeltgen, S., Miller, M., & Scholten, I. (2015). A descriptive study of the fluid intake, hydration, and health status of rehabilitation inpatients without dysphagia following stroke. *Journal of Nutrition in Gerontology and Geriatrics*, 34(3), 292-304.

Murray, J., Miller, M., Doeltgen, S. & Scholten, I. (2014). A survey of thickened fluid prescribing and monitoring practices of Australian health professionals. *Journal of Evaluation in Clinical Practice*, 20(5), 596-600.

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Presentations Arising from this Thesis

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National

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Murray, J. (2006, October). *Aspiration of water – is it as harmful as we think?* Paper presented at Stroke Society of Australasia 2006 Annual Scientific Meeting, Adelaide, South Australia.

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List of Abbreviations

AusTOMS	Australian Therapy Outcome Measure		
CCF	Congestive cardiac failure		
COPD	Chronic Obstructive Pulmonary Disease		
FBC	Fluid balance chart		
FEES	Fibreoptic Endoscopic Evaluation of Swallowing		
FIM	Functional Independence Measure		
FMC	Flinders Medical Centre		
GI	Gastrointestinal		
GORD	Gastroesophageal reflux disease		
HRC	Hampstead Rehabilitation Centre		
ICD	International Classification of Disease		
ISAAC	Integrated South Australian Activity Collection		
IVT	Intravenous therapy		
LMH	Lyell McEwin Hospital		
NAD	No abnormality detected		
NET	Nasoenteric tube		
NIHSS	National Institute of Health Stroke Severity		
NSF	National Stroke Foundation		
PEG	Percutaneous endoscopic gastrostomy		
RAH	Royal Adelaide Hospital		
RCT	Randomised controlled trial		
RGH	Repatriation General Hospital		
RDI	Recommended daily intake		
SA	South Australia		
SMRH	St Margaret's Rehabilitation Hospital		
TQEH	The Queen Elizabeth Hospital		
U/Cr	Urea/Creatinine ratio		
UTI	Urinary tract infection		
VFSS	Videofluoroscopic Swallow Study		

PART I Introduction and Background

Chapter 1: Introduction

Water is essential for human existence. Most people take for granted that they will consume enough fluids on a daily basis to maintain adequate hydration and stay healthy but this isn't always the case. The focus of this thesis is on people with acquired swallowing impairment following stroke who develop difficulties with drinking, what and how much they drink orally and their subsequent hydration and health outcomes. Swallowing impairment, also known as dysphagia, can be caused by many and varied medical conditions including stroke and other brain injury, progressive neurological disease such as dementia or Parkinson's disease, head and neck cancer and generalised debility (Logemann, 1998). The consequences of dysphagia can be serious. Impaired swallowing may compromise airway protection, resulting in aspiration of saliva, food or liquid into the airway (Logemann, 1998). Aspiration may lead to choking or pneumonia and in turn even death (Marik, 2001; Martino et al., 2005). Furthermore, inability to safely eat or drink because of impaired swallowing predisposes affected individuals to malnutrition or dehydration (Foley, Martin, Salter, & Teasell, 2009; Leibovitz et al., 2007). These conditions can have further deleterious effects on health and well-being such as infection, confusion, lethargy and organ damage (Weinberg, Minaker, & American Medical Association Council on Scientific Affairs, 1995). It is vital, therefore, that health professionals have management strategies that maximise swallowing function and minimise the risks that may cause harm.

Speech pathologists play an important role in the management of dysphagia. They evaluate the nature and extent of the individual's dysphagia and provide therapy to improve the person's ability to swallow (Logemann, 1998). If the individual is deemed safe to eat and drink orally, the speech pathologist will recommend a diet and fluids of a consistency that will minimise the risk of aspiration and consequently pneumonia. Of equal importance is that the individual is able to consume the recommended diet and fluids in sufficient quantities to maintain adequate hydration and nourishment (National Stroke Foundation, 2010a). Finding the appropriate diet and fluid regime to achieve this balance is crucial to a patient's well-being and recovery, but can be a difficult challenge for the speech pathologist and other

members of the clinical team. If the speech pathologist prescribes a modified consistency diet and fluids that are deemed safest in terms of aspiration risk but are not consumed in adequate amounts, a dilemma arises. What is the solution for avoiding the risk of pneumonia *and* the risk of malnutrition and dehydration to facilitate the optimum health and well-being of the patient? Answering this question is a very real day to day clinical dilemma and was the genesis for the research agenda outlined in this thesis.

To date, considerable attention has been given to the risk of pneumonia as a result of aspiration for patients with dysphagia and management strategies that will reduce that risk of aspiration (Loeb, Becker, Eady, & Walker-Dilks, 2003; Marik, 2001; Martino, et al., 2005; Pikus et al., 2003; Schmidt, Holas, Halvorsen, & Reding, 1994). Researchers have shown that patients with dysphagia, especially those who aspirate, are at higher risk of developing pneumonia than those who do not have impaired swallowing and do not aspirate (Schmidt, et al., 1994). However, it is also known that not all patients with dysphagia will develop aspiration pneumonia. Risk is mediated by the substance and amount that is aspirated and the patient's own ability to ward off infection through their immune system, cough and lung defences, general and oral health (Langmore et al., 1998). Increasingly, there is recognition that factors other than dysphagia alone impact on the risk of developing pneumonia.

Consequences of dysphagia other than aspiration, such as malnutrition and dehydration, have until recently received less attention in the literature. Some researchers have highlighted the inadequacy of fluid intake of people with dysphagia, especially if reliant on oral intake alone (Finestone, Foley, Woodbury, & Greene-Finestone, 2001; Whelan, 2001). In some settings, inadequate intake can be supplemented by non-oral feeding methods such as enteral tube feeding or intravenous fluids (Dennis, Lewis, Cranswick, & Forbes, 2006). However, for patients with dysphagia who are consuming an oral only diet and fluids (often those in the sub-acute or chronic phase post-stroke), intake and subsequent nutrition and hydration status can be sub-optimal (Foley, et al., 2009; Vivanti, Campbell, Suter, Hannan-Jones, & Hulcombe, 2009). Greater emphasis has been placed on adequacy of nutrition in the last decade but it is only in recent years that researchers have highlighted the poor hydration of patients with dysphagia post-stroke (Crary et al.,

2013; Rowat, Graham, & Dennis, 2012). Very few, however, have proceeded to that next step of investigating the health complications of poor hydration.

The reasons for sub-optimal fluid intake and hydration of people with dysphagia have also not been well-investigated. Patients with dysphagia of a neurological origin are known to be at particular risk of aspirating thin fluids (Huckabee & Pelletier, 1999). For this reason they are commonly prescribed thickened fluids (fluids thickened with a thickening agent to a consistency which prevents aspiration) (Mertz-Garcia, Chambers, & Molander, 2005). It is postulated that patients do not like to drink thickened fluids and that this is the reason for their sub-optimal intake (Colodny, 2005; King & Ligman, 2011; Mertz-Garcia, et al., 2005). Alternative explanations have not been widely explored. Does dysphagia itself preclude greater intake or could it be due to institutional factors such as patients having reduced access to drinks?

This thesis represents the author's attempt to answer these clinical questions. The clinical questions that were the genesis for this research are presented in Table 1 along with the studies that were conducted in an attempt to find answers. Each chapter in Part II and Part III of this thesis reports on one of these studies. These chapters were written as 'stand-alone' studies and for this reason there may be some unintended redundancy of information. Effort has been made, however, to integrate each study into the thesis as a 'whole' to establish an overarching narrative. The chapters contained in the four major parts of the thesis are described in more detail below the summary.

	Guiding clinical questions	Thesis chapters
PART I Introduction and Background	What is already known about optimising the safety and hydration of hospitalised patients with dysphagia post-stroke?	Chapter 1 Introduction Chapter 2 Literature review
PART II Background Retrospective Studies	What is the size of the problem of stroke, dysphagia and dehydration in SA hospitals?	Chapter 3 Incidence of stroke and comorbidities in South Australia
	How much do hospitalised patients post-stroke consume when prescribed thickened fluids?	Chapter 4 Consumption of thickened fluids by inpatients with dysphagia post- stroke: a retrospective audit
	If inadequate, why? Do institutional factors play a role?	Chapter 5 Thickened fluid prescribing and monitoring practices by Australian health professionals: a self-report survey
PART III Prospective Studies	How can we measure fluid intake, hydration and health outcomes?	Chapter 6 Methods for prospective studies
	What is the fluid intake and hydration of individuals post-stroke <i>without</i> dysphagia? Do stroke factors play a role?	Chapter 7 Beverage intake and hydration status of hospitalised individuals without dysphagia following stroke: a cohort
	Does dysphagia itself or dislike of thickened fluids contribute to inadequate intake? Can a water protocol improve the fluid intake and hydration of individuals with dysphagia post-	study Chapter 8 Beverage intake and hydration status of hospitalised individuals with dysphagia following stroke: the outcomes of an RCT
	stroke? How does the intake and hydration of individuals with and without dysphagia post-stroke compare?	Chapter 9 Comparison of individuals with and without dysphagia post-stroke
PART IV Conclusions and Recommendations	What are the implications for practice, policy and future research?	Chapter 10 Conclusion and recommendations

Table 1 Overview of thesis

In **Part I** of the thesis, the clinical questions that were the genesis of the research are presented in more detail in this introductory chapter, along with a brief explanation of how each chapter of the thesis will address these issues. A discussion of what is already known about optimising the safety and hydration of hospitalised individuals with dysphagia is presented in the Literature review in Chapter 2. Particular attention is given to the consequences of dysphagia with respect to aspiration pneumonia and

dehydration in order to illustrate the significance of adequate management of these risks. Current knowledge about the fluid intake and hydration of different cohorts of the population including those with dysphagia is summarised and compared against recommended standards for fluid intake and hydration levels. This review was undertaken to highlight what is already known about the sub-optimal fluid intake and hydration of individuals with dysphagia and to identify gaps in this knowledge base. An overview of the management practices for patients with dysphagia post-stroke is also included with particular discussion of the reason for and concerns about the prescription of thickened fluids and newer fluid regimes such as water protocols. This review provides a context for the research studies that follow in this thesis and also informs the methodology of the two prospective studies.

The main focus of this thesis is the fluid intake, hydration and health status of patients in inpatient rehabilitation after stroke who rely on an oral only diet. In particular, the fluid regimes commonly recommended for patients with dysphagia post-stroke are evaluated. The major experimental research presented in this thesis is a randomised control trial (RCT) which investigates the effectiveness of the traditional regime, thickened fluids, versus an alternative fluid regime, water protocols, in achieving adequate fluid intake. Water protocols allow patients to drink water despite their known aspiration of thin fluids but under specific conditions (Panther, 2003). Previous researchers have studied water protocols in terms of their effectiveness in improving fluid intake without increasing the risk of aspiration pneumonia (Carlaw et al., 2012; Garon, Engle, & Ormiston, 1997; Karagiannis, Chivers, & Karagiannis, 2011). However, none have explored the effects of these fluid regimes on the hydration status and other health outcomes of patients with dysphagia post-stroke. This is a unique element of the RCT presented in Chapter 8. The purpose of the RCT was to answer the primary clinical question of this author: what strategies can be employed to improve the fluid intake and hydration of patients with dysphagia whilst still keeping them safe from health complications such as pneumonia?

In the preparation of the research design and methodology for the RCT, it became clear that there were many more gaps in the published knowledge about stroke, dysphagia, fluid intake, hydration and associated adverse health events. Scarce information was available about: the size of the problem of dysphagia and dehydration for patients post-stroke in South Australia (SA); the amount that patients in hospitals across SA consume when prescribed thickened fluids; and current practice in the provision of thickened fluids to patients. To provide some of this background and comparison data, three further studies were designed and are presented in Chapters 3, 4 and 5 in **Part II** of this thesis. The content of these chapters is detailed below.

The National Stroke Foundation estimates that 60,000 people in Australia have a new stroke each year (National Stroke Foundation, 2012). It is suggested in the literature that between 37% and 78% of patients will have dysphagia as a result of their stroke (Martino, et al., 2005). Extrapolating from these figures, the potential impact of dysphagia on patient well-being and hospital costs is significant each year. No studies have quantified the size of these issues specifically in SA. Furthermore, none of the previous population based incidence studies in Australia (Islam et al., 2008; Leyden et al., 2013; Thrift, Dewey, Macdonell, McNeil, & Donnan, 2000) or stroke hospitalisation audits (Australian Institute of Health and Welfare, 2013; National Stroke Foundation, 2009, 2010b) reported on adverse health outcomes that are the focus of the prospective studies in this thesis, namely: aspiration pneumonia, dehydration, urinary tract infection, and constipation. To this end, an incidence study was conducted using the South Australian database for hospital separations over 14 years from July 2000 to June 2014. The outcomes of this study are reported in Chapter 3 including the incidence of stroke and stroke related dysphagia in SA, and the incidence of aspiration pneumonia, dehydration, urinary tract infection and constipation in this sample of stroke patients. These figures are compared with the incidence of the same complications in a sample of general hospital admissions to determine whether, as hypothesised, patients admitted following a stroke are at greater risk.

The study presented in Chapter 4 of this thesis aimed to quantify the amount of thickened fluid consumed by hospitalised patients with dysphagia post-stroke in SA. A medical record audit was conducted in 2012 in four acute hospitals and three rehabilitation inpatient facilities in metropolitan Adelaide. Fluid balance charts of patients with stroke-related dysphagia were analysed to determine their thickened

fluid intake and whether any particular demographic or stroke related characteristics were associated with how much they consumed. The information from this audit contributed to the planning and sample size calculation for the RCT presented in Chapter 8.

Before even considering changing practice around thickened fluids, a snapshot was needed about how thickened fluids are supplied and consumption is presently monitored in health institutions around Australia. This was obtained by conducting an on-line survey of health professionals. The results of this survey of current practice are presented in Chapter 5. It summarises, through self-reports of nurses, speech pathologists and dietitians, how thickened fluids are supplied to patients with dysphagia in their workplaces and the processes by which patients' consumption of thickened fluids and hydration status are monitored, thereby contributing information regarding the impact that institutional factors may have on fluid intake and dehydration.

Part III of the thesis advances to the prospective studies of the research agenda. Given the number and variety of reasons that may contribute to the inadequacy of fluid intake, it was thought a more valid comparison of the fluid intake of patients with dysphagia post-stroke would be with other stroke patients who are in hospital but who do not have dysphagia. This would help to determine whether factors other than dysphagia and being prescribed thickened fluids may contribute to an individual's fluid intake, such as being hospitalised following stroke or having multiple stroke co-morbidities. Patients in an institutionalised setting often do not have free access to fluids but rather these are provided to them in finite quantities at prescribed times throughout the day. Furthermore, they may be reliant on staff assistance to obtain and consume drinks because of functional dependency (Kayser-Jones, Schell, Porter, Barbaccia, & Shaw, 1999). There is sparse information in the literature about the fluid intake and hydration of patients who do not have dysphagia post-stroke to determine whether these factors do have an impact. The study presented in Chapter 7 is a prospective cohort study of hospitalised stroke patients without dysphagia. It was conducted in 2009-2012 across three rehabilitation centres in Adelaide, SA. It measured how much patients consumed on average during a week of their inpatient admission, their hydration levels via the biochemistry analysis of

blood samples and their incidence of pneumonia, urinary tract infections, constipation and dehydration, the latter of which are common adverse outcomes of poor hydration. These data provide the aetiology-matched normative data against which similar measures for patients with dysphagia can be more validly compared.

The methods of the two prospective studies of the research agenda, the observational cohort study in Chapter 7 and the RCT in Chapter 8, were designed to be as similar as possible so that findings about fluid intake, hydration status and health outcomes could be compared across these two patient cohorts (those *with* and *without* dysphagia). The methods of both studies are presented in Chapter 6 including the design for each study, ethical approval, inclusion and exclusion criteria, consent processes, assessments, outcome measures and process for analysis of results. The direct comparison of the fluid intake, hydration and health outcomes of patients *with* and *without* dysphagia post-stroke is presented in Chapter 9. The aim of this chapter was to explore whether the fluid intake and hydration status is, as surmised, worse for patients *with* dysphagia compared to their aetiology matched peers *without* dysphagia. If findings support this hypothesis, it can be concluded that dysphagia itself has the greatest influence on these outcomes. The alternative hypothesis is also explored; that stroke co-morbidities or institutional factors influence fluid intake and hydration for all stroke patients.

Finally, **Part IV** concludes the thesis with a summary of the collective study results in Chapter 10 along with a discussion of implications for clinical practice and future research. The findings of the studies together with existing guidelines in the literature are used to develop and discuss new recommendations for practice with the aim of improving the fluid intake, hydration and health status of all patients following stroke. It is hoped that this product of the research can form a solid basis for consultation with experts in dietetics, medicine, nursing and speech pathology to generate practical and measurable clinical guidelines for hydration following stroke.

It should be noted at this point that whilst some studies in this thesis, such as the survey of health professionals, explore patient populations and settings other than stroke and inpatient rehabilitation, most of the unique findings from this research agenda come from the prospective studies conducted in inpatient rehabilitation facilities, with patients in the sub-acute phase post-stroke who are on full oral only
diets (i.e. not receiving supplementary non-oral feeding). In doing so, this thesis makes an original contribution to the knowledge base about the fluid intake and hydration of stroke patients.

Chapter 2: Literature Review

The purpose of this chapter is to present a comprehensive review of the literature in the areas of stroke and dysphagia, with a particular focus on aspiration and dehydration as a consequence of stroke-related dysphagia. Current assessment and management practices for dysphagia in relation to aspiration are reviewed including the prescription of thickened fluids for patients with dysphagia for thin fluids. Also presented is the current knowledge about the fluid intake and hydration of 'at-risk' patients such as the elderly, residents in long-term care facilities and individuals with dysphagia, contextualised against recommended standards for fluid intake and hydration levels. Finally, previous efforts to improve the fluid intake of patients with dysphagia via water protocols are explored. This review of the literature provides a context for the research studies that follow in this thesis by indicating the gaps in current understanding and highlighting how this research will add to the knowledge base in this field. It also informs the methodology of the two prospective studies in this thesis with respect to inclusion/exclusion criteria for recruitment, validity of assessment tools and valid measurement of outcomes.

Stroke in Australia

A stroke occurs when the blood supply to the brain is disrupted. This may be due to a blockage in the artery by a blood clot or plaque (infarct) or due to rupture of the artery (haemorrhage). The disruption of blood flow results in the brain being deprived of oxygen and nutrients and brain cells die. The way in which people are affected by stroke depends on where in the brain the stroke occurs, and on the size of the stroke and therefore extent of brain damage (Norrving, 2014). Stroke may lead to death, coma, total or partial paralysis of one side of the body (hemiplegia), loss or partial loss of sensation to one side of the body (paraesthesia), loss of coordination of movement or poor balance, visual impairment, cognitive impairment, an inability to initiate, plan and sequence voluntary movements (dyspraxia), inattention to one side of the body, incontinence, speech or language difficulties and difficulty swallowing (dysphagia) (Ferro & Fonseca, 2014). The primary focus of the research presented in this thesis is dysphagia but it also explores the impact these other stroke comorbidities have on the outcomes of interest, namely fluid intake and hydration.

To contextualise the size of the problem in Australia, it is estimated that 60,000 Australians have a new or recurrent stroke each year (National Stroke Foundation, 2008, 2012). Stroke is the second biggest cause of death in Australia and a leading cause of disability. One in five people having their first stroke will die within one month and one in three will die within a year. One third of stroke survivors each year will experience permanent disability that may affect their quality of life and ability to function in society (National Stroke Foundation, 2008, 2012). These estimates are based on population studies of stroke incidence from Perth and Melbourne which are described in more detail below. Further studies have been conducted within Australian hospitals to describe the typical profile and outcomes of individuals with stroke and are also described below. The findings of all of these studies are summarised in Table 2.

The North East Melbourne Stroke Incidence Study (NEMESIS) reported that in a geographically defined population during the 12-month study period 1996/97, a total of 381 strokes occurred in 353 people. From these data the researchers calculated a crude annual incidence rate (first-ever strokes) of 206 per 100 000. The mean age of individuals having a first-ever stroke was 72 years for males and 77 years for females. Of those, 20% had died at 28 days post stroke (Thrift, et al., 2000). The stroke incidence study in Perth collected data at three time points from 1989 to 2001. Crude stroke incidence per 100,000 was 191 in 1989/90, 157 in 1995/96 and 128 in 2000/01. The median age of patients having a first-ever stroke during each 12-month study period was 76 years, 79 years and 77 years respectively and the 28 day mortality for first ever strokes was 22%, 23% and 20% respectively (Islam, et al., 2008).

A further study was conducted more recently in Adelaide in 2009/10 (Leyden, et al., 2013). Despite these figures not being included in the National Stroke Foundation (NSF) estimate, this incidence study could be considered the most applicable to this current research given its data collection was in a defined area of Adelaide. In this study, 318 stroke events were recorded in 301 individuals in a designated western area of the city which, according to the authors, has a comparatively older population than the rest of Adelaide and the nation. The crude stroke incidence per 100,000 was 161 and first ever stroke mortality at 28 days was 18%. The majority of strokes were

ischaemic (84%) followed by intracerebral haemorrhage (11%) and subarachnoid haemorrhage (3%), with 3% subtype undetermined (Leyden, et al., 2013).

Interestingly, in developed countries such as Australia, stroke incidence is declining as health promotion and preventative care programs are taking effect, such as smoking cessation, blood pressure and diabetes management programs (Kleinig, Kimber, & Thompson, 2009; National Stroke Foundation, 2010a). However, in Australia, this decline in incidence is being countered by the rapidly increasing ageing population with a net effect that just as many stroke admissions occur annually (Australian Institute of Health and Welfare, 2013).

The studies summarised above were population based incidence studies and, as far as possible, included all people who had been diagnosed with stroke, not only those admitted to hospital. Information about hospitalisations due to stroke was obtained through an Australian Institute of Health and Welfare (AIHW) study of stroke management in Australia (Australian Institute of Health and Welfare, 2013). In 2009/10 there were 35,345 acute hospitalisations across Australia with a principal diagnosis of stroke and 25,800 hospitalisations for rehabilitation care associated with stroke. The average length of stay for stroke hospitalisations was 10.4 days. Stroke hospitalisations accounted for 0.7% of all hospitalisations in 2009/10 but represented almost 3% of all patient days. Males had higher stroke hospitalisation rates than females in all age groups (52% and 48% respectively). The strokes were classified as 48% ischaemic, 29% haemorrhagic and 23% unspecified. Hospitalisation rates increased substantially with age; the majority (70%) of patients hospitalised were aged 65 years and over. Fourteen percent of all stroke hospitalisations ended with death in hospital (Australian Institute of Health and Welfare, 2013). This information is also presented for comparison with the population studies in Table 2.

Finally, information about typical stroke presentations was gleaned from clinical audits conducted in acute and rehabilitation settings by the NSF. In a clinical audit of 3307 patient records in acute services, 53% of patients were males, median age was 77 years, 82% had an ischaemic stroke, 14% died while in hospital, 47% had dysphagia and 10% developed aspiration pneumonia (National Stroke Foundation, 2009). A similar audit of 2985 patient records in rehabilitation facilities post stroke revealed 54% were males, median age was 76 years, 77% had an ischaemic stroke,

1% died while they were in hospital and 40% had dysphagia (National Stroke Foundation, 2010b). This information is also summarised in Table 2.

	NEMISIS (Melb)		Perth		Adelaide	AIHW	NSF audit- acute	NSF audit- rehab
Date	1996/97	1989/90	1995/96	2000/01	2009/10	2009/10	2009	2010
Crude incidence rate per 100,000	206	191	157	128	161			
Mortality rate	20%	22%	23%	20%	18%	14%	14%	1%
Ischaemic stroke					84%	48%	82%	77%
Haemorrhagic stroke					14%	29%		
Male						52%	53%	54%
Ave. age (years) Male/Female	72/77	76	79	77			77	76
Ave. LoS (days)						10.4		
Dysphagia							47%	40%
Aspiration pneumonia							10%	

Table 2 Summary of Australian stroke incidence studies and audits

NEMISIS - North East Melbourne Stroke Incidence Study AIHW - Australian Institute of Health and Welfare NSF – National Stroke Foundation LoS – Length of stay

Not only is the magnitude of the problem of stroke in Australia demonstrated through these studies, but the typical profile of stroke patients is also illustrated. This profile is used to gauge whether the participants recruited to the prospective studies in this present research can be considered typical and whether findings are therefore generalisable to the wider stroke population in Australia. Unfortunately, the incidence of stroke comorbidities or clinical outcomes of interest in this research thesis, namely dysphagia, aspiration pneumonia or dehydration, are not reported by the authors of the population studies. The NSF clinical audits report on dysphagia but only the acute audit reports on aspiration pneumonia. None of the studies include incidence data on the other health outcomes of dehydration, urinary tract infections or constipation. Information about these health outcomes is essential to contextualise the findings of the prospective studies about patients with and without dysphagia post-stroke. Given this gap in the literature, the study on the incidence of stroke and co-morbidities in SA presented in Chapter 3 specifically aims to quantify these comorbidities from a large stroke sample in South Australia.

Acute stroke care focusses on rapid and thorough assessment and early management. Medical management of stroke has made many advances in the last decade. Previously very little could be done medically in the acute phase to minimise the effect of a stroke on an individual. If the person with stroke survived, it was a matter of managing complications and implementing secondary prevention measures. Currently, the main aim of acute ischaemic stroke management is tissue reperfusion either through thrombectomy (recovery of the clot surgically) or through administration of thrombolytic drugs (Intercollegiate Stroke Working Party, 2012; Jauch et al., 2013; National Stroke Foundation, 2010a). Early rehabilitation is also a hallmark of quality stroke care with a focus on improving function and/or avoiding deterioration in function to maximise independence. Recovery from the effects of stroke through rehabilitation is thought to be due to the reorganisation of the relationships between brain structures and functions, a process known as neuroplasticity. Intensive and task directed therapy is aimed at maximising the neuroplastic properties of the brain so that other parts of the brain can take over the function of the affected area (Kleim & Jones, 2008; Martin, 2009). This concept is discussed later in this chapter with respect to dysphagia rehabilitation.

Dysphagia

Dysphagia, a difficulty swallowing food, fluid or saliva, is a common consequence of stroke. As mentioned previously, an estimated 37% to 78% of patients will have dysphagia as a result of their stroke (Martino, et al., 2005). Dysphagia may occur as a result of decreased strength or coordination of the oropharyngeal muscles because of a disruption of the neurological control of swallowing anywhere along the motor control pathway. Furthermore, stroke can disrupt sensation to the oropharyngeal structures which can have an impact on the oral preparation of food and also result in poor airway protection (Logemann, 1998).

For descriptive purposes, the act of swallowing is typically divided into a number of phases. These may include the pre-oral preparatory, oral, pharyngeal and oesophageal phases, defined according to the location of the bolus (Matsuo &

Palmer, 2008). Dysphagia as a result of stroke commonly affects the oral phase of swallowing, particularly the ability to chew and control solids and hold liquids in the oropharynx. Delayed oral transit is a common problem (Logemann, 1998; Mann, Hankey, & Cameron, 1999). The pharyngeal phase of swallowing can also be affected, particularly the ability to initiate a swallow at all or quickly enough to protect the airway (Logemann, 1998). In one study of swallowing immediately poststroke, a delayed or absent swallow response was found in 49% of cases and laryngeal penetration in 44% of cases (Mann, et al., 1999). It is often the delay in the initiation of the swallow that puts stroke patients at particular risk of aspirating thin fluids which move quickly and are harder to control intra-orally than thicker liquids or solids. It is widely accepted that patients with dysphagia as a result of stroke are more likely to aspirate thin fluids compared with thicker or solid consistencies (Bulow, Olsson, & Ekberg, 2003; Kuhlemeier, Palmer, & Rosenberg, 2001; Logemann, 1998).

Consequences of Dysphagia Following Stroke

Dysphagia at its most severe can lead to aspiration, lower respiratory tract infection (pneumonia), choking or complete airway obstruction, hypoxia and death (Daniels et al., 1998; Kedlaya & Brandstater, 2002; Schmidt, et al., 1994; Smithard et al., 1996; Teasell, Bach, & McRae, 1994). Mortality rates reported for patients with dysphagia post-stroke vary. In a study of 88 acutely hospitalised patients in Western Australia with dysphagia post-stroke, 9% had died within the follow up period of 30 days (Langdon, Lee, & Binns, 2007). Other studies report relative risk ratios. The presence of dysphagia during the acute phase of stroke was associated with a two-fold increase risk of mortality compared with patients without dysphagia (Smithard, Smeeton, & Wolfe, 2007). In the rehabilitation setting, patients with dysphagia have a 13 times greater risk of mortality during their hospitalisation than those who do not (Altman & Yu, 2010).

Mortality associated with dysphagia post-stroke is strongly linked to the increased risk of aspiration and aspiration pneumonia for these patients. Aspiration pneumonia is the most common cause of death in patients with dysphagia of a neurological origin (Marik, 2001). If elderly patients develop aspiration pneumonia, even if identified and treated, their mortality rates are higher, ranging from 40% to 71%

(Kayser-Jones & Pengilly, 1999). Much of the speech pathology literature about dysphagia, therefore, discusses the importance of assessing for and minimising aspiration risk for patients with new strokes (National Stroke Foundation, 2010a). This will be discussed in more depth later in the chapter.

In the longer term, if dysphagia is unrecognised and left untreated, it can lead to malnourishment, weight loss and dehydration (Foley, et al., 2009; Kedlaya & Brandstater, 2002). Malnutrition and dehydration have an enormous impact on physical and cognitive function, recovery and quality of life. Without adequate nutrition and hydration patients may be more susceptible to low blood pressure, falls, pressure ulcers, infection and organ failure (Weinberg, et al., 1995). Malnutrition is reported to be present in up to 30% of patients post-stroke (Crary, et al., 2013; Davis, Wong, Schluter, Henderson, & O'Sullivan, 2004; Dennis, et al., 2006; Martineau, Bauer, Isenring, & Cohen, 2005; Yoo et al., 2008) and is associated with a worse outcome and a slower rate of recovery from stroke (Davis, et al., 2004). Some authors contend that stroke patients with dysphagia are more at risk of malnutrition due to inability to eat and drink normally (Martineau, et al., 2005) whereas others have found no difference in the rates of malnutrition between patients with and without dysphagia in an acute setting (Crary, et al., 2013). Of concern is that the risk of malnutrition increases with increasing duration of hospital stay (Yoo et al 2008). Dehydration will be discussed in depth later in this chapter.

Dysphagia can also result in patients being unable to swallow the medications that are required to treat their underlying medical conditions such as high blood pressure or diabetes, or the stroke co-morbidities such as depression or spasticity, which puts their health at further risk. In recognition of this, most stroke clinical guidelines recommend that alternative routes for the administration of medication be considered as soon as a patient has been diagnosed with dysphagia post-stroke (Intercollegiate Stroke Working Party, 2012; National Stroke Foundation, 2010a). Recently, researchers have highlighted the concerns for absorption of medication when administered with thickened fluids, discovering that drug release may be retarded by the thickening agents themselves (Cichero, 2013). This finding is particularly relevant to the present research agenda, as all patients with dysphagia in the prospective study are reliant on oral only diets and have been prescribed thickened fluids.

From a health economics point of view, dysphagia has a significant impact on hospital resources and length of stay, and hence on expenditure (Odderson, Keaton, & McKenna, 1995). The presence of dysphagia is associated with a 40% increase in the length of stay in all age groups. The longer hospital admission is compounded by costs associated with additional diagnostic studies, possible orotracheal intubation and enteral feeding tube placement (Altman & Yu, 2010; Mann, Hankey, & Cameron, 2000).

As can be seen from the above discussion, dysphagia can have significant consequences for the individual and the health system. In the next sections of this literature review, the consequences of dysphagia of most relevance to this research agenda, namely aspiration pneumonia and dehydration, are discussed in detail.

Aspiration and Pneumonia

Aspiration occurs when gastric or oropharyngeal contents (i.e. food, fluid or saliva) are misdirected into the larynx below the level of the true vocal folds or lower respiratory tract. The prevalence of aspiration following stroke is between 20% and 50% (Horner, Massey, Riski, Lathrop, & Chase, 1988; Splaingard, Hutchins, Sulton, & Chaudhuri, 1988). Aspiration pneumonia may result from a single incident of aspiration or prolonged chronic aspiration. Aspiration of colonised secretions from the oropharynx is the primary mechanism by which bacteria gain entrance to the lungs (Marik, 2001).

A systematic review by Martino et al. (2005) analysed not only the incidence of dysphagia and aspiration after stroke but also the incidence of pulmonary complications. The rates of pneumonia were reported from seven studies: four conducted in acute settings and three in rehabilitation. Incidence rates of pneumonia in the acute settings varied between 16% and 33% for patients with dysphagia compared with rates ranging from 2% to 16% for patients without dysphagia. For patients with dysphagia in rehabilitation settings, incidence rates of pneumonia ranged from 7% to 29%. The authors completed a pooled analysis and concluded that there was a 3-fold increase in pneumonia risk among patients who have dysphagia

post-stroke and an 11-fold increase in risk among a subset of more severely impaired patients with confirmed aspiration (Martino, et al., 2005).

However, while aspiration is a pre-requisite for aspiration pneumonia, not all who aspirate will develop a lower respiratory tract infection. Healthy adults aspirate small amounts of oropharyngeal secretions during their sleep. Because they are able to cough forcefully and have active ciliary transport and normal immune mechanisms, they are able to clear the aspirate without consequence (Marik, 2001). It is recognised that factors other than dysphagia contribute to the risk of developing pneumonia. Langmore et al. (1998) followed 189 elderly patients (over 60 years of age) from outpatient clinics, acute care wards and nursing home care for up to four years to determine the most significant predictors of developing aspiration pneumonia. They evaluated risk factors such as dysphagia, medical conditions, functional status, feeding status and oral/dental health. Twenty one percent (21%) of their subjects developed aspiration pneumonia at an average time of 11 months post baseline measure. The highest incidence of aspiration pneumonia occurred in the nursing home population (44%) and the factors significantly associated with pneumonia were the presence of chronic obstructive pulmonary disease (COPD), dysphagia and dependency for feeding. For the hospital inpatients and outpatients, the highest predictor of pneumonia was the number of decayed teeth. The medical conditions most predictive of pneumonia were COPD, gastrointestinal (GI) disease, congestive heart failure and stroke. The subjects with both COPD and GI disease had the highest rate of pneumonia at 50% incidence rate. For all subjects, the highest predictors of aspiration pneumonia were being tube fed or dependent for oral care. Langmore et al (1998) concluded that the development of aspiration pneumonia is multi-factorial and no single predictor can cause the disease. They recommend that clinicians focus on treatment of all risk factors, not just dysphagia, in order to prevent aspiration pneumonia i.e. implement safe feeding techniques, provide dental treatment as required, provide aggressive oral hygiene and aggressive suctioning of oro-pharyngeal secretions, as well as increase activity levels and sitting out of bed to improve pulmonary clearance (Langmore, et al., 1998).

Adding further detail to issues raised in the seminal paper by Langmore et al (1998), Marik (2001) reported that the characteristic of the aspirate is also crucial in determining the risk of pneumonia in terms of the volume aspirated, the pH level and the bacterial load (Marik, 2001). A greater volume of aspirated material poses more risk than a trace amount. Acidic substances cause the greatest damage to lung tissue; the more pH neutral a substance the less harm it is likely to do to the pleural linings. If the substance carries a high bacterial load it is more likely to become colonised in the lungs and cause infection (Marik, 2001). This has implications for the diet and fluids health professionals prescribe to patients with dysphagia. It has been demonstrated that thickened fluids or solids are more harmful if aspirated than thin. The odds ratio of developing pneumonia or of dying is 9.2 times greater if a patient aspirates thickened fluids or more solid substances as compared with thin fluids (Schmidt, et al., 1994). Speech pathologists prescribing thickened fluids because of their concern about their patient aspirating thin fluids, need to be confident in their diagnosis as, paradoxically, they may expose their patients to greater risk if the prescribed thickened fluids are not swallowed safely at all times.

As reported by Langmore et al (1998) and reinforced by subsequent studies, the individual's overall health status also impacts on the ability to tolerate and defend the body against aspiration pneumonia. Of particular importance is the individual's immune status, the efficiency of their pulmonary clearance and their oral hygiene (Brady, Furlanetto, Hunter, Lewis, & Milne, 2006; Langmore, et al., 1998; Terpenning et al., 1993; Yoneyama et al., 2002). If an individual is immuno-suppressed for any reason, they are less likely to tolerate small amounts of aspiration before developing lung complications. Furthermore, if they have COPD, other lung conditions, immobility or are a current smoker, they are likely to have more difficulty clearing aspirated material in the way the respiratory system normally clears foreign material (Good-Fratturelli, Curlee, & Holle, 2000; Langmore, et al., 1998). Criteria for the RCT presented in Chapter 8 were based on this literature; individuals with poor immune status or COPD were excluded.

Good oral hygiene is increasingly being seen as important in preventing pneumonia in patients with dysphagia (Brady, et al., 2006). Having a clean mouth by removing dental plaque and traces of food is a crucial factor in maintaining the health of the mouth, teeth and gums for all individuals (South Australian Dental Service, 2004). Patients with dysphagia post-stroke are at increased risk of poor oral hygiene for a

number of reasons. They often have reduced movement of and sensation to their oral structures. If the patient's tongue is not constantly moving in their mouth and having contact with their teeth or food, the papillae on the surface of the tongue can become overgrown. These papillae can harbour bacteria from the food debris and plaque which results in a discoloured and odorous tongue. In turn, these oral bacteria can colonise and lead to pathogenic saliva. When this mixes with food or fluid or normal secretions and is aspirated, pneumonia may be the result. If an individual's mouth is kept clean through routine oral hygiene, it is less likely that colonised bacteria will be transported into the lungs along with the aspirated substance. It is recognised that the risk of aspiration pneumonia is lower in patients without teeth and in elderly patients in institutional settings who receive aggressive oral care (Brady, et al., 2006; South Australian Dental Service, 2004; Terpenning, et al., 1993; Yoneyama, et al., 2002). Patients post-stroke may need assistance with oral care in order to maintain good oral hygiene. They may experience fatigue, have poor sitting posture and balance, reduced dominant upper limb activity or reduced insight. Additionally, they may be on medications that cause dry mouth (Langmore, et al., 1998). In recognition of the importance of good oral health for minimising the risk of aspiration pneumonia, oral health assessments and strict oral hygiene routines were implemented with all participants in both of the prospective studies of this present research.

Assessment of Dysphagia

Given the significance of the potential consequences of dysphagia, it is essential that swallowing difficulties are recognised early to allow appropriate and timely management. There are three approaches that can be taken to identify the presence of dysphagia: use of an initial screening test, a clinical examination or instrumental testing. All play a role in dysphagia management but each should be used for its specified purpose. An initial screening test is commonly administered to a newly admitted patient by any trained member of the health care team. The purpose of screening is to identify the likely presence or absence of dysphagia. Early swallow screening is becoming increasingly recognised as crucial to a patient's outcome, recovery and length of stay. Adherence to dysphagia screening protocols has been shown to reduce the incidence of pneumonia in acute stroke patients (Hinchey et al., 2005; Odderson, et al., 1995; Perry & Love, 2001) and is therefore mandated in many stroke clinical guidelines world-wide (Intercollegiate Stroke Working Party, 2012; Lindsay, Gubitz, Bayley, Phillips, & Canadian Stroke Best Practices and Standards Advisory Committee, 2013; National Stroke Foundation, 2010a). Many screening tools include a water test but, as identified in a systematic review, these vary greatly in terms of their administration and interpretation (Martino, et al., 2005). For example, the amount of water patients are asked to swallow ranges from 10ml to 150ml; some tests require patients to take small sips and others consecutive swallows as quickly as possible; some performance is timed and normed, while other tests have dichotomous pass or fail interpretation (DePippo, Holas, & Reding, 1992; Gottlieb, Kipnis, Sister, Vardi, & Brill, 1996; Hughes & Wiles, 1996; Kidd, Lawson, Nesbitt, & MacMahon, 1993; Lim et al., 2001). The authors of these water tests also report varying sensitivity and specificity for their tests. Increasingly, validated swallowing screening tools are becoming available, particularly for the stroke population (Antonios et al., 2010; Martino et al., 2009).

If the presence of dysphagia is suspected, a more comprehensive clinical assessment is conducted by a more extensively trained clinician, usually a speech pathologist. A clinical assessment typically includes gathering history from the medical records and patient or family, observing conscious status, cognition and cooperation to determine ability to participate in an assessment, and gauging posture and respiratory status. The examination usually incorporates an oro-motor assessment, including testing of cranial nerve function, and observation of voice quality and protective oropharyngeal reflexes. Finally, oral trials of various food or fluid consistencies are conducted with observation of oral control, swallow initiation, hyo-laryngeal movement and postswallow respiration and voice quality. There are few published clinical assessment tools, with varying reported sensitivity and specificity results (Linden, Kuhlemeier, & Patterson, 1993; Mann, 2002). A systematic review revealed that although clinical assessments are safe and easy to administer, they have variable sensitivity (42% to 92%), specificity (59% to 91%), and interrater reliability (κ =0 to 1.0) (Ramsey, Smithard, & Kalra, 2003). They are also poor at detecting silent aspiration. Clinicians fail to identify approximately 40% of aspirating clients on clinical examination (Linden, et al., 1993; Linden & Siebens, 1983; Logemann, 1998). A major criticism of clinical assessments is that patients who aspirate silently are likely to be incorrectly diagnosed and therefore mismanaged. Use of a clinical assessment alone to classify participants as 'aspirators' is also, therefore, a frequent criticism of dysphagia intervention research.

Results from a clinical examination may indicate the need for further testing with instrumentation to determine the mechanism of the swallowing disorder. Furthermore, when a patient is suspected of aspirating, an instrumental assessment is the only approach that can confirm this diagnosis. The instrumental test considered by many to be the gold standard, by which the accuracy of other techniques is compared, is a videofluoroscopic swallow study (VFSS). During VFSS, the patient is placed in a sitting position and radiopaque materials of different liquid and food textures are presented for swallowing. The videofluoroscopic image, displayed in real time, shows the bolus move from the lips to the oesophagus, allowing a view of the swallowing anatomy and timing and any associated penetration or aspiration of food or fluid into the airway. There are varying protocols for the administration of VFSS and for the interpretation of results (Martin-Harris & Jones, 2008). Some clinicians use standard protocols; many more use protocols tailored to their individual institution and client group (Speech Pathology Association of Australia Limited, 2013). Unfortunately, there is poor inter-rater reliability between clinicians in the interpretation of findings on VFSS, even for the highly salient observations of laryngeal penetration and aspiration (Wilcox, Liss, & Siegel, 1996). Videofluoroscopy has other disadvantages: it is difficult to perform if a patient is unable to sit upright or has cognitive impairment and is unable to cooperate with instructions; there is an amount of radiation exposure; food and liquids are altered from normal viscosity by the addition of barium; and the short duration of the study means the swallows captured during the examination may not be representative of eating and drinking performance over an extended time period (Martin-Harris & Jones, 2008; Sonies, 1991).

An equally valid instrumental assessment of swallowing is the fibreoptic endoscopic evaluation of swallowing (FEES) (Langmore, 2001). The endoscope accommodating a camera is placed through the patient's nose into the hypopharynx and gives a view of the laryngeal inlet as the individual swallows. Unique to FEES is the ability to directly test sensation of the laryngeal and pharyngeal region and observe aspiration of saliva. Other advantages of FEES are that it is portable and can go to a patient's

bedside and there is no radiation exposure. A downside to FEES is that there is a whiteout period at the time of the swallow so aspiration can only be inferred from entry of the bolus into the airway pre-swallow or from residue after the swallow. A further disadvantage is that patients have varying tolerance of the nasendoscope (Hiss & Postma, 2003; Logemann, 1998; Sonies, 1991).

Instrumental assessment, despite the disadvantages detailed above, is by far the most sensitive and specific approach for identifying dysphagia and aspiration (Martino, et al., 2005; Ramsey, et al., 2003). However, it is not always a viable option for all patients or accessible for all clinicians. This prompted researchers to investigate which clinical signs correlate most closely with aspiration on an instrumental assessment. The following clinical signs were significantly associated with VFSS evidence of aspiration: dysphonia, delayed swallow response and reduced pharyngeal peristalsis (Horner, et al., 1988); incomplete bolus clearance from the oral cavity, delay in oral transit time, impaired palatal function, and impaired pharyngeal response (cough/gurgle) (Mann & Hankey, 2001); both weak cough and dysphonia (Horner & Massey, 1988); abnormal pharyngeal sensation and abnormal water test (Kidd, et al., 1993); a combination of wet-hoarse voice quality and impaired pharyngeal gag reflex (Linden & Siebens, 1983); mild, moderate or severe dysphonia, wet, harsh or breathy phonation, abnormal or absent laryngeal elevation, wet spontaneous cough, abnormal palatal gag, and some or no swallowing of secretions (Linden, et al., 1993).

Perceptual findings from clinical assessment can be augmented by other tools available at bedside such as cervical auscultation using a stethoscope and pulse oximetry monitoring. The focus of much of the literature on cervical auscultation is in the procedural aspects of using this tool: the equipment, the site of placement and how to interpret the sounds (Cichero & Murdoch, 2002). In terms of detecting aspiration, Stroud et al (2002) found that speech pathologists could not reliably identify swallows with aspiration and those without (Stroud, Lawrie, & Wiles, 2002). There tended to be a problem of over detection of aspiration, potentially resulting in unnecessarily restrictive diets. Although pulse oximetry is quick and non-invasive, researchers have found low sensitivities/specificities in detecting aspiration. Combined with a clinical assessment, however, pulse oximetry conducted during a

water test correctly identified 86% penetration/aspirators in patients with dysphagia following acute stroke (Smith, Lee, O'Neill, & Connolly, 2000).

In summary, clinical assessments can be useful to identify swallowing impairments and gain an overview of a patient's functional ability to eat and drink. However, to identify aspiration and diagnose the underlying mechanisms contributing to dysphagia objectively, instrumental assessment is required. For research studies, in which interventions to minimise aspiration are being evaluated, instrumental assessment of swallowing is mandatory. The methodology for assessment in the two prospective studies in this thesis, as presented in Chapter 6, was guided by this extensive review of literature regarding assessment of dysphagia.

Management of Dysphagia After Stroke

For the majority of stroke patients with dysphagia, swallowing improves within days and impairment often resolves after two weeks. For others, dysphagia may persist for months or years (Mann, et al., 1999; Martino, et al., 2005; Smithard, et al., 1996). The purpose of the speech pathology assessment of dysphagia is to accurately assess the nature and degree of impairment and to determine appropriate management. Unfortunately, the evidence base for dysphagia interventions varies in its quality and uptake by practising clinicians (Carnaby & Harenberg, 2013).

For many acute stroke patients, speech pathology management takes a compensatory approach, aiming to minimise complications while dysphagia improves spontaneously. Compensatory interventions may include dietary modifications of food and fluid, advice on safe posture and strategies for eating, behavioural manoeuvres such as voluntary airway protection and effortful swallowing and implementing oral hygiene regimes (Logemann, 1995). If the dysphagia is severe, it may be recommended that the patient remain nil orally and be temporarily nourished and hydrated via an alternative route such as intravenous therapy (IVT) delivering dextrose or saline solutions, subcutaneous fluids (hyperdermoclysis), or enteral feeding tube, usually nasogastric tube (NGT) or a percutaneous endoscopic gastrostomy (PEG). Notably, it has been found that enteral instead of oral feeding does not necessarily negate the risk of aspiration pneumonia (Finucane & Bynum, 1996). Over the long term, aspiration pneumonia is the most common cause of death

in patients fed by gastrostomy (Norton, Homer-Ward, Donnelly, Long, & Holmes, 1996). This is, in part, because feeding tubes offer no protection from colonised oral secretions (Baeten & Hoefnagels, 1992; Park, Allison, & Lang, 1992). Comparing the two enteral feeding methods, it has been reported that NGT feeding was associated with a higher risk of death and worse outcomes, such as being malnourished, when compared with PEG tubes (Norton, et al., 1996; Raymond, 2006). However, results of a larger and higher quality trial indicated that patients fed by NGT were less likely to experience either death or poor functional status when compared to patients fed via PEG (Dennis, et al., 2006). This robust multi-centre, multi-national trial (n=321) has been included in many countries' stroke guidelines. It is now widely recommended that patients who are likely to recover their swallowing abilities within a few weeks should not be considered for gastrostomy and that NGT feeding is the preferred route in the first month post-stroke (Intercollegiate Stroke Working Party, 2012; Marik, 2001; National Stroke Foundation, 2010a).

Direct swallowing therapies are also utilised. These therapies focus on improving swallowing physiology through oro-pharyngeal exercises, thermo-tactile stimulation, transcutaneous neuromuscular electrical stimulation or olfactory stimulation (Logemann, 1995). Some of these therapies are based on evidence which support their efficacy but these are limited and not widely utilised by practising clinicians (Carnaby & Harenberg, 2013). Findings from a survey of speech pathologists suggest great variability in practice patterns in the management of dysphagia. For a single patient case, the 254 speech pathologists who responded to the survey offered 90 different combinations of therapy techniques that they would use to treat this individual, many of which did not directly correspond to the patient's specific symptoms or physiologic abnormality. Furthermore, there was a lack of consistency in the food textures chosen for use in therapy with this patient (Carnaby & Harenberg, 2013).

The authors of a systematic review of 15 randomised control trials of interventions for dysphagia found it difficult to interpret the evidence, as few studies used the same interventions or outcome measures. Nevertheless, they concluded that there was general support for dysphagia interventions, especially when compensatory and direct swallowing techniques were combined with texture modified diets to increase swallowing safety, but that more high quality research was needed (Foley, Teasell, Salter, Kruger, & Martino, 2008).

Despite the poor uptake of the exercise based interventions in dysphagia management, the compensatory strategy of prescribing texture modified food and fluids is very common (Mertz-Garcia, et al., 2005). The exact food and fluid texture speech pathologists recommend is usually based on the patient's observed swallowing abilities and protective reflexes. Foods range in texture from smooth pureed, minced and moist to soft food. Fluids are modified by thickening their viscosity to a level that minimises aspiration risk, from mildly to moderately to extremely thick fluids (Atherton, Bellis-Smith, Cichero, & Suter, 2007). The prescription of thickened fluids in particular is prevalent following stroke because of the known difficulty patients have managing thin fluids (Bulow, et al., 2003; Kuhlemeier, et al., 2001). A survey of 149 speech pathologists in the United States showed that 85% of respondents regularly recommended the use of thickened fluids for patients who are suspected of aspirating thin fluids (Mertz-Garcia, et al., 2005). Fluid intake and hydration of stroke patients with dysphagia is the focus of the research presented in this thesis, so the use of thickened fluids is reviewed in detail in the next section.

Thickened Fluids

Thickened fluids are often recommended when oral control is diminished, the pharyngeal swallow is slow or delayed and when laryngeal closure is reduced (Logemann, 1998). It is argued that patients with a delay in triggering the pharyngeal swallow have less difficulty with thickened than thin fluids because the thicker fluid slides more slowly and often remains in the valleculae during the pharyngeal delay rather than entering the open airway (Logemann, 1998). By thickening a liquid, its flow rate is reduced, it becomes more cohesive and dense and this makes it easier for many patients to control intra-orally (Hamlet et al., 1996; Huckabee & Pelletier, 1999). There is evidence that thickening fluids reduces aspiration occurrence. In a study of patients with mild-moderate dysphagia, significantly less laryngeal penetration and tracheal aspiration was found with nectar-thick fluids than thin fluids, and significantly less penetration and aspiration was found with ultra-thick

fluids than nectar-thick (Kuhlemeier, et al., 2001). Other researchers also found significantly less airway penetration /aspiration with thickened fluids than with thin fluids in a videofluoroscopic study of patients with dysphagia of a neurological origin (Bulow, et al., 2003).

More recently, however, authors have found that very thick fluids require greater tongue and pharyngeal muscle strength to propel the bolus through the oropharynx and hypopharynx which results in greater pharyngeal residue (Clavé et al., 2006; Steele & Huckabee, 2007). While most of these studies to date have been conducted with healthy adults, authors urge caution when prescribing thickened fluids. Clinicians need to identify a consistency that is thick enough to be swallowed safely by preventing aspiration before and during the swallow while avoiding the potential of aspiration post swallow from pharyngeal residue (Steele et al., 2014). Furthermore, there is limited empirical evidence of the medical effectiveness of fluid intake (Foley, et al., 2008; Goulding & Bakheit, 2000). Authors reporting positive effects of thickened fluids in reducing aspiration risk agree that further research is required to define the clinical value and therapeutic effect of treatments on chest infection, nutritional status, hydration and mortality (Clavé, et al., 2006).

It is well recognised that evidence based practice integrates empirical evidence from scientific research, clinical skills and judgement, and patient preferences and values (Hoffmann, Bennett, & Del Mar, 2009). Interestingly, patient preference does not always coincide with the most effective treatment regime for minimising aspiration risk. In a study of patients with progressive neurological disease, the most effective strategies for reducing aspiration were found to be the prescription of honey (moderately) thick fluids, followed by nectar (mildly) thickened fluids, then use of a chin-tuck posture. However, patients predominantly preferred the chin-tuck posture strategy over fluids thickened to either consistency (Logemann et al., 2008). Patient compliance with swallowing recommendations has received limited attention in the literature. In one study of patient adherence at an acute hospital, 39% of 140 patients diagnosed with dysphagia died and in 52% of these cases aspiration pneumonia was the definite or probable cause of death. For seven patients whose records included a deliberate and documented decision not to comply with dysphagia recommendations,

six died. Furthermore, 21% of the survivors never complied with the swallowing advice given. These non-compliers had significantly more chest infections, courses of antibiotics and hospital readmissions (Low, Wyles, Wilkinson, & Sainsbury, 2001). Colodny (2005) investigated the reasons patients gave for non-compliance with swallowing recommendations. Several themes emerged, including a denial of swallowing difficulties and being prepared to take a calculated risk of the consequences. A strong theme of interest to this thesis was the dissatisfaction with modified preparations such as thickened liquids or pureed foods. Typical complaints toward thickened fluids included an aversion to the taste, feeling full, and a sensation of constant thirst (Colodny, 2005). Free water protocols were developed (Panther, 2005) in recognition of the issue of patient non-compliance, particularly with thickened fluids. The use and effectiveness of water protocols is a main emphasis of this present research and relevant literature is further discussed towards the end of this chapter.

Another concern about thickened fluids is whether patients drink enough and whether the benefits of minimizing aspiration through the prescription of thickened fluids outweigh the risk of dehydration. The next section of this chapter discusses the issues of oral fluid intake and hydration.

Hydration and Dehydration

Water is an essential nutrient. It accounts for 50-80% of a human's body weight, filling the spaces in and between cells. It is required for digestion, absorption, transportation and suspension of nutrients, eliminates waste and regulates the body's temperature. The body needs approximately 2,500 to 3,000ml of water per day. It produces approximately 250ml of this from metabolism and the remainder is consumed from food and fluids (Kleiner, 1999).

If the body does not get the water it needs, a condition of dehydration may develop. Dehydration is a term used to reflect several physiological states based on the imbalance between intake and loss of water and the accompanying sodium status (Leibovitz, et al., 2007; Thomas et al., 2008). It can arise from water depletion, sodium depletion or both. In the strictest physiological sense, dehydration refers to a loss of total body water from within the cells of the body. In a clinical sense,

dehydration may also be used to describe a condition of volume depletion, usually from a loss of extracellular fluid in the vascular system. Different types of dehydration can occur depending on the antecedent; a complete fast or episodes of vomiting or diarrhoea will lead to a different type of dehydration compared with the overuse of diuretics, or if a person has a fever. The type of dehydration that is the focus of this present research is volume depletion from decreased fluid intake, most commonly referred to as hypernatraemia (Hodgkinson, Evans, & Wood, 2003; Thomas, et al., 2008).

Measurement of Dehydration

The clinical diagnosis of dehydration is complex and highly variable in any clinical setting. There are clinical correlates with dehydration. These are skin turgor, dry mucous membranes in the mouth, weight loss, reduced axillary sweating, a decline in orthostatic blood pressure, increase in orthostatic pulse, decreased urine output and increased urine concentration, constipation and urinary tract infection (Bennett, 2000). Another commonly used definition of dehydration based on clinical presentation is rapid weight loss of greater than 3% of body weight (Weinberg, et al., 1995). However, all of these findings may also be indicative of other conditions so cannot be interpreted in isolation.

Other measures of dehydration come from biochemical analysis of a blood sample. The measures that are indicative of the body's dehydration status reported in standard international units are: serum osmolality > 300 mmol/kg; serum sodium > 145mmol/litre; urea/creatinine ratio > 80:1 (Weinberg, et al., 1995). Again, it is recognised that these values can all be affected by medical conditions other than dehydration by volume depletion so must be interpreted in context by trained physicians. A change in baseline of these values for an individual may be more significant than absolute values in the elderly with multiple medical conditions (Weinberg, et al., 1995).

For the above reasons, medical diagnosis of dehydration typically relies on a multitude of sources of information: the patient's clinical presentation, urine analysis, weight loss reflecting water depletion and multiple biochemical indices, all considered in the context of other medical conditions such as kidney and cardiac

disorder and medication use (Thomas, et al., 2008; Thomas, Tariq, Makhdomm, Haddad, & Moinuddin, 2003; Wallach, 2007; Weinberg, et al., 1995).

In the literature investigating hydration in the elderly, some researchers argue that biochemical parameters are necessary (Weinberg, et al., 1995), whereas others suggest physical parameters such as systolic blood pressure drop on standing, sternal skin turgor, tongue dryness and body mass index are more reliable (Vivanti, 2008). One measure commonly cited in the dysphagia literature relating to the effect of fluid intake on hydration is the blood urea nitrogen/creatinine ratio (Crary, et al., 2013; Leibovitz, et al., 2007; Rowat, et al., 2012; Whelan, 2001). The most commonly used cut-off point to classify a patient as dehydrated was a ratio greater than 80:1 (Leibovitz, et al., 2007; Rowat, et al., 2012; Whelan, 2001). Urea and creatinine levels are commonly reported in routine blood analysis in inpatient settings and so are readily accessible. The outcome measures for dehydration selected for the prospective studies in this thesis and presented in Chapter 6 were guided by this review of the literature.

Sequelae of Dehydration

Dehydration can lead to impaired physiological reactions and affect physical and cognitive functions. Sudden water depletion can lead to heat exhaustion, loss of consciousness and heat stroke (Cheung & McLennan, 1998). Ongoing poor fluid intake can lead to chronic dehydration and result in hypotension, infection, (particularly urinary tract infections), constipation and delirium (Bennett, 2000; Weinberg, et al., 1995). The hypotension that results from poor fluid intake is a high risk factor for falls which in turn may lead to any number of debilitating conditions such as subdural haemorrhage or fractures. Longer term dehydration can result in kidney failure, urinary tract cancers (Michaud et al., 1999; Wilkens, Kadir, Kolonel, Nomura, & Hankin, 1996), colon cancer (Shannon, White, Shattuck, & Potter, 1996) and mitral valve prolapse (Lax, Eicher, & Goldberg, 1992). Dehydration has an impact on hospitalisation rates, length of stay and ultimately on health care costs (American Medical Directors Association, 2001 Reviewed 2007; Bennett, 2000; Weinberg, et al., 1995).

Dehydration Following Acute Stroke

Adequate hydration after stroke is particularly important. Dehydration may exacerbate confusion in a patient who is cognitively impaired (Mentes, 2006; Thomas, et al., 2008). There is also evidence that the hypotensive effect of dehydration may affect the ischaemic penumbra and influence the evolution of the stroke itself in the acute phase (Britton, de Faire, & Helmers, 1980). Dehydration after an acute ischaemic stroke is strongly associated with an increased risk of venous thromboembolism (Kelly et al., 2004). Raised plasma osmolality may actually induce neurological deterioration and is associated with stroke mortality, whether patients are hydrated orally or intravenously (Bhalla, Sankaralingam, Dundas, Swaminathan, & Wolfe, 2000). Blood urea nitrogen/creatinine ratio greater than 15:1 (61 in standard international units) was found to be an independent risk factor for early neurological deterioration in ischaemic stroke (Bhatia, Mohanty, Tripathi, Gupta, & Mittal, 2015). These authors all call for a systematic approach to correcting dehydration after stroke.

Hydration of the Elderly

An individual's hydration status is affected by his or her fluid intake, weight, sex, metabolic rate and kidney function. External factors such as the environmental temperature and amount of physical activity also impact on hydration status as do physiological factors such as levels of neurotransmitters in the brain and even involuntary activity from tremors and dystonias (Kleiner, 1999; Thomas, et al., 2008). For these reasons, the fluid requirement for each individual to maintain an adequate degree of hydration varies considerably. The amount of fluid an individual consumes under normal circumstances is dictated by their thirst. Thirst is regulated through complex interactions between osmoreceptors and neurotransmitters in the brain (Thomas, et al., 2008).

The elderly are at an increased risk of dehydration for many reasons. They may have decreased fluid intake because of altered thirst sensation. This means they often fail to recognise the need to drink more in response to normal fluid losses (Thomas, et al., 2008). In addition, total body water decreases with age; 80% of a child's weight is water compared with 43.4% of a woman's weight aged 61-74 years and 50.8% of a

man's weight aged 61-74 years. Thus a small decrease in fluid intake can cause proportionately more dehydration in the aged (Bennett, 2000). The elderly are also at risk of increased fluid losses because the kidneys' ability to concentrate urine declines with age. If the elderly person's fluid intake decreases, but urine flow does not, this results in a nett excess of fluid loss and possibly dehydration (Thomas, et al., 2008). Medications commonly taken by the elderly can also affect water losses, particularly diuretics, sedatives, antipsychotics, tranquilizers, and non-steroidal antiinflammatory drugs (Lavizzo-Mourey, Johnson, & Stolley, 1988).

Despite consensus in the literature that the elderly have an increased risk of dehydration, there is still contention as to whether this is solely to do with the ageing process. No differences in water input, output and hydration status (using the measures of plasma osmolality and urine specific gravity) were found between a group of older adults aged 63-81 years and a group of younger adults aged 23-46 years (Bossingham, Carnell, & Campbell, 2005). Similarly, hydration measures of community-living adults aged 65-93 years were within the normal range using the indices of osmolality and urine specific gravity (Morgan, Masterton, Fahlman, Topp, & Boardley, 2003). These researchers contend that dehydration is not solely a function of the ageing process, but may be more related to concomitant medical conditions or dependent living. Other authors urge caution when interpreting prevalence figures about dehydration in the community-living elderly population, claiming the conclusions drawn are dependent on the indices of dehydration used (Stookey, Pieper, & Cohen, 2005). In a large study of over 1700 community-living adults over 70 years of age, the prevalence of dehydration ranged from 0.5% using a measure of plasma tonicity to 60% using the measures of plasma sodium and blood urea nitrogen/creatinine ratio. These researchers found that dehydration was most closely associated with chronic disease and functional impairment (Stookey, et al., 2005).

A systematic review also criticised the contemporary literature reporting on dehydration in the elderly (Hodgkinson, et al., 2003). The authors of the review argued that many of the studies included had poor research design, inadequate reporting of data, were non-randomised and had poor control conditions, and the findings were contradictory about whether older age, female sex, poorer functional

status and incontinence were risk factors for dehydration. They concluded that people who seemed most at risk of dehydration were not the most dependent patients, but rather the semi-dependent people who appear capable of obtaining their own fluids but are not able to achieve this successfully in practice (Hodgkinson, et al., 2003).

Locally, a large population-based longitudinal study, the Australian Longitudinal Study of Ageing (ALSA) examined the health and well-being of community dwelling individuals over 70 years of age (Luszcz et al., 2007). In two of the waves of the study, urea and creatinine were measured from blood samples. With the permission of the research team, the raw data from these two waves of the data collection were used to calculate participants' urea/creatinine ratio as an indication of their hydration status. In wave 1 of the study, as per the research design, participants were evenly distributed across the age groups of 70-74 years, 75-79 years, 80-84 years and over 85 years. The mean urea/creatinine ratio of 1162 participants from wave 1 was 64 (SD 16.17) with 15% of this cohort having results indicative of dehydration using a cut-off point of >80. In wave 3 of the study conducted two years later, the mean urea/creatinine ratio of the 1216 participants was 76.67 (SD 20.36) and 37% of the cohort had results elevated beyond 80, indicating dehydration. The decline in hydration status may be attributed to the increasing age of the cohort. Other reasons cannot be hypothesised as no other background information was available from the original ALSA researchers. This study was invaluable in providing the raw results against which the hydration results of participants in the prospective studies of this thesis could be directly compared.

Elderly people in residential care are considered to be at a higher risk of dehydration than the community-living elderly because, in addition to the factors outlined above about increased risk of dehydration for the elderly, they are usually disabled or debilitated and dependent on others for care (Kayser-Jones & Pengilly, 1999; Kayser-Jones, et al., 1999). Forty-six percent (46%) of elderly residents in a longterm care facility had one or more clinical symptoms of dehydration (Holben, Hassell, Williams, & Helle, 1999). The highest risk for developing dehydration (as measured by blood urea nitrogen/creatinine ratio and serum sodium levels) was found for nursing home residents who had four or more chronic disease conditions (OR 4), took four or more medications (OR 2.8) or were bedridden (OR 2.9) (Lavizzo-Mourey, et al., 1988).

Hydration of Individuals with Dysphagia

Individuals with dysphagia are particularly at risk of dehydration. It is widely recognised that between 40-60% of people in residential care have symptoms of dysphagia further affecting their ability to consume adequate fluids to maintain hydration (Steele, Greenwood, Ens, Robertson, & Seidman-Carlson, 1997). In a study of residents with dysphagia in the long-term care wards of a geriatric hospital, 75% of the orally fed group and 14% of the NGT fed group were dehydrated based on a combination of four dehydration indices from blood and urine samples (blood urea nitrogen, blood urea nitrogen /creatinine ratio, urine/serum osmolality ratio and urine osmolality) (Leibovitz, et al., 2007).

Schmidt et al. (1994) specifically studied a population of patients who had dysphagia as a result of stroke. They grouped the patients as either aspirating or non-aspirating, as demonstrated on videofluoroscopy, and analysed the incidence of death, pneumonia and dehydration. Based on measures of dehydration using serum sodium and blood urea nitrogen (BUN), they found there was no significant difference between the aspirators and non-aspirators and concluded that the intensive dysphagia intervention they provided may have reduced the prevalence of dehydration (Schmidt, et al., 1994). In contrast to these findings, researchers who studied 24 patients with dysphagia following stroke who were prescribed thickened fluids, found six were diagnosed with urinary tract infections, two with hypernatremia, 12 with hyperuraemia and three with hypercreatininaemia (Whelan, 2001). Unfortunately, neither of these studies included a control group of patients without dysphagia against which the hydration status could be compared.

The results of two more recent studies have provided information about the hydration of patients admitted acutely to hospital post-stroke (Crary, et al., 2013; Rowat, et al., 2012). Both research groups included patients with and without dysphagia and both used the blood urea/creatinine ratio as their measure of hydration. However, they used different cut-off points to classify patients as dehydrated. Rowat et al (2012) found that of 2591 patients, 36% were dehydrated on admission to hospital and 62%

were dehydrated at some point in their admission using the urea/creatinine ratio cutoff point of >80. They found the risk factors that were significantly associated with dehydration were older age and female sex (p<0.001), a total anterior circulation stroke as an indicator of severity and dependency (OR 2.61, 95% CI 1.92-3.56) and prescribed diuretics (OR 1.98, 95% CI 1.50-2.59). Patients who were dehydrated were significantly more likely to have poorer outcomes including death and dependency on discharge (Rowat, et al., 2012). Crary et al (2013) used a lower threshold for classifying patients as dehydrated (blood urea nitrogen/creatinine > 15, which equates to 61 in standard units) as previous research had indicated hydration at this level was a risk factor for stroke-in-evolution (Bhatia, et al., 2015). Using this cut-off, 53% of the patients were dehydrated on admission to hospital with ischaemic stroke and 66% were dehydrated at discharge. Patients diagnosed with dysphagia had significantly worse hydration results than patients without dysphagia (Crary, et al., 2013). In response to personal communication with the authors of this study, the raw data of hydration measures were obtained. Patients with dysphagia had an average urea/creatinine ratio (converted to standard units) of 82.95 at admission, worsening to 106.29 at discharge. Those without dysphagia had an average urea/creatinine ratio of 65.22 at admission and 68.13 at discharge (M. Crary, personal communication, 25 March, 2014). These data clearly illustrate the difference in hydration between patients with and without dysphagia in the acute setting. They also provide an invaluable opportunity for direct comparison with the hydration results in the prospective studies in this thesis.

Hydration Guidelines

In recognition of the prevalence of dehydration and its consequences, various health organisations have developed guidelines for certain at risk cohorts, including patients post-stroke. Guidelines for hydration are usually encompassed in the nutrition or dysphagia sections of clinical guidelines for stroke and tend to be secondary to nutrition. For example, the British National Guideline for Stroke (2012) recommends that all stroke patients, on admission, be screened for malnutrition by a trained person using a validated procedure. Further, they recommend that fluid balance and nutritional intake should be monitored in all stroke patients who are at high risk of malnutrition, are malnourished and/or have swallowing problems (Intercollegiate

Stroke Working Party, 2012). They do not qualify, however, specifically how hydration should be screened and how to intervene if found to be sub-optimal. Similarly, the Australian Clinical Guidelines for Stroke Management (2010) suggests that the hydration status of all stroke patients be assessed, monitored and managed but do not specify how. They do specifically mention that the intake of patients on a modified diet should be closely monitored along with their tolerance of and ongoing need for that diet. They also recommend that appropriate fluid supplementation should be used to treat or prevent dehydration (National Stroke Foundation, 2010a). The Canadian Stroke Best Practice Recommendations indicate that stroke patients with suspected nutritional concerns, hydration deficits, dysphagia, or other comorbidities that may affect nutrition (such as diabetes) should be referred to a dietitian for recommendations. They specifically mention referral to a dietitian to meet patients' nutrient and fluid needs orally while supporting alterations in food texture and fluid consistency recommended by a speech-language pathologist or other trained professional (Lindsay, et al., 2013).

A logical strategy for improving a patient's hydration status is to increase their fluid intake. In the next section of this literature review, the fluid intake of various cohorts of the population is explored and contextualised against published standards.

Fluid Intake

Daily fluid intake is the total amount of fluid ingested from food and beverages. The majority of a human's daily fluid intake comes from beverages we drink (water or other fluids), with approximately 20% coming from solid foods. Fluid contribution from food is defined as any non-beverage oral intake such as milk-based puddings, custards, yoghurts, ice-cream, or from fruits or vegetables and soups (National Health and Medical Research Council, 2003). For most people, fluid intake comes from what is consumed orally but for those who are ill or unable to eat and drink normally, it may be supplied enterally, intravenously or subcutaneously.

Measure of Fluid Intake

When reviewing studies that report fluid intake, the source of fluid intake is often defined inconsistently, making appropriate comparisons between studies difficult.

Some researchers measure total fluid intake from food and fluids (Chidester & Spangler, 1997). Others specify that they are measuring beverage intake only (Garon, et al., 1997; McGrail & Kelchner, 2012). In the majority of these studies, beverages are considered to be drinks plus any food that is liquid at room temperature (Finestone, et al., 2001). In other studies, liquid foods such as broth, ice-cream or jelly have not been included as beverage intake (McGrail & Kelchner, 2012).

Furthermore, methods for recording fluid intake vary significantly. Some investigators attempt to measure exact amounts by using fluid balance charts or by weighing food and drinks (Finestone, et al., 2001; Holben, et al., 1999; McGrail & Kelchner, 2012), and others estimate amounts through food diaries, body weight or plate/cup wastage (Vivanti, et al., 2009).

Lastly, interpretation of fluid intake is made in different ways. Some authors report the percentage of participants who meet certain standards of fluid intake even though the standards used vary (Chidester & Spangler, 1997); others report the actual amount of intake in ounces or millilitres (Garon, et al., 1997; Karagiannis, et al., 2011; Whelan, 2001). These variations in methods create difficulty when comparing the results of different studies of fluid intake. The need for clearly defined criteria for measurement of fluid intake for the prospective studies in this thesis was highlighted through this review of the literature.

The Standards for Fluid Intake

Recommendations for the ideal amount of fluid intake per day vary widely. Most standards take into account the weight, sex and age of the person as the body's need for water varies according to these factors. However, the body's need for fluid is also affected by environmental conditions, the level of physical activity and individual metabolism. Whilst this is acknowledged by most authors, it is not very often taken into account when calculating requirements.

Three commonly used standards in the literature as cited in Chidester & Spangler (1997) are: (i) 30mls per kg of body weight (Chernoff, 1994); (ii) 1ml for every calorie of energy consumed (National Research Council Committee on Dietary Allowances, National Research Council Food, & Nutrition Board, 1980); and (iii) 100ml per kg for first 10kg, 50ml for next 10kg, and 15ml per remaining kgs

(Skipper, 1998). Some researchers have used these formulae and determined that for an adult weighing between 50 and 80 kilograms, an intake of 1500ml to 1600ml per day is required to meet minimum fluid requirements (Gasper, 1999; McGrail & Kelchner, 2012).

Recommended daily intakes of fluids have been published in various countries for the general healthy population. The Australian and New Zealand Nutrient Reference Values of 2006 were established based on median population intakes in Australia across various age groups (Australian National Health and Medical Research Council, 2005). A total water intake from food and fluids of 3400ml per day is recommended for adult males, with 2600ml coming from beverages; and a total of 2800ml is recommended for females per day, with 2100ml from beverages. A similar national survey of health and nutrition in the USA found an average fluid intake for the general population of 3180ml, with 2580ml coming from beverages (Kant, Graubard, & Atchison, 2009) and subsequent reference values were based on this (Institute of Medicine of the National Academies, 2004). The World Health Organization has also published recommended standards that take into account various climates and working conditions (Grandjean, 2005). The actual amounts recommended are tabulated in Table 3 below.

Recommended Adequate Intakes of beverages per day	Male	Female
US and Canada (Institute of Medicine of the National Academies, 2004)	3000ml	2200ml
Australia and New Zealand (Australian National Health and Medical Research Council, 2005)	2600ml	2100ml
World Health Organization	2900ml	2200ml
Hard labour, hot climate (Grandjean, 2005)	4500ml	4500ml

	Table 3 Recommended	daily	beverage intake	by peak	organisations	world-wide
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Fluid Intake of the Healthy Elderly

The fluid intake of patients following stroke is the main focus of this thesis. The majority of strokes occur in the older age groups, as can be seen from average ages

of stroke cohorts in Table 2. It is pertinent, therefore, to review the literature about the fluid intake of the elderly as a sub-group of the healthy population. The Australian Longitudinal Study of the Aging measured many parameters of Australians over 70 years, including their fluid intake. Researchers found the average intake of beverages for older Australian males was 1868mls and 1909mls for females (Luszcz, et al., 2007).

Other authors confirm that the majority of independently living elderly, without major health problems, drink enough fluid to maintain adequate hydration. Investigators comparing an older group of adults aged between 63 and 81 years and a younger group aged between 23 and 46 years found that age did not influence water intake from drinks. On average the younger group of men drank 1720ml of water, the older men 1830ml, the younger women 1350ml and the older women 1640ml. The total fluid intake (i.e. from food and beverages) for the older men was 3700ml and for the older women was 3300ml (Bossingham, et al., 2005). In contrast, a study of over 4000 adults over the age of 65 years living independently in Germany revealed a much lower intake of beverages. Median beverage consumption for men was 1567ml and 1400ml for women. The total fluid intake for each group was 2387ml and 2224ml respectively. This was an age stratified study and the authors did find that beverage intake and total fluid intake decreased in both sexes with increasing age (Volkert, Kreuel, & Stehle, 2005). In a published survey of the literature, authors reported that very few studies quoted absolute figures for fluid intake in the healthy elderly. However, they furnished a figure of 2100ml as the amount that the healthy elderly drink per day. The authors of this systematic review concluded that there is no evidence in the literature that the healthy elderly drink any less than young adults and that, when determining the amount of fluid to administer to an individual elderly patient, the amount should not be underestimated (Bastiaansen & Kroot, 2000).

The only known study that compared the intake of hospitalised patients with and without dysphagia with a cohort of community dwelling older adults found that the healthy adults living at home consumed on average 1961ml (SD 529ml) per day (McGrail & Kelchner, 2012). The results from this study for the hospitalised patients with dysphagia are presented in a later section of this chapter.

In summary, the fluid intake of the healthy elderly is on par or just slightly below what is recommended for the general population of adults. The fluid intake from each of these studies is presented graphically in Figure 1 at the end of the chapter.

Fluid Intake of Patients in Residential Care

Fluid intake of elderly patients in residential care has been widely reported in the literature (Armstrong-Esther, Browne, Armstrong-Esther, & Sander, 1996; Chidester & Spangler, 1997; Gasper, 1999; Hodgkinson, et al., 2003; Holben, et al., 1999; Oh, Hur, & Kim, 2006). This cohort is considered at risk of poor fluid intake for a number of reasons. They may only be offered fluids when staff or family are available, usually only at prescribed meal or snack times. They are usually dependent on others for mobilising and positioning and likely to be unable to source fluids themselves. They may have cognitive impairment and be unable to recognise the need to drink. Communication difficulties associated with aphasia, dementia or being unable to speak English may mean they are unable to ask for a drink (Kayser-Jones, 2006; Kayser-Jones, et al., 1999). Furthermore, they may refuse food and fluids due to cognitive/behavioural problems associated with dementia and of course many residents have dysphagia (Steele, et al., 1997).

The fluid intake of participants in these studies varies considerably. A study of 121 nursing home residents found the average total fluid intake of 1982ml per day which met the requirements for all three standards as described above (Holben, et al., 1999). Authors of another study of 99 nursing home residents found an average daily intake of 1968ml with a mean from beverages of 1468ml but reported that only 8% of the residents met their standard of 1600ml (Gasper, 1999). Chidester and Spangler (1997) found a mean fluid intake of 1632ml for 40 nursing home residents. The percentage of those with fluid intakes below standards (i), (ii) and (iii) described above were 52%, 60% and 90% respectively but the authors argued that calculations of fluid requirements based on standards (i) and (ii) were unrealistically low when given the consensus opinion that a minimum of 1500ml is required per day. They considered that standard (iii) (100ml per kg for first 10kg, 50ml for next 10kg, and 15ml per remaining kgs) is the most appropriate standard to be applied in the nursing home setting given that nursing home residents are frequently underweight and have low energy requirements. Other investigators have reported much lower intakes. One

group reported an average fluid intake for 111 nursing home residents of 1035ml, with 52% having inadequate intake (Oh, et al., 2006). Patients on a geriatric assessment unit, a psychogeriatric unit and a long term care unit had an average fluid intake of 1141ml, 1118ml and 1002ml respectively, all below the recommended intake of 2000-2500ml per day (Armstrong-Esther, et al., 1996). As can be seen from the above summary, not only do the fluid intake amounts vary considerably from study to study but so too do the standards that each apply to determine adequacy of intake. In order to summarise the findings of these many studies, the fluid intake of the elderly in residential care is illustrated alongside the other cohorts in Figure 1 at the end of the chapter.

In a systematic review of hydration in the elderly, Hodgkinson et al. (2003) reinforced that it is difficult to determine the adequacy of fluid intake in this population as there is no single recommended daily intake (RDI) measure and all studies used different RDIs. They did comment that the fluid received by patients when taking medications was found to be essential to patients meeting their RDI (Hodgkinson, et al., 2003).

Fluid Intake of Patients with Dysphagia

The adequacy of fluid intake for patients with dysphagia following stroke has long been of concern and has been the focus of several studies conducted in both the acute setting (Finestone, et al., 2001; McGrail & Kelchner, 2012; Vivanti, et al., 2009; Whelan, 2001) and in rehabilitation (Patch, Mason, Curcio-Borg, & Tapsell, 2003). The results of these studies in terms of thickened fluid intake are discussed below and are illustrated in Figure 1 at the end of the chapter.

In a small but often cited study by Finestone et al. (2001), the fluid intake of patients with dysphagia post-stroke on an oral diet only, including thickened fluids (n=7), was compared with a group who received enteral or intravenous feeding (n=6). The average fluid intake of the orally fed group was 755ml (SD=162ml) and for the non-orally fed group was 3158ml (SD= 23). The authors concluded that patients with dysphagia following stroke on thickened fluids do not consume enough fluids to meet their needs and are at risk of developing dehydration and its consequences (Finestone, et al., 2001).

Whelan (2001) studied 24 patients with dysphagia post-stroke in an acute hospital setting, randomised to either receive ready prepared pre-thickened drinks or hospital prepared powder-thickened drinks. The mean intake of thickened fluids in both groups was 455ml (SD=70ml), with an additional 742ml (SD=132) provided in non-oral supplementary fluids. The patients on the commercially available pre-thickened drinks consumed significantly more than those on the hospital prepared powder-thickened drinks but still did not meet their fluid requirements. This study also measured hydration but found no correlation between biochemical markers of hydration and fluid intake. Whelan concluded that hospital staff need to be aware of the risk of dehydration in patients with dysphagia post-stroke and ensure an adequate provision of supplementary fluids (Whelan, 2001).

Patch et al. (2003) used a similar methodology to that above, investigating the thickened fluid intake of 63 patients with dysphagia, but this study was conducted in a rehabilitation setting. Half of the participants received commercially available preprepared drinks and the others received hospital prepared powder-thickened drinks. Of the 1500ml of thickened fluids offered daily, only 40% (600ml) was consumed and there was no difference in intake based on whether patients were allocated the pre-prepared or powdered thickened drinks (Patch, et al., 2003). Apart from the obvious cost implications from these findings, the study also reinforced concerns about inadequacy of thickened fluid intake despite the access to a presumed superior product.

Vivanti et al. (2009) analysed the fluid intake of 25 patients with dysphagia from varying diagnoses in an acute hospital. The patients were all prescribed thickened fluids; some of them were on an oral diet only, while others received supplementary enteral or intravenous fluids. None of the patients achieved their calculated fluid requirements unless enteral or intravenous fluids were received. The average fluid intake from all sources for the total sample was 1371ml (SD=685ml) with 351ml (SD= 79ml) from beverages, 739ml (SD=396ml) from food and 299ml (SD=728ml) from additional enteral or intravenous fluids. The mean intake from thickened fluids was less than 400ml per day. The authors concluded that individuals with dysphagia requiring thickened fluids are unlikely to meet minimum fluid requirements and that,

given the greatest source of fluid intake is from food, the way forward is to focus on providing more fluid dense food to this population (Vivanti, et al., 2009).

McGrail & Kelchner (2012) compared the fluid intake of hospitalised patients poststroke with and without dysphagia. This is the only known study to have compared the fluid intake of patients with dysphagia on thickened fluids (n=10) with a group of patients matched for the diagnosis of stroke but without dysphagia (n=10). A group of community dwelling older adults was also included (these results are discussed in the section above). The participants without dysphagia permitted thin liquids drank significantly more than those with dysphagia prescribed thickened liquids (mean of 1237ml and 947ml, respectively), although only one patient from the total sample of patients met the minimum standard of fluid intake set at 1500ml (McGrail & Kelchner, 2012).

Many of these researchers concluded that the fluid intake of patients with dysphagia was inadequate and most supplemented their patients' oral fluid intake with enteral fluids. There was consensus that the reasons for poor fluid intake of patients on thickened fluids were multifactorial; thickened fluids themselves could be the cause of the poor fluid intake, because patients don't like their taste and viscosity; the dysphagia requires greater effort and makes it more time consuming to drink adequate fluids; and lack of adequate staff assistance for dependent patients could contribute to poor intake. However, few of these studies included aetiology-matched patients without dysphagia to act as controls to allow valid conclusions about the reasons. Furthermore, few of the studies measured the health consequences of the inadequate fluid intake.

As mentioned previously in this chapter, patient non-compliance with thickened fluids was a catalyst for the development of water protocols. There was hope that these new protocols would improve the fluid intake of patients with dysphagia and mitigate their increased risk of dehydration. Water protocols and results of studies investigating their effectiveness are discussed in detail below.
Water Protocols

The Frazier Rehabilitation Centre in the USA was the first known institution to change from traditional practice of prescribing thickened fluids for patients known to aspirate to a 'free water protocol' because of concern over patient non-compliance with thickened fluids (Panther, 2005). From 1984, oral intake of water by patients with dysphagia was permitted, following a protocol typically labelled the Frazier Water Protocol. It was argued that the aspiration of small quantities of water, a pH neutral substance, did no harm, and that the benefits of allowing water outweighed risks associated with its aspiration. The rationale for this protocol and positive outcomes determined from retrospective medical record review have been reported (Panther, 2005).

Free water protocols, hereafter referred to as water protocols, allow patients to drink water between meals even though they are known to aspirate thin fluids. The premise supporting the consumption of water is that water is pH neutral and if aspirated will do no harm to the lungs. It will be absorbed into the bloodstream by the alveoli. The protocol does not, as its name suggests, allow uncontrolled access to water. Rather, patients are only permitted water between meals, not during meals or when taking medication, in order to avoid aspirating any other material with the water. They are also required to implement a very strict oral hygiene program to reduce the risk of bacteria in the mouth being aspirated into the lungs with the water (Panther, 2003). If a patient is prescribed modified (thickened) fluids, the water is offered in addition to their thickened fluids. The patient chooses whether and how much of the water they drink. Water protocols can also be recommended for patients with severe dysphagia who are otherwise consuming nil orally.

Garon, Engle and Ormiston (1997) investigated the outcomes for patients with dysphagia post-stroke allowed controlled access to water versus thickened fluids. In a randomised control study of 20 inpatients in a stroke rehabilitation unit, no patient in either the thickened fluid group (n=10) or the group allowed access to water (n=10) developed pneumonia, dehydration or complications. There was no statistically significant difference between the groups in the time taken for the resolution of aspiration of thin liquids. There was an increased total fluid intake for those on the water protocol but this difference was not statistically significant; those

in the water protocol group consumed on average 1318ml (range 800-1900ml) of fluid per day compared with those in thickened fluids only group of 1210ml (range 400-1800ml). Poor satisfaction with thickened fluids was reported by 19 of the 20 patients. This first published study of the effectiveness of water protocols made a valuable contribution to our knowledge of this new intervention. However, it remains limited in its clinical application due to small subject numbers, exclusion of patients presenting with co-morbidities that are common in the stroke population such as impulsivity, and employment of a rigid water protocol where participants had to request water (Garon, et al., 1997).

More recently, three further evaluations of water protocols have been published. The first was a retrospective cohort study. Frey & Ramsberger (2011) reported on the outcomes for two matched cohorts of acute stroke patients. They were specifically interested in the incidence of aspiration pneumonia before and after the implementation of a water protocol at their institution. Retrospective medical review revealed that there was no increase in aspiration pneumonia after the introduction of the water protocol (0/30 patients). In fact, pneumonia rates were worse for the cohort of patients audited before introduction of the water protocol (2/28 patients). The authors acknowledged the limitations of this study; the research design did not permit causal relationships to be drawn; not all patients were objectively assessed as aspirating thin fluid; and information about fluid intake and hydration were not available. They concluded that larger prospective randomised studies are needed to determine if water protocols are clinically efficacious and patient and family endorsed (Frey & Ramsberger, 2011).

As an aside, an interesting finding of Frey & Ramsberger (2011) was that, of the 193 patients identified as having dysphagia post-stroke over three years at this institution, only 30 patients (16%) were placed on a water protocol. Although water protocols have been recognised as an intervention for dysphagia, uptake has been sporadic (Langdon, 2009). Many clinicians are waiting for more empirical evidence before implementing them with their patients.

A large randomised control trial (RCT) was published in 2011 (Karagiannis, et al., 2011). One hundred patients hospitalised in an acute or sub-acute facility were recruited to the trial which randomised them to either a water protocol group or the

control condition of receiving thickened fluids only. Patients had various and multiple diagnoses causing their dysphagia including stroke, cancer and progressive neurological conditions. Notably the patients only underwent a clinical assessment to determine whether they were aspirating thin fluids, with only 10 of the patients (10%) having this confirmed by a videofluoroscopic swallow study. This is a major limitation in the methodology of this study as it cannot be concluded that all participants had definitive aspiration of thin fluids. Another flaw of this study is that the data from the 24 acute patients in the study did not proceed to analysis and were not published for reasons which are not well explained by the authors. The results of the 76 sub-acute patients were published. Of participants randomised to the water protocol condition, six (14%) developed lung-related complications, although confirmation of pneumonia was only determined in three cases. None in the control group developed lung related complications. The authors reported this as a significant difference and concluded that aspiration of water has a causal relationship with development of lung complications, including aspiration pneumonia. They concluded that the patients at highest risk are those with degenerative neurological dysfunction who are immobile or have low mobility and that these populations should not be prescribed a water protocol. In terms of oral fluid intake, participants in the water protocol group demonstrated a significantly higher fluid intake on average (mean=1767ml, SD=11ml) compared with the control group on thickened fluids only (mean=1378ml, SD=34ml). Water intake accounted for an average 582ml of the daily oral fluid intake of those in the water protocol group. The authors also measured quality of life via a purpose designed survey. Participants in the water protocol group reported significantly higher levels of satisfaction with the drinks, level of thirst and mouth cleanliness compared to the control group (Karagiannis, et al., 2011). Whilst this is the biggest study of free water protocols to date, the methodology in terms of diagnosis of aspiration and pneumonia has flaws and this brings into question the validity of the authors' conclusions.

Most recently, Carlaw et al (2012) evaluated the use of a water protocol with 15 inpatients in a rehabilitation setting. The patients had a diagnosis of stroke, spinal cord injury or traumatic brain injury and all had evidence of thin fluid aspiration from videofluoroscopy. They were all offered fluids according to the GF Strong Water Protocol, an interdisciplinary designed water protocol specific to their

institution, but were randomised to immediate or delayed commencement in a crossover design. The control condition was standard care which for some participants meant oral fluid intake via thickened fluids but for others was enteral tube feeding. None of the patients suffered adverse events such as pneumonia although the authors admit their study was not powered sufficiently to draw conclusions about this outcome. The mean fluid intake increased significantly in the water protocol condition, with an average intake of 1845ml (range 1520-2169ml) compared to the control condition with an average intake of 1474ml (range 1113-1836ml). Oral water accounted for 563ml of the daily average fluid intake but there was considerable variation between individuals. The participants also reported favourable quality of life outcomes in the access to oral water phase.

In summary, individuals receiving access to water in rehabilitation settings appear to have positive outcomes. Of note is that all of the data published from the studies at the higher level of evidence (RCTs) are collected from patients in rehabilitation settings. Only the cohort study of Frey & Ramsberger (2011) published data from acute patients. In terms of the safety of water protocols, patients did not appear to have increased rates of aspiration pneumonia. Only Karagiannis et al (2011) reported adverse outcomes of pneumonia particularly for patients with progressive neurological disease and poor mobility. It should be acknowledged, however, that none of the studies were powered sufficiently to conclude definitively that water protocols are safe. Individuals on the water protocol also appeared to have increased satisfaction and quality of life. Whilst all three RCTs reported on fluid intake, only two (Carlaw, et al., 2012; Karagiannis, et al., 2011) found that water protocols significantly improved intake. The fluid intakes of patients assigned to the water protocol group and thickened fluids only control group are presented graphically alongside the intake of the healthy elderly, those in residential care and those with dysphagia on thickened fluids from the previous discussed studies in Figure 1.

Unfortunately, adverse health outcomes related to fluid intake such as dehydration, constipation and urinary tract infection were not measured in any of the water protocol studies. All authors concurred that further well-designed prospective studies of the efficacy of water protocols are needed, particularly to pinpoint the patient groups that are most likely to benefit or alternatively be put at risk. The aim of the

RCT presented in this thesis is specifically to evaluate the efficacy of a water protocol for patients with dysphagia post-stroke. Efficacy will be evaluated, not only in terms of fluid intake and pneumonia risk, but also hydration status and alternative adverse health outcomes.

This review of the literature has identified where there are still some deficiencies in our current understanding of dysphagia and its impact on dehydration. In Part II of this thesis, three background studies are presented which aim to address some of these gaps identified in the published literature and to provide further context to the prospective studies which are featured in Part III. In addition, this review of the literature has informed much of the methodology for the prospective studies presented in Part III.



Figure 1 Beverage intake of the healthy elderly, individuals in residential care and individuals with dysphagia

PART II Retrospective Studies

Chapter 3: Incidence of Stroke and Comorbidities in South Australia

Introduction and Purpose

The NSF estimates that 60,000 people in Australia have a new stroke each year (National Stroke Foundation, 2012). It is suggested in the literature that between 37% and 78% of patients will have dysphagia as a result of their stroke (Martino et al., 2005). A United States based study demonstrated an increased length of stay and use of hospital resources along with poorer outcomes for hospitalised patients with dysphagia compared to those without dysphagia (Altman & Yu, 2010). Australia-wide, the impact of stroke and dysphagia on patient well-being and hospital costs is estimated to be similarly significant although exact physical, psychosocial or economic costs have not been calculated. To date, no studies have quantified the size of these issues specifically in South Australia (SA).

The purpose of the present descriptive study was to explore a database of stroke admissions to the four major acute hospitals in SA over a 14 year period from July 2000 to June 2014 to determine the incidence of stroke and dysphagia in the acute hospital population in SA. This study also examined the incidence of co-morbidities that frequently co-occur with stroke and dysphagia, namely aspiration pneumonia, dehydration, urinary tract infection, and constipation. None of the previous population based incidence studies (Islam, et al., 2008; Leyden, et al., 2013; Thrift, et al., 2000) or stroke hospitalisation audits (Australian Institute of Health and Welfare, 2013; National Stroke Foundation, 2009, 2010b) have reported on these adverse health outcomes. This study thereby contributes unique information to the field. The stroke admission data were contextualised against the published literature and the incidence of the same co-morbidities in a matched sample of the general SA hospital admissions to determine whether, as hypothesised, patients are at greater risk for these complications post-stroke. The impact of stroke and dysphagia or the associated comorbidities from an economic or psychosocial perspective was not the remit of this study.

The validity of the incidence figures is reliant on the accurate recording and coding of diagnoses, so a sub-study was conducted to check coding accuracy. The diagnoses of the 100 patients who were included in the two prospective studies of this research presented in Part III were cross-checked with the coding of these diagnoses in the hospital database (stroke, dysphagia, aspiration pneumonia, dehydration, urinary tract infection and constipation).

Ultimately this study aimed to provide context to the size and breadth of the problems associated with stroke, stroke-related dysphagia and related adverse health outcomes in the local context of SA as a backdrop for the prospective studies presented in Part III of this thesis.

Research Questions

- 1. What is the accuracy of medical record coding compared to prospective data collection for the diagnoses of interest in this total stroke population?
- 2. What is the incidence of stroke admissions to dedicated stroke hospitals in South Australia from July 2000 to June 2014 and what are the demographics of this population?
- 3. What is the ratio of stroke admissions compared with the general hospital admission rate?
- 4. What is the incidence of dysphagia, dehydration, UTI, constipation and pneumonia as coded co-morbidities in this total stroke population?
- 5. What is the incidence of coded dehydration, UTI, constipation and pneumonia as co-morbidities in the subset of this stroke population that is also coded as having dysphagia?
- 6. What is the incidence of coded dehydration, UTI, constipation and pneumonia as co-morbidities in a matched general hospital population admitted for diagnoses other than stroke?

Method

Data were extracted from the Integrated South Australian Activity Collection (ISAAC), a state-wide database which captures information about patients discharged from public and private hospitals across South Australia (Information Assembly Data and Reporting Services, 2014). Ethics approval to access and analyse these data was provided by SA Health Human Research Ethics Committee on 7 November 2012 (HREC/12/SAH/78) – see Appendix 1. The Flinders Centre for Epidemiology and Biostatistics provided assistance to extract these data. The time period from July 2000 to June 2014 was selected as the data capture period for the purposes of this analysis because the researchers at this Centre have been collecting specific data related to stroke since July 2000.

The data have been analysed by financial year rather than calendar year to ensure consistency of coding across all hospital admission data sources. Medical diagnosis coding changes are made at the beginning of financial years. If there were coding changes for certain medical diagnoses or comorbidities, the effect of the coding changes would be consistent across both the stroke data and the matched sample in any given financial year.

Stroke Data

Inclusion criteria for the stroke data extraction included:

 Admission to one of the dedicated acute stroke hospitals in SA: Flinders Medical Centre (FMC), Lyell McEwin Hospital (LMH), Royal Adelaide Hospital (RAH) or The Queen Elizabeth Hospital (TQEH).

These four hospital were chosen for data extraction as the South Australian Stroke Service Plan 2009-2016 mandated that all suspected strokes in metropolitan Adelaide be transported to one of these four major hospitals (South Australian Department of Health Statewide Service Strategy Division, 2009) ii. ICD-10 codes: I60 Subarachnoid haemorrhage; I61 Intracerebral haemorrhage; I63 Cerebral infarction; and I64 Stroke not spec haemorrhage/infarct.

Excluded were diagnoses of subdural haemorrhage (I62).

Comorbidities of interest were dysphagia (R13), dehydration or hypernatraemia (E870), constipation (K590), urinary tract infection (N390) and aspiration pneumonia (J690).

Matched General Hospital Population

Data were extracted from ISAAC from emergency admissions to any one of the major acute hospitals with a dedicated stroke service: FMC, LMH, RAH or TQEH. Admissions were matched to the stroke admissions on the basis of age, sex, Charlson index, length of stay and financial year of admission. The Charlson index is a measure of the number of medical conditions a person has as a primary or secondary diagnosis so the matching is therefore of patients who have a similar burden of disease as the stroke patients. Stroke and non-stroke admissions were matched on a Charlson index category of 1, 2 or 2+. Length of stay was matched by category: 0 to <3 days; 3 to <7 days; 7 to <14 days; 14 to <28 days; or 28 days or over. Age (in years) and sex were matched exactly.

Excluded from the data extraction of the matched pairs was any diagnosis of stroke (I60, I61, I63, and I64), admissions for pregnancy and childbirth, newborns and neonates, elective surgery admissions and day admissions.

Coding Accuracy

In the collection of data for the prospective studies on patients following stroke detailed in Chapters 7 and 8 of this thesis, diagnosis of specific medical conditions or comorbidities was recorded for 100 patients in total. Diagnosis of stroke was recorded from the admitting medical officer's admission report which included CT evidence. Diagnosis of dysphagia or no dysphagia came from the treating speech pathologist's assessment report and/or videofluoroscopic evaluation of swallowing report. Diagnoses of dehydration, urinary tract infection or constipation were taken

from the medical record entries of the treating team. For this coding accuracy analysis, hospital admission data for these same 100 patients were extracted from the SA hospitals admissions database (ISAAC). The rehabilitation admission that matched the prospective data collection period was identified and analysed according to ICD-10 diagnoses coded for that admission. This was matched for accuracy with the medical diagnoses attributed to each patient by the treating team during the prospective study as detailed above. For example, if dysphagia was diagnosed in the prospective study and also coded as R13 in the ISAAC data, this was considered a positive match. If constipation was not diagnosed in the prospective study but a code for K590 was present in the ISAAC admission, this was a negative result.

Analysis

Incidence data were analysed using descriptive statistics (mean or median and standard deviation or interquartile ranges according to normality of distribution) and presented as frequencies and percentages. Differences in any incidence figures between the stroke and matched samples were compared using chi-square statistics. Coding accuracy for positive-positive matches and negative-negative matches was calculated and presented as percentage agreement.

Results

Answers to Research Questions

Research question 1: What is the accuracy of medical record coding compared to prospective data collection for the diagnoses of interest?

All 100 patients' rehabilitation admissions from the prospective studies (Chapters 7 and 8) were matched with their corresponding admission in the ISAAC system. The percentage accuracy of coding was 100% for the diagnosis of stroke, 89% for dysphagia, 94% for dehydration, 86% for constipation, 88% for urinary tract infection and 100% for aspiration pneumonia as illustrated in Figure 2.



Figure 2 Coding accuracy-percentage agreement between medical diagnosis and coding

Of those with less than 100% accuracy, 10 of the 11 patients coded for dysphagia did not have dysphagia according to the prospective assessment representing false positives. Similarly, 10 of 12 patients coded with UTI were not assessed prospectively as having UTI again representing mostly false positives. In contrast, 10 of the 14 patients assessed with a diagnosis of constipation were not coded as such i.e. the discrepancies were false negatives.

Research question 2: What is the incidence of stroke admissions to SA hospitals and what are the demographics of this population?

The total number of admissions to the four major acute hospitals in SA in the 14 years from July 2000 to June 2014 was 320,391. Of these 16,104 (5.3%) were for a primary diagnosis of stroke. This equates to an average of 1150 stroke admissions per year across these four major acute hospitals.

Of all patients admitted with stroke, 51.3% were male and 48.7% female and the median age was 77 years (interquartile range (IQR) 66, 84). Ischaemic stroke was the diagnosis for 76.2% of the patients, with 23.8% diagnosed as haemorrhagic or other causes. The median length of stay was 8 days (IQR 4, 16). These factors remained relatively constant over time, as illustrated in Figure 3.



Figure 3 Demographics of stroke admissions from 2000/01 to 2013/14

Research question 3: How does stroke incidence fit within the general hospital admission rate?

Stroke accounts on average for 5.3% of the total admissions to the four major acute hospitals in South Australia over this time period. The number of stroke admissions per year over 14 years shows a steady increase in-line with the gradual increase in total hospital admissions as illustrated in Figure 4.



Figure 4 SA hospital admissions from 2000/01 to 2013/14

Research question 4: What is the incidence of dysphagia, dehydration, UTI, constipation and pneumonia as coded co-morbidities in this total stroke population?

Of the 16,104 stroke admissions, 3243 (20.1%) were coded with a diagnosis of dysphagia. Over 16% of the stroke admissions died while in hospital, 6.2% were coded with dehydration, 3.1% with constipation, 12% with urinary tract infections and 7.3% with aspiration pneumonia (refer to Table 4).

Research question 5: What is the incidence of coded dehydration, UTI, constipation and pneumonia as co-morbidities in the subset of this stroke population that is also coded as having dysphagia?

For the sub-sample of stroke patients coded with dysphagia, 10.7% were also coded with dehydration, 21.6% with UTI, 6.4% with constipation and 17.5% with aspiration pneumonia (refer to Table 4).

Research question 6: What is the incidence of coded dehydration, constipation, UTI and pneumonia as co-morbidities in a matched general hospital population admitted for diagnoses other than stroke?

Of the admissions matched in sex, age, Charlson index, length of stay and financial year but admitted for a diagnosis other than stroke, 832 patients (5.2%) were coded with a diagnosis of dysphagia, 7.8% died in hospital, 13.3% were coded with dehydration, 5.1% with constipation, 11.4% with urinary tract infections and 2.1% with aspiration pneumonia (refer to Table 4). In direct comparison, the patients admitted with stroke had a significantly higher incidence of dysphagia (p<0.001) and aspiration pneumonia (p<0.001) but significantly lower incidence of dehydration (p<0.001) and constipation (p<0.001) than the matched sample. There was no significant difference in the incidence of UTI between the stroke and non-stroke matched sample (p=0.11).

	All stroke patients	Stroke patients with dysphagia	Matched non-stroke hospital admissions
Total 2000/01 - 20013/14	16104	3243	16104
Ave no. admissions per year	1150	232	1150
Male	51.3%	46.9%	51.4%
Ischaemic	76.2%	83.2%	N/A
Deceased	16.6%	15%	7.8%
Dysphagia	20.1%	N/A	5.2%
Dehydration	6.2%	10.7%	13.3%
Constipation	3.1%	6.4%	5.1%
UTI	12%	21.6%	11.4%
Aspiration Pneumonia	7.3%	17.5%	2.1%

Table 4 Incidence rates for stroke patients, stroke patients with dysphagia andmatched hospital admissions in SA from 2000/01 to 2013/14

Discussion

As with all information extracted from databases of hospital admissions, the validity of this incidence study was reliant on the accuracy of the coding of hospitalised patients' medical diagnoses. The first part of this study quantified the coding accuracy and, with an overall accuracy of 93%, it was considered to be acceptable for the purposes of reporting in this thesis.

Hospital admission rates annually in SA were variable over the studied period of 14 years but the overall trajectory was of an increase over time. The admissions for stroke consistently increased year by year. This finding is in keeping with trends for stroke hospitalisations across Australia. It is recognised that the crude incidence rate of stroke (number of new strokes per 100,000 in the population) has fallen by 25% over the last decade according to population based incidence studies (Islam, et al., 2008; Leyden, et al., 2013; Thrift, et al., 2000). However, the total number of Australians having a stroke has actually increased by 6% over the same period, reflecting the ageing of the population (Australian Institute of Health and Welfare, 2013). Admissions for stroke represented 5% of the total hospital admissions at these four major acute hospitals in SA from 2000 to 2014. This is higher than the average rate of stroke admissions of 0.7% of hospital admissions nationally in 2009-10 (Australian Institute of Health and Welfare, 2013). Stroke is primarily a disease affecting older individuals and the higher hospitalisation figures for stroke in this data extraction compared to the national average may reflect the particularly high numbers of the elderly and ageing living in SA (Australian Bureau of Statistics, 2015). The release of the South Australian Stroke Service Plan 2009-2016 (South Australian Department of Health Statewide Service Strategy Division, 2009), which mandated that all suspected strokes in metropolitan Adelaide be transported to one of these four major hospitals, may have artificially increased the proportion of stroke admissions to these hospitals compared to the national average. As another explanation, the NSF's FAST education campaign (National Stroke Foundation, 2014) may have impacted on the trend of increasing hospitalisations for stroke. This program encourages patients, their families, paramedics and primary health care workers to recognise the first signs of stroke ("Face: Check their face. Has their mouth drooped? Arms: Can they lift both arms?; Speech: Is their speech slurred? Do they understand you?, Time: Is critical") (National Stroke Foundation, 2014) and to seek immediate medical attention at an emergency department. It could be hypothesised that even if stroke rates are stable, the number of hospital presentations are increasing because of these education campaigns and local health policy changes.

The characteristics of the stroke patients from the SA database followed the expected profile of stroke across Australia according to the published literature. Of the stroke admissions in South Australia, 51% were male and the median age of patients was 77 years. This finding is consistent with the National Stroke Foundation (NSF) acute and rehabilitation audit figures of 53% and 54% males respectively and median age of 77 and 76 years respectively (National Stroke Foundation, 2009, 2010b) and the population based incidence studies (Islam, et al., 2008; Thrift, et al., 2000). In the South Australian data extraction, the rate of ischaemic stroke (76%) was also on par with the NSF audits (82% and 77% respectively) and the population incidence studies (Islam, et al., 2008; National Stroke Foundation, 2009, 2010b; Thrift, et al., 2000).

The number of deaths from stroke in this data extraction (16.6%) was on par with the figures quoted in the National Stroke Foundation audit of acute services in which 14% of the sample of stroke patients died in hospital (National Stroke Foundation, 2009). The rate of deaths in SA was also comparable with the population based studies of approximately 20% mortality at 28 days post-stroke (Islam, et al., 2008; Thrift, et al., 2000).

The presence of coded dysphagia in this data set of stroke admissions (20%) was lower than that reported in the NSF audits (47% of acute and 40% of rehabilitation patients had dysphagia) and lower than that quoted in a systematic review of dysphagia incidence of between 37% to 78% (Martino, et al., 2005). It is unclear whether this difference reflects coding inaccuracy or truly lower rate of dysphagia than expected in an acute stroke sample. The coding accuracy for dysphagia was 89% according to the coding accuracy sub-study so inaccurate coding is unlikely to completely account for this markedly lower incidence rate of dysphagia in South Australia. Furthermore, many of the coding errors were false positives; coding indicated dysphagia was present when prospective assessment indicated it was not, which would indicate the true incidence rate of dysphagia is even lower than 20%. As expected however, the incidence of dysphagia was significantly higher in the stroke admissions than in a matched sample of general hospital admissions. Interestingly, but for reasons unknown, the presence of dysphagia in 5% of the general hospitalised patients of this sample was comparatively higher than detected in a recent survey of hospitalised adults in the United States in which dysphagia was coded for only 0.35% of discharges from short-stay hospitals (Altman & Yu, 2010).

Infection is a common complication in the acute phase post-stroke. There is increasing evidence suggesting a critical period of central nervous system induced immunosuppression after stroke (Emsley, Hedley, & Hopkins, 2010). It is hypothesised that inflammation in the brain may trigger major systemic, counterinflammatory responses that ultimately compromise immune mechanisms required to combat pathogens. This may contribute to the heightened risk of infection for acute stroke patients (Emsley, et al., 2010). The critical time for developing infection is hypothesised as being within two to three days of hospital admission (Brogan, Langdon, Brookes, Budgeon, & Blacker, 2015; Westendorp, Nederkoorn, Vermeij, Dijkgraaf, & van de Beek, 2011). A systematic review provided a pooled estimate of 30% infection rate overall for acute stroke patients with a 10% pooled pneumonia rate and 10% pooled UTI rate (Westendorp, et al., 2011). Pneumonia and urinary tract infection were both found to increase the risk for unfavourable outcomes and pneumonia was associated with mortality with an odds ratio of 3.62 (Westendorp, et al., 2011). In the local Australian context, respiratory infection rates post-stroke were found to be 11% for all patients and 17% for a sub-group with dysphagia (Brogan, Langdon, Brookes, Budgeon, & Blacker, 2014). The incidence of aspiration pneumonia in the South Australian data extraction, at 7%, was lower than in these studies (Brogan, et al., 2014; Westendorp, et al., 2011) and the national average incidence of 10% in the latest NSF audit of stroke patients in acute hospitals (National Stroke Foundation, 2009), but far lower than the range of 16% to 33% typically reported in the literature as a complication of stroke (Martino, et al., 2005). These differences in rates of aspiration pneumonia may be accounted for by the different methodologies used to obtain the incidence figures; the SA data extraction used coded comorbidities from a large database of hospital patients compared with a medical record audit by trained auditors in the NSF audit, and actual patient screening, clinical assessment or instrumental assessment in the research papers comprising the systematic review conducted by Martino and colleagues. An alternative explanation may be that stroke clinical practices have improved over time, such that clinicians are better recognising the risk factors for aspiration pneumonia and acting sooner to mitigate the risks hence lowering the incidence rate.

Consistent with expectations, the incidence of aspiration pneumonia was significantly higher in the stroke admissions of the present study than in the general hospital admissions. The incidence of urinary tract infection was similar across both groups (11% in the matched sample and 12% of the stroke admissions) and also consistent with previously published incidence rates of UTI in an acute stroke population at 10% (Westendorp, et al., 2011).

With respect to dehydration, there is evidence that patients who are dehydrated at admission post-ischaemic stroke with a BUN/Cr ratio >15:1 (61 in standard international units), are significantly more likely to develop an infection, have a longer and more expensive length of stay, and poorer functional outcomes including higher mortality than those not classified as dehydrated (Liu et al., 2014). Unexpectedly, the incidence of dehydration was significantly higher in the matched sample of general hospital admissions than the stroke admissions in the present study (13% and 6% respectively). Similarly, the incidence of constipation was significantly higher in the general hospital admissions compared with the stroke admissions (5% and 3% respectively). Dehydration, constipation or urinary tract infection was not an outcome reported in any of the national stroke audits or population based studies so no further comparison can be made. As indicated, the matched sample in this data extraction consisted of SA hospital admissions matched on age, sex, length of stay and the Charlson index (a measure of the number of comorbidities). This matched sample was therefore presumed to be equivalent in terms of demographics and level of acuity to the stroke admissions. It is unclear from this SA data sample whether these comorbidities were the *cause* of admission, whether these conditions were acquired *during* the admission, or in fact whether these conditions were *chronic* underlying medical conditions for certain patients. Nevertheless, the findings reinforce the belief that many older, unwell people who are admitted to acute hospitals are dehydrated and commonly suffer from UTIs and constipation (Bennett, Thomas, & Riegel, 2004). Dehydration is a common cause of hospitalisation for the elderly although frequently under-reported in medical records and therefore underestimated from coded hospitalisations (Vivanti, 2008). The coded incidence of dehydration in this sample of acute hospitalisations in South Australia of 13% was consistent with the rate of 16% found in a prevalence study of admissions to a geriatric unit in Queensland, Australia for patients over 60 years (Vivanti, 2008).

Another consideration is that some of the patients diagnosed with dehydration may have acquired the condition *during* their hospitalisation which reinforces the belief of some authors (Bennett, et al., 2004; Kayser-Jones, 2002; Kayser-Jones, et al., 1999) that clinicians are not recognising the risk factors and not intervening early enough in the care of the hospitalised elderly to prevent such comorbidities.

The findings of this incidence study from the hospitals admissions database in SA examining patients with stroke and a matched sample without stroke, and the comparison with relevant published literature, provide a context for the prospective studies of patients with and without dysphagia post-stroke presented later in this thesis. The incidence of dysphagia, aspiration pneumonia, dehydration, urinary tract infection and constipation of the patients in the prospective studies presented in this thesis will be compared and contextualised with the incidence of these coded comorbidities from this large database of hospital admissions.

Chapter 4: Consumption of Thickened Fluids by Inpatients with Dysphagia Post-stroke: A Retrospective Audit¹

Introduction and Purpose

The prescription of thickened fluids is a common practice of speech-language pathologists when patients present with dysphagia (difficulty swallowing) for thin liquids (Lazarus et al., 1993; Logemann, 1998). However, there is widespread concern that individuals with dysphagia as a result of stroke do not drink enough when prescribed thickened fluids. Anecdotally, patients are known to dislike the taste and viscosity of thickened fluids (Colodny, 2005; Mertz-Garcia, et al., 2005). There is further argument that swallowing a liquid of higher viscosity requires greater recruitment of pharyngeal muscles and may lead to fatigue, further affecting fluid intake (Daniels, 2008; Groher, Crary, Carnaby, Vickers, & Aguilar, 2006). Many hospitals aim to provide at least 1500ml to 1600ml of fluid for their patients to drink per day. This figure is based on the needs of a 50-80 kg elderly adult (Armstrong-Esther, et al., 1996; Gasper, 1999; Holben, et al., 1999). The evidence suggests that patients on thickened fluids do not meet this target, especially in the acute setting (Finestone, et al., 2001; McGrail & Kelchner, 2012; Patch, et al., 2003; Vivanti, et al., 2009; Whelan, 2001). The amount of thickened fluids consumed by stroke inpatients with dysphagia in SA hospitals is not known. This was of interest to the current research agenda as the SA hospital system, introduction of clinical stroke guidelines (National Stroke Foundation, 2010a) and the move of many hospitals towards provision of commercially available pre-packaged thickened fluids products may have differentially impacted the intake of patients prescribed thickened fluids compared with the settings in which these other studies were conducted.

This retrospective audit was designed to determine the average amount of fluid consumed from beverages alone by inpatients who have been prescribed thickened fluids post-stroke, across both acute and rehabilitation inpatient settings in

¹ Content provided in this chapter has been summarised and published as:

Murray, J., Miller, M., Doeltgen, S., & Scholten, I. (2014). Intake of thickened liquids by hospitalized adults with dysphagia after stroke. *International Journal of Speech-Language Pathology*, *16*(5), 486-494.

The abstract of this paper is included in Appendix 2.

metropolitan Adelaide, SA. The association between amount of fluid intake and particular demographic or clinical factors was also explored.

Research Questions

- 1. What is the average thickened fluid intake of patients with dysphagia poststroke in metropolitan Adelaide hospitals?
- 2. Is the amount of thickened fluid intake correlated with variables such as age, stroke severity or the presence of supplementary non-oral feeding?

Method

This study was conducted as a retrospective audit. Ethics approval was obtained from the following Ethics committees governing research at all hospitals involved: Royal Adelaide Hospital Research Ethics Committee 6 March 2012 (protocol 090430c); Southern Adelaide Clinical Human Research Ethics Committee 15 March 2012 (protocol 91.12); Human Research Ethics Committee (TQEH, LMH, MH) 12 April 2012 (protocol number 2011212)—see Appendix 1.

Participants

Participants were included if they had been admitted to hospitals across Adelaide with a primary admission diagnosis of stroke, had dysphagia for thin fluids and were prescribed thickened fluids. These patients were identified by their treating speech pathologist or dietitian in hospitals across Adelaide including Royal Adelaide Hospital (RAH), Hampstead Rehabilitation Centre (HRC), Repatriation General Hospital (RGH), Flinders Medical Centre (FMC), The Queen Elizabeth Hospital (TQEH), St Margaret's Rehabilitation Hospital (SMRH) and Lyell McEwin Hospital (LMH). Speech pathologists or dietitians used records to retrospectively identify patients who had been on thickened fluids from admissions in the previous 6 to 12 months across 2011 and early 2012. To the knowledge of the researcher, there was no bias in the selection of patients for inclusion. Participants were excluded if there was no formal record (via fluid balance chart) of thickened fluid consumption.

Audit Procedure

Medical records of the identified patients were audited by the researcher and three final year speech pathology students. The thickened fluid intake from a minimum of two days of fluid balance charts (FBC) was recorded for each identified patient along with variables such as sex, age, severity of stroke and the presence of supplementary non-oral feeding/hydration on a purpose-designed audit tool included in Appendix 6. Participants' FBCs were not included if they were obviously incomplete (e.g. a full nursing shift was missing, or the patient was discharged half-way through the 24 hour period). The computation of totals recorded on the FBCs was checked for accuracy by the researchers.

Thickened beverages (water, cordial, coffee, tea, milo, flavoured milk, fruit juices, high energy drinks) were the only fluids included in the total. Fluids that begin as foods i.e. soups, custards, ice-cream or yoghurt were excluded from the total. Whilst it is recognised that there is a significant contribution of fluid from food sources, it was the specific aim of this study to examine consumption from beverages only. In addition, if the patient was allowed sips of water or ice chips, this was not included as consumption of thickened fluids was the focus of the study. Unfortunately, at one of the rehabilitation sites, an aggregate of fluid intake per day was the only record available on a single observation chart. The individual FBCs had been discarded and could therefore not be examined by the researchers for drinks included or checked for calculation accuracy. These aggregated data were still used in the analysis.

Severity of stroke for the participants in the acute hospitals was estimated using the National Institute of Health Stroke Severity (NIHSS) scale which rates level of consciousness, ability to follow commands, motor weakness, sensation, speech and language, gaze and vision to obtain a total score from 0 to 42; the higher the score, the more severe the stroke presentation. The NIHSS provides four severity groupings based on scores; <5 represents a mild impairment, 4 to 15 represents a moderate impairment, 15 to 24 severe and >25 very severe impairment. In the rehabilitation setting, the Functional Independence Measure (FIM) was recorded for each participant. This rates patient independence in functional areas such as eating, mobility, dressing, toileting, speaking and problem solving to obtain a total score from 18 to 126; a higher score representing greater independence.

Supplementary feeding and /or hydration was marked as *present* if a PEG, NGT or IVT was in use as evidenced by regular input in the non-oral column of the FBC and dated entries in the medical records.

Analysis

The Statistical Package for Social Sciences, version 20.0 (IBM Corp, Released 2011) was used to analyse the data from this study. Descriptive statistics were used to illustrate the profile of the participants from a demographic perspective and to detail their stroke severity. Some data were not available in some of the participants' records, predominantly NIHSS or FIM score. There was no interpolation of these missing data points; only the data collected were used in the analysis and consequently some results are presented with a denominator less than the total number of participants in the full sample.

The numbers of completed FBCs for each patient varied considerably, from 1 day to 7 days. Only patients with two or more days of completed FBCs were included in the analysis. Further, it was decided to calculate the average intake from only two days of consumption; those days closest to cessation of thickened fluids. These calculations would at least offer a consistent approach for each participant and possibly represent the best case scenario for patients; that is, when their consumption of fluids would be at its best.

The means and standard deviations of thickened fluid intake were calculated from the total sample of patients and from sub-samples based on level of care. An analysis of variables, such as age, sex and hospital site, with the 2-day average fluid intake was undertaken using two tailed independent sample t-tests and one-way ANOVA. Patients were grouped into three age ranges that are commonly used in the literature to represent younger adults (up to 64 years), the older population (65 to 75 years) and the elderly consisting of the old and the oldest old (over 75 years) (Australian Institute of Health and Welfare, 2014). Correlations were calculated between average fluid intake and stroke severity scores.

Results

Demographics

The sample consisted of 72 patients: 48 from four acute hospitals and 24 from three inpatient rehabilitation facilities. Three patients were excluded as they had less than two days of fluid intake recorded. The profile of the 69 participants whose data proceeded to analysis is illustrated in Table 5. Males and females were relatively equally represented. Their ages ranged from 41 to 99 years and the majority of participants were in the elderly age range with a mean age of 78 years (SD 12.3 years). For acute patients, median NIHSS score was 17.5 (n=14, IQR= 8 - 20) and median FIM score for the rehabilitation patients was 60 (n=8, IQR=34-84).

		Acute n (%)	Sub-acute/Rehab n (%)	Total n (%)
Number of records audited		45 (65)	24 (35)	69 (100)
Sex	Male	23 (51)	15 (63)	38 (55)
	Female	22 (49)	9 (37)	31 (45)
Age range (years)	<65	8 (18)	3 (12)	11 (16)
	65-75	7 (15)	5 (21)	12 (17)
	>75	30 (67)	16 (67)	46 (77)
Supplementary feeding	Yes	34 (76)	4 (17)	38 (55)
	No	11 (24)	20 (83)	31 (45)

Table 5 Profile of stroke inpatients

Answers to Research Questions

Research question 1: What is the average thickened fluid intake of patients poststroke in metropolitan Adelaide hospitals?

The mean daily thickened fluid consumption of the whole sample (n=69) was 781ml (SD=507ml). There was a significant difference between the thickened fluid consumption of the 45 patients in acute care (RAH, FMC, LMH, TQEH) with a mean of 519ml (SD=305ml) and the 24 patients in rehabilitation/sub-acute care (RGH, SMRH, HRC) with a mean of 1274ml (SD=442ml t_{67} =-8.341, p<0.001). The



mean intake of thickened fluids by patients at each individual hospital site is illustrated in Figure 5.

Figure 5 Thickened fluid intake of acute and rehabilitation/sub-acute inpatients post-stroke in South Australian hospitals

Research question 2: Is the amount of thickened fluid intake correlated with variables such as age, stroke severity or the presence of supplementary non-oral feeding?

The acute and rehabilitation sub-samples were analysed separately. There was no significant difference in thickened fluid intake between males and females in either the acute hospitals (t_{43} =0.487, p=0.629) or the rehabilitation centres (t_{22} =-0.160, p=0.874) as illustrated in Table 6.

There was a significant difference in thickened fluid consumption in the acute setting between the different age ranges ($F_{2,42}$ =4.699, p=0.014) with those in the younger age group (<65 years) consuming a greater amount of thickened fluid when compared directly to their elderly peers (>75 years) using the post hoc test *Tukey* (p=0.011) as

illustrated in Table 6. This difference in intake between age groups was not replicated in the sub-acute/rehabilitation setting ($F_{2,21}$ =1.430, p=0.262).

		Acute Mean (SD)	Sub-acute/Rehab Mean (SD)
Sex	Male	541ml (278ml)	1262ml (554ml)
	Female	496ml (336ml)	1293ml (154ml)
Age range (years)	<65	795ml* (250ml)	1476ml (966ml)
	65-75	487ml* (247ml)	998ml (190ml)
	>75	452ml* (296ml)	1322ml (360ml)

Table 6 Thickened fluid intake according to sex and age range

* significant difference in intake between three age ranges at p<0.05 level

There was no significant difference in thickened fluid consumption depending on what acute hospital the patient was admitted to ($F_{40,4}$ =1.716, p=0.323). In the sub-acute/rehabilitation sites patients at RGH appear to be drinking noticeably more than patients at the other rehab sites. However, a t-test between RGH and HRC (SMRH not included as it only had one participant) revealed no statistically significant difference in the thickened fluid consumption at these sites (t_{21} =1.760, p=0.093).

When the rehabilitation centre which provided only an aggregated figure of fluid intake (RGH) was removed from the analysis, there was still a statistically significant difference in mean thickened fluid intake between patients in the acute setting compared to the rehabilitation setting (519ml and 901ml, respectively) (t_{48} =-2.559, p=0.014).

When the total sample was analysed together, there was a significant difference between the thickened fluid consumption of patients if they had supplementary feeding all or some of the time (mean 549ml) *versus* none of the time (mean 1066ml) (t_{67} =-4.870, p<0.001). The majority of patients receiving supplementary feeding were in the acute setting, whereas the majority of patients not receiving supplementary feeding were in the rehabilitation setting. Univariate analysis revealed that this difference was attributable to the level of care ($F_{1,66}$ =37.008, p<0.001) not the presence or absence of supplementary feeding ($F_{1,66}$ =2.424, p=0.124).

Supplementary feeding/hydration	Acute Mean (SD)	Sub-acute/Rehab Mean (SD)
Yes, some or all of the time	488ml (300ml)	1062ml (771ml)
No, not at any time	613ml (314ml)	1316ml (363ml)

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There was no significant correlation between thickened fluid intake and stroke severity according to NIHSS (r=-0.415, p=0.106) or FIM score (r=-0.333, p=0.420).

Discussion

This study confirms the widely held belief that patients with dysphagia who are prescribed thickened fluids consume inadequate amounts to meet their estimated requirements. The average daily intake of thickened fluids of 781mls by inpatients across acute and rehabilitation settings is only half the recommended consumption for hospital inpatients (1500-1600ml) (Chernoff, 1994) and well below the recommended intake for the general community (2100ml for females and 2600ml for males) (Australian National Health and Medical Research Council, 2005). Interestingly, there was no statistically significant difference in the intake between males and females despite the biological need of males to consume more on average than females. In the acute setting, males drank on average marginally more than females, but in the rehabilitation setting, females drank marginally more than males. Perhaps thickened fluids was the equaliser; the patients' dysphagia, or their common dislike of thickened fluids, or the common system on which they rely for fluid provision resulted in sub-optimal intake equally for both sexes. This is particularly concerning for the males as they may be proportionally more affected by the low fluid intake than the females.

Intake was especially poor in the acute setting where the mean daily intake of thickened fluids was only 518mls. This finding compares very closely with the findings of previous studies conducted in acute settings: 400ml per day (Vivanti, et al., 2009) and 455ml per day (Whelan, 2001). The present study used fluid balance charts from days closest to cessation of thickened fluids to represent the best possible

intake scenario which may explain why the intake in the present study was somewhat higher than reported in these previous studies.

Most of the acute patients in the present study received supplementary non-oral feeding/hydration some or all of the time (76%). This is the most common way to address fluid intake shortfall in the acute setting where patients are more likely to be medically unstable and less mobile. However, even though the remaining 24% of acute patients not receiving supplementary non-oral feeding/hydration did drink more than acute patients who were on supplementary non-oral feeding/hydration, it was not a significantly greater amount and was still sub-optimal. Examining the health outcomes of these patients was not part of this study but would have added valuable information. Perhaps the patients not receiving supplementary non-oral feeding/hydration with their swallowing and it was considered that supplementation was not required.

The significant effect of age on the daily thickened fluid consumption in the acute setting is of interest. In the healthy population, it is argued that age itself has no effect on the amount of daily fluid intake. Researchers have reported that healthy individuals in older age groups living independently in the community drink just as much as younger individuals (Bastiaansen & Kroot, 2000; Bossingham, et al., 2005). It is generally agreed that the level of functional dependence and the number of medical conditions an individual has impacts on fluid intake, and hence proportionately affect the fluid intake of older individuals to a greater extent (Morgan, et al., 2003). Age itself is known to negatively affect swallowing (Logemann, Pauloski, Rademaker, & Kahrilas, 2002) and the older individuals in this study may have, therefore, been less able than their younger counterparts to compensate for their stroke-related dysphagia. Additionally, co-morbidities such as congestive cardiac failure, chronic obstructive airways disease, gastro-oesophageal reflux disease, renal impairment and dementia, which can further affect swallowing, are more prevalent in the elderly. In this sample those in the elderly age group (>75 years) in the acute setting drank significantly less than those in the younger age group (<65 years). Unfortunately, information about co-morbidities was not collected in this study, so definitive conclusions from these findings cannot be drawn.

Nevertheless, this finding confirms that hospitalised older and elderly individuals with dysphagia are at greater risk of poor oral fluid intake.

There was no significant correlation between thickened fluid consumption and stroke severity or level of dependency although the direction of the correlation was in the expected direction; those with a more severe stroke or greater dependency consumed less. However, numbers of patients that were attributed a NIHSS or FIM score in their medical record were small, so it is difficult to generalise about the effect of stroke severity itself on fluid intake. Researchers have demonstrated that swallowing severity is associated with larger and more severe strokes (Langdon, et al., 2007) so it seems intuitive that fluid consumption would also be associated with stroke severity. Future research may confirm this hypothesis.

The average thickened fluid intake per day for patients in the rehabilitation setting in the present study was 1274ml which is very similar to thickened fluid intake reported in the literature by other studies conducted in the rehabilitation setting, namely 1210ml (Garon, et al., 1997), 1474ml (Carlaw, et al., 2012) and 1378ml (Karagiannis, et al., 2011). These figures are all significantly better than intake figures quoted in two earlier studies of 755ml and 600ml respectively (Finestone, et al., 2001; Patch, et al., 2003). The improved thickened fluid intake in the more recent studies (recognising that the study by Garon et al (1997) was not as recent and is the exception) may be an indication of heightened awareness of adequate nutrition and hydration for the elderly and for recovery from illness. It may point towards positive changes in hospital systems and the way thickened fluids are supplied and consumption monitored. It may also be attributable to differences in methodologies and measurement in the various studies.

A significant finding of the present study was the considerable difference between the average daily thickened fluid intake of patients in the acute setting (518ml) and the rehabilitation setting (1274ml). Given that this study used consistent methodology across both settings, the significant difference is not likely to be due to sampling error. Instead, it is hypothesised that the difference in intake may be due to the severity of dysphagia itself, with stroke patients likely to have more severe dysphagia in the acute period post-stroke with improving function as they transition to rehabilitation (Smithard et al., 1997). Alternatively, dissimilar operational factors in acute and rehabilitation settings may impact differently on the provision and encouragement of consumption of fluids. Acute hospitals are focussed on investigation of stroke causes and secondary prevention of further events and complications. A patient's sub-optimal fluid intake is likely to be addressed by medical intervention via IVT, NGT or PEG. In the rehabilitation setting, where the aim is to recover or 'maximise' a patient's function, patients with sub-optimal intake will be encouraged to drink more by rehabilitation staff in the first instance to improve fluid intake (Kayser-Jones, et al., 1999). Perhaps also as a patient becomes more mobile and functionally able and transitions to the rehabilitation setting, they can access drinks more independently and in a greater variety of settings (bedside, dining room, therapy area, kiosk) than in the acute setting where fluids are often only available at bedside. Finally, individuals in a rehabilitation setting are often more active than those in an acute hospital (West & Bernhardt, 2012) which may be a physiological driver of thirst and consequently greater fluid intake. Further examination of the impact that independence and activity level had on intake was not possible from the data in this study, as the FIM scores of only a small number of participants were available for analysis.

Limitations

It is recognised that there were limitations to the study presented here. The results depended on the accuracy of recordings and diligent filing of FBCs by nursing staff. In order to minimise inaccuracies, incomplete FBCs were excluded from analysis, but it was not possible in a retrospective audit to check the accuracy of the data that were included.

The intake of patients in one rehabilitation site (RGH) may have been marginally inflated as the researchers could only use the aggregate intake figure which may have included food items or water. For the purposes of this study, thickened fluid intake was defined as thickened beverages only, and when individual FBCs were available, the food items or water consumed in oral trials was excluded from the total intake. In recognition of this limitation and in order to avoid bias from this hospital's figures, fluid intake was re-analysed excluding RGH data. The differences that were significant using the total rehabilitation sample were still significant without this subset of data included.

Another limitation was that different sites had different protocols for the provision of thickened fluids. For example, RGH had commercial pre-packaged drinks available to patients at every meal time delivered on the meal trays as well as jugs of hospital prepared thickened fluids at bedside. HRC had hospital prepared thickened fluids at bedside only, with a one litre jug delivered once per day. It was left to the patient or clinical staff to take a drink from the bedside to the dining room to consume with meals. The audit was unable to control for the variable amount of thickened fluid offered to patients at different hospital sites.

A further limitation of the study was that the patients' medical acuity/stability was not recorded. Some patients in the sample may have been medically unstable, have had multiple medical co-morbidities or have been palliative, which would have significantly affected fluid intake, but this was not taken into account in the findings of this study.

Conclusion

This study confirmed a widely held belief that stroke inpatients with dysphagia on thickened fluids do not drink enough. Of particular concern was the sub-optimal fluid consumption by patients in acute settings, especially when not receiving supplementary non-oral feeding or hydration. The elderly, those over 75 years of age, were particularly at risk of poor fluid intake in the acute setting. Even patients in rehabilitation did not drink the amount hospitals intend their patients to consume and certainly did not meet recommended fluid intake standards for healthy adults.

Future Research

Future research is warranted to evaluate ways to improve the fluid intake of patients with dysphagia post-stroke especially in the acute setting and particularly for the elderly. Changes to care protocols are critical to ensure intake is monitored and timely actions are taken when inadequate intake is recognised. These actions may include providing increased amounts of thickened fluid per day, improved patient access to drinks at the bedside and increased responsibility of nursing staff to regularly offer, observe and record consumption. Alternatives such as the implementation of water protocols or routine use of supplementary non-oral hydration could be trialled. All of these actions require prospective evaluation, to

ensure they are effective in improving fluid intake and sustainable and cost-effective for the hospital. Ideally, evaluation would include a measure of how these actions impact not only patients' fluid intake but their overall health outcomes as well.

The next chapter in this thesis explores the provision of thickened fluids from the viewpoint of a practicing clinician and how consumption is monitored.
Chapter 5: Thickened Fluid Prescribing and Monitoring Practices by Australian Health Professionals: A Self-report Survey²

Introduction and Purpose

The reasons for sub-optimal fluid intake by patients with dysphagia are not definitive from the evidence to date. Is the sub-optimal fluid intake a result of (i) the dysphagia itself such that a patient cannot drink a greater quantity orally no matter what fluid is provided, (ii) the patients' dislike of thickened fluids and feelings of fullness and therefore non-compliance with drinking enough of what is offered, or (iii) institutional frameworks related to the way thickened fluids are supplied, staff assistance is provided and consumption is monitored which means intervention is inadequate or ill-timed?

Previous surveys of speech pathologists' opinions around the issue of thickened fluid consumption have focussed on the preparation of thickened fluids and internal patient factors for non-compliance (Colodny, 2005; King & Ligman, 2011; Mertz-Garcia, et al., 2005), largely addressing the issues raised in question (ii) above. Whether or not institutional frameworks contribute to poor thickened fluid intake has so far not been investigated. However, there has been some debate in the literature about the fluid intake of institutionalised patients in general. Some authors argue that a lack of well-educated and supervised staff, particularly in residential aged care facilities, contributes to inadequate intake, as staff do not have the time or expertise to successfully feed multiple residents at mealtimes who present with dysphagia, cognitive or other functional impairment (Armstrong-Esther, et al., 1996; Burger, Kayser-Jones, & Prince-Bell, 2000; Kayser-Jones, et al., 1999). However, other authors argue that dehydration develops because of disease processes which result in increased fluid losses coupled with decreased fluid intake related to decreased thirst, and that dehydration is rarely due to neglect (Thomas, et al., 2008).

² Content provided in this chapter has been summarised and published as:

Murray, J., Doeltgen, S., Miller, M., & Scholten, I. (2014). A survey of thickened fluid prescribing and monitoring practices of Australian health professionals. *Journal of Evaluation in Clinical Practice*, 20(5), 596-600.

The abstract of this paper is included in Appendix 2.

This study surveyed Australian speech pathologists, dietitians and nurses who work with adult patients with dysphagia. The purpose was to determine how thickened fluids are supplied to patients with dysphagia in their workplaces and the processes by which patients' consumption of thickened fluids and hydration status are monitored, thereby contributing information to the impact that institutional factors may have on fluid intake and dehydration.

Methods

Ethics approval for this study was obtained from the Social and Behavioural Research Ethics Committee at Flinders University on 21 September 2012 (protocol 5767) – see Appendix 1.

Questionnaire Design and Distribution

Two expert reference groups were convened at two separate hospitals in Adelaide, South Australia to assist with questionnaire design. These groups consisted of an experienced speech pathologist, dietitian and senior nurse working clinically in stroke and rehabilitation units. Further input was provided on request by a resident medical officer at one of the hospitals. Questions for the survey were drafted by the author of this thesis then discussed and refined based on the clinical issues seen as relevant to the expert reference group members. The survey was piloted for ease of use and time required. Pilot feedback indicated that the survey questions were clear and took about 8 to 10 minutes to answer.

The questionnaire, developed using SurveyMonkey ("SurveyMonkey," 2013), consisted of 15 multiple choice questions. For most questions, respondents were able to choose more than one answer (i.e. select all answers that apply) and had the option of recording free text to qualify their answers. The questionnaire is included as a hard-copy in Appendix 7.

The survey was electronically distributed to Australian speech pathologists, dietitians and nurses via a paid advertisement through their respective professional networks namely: Speech Pathology Australia (SPA); the Rehabilitation and Aged Care Interest Group, Nutrition and Disability Interest Group and Nutrition Support Interest Group of Dietitians Association of Australia (DAA), and the Australian Rehabilitation Nursing Association (ARNA). The advertisement invited members to take part anonymously in the online survey in April 2013. A period of 43 days was allowed for replies with a reminder sent via email at the 36 day mark.

Data Analysis

The data from the completed surveys were entered into the Statistical Package for Social Sciences, version 20.0 (IBM Corp, Released 2011) and analysed using descriptive statistics. Given that respondents were able to choose multiple answers to most questions, the response percentages presented in the text below do not always total 100%.

Results

Response Rate

The survey was sent to all members of Speech Pathology Australia which includes academics, students and practising clinicians including those working in fields unrelated to dysphagia such as child speech and language. Of the 4553 members, 387 participated in the survey indicating a response rate of 8.5%. It was also sent to dietitians who were members the following DAA interest groups: Nutrition support (1367 members), Rehab and Aged Care (918 members), and Nutrition and Disability (360 members). The memberships of these interest groups may overlap so the 131 responses from dietitians equates to a response rate of at least 5%. Additionally, the survey was sent to 1102 members of ARNA with 155 responses from nurses equating to a response rate of 14.1%.

Characteristics of Participants

A total of 676 health professionals participated in the survey: 57% (n=387) speech pathologists, 23% nursing staff (either enrolled nurses n=23 or registered nurses n=132), and 19% dietitians (n=131). Respondents came from across the states and territories of Australia in a spread representative of the population spread across the country, and from a variety of locations ranging from capital and regional cities to rural and remote centres. The majority of respondents worked in acute (55%) or rehabilitation (44%) inpatient facilities, but they also worked in residential aged care

facilities (24% in high level of care facilities), community health settings and in clients' homes, many across multiple settings.

Supply of Thickened Fluids

Thickened fluids are supplied to patients in 98% of the facilities in which respondents worked. The majority of respondents (82%) indicated that thickened fluids are supplied to their patients in pre-packaged containers of commercially available products. Thirty-five percent (35%) indicated that their hospital service prepares thickened fluids in bulk from a powder thickener and 38% indicated that thickened drinks are prepared individually by staff using thickening powder as required. The most common location for thickened fluids to be supplied to a patient is at their bedside (81%), or on their meal-tray (77%), then in the dining room (47%) or on a mobile drink trolley (47%). Only 16% of respondents indicated that thickened fluids are kept chilled in fridges on the ward and are carried on medication trolleys. The most common schedule for delivery of thickened fluids to patients is at every meal and snack time i.e. 5-6 times per day (60%). Some facilities have thickened drinks at any time on their request.

Responses about the amount of thickened fluid supplied in a 24 hour period varied considerably. Many participants reported that the amount supplied is calculated on an individual basis according to the patient's clinical presentation (24%). Others estimated an amount between 1200ml to 1400ml is offered per day (24%), with some indicating a greater amount is offered (1500 to 1700ml [13%] and 1800 to 2000ml [6%]). A small number of respondents (0.5%) indicated their patients were offered less than 1000ml per day. Many health professionals indicated that they didn't know how much their patients on thickened fluids are offered to drink per day (23%).

Monitoring of Thickened Fluid Consumption

About two-thirds of respondents (67%) indicated that the consumption of thickened fluid is monitored but only when a clinical need is recognised on a case by case basis. Some facilities monitor consumption routinely for all patients on thickened fluids (17%) whereas a small number do not monitor consumption at all (8%). The

most common method used to monitor consumption is through the completion of Fluid Balance Charts (FBCs) (64%) or a similar individual food and fluid intake chart (49%). Very few facilities calculate consumption through wastage (6%) or through sample auditing (3%). Free text comments indicated that some facilities leave it to the patient or family themselves to report how much they are drinking. Some respondents indicated they did not know how consumption was monitored (11%). Of these, the majority were speech pathologists (16%), compared with enrolled nurses (9%), dietitians (5%) and registered nurses (3%).

In the opinion of about half of the respondents (51%), patients on thickened fluids at their facility do not drink an adequate amount. Only 9% believed their patients do drink adequate amounts and many respondents believe adequacy of intake varies from client to client (37%). There was a significant association between the profession and whether or not the respondent believed patients drank adequate amounts ($\chi^2(3)=13.11$, p=0.004). Dietitians were much more likely to answer 'no', that intake was not adequate (64%), followed by registered nurses (51%), speech pathologists (48%) and then enrolled nurses (30%).

The perceived reasons for patients not drinking enough are varied; many respondents believe patients dislike the texture and feel in the mouth (80%), or the taste of thickened fluids (63%). Others believe that the patients' dysphagia prevents them from drinking enough (42%). Some respondents attributed inadequate intake to the hospital system, that patients aren't offered enough thickened fluid (26%) or their consumption is not monitored closely enough (37%). Several respondents offered additional reasons for inadequate intake in the open comments section. Some (11%) indicated that the patient's functional disabilities (immobility, poor fine motor control, communication and cognitive impairment) resulted in them being unable to open packages and access drinks independently. It was the opinion of some respondents (11%) that the provision of assistance by staff was inadequate for these dependent patients, lack of education and support or poor attitude by staff. There were a few respondents (3%) who felt that the preparation of thickened fluids by staff contributed to poor consumption, with fluids being thicker than required, left

to go warm, and staff not being prepared to thicken drinks of the patient's choice individually (such as water or coffee or tea).

Monitoring of Hydration

The majority of respondents indicated that the hydration of their patients is monitored by clinical measures either through observation of clinical signs such as dry mouth, skin turgor, headaches or the colour of urine (70%), or the standard nursing observations of blood pressure, pulse and respiratory rate (62%). Thirty-seven percent (37%) of respondents reported the use of biochemical analysis of blood samples to monitor hydration and 28% indicated that urine analysis is performed. Through open comment, some respondents indicated that it was left to the patient to self-report on their hydration (if they felt thirsty, lethargic, dry mouth etc.) and others reported that hydration is not monitored at all. A number of respondents did not know how hydration was monitored (18%). Again the majority of these were speech pathologists (28%), followed by dietitians (10%) and registered nurses (<1%).

If thickened fluid intake and hydration were considered inadequate for patients, respondents indicated that a multitude of strategies were used in their facilities. The most frequently used approach was for nursing staff to encourage ("push") the patient to drink more fluids (87%), followed by the use of non-oral supplementary fluid through hyperdermoclysis or enteral tube feeding (66%). Many respondents indicated they would educate the patient and their family about the importance of drinking more and staying hydrated (64%). Open comments also suggested that nursing staff and care staff need similar education. Referral for specific medical or dietetic assessment was frequently indicated (44% and 64%, respectively). Other common strategies were to offer alternative flavours of thickened fluids (59%) or order more thickened fluids for patients (46%). Some would offer more foods high in fluid content (23%). Only 14% would implement water protocols (where water is offered between meals under controlled conditions even though the patient is known to aspirate thin fluids). More respondents were likely to cancel the thickened fluids and upgrade their patient to thin fluids sooner than they otherwise would have with recognition and acceptance of associated risk (23%). The strategy of setting small but regular targets for fluid intake throughout the day with increased monitoring was

only implemented by 11% of respondents. Most professions suggested the use of the common strategies mentioned above in equal proportions, but there was some variation as to which strategies certain professions would suggest. Education of the client and family was more likely to be suggested by enrolled nurses (83%) and registered nurses (77%) than the other professions of speech pathology (63%) and dietitians (50%). The setting of small targets for fluid intake throughout the day was suggested by enrolled nurses (26%), registered nurses (17%), speech pathologists (9%) and dietitians (4%). Speech pathologists were more likely than the other professions to suggest an upgrade of fluids sooner than clinically indicated: speech pathologists (29%), enrolled nurses (22%), registered nurses (18%) and dietitians (12%); and were also were more likely to suggest the implementation of water protocols: speech pathologists (20%), enrolled nurses (9%), dietitians (8%) and registered nurses (6%).

Discussion

This survey recorded the self-reported practices of 676 Australian dietitians, nurses, and speech pathologists related to the provision of thickened fluids to clients with dysphagia. The findings highlight where health professionals have concerns.

One of the most prevalent responses from health professionals was the opinion that clients do not drink adequate amounts when prescribed thickened fluids (51% of respondents). The literature and other responses from this survey would appear to support this perception. With respect to the amount of thickened fluids offered per 24 hour period, the largest response from the survey (24%) was that an estimated 1200ml to 1400ml is offered per day or is calculated on an individual basis according to the patient's clinical presentation. Even if clients drink all fluid offered, their intake would still be well below the beverage intake recommended for healthy adults. According to nutrient reference values males should consume between 2600ml and 3000ml per day from beverages alone, and females between 2100ml to 2200ml per day (Australian National Health and Medical Research Council, 2005; Grandjean, 2005; Institute of Medicine of the National Academies, 2004). However, in recognition that it is difficult to apply reference values to vulnerable populations such as the elderly and ill, many hospitals aim to provide a lesser amount but at least 1500ml to 1600ml of beverages for inpatients to drink per day (Chernoff, 1994;

Chidester & Spangler, 1997). From the findings in this study it appears that hospitals provide an even lesser amount of fluids to patients with dysphagia on thickened fluids than they expect other hospitalised patients to consume as a minimum.

Health professionals still have concerns about the palatability and acceptability of thickened fluids to clients. Many respondents attributed dislike of texture (80%) and taste (63%) as barriers to adequate consumption by clients. One respondent indicated that they commonly hear staff comment on the drinks being "yuck" or "you poor thing having to drink those thickened drinks". The issue of palatability is prevalent even though the majority of respondents (82%) indicated that their hospital supplies pre-packaged commercially available products which are thought to be more acceptable to clients and known to be more consistent in their viscosity (McCormick, Stafford, Saqib, Chroinin, & Power, 2008). Many hospitals do still use powdered thickeners (35%) in addition to pre-prepared products. Nevertheless, this survey reflects an increase in the use of pre-prepared products over recent years; 34% of respondents in an American survey in 2004 reported the use of pre-prepared products (Mertz-Garcia, et al., 2005) whereas powdered thickeners were the most commonly used agents in an informal survey in 1996 (Robbins et al., 2002). Many respondents in this survey also expressed concern about the quality of on-site prepared thickened fluids in that they are often lumpy, thicker than prescribed, and are left unrefrigerated. It appears that, despite advances in product quality, many health professionals still have the impression that their clients don't like drinking thickened fluids.

Another prevalent concern of health professionals was the client's ability to access drinks. Although the majority of respondents indicated that thickened fluids are available 5-6 times per day (80%) or all day (23%), many reported their concerns about clients' ability to drink them because of functional dependency. It is relatively easy for most healthy adults to maintain adequate hydration by drinking when they feel thirsty. But many hospitalised patients or long-term care residents are unable to drink independently; they require full or partial assistance or supervision to drink and so are at risk of dehydrating (Kayser-Jones, et al., 1999). In addition, some respondents indicated in free-text that staff do not offer enough assistance. This was attributed to facilities being inadequately resourced, nursing and care staff being time

poor or having poor knowledge and attitudes about feeding dependent clients, an opinion consistent with the concerns reported over 15 years ago (Armstrong-Esther, et al., 1996; Chernoff, 1994; Kayser-Jones, et al., 1999).

With respect to the knowledge of health professionals about hydration, studies indicate that nursing knowledge of dehydration risks and assessment is poor (Armstrong-Esther, et al., 1996; Kayser-Jones, et al., 1999). The findings of this survey would suggest this is equally the case for speech pathologists. There were a substantial number of respondents who did not know the amount of thickened fluids offered to their clients per day (23%), whether or how consumption is monitored (11%) or whether or how dehydration is monitored (18%). Even though the recommendations of speech pathologists will have an impact on fluid intake and potential health complications for their clients, it appears from the findings of this survey that knowledge of these complications is not always optimal.

In terms of monitoring, the findings of this survey indicate that health facilities do not routinely or objectively monitor the fluid intake and hydration of clients with dysphagia who are on thickened fluids, even though the literature indicates that they are at risk of poor fluid intake and dehydration. Most respondents indicated that monitoring occurred only if a clinical need was identified. Unfortunately, because knowledge of the clinical staff about dehydration is sub-optimal, and patients are often unable to self-report accurately, the clinical need of many patients at risk may not be identified without routine screening. Even with the screening processes in place, the choice of monitoring tool may not be optimal. The most prevalent choice of tool for measuring fluid intake was fluid balance charts. Anecdotally it is known that, without regular training, FBCs are poorly completed and at best an estimate of oral fluid intake (Scales & Pilsworth, 2008; Whelan, 2001). Several respondents indicated in free text that FBCs or food charts are not completed well in their facility. The most prevalent way for dehydration to be monitored was through clinical signs such as lethargy, headaches, falls, dry mouth and colour of urine. These clinical signs can easily be attributed to other clinical conditions, medications, or patient function and compliance, giving them poor specificity for monitoring dehydration. Approximately 50% of dietitians and registered nurses indicated a patient's biochemistry from blood sampling would be used to monitor hydration.

Unfortunately, there is little agreement amongst experts about the best way to screen for dehydration. Although researchers all agree that the diagnosis of dehydration or hypovolaemia from poor fluid intake is complex, some argue that biochemical parameters are necessary (Weinberg, et al., 1995), whereas others suggest physical parameters such as systolic blood pressure drop on standing, sternal skin turgor, tongue dryness and body mass index are more reliable (Vivanti, 2008).

In an attempt to improve the intake and hydration of patients with dysphagia on thickened fluids, previous studies have suggested interventions such as offering more pre-packaged thickened drinks, offering fluids at snack times as well as mealtimes and offering more high fluid content foods such as custards, yoghurts and soups (Patch, et al., 2003; Vivanti, et al., 2009; Whelan, 2001). It appears these strategies have been taken up to varying degrees across institutions in Australia. The survey of health professionals indicated that 81% offer pre-packaged thickened fluids, 23% consider offering food high in fluid content, but only 11% use the strategy of setting small but regular targets for fluid intake throughout the day. By far the most prevalent strategies used was for nursing staff to provide encouragement to patients to drink more by "pushing fluids" or the use of non-oral supplementary fluids.

Again the question can be asked; who is responsible and accountable for encouraging patients to drink more? Is it solely the responsibility of nurses to "push" or encourage fluids when a client is suspected of having inadequate intake, or is it the responsibility of *all* clinical staff working with an individual to ensure they are offered and have access to fluids and are provided with assistance (if necessary) to drink. Sharing the responsibility amongst all clinicians, as occurs for reducing falls risk and infection in hospitals, may be the most effective way of having an impact. But, for this to occur, availability of drinks will need to improve as, for example, very few respondents (16%) indicated that thickened drinks are available in group/therapy areas where clients are presumably spending time and expending quite an amount of energy.

Limitations

This study had limitations inherent in the methodology of surveying targeted groups. The findings are based on self-report of practice, not observed practice. The survey was voluntary and therefore self-selective of those who have an interest in the area, and not necessarily representative of the whole population of health professionals working with clients with dysphagia on thickened fluids. However, the relatively large number of respondents to a survey of this type gives high validity to the findings.

Conclusion

This study surveyed 676 Australian speech pathologists, dietitians and nurses to obtain a snapshot of how thickened fluids are supplied to clients with dysphagia in hospitals and how clients' consumption of thickened fluids and hydration status is monitored. Over half of the respondents do not believe that clients with dysphagia receiving thickened fluids drink enough. They indicate palatability of the thickened products themselves and patients' dependence on others for drinking have an impact on fluid intake. In addition, they highlight institutional factors such as inadequate assistance from staff and inconsistent systems for monitoring fluid intake and signs of dehydration. The findings of this survey suggest health facilities do not routinely or objectively monitor the fluid intake and hydration of clients with dysphagia who are prescribed thickened fluids, even though the literature indicates they are at risk of poor fluid intake and dehydration (Crary, et al., 2013; Finestone, et al., 2001; Leibovitz, et al., 2007; Murray, Miller, Doeltgen, & Scholten, 2013; Vivanti, et al., 2009; Whelan, 2001).

Implications for practice include the need to educate all clinical staff about the risks of dehydration and the development of clinical pathways for clients with dysphagia which include routine monitoring of oral fluid consumption and dehydration and timely intervention. Focus should be on those aspects of service delivery that health professionals can change including: i) design and evaluation of education programs for all clinical staff who work with clients with dysphagia about the importance of adequate fluid intake and the risks of dehydration; ii) procedures which outline clear expectations and accountability for all clinical staff with respect to drinking and hydration; and iii) establishing and auditing care plans for clients with dysphagia which include the routine offering of fluids, recording of intake and assessment against target amounts throughout the day, assessing for dehydration, and implementing and evaluating intervention strategies. This concludes Part II of the thesis which aimed to provide background about the current situation with respect to patients with dysphagia post-stroke particularly their thickened fluid consumption. Part III introduces the prospective studies which investigated the fluid intake, hydration and health status of patients with and without dysphagia post-stroke.

PART III Prospective Studies

Chapter 6: Methods for Prospective Studies

Introduction and Purpose

This chapter outlines the methods for the two prospective studies in this thesis:

- a. the observational cohort study involving patients *without* dysphagia post-stroke; and
- b. the randomised controlled trial involving patients with dysphagia post-stroke.

Despite the difference in research designs, the methods for both studies were designed to be as similar as possible so that findings about fluid intake, hydration status and health outcomes could be compared across these different patient groups (those *with* and *without* dysphagia). This chapter outlines the research questions for each study, the study design, ethical approval, inclusion and exclusion criteria for each study, consent processes, assessments, outcome measures and process for analysis of findings. The Results and Discussion for each study are presented separately in Chapters 7 and 8. Chapter 9 is dedicated to the presentation and discussion of the findings about fluid intake and hydration for both studies combined, allowing a comparison of the outcomes of the patients *with* and *without* dysphagia.

Research Questions

- a. For patients without dysphagia post-stroke
 - 1. What is the average daily fluid intake from beverages (in ml) of hospitalised patients without dysphagia following stroke and how does this compare with the healthy elderly?
 - 2. Is beverage intake associated with stroke severity or particular stroke comorbidities?
 - 3. What is the hydration status of hospitalised stroke patients without dysphagia following stroke as measured by urea/creatinine ratio and how does this compare with the healthy elderly?

- 4. Is hydration status associated with stroke severity or particular stroke comorbidities?
- 5. What is the incidence of the adverse health outcomes of aspiration pneumonia, urinary tract infection, constipation, and/or dehydration associated with different levels of fluid intake of hospitalised patients without dysphagia following stroke?
- b. For patients with dysphagia post-stroke
 - 1. What is the average daily fluid intake from beverages of stroke patients with dysphagia having oral-only intake who are prescribed thickened fluids compared with a water protocol?
 - 2. Is beverage intake of patients with dysphagia associated with stroke severity or particular stroke co-morbidities?
 - 3. What is the hydration status of stroke patients with dysphagia having oralonly intake who are prescribed thickened fluids compared with a water protocol?
 - 4. Is hydration status of patients with dysphagia associated with stroke severity or particular stroke co-morbidities?
 - 5. What is the incidence of adverse health outcomes associated with fluid intake, namely aspiration pneumonia, dehydration, constipation or urinary tract infections of stroke patients with dysphagia who are prescribed thickened fluids compared with a water protocol?
 - 6. Does a water protocol result in faster resolution of dysphagia for thin fluids?
 - 7. Do patients with dysphagia prefer to drink thickened fluids or water if given a choice?

Study Designs

a. For patients without dysphagia post-stroke

This study was designed to be an observational cohort study

b. For patients with dysphagia post-stroke

This study was designed as a randomised controlled trial (RCT). Consented patients who were assessed as eligible for inclusion were randomised into two groups, one receiving thickened fluids only (standard care) and the other placed on a water protocol.

Ethical Approval

Ethics approval was granted for both studies simultaneously by the Human Research Ethics Committees governing seven hospitals in South Australia: Royal Adelaide Hospital Research Ethics Committee 29 June 2009 (protocol 090430); Southern Adelaide Clinical Human Research Ethics Committee 8 June 2010 (protocol 073.10); Human Research Ethics Committee (TQEH, LMH, MH) 20 December 2010 (protocol number 2011212) – see Appendix 1.

Site approval was granted by the General Manager and clinical directors of the stroke service at each of the following hospitals: Flinders Medical Centre (FMC); Repatriation General Hospital (RGH); Hampstead Rehabilitation Centre (HRC); Royal Adelaide Hospital (RAH); and St Margaret's Rehabilitation Hospital (SMRH). The RCT was registered with the Australian and New Zealand Clinical Trials Registry # ACTRN12610000752066.

Sample Size Calculation

Sample size calculations were made on the basis of the primary outcome measure for both studies, namely fluid intake from beverages alone.

a. For patients without dysphagia post-stroke

The sample size for the cohort study was calculated using the mean and standard deviation of fluid intake from a study of institutionalised elderly population

(Chidester & Spangler, 1997) and the mean and standard deviation beverage intake for patients without dysphagia following stroke collected in a pilot study conducted by this author in 2006. The results from the study by Chidester et al (1997) were used as they are frequently cited due to the study's robust methodology. Furthermore, this study had similar methodology to the present study: fluid intake was measured from beverages only; the definition of what was considered a beverage matched the present study's definition; the participants ranged in age from 65 to 100 years; the setting was intermediate level of residential care considered similar in nature to the sub-acute setting of this present study; and participants were free from acute illness or infection. Aiming for a p value of less than 0.05 and powered at 80%, the study required a sample size of 86 participants.

b. For patients with dysphagia post-stroke

The sample size for the RCT was calculated based on numbers that would be required to demonstrate a clinically meaningful difference between groups for the primary outcome of beverage intake (nominated as 200ml). The mean and standard deviation of fluid intake from the 2006 pilot study were used for the calculation; fluid consumption of three patients on thickened fluids only (mean 972ml, SD 498ml) was compared with three patients on a water protocol (mean 1162ml, SD 251). Aiming for a p value of less than 0.05 and powered at 80%, the study required a sample size of 138 participants; 69 in each arm of the RCT.

Participants

Recruitment of patients to both studies occurred simultaneously at Hampstead Rehabilitation Centre (HRC), Repatriation General Hospital (RGH), St Margaret's Rehabilitation Hospital (SMRH), Royal Adelaide Hospital (RAH) and Flinders Medical Centre (FMC) from November 2009 to February 2013. The data sets from 18 patients without dysphagia and three patients with dysphagia recruited from HRC to the pilot study in 2006 were also included in the cohort study and RCT, respectively.

Inclusion Criteria

i. Hospital inpatients in dedicated stroke units

Patients were recruited from dedicated stroke units so that processes across participating hospital sites were similar, based on established stroke care planning, thereby reducing the variability in care received by participants.

ii. Medical diagnosis of stroke resulting in the current admission

Patients were included if they had an admission diagnosis of ischaemic or haemorrhagic stroke (according to ICD-10 coding). It was intended to limit the heterogeneity of the clinical population so that conclusions could be drawn specifically about the stroke population.

- a. For patients without dysphagia post-stroke
- iii. Clinical evaluation suggested no dysphagia for any food or fluid consistency

To be classified as not having dysphagia and therefore eligible for inclusion, participants needed a 'no abnormality detected' rating on the oro-motor and mealtime assessment according to the AusTOMS criteria for dysphagia and aspiration (Perry & Skeat, 2004) and were required to pass the water test according to the norms for age and sex (Hughes & Wiles, 1996). Ideally, a videofluoroscopic swallow study (VFSS) or flexible endoscopic evaluation of swallowing (FEES) would have been conducted with each participant as clinical assessments alone are deemed to have limited sensitivity and specificity (Logemann, 1998). The original research protocol included such an assessment and several participants had an objective assessment completed. However, recruitment proved to be problematic, especially when patients were deemed to be eating and drinking safely and well established on a normal diet and fluids. Such potential participants did not wish to undergo either of these instrumental assessments of their swallowing, especially as for many this required travelling in a taxi to another hospital for the procedure. Given that this study was an observational study and aimed to measure current clinical practice, rather than an experimental study or one which would alter intervention based on this assessment, a clinical assessment alone was deemed sufficient. The amendment to the protocol, to omit an objective assessment and rely on a clinical assessment alone, was approved by the relevant Ethics committees.

iv. Patient was on a General Diet and thin fluids

Patients who were deemed to have unimpaired swallowing were only included if they were safely managing a normal diet (no modifications of food or fluid textures), so there was no question as to their oral, pharyngeal or oesophageal function.

- b. For patients with dysphagia post-stroke
- iii. Clinical evaluation suggested dysphagia for thin fluids

The clinical assessment was followed with a videofluoroscopic swallow study (VFSS). Patients were eligible for inclusion if they were aspirating thin consistencies of fluids but were safe on a thickened fluid consistency. Detailed criteria are outlined in the Assessment section of this chapter.

iv. Patient was receiving a full oral diet (of any consistency) and thickened fluids

The aim of the study was to determine whether patients with dysphagia receive adequate fluid intake and hydration when on an oral diet but require modified texture fluids, therefore only patients managing an oral diet and prescribed thickened fluids were included in the study.

Exclusion Criteria

- Known progressive neurological conditions such as Multiple Sclerosis, Motor Neurone Disease, Parkinson's disease or dementia
- ii. History of brain tumour or traumatic brain injury
- iii. History of head or neck cancer

The above three criteria ensured that any swallowing problems identified were attributable to the stroke and conclusions could be drawn based on the stroke related dysphagia rather than another contributing condition.

iv. Acute medical illness such as pneumonia, acute exacerbation of congestive cardiac failure (CCF) or acute renal failure

Participants were required to be medically stable. Outcomes being measured were the presence of pneumonia, urinary tract infection or dehydration. It was therefore necessary that the patients did not have an existing acute medical illness before joining the study.

v. Medical order for fluid restriction

It was important to measure how much patients drink and their associated hydration levels when intake was not restricted by other clinical factors. Therefore patients were excluded if they had a medical order for fluids to be restricted to a certain amount.

vi. Pregnant or breast feeding

Fluid requirements are different when a female is pregnant or breast feeding. It was also not ethical to include these patients as radiation exposure through the VFSS was part of the research protocol.

Additional exclusion criteria for b) the RCT involving patients *with* dysphagia poststroke

vii. Chronic suppressed immune system

Given that the premise of the experimental condition was that patients would likely aspirate some of the water that they drank, it was considered too risky and unethical to include individuals whose immune system may have been unable to tolerate the aspirated material (Langmore, et al., 1998).

viii. Chronic obstructive pulmonary disease (COPD)

Individuals with COPD are at increased risk of dysphagia and aspiration from the COPD itself and also have difficulty clearing aspirated material from their compromised pulmonary system (Good-Fratturelli, et al., 2000; Langmore, et al., 1998; Mokhlesi, 2003). It was considered high risk and unethical to include patients with known chronic lung conditions

ix. Receiving alternative or supplementary non-oral forms of nutrition or hydration such as IVT, NET, PEG

Patients receiving alternative or supplementary non-oral forms of nutrition or hydration were not included as these forms of nutritional and liquid intake would have impacted on the outcomes measure, urea/creatinine ratio and made it impossible to draw conclusions about hydration from oral fluids.

x. Aspirating smooth pureed food and/or moderately thick fluids

Patients included in this study needed to be on a full oral diet and not receiving nonoral supplementation. If they were aspirating the safest of food and fluid consistencies it was not likely that they would be meeting their nutritional requirements orally. Furthermore, aspiration of thickened fluids is known to be more harmful than thin (Schmidt, et al., 1994) so it would be unethical to include this group in the study. This study was designed to specifically investigate the outcome of aspirating water only.

Consent

Patients were approached in person by the researcher or another speech pathologist in the hospital, usually within two days to two weeks after admission. They were given verbal information in conjunction with pictorial and gestural visual support if needed. If they had aphasia, cognitive impairment or were unable to speak and comprehend English, a family member was asked to be present for an explanation of the project or this was provided to them over the phone. "Aphasia-friendly" written material with picture support or the longer written patient information sheet was left with the patient for at least 24 hours to allow them time to speak with family members and consider their participation. They were then approached a second time to give their signed consent. Again, if they had aphasia, cognitive impairment or limited English proficiency, a family member was asked to provide the written consent after confirming the patient wishes directly with them via yes/no questioning (Braunack-Mayer & Hersh, 2001; Kagan & Kimelman, 1995).

Assessments

Demographic Data

Demographic data were collected from the participants' medical records about age, sex, and admitting hospital.

Stroke Characteristics and Comorbidities

Stroke characteristics of each participant were recorded, including stroke type (infarct or haemorrhage), stroke location and lateralisation, and time post-stroke when recruited to the study. The admission Functional Independence Measure (FIM) was recorded for each participant as an indication of dependency. This measure rates a patient's independence in areas such as eating, mobility, dressing, toileting, speaking and problem solving to obtain a total score from 18 to 126; a higher score represents greater independence. Stroke co-morbidities were recorded including the presence or absence of aphasia, cognitive impairment, dysarthria, apraxia of speech, motor or ideational apraxia. Level of mobility was classified according to level of exertion required ranging from i) bedbound to ii) predominantly sitting to iii) exerting to mobilise either by walking or self-propelling in a wheelchair. The patient's independence in pouring drinks and drinking from a cup, along with their independence for oral hygiene was also recorded. Other medical information was recorded from medical records including weight at admission and relevant past medical history. Refer to Appendix 8 for patient data collection form.

The following clinical assessments were conducted to confirm eligibility for the research once patients had passed the initial screening process and consented to inclusion. These comprised of an oro-motor assessment, mealtime observations, 150ml timed water test and oral health assessments as outlined below:

Oro-Motor Assessment and Mealtime Observations

The oro-motor and mealtime swallowing assessment particularly focussed on factors that have been closely correlated with aspiration during VFSS, namely changes in voice quality, palatal and gag responses, and reduced hyolaryngeal excursion (Horner, et al., 1988; Kidd, et al., 1993; Linden, et al., 1993; Mann, et al., 2000).

Once assessed for the presence or absence of these factors, patients were given a severity rating for: dysphagia for food; dysphagia for thickened fluids; dysphagia for thin fluids; aspiration of food; aspiration of thickened fluids; and aspiration of thin fluids. They were rated according to the AusTOMS severity rating scale as having no abnormality detected (NAD), mild impairment, moderate impairment or severe impairment (Perry & Skeat, 2004) – see Appendix 9.

150ml Water Test

This is a validated test that is normed for female and males of varying age cohorts (Hughes & Wiles, 1996). The examiner provides a precisely measured 150ml of water in a cup and asks the patient to drink it "as fast as is comfortably possible". The examiner times the patient with a stopwatch and counts the number of swallows taken to drink the 150ml. If the patient is unable to consume the full 150ml, the amount consumed is calculated from the measured remainder – see Appendix 11). The total score is summed; the lower the score, the better the oral health.

Videofluoroscopic Swallow Study (VFSS)

b. For the RCT involving patients with dysphagia post-stroke only

A VFSS was conducted by a trained speech pathologist using a formal research protocol (see Appendix 12). The protocol required the speech pathologist to make decisions according to how the patient progressed. The patient needed to aspirate on 2 out of 3 thin liquid swallows and <u>not</u> aspirate on one consistency of thickened fluid and smooth pureed food to be included in the study. Aspiration was defined as a score of >=6 on the Aspiration-Penetration (ASPEN) scale (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996).

Randomisation

b. For the RCT involving patients with dysphagia post-stroke only

Once assessed by the speech pathologist as aspirating thin fluids but safe on one consistency of thickened fluids, patients were randomly allocated to one of two treatment arms: Thickened fluids only or Water Protocol. The randomisation process occurred through a custom-designed website. The patient's identifying number was

entered by the researcher and an allocation to one of the two groups was computer generated; the group allocated to this patient was communicated automatically by email to the researcher and the treating speech pathologist. When establishing the website, a total number of 138 patients were expected to be randomised. The researcher, clinicians and patients could not be blinded to the group allocation as all were involved in delivering the intervention.

Interventions

Provision of Fluids

a. For the cohort study of patients without dysphagia post-stroke

In this study there were no specific interventions with respect to fluid intake or hydration. Each patient was provided with a 1000ml jug of water or cordial at their bedside every 24 hour period. They were also offered hot or cold beverages in cups of measured sizes (150-250ml) six times throughout the day. In theory, if they were to consume just one drink at each set time plus drink the contents of their jug they could consume 2200ml per day. In addition most patients were offered extra fluid with their medication and could access drinks from the hospital cafeteria/kiosk or via relatives and friends. Information sheets were provided to participants and family informing them to notify nursing staff if extra drinks were consumed and not to discard residuals in cups or jugs. The purpose was to observe/record intake with no attempt to limit or control the amounts of fluid offered.

b. For the RCT involving patients with dysphagia post-stroke only

Thickened Fluids Only

In the thickened fluid only intervention, patients were allowed to drink only the thickened fluid of the consistency deemed safe from their assessment. This was either mildly, moderately or extremely thick fluids as per the Australian National Standards for fluid viscosity (Atherton, et al., 2007). Each hospital site from which patients were recruited observed a slightly different process for providing thickened fluids. At HRC each patient was provided with a 1 litre jug of thickened fluids at their bedside per day. This was prepared by the hospital food service from powdered

thickener according to standard recipes but came in only one flavour per jug (e.g. orange cordial). They were offered powder thickened hot drinks on an individual basis prepared by nursing staff. At RGH each patient was offered 6 x 175ml prepackaged thickened drinks per day. At SMRH each patient was offered a jug of powder-thickened fluids at their bedside and additional jugs of thickened fluids were available in the dining room at meal times.

Water Protocol

The water protocol used in this research was adapted from the original Frazier Water Protocol (Panther, 2003). Water is permitted any time between meals but not at mealtime or with food as the food may be aspirated along with the water. For the same reason, water is not allowed for 30 minutes after a meal as this allows spontaneous swallows to clear any pooled food residue. Medications are never given with water as they too may be aspirated with the water. Nursing and other staff are informed that the patient may cough but should not be stopped from drinking unless they show signs of distress. An important part of this protocol is that regular and rigorous oral care is provided. In addition to the water between meals which the patient may consume freely, they also have access to the appropriate thickened fluid they were assessed to be safely consuming (see Appendix 13). Participants in the thickened fluids only group, although not permitted water as such, had small amounts with their clinician when assessing readiness for upgrade to thin fluids.

Oral Hygiene Protocol

All participants in both studies were required to adhere to a daily oral hygiene routine, which involved brushing the teeth or dentures twice daily, after breakfast and in the evening, and rinsing their mouth after lunch. This oral hygiene protocol was adapted from the South Australian Dental Service's oral health protocols for residential aged care facilities (South Australian Dental Service, 2004) (see Appendix 14).

To gauge compliance with the oral hygiene protocol, purpose-made stickers were placed at the corresponding time points on each day's fluid balance chart and the nursing staff or the patient themselves were asked to sign off once they had cleaned their teeth or rinsed their mouth (see example in Appendix 15).

Outcome Measures

The primary outcome was average daily beverage intake (how much a patient consumed of their prescribed oral fluids per day).

Daily Beverage Intake (mls)

Daily beverage intake was measured by calculating an average intake from the completion of fluid balance charts (FBC). Fluid balance charts were considered the most familiar method for nursing staff to record intake. In order to reinforce the correct way to complete FBCs, an exemplar was displayed at the nurses' station on the ward for nursing staff to use. Prior to the research commencing and throughout the duration of the research, senior nursing staff were asked to revise the education of nursing staff about the correct completion of FBCs.

A fluid balance chart has a column of times in hour intervals running vertically along the left hand side of the page. Whenever a drink is consumed, that drink is recorded (type and amount) in the column alongside the appropriate time slot. For the purposes of this research only the input was recorded. A record of the fluid output via urine, stools or vomiting was not required. A balance was therefore not calculated. A de-identified example of a participant's FBC is included in Appendix 15.

Participants' FBCs were not included in the analysis if they were obviously incomplete (e.g. a full nursing shift missing or a patient was discharged half-way through the 24 hour period). Each FBC was totalled twice by the researcher to ensure accuracy in calculations. Fluids that were counted were those that were beverages (water, cordial, coffee, tea, milo, soft-drinks, milk, flavoured milk, fruit juices). Not included were fluids that began as foods i.e. soups, custards, ice-cream, or yoghurt.

For the cohort study of patients without dysphagia, FBCs were completed for 7 days. For the RCT, FBCs were completed for every day that the patient was on modified fluids until no longer aspirating or until discharge, whichever came first.

This outcome measure could not be blinded to group assignment as the specific beverage type consumed had to be totalled separately (thickened fluid or water).

Nursing staff, who were responsible for recording this measure, also had a duty of care to ensure the patient was complying with the prescribed intervention so they had to be aware of the patient's allocated group.

The other outcomes were hydration status, health status, time to resolution of dysphagia for thin fluids, and patient satisfaction.

Level of Hydration (Urea/Creatinine Ratio)

The objective measure used to provide an indication of hydration in this study was the urea/creatinine ratio. It was determined from biochemical analysis of a blood sample as blood samples are reported to provide more robust measures than urine measures (Mentes, 2006). While other measures such as sodium and osmolality may be indicative of total body water status and are equally valid, the urea/creatinine ratio is the measure used most commonly in the literature relevant to the speech pathology and dysphagia field (Crary, et al., 2013; Leibovitz, et al., 2007; Rowat, et al., 2012). Urea is a waste product created from the breakdown of protein in the body. It is made in the liver and passes out of the body through the kidneys. If the kidneys are not able to remove urea from the blood normally, the urea level in the blood rises. Creatinine is a by-product of normal muscle contractions. It is produced at a fairly constant rate by the body although each person's baseline rate may be different depending on skeletal muscle mass. Creatinine is mainly filtered out of the blood by the kidneys. If the filtering function of the kidney is impaired, the level of creatinine in the blood will rise. Creatinine is therefore used as a measure of kidney function. Urea and creatinine tests can be used together to find the urea-to-creatinine ratio. Kidney disease or blockage of the flow of urine from the kidney would cause both urea and creatinine levels to increase. Since the creatinine level of a person without primary renal failure should be relatively constant, an increase in the urea disproportionate to the creatinine in the blood, may indicate a pre-renal problem that has caused a decrease in the flow of blood to the kidneys, such as congestive heart failure or volume depletion (from inadequate fluid intake). Low blood volume from inadequate fluid intake generally causes urea levels to rise more than creatinine levels, causing a high urea-to-creatinine ratio (Wallach, 2007). A normal range of urea-to-creatinine ratio is considered to be between 40 and 80. Blood urea nitrogen/creatinine ratio greater than 15 (equivalent to 61 in standard international

units) was found to be an independent risk factor for early neurological deterioration in ischaemic stroke (Bhatia, et al., 2015) and this was subsequently the cut-off used in a study of dehydration in acute stroke by Crary et al., (2013). However, data collection for the present studies commenced prior to these publications and at the time the most commonly used cut-off point was a ratio greater than 20 (equivalent to 80 in standard international units) as an indicator of dehydration (Leibovitz, et al., 2007; Rowat, et al., 2012; Whelan, 2001). Data analysis proceeded with this more liberal cut-off point.

The venepuncture nurse who took the blood samples and the biochemist who analysed the samples were blinded to the patient's group allocation. The researcher who recorded these data and the medical officer who interpreted them for clinical care were not blinded.

Adverse Health Outcomes

Incidence of dehydration (from clinical diagnosis recorded in the medical record)

Given the complexity of diagnosing dehydration, it was decided to use the presence of a clinical diagnosis of dehydration by a physician as recorded in the medical record for this health outcome measure. This is typically based on a profile of biochemical markers, and clinical indicators in the context of known kidney function.

Incidence of UTI (from clinical diagnosis recorded in the medical record)

The presence of a clinical diagnosis of urinary tract infection by a physician as recorded in the medical record was used for this health outcome measure. The physician bases this diagnosis on clinical observations such as offensive smelling urine, patient report of pain, increased temperature, response to antibiotics, or confirmation by pathology analysis of a urine sample.

Incidence of constipation (from clinical diagnosis recorded in the medical record)

The presence of a clinical diagnosis of constipation by a physician or registered nurse as recorded in the medical record was used for this health outcome measure. This diagnosis is based on knowledge of patient history, observations of use of bowels, abdominal pain and discomfort, fluid intake, response to aperients and laxatives, per rectum examination or abdominal X-ray.

Incidence of pneumonia

The presence of a clinical diagnosis of pneumonia by a registered medical officer was recorded in the medical record as per standard practice, namely abnormal chest X-ray plus one or more of the following: fever, purulent sputum, tachycardia, tachypnoea, inspiratory crackles, arterial hypoxemia, or positive stain and culture. Because of the known association between aspiration and pneumonia, chest status was monitored on a daily basis by the medical team for all participants in the RCT as per the medical checklist see Appendix 16).

These outcome measures were not blinded as the treating team who recorded these medical diagnoses may have been aware of the allocated dysphagia intervention from the medical records. The researcher who extracted the data on medical diagnoses was not blinded to group allocation.

b. For the RCT involving patients with dysphagia post-stroke, the following additional outcome measures were recorded.

Time to Resolution of Dysphagia for Thin Fluids

The number of days was calculated from date of stroke to date of resolution of dysphagia and upgrade to thin fluids as determined by a qualified speech-language pathologist assessment or following VFSS.

Patient Satisfaction

Patients completed a purpose designed survey of five questions with choice of five pictorial responses on a Likert scale (see Appendix 17).

The simply phrased written questions and answers with pictorial support were designed to be accessible for cognitively and communicatively impaired participants. Questions focussed on coughing, distress, taste, thirst quenching and feel in the mouth. The highest possible score was 25; the higher the score, the greater the patient's satisfaction with the oral fluid offered. A survey about thickened fluids was

completed on a weekly basis (at day 7, day 14 and day 21) by participants in the thickened fluids only group. The same survey plus an additional survey (comprised of the same questions) was completed about water for those in the water protocol group. In addition participants in this group were asked whether they preferred to drink thickened fluids or water.

The research protocol is illustrated in Figure 6 below



Figure 6 Research protocol

Analysis

The Statistical Package for Social Sciences, version 22.0 (IBM Corp., 2013) was used to analyse the data from these studies separately, as presented in chapters 7 and 8, and then together, as presented in chapter 9. Descriptive statistics were used to illustrate the profile of the participants from a demographic perspective and to detail their stroke characteristics and co-morbidities. These characteristics were analysed according to the hospital site from which the participants were recruited to determine whether the total sample was similar in baseline characteristics. Some data were not available in some of the participants' records, predominantly admission weight, FIM score or documentation of dependency/mobility. There was no interpolation of these missing data points; only the data collected were used in the analysis. Included in the descriptive statistics is an analysis of the participants' clinical assessment results.

For the comparison of results presented in Chapter 9, demographic information, clinical characteristics, assessment results and outcome measures from the participants in the RCT and cohort studies were combined and analysed in one database in SPSS (IBM Corp., 2013). The participants recruited to the RCT with known thin fluid aspiration, were pooled into the one group and categorised as the *dysphagia group*. This allowed them to be directly compared with the group of participants with *no dysphagia*. Demographic and clinical characteristics of participants in both studies were directly compared using independent sample t-tests for continuous variables and Pearson's chi-square for categorical data to determine whether the two cohorts were comparable and equally representative of a typical stroke population. The assessment results and outcomes measures of fluid intake, hydration status and adverse health outcomes were compared by analysing between group differences (dysphagia versus no dysphagia).

The quantitative data of average beverage intake and urea creatinine ratios were tested for assumptions of normality in order to determine whether to analyse them with parametric or non-parametric statistics. The frequency distributions were plotted using histograms and probability-probability plots to look at the shape of the distribution. The skewness and kurtosis of the distributions were quantified along with their standard errors, and z scores for skewness and kurtosis were calculated. The Kolmogorov-Smirnov test and the Shapiro-Wilk test were conducted to explore

the distribution of the sample and whether it deviated from a normal distribution. Fluid intake data for all participants in the cohort study of patients without dysphagia and the RCT were normally distributed and thus means and standard deviations were used to describe averages.

Data for percentage of required fluids consumed were only available for participants whose weight was recorded in the cohort study and the RCT and only the data of these participants were used in the respective analyses. Missing data points were not interpolated or otherwise derived. Differences between groups in the RCT for beverage intake were analysed using independent samples t-tests. Further analysis was undertaken to determine whether differences in mean fluid intake were attributable to any particular patient variables (such as age, sex, stroke severity, and stroke comorbidities). Univariate analyses were used to investigate the interaction of variables of age and sex; independent samples t-tests examined binary stroke comorbidities of presence/absence of aphasia, cognitive impairment, dependence for drinking; and one-way ANOVAs examined variables with more than two categories (site of rehabilitation admission, age range, mobility, nature of stroke, range of time post-stroke, and location of stroke). For mobility status, the bed-bound group was combined with the predominantly sitting group to form a "not exerting to mobilise" category which was then used in a binary comparison with "exerting to mobilise" using t-tests.

In the comparison of outcomes for the dysphagia versus no dysphagia groups presented in Chapter 9, differences between groups for the continuous variables such as average daily fluid intake and hydration at day 0 and day 7 were analysed using independent sample t-tests or one-way ANOVAs.

Results for the hydration index of urea/creatinine ratio were not normally distributed for the cohort study so analysis proceeded with non-parametric statistics. Missing data points were not interpolated or otherwise derived. Differences between groups were analysed using Mann Whitney U tests at the different time points. Results for the urea/creatinine ratio in the RCT were normally distributed so analysis proceeded along the same lines using parametric statistics. Repeated measures ANOVA was used to determine differences in urea/creatinine ratios across time (Day 0, Day 7, Day 14) and groups. Pearson's correlations were performed to determine whether any of the dependent variables of fluid intake, percentage of required fluid consumed or urea/creatinine ratios were associated with each other. Correlations were performed to determine whether there were associations between any of these outcome measures with the independent continuous variables of age, admission FIM or days post-stroke. Effect sizes were calculated for any significant results (p<0.05) using Cohen's d coefficient, r values from correlations or regression analysis. Further pooling of the data into one total cohort of sub-acute stroke patients occurred in order to investigate whether fluid intake was correlated with the hydration measure and whether there were any associations between outcomes measures and particular demographic or stroke characteristics/comorbidities in the combined sample presented in Chapter 9.

Adverse events were analysed using descriptive statistics. Differences in incidence of adverse events between the groups in the RCT were analysed using chi square statistics. Chi square analysis along with logistic regression was performed to determine whether any of the other outcome measures or independent variables had a predictive association with an adverse health outcome.

Time to resolution of dysphagia for thin fluids between the groups in the RCT was compared using a two-tailed t-test. Patient satisfaction survey scores from the RCT were analysed using descriptive statistics and between group differences compared using two-tailed t-tests.

The results of data collection and analysis are presented and discussed in the following three chapters.
Chapter 7: Beverage Intake and Hydration Status of Hospitalised Individuals w*ithout* Dysphagia Following Stroke: A Cohort Study³

Introduction and Purpose

As discussed earlier in this thesis, the reasons for sub-optimal intake of thickened fluids by patients with dysphagia are not definitive, as previous studies have lacked the necessary control conditions or participants (Carlaw, et al., 2012; Finestone, et al., 2001; Garon, et al., 1997; Karagiannis, et al., 2011; Leibovitz, et al., 2007; Whelan, 2001). Suggested reasons for the sub-optimal fluid intake are the dysphagia itself, the patients' dislike of thickened fluids, or systems issues in the way thickened fluids are provided and consumption is monitored. An alternative explanation may be that the stroke itself, its co-morbidities or the patient's situation of being institutionalised in a hospital environment may impact directly, or indirectly, on intake of fluids.

The general population including the healthy elderly living in the community are typically able to access fluids freely. They are mobile, usually independent with food and drink preparation, have immediate access to a fridge, a kettle or a tap and are cognitively intact enough to source a drink when they would like one. Their fluid intake is governed only by their own preferences for how much to drink each day. Conversely, immediately following their stroke, patients are usually in a hospital setting. In most cases they do not have free access to a source of fluids. Fluids are provided for them in a finite quantity at prescribed times throughout the day. They often have impaired mobility, and may not be able to mobilise or even sit independently to access a drink in their room. Even if the drink is sufficiently close to the bed for them to reach, they may not have the upper limb function or motor planning to reach for, hold and tip a cup effectively. In addition, they may have

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Appendix 4.

cognitive impairment as a result of their stroke which impacts their recognition of the need to drink or to ask for help if needed. Communication and the ability to ask may be impaired by aphasia, dysarthria or apraxia of speech. Furthermore, there is anecdotal evidence that some patients in hospital do not like to be a 'nuisance' or a burden to the nursing staff, so do not like to ask for a drink if they cannot drink independently. Stroke patients often have incontinence and many patients are reluctant to drink for the fear of being unable to get to the toilet and being incontinent.

At the time of preparing this research agenda, there was no published literature about the fluid intake of hospitalised individuals who do not have dysphagia following their stroke. It was anticipated that this current study would provide a valid aetiology matched control group, with which the intake of the individuals with dysphagia could be compared. This would help to determine whether factors relating to the stroke (apart from dysphagia) or residing in a healthcare institution affects fluid intake for all patients following stroke. There has recently been one study published comparing the fluid intake of 10 patients with dysphagia on thickened fluids with 10 patients without dysphagia consuming normal drinks (McGrail & Kelchner, 2012). This is the first study permitting this direct comparison and findings will be discussed later in this chapter.

The purpose of this study was to determine the average beverage intake, hydration status and health status of patients in hospital following a stroke who do *not* have dysphagia. This cohort of patients would be residing in an inpatient facility, with prescribed systems for accessing fluids throughout the day. They would have the same range of co-morbidities as a result of their stroke as individuals *with* dysphagia following stroke, with similar deficits in mobility, self-care, communication, cognition and toileting. Therefore, this study aimed to provide the aetiology matched data needed to allow a valid comparison for fluid intake and hydration studies of patients with dysphagia. The study also aimed to determine whether hospitalised patients without dysphagia following stroke are meeting fluid intake standards and are adequately hydrated. If not, the implementation of hydration protocols in hospitals for all patients, not just those with dysphagia, would be justified, as

adequate hydration has been shown to be vital to recovery from stroke (Bhalla, et al., 2000; Bhalla, Wolfe, & Rudd, 2001).

Research Questions

- 1. What is the average daily fluid intake from beverages (in ml) of hospitalised patients without dysphagia following stroke and how does this compare with the healthy elderly?
- 2. Is beverage intake associated with stroke severity or particular stroke comorbidities?
- 3. What is the hydration status of hospitalised stroke patients without dysphagia, following stroke as measured by urea/creatinine ratio and how does this compare with the healthy elderly?
- 4. Is hydration status associated with stroke severity or particular stroke comorbidities?
- 5. What is the incidence of adverse health outcomes, i.e. UTI's, constipation, and/or dehydration, associated with different levels of fluid intake of hospitalised patients without dysphagia following stroke?

Method

The Methods are presented in Chapter 6.

Results

Numbers Screened and Included/Excluded

In total 462 patients admitted to hospital post-stroke were screened for inclusion in the study – refer to **Figure 7**. These patients were screened at Hampstead Rehabilitation Centre (HRC), Repatriation General Hospital (RGH), Flinders Medical Centre (FMC) and St Margaret's Rehabilitation Hospital (SMRH) from November 2009 to July 2012. There was an additional screening period at HRC in 2006 when subjects were screened for recruitment to the pilot study. Royal Adelaide Hospital (RAH) had agreed to participate but did not provide any patient screening data.



Figure 7 Recruitment to cohort study

Of the 462 patients screened, 188 presented with exclusion criteria and 96 declined consent. All patients screened at FMC had exclusion criteria present or were discharged prior to consent. The main reason for refusal of consent for patients at the rehabilitation centres was the requirement for blood tests or competing demands on their time in rehabilitation. Ninety-three patients were included but after seven subsequent withdrawals, 86 complete data sets proceeded to analysis. Most of the withdrawals occurred before the research protocol was amended and still required an instrumental assessment of swallowing: one participant refused to participate in the VFSS, one was car-sick in transit to the VFSS, four were unable to tolerate the FEES and one did not want a second blood test as the first was a traumatic experience for them. It was because of this high rate of drop-out in the initial stages of recruitment associated with the instrumental assessment of swallowing, that this part of the protocol was modified as described in Chapter 6.

Demographics of Participants

The demographics of the sample of patients without dysphagia are outlined in Table 8, presented as the frequency (percentage) of the total sample. There was a higher

proportion of males in the sample (64%) compared with females (36%). The age of participants ranged from 44 years to 88 years, with a mean age of 69 years (SD 11 years). Participants were distributed evenly across the three age ranges of younger adults (<65 years), older adults (65-75years) and the elderly (>75 years). The hospital to which participants were admitted is also presented in Table 8. All were recruited at rehabilitation centres with none from acute hospitals. The majority of participants were recruited at Hampstead Rehabilitation Centre (61%).

Stroke Characteristics of Participants

Stroke characteristics of each participant were analysed by frequency including type of stroke, anatomical location of the stroke and lateralisation of the stroke. The majority of participants in this sample (83%) had an infarct. More of this sample had cortical strokes (68%) than sub-cortical or brainstem strokes and the strokes were equally distributed between left and right side. The number of days post stroke when participants entered the study was calculated, with a mean of 39 days (SD 34 days) post-stroke. Most of the participants (77%) were between 2 weeks to 3 months post stroke. These data are also illustrated in Table 8.

		Ν	(%)
Total sample		86	(100)
Sex	Male	55	(64)
	Female	31	(36)
Age range (years)	<65	29	(34)
	65-75	26	(30)
	>75	31	(36)
Mean age in years (SD)		69	(11)
Hospital site	HRC	52	(61)
	RGH	19	(22)
	SMRH	15	(17)
Stroke Type	Infarct	71	(83)
	ICH	14	(16)
	SAH	1	(1)
Stroke Location	Cortical	58	(68)
	Sub-cortical	15	(17)
	Brainstem	7	(8)
	Cerebellar	6	(7)
Stroke Lateralisation	Left	42	(49)
	Right	40	(46)
	Bilateral	4	(5)
Time post stroke (days)	1-14	15	(17)
	15-30	31	(36)
	30-90	35	(41)
	>90	5	(6)

Table 8 Demographic and stroke characteristics of participants withoutdysphagia

Stroke and Medical Co-morbidities

Based on FIM scores, participants in the sample were at varying levels of independence, with an average FIM score at admission of 73 (SD 25). One third of the sample presented with aphasia and 29% had cognitive deficits. Only 22% of this sample were unable to exert themselves to mobilise (i.e. they were unable to walk with or without an aid or they were unable to self-propel in a wheelchair). The majority of participants were able to pour drinks for themselves (93%) and drink

from a cup independently (100%). The majority were also independent for oral care once set up (92%). Refer to Table 9.

Other medical information is presented, including relevant past medical history. About 17% of this sample had had a previous stroke, 21% were current smokers and 16% had gastro-oesophageal reflux. The average weight of participants was 80.2 kg (SD 20.4kg). Refer to Table 9.

		Ν	(%)
Total sample		86	(100)
Mean FIM (SD)		73	(25)
Stroke co-morbidities	Aphasia	29	(34)
	Cognitive impairment	25	(29)
	Not exerting to mobilise (bed-bound or predominantly sitting)	19/71	(27)
	Motor or ideational apraxia	12	(14)
	Dependence for oral care	7/71	(8)
	Dysarthria	21	(24)
	Apraxia of speech	10	(12)
	Dependence for pouring drinks	6/71	(7)
	Dependence for drinking from a cup	0/71	(0)
Past medical history	Previous stroke	15	(17)
	COPD	6	(7)
	GORD	14	(16)
	CCF	4	(5)
	Current smoker	18	(21)
	Renal impairment	6	(7)

Table 9 Stroke and medical co-morbidities of participants without dysphagia

Selected demographics and stroke characteristics of participants at the three different sites are presented in Table 10 to illustrate homogeneity of the sample.

		Н	RC	R	GH	SM	RH
		Ν	(%)	Ν	(%)	Ν	(%)
Sou	Male	34	(65)	13	(68)	8	(53)
Sex	Female	18	(35)	6	(32)	7	(47)
Mean age (years)			57	7	2	7	70
	<65	18	(35)	5	(26)	6	(40)
Age range (years)	65-75	18	(35)	4	(21)	4	(27)
	>75	16	(30)	10	(53)	5	(33)
Mean days post-stroke		45		33		24	
Time post stroke (days)	1-14	2	(4)	7	(37)	6	(40)
	15-30	19	(36)	6	(32)	6	(40)
	30-90	27	(52)	5	(26)	3	(20)
	>90	4	(8)	1	5	0	(0)
Mean admission FIM score		6	6*	7	4	8	8^*
Mean weight at admission		8	30	77	7.8	8.	3.8
Mean oral health score day 0		2.	42 [*]	2.	26	1.	07^*

Table 10 Demographics and clinical features of participants without dysphagiaat each hospital site

* Significant difference at p<0.05

Using one-way ANOVA it was demonstrated that there were no significant differences in the mean age of participants ($F_{2,83}$ =1.261, p=0.289), the mean number of days post-stroke ($F_{2,83}$ =2.711, p=0.072), or the mean weight of participants at the three hospitals ($F_{2,52}$ =0.344, p=0.710). There were significant differences in the average FIM scores at admission ($F_{2,61}$ =4.245, p=0.019) and the mean oral health scores at Day 0 ($F_{2,83}$ =3.323, p=0.041). The post-hoc *Tukey test* demonstrated that the difference was most significant between HRC and SMRH, with participants at SMRH having a higher FIM score at admission (less dependent) and having better oral health than HRC participants. Although there was no significant difference in time post stroke for participants at the different sites, the difference appears large. When time post stroke was analysed as a covariant using a univariate analysis of variance, it was found that the time post stroke for the participants at the different sites was significantly related to their admission FIM score ($F_{1,60}$ =10.738, p=0.002). After controlling for this covariant of time post stroke, there was no significant different sites at the difference between admission FIM scores of the participants at the different sites

(p=0.076). Given the similarity of demographic and clinical features of participants at the three sites, all data were subsequently pooled and analysed as a total sample.

Assessment Results

Results from the clinical assessments of all participants conducted on Day 0 are presented here.

i. Oro-motor assessment and mealtime observations

On the dysphagia for food rating scale, 83 participants (97%) rated NAD and 3 (3%) rated in the mild category because of limited dentition. All participants (100%) rated NAD for dysphagia for thin fluids, aspiration of food and aspiration of thin fluid.

ii. 150ml water test

The average volume consumed per swallow was 20ml (SD 6.5ml). The number of participants who were within the norms for this measure was 54 (63%), with 17 (20%) below normal limits i.e. outside the normative range (20mls to 37.5mls per swallow) provided for their age. Fifteen participants (17%) had this information missing.

The average time taken per swallow was 2 seconds (SD 1.1 sec). The number of participants who were within normal limits for this measure was 33 (38%) with 38 (44%) below normal limits i.e. outside the normative range (1.1 to 1.5 seconds per swallow) provided for their age. The same fifteen participants (17%) had this information missing.

The average volume of water consumed per second was 13ml (SD 6.9ml). All participants had this measure recorded; 80 participants (93%) were within normal limits and 6 participants (7%) outside of the normal range of 7.5 to 31.9mls per second.

The number of participants who showed no signs of aspiration (described as coughing, drooling or altered voice) was 79 (92%). Seven of the participants (8%) did show clinical signs but only 2 of these were coughing, the remainder were drooling (oral spillage of the water).

iii. Oral health assessment

The average oral health score when participants commenced the study was 2.15.

After 7 days of implementing of the oral hygiene protocol, the average oral health score at day 7 was 2.0.

Answers to Research Questions

Research question 1: What is the average daily fluid intake from beverages of hospitalised stroke patients without dysphagia and how does this compare with the healthy elderly?

The average beverage intake data was considered to be normally distributed (Z $_{skewness}=1.865$, Z $_{kurtosis}=-0.593$, Kolmogorov-Smirnov test revealed D₍₇₉₎= 0.059, p=0.200, Shapiro-Wilk test = 0.978, p=0.192) and was therefore analysed using parametric statistics.

The mean daily beverage intake was 1504ml (SD=359ml). Of the 86 participants in this study only two (2%) met the estimated beverage intake requirement for their age and sex of 2600mls for males and 2100ml for females as recommended by the Australian Nutrient Reference values (Australian National Health and Medical Research Council, 2005). Applying the more conservative standard of consuming 30ml per kilo of weight (Chidester & Spangler, 1997), only 4 (7.3%) of the 55 participants whose weight was recorded met their calculated beverage requirement. The amount participants consumed on average represented 67% of the amount of fluid they should have consumed (estimated as 2406ml) based on their calculated requirements from their weight.

Research question 2: Is beverage intake associated with stroke severity or particular stroke co-morbidities?

There was no significant difference in beverage intake between male and female participants (t_{84} =1.014, p=0.314) or the percentage of fluid requirements consumed (65% and 68% respectively, t_{53} =-0.541, p=0.591). There was also no significant difference in beverage intake between participants in varying age groups ($F_{2.83}$ =0.811, p=0.448). Similarly, there was no significant difference in the

percentage of calculated requirements consumed between participants in varying age groups ($F_{2,52}$ =0.326, p=0.723). There was no significant correlation found between the participants' actual age in years and their average fluid intake (r=-0.144, p=0.187) or percentage of calculated requirements consumed (r=0.137, p=0.318). The hospital site to which the participants was admitted also did not differentially affect beverage intake ($F_{2,83}$ =1.357, p=0.263) or percentage of calculated requirements consumed (r=0.131).

		Averag	verage daily beverage intake		Percentage of calculated fluid requirements			
		Ν	Mean	SD	Ν	Mean	SD	
Sex	Male	55	1534ml	370ml	34	65%	19%	
	Female	31	1452ml	336ml	21	68%	20%	
Age	<65	29	1525ml	383ml	18	63%	20%	
range (vears)	65-75	26	1557ml	355ml	17	68%	21%	
() • • • • • •	>75	31	1441ml	324ml	20	68%	19%	
Hospital	HRC	52	1511ml	367ml	23	66%	18%	
site	RGH	19	1583ml	365ml	18	71%	20%	
	SMRH	15	1382ml	286ml	14	61%	20%	

Table 11 Beverage intake of participants without dysphagia according todemographic factors

There was no significant difference in beverage intake between stroke patients recruited at different times post-stroke ($F_{3,83}$ =0.693, p=0.559). When comparing the percentage of calculated requirements consumed between participants recruited at various times post-stroke there was no significant difference between the various time points collectively ($F_{3,51}$ =2.563, p=0.065). However, participants recruited at 1-14 days post stroke consumed a significantly greater percentage of their calculated fluid requirements than those recruited 31-90 days post-stroke according to Tukey post hoc test (MD=18.734, SE=6.831, p=0.041). Refer to Table 12.

Time post- stroke	Ave	Average beverage intake			Percentage of calculated fluid requirements			
	Ν	Mean	SD	Ν	Mean	SD		
1-14 days	15	1576ml	394ml	12	$79\%^*$	21%		
15-30 days	31	1539ml	367ml	21	66%	17%		
31-90 days	35	1439ml	345ml	19	$60\%^*$	19%		
>90 days	5	1536ml5	318ml	12	79%	19%		

 Table 12 Beverage intake of participants without dysphagia according to time

 post-stroke

* Significant at p<0.05

Pearson's correlation (two-tailed) revealed a significant but small correlation (n=64, r=0.252, p=0.044) between participants' admission FIM scores and average fluid intake, indicating the more independent a participant was, the more they drank, as illustrated in Figure 8.



Figure 8 Correlation between admission FIM and average beverage intake for participants without dysphagia

Given the previously recognised influence of time post stroke intake, a *univariate analysis* was performed to determine the correlation between admission FIM and average beverage intake, with time post stroke as a covariant. After controlling for time post stroke, the correlation between admission FIM and average beverage intake was still significant (r=0.282, p=0.025). When age of participants was controlled for, the correlation between admission FIM and average beverage intake remained significant (r=0.269, p=0.033).

There was also a significant positive correlation (small to medium in strength) between the raw admission FIM and the percentage of calculated requirements consumed by participants (r=0.314, p=0.020), indicating that the more independent the participants, the higher percentage of calculated fluid requirements they consumed. This difference remained significant after controlling for the co-variants time post stroke (r=0.298, p=0.030) and age (r=0.308, p=0.025).

A linear regression was performed to determine how well the admission FIM score would predict the fluid intake of an individual. The significant result indicates that FIM score is a valid predictor of fluid intake ($R^2=0.064$, F=4.21, $\beta=0.252$, p=0.044). FIM score is also a significant predictor of the percentage of calculated fluid requirements an individual will consume ($R^2=0.099$, F=5.714, $\beta=0.315$, p=0.02).

There was no significant difference in beverage intake or percentage of calculated requirements consumed depending on whether or not the participant had the following stroke co-morbidities: cognitive impairment, reduced mobility (being unable to exert effort to mobilise by either walking or self-propelling in a wheelchair), aphasia, motor or ideational apraxia or dependence for oral care. Refer to Table 13 for details.

		A	Average beverage intake			Percentage of calculated fluid requirements			
		Ν	Mean	SD	р	Ν	Mean	SD	р
Aphasia	Yes	29	1411ml	309ml	0.087	17	70%	20%	0.377
	No	57	1552ml	375ml		38	65%	19%	
Cognitive	Yes	25	1435ml	312ml	0.254	15	58%	14%	0.056
impairment	No	61	1533ml	375ml		40	70%	20%	
Reduced	Yes	19	1568ml	475ml	0.318	13	61%	21%	0.263
exerting to mobilise)	No	52	1467ml	330ml		40	68%	19%	
Motor or	Yes	12	1442ml	278ml	0.520	8	66%	23%	0.974
Ideational Apraxia	No	74	1514ml	371ml		47	67%	19%	
Dependent for	Yes	7	1361ml	273ml	0.323	6	57%	10%	0.183
oral care	No	64	1509ml	382ml		49	68%	20%	

Table 13 Beverage intake of participants without dysphagia according to stroke comorbidities

Research question 3: What is the hydration status of hospitalised stroke patients without dysphagia?

Using the biochemical index of urea/creatinine ratio, an average was calculated for all participants in the sample at Day 0 (the day they joined the study and when fluid measurement began) and Day 7 (when fluid measurement ceased). Urea/creatinine results were not normally distributed at day 0 or day 7, so median and interquartile ranges are used to describe the results of the sample. Urea/creatinine ratio results at Day 0: $Z_{skewness}=3.387$ which is considered skewed, $Z_{kurtosis}=2.242$, Kolmogorov-Smirnov D₍₇₉₎= 0.108, p=0.023 and Shapiro-Wilk test = 0.955, p=0.007 were both significant which breaches the asumptions of normality. Urea/creatinine results at day 7: $Z_{skewness}=3.026$ which is considered significantly skewed, $Z_{kurtosis}=2.045$, Kolmogorov-Smirnov D₍₇₉₎=0.081, p=0.200 is not significant but Shapiro-Wilk test = 0.978, p=0.011 is significant at p<0.05.

The median urea/creatinine ratio at Day 0 was 76.7 and at Day 7 was 77.94. Given that the normal range for this biochemical index is between 40 and 80, this sample had results at the high end of the normal range at both measurement points. Each

participant's urea/creatinine ratio result was classified as within normal range (40-80) or elevated beyond normal limits (>80). Table 14 illustrates the raw urea/creatinine ratio results and the percentage of the sample whose results fit within each range.

		Day 0	Day 7
Urea/creatinine ratio	Ν	85	79
	Median	76.7	77.94
	Interquartile range	64.91 - 93.1	65.48 - 94.73
Urea/Creatinine ratio range	Within normal range (40-80)	56%	53%
	Elevated beyond normal limits (>80)	44%	47%

Table 14 Urea/creatinine results of participants without dysphagia

Research question 4: Is hydration status associated with stroke severity or particular stroke co-morbidities?

Further analysis of differences in urea/creatinine results was conducted based on certain demographic factors and stroke co-morbidities using non-parametric tests of difference or association. There was no significant difference in urea/creatinine results depending on the sex of the participant at Day 0 or Day 7 according to the Mann-Whitney U test. There was a significant difference in urea/creatinine ratios between participants in the different age ranges at day 0 and day 7 according to the Kruskal-Wallis test; the older the participant, the worse their hydration. Refer to Table 15.

			Day 0	Day 7
Sex	Male	Ν	54	49
		Median	74.66	75
	Female	Ν	31	30
		Median	83	90
		p value	0.132	0.061
Age range	<65 years	Ν	28	26
		Median	69.86*	75.00*
	65-74 years	Ν	26	25
		Median	74.66*	72.04*
	>75 years	Ν	31	28
		Median	83.00*	88.91*
		p value	0.017	0.037

 Table 15 Urea/creatinine results of participants without dysphagia according to demographic characteristics

* Significant difference (p<0.05)

Spearman's rho correlation was significant for a correlation between participant's actual age and their urea/creatinine ratio at Day 0 (r=0.275, p=0.011) but the correlation was small (Figure 9). When the influence of admission FIM was controlled for, the correlation between age and urea/creatinine ratio at Day 0 remained significant (r=0.265, p=0.037). There was no correlation between age and urea/creatinine ratio at Day 7 (r=0.162, p=0.153).



Figure 9 Correlation between urea/creatinine at Day 0 and age for participants without dysphagia

Spearman's rho correlation revealed no significant correlations in raw admission FIM scores with urea/creatinine ratios at Day 0 (r=-0.090, p=0.482) or Day 7 (r=0.056, p=0.678). When the influence of time post stroke was controlled for, there was also no significant difference between admission FIM and urea/creatinine at Day 0 or Day 7 (p=0.402 and p=0.657, respectively). Similarly, there was no significant correlation between admission FIM score and urea/creatinine ratio when age was controlled for at Day 0 and Day 7 (p=0.301 and p=0.617, respectively).

There were no difference in urea/creatinine ratios based on the presence or absence of common stroke co-morbidities such as aphasia, cognitive impairment, motor or ideational apraxia or dependence for oral care. Refer to Table 16. However, there was a significant difference in urea/creatinine ratios at Day 0 based on the participants' mobility. If they were unable to exert themselves to mobilise and were therefore bed-bound or predominantly sitting, their urea/creatinine ratio was higher (worse) (p=0.027). Cohen's coefficient was calculated at 0.58 which indicates a medium sized effect.

			Day 0			Day 7	
		Ν	Median	р	Ν	Median	р
Aphasia	Yes	29	75.00	0.897	27	77.05	0.820
	No	56	77.06		52	78.1	
Cognitive	Yes	25	76.7	0.298	22	83.24	0.141
impairment	No	60	75.44		57	73.91	
Reduced Mobility (not	Yes	19	87.84*	0.027	17	80.28	0.314
exerting to mobilise)	No	51	75.76*		48	77.5	
Motor or Ideational	Yes	12	75.38	0.930	11	77.94	0.910
Apraxia	No	73	77.03		68	77.76	
Dependent for	Yes	7	70.18	0.269	6	61.65	0.147
oral care	No	63	78.48		59	79.63	

 Table 16 Urea/creatinine of participants without dysphagia according to stoke

 comorbidities

* Significant difference (p<0.05)

There was no difference in urea/creatinine ratios based on the presence or absence of certain medical conditions in participants' past medical history except renal impairment. There was a significant difference in urea/creatinine results at both data collection points if a participant had renal impairment in their past medical history. When participants with renal impairment were removed from the analysis, the median urea/creatinine ratios at Day 0 and Day 7 for the remaining participants in the sample were 75.67 and 75.82, respectively.

To determine whether there was any correlation between the fluid intake of participants and their urea/creatinine ratio, a bivariate analysis was performed using Spearman's rho correlation at Day 0 and Day 7, respectively. The correlation was not significant (r=-0.121, p=0.269) at Day 0 or at Day 7 (r=-0.156, p=0.169) although the correlation was in the expected direction; the more a person drank, the lower, and therefore better, their hydration results.

Research question 5: What is the incidence of adverse health outcomes, i.e. UTI's, constipation, and/or dehydration, associated with different levels of fluid intake of hospitalised patients without dysphagia following stroke?

The incidences of clinically diagnosed dehydration, urinary tract infection and constipation were calculated using frequencies of the presence or absence of each diagnosis at any time during a participant's admission. Two participants were diagnosed with dehydration (2.3%), 7 with UTI (8.1%), 9 with constipation (10.5%) and none developed pneumonia during their admission. In total 16% of the participants were diagnosed with one or more adverse health outcomes.

Further analysis was conducted to determine whether there was any difference in fluid intake or percentage of calculated requirements consumed or urea/creatinine results based on whether or not the participants had been diagnosed with an adverse fluid-related health outcome. There was no statistically significant difference in any of these measures between those with an adverse health outcome and those without. Refer to Table 17.

		Dehyd	Iration	U	TI	Const	ipation
		Yes	No	Yes	No	Yes	No
Average	Ν	2	84	7	79	9	77
beverage intake	Mean	1608ml	1502ml	1427ml	1511ml	1578ml	1496ml
	р	0.682		0.5	553	0.:	509
Percentage of	Ν	2	53	6	49	9	46
calculated requirements	Mean	80%	66%	72%	66%	68%	66%
consumed	р	0.690		0.4	0.491 0.		829
Day 0	Ν	2	83	7	78	9	76
U/Cr ratio	Median	78.76	76.7	75.93	76.8	75.93	76.8
	р	0.	809	0.5	576	0.′	710
Day 7	Ν	2	77	7	72	9	70
U/Cr ratio	Median	93.50	77.58	87.5	76.7	79.63	77.76
	р	0.2	286	0.2	224	0.	871

 Table 17 Relationship between outcome measures and adverse health events for participants without dysphagia

Pearson's Chi-square test (with Fischer's exact test applied) also determined that there was no association between whether a participant met their calculated fluid requirements and whether they experienced an adverse health outcome during their admission (χ^2_1 =1.661, p=0.234). Similarly, there was no association between whether

the participant had hydration measures that exceeded the normal range (>80) and whether they experienced one or more adverse health outcomes during their admission at day 0 (χ^2_1 =0.128, p=0.775) or at day 7 (χ^2_1 =0.509, p=0.476).

Given that FIM score significantly predicted fluid intake, a logistic regression was performed using the FIM score to test whether this could also predict an adverse health outcome (one or more of the diagnoses dehydration, urinary tract infection or constipation). FIM was found to be a significant but weak predictor of an adverse health outcome (Wald=4.792, b=.035, Exp(B)=1.036, p=0.029).

Discussion

The purpose of this study was to determine the average beverage intake, hydration status and health status of patients in hospital following a stroke who do not have dysphagia and whether stroke related factors, other than dysphagia, influence these outcomes. The demographic data and stroke characteristics show that participants in this study were reasonably representative of a stroke population in inpatient rehabilitation in Australia (National Stroke Foundation, 2010b). The average age of 69 years in this sample was lower than the median age (77 years) of patients in the most recent national audit of rehabilitation facilities conducted by the National Stroke Foundation of Australia (NSF) (National Stroke Foundation, 2010b). Additionally, this present sample had more male participants (64%) compared with 54% males in the NSF audit. However, the prevalence of all other stroke presentations such as type and location of stroke and the presence of stroke comorbidities such as aphasia and cognitive deficits were equivalent. The average admission FIM of participants in this sample of 73 compares very closely with the NSF audit of 77 and indicates the two cohorts have similar levels of dependency. The author is confident, therefore, that this sample of patients with stroke is representative of stroke cohorts in inpatient rehabilitation across Australia and that the findings are generalizable to other comparable populations.

A surprising finding was that some of the participants classified as not having dysphagia as they passed the 150ml water test, were below the normal limits on certain of the normed parameters (Hughes & Wiles, 1996). For the time per swallow parameter, 40% of the participants without dysphagia were considered below normal

limits. This may be indicative of the reduced capacity for speed with cognitive and motor tasks compared with normal function that is argued to affect all patients poststroke (Pohl, McDowd, Filion, Richards, & Stiers, 2006; Su, Wuang, Lin, & Su, 2015).

Fluid Intake

The patients without dysphagia post stroke in this research study were all inpatients in rehabilitation facilities. Typically, they were engaged in an active rehabilitation program including multiple daily therapy sessions aimed at maximising their recovery and independence. Their beverage intake on average was 1504ml (SD 359ml). The estimated daily requirements for adult males and females to achieve an adequate intake (AI) of fluids according to the Nutrient Reference Values for Australia and New Zealand are 2600ml and 2100ml, respectively (Australian National Health and Medical Research Council, 2005). The average beverage intake of this sample falls well below this requirement. When each participant's intake was compared individually with this standard, according to age and sex, only 2% of this sample met the recommended intake figure. The assertion that the fluid intake was largely sub-optimal in this sample was supported by the finding that 51of the 54 participants whose weight was recorded (92.7%) did not meet their individually calculated fluid requirements according to another fluid intake standard of 30ml per kilo of weight. This is a standard that many acute hospitals and residential facilities use, aiming for their patients to consume at least 1500ml to 1600ml of fluid from beverages per day given an average weight of a 50-80 kg elderly adult (Armstrong-Esther, et al., 1996; Chidester & Spangler, 1997; Gasper, 1999; Holben, et al., 1999). The mean weight of participants in this sample of patients without dysphagia was at the upper end of this range (80kg). According to this standard, participants in this present sample only consumed on average 67% of their daily fluid requirements. It is reasonable to expect that the physiological need for fluid of these participants who were engaged in active therapy would be higher than an acute patient whose physical activity is often limited. Therefore, according to this conservative standard, the participants in this sample were not meeting their fluid requirements.

Five studies have detailed the beverage intake figures of "average" residents in longterm care facilities. The reported intake ranges from 1002ml to 1982ml (ArmstrongEsther, et al., 1996; Chidester & Spangler, 1997; Gasper, 1999; Holben, et al., 1999; Oh, et al., 2006). The average beverage intake of participants in this present study (1504ml) falls within the range of the studies above. However, given the likely disparity of dependency, age and activity levels in an active rehabilitation population compared with a residential care population, it would be reasonable to expect that the beverage intake of this sample would exceed that of the residential care population.

Another comparison of beverage intake can be made with the healthy elderly who are living independently in the community. Studies have reported the beverage intake of the healthy elderly as ranging from 1400ml to 2100ml (Bastiaansen & Kroot, 2000; Bossingham, et al., 2005; Luszcz, et al., 2007; McGrail & Kelchner, 2012; Volkert, et al., 2005). The mean intake of this current sample by sex (1534ml for males and 1452ml for females) is similar to the findings of the study by Volkert et al (2005) (1567ml for males and 1400ml for females). However, the intake is lower than that of the healthy elderly in the other studies. One of these studies, the ALSA, was a longitudinal study of the elderly (over 70years) in South Australia and would represent the closest comparative population to the participants in the present study (Luszcz, et al., 2007). The beverage intake quoted in that study was 1868ml for males and 1909ml for females. Using these figures as a comparison, the intake of the participants in the current study falls well short. Perhaps this is because the healthy elderly living in the community have free access to drinks throughout the day (access to taps, kettles, fridges, shops etc.). The inpatients in stroke rehabilitation are largely reliant on the routine of the hospital for their source of fluids; they may have a jug of water at bedside but rely on being offered extra drinks throughout the day by hospital staff at prescribed times. Many of them do not have the functional ability to make their own drinks, walk to the hospital kiosk to buy drinks, or even have the cognitive/communication capacity to solve access issues. The findings of this study, that time post stroke was negatively related to percentage of required fluid intake consumed (the participants who were in hospital for between 1-3 months when recruited to the study consumed a lower percentage of their required fluid intake than those recruited within their first two weeks of hospitalisation), may suggest that institutional factors do play a part in contributing to poor intake.

In this study, age was not correlated with fluid intake; older participants did not necessarily drink less than their younger peers. This finding is consistent with some literature that older individuals drink just as much as their younger peers when they are healthy and living independently (Bastiaansen & Kroot, 2000; Bossingham, et al., 2005). However, these findings are contrary to concerns about the elderly expressed in the literature related to their impaired perception of thirst (Bennett, 2000; Lavizzo-Mourey, et al., 1988).

Interestingly, the individual comorbidities resulting from a person's stroke such as mobility, communication or cognition did not significantly affect their fluid intake. There was a small correlation, however, between overall dependency and fluid intake; the lower a participant's FIM score at admission (i.e. the more dependent), the less their average daily fluid intake. The correlation between dependency level and fluid intake remained significant even when the factors of time post stroke and age were controlled for. Whilst it is acknowledged that the statistical association in this study was relatively weak and should be interpreted with caution, the finding is in line with previous research documenting a relationship between dehydration and stroke severity and impairment in the acute phase post stroke (Crary, et al., 2013; Rowat, et al., 2012). This is further supported by the literature about populations other than stroke that states that the number of medical conditions and the level of dependency have the greatest influence on fluid intake (Morgan, et al., 2003). It is intuitive that measures of stroke severity and functional dependence may be a useful adjunct to other relevant clinical measures to identify patients who require greater assistance and encouragement to drink and close monitoring of fluid intake and hydration levels. These findings do raise questions about clinical care. Do patients, particularly those who are more dependent, fail to consume an adequate amount of fluid offered per day because of their own choice, because they are physically unable to access these drinks, or because of a lack of staff surveillance and intervention? The latter two possibilities would suggest an inadequacy of current hospital patient care in that staff may not be adequately monitoring fluid consumption and recognising when patients require greater assistance and encouragement to drink.

Hydration

Of importance is whether this barely satisfactory beverage intake affected participants' hydration as measured by the hydration index urea/creatinine ratio from blood analysis. Poor hydration has documented effects on concentration, new learning, fatigue levels, blood pressure and therefore balance and falls risk, and infection risk. This potentially may adversely affect rehabilitation length of stay and ultimately patient outcomes if not recognised and corrected (Thomas, et al., 2008; Weinberg, et al., 1995). A normal range for urea/creatinine ratio is between 40 and 80. The average (median) for participants in this sample was 77 at day 0 and 78 at day 7 which is at the upper end of the normal range. Using the cut-off point of >80, approximately 44% of the participants in this study were classified as dehydrated.

These figures compare unfavourably with a cohort of community dwelling people aged over 70 years from the ALSA. The raw data of urea and creatinine from a blood sample taken from each participant at commencement of the study was generously provided by the authors of this study (Luszcz, et al., 2007). The urea/creatinine ratio was calculated and a mean of 64 was found, with 15% of participants categorised as being dehydrated. Wave 1 data were used as the comparator with the current cohort of patients post-stroke as participants in the longitudinal study would have been at their youngest at this first measurement point and increasing in age at subsequent measurement points. Given this present sample had a mean age of 69 years, the community dwelling participants, who only entered the study if they were over 70 years, would already have been older. Despite their older age, these community dwelling adults had a superior level of hydration than those in this study who had been hospitalised following stroke.

The percentage of participants with poor hydration measures in this sample was similar to that reported for patients with and without dysphagia in *acute* hospitals following stroke (36-66%) (Crary, et al., 2013; Rowat, et al., 2012). A direct comparison of the present study's hydration results can be made with a cohort of acute patients *without* swallowing impairment in a United States hospital thanks to personal communication with Dr Michael Crary who provided the raw data collected for the cited study (Crary, et al., 2013). This cohort of acute stroke patients had a lower mean urea/creatinine ratio of 68 (SD 22) seven days following admission,

representing better hydration than participants in the present study. Notably, patients' hydration in that study declined over time from admission to discharge. The present study reveals even poorer hydration in the rehabilitation setting. This unfavourable comparison with patients in acute settings (i.e. earlier in their health care journey) again raises the question of whether fluid intake and hydration levels are adequately monitored in the stroke population as they transition through different care settings, and whether prevention of, and interventions for, dehydration are implemented in an adequate and timely manner.

Hydration measures were worse for the older participants in this study, especially for women in the older age group (65-75 years), a finding that is consistent with previous research documenting older age and female sex to be independent risk factors for dehydration (Rowat, et al., 2012). This finding is also consistent with the general acceptance that the elderly are at greater risk of dehydration due to their reduced ability to concentrate urine and frequent use of medications that result in water loss (Bennett, 2000; Lavizzo-Mourey, et al., 1988). Additionally, in this present study, poor mobility was significantly associated with poorer hydration measures, a finding that is consistent with literature suggesting the level of functional dependence and the number of confounding medical conditions have a significant impact on fluid intake and hydration (Armstrong-Esther, et al., 1996; Chidester & Spangler, 1997; Morgan, et al., 2003; Rowat, et al., 2012). In the present study, if participants were predominantly bed-bound or sitting and not able to exert themselves to mobilise, their urea/creatinine ratios were significantly higher (worse) on average than their more mobile peers, even though their average fluid intake was not significantly less. Perhaps the immobility does not affect how much a participant drinks but rather the body's ability to metabolise and discard waste.

When hydration levels were categorised as within or outside the normal range, 44% of participants were classified as having a urea/creatinine ratio beyond normal limits indicative of dehydration. Interestingly, only 2.3% of the sample was given a medical diagnosis of dehydration by the treating medical staff. This demonstrates the complexity of making the clinical diagnosis of dehydration and that biochemical indices do not always correlate with clinical diagnosis. Medical diagnosis of dehydration relies on a multitude of sources of information: the patient's clinical

presentation, urine analysis, weight loss reflecting water depletion and multiple biochemical indices, all considered in the context of other medical conditions such as kidney and cardiac disorder and medication use (Thomas, et al., 2008; Thomas, et al., 2003; Wallach, 2007; Weinberg, et al., 1995). The discrepancy between biochemical results and the diagnosis of dehydration raises other important questions. Is it invalid to use a single biochemical measure to draw conclusions about dehydration as researchers have done for many years? Or is an alternative explanation possible? Is there inadequate surveillance of hydration related symptoms by the treating clinical team and subsequent under diagnosis and reporting of dehydration?

Adverse Health Outcomes

Sixteen percent of participants in this study experienced one or more adverse health outcomes of dehydration, urinary tract infection or constipation. Interestingly, neither the amount of fluid intake nor their hydration measure was predictive of whether they experienced an adverse health outcome. The only demographic or clinical factor that was predictive of an adverse health outcome was the participant's FIM at admission; the more dependent the patient, the more likely they were to have an adverse health event. Ultimately, clinicians want to minimise the risk of patients developing adverse health outcomes. Perhaps they need to have heightened awareness of other factors, such as dependency, when assessing a patient's risk of developing an adverse health outcome related to fluid intake.

Limitations

It is acknowledged that this study had methodological limitations and the findings should be interpreted in this context. The use of fluid balance charts as a measure of fluid intake may have resulted in inaccurate amounts being recorded. To mitigate this potential source of error, regular training sessions for nursing staff were conducted, there was consistent use of clearly measured containers, and information sheets were provided to participants and families. It is acknowledged that the amount of fluid offered to individual participants in this study by the institution or the amount they could access from externals sources such as family members or the hospital kiosk was not controlled and may have therefore varied between individuals. This in turn may have differentially influenced consumption as participants were able to consume as much or as little as they chose or were able to. However, this study intended to measure actual consumption under normal, not experimental, conditions and it is considered that this aim was met. Furthermore, it is recognised that the classification of participants as not having dysphagia was based on a clinical assessment alone which could have resulted in the erroneous inclusion of some patients with subclinical dysphagia. However, the study sought to describe the intake of patients on normal diets post stroke and this aim was met. As mentioned above, it is also accepted that the clinical diagnosis of dehydration is complex and highly variable in any clinical setting and the use of a single biochemical metric is a limitation of this study. Finally, it is acknowledged that a descriptive study is not a research design from which causal relationships can be derived so associations and differences should be interpreted accordingly.

Conclusion

In summary, the average beverage intake of this sample of 1504ml was equivalent to the intake expected of those in acute hospitals and those in residential facilities, even though it is assumed that the physiological demand for fluids by participants in rehabilitation would be higher. Their intake is below that of their healthy elderly peers living in the community and well below estimated requirements for the general population. The findings of this study, supported by the literature, suggest dependency resulting from stroke or being a resident in a health care institution may be the most significant factors affecting fluid intake. Similarly, higher dependency was associated with developing an adverse health outcome. Hydration levels for participants this study were also poorer than those of healthy community dwelling elderly peers and even of a known cohort of patients following stroke in an acute setting. Consistent with the literature, older age and poor mobility were the factors significantly associated with poor hydration. Given these findings, that even patients with unimpaired swallowing function post stroke are at risk of poor fluid intake and dehydration, development of guidelines and training programs that address health care staff responsibilities in monitoring and improving patient fluid intake and hydration levels are warranted.

Chapter 8: Beverage Intake and Hydration Status of Hospitalised Individuals w*ith* Dysphagia Following Stroke: The Outcomes of a Randomised Controlled Trial⁴

Introduction and Purpose

This chapter reports on the second experimental study in this thesis, a randomised controlled trial conducted with hospitalised individuals with dysphagia post-stroke. The purpose of this study was to determine the average beverage intake, hydration status and health status of patients with dysphagia who are on a full oral diet but require modified fluid consistencies. Further, this study aimed to determine whether water protocols result in better outcomes with respect to fluid intake, hydration status and general health status compared to the prescription of thickened fluid only. Patients with dysphagia were randomised to receive thickened fluids only as their source of fluids or a water protocol. Previous studies have shown that water protocols do indeed increase the fluid intake of patients with dysphagia in rehabilitation compared to those receiving thickened fluids alone. However, none of the previous studies have measured fluid intake along with the hydration status and fluid related health outcomes for these patients (Carlaw, et al., 2012; Garon, et al., 1997; Karagiannis, et al., 2011). Results are presented on the effectiveness of thickened fluids and water protocols in achieving adequate fluid intake, hydration and health status for this cohort of patients with dysphagia.

⁴ Content provided in this chapter has published as:

Murray J, Doeltgen S, Miller M, Scholten I (2016) Does a water protocol improve the hydration and health status of individuals with thin liquid aspiration following stroke? A randomized-controlled trial. *Dysphagia* 31(3), 424-433.

The abstract of this paper is included in Appendix 5.

Research Questions

- 1. What is the average daily fluid intake from beverages of stroke patients with dysphagia having oral-only intake who are prescribed thickened fluids compared with a water protocol?
- 2. Is beverage intake of patients with dysphagia associated with stroke severity or particular stroke co-morbidities?
- 3. What is the hydration status of stroke patients with dysphagia having oralonly intake who are prescribed thickened fluids compared with a water protocol?
- 4. Is hydration status of patients with dysphagia associated with stroke severity or particular stroke co-morbidities?
- 5. What is the incidence of adverse health outcomes associated with fluid intake, namely aspiration pneumonia, dehydration, constipation or urinary tract infections of stroke patients with dysphagia who are prescribed thickened fluids compared with a water protocol?
- 6. Does a water protocol result in faster resolution of dysphagia for thin fluids?
- 7. Do patients with dysphagia prefer to drink thickened fluids or water if given a choice?

Method

The Methods for this study are presented in Chapter 6.

Results

Numbers Screened and Included/Excluded

In total 165 patients were screened for inclusion in the study following a stroke. These patients were screened at Hampstead Rehabilitation Centre (HRC), Repatriation General Hospital (RGH), Royal Adelaide Hospital (RAH), Flinders Medical Centre (FMC) and St Margaret's Rehabilitation Hospital (SMRH) from November 2009 to July 2012. There was an additional screening period at HRC in 2006 when three subjects were recruited to the pilot study. Of the 165 patients screened, 131 were excluded either because they met exclusion criteria (106) or they declined consent (6). The most common reasons for exclusion were:

- Dysphagia was present but the patient had been upgraded to thin fluids by his/her speech pathologist before being consented
- Past medical history included chronic obstructive pulmonary disease (COPD)
- The patient was receiving supplementary non-oral feeding
- Consent could not be gained due to severity of aphasia and/or cognition in the context of no family being available
- Patient was unable to participate in a videofluoroscopic swallow study (VFSS)

Thirty-one patients were consented and proceeded to a full assessment. Fifteen were later excluded after they were found not to be aspirating thin fluid on VFSS (n=12) or were not tolerating any thickened fluid consistency safely (n=2). Sixteen patients proceeded to randomisation and group allocation, with one further withdrawal post group allocation due to being placed on a fluid restriction for medical reasons. Fifteen patients had data sets completed. Please refer to Figure 10 for illustration of recruitment.

There was only one patient from an acute hospital with a completed data set in the sample. It was decided to exclude this one patient and proceed to analysis with only the 14 patients in inpatient rehabilitation facilities, to provide a more homogeneous cohort and to allow direct comparison with the sample of rehabilitation patients without dysphagia presented in Chapter 7. The data for the acute patient are presented separately in Appendix 18 and not included in the results presented in this chapter.



Figure 10 CONSORT Flow Diagram for RCT

Total Sample Demographics

The demographics of the sample of rehabilitation patients with dysphagia (n=14) are summarised in Table 18, presented as the frequency and percentage of the total sample. The majority of the sample were male (n=10, 71%) and over 75 years of age (n=10, 71%). The age of participants ranged from 66 years to 91 years, with a mean age of 79 years (SD=6.4 years). The hospital to which participants were admitted is also presented in Table 18.

Stroke Characteristics

Stroke characteristics of each participant were analysed by frequency including type of stroke, anatomical location of the stroke and lateralisation of the stroke. The majority of participants in this sample (n=13, 93%) had an infarct, with only one having an intracerebral haemorrhage. More of this sample had cortical strokes (n=7, 50%) than sub-cortical (n=4, 29%) or brainstem strokes (n=3, 21%) and the strokes were predominantly in the left hemisphere (n=10, 71%). The mean number of days post stroke when participants entered the study was 19 days (SD=8 days). Most of the participants (n=13, 93%) were between 1 day and 30 days post stroke. These data are also illustrated in Table 18. Based on participants' FIM scores, they were at varying levels of independence, with an average FIM score at admission of 59 (SD=19). The average weight of participants was 78.7 kg (SD=19.6 kg).

Before analysing the outcome measures for the participants allocated to the two groups, baseline demographic and stroke characteristics were compared to determine whether the groups were equivalent. Differences in continuous variables were analysed using two-way independent samples t-tests and categorical data were analysed using Chi-squares. There were no significant differences in the demographic or clinical features of sex, age, days post-stroke, admission FIM or weight at admission between patients allocated to the two groups (water protocol or thickened fluids only). These comparisons are also illustrated in Table 18.

		Total sample N (%)	Water Protocol N	Thick only N	p value
Participants		14 (100)	8	6	
Sex	Male	10 (71)	6	4	0.733
	Female	4 (29)	2	2	
Age	Mean in years (SD)	79 (6.4)	78 (6.8)	80 (6.4)	0.691
Age range	<65 years	0 (0)	0	0	0.733
	65-75 years	4 (29)	2	2	
	>75 years	10 (71)	6	4	
Hospital site	HRC	6 (43)	3	3	0.226
	RGH	3 (21)	3	0	
	SMRH	5 (36)	2	3	
Stroke Type	Infarct	13 (93)	7	6	0.369
	ICH	1 (7)	1	0	
Stroke Location	Cortical	7 (50)	3	4	0.233
	Sub-cortical	4 (29)	2	2	
	Brainstem	3 (21)	3	0	
	Cerebellar	0 (0)	0	0	
Stroke	Left	10 (71)	7	3	0.124
Lateralisation	Right	4 (29)	1	3	
	Bilateral	0 (0)	0	0	
Time post stroke	Mean no. days (SD)	19 (8)	19.1 (8.4)	19.7 (9.3)	0.911
	1-14 days	5 (36)	3	2	0.486
	15-30 days	8 (57)	5	3	
	30-90 days	1 (7)	0	1	
	>90 days	0 (0)	0	0	
Independence	Mean FIM score (SD)	59 (19)	57 (6.4)	60 (22.4)	0.864
Weight	Mean kg (SD)	78.7 (19.6)	99 (1.4)	70.6 (17)	0.075

Table 18 Demographic and stroke characteristics of participants in the RCT

Stroke and Medical Co-morbidities

Stroke co-morbidities are presented as a frequency of the total sample and per group. Over one third of participants (n=5, 36%) presented with cognitive impairment and three participants (21%) presented with aphasia. Two thirds of participants (n=9,

64%) were unable to exert themselves to mobilise (i.e. they were unable to walk with or without an aid or they were unable to self-propel in a wheelchair). The majority of participants (n=12, 86%) were able to pour drinks for themselves and all (n=14, 100%) were able to drink from a cup independently. Most were also independent for oral care once set up (n=10, 71%). Other medical information is presented including relevant past medical history. Four participants (29%) had had a previous stroke and three (21%) had gastro-oesophageal reflux. Refer to Table 19.

		Total sample N (%)	Water Protocol N	Thick only N
		14 (100)	8	6
Stroke co-morbidities	Aphasia	3 (21)	1	2
	Cognitive impairment	5(36)	3	2
	Not exerting to mobilize	9 (64)	5	4
	Motor or ideational apraxia	1(7)	0	1
	Dependence for oral care	4 (29)	1	3
	Dysarthria	12 (86)	7	5
	Apraxia of speech	2 (14)	0	2
	Dependence for pouring drinks	2 (14)	0	2
	Dependence for drinking from a cup	0 (0)	0	0
Past medical history	Previous stroke	4 (29)	3	1
	GORD	3 (21)	0	3
	CCF	1 (7)	1	0
	Renal impairment	0 (0)	0	0

Pre-study Assessment Results

i. Clinical assessment

Participants were given a dysphagia and aspiration severity rating according to the AusTOMS (Perry & Skeat, 2004) for food and thin fluids prior to their commencement in the study. Most participants had a moderate (n=8) or mild (n=5) severity of dysphagia for food and either no (n=5) or a mild (n=6) aspiration risk for food. The majority (n=11) had a moderate dysphagia for thin fluids with a moderate

(n=9) aspiration risk as seen in Figure 11. There were no significant differences in severity of dysphagia or aspiration between the groups at baseline.



Figure 11 Severity of dysphagia ratings for participants in the RCT

All participants were consuming modified consistency diets, with half (n=7) being prescribed a minced and moist diet at entry to the study. Again there were no significant differences in diets between the groups at baseline. Twelve participants were consuming mildly thickened fluids and two moderately thickened fluids. There were no significant differences in prescribed fluids between the groups at baseline.

ii. 150ml Water test

The data from two of the three parameters of the 150ml water test did not meet the assumptions of normality, therefore median scores and interquartile ranges are presented. The median volume of water consumed per swallow was 9.69ml (IQR=7.92ml), with 70% of participants being below the normal limits according to the test norms based on their age and sex. The median time per swallow was 2.6 seconds (IQR=4.05 sec), with 90% being below normal limits. The median volume per time was 2.85mls per second (IQR=5.69mls/sec), with 42% of participants
categorised as below normal limits on this parameter. All failed the cough/gurgle test. There were no significant differences between groups on any of the measures at baseline.

iii. Oral health assessment

The oral health data were normally distributed so the means and standard deviations were used to describe the participants' scores. At Day 0, the mean oral health score was 4.85 (SD=3.44) but the scores ranged from 0 (no oral health problems identified) to 11 (severe oral health issues). There were no significant differences between groups on oral health scores at baseline.

The following sections of this chapter outline the findings of the RCT with respect to each research question.

Answers to Research Questions

Research question 1: What is the average daily fluid intake from beverages of stroke patients with dysphagia having oral-only intake who are prescribed thickened fluids only compared with a water protocol?

The data for average total daily beverage intake for each group met the assumptions for normality so means and standard deviations were used to describe averages and differences were analysed using parametric statistics. Participants in the water protocol group, who drank both thickened fluids and water, consumed on average 1103ml (SD 215ml) of beverages per day. This total beverage intake was not significantly different to the total beverage intake of participants in the thickened fluids only group; in fact, the mean was exactly the same (mean=1103ml, SD=247ml, t_{12} =-0.002, p=0.998, 95% CI=-269.641 to 269.141). These findings are illustrated in Table 20. For the participants whose weight was recorded, those in the water protocol group consumed on average 38% of their calculated daily fluid requirements, a difference that is not significant (t_5 =-1.437, p=0.195, 95% CI=-66.561 to 36.525).

The participants in the thickened fluids only group tended to consume more thickened fluids per day on average (1068ml, SD 226ml) than those in the water protocol group (807ml, SD 364ml), but this difference was not significant (t_{12} =-1.539, p=0.150). Participants in the water protocol group consumed on average 299ml (SD 274) of water per day, which represented 27% of their total beverage intake per day. Participants in the thickened fluids only group, consumed small amounts when being assessed on thin fluids. This difference in water intake between the groups was significant as expected (t_{12} =2.3, p=0.040). Table 20 summarises these results and the statistical analysis of differences. Figure 12 illustrates these findings graphically.

Table 20 Comparison of fluid intake of participants in the Water Protocolgroup and Thickened Fluids only group

	Allocated Group	Ν	Mean	SD	t value	p value
	Water Protocol	8	807	364	-1.539	0.150
Ave daily thick fluid intake	Thick fluids only	6	1068	226		
Ave daily water intake	Water Protocol	8	299	274	2.3	0.040
	Thick fluids only	6	36	53		
A	Water Protocol	8	1103	215	0.002	0.998
Ave total daily beverage intake	Thick fluids only	6	1103	247		
Percentage of beverage requirement	Water Protocol	2	38%	12.7	-1.494	0.195
consumed	Thick fluids only	5	53%	11.8		



Figure 12 Comparison of fluid intake of participants in the Water Protocol group and Thickened Fluids only group

Research question 2: Is beverage intake of patients with dysphagia associated with stroke severity or particular stroke co-morbidities?

Given the participants in each group had an identical average daily intake of beverages, the whole sample was used to conduct further analysis of whether fluid intake is associated with various demographic characteristics and stroke co-morbidities. There was no significant difference in beverage intake between males and female participants or depending on the hospital to which the participant was admitted as illustrated in Table 21.

Average total dail beverage intake	у	Ν	Mean	SD	t value	p value
Sex	Male	10	1142	230	1.040	0.319
	Female	4	1007	182		
Site	HRC	6	1068	113	1.980	0.184
	RGH	3	1309	194		
	SMRH	5	1023	284		

 Table 21 Fluid Intake of participants in the RCT according to sex and hospital site

Pearson's correlation (two-tailed) revealed no significant correlation between the participants' average fluid intake and their age in years and (r=-0.395, p=0.163) or the number of days post-stroke (r=-0.182, p=0.533). For the eight participants whose FIM was recorded, Pearson's correlation (two-tailed) revealed no significant correlation between their average total daily beverage intake and their level of independence (r=0.152, p=0.720).

Research question 3: What is the hydration status of stroke patients with dysphagia having oral-only intake who are prescribed thickened fluids compared with a water protocol?

The data for urea/creatinine ratios for each group met the assumptions for normality at Day 0 and Day 7 but the water protocol group data at Day 14 did not. With five of the six measures being normally distributed analysis proceeded using means, standards deviations and parametric statistics. Participants in the water protocol group had a decreasing average urea/creatinine ratio from commencement of the study at Day 0 (n=8, mean=90.71) to Day 7 (n=8, mean=85.17) to Day 14 (n=6, mean=82.52), indicating an improvement in their hydration status over the two weeks although repeated measures ANOVA revealed within group differences over time were not significant ($F_{2,16}$ =0.615, p=0.553, 95% CI=-5.526 to 5.705). The participants in the thickened fluids only group had an increasing average urea/creatinine ratio from commencement of the study at Day 0 (n=6, mean=81.90) to Day 7 (n=6, mean=87.33) to Day 14 (n=4, mean=100.55) indicating a deterioration in their hydration status over the two weeks. Refer to Table 22. Despite this trend, the difference in mean urea/creatinine ratio between the two groups was not significant at any time point (Day 0, t_{12} =-1.070, p=0.306; Day 7, t_{12} =-0.190, p=0.853 and Day 14, t_8 =-0.837, p=0.427).

		Water Protocol			Thickened Fluids Only			
Time point	Ν	Mean	SD	Ν	Mean	SD		
Day 0	8	90.71	14.92	6	81.90	15.67		
Day 7	8	85.17	9.98	6	87.33	30.46		
Day 14	6	82.52	11.65	4	100.55	52.34		

 Table 22 Urea/creatinine results of participants in the Water Protocol group

 and Thickened Fluids Only group

Further analysis was conducted to determine the magnitude of the change in urea/creatinine over time for each group and make a direct comparison between groups of this change using a two-tailed t-test. The change in urea/creatinine ratio from Day 0 to Day 7 between the water protocol group and the thickened fluids only group was not significantly different but the effect size was medium (d=0.70). Similarly, the change in urea/creatinine ratio from Day 0 to Day 14 between the water protocol group and the thickened fluids only group was not significantly different but the effect size was large (d=0.84) as illustrated in Figure 13.



Figure 13 Changes in urea/creatinine ratio for participants in the RCT over

time

When participants were classified as dehydrated or not according to the urea/creatinine ratio cut-off of >80, a large proportion were dehydrated in both groups. The numbers of participants classified as dehydrated in the water protocol group decreased over time compared to the thickened fluids only group, which remained steady but chi-square statistics revealed no significant difference in these percentages between the groups at any time point (refer to Table 23).

	Wa	ter Protocol	Thickened Fluids Only		χ2	p value
Time point	Ν	Dehydrated (U/Cr>80)	Ν	Dehydrated (U/Cr>80)		
Day 0	8	88%	6	50%	2.363	0.124
Day 7	8	75%	6	50%	0.933	0.334
Day 14	6	67%	4	50%	0.278	0.598

Table 23 Percentage of participants in Water Protocol Group and ThickenedFluids Only group classified as dehydrated

Research question 4: Is hydration status of patients with dysphagia associated with stroke severity or particular stroke co-morbidities?

Given there were no significant differences between the urea/creatinine ratios of the groups at any given time point, analysis of whether urea/creatinine results were associated with any demographic factors and stroke co-morbidities was conducted using the data of the total sample. Independent samples t-tests (two-tailed) indicated there was no significant difference between the participants' urea/creatinine ratios according to sex at Day 0 (t_{12} =-0.187, p=0.855), Day 7 (t_{12} =0.056, p=0.956) or Day 14 (t_8 =-0.994, p=0.349). A one-way ANOVA revealed no significant difference in urea/creatinine ratios depending on the hospital to which the participant was admitted at Day 0 ($F_{2,11}$ =0.289, p=0.754), Day 7 ($F_{2,11}$ =0.029, p=0.972) or Day 14 ($F_{2,11}$ =0.387, p=0.693).

There was no significant correlation between urea/creatinine ratios and the participants' age at Day 0 (r=0.304, p=0.291), Day 7 (r=0.026, p=0.931) or Day 14 (r=0.355, p=0.315) or number of days post-stroke at Day 0 (r=-0.332, p=0.246), Day 7 (r=-0.359, p=0.208) or Day 14 (r=-0.333, p=0.348). For the eight participants

whose FIM was recorded, Pearson's correlation (two-tailed) revealed no significant correlation between their urea/ creatinine ratios and their level of independence at Day 0 (r=0.096, p=0.821), Day 7 (r=-0.235, p=0.575) or Day 14 (r=0.281, p=0.589).

Research question 5: What is the incidence of adverse health outcomes associated with fluid intake, namely dehydration, constipation, and urinary tract infections of stroke patients with dysphagia who are prescribed thickened fluids compared with a water protocol?

The prevalence of clinically diagnosed dehydration, urinary tract infection, constipation and pneumonia was calculated using frequencies of the presence or absence of this diagnosis at any time in their admission and results are presented in Table 24. The thickened fluids only group had a higher proportion of participants with one or more adverse events (3 out of 6 participants) compared with the water protocol group (3 out of 8 participants) but this difference was not significant (χ^2 =0.219, p=0.640). Comparing the groups on specific diagnoses, there was no significant difference between the groups for incidence of dehydration (χ^2 =0.884, p=0.347) or constipation (χ^2 =0.117, p=0.733), but the thickened fluids only group had a significantly higher proportion of participants with UTI compared to the water protocol group (χ^2 =5.091, p=0.024). No participants in either group were diagnosed with pneumonia.

	Water Protocol		Thickened fluid only		χ^2	p value
	Ν	%	Ν	%		
Any adverse event	3	38%	3	50%	0.219	0.640
Dehydration	1	13%	2	33%	0.884	0.347
Constipation	2	25%	2	33%	0.117	0.733
UTI	0	$0\%^*$	3	50%*	5.091	0.024^{*}
Pneumonia	0	0%	0	0%		

Table 24 Adverse health events for participants in Water Protocol group andThickened Fluids Only group

* Significant at p<0.05

Research question 6: Does a water protocol result in faster resolution of dysphagia for thin fluids?

The time to resolution of dysphagia for thin fluids could only be calculated for 10 of the 14 participants. The remaining participants were discharged before their dysphagia for thin fluids resolved. These data were not normally distributed so medians and non-parametric statistics were used for analysis. The median number of days and interquartile range until resolution of dysphagia for thin fluids (and upgrade to thin fluids) for the water protocol group was 27 days (IQR=20-59 days) and for the thickened fluids group was 38 days (IQR=24-42 days). This difference was not significant according to the Mann Whitney U Test (p=0.548).

Research question 7: Do patients with dysphagia like to drink thickened fluids and water and which do they prefer if given a choice?

Patient satisfaction scores for drinking thickened fluids were determined at weekly intervals for both groups and satisfaction for drinking water was determined for the water protocol group only. Median scores are provided, as ratings were not normally distributed. Satisfaction scores are displayed in Table 25.

Max. score of 25		Day 7	Day 14	Day 21
Satisfaction with thickened fluids	Thick only	19	21	N/A
	Water Protocol	14.5	17	19
Satisfaction with water	Water Protocol	16.5	17	18

Table 25 Satisfaction scores of participants in the RCT

Averages reported are median values

The difference in satisfaction scores for thickened fluids between the groups was not significant according to independent samples Mann-Whitney U test at Day 7 (p=0.127) or at Day 14 (p=0.629). The differences in satisfaction ratings between water and thickened fluids for those in the water protocol group were also not significant at Day 7 (p=1.0), Day 14 (p=0.414) or Day 21 (p=0.655).

An analysis of ratings for each question, such as the amount and distress of coughing experienced or the rating of taste and thirst, revealed little difference between the groups as illustrated in Table 26.

Max score of 5 per question		Amount of coughing	Distress at coughing	Taste	Feel in mouth	Quench thirst
Satisfaction with thickened fluids	Thick only	4.14	4.86	3.86	3.29	3.57
	Water Protocol	3.94	3.69	3.19	3.13	3.00
Satisfaction with water	Water Protocol	3.00	3.15	3.08	3.15	3.85

Table 26 Ratings of thickened fluids and water by participants in the RCT

Averages reported are median values

The participants in the water protocol group were asked to nominate their preference for water or thickened fluids. At Day 7, five of the eight participants (63%) who completed the survey preferred water and three (37%) preferred thickened fluids. At Day 14, two of four participants preferred water and at Day 21, one of two participants preferred water.

Individual patient comments included:

"Prefer taste of thick. Don't like the chlorine taste of water"

"Like thick better because of the taste. You guzzle water and it makes you cough"

Clinical Assessment at End of Study

i. Diet and fluids

At time of discharge and therefore at the end of the study, three participants had been upgraded to a general diet, the majority were on a soft diet (n=7), one on modified soft, two on minced and moist and one on a smooth pureed diet. Nine participants at discharge had been upgraded to thin fluids (64%), with four remaining on mildly thickened fluids and one on moderately thickened fluids.

ii. Oral health

The mean oral health scores of the whole sample improved from a mean (SD) of 4.85 (3.4) at entry to the study to mean scores of 2.77 (1.6) at Day 7 and 3.33 (2.4) at Day 14. Paired samples t-test, as an analysis of within-subject change across time, indicated a significant improvement in oral health between Day 0 and Day 7

(t=2.569, p=0.026). There was no difference in oral health scores between the water protocol and thick fluids only groups at any time point (Day 0, t_{12} =-0.551, p=0.592; Day 7, t_{12} =0.918, p=0.377; and Day 14, t_4 =1.447, p=0.221).

Discussion

The purpose of this study was to determine the fluid intake and hydration status of patients with dysphagia post-stroke and whether a water protocol resulted in improved intake and hydration. The sample size calculation performed prior to implementation of the research indicated 69 patients were required for each arm of the RCT to show a clinically meaningful difference in fluid intake of approximately 200ml between the two groups. Unfortunately, substantial difficulties in recruitment meant the study was underpowered, with only 15 complete data sets collected. The study was set up to be a multi-centre RCT, and ethics approval was obtained, cooperation canvassed and education conducted at seven sites in South Australia. Despite these intentions, the number of patients identified for screening (n=165) was small. Two sites declined to participate explicitly after ethics approval was received because of clinical workloads and another large acute hospital did not identify any patients for screening despite both their speech pathology and dietetics departments agreeing to participate and being followed up regularly. The researcher was reliant on clinicians at the individual hospitals to identify potential candidates for the research and, with busy clinical workloads, many potential candidates may have been missed. When this inconsistent screening process was identified, the researcher undertook to visit most sites on a weekly basis to identify potential research candidates and this did improve screening rates.

Once screened, however, the stringent exclusion criteria resulted in many patients being ineligible for inclusion. Review of these criteria mid-data collection indicated they were well justified and were therefore not altered. It was considered that inclusion of the many patients with COPD and supressed immune status would have been unethical as previous research has shown that these patients are at increased risk of pulmonary complications if they aspirate (Good-Fratturelli, et al., 2000; Langmore, Skarupski, Park, & Fries, 2002; Langmore, et al., 1998). Notably, water protocols have been implemented in other institutions with patients with known respiratory conditions on the advice of their treating physician since this study was

conducted. Furthermore, after presentation of the findings from this RCT at national conferences, physicians have questioned these tight exclusion criteria and have indicated that, with close monitoring, patients with COPD could be included. Future studies of water protocols would benefit from a thorough interdisciplinary review of patient factors when considering exclusion criteria.

In examining the other exclusion criteria, results for hydration would not have been meaningful had patients on non-oral supplementary feeding been included as the non-oral intake would have skewed results. Further, inclusion of patients with progressive neurological conditions in addition to their stroke would have confounded the results. One substantial limitation in recruitment came from the narrow window of time that existed to recruit patients; this period spanned between the patient with dysphagia no longer requiring supplementary non-oral feeding, and therefore eating and drinking a full but modified consistency oral diet, and not yet being ready for upgrade to thin fluids. The nature of dysphagia post-stroke is that there is rapid recovery for most patients in the first weeks and months (Smithard, et al., 1997) and dietary prescriptions change frequently. In this study, many patients identified as aspirating thin fluids at screening had improved and been upgraded by their treating clinician to thin fluids before being consented and assessed for the study.

An unforeseen factor affecting recruitment was the imprecision of clinical assessment in the diagnosis of aspiration of thin fluids. This proved to be the case for many of the patients who consented to the research and who were clinically deemed to be aspirating thin fluids but subsequently had to be excluded as aspiration of thin fluid was not detected by the objective VFSS. Additionally, strict criteria were placed on aspiration for the VFSS research protocol; potential research participants had to demonstrate aspiration below the level of the true vocal folds on two out of three water swallows (sips or consecutive swallows). This too added to the number of inadmissible potential participants.

Two previous studies of water protocols which included patients post-stroke also recruited small numbers. Garon et al (1997) and Carlaw et al (2012) had 20 and 15 participants, respectively. Garon et al (1997) acknowledged their sample size was limited due to refusal to consent by many potential participants (n=34) and potential

participants not meeting inclusion criteria (n=94). Carlaw et al (2012) also acknowledged that their study was underpowered particularly for the outcome of pneumonia. A third study by Karagiannis et al (2011) recruited more participants, with 79 progressing to analysis, however, the assessment of patients for inclusion in this study was a clinical assessment alone. The literature, reinforced by the findings of this present study, indicates that clinical assessment alone does not have high sensitivity or specificity for detecting aspiration (Logemann, 1998; Ramsey, et al., 2003). An unknown number of patients in the study by Karagiannis et al (2001) may therefore not have been aspirating thin fluids or safely tolerating the thickened fluids and may have been invalidly included in the study.

Potentially, the small sample size may have contributed to the non-significance of differences between groups. Many of the hypothesised differences, such as greater intake and better hydration in the water protocol condition, were not supported by the analysis of results. Nevertheless, findings including some interesting trends are discussed further below.

The participants who were included in the study were reasonably representative of a stroke population according to most demographic and stroke characteristics. The average age of 79 years was similar to the median age of 76 and 77 years of patients included in the most recent clinical audits of rehabilitation and acute services, respectively, by the National Stroke Foundation (National Stroke Foundation, 2009, 2010b). There were more males in this study (71%) compared with other stroke data in Australia which typically demonstrate a more even distribution of male and females (Australian Institute of Health and Welfare, 2013; National Stroke Foundation, 2009, 2010b). The proportion of participants who presented with an infarct in this study (93%), was higher than typically reported; 77% and 82% of patients in the NSF rehabilitation and acute audits, respectively (National Stroke Foundation, 2009, 2010b). The participants in this study, with an average admission FIM of 59, were more dependent than those in the NSF rehabilitation audit (median FIM of 77). This may be because all patients in this study had dysphagia which is often associated with a more severe stroke and typically a poorer prognosis than for patients post-stroke without dysphagia (Mann, et al., 1999; Smithard, et al., 1997; Smithard, et al., 1996).

There were no significant differences in the demographic or clinical features of sex, age, days post-stroke or admission FIM score between patients allocated to the two arms of the RCT (water protocol or thickened fluids only). Similarly, there were no differences in baseline assessment results in terms of swallowing severity, modified diet and fluid consistency, 150ml water test or oral health scores. This demonstrates that the groups were comparable at baseline.

Fluid Intake

The patients with dysphagia post-stroke, who were reliant on oral fluids only, did not consume adequate amounts according to any recognised fluid intake standards for adults (Australian National Health and Medical Research Council, 2005; Chernoff, 1994). Contrary to expectations, the total intake of participants in the water protocol group was no higher than those who consumed thickened fluids only. These participants appeared to offset the amount of water they consumed by drinking less of the thickened fluids. That is, the type of beverage offered did not change their overall consumption. Even when allowed water, they did not or were unable to drink adequate amounts. Given there was no other influence on fluid intake from demographic or stroke related clinical factors such as age, sex, mobility or level of interest is that even when given the choice of water or thickened fluids, patients in this group drank more thickened fluids (807mls) than water (299mls). If this was their preference, it may have been because they perceived thickened fluids to be easier and safer to swallow as was illustrated in a patient quote:

"You guzzle water and it makes you cough"

It may also have been that they disliked the taste of the tap water offered or preferred the sweetness of the thickened fluids:

"Prefer taste of thick. Don't like the chlorine taste of water"

"Like thick better because of the taste".

An alternative explanation to them drinking more of the thickened fluids than water could be that the thickened fluids were more accessible to them in their inpatient setting. It is usual practice for thickened fluids to be offered at every mealtime on a patient's meal tray and this is the only fluid allowed during meals under water protocol conditions. Other authors have confirmed that the majority of fluid intake for patients with dysphagia on thickened fluids comes at mealtimes when patients are assisted and supervised (Patch, et al., 2003). At other times of the day and night, this assistance to drink from either their thickened fluids container or water jug may not be available. Furthermore, nursing staff, who have been trained to strictly adhere to thickened fluid regimes, may have been unaccustomed and reluctant to offer water as indicated in open comments in the survey of provision of thickened fluids presented in Chapter 5 (Murray, Doeltgen, Miller, & Scholten, 2014).

The findings of this study, that water protocols did not significantly increase fluid intake, is comparable to one previous publication on water protocols (Garon, et al., 1997). The participants recruited to that study were similar to those recruited to the present study; they were patients with dysphagia as a result of stroke, residing in inpatient rehabilitation with a mean age of 77 years. The 10 patients on the water protocol had an increased total fluid intake (1318ml) compared with the 10 patients on thickened fluids only (1210ml) but, in keeping with the present study, this difference of approximately 100ml was not significant. Consistent with the findings of the present study, participants in the water protocol group appeared to offset the intake of water (mean of 462ml) by decreasing the amount of thickened fluid consumed and total fluid intake was not associated with moderator variables of age, sex or stroke location. As a point of difference between the studies, patients with comorbidities that are common in the stroke population such as cognitive deficits were excluded, which may account for the slightly higher total fluid intake compared with the present study.

A second study of water protocols included patients with diagnoses other than stroke, namely spinal cord injury and traumatic brain injury (Carlaw, et al., 2012). The participants in this study were subsequently younger, with a mean age for the males of 54 years and females 44 years. Furthermore, the 15 participants were not limited to oral fluid only in either arm of the cross-over RCT. Fluid intake was measured from oral and non-oral enteral tube feeding, and pre-and post-study fluid measurements occurred over only 48 hours as opposed to throughout the duration of the intervention. Thus the findings of a significant increase in fluid intake under the

water protocol conditions (1845ml) compared to standard care conditions (1474ml), with an average intake of water of 563ml per day, is not directly comparable to this present study which measured intake from oral fluids only and across a longer time frame. The third published study of water protocols included participants from acute and sub-acute care settings with various and multiple diagnoses causing their dysphagia, including stroke, cancer and progressive neurological conditions such as dementia and so is not directly comparable to this present study (Karagiannis, et al., 2011). Participants in the water protocol group consumed significantly more fluid (on average 400ml more) than the control group on thickened fluids only. Unfortunately, parts of the methodology of this study were flawed by an inadequate description of illness severity, diagnosis of aspiration and pneumonia, and therefore findings may not be valid.

In summary, results from the present study and that of the most comparable (Garon, et al., 1997) indicate that water protocols do not necessarily increase the total fluid intake of patients with dysphagia in the sub-acute phase post-stroke when patients are reliant on oral intake alone. Any additional intake that comes from water appears to be offset by a corresponding decrease in the amount of thickened fluids consumed.

Hydration

The present study sought to investigate the relationship of thickened fluids to hydration for patients with dysphagia consuming oral fluids only by introducing an alternative oral fluid source, water. The change in hydration over time between the water protocol group and thickened fluids only group displayed an interesting trend. The hydration results of participants in the water protocol group tended to improve over time, whereas the hydration results of those in the thickened fluids only group tended to worsen (refer to Figure 13). Although none of these changes over time were statistically significant (a likely result of inadequate sample size), the calculated effect sizes were promising. The change in hydration results between the two groups from Day 0 to Day 7 was medium (d=0.7) and between Day 0 and Day 14 was large (d=0.84). This suggests that even though the patients in the water protocol group did not drink any more in total, their hydration was on a comparably better trajectory of change. Given there was no difference in hydration measures between the groups according to demographic factors or stroke factors such as age, sex or dependency,

the finding suggests that water may have been the main contributor to the effect. Even a small amount of water (those in the water protocol group consumed only 300ml of water on average daily) may have been sufficient to change the trajectory of their hydration status.

The exact mechanism for this apparent difference in hydration, without an associated increase in total fluid intake, from a physiological and biochemical point of view is not known. It could be hypothesised that water is more accessible to the body than thickened fluids for the purposes of hydration. Urea, a waste product made when protein is broken down in the body, passes out of the body through the kidneys (Wallach, 2007). Water may help the kidneys remove urea from the blood more effectively. This hypothesis may seem in conflict with a seminal publication about the accessibility of fluid from thickened liquids for rats and humans which indicated there is no evidence for the reduced availability of water from thickened fluids (Sharpe, Ward, Cichero, Sopade, & Halley, 2007). However, the measures used in that study of absorption rates by the gut and concentrations of water in blood and saliva samples (Sharpe, et al., 2007) were different from those used in the present study (urea and creatinine) so findings are not immediately comparable. Further exploration about the possible mechanism behind this change in trajectory of hydration, with experts such as biochemists and urologists, is currently in progress to determine whether this phenomenon is a physiologic possibility and worthy of future research.

The hydration findings of this study are comparable to the acute setting. Patients with dysphagia in an acute setting immediately post-stroke had a mean urea/creatinine ratio of 83 at admission to hospital, increasing to a mean of 106 within a few days, despite comprehensive stroke unit care pathways which may have included the delivery of intravenous or enteral fluids (Crary, 2014). Similar to the present study, it was noted that demographic factors such as sex or age were not related to hydration status in the cohort of acute patients with dysphagia. However, stroke severity and impairment were significantly associated with poor hydration. Furthermore, those on a more restrictive oral food and fluid regime, according to the Functional Oral Intake Scale (Crary, Carnaby Mann, & Groher, 2005), had correspondingly worse hydration. Future research was suggested to investigate the potential relationship

between dysphagia management practices, specifically the use of thickened fluids, and dehydration (Crary, et al., 2013). The results of this present RCT have not confirmed the suggestion that restricting oral fluids to thickened fluids only results in poorer hydration, but the trajectory of hydration measures over time found in this study does add weight to this hypothesis.

Adverse Health Outcomes

Collectively, the participants with dysphagia post-stroke in this study had a high incidence of adverse health outcomes; six of the 14 participants with dysphagia (43%) were diagnosed with at least one adverse health outcome related to fluid intake during their admission (dehydration, urinary tract infection or constipation). In contrast to expected rates of pneumonia according to the published literature (Martino, et al., 2005), but in keeping with two other studies of water protocols (Carlaw, et al., 2012; Garon, et al., 1997), none of the participants in this study were diagnosed with pneumonia. The small sample sizes may have contributed to this finding. An alternative explanation, worthy of consideration, was the compliance with the mandated oral hygiene regime in all of these studies. Poor oral hygiene is a known risk factor for aspiration pneumonia (Langmore, et al., 1998) and oral care has been shown to reduce the incidence of pneumonia in residential care facilities (Yoneyama, et al., 2002). The participants completed a three times-a-day oral hygiene routine in the present study and demonstrated a significant improvement in oral health scores in just one week from enrolment. Having an oral hygiene regime as a mandatory part of the research protocol may have contributed to there being no diagnoses of pneumonia in this sample of participants.

The finding of a 21% incidence of medically diagnosed dehydration documented in this study is in contrast to the findings of the previous studies of water protocols which found no adverse events for any of their participants (Carlaw, et al., 2012; Garon, et al., 1997). The differing definitions for these adverse events and follow-up periods may explain this discrepancy. This study relied on a medical diagnosis of dehydration independent of the treatment that ensued, whereas another water protocol study defined an adverse event as a new need to initiate intravenous fluids, a new need to initiate tube-feeding or acute-care hospitalization (Carlaw, et al., 2012).

Comparing the two fluid regimes in the present study, the thickened fluids only group had a higher proportion of participants with one or more adverse health outcomes (50%) in contrast to the water protocol group (38%) but this difference was not significant overall. They did have a significantly higher proportion of participants with UTI compared to the water protocol group. Whilst it is recognised that UTIs (and in fact all of these health recorded outcomes) can be associated with many factors other than fluid intake, such as incontinence, catheterisation, medications, mobility etc., in theory these other factors should have been accounted for by the randomisation process. However, given the small numbers in each group diagnosed with an adverse event, no definitive conclusions about the benefits of a water protocol or deleterious effects of thickened fluids on health outcomes can be drawn from these findings.

Time to Resolution of Dysphagia for Thin Fluids

The resolution of dysphagia for thin fluids for participants in the water protocol group was faster (median of 27 days) than for those in the thickened fluids only group (median of 38 days) although this difference was not statistically significant. These findings are consistent with Garon et al's (1997) study in which the participants in the water protocol also had faster, although not significantly so, resolution of thin fluid aspiration (mean of 33 days) than those in the thickened fluids only group (mean of 39 days). Together, the findings may indicate that allowing patients to "practise" drinking thin fluids in the relatively safe form of water, may in fact promote recovery, through improved timing and coordination of the swallowing mechanism, consistent with the principles of experience dependent neuroplasticity (Kleim & Jones, 2008; Robbins et al., 2008). The premise of using the swallowing mechanism functionally (by eating and drinking) and challenging it systematically with increasingly demanding exercises and more difficult material to swallow is the basis for the McNeill Dysphagia Therapy Program which aims to rebuild functional patterns of swallowing movement (Carnaby-Mann & Crary, 2010). It follows that swallowing water may well facilitate the recovery of swallowing thin fluids safely.

Patient Satisfaction

It is often reported that patients with dysphagia dislike thickened fluids and that this is one of the major reasons for non-compliance with prescribed dysphagia interventions (Colodny, 2005; Goulding & Bakheit, 2000; Macqueen, Taubert, Cotter, Stevens, & Frost, 2003). In order to explore patient perceptions about fluids further such as their taste, thirst quenching properties and ease of drinking, a purpose-specific 'aphasia and cognitive friendly' survey was designed and implemented in this study. It was felt that the only validated quality of life survey specific to swallowing, the SWALQoL, a 44-item validated tool that evaluates ten quality-of-life domains (McHorney et al., 2002), was too comprehensive and lengthy to administer as it covers all aspects of swallowing not just drinking. In this study, participants who were allowed thickened fluids only rated their satisfaction for thickened fluids at 18 (from a possible maximum score of 25) at Day 7 increasing to 22 at Day 14. As would be expected, they rated highly their experience of reduced coughing. Surprisingly, they did not rate the taste, feel in the mouth and thirst quenching properties of thickened fluids as poorly as may have been expected. Perhaps the common use of pre-packaged thickened fluids has contributed to the improved palatability of thickened fluid products. Furthermore, many older individuals enjoy the sweetness of flavoured fluids (albeit thickened) that water does not provide.

Those in the water protocol group rated their overall satisfaction with water quite similarly to that for thickened fluids. The only factor that they rated higher for water than for thickened fluids related to the thirst quenching properties. A surprising finding was that on average they rated the taste of thickened fluids higher than the taste of water. When asked their preferred drink, participants in the water protocol group were quite evenly split in their choice between water and thickened fluids and, even across time, some of them changed their preference from water to thickened fluids or vice versa. One participant commented that he preferred the taste of the thickened drinks and another disliked the chlorine taste of the water. Interestingly, participants in the water protocol group, who were given a choice to drink as much or as little water as they wished, only chose to drink on average 300mls of water per day and the majority of their daily intake came from thickened fluids.

suggest patients with dysphagia are quite ambivalent about thickened fluids, not as adverse to them as commonly believed. It would appear that individuals' taste preferences play an important role in what they drink when given a choice; some like the taste of tap water, others don't. It should be noted as a limitation of this study that the tap water provided was not filtered at all facilities.

The findings of this study are in contrast to patient satisfaction ratings from two previous studies of water protocols (Carlaw, et al., 2012; Karagiannis, et al., 2011) in which participants rated their satisfaction with the water protocol higher than thickened fluids only. On the 'symptom' sub-scale of the SWAQoL, those in the water protocol phase perceived an improvement in symptoms of dysphagia while those in the control phase perceived worsening of symptoms (Carlaw, et al., 2012). Similarly, the 18 participants in the water protocol group reported significantly higher levels of satisfaction with the drinks, level of thirst and mouth cleanliness compared with the control group who were allowed thickened fluids only (Karagiannis, et al., 2011). However, the questionnaire was administered at the end of five days of intervention, a period much shorter than that of the present study.

The findings of patient satisfaction from this study, that patients rated their satisfaction of thickened fluids and water equally, also contradict the view of many clinicians. Health professionals, including speech-language pathologists, frequently report that patients' dislike of thickened fluids is the main reason for their poor intake, as outlined in Chapter 5 and in the published literature (Mertz-Garcia, et al., 2005; Murray, et al., 2014). Perhaps with the improvement in commercially available thickened fluid products and with more hospitals choosing to provide this option, patients with dysphagia are becoming more accepting of thickened fluids than clinicians perceive. Furthermore, the alternative choice provided in water protocols, which is usually tap water, whilst safe from a water standards point of view, can be of varying taste quality and may not be as appealing to older adults as clinicians believe. An alternative explanation for the poor intake as suggested by the findings of this present study may be that the dysphagia itself precludes higher amounts of fluid consumption no matter what fluids are offered.

Limitations

It is acknowledged that this study had methodological limitations, some of which were similar to those discussed in Chapter 7, and the findings should therefore be interpreted in this context. The use of fluid balance charts as a measure of fluid intake may have resulted in inaccurate amounts being recorded. As discussed previously in Chapter 6, procedures were put in place to minimise inaccuracies (regular training sessions for nursing staff were conducted, with consistent use of clearly measured containers and information sheets for participants and families), however, errors may still have occurred in the recording of fluid intake. It is acknowledged that the amount of fluid offered to individual participants in this study was not controlled or recorded and may have varied between individuals and institutions. This in turn may have differentially influenced consumption as participants were only able to consume as much as was offered. Furthermore, it is acknowledged that the clinical diagnosis of dehydration is complex and highly variable in any clinical setting and the use of a single biochemical metric is a limitation of this study. By far the most critical limitation of this study was that it was underpowered, due to recruitment difficulties, to demonstrate possible significant differences between the two arms of the RCT.

Conclusion

Despite the limitations, it is clear that participants in this study did not drink an adequate amount of beverages per day even when given the choice to drink water. The water that participants in the water protocol group did consume was offset by them consuming less of the thickened fluids offered which therefore did not increase their total intake. The dysphagia itself or taste preferences seemed to influence how much all patients drank. Participants were not as adverse to the taste of thickened fluids as is commonly perceived. Despite the equally poor intake across both groups, those who were allowed to drink water had an improving trajectory for their hydration levels compared to those on thickened fluids only whose hydration seemed to decline. Even a small amount of water per day may make a difference to whether hydration levels improve or not. There was a trend for those who were allowed water to have fewer adverse health outcomes and to resolve their dysphagia for thin fluids faster. Given there were no increased adverse outcomes for participants who were

allowed water and, significantly, there were no diagnoses of pneumonia, it seems reasonable to suggest that patients with dysphagia in rehabilitation be offered water so that they can potentially benefit from improved hydration. Of course this recommendation would only be for patients without a history of COPD, reduced immune status, neuro-degenerative disease or head and neck cancer, and would need to be under the strict conditions of a water protocol with strict oral hygiene and frequent monitoring.

Future Research

Future research using a similar RCT design but with larger sample sizes should specifically aim to confirm the improvement in hydration status that water protocols may offer patients with dysphagia compared to thickened fluids alone as the present findings suggest. Further investigation using spring or filtered water may confirm whether taste has an over-riding influence on how much patients consume when given a choice or whether it is truly the dysphagia that limits how much patients can drink per day.

Priority for future research into the effectiveness of water protocols should be given to patients in acute settings. The three published RCTs that have been conducted to date, along with the present study, were conducted in rehabilitation facilities (Carlaw, et al., 2012; Garon, et al., 1997; Karagiannis, et al., 2011). Findings about the safety of water protocols can therefore only be generalised to patients in rehabilitation settings at this point in time. Despite efforts to include patients from acute settings in the present study and that by Karagiannis et al. (2011), the inclusion and exclusion criteria and perhaps research design have resulted in poor recruitment from this setting. Future studies will need to consider alternative research protocols to maximise inclusion of patients in acute settings. Perhaps revisiting the strict exclusion criteria many studies have set, with the support of a broader interdisciplinary team, would be beneficial.

The results of the participants *with* dysphagia from this RCT have been compared directly with the same outcomes of the cohort of participants *without* dysphagia and are presented and discussed in the next chapter.

Chapter 9: Comparison of Individuals with and without Dysphagia Post-stroke

Introduction and Purpose

As previously discussed, many studies examining the fluid intake or hydration status of patients with dysphagia have not included a control group against which the measure of "enough" and "adequate" could be accurately gauged (Carlaw, et al., 2012; Finestone, et al., 2001; Garon, et al., 1997; Karagiannis, et al., 2011; Leibovitz, et al., 2007; Whelan, 2001). In an attempt to redress this short-coming, data were collected in this present research about the fluid intake and hydration of a cohort of patients without dysphagia (presented in Chapter 7) who were inpatients in the equivalent setting and conditions to the participants with dysphagia. This chapter pools the data from the two prospective studies (the RCT and the cohort study) and presents a direct comparison of the fluid intake, hydration and health outcomes of patients with and without dysphagia post-stroke. It aims to explore whether the fluid intake and hydration status is, as surmised, worse for patients with dysphagia compared to those *without* dysphagia. Such a finding would support the hypothesis that it is the dysphagia itself that has the greatest influence on these measures given the two groups have a similar clinical condition and are inpatients in the same rehabilitation facilities. The alternative hypothesis could therefore also be explored; that stroke co-morbidities or institutional factors may influence fluid intake and hydration for all stroke patients.

Research Questions

- 1. Do patients with dysphagia in inpatient rehabilitation settings post-stroke drink less than their peers without dysphagia?
- 2. Is the fluid intake of patients in inpatient rehabilitation associated with demographic factors, stroke severity or particular stroke co-morbidities?
- 3. Do patients with dysphagia in inpatient rehabilitation settings post-stroke have poorer hydration than their peers without dysphagia?

- 4. Is the hydration status of patients in inpatient rehabilitation associated with demographic factors, stroke severity or particular stroke co-morbidities?
- 5. Do patients with dysphagia in inpatient rehabilitation settings post-stroke have more fluid-related adverse health outcomes than their peers without dysphagia?

Methods

The methods for data combination and analysis are presented in Chapter 6.

Results

Demographics and Stroke Characteristics

The demographic, clinical and stroke characteristics of the participants in the dysphagia group (n=14) and the no dysphagia group (n=86) are presented in Table 27. The participants with dysphagia were significantly older on average (mean 79 years, SD 6 years) than their peers without dysphagia (mean 69 years, SD 11 years) (t₉₉=-3.266, p=0.002). According to chi-square tests there were no differences in stroke type, location or lateralisation between the groups (p>0.05) but the participants in the dysphagia group were significantly fewer days post-stroke when recruited to the study (mean=19 days) than those in the no-dysphagia group (mean=39 days) (t₉₈=2.130, p=0.036). – refer to Table 27.

The dysphagia group had significantly worse mobility with only 36% exerting themselves to mobilise compared to 61% of the no-dysphagia group ($\chi^2_{(1)}=7.454$, p=0.011). The groups were equivalent in terms of: the proportion of participants who were independent for pouring drinks and drinking from a cup; having aphasia or cognitive impairment; and admission weight (p>0.05). The admission FIM of the dysphagia group, whilst lower, representing greater dependency (mean=59, SD=19), was not significantly different to the no-dysphagia group (mean=73, SD=25, t₇₀=1.54, p=0.128).

		Dysphagia	No dysphagia	p value
		n (%)	n (%)	
Participants		14 (100)	86 (100)	
Sex	Male	10 (71)	55 (64)	0.765
Age, years	Mean (SD)	79 (6.4)	69 (11)	0.002*
Stroke type	Infarct	13 (93)	71 (83)	0.540
	ICH	1 (7)	15 (17)	-
Stroke Location	Cortical	7 (50)	58 (68)	0.169
	Sub-cortical	4 (29)	15 (17)	-
	Brainstem	3 (21)	7 (8)	-
	Cerebellar	0 (0)	6 (7)	-
Stroke	Left	10 (71)	42 (49)	0.275
Lateralisation	Right	4 (29)	40 (46)	-
	Bilateral	0 (0)	4 (5)	-
Time post stroke, days	Mean (SD)	19 (8)	39 (34)	0.036*
FIM/max 126	Mean (SD)	59 (19)	73 (25)	0.128
Weight, kg	Mean (SD)	78.7 (19.6)	80.2 (20.4)	0.853
Stroke	Aphasia	3 (21)	29 (34)	0.539
comorbidities	Cognitive impairment	5 (36)	25 (29)	0.754
	Not exerting to mobilize	9 (64)	19 (27)	0.030*
	Motor or ideational apraxia	1 (7)	12 (14)	0.687
	Dysarthria	12 (86)	21 (24)	0.001*
	Apraxia of speech	2 (14)	10 (12)	1.000
	Dependence for oral care	4 (29)	7 (10)	0.78
	Dependence for pouring drinks	2 (14)	6 (9)	0.392
	Dependence for drinking from a cup	0 (0)	0 (0)	

Table 27 Demographic and stroke characteristics of combined sample

Assessment Results

As would be expected, the clinical swallow assessments results on the 150ml water test (Hughes & Wiles, 1996) were significantly worse for the dysphagia group than for the no-dysphagia group on all parameters as illustrated in Table 28.

	Dysphagia		No-dy	vsphagia	t value	p value
	Mean (SD)	% below normal limits	Mean (SD)	% below normal limits		
Time per swallow (sec)	4.24 (3.61)	90%	2.02 (1.07)	44%	-4.161	< 0.001
Volume per swallow (ml)	9.93 (5.54)	70%	20.04 (6.49)	20%	4.685	< 0.001
Volume per time (ml/sec)	4.29 (4.32)	42%	13.07 (6.86)	7%	4.471	< 0.001

 Table 28 Water test results of participants in the combined sample

Oral health was scored on a rating scale with a maximum score of 16; the lower score the better the oral health (South Australian Dental Service, 2004). At entry to the study (Day 0), the oral health scores of the participants with dysphagia were significantly worse than their no-dysphagia counterparts (mean of 4.85 and 2.15 respectively) (t_{97} =-4.278, p=<0.001). The oral health scores improved for both groups after they had completed a full week of the oral hygiene protocol. By Day 7, the difference between groups was no longer significant. Refer to Table 29.

 Table 29 Oral health scores of participants in the combined sample

Oral health score (0-16)	Dysphagia Mean (SD), Range	No-dysphagia Mean (SD), Range	t value	p value
Day 0	4.85 (3.44), 0-11	2.15 (1.86), 0-8	-4.278	< 0.001
Day 7	2.77 (1.59), 0-8	2.00 (1.82), 0-9	-1.417	0.160

Answers to Research Questions

Research question1: Do patients with dysphagia in inpatient rehabilitation settings post-stroke drink less than their peers without dysphagia?

The mean total daily beverage intake calculated for all participants with dysphagia in the RCT was 1103ml (SD=220ml). This total beverage intake was comprised of thickened fluids (mean=919ml, SD=330) plus water for some participants (mean=186ml, SD= 245ml). These participants drank significantly less on average per day than participants in the no dysphagia group (mean=1504ml, SD=359ml) (t_{98} =4.051, p<0.001, 95% CI=204.537 to 597.416) as illustrated in Figure 14. The

percentage of calculated fluid requirements consumed by participants in the dysphagia group (mean=49%, SD=13%) was also significantly lower than that consumed by participants in the no-dysphagia group (mean=67%, SD= 19%, t_{60} =2.381, p=0.020, 95% CI=5.356 to 30.545).



Figure 14 Average daily beverage intake of participants with and without dysphagia

Research question 2: Is the fluid intake of patients in inpatient rehabilitation associated with demographic factors, stroke severity or particular stroke co-morbidities?

A univariate analysis was conducted to determine which of the co-variates of age, days post-stroke, admission FIM, mobility and dysphagia status were independently associated with fluid intake. The factors significantly and independently associated with average fluid intake for participants whose data were recorded for all of these variables (n=72) were admission FIM ($F_{1,66}$ =10.676, p=0.002), dysphagia ($F_{1,66}$ =4.521, p=0.037) and mobility status ($F_{1,66}$ =4.907, p=0.030). Participants who were exerting to mobilise by walking or self-propelling in a wheelchair, those who

did not have dysphagia and those who were more independent had significantly greater daily fluid intake.

Research question 3: Do patients with dysphagia in inpatient rehabilitation settings post-stroke have worse hydration than their peers with dysphagia?

The mean (SD) urea/creatinine ratio of all participants with dysphagia in the RCT sample was 86.94 (15.32) at Day 0, 86.00 (20.29) at Day 7 and 89.73 (32.81) at Day 14. Each participant's urea/creatinine ratio result was classified into one of two categories: within normal range (<80) or elevated beyond normal limits (>80). A large percentage of the total sample (71%) was classified as dehydrated at entry to the study on Day 0. The proportion who were classified as dehydrated decreased over the 2 weeks from 64% at Day 7 to 43% at Day 14.

There was no significant difference in hydration results between the dysphagia group and the no-dysphagia group at Day 0 (t₉₇=-1.168, p=0.245) or Day 7 (t₉₁=-0.864, p=0.390) based on the raw figures of urea/creatinine ratio. However, when classified as dehydrated or not, those in the dysphagia group were significantly more likely to be classified as dehydrated at Day 0 (χ^2 =4.809, p=0.041) as illustrated in Table 30.

U/Cr ratio	Mean	Mean (SD) t p Dehydrated (U/Cr>80)		χ^2	р			
	Dysphagia	No- dysphagia			Dysphagia	No- dysphagia		
Day 0	86.93 (15.32)	79.93 (21.51)	- 1.168	0.245	71%	40%	4.809	0.041*
Day 7	87.00 (20.29)	80.55 (22.43)	- 0.864	0.390	64%	44%	1.905	0.246

Table 30 Hydration results for participants with and without dysphagia

Research question 4: Is the hydration status of patients in inpatient rehabilitation associated with demographic factors, stroke severity or particular stroke co-morbidities?

As a combined sample of 100 rehabilitation inpatients post-stroke, 44% were classified as dehydrated (urea/creatinine >80) on Day 0 and 47% at Day 7. To determine whether any of the demographic or stroke factors were associated with

hydration measures, a partial correlation of the variables age, days post-stroke, admission FIM and urea/creatinine ratio at day 0 and day 7 was conducted with the presence or absence of dysphagia controlled for. Age was the only factor that was significantly and independently correlated with hydration measures for the combined sample and only at Day 0 (r=0.237, p=0.048); the older the participant, the worse their hydration results. Hydration measures were not significantly different between participants who were able to exert to mobilise or not at either Day 0 (t₈₂=-1.696, p=0.94) or Day 7 (t₇₇=-0852, p=0.397).

The amount of fluid intake did not correlate with hydration measures at Day 0 (r=-0.152, p=0.132) or Day 7 (r=-0.121, p=0.247) although, as expected, there was a trend for those participants who drank less to have worse hydration. Refer to Figure 15.



Figure 15 Correlation between fluid intake and hydration results for participants with and without dysphagia

Research question 5: Do patients with dysphagia in inpatient rehabilitation settings post-stroke have more fluid-related adverse health outcomes than their peers without dysphagia?

As previously indicated, of the total sample of 14 participants with dysphagia, six (43%) were diagnosed with an adverse event during their admission: there were three diagnoses of dehydration, three of urinary tract infection, four of constipation and

none of pneumonia. The participants with dysphagia had significantly more adverse fluid-related health events in total than those without dysphagia (16%) ($\chi^2_{(1)}$ =5.316, p=0.021). Specifically they had significantly more diagnoses of dehydration (χ^2 =9.250, p=0.002), but there was no statistically significant difference in their incidence of pneumonia, UTI or constipation. Logistic regression indicated that if a participant was classified as having dysphagia, he/she was almost 4 times more likely to be diagnosed with one or more adverse health outcomes than if he/she didn't have dysphagia (Wald=4.834, b=1.350, Exp(B)=3.857, p=0.028).

As a combined sample of 100 rehabilitation inpatients post-stroke, twenty percent (n=20) were diagnosed with one or more adverse health outcomes; 5% with dehydration, 13% with constipation and 10% with UTI.

Discussion

The aim of this chapter was to directly compare the fluid intake and hydration status of patients with and without dysphagia in inpatient rehabilitation post-stroke. The direct comparison was possible because both samples of patients included in the RCT (Chapter 8) and the cohort study (Chapter 7) were residing in the same rehabilitation centres, with the same staff, facilities and clinical care, and data were collected using the same methodology over the same timeframe. This direct comparison, however, had its limitations as the two samples of participants weren't exactly equivalent at baseline. The dysphagia group had fewer participants and they were significantly older than the no-dysphagia group. They were also significantly more dependent according to admission FIM and at an earlier time point in their recovery (closer to the date of their stroke) at the time of recruitment. According to the literature, these differences between patients with and without dysphagia should be expected. Dysphagia as a symptom is often associated with a more severe stroke and patients typically have a poorer prognosis than those without dysphagia poststroke (Mann, et al., 1999; Smithard, et al., 1997; Smithard, et al., 1996). The elderly may be particularly vulnerable to the effects of dysphagia following stroke because of the already decreased swallowing reserve that occurs with age (Logemann, Pauloski, Rademaker, & Kahrilas, 2002; Logemann, Pauloski, Rademaker, Colangelo, Kahrilas, & Smith, 2000; Robbins, Duke Bridges, & Taylor, 2006) and as illustrated, the participants with dysphagia in this study were significantly older than those without dysphagia. The majority of patients that present with dysphagia post stroke recover their ability to swallow within weeks (Holas, DePippo, & Reding, 1994; Smithard, et al., 1997) which may be the case with the participants in the nodysphagia group in this study. Given they were recruited at an average time of 39 days post stroke, recovery of any potential initial swallowing difficulty may have already occurred. In summary, the differences between the two groups, those with and without dysphagia, at baseline are typical. Whilst statistical procedures controlled for between group differences, the comparison of outcomes of the two groups should still be interpreted with caution in light of these baseline differences.

As expected, the results of the clinical assessments demonstrated that the patients with dysphagia had significantly poorer swallowing function than those classified as having no dysphagia. The significantly poorer oral health scores of the dysphagia group compared with the no-dysphagia group is a finding that is consistent with the literature. It is widely recognised that the inactivity of the mouth and tongue, poor oral sensation and tube feeding associated with dysphagia after a stroke can lead to a build-up of bacteria in the saliva and coating of the tongue and oral mucosa (Langmore, et al., 1998). Pleasingly, after one week of an oral hygiene protocol, which required brushing the teeth or dentures twice a day and a mouth rinse after lunch, the oral health of both groups improved. The oral health of the dysphagia group was no longer significantly different to their no-dysphagia peers within the one week timeframe. This study did not set out to demonstrate the effectiveness of the oral hygiene protocol as an intervention and conclusions about causation cannot be drawn from the research design for this measure. The findings suggest, however, that clinically meaningful improvements can be made by an easily manageable and regular oral hygiene regime.

Fluid Intake

The participants with dysphagia drank significantly less on average per day (1103ml) than their peers without dysphagia (1504ml). There is only one other known published study that presents an equivalent comparison of fluid intake between two cohorts of patients in hospital post-stroke (McGrail & Kelchner, 2012). The fluid intake of 10 patients prescribed thickened fluids, consuming on average 947ml per day, was significantly less than the 10 patients drinking thin fluids who consumed on

average 1237ml per day (McGrail & Kelchner, 2012). Although consuming less overall in this study compared with the present study, the proportion of fluid consumed by patients on thickened fluids was similar (approximately three quarters of that consumed by patients drinking normal fluids). It appears that the viscosity of fluid offered (thick or thin) significantly affects fluid consumption although it cannot be concluded from either study whether this is due to the palatability of the different fluids or due to dysphagia itself.

The participants with dysphagia in the present study consumed a significantly lower percentage of their calculated fluid requirements than the participants without dysphagia, 49% compared with 67%, respectively which again supports the assertion that people with dysphagia are at greater risk of sub-optimal intake. Based on the conservative standard of 30ml per kg (Chernoff, 1994), the mean beverage consumption for the participants with dysphagia in the study should have been 2361ml. The mean intake of this sample of 1103ml fell well below this. Notably, of the 100 participants, with and without dysphagia, only 8% drank as much fluid as they should have according to this standard. An even lower percentage (2%) achieved the Australian and New Zealand Nutrient Reference Values of 2600ml per day for healthy males and 2100mls for females (Australian National Health and Medical Research Council, 2005). The study by McGrail &Kelchner (2012) similarly found that only one of their 20 hospitalised participants met the standard intake of 1500ml per day.

Direct comparison with the fluid intake of the healthy elderly confirms that the fluid intake of this sample of patients post-stroke was sub-optimal. Despite their comparable age, healthy adults living in the community consume significantly greater amounts than the inpatients in the present study (Bastiaansen & Kroot, 2000; Bossingham, et al., 2005; Luszcz, et al., 2007). In a direct comparison with patients consuming thin or thickened fluids in inpatient rehabilitation post-stroke, McGrail & Kelchner (2012) reported that 10 age-matched participants living in the community consumed significantly more than either of the other groups and 80% of them consumed more than the standard of 1500ml per day. If it is assumed that age is not the crucial factor influencing intake, why do the patients in rehabilitation post-stroke consume significantly less than their community dwelling peers? In this present

study it was the patients' dependency and mobility that significantly affected fluid consumption. When age and dysphagia were controlled for, a patient's dependency, based on their admission FIM, was a significant predictor of their fluid intake; the more dependent they were, the less they drank. Additionally, if they were unable to exert to mobilise they consumed a significantly lower percentage of calculated fluid required than those who were more mobile. This finding is consistent with the literature that number of illnesses and level of dependency significantly affects intake as opposed to age itself (Morgan, et al., 2003).

Hydration

Patients with dysphagia post-stroke in inpatient rehabilitation settings in the present study had poorer hydration than those without dysphagia. Using the cut-off of urea/creatinine ratio >80, a significantly greater percentage of patients in the dysphagia group were classified in the dehydration range across two time points (64% and 71%) compared with those without dysphagia (40% and 44%). This finding is consistent with other studies of hydration using the same urea/creatinine measure for patients post-stroke albeit in an acute setting; patients with dysphagia, even with supplementary non-oral intake, have worse hydration than their counterparts without dysphagia (Crary, et al., 2013; Rowat, et al., 2012). It is incumbent upon stroke clinicians, therefore, to be highly vigilant about the risk of dehydration for patients with dysphagia post-stroke.

Further to this concern for patients with dysphagia, patients post-stroke without dysphagia should also be considered at risk of dehydration. As a combined sample of 100 patients in inpatient rehabilitation post-stroke, 44% were classified as dehydrated on Day 0 and 47% at Day 7. In this study, age was associated with poor hydration measures; the older the participant, the worse their hydration results. The factors of dependency and mobility were not significantly associated with hydration. However, it cannot be assumed that age is the only contributing factor. The participants in the present study (mean urea/creatinine ratio of 81) had worse hydration than of a cohort of community dwelling people aged over 70 years from the Australian Longitudinal Study of Ageing (Luszcz, et al., 2007). This elderly cohort had a mean urea/creatinine ratio of 64, with only 15% classified in the dehydration range. This may indicate that place of dwelling, number of medical conditions, access to

preferred fluids, activity levels and a multitude of other factors influence hydration. Some of these factors relate to institutionalisation. If an elderly person is not in their home environment with their regular routine and access to preferred fluids, hydration may decline.

In summary, the findings from the present study and the literature indicate that patients in facilities post-stroke are at higher risk of dehydration than their community dwelling elderly peers due to comorbidities associated with their health status or institutional factors. This risk is elevated even further if they also have dysphagia as a result of their stroke.

Adverse Health Outcomes

The participants with dysphagia had significantly more medically diagnosed adverse health events in total (43%) than their peers without dysphagia (16%). Specifically, they had significantly more diagnoses of dehydration. There is very little literature with which these findings can be compared. Rates of aspiration pneumonia are reported in the National Stroke Foundation audits (National Stroke Foundation, 2009, 2010b) but the other diagnoses recorded in this study of urinary tract infections, constipation and dehydration are not documented. Aspiration pneumonia is also commonly reported as an adverse health outcome in the dysphagia literature but constipation and UTI are not. If dehydration is included as a health outcome in the dysphagia literature, the classification is usually determined by a single index or combination of biochemical indices rather than being based on a medical diagnosis as it is for this outcome measure of the present study. The most objective source of comparison for the results of the present study comes from the information collected in the incidence study presented in Chapter 3. According to the Integrated South Australian Activity Collection (ISAAC) of hospital admissions, patients admitted to hospitals from 2000-2014 with stroke were diagnosed with the following complications at the following rates: dehydration, 6.2%; constipation, 3.1%; UTI, 12%; and aspiration pneumonia, 7.3%. From the combined sample of 100 rehabilitation inpatients post-stroke, the percentage of adverse health outcomes in the present study were quite comparable to the ISAAC data extraction for diagnoses of dehydration and UTI, but not for the diagnoses of constipation and aspiration pneumonia (refer to Table 31). These differences may be explained by the different acuity levels of the patients from whom data were collected. In the ISAAC data extraction, patients were in the acute stage of their stroke compared with the present study where they were all in inpatient rehabilitation. Aspiration pneumonia may occur more frequently in the acute stage post-stroke when patients have lower levels of consciousness, poorer mobility and more severe dysphagia. Constipation, on the other hand, may more readily be diagnosed in the rehabilitation setting when patients are increasingly reliant on oral intake alone, have longer-term mobility issues, longer term use of medications and have more chronic sub-optimal bowel use.

	Dysphagia- from RCT	No- dysphagia- from cohort study	Combined sample from prospective studies	Stroke patients with dysphagia from ISAAC	All stroke patients from ISAAC
Ν	14	86	100	3243	16104
Dehydration	21%	2.3%	5%	10.7%	6.2%
Constipation	29%	10.5%	13%	6.4%	3.1%
UTI	21%	8.1%	10%	21.6%	12%
Aspiration Pneumonia	0%	0%	0%	17.5%	7.3%

Table 31 Incidence of adverse health outcomes

Notwithstanding these differences in the incidence of diagnoses from the acute patients in the ISAAC data compared with the rehabilitation patients in the present study, it can be seen from both sets of data that all stroke patients are at some risk of these adverse health outcomes. The direct comparison, however, shows that patients with dysphagia are at far greater risk than their counterparts without dysphagia post-stroke and reinforces the need to be particularly vigilant in screening for these health outcomes in patients with dysphagia.

Conclusion

By pooling and directly comparing the results of two cohorts of patients following stroke, it is clear that patients with dysphagia, when reliant on oral intake only, are at significantly higher risk of sub-optimal fluid intake, dehydration and adverse health outcomes than their peers without dysphagia. However, even those without dysphagia are at risk compared with the healthy elderly living in the community. Inpatients who are more dependent and have poor mobility seem to be at greatest risk of sub-optimal fluid intake, and those who are older have an increased risk of dehydration. It also appears that being cared for and reliant on institutional care may be a contributing factor to sub-optimal fluid intake and hydration.
PART IV Conclusion and Recommendations

Chapter 10: Conclusion and Recommendations

This research explored the fluid intake of inpatients with dysphagia post-stroke especially when they are reliant on oral fluids only. It specifically investigated whether fluid intake is sub-optimal, and if so, the reasons why. Further, it evaluated the efficacy of a water protocol in improving the fluid intake of patients with known thin fluid aspiration. Unique to this research, the hydration status and adverse fluidrelated health outcomes were measured to discover the implications of this suboptimal fluid intake for the health and well-being of patients post-stroke. These investigations were undertaken to provide a systematic evaluation as the basis for a larger research program which aims to generate and evaluate possible improvements to clinical practice. The ultimate aim of the first author is to work towards improving the health and quality of life of individuals with dysphagia.

This chapter provides a summary of the collective findings of the five studies in this thesis and discusses their significance in the context of existing knowledge. Subsequently, recommendations are made for clinical practice improvements, policy and future research.

Summary of Findings

The major findings of each of the original studies of this thesis are summarised in Table 32.

Study	Participants	Main findings
Incidence study Chapter 3	16104 stroke admissions From 2000/01 to	Average of 1150 stroke admissions per year across the four major acute hospitals in SA
	2013/14	Stroke accounts for 5.3% of total hospital admissions
	16104 matched non-	16% of stroke admissions died in hospital
	stroke admissions Median age 77 years	20% had dysphagia (significantly higher than a matched sample of non-stroke hospital admissions)
	Median LoS 8 days	12% had UTI (no different to matched sample)
		7% had aspiration pneumonia (significantly higher than the matched sample)
		6% had dehydration (significantly lower than the matched sample)
		3% had constipation (significantly lower than the matched sample)
		Patients with dysphagia post-stroke had a higher incidence of aspiration pneumonia (18%), dehydration (11%) and UTI (22%) than patients without dysphagia or the matched sample.
Retrospective audit of consumption of thickened fluids Chapter 4	69 patients hospitalised in SA post-stroke Mean age 78 years	Average daily consumption of thickened fluids was 781ml
		Average consumption for patients in 4 acute hospitals was 519ml which was significantly less than the average of 1274ml for patients in 3 rehabilitation centres
		The elderly (>75years) in the acute settings drank significantly less (452ml) than the younger stroke patients aged 41-64 years (795ml)
Survey of Australian health professionals	676 health professionals participated in the survey (57% speech pathologists, 23% nurses, 19% dietitians)	82% indicated thickened fluids are supplied in pre- packaged containers of commercially available products
chapter e		81% at bedside or 77% on their meal-tray
		60% supplied thickened fluids 5-6 times per day; only 6% indicated patients could access drink at any time on their request
		The most common amount to be offered per day was 1200-1400ml
		17% monitor consumption on a routine basis. 8% do not monitor consumption at all.
		51% indicated their patients did not drink enough of the thickened fluids
		80% attributed this to the feel in the mouth and 63% to taste; 37% attributed this to the dysphagia itself; 26% indicated not enough was offered; 37% believed they weren't monitored closely enough; 11% assistance was inadequate
		70% monitor hydration through clinical signs; 37% reported the use of blood test or 28% urine tests
		Most common strategy for addressing poor intake or hydration was for the nurses to encourage drinking (87%); only 14% indicated the consideration of water protocols

Table 32 Summary of original studies in this thesis

Study	Participants	Main findings
Cohort study of individuals without dysphagia following stroke Chapter 7	86 rehabilitation inpatients without dysphagia on normal diets Mean age 69 years	The average daily intake of beverages per day was 1504ml
		2% met the standards recommended by the Australian Nutrient Reference values; 7% met the conservative standard of 30mls per kg
		They consumed 67% of their calculated requirements
		Intake is well below that of the healthy elderly living in the community
		Increased dependency from stroke significantly affected their fluid intake
		44% were dehydrated according to the biochemical index of urea/creatinine ratio>80
		Hydration was significantly worse for the older participants and those with poor mobility
		16% had adverse health outcomes; 11% medically diagnosed with constipation; 8% with UTI; 2% with dehydration and none with aspiration pneumonia
		Greater dependency was a predictor (albeit weak) of having an adverse health outcome
RCT of individuals with dysphagia following stroke Chapter 8	14 rehabilitation inpatients with aspiration of thin fluids randomised to Thickened Fluids Only (n=6) and Water Protocol (n=8) Mean age 79 years	The average daily intake of beverages per day for water protocol group was 1103ml (299ml of this total was water)
		This intake was no different to Thickened Fluid Only group (1103ml)
		The water protocol group consumed 38% of their calculated requirements
		The thickened fluids only group consumed 53% of their calculated requirements (no significant difference)
		There was no significant association of fluid intake with any demographic factors or stroke co- morbidities
		88% of water protocol group were classified as dehydrated (urea/creatinine ratio>80). Hydration results improved with time.
		50% of thickened fluids only group classified as dehydrated. Hydration results declined with time (no significant difference).
		There was no significant association of hydration measures with any demographic factors or stroke co- morbidities
		Greater proportion of thickened fluids only group had adverse events but only UTI was significantly greater
		Water protocol group resolved dysphagia for thin fluids faster but not significantly so
		No difference in satisfaction for thickened fluids between the two groups

Study	Participants	Main findings	
Comparison of individuals with and	100 rehabilitation inpatients -	Dysphagia group drank significantly less per day (1103ml) than no dysphagia group (1504ml)	
without dysphagia post-stroke Chapter 9	14 with dysphagia 86 no dysphagia (from compiled data of studies above)	Greater dependency and reduced mobility were significantly associated with fluid intake	
		Those with dysphagia were significantly more dehydrated (71%) than those without dysphagia (40%) at entry to the study	
		Older age was significantly associated with poorer hydration	
		Dysphagia group had significantly more adverse events (43%) than those without dysphagia (16%), specifically more medical diagnoses of dehydration	
		There were no diagnoses of aspiration pneumonia	

The present research confirms that individuals with dysphagia consuming thickened fluids do not drink enough orally. The retrospective audit demonstrated that those in the acute setting were at highest risk of consuming sub-optimal amounts of thickened fluids. Whilst patients in rehabilitation consumed more than their acute counterparts, their daily average intake was still only half that *recommended* for healthy adults in Australia and shown to be consumed by the community dwelling elderly (Australian National Health and Medical Research Council, 2005; Luszcz, et al., 2007). Contrary to expectations, being offered water in addition to the prescribed thickened fluids (via a water protocol) did not improve the overall daily fluid intake of individuals with dysphagia. The amount of water they did drink (on average 299ml) was off-set by them consuming less of the thickened fluids offered, resulting in no nett improvement in total intake. This finding suggests that it was the dysphagia itself that prevented them from drinking adequate fluids as, no matter what fluid they were offered, they did not consume any more. Adding weight to this hypothesis were the results of the satisfaction questionnaire in the RCT. Patients were not as adverse to the taste and palatability of thickened fluids as is commonly thought, and even when given a choice to drink water, some preferred the taste of the thickened fluids. Perhaps this change in attitude towards thickened fluids is a result of more institutions providing thickened fluids in commercially produced pre-packed containers, as demonstrated in the survey presented in this thesis, with subsequent improvement in taste and viscosity. It seems that clinicians' attitudes, however, have not kept pace with patient attitudes, with a large percentage of the survey's respondents attributing poor intake to patient dislike of the feel of thickened fluids in the mouth and taste.

Alternative reasons for the sub-optimal intake of patients with dysphagia post-stroke were also explored in this thesis, namely stroke related dependency and institutional factors. Respondents to the survey had identified stroke dependency and insufficient staff to provide assistance to drink as possible reasons for the sub-optimal intake of patients with dysphagia on thickened fluids. The cohort study of patients *without* dysphagia residing in the same rehabilitation facilities allowed a direct and, therefore, unique comparison with those *with* dysphagia. This study did indeed demonstrate that patients without dysphagia post-stroke do not achieve recommended daily fluid intakes and that greater dependency was significantly associated with lower fluid intake. The average daily fluid intake of those with dysphagia leading to the conclusion that stroke related dependency does impact on fluid intake but dysphagia is by far the biggest risk factor for poor intake.

This thesis also addressed the impact of fluid intake on hydration. This was another unique aspect to the research as previous studies have reported on one or the other but not both measures within the same cohort of patients (Crary, et al., 2013; Finestone, et al., 2001; Leibovitz, et al., 2007; McGrail & Kelchner, 2012; Rowat, et al., 2012; Whelan, 2001). Remarkably, the amount of fluid intake and hydration were not significantly correlated with each other. The trend was, as expected, that the less fluid an individual drank, the poorer his/her hydration was. However, this nonsignificant correlation suggests that caution should be taken when considering a patient's hydration status; clinicians cannot rely on the measure of fluid intake alone as an indicator of adequate hydration or dehydration. Nevertheless, of concern was the classification of dehydration for 71% of the patients with dysphagia and 40% of those without dysphagia. Age was a demographic factor that was significantly associated with hydration; the older an individual, the worse their hydration. However, age alone may not be the only factor associated with poor hydration, as the hydration results of these patients in rehabilitation post-stroke compare poorly with the hydration of similar aged cohorts of individuals living in the community (Luszcz, et al., 2007; McGrail & Kelchner, 2012). It can be concluded that the hydration status of all stroke patients is sub-optimal and that age and institutionalisation are important risk factors. But again the biggest risk factor for poor hydration following stroke is the presence of dysphagia.

In an attempt to improve the hydration of patients with dysphagia post-stroke, this thesis evaluated the efficacy of a water protocol compared to thickened fluids only. Again, no other studies of water protocols have explicitly reported on hydration in conjunction with intake (Carlaw, et al., 2012; Garon, et al., 1997; Karagiannis, et al., 2011). Results were promising. Patients on the water protocol demonstrated a trajectory of improving hydration as measured over three weeks whilst those on thickened fluids only had hydration results that were deteriorating. Surprisingly, this positive result for hydration was in the context of the water protocol group drinking no more in total than those on thickened fluids only. The difference in hydration between the groups, whilst not significant, could indicate that even a small amount of water per day (as little as 300ml) assists the body's ability to better achieve fluid balance. Unfortunately, results from the survey suggest that water protocols are not widely implemented Australia-wide so patients may not be receiving the potential benefits.

Notably, even the hydration results of stroke patients in acute hospitals were better than those of the inpatients in this study who were residing in rehabilitation facilities (Crary, 2014; Crary, et al., 2013). Perhaps the longer a person is an inpatient, the greater the impact their stroke or the institutional factors have on their hydration and well-being. This raises concerns about current clinical practices with respect to monitoring hydration and whether preventative action is implemented in a timely enough manner. The survey indicated that hydration is most commonly monitored through clinical signs such as dry mouth, colour of the urine or headaches. Only 37% reported the use of blood tests and 28% the use of urine tests and only when a clinical need is identified. The high numbers of patients falling into the category of dehydration in these present studies suggests our current clinical practices for screening hydration are inadequate.

The last major area of enquiry in this thesis concerned the impact of fluid intake and hydration on patients' health status. According to the incidence study of acute hospital admissions in SA, stroke patients had a significantly higher incidence of dysphagia and aspiration pneumonia than patients admitted to hospital for reasons other than stroke. Unexpectedly, they had no greater incidence of dehydration, urinary tract infection (UTI) or constipation than the matched sample of non-stroke admissions. However, the sub-sample of stroke patients with dysphagia had significantly higher incidence of all of these diagnoses (aspiration pneumonia 18%, dehydration 11% and UTI 22%) compared with the total stroke admissions and the matched non-stroke admissions. Similarly, in the prospective studies of this thesis, patients in rehabilitation *with* dysphagia had significantly more adverse health events (43%) compared with those without dysphagia (16%). It was calculated that patients were four times more likely to be diagnosed with an adverse health event if they had dysphagia. Specifically, the patients with dysphagia had significantly more diagnoses of dehydration than patients without dysphagia (21% compared with 2% respectively). Notably there were no diagnoses of aspiration pneumonia for any of the stroke patients in rehabilitation in these present studies. Perhaps the implementation of a strict oral hygiene regime for all participants contributed to this positive outcome. Again, this research uniquely emphasises that all stroke patients are at risk of adverse health events related to fluid intake such as dehydration, constipation and UTIs, but that patients with dysphagia are at far greater risk. Patients with stroke but without dysphagia are at no higher risk of these adverse health events than the general hospitalised patient population.

As to whether a water protocol is beneficial to the health status of patients with dysphagia, the results of the present research were promising. Those in the water protocol group had fewer adverse health diagnoses than those on thickened fluids only, specifically UTIs. Again, a positive outcome was that none of the participants in the RCT were diagnosed with pneumonia. Although the study's sample size meant it was not powered adequately to detect a significant difference in the rate of pneumonia, the outcome of having no diagnoses of pneumonia bodes well for the safety of water protocols for comparable patients.

In summary, the water protocol did not make any significant difference to patients' fluid intake, hydration or adverse events compared with consuming thickened fluids only but the improving trajectory of their hydration and health status was promising. Importantly they did not have any increased incidence of aspiration pneumonia. It

seems reasonable to recommend that patients in inpatient rehabilitation, with similar demographic and stroke characteristics as the present sample, be trialled on a water protocol as a potential avenue for improving hydration and health status.

The findings of this research confirm that patients with dysphagia post-stroke are at higher risk of sub-optimal fluid intake, hydration and adverse health outcomes than their counterparts without dysphagia. The dysphagia itself rather than a dislike of thickened fluids appears to be the reason for poor intake. Factors such as older age, greater dependency as a result of the stroke, and restricted mobility also play a significant role in fluid intake and hydration. The latter factors also hold true for patients post-stroke without dysphagia. They too are at increased risk of sub-optimal intake and dehydration, not necessarily compared with other hospitalised individuals, but certainly compared with healthy adults living in the community. Future recommendations for hydration should therefore include all patients hospitalised post-stroke.

Limitations

The poor recruitment to the RCT was the major limitation in being able to draw conclusions from this research. Strict exclusion criteria, the nature of recovery of dysphagia post-stroke and reduced capacity at some hospitals to identify potential participants, meant inadequate numbers were recruited to power the study to demonstrate significant differences. The trend of improvement in hydration under the water protocol condition may have reached significance with a greater number of participants, and is, therefore, worth exploring further in a larger study.

Another limitation of the prospective studies in this thesis which may impact on interpretation of findings was the choice of outcome measures for fluid intake and hydration. With respect to hydration, a single biochemical measure with a designated cut-off threshold was used to classify participants as dehydrated or not. Whilst this same measure has been used previously in dysphagia research to investigate dehydration, it is recognised that the nature and diagnosis of dehydration is complex and perhaps use of a suite of indices would have been preferable. Similarly, measurement of fluid intake using fluid balance charts may have introduced a degree of inaccuracy to the results. Although instructed to measure intake as accurately as

possible, nursing staff may have occasionally estimated amounts consumed rather than exactly measuring fluid offered and residuals.

A further potential confounding factor for the outcome of fluid intake in the RCT was the use of tap water in the water protocol condition. Tap water in Adelaide, South Australia, whist meeting all water quality standards, has a slight chlorine taste. In hindsight, the use of filtered water may have been preferable to eliminate water taste as a confounder.

Lastly it is acknowledged that this research agenda did not consider the impact of fluid regimes (thickened fluids, water protocol or normal drinks) on the global nutritional status of patients post-stroke. A valid investigation of overall nutritional status, including hydration, would need to measure intake from all sources including food, not just beverages.

The next section of this chapter discusses recommendations for clinical practice with respect to fluid intake and hydration in a framework of the presented findings and the published literature.

Recommendations for Clinical Practice

From the present research, it has become clear that stroke patients, particularly those with dysphagia, are at risk of sub-optimal intake and dehydration and knowledge of clinical staff about these risks is limited. It is therefore recommended that changes to clinical practice be made in two domains: education of clinical staff about the importance of adequate fluid intake and the risks of dehydration; and the development of specific clinical pathways/guidelines for stroke patients with respect to hydration.

Education

Education could be provided to all clinical staff working in hospital settings, inpatient and ambulatory rehabilitation settings and residential care settings. It needs to be targeted at multiple disciplines, not just nurses, as all clinical staff should take responsibility for ensuring their patients drink sufficient amounts just as they are all responsible for managing falls risks and infection control. Approaches to education

could be through multiple modalities such as written information, face to face presentations, e-learning platforms such as Moodles or reminder posters such as "Have you offered your patient a drink?". Education could occur during Orientation for new staff and students and at regular time intervals as per Falls education. Furthermore, knowledge and competencies could be assessed through Moodles as is the case currently with emergency and life support training or fire and safety training.

Clinical Guidelines

Clinical practice guidelines are now a common feature of clinical practice and aim to facilitate more consistent, effective and efficient practice, and improve health outcomes. It is recommended that clinical guidelines be written for all patients post-stroke with respect to drinking and hydration. This would ensure that there are clear procedures that outline expectations of clinical staff as well as accountability. Clinical guidelines would need to be developed by an interdisciplinary team including the medical officers, dietitians, nursing staff, speech pathologists and occupational therapists. These guidelines could either be a stand-alone document with the decision to implement them made by individual institutions or incorporated into existing stroke guidelines after due process. The specific content of the guidelines is outside the scope of this thesis, but based on the literature and the findings of the present research should include components such as:

- risk assessment with recognition that older age, female sex, multiple health conditions, multiple medications, dysphagia, functional dependency and poor mobility put patients at higher risk of dehydration;
- routine screening of hydration at admission for all patients with acute stroke, with regular monitoring. The exact method of screening and frequency of review would need to be decided by the interdisciplinary team but may include clinical and biochemical measures;
- a calculation by the dietitian (or another trained staff member based on an accepted formula) of the amount of fluid required for every patient with a recognised risk of dehydration;

- a calculation by the dietitian of the amount of fluid required for every patient with dysphagia on thickened fluids;
- early implementation and evaluation of intervention strategies; and
- an individualised client care plan for patients at risk of dehydration and for all patients with dysphagia which includes specific strategies for improving intake and monitoring intake.

Strategies that may be incorporated into individualised care plans to improve fluid intake may include:

- regular offering of fluids at set times throughout the day with recording of this intake and assessment against target amounts throughout the day;
- implementation of a water protocol for patients with dysphagia prescribed thickened fluids in rehabilitation with in-built oral hygiene regime;
- provision of more fluid rich foods;
- greater accessibility to fluid through drink carts in therapy and communal areas; and
- assistance to open every package of pre-thickened drinks or pour from a jug.

The research findings also support the implementation of routine oral hygiene protocols as a way of reducing pneumonia risk for all stroke patients.

Recommendations for Policy

If hydration guidelines are established, evaluated and implemented widely, there may be policy implications for national guidelines and accreditation standards. National stroke guidelines may incorporate more detail about hydration in future publications. As a member on the Speech Pathology working party for the review of the 2010 Stroke Guidelines, I am in a position to ensure the issue of hydration is thoroughly considered. Health Care Accreditation standards may also incorporate key indicators around nutrition and hydration as has recently been the case regarding incidence of falls and medication safety.

Recommendations for Future Research

The following recommendations for research are based on the recognised limitations of this present research agenda and the potential benefits from expansion into other clinical arenas.

A large scale RCT (water protocol vs thickened fluids) with patients with thin fluid aspiration should be conducted with the following changes:

- This research has wide ranging implications for multiple disciplines so future research efforts need to be interdisciplinary at the planning, implementation and analysis phase.
- Research should be multi-site and conducted at larger institutions to ensure a bigger pool of potential participants. This would ensure a sample size sufficient to detect a clinically meaningful difference in hydration measures between groups.
- Recruitment should focus on patients in acute settings. These patients have been shown to be at highest risk for inadequate oral intake of thickened fluids and there are no published RCTs that have evaluated water protocols in acute settings.
- Participants should be recruited separately from specific clinical populations such as stroke or neurodegenerative diseases so that findings can be generalised with more confidence to other patients within each clinical population.
- The primary outcome measure should be hydration as this measure has demonstrated the most potential for change in the present RCT and is of greatest clinical relevance. Multiple biochemical and clinical indices should be used to measure hydration. As per the present RCT, there should be synchronous measurement of health outcomes of medically diagnosed dehydration. An interdisciplinary team should explore the possible physiological mechanism behind changes to hydration, so future care can be based on a firm theoretical basis.

- The water protocol group should have access to filtered water to control for the confounding variable of taste.
- If fluid intake is to be a primary or secondary outcome measured, fluid from food and beverages should be measured in order to consider total fluid intake and its relationship with hydration.

Results from this research agenda, previously published studies and expert opinion should be compiled and a set of guidelines for hydration be developed. Future research would need to be conducted to:

- establish validity and reliability of the guidelines and evaluate quality against international standards for guideline development (Brouwers et al., 2010);
- measure the success of implementation of clinical guidelines for hydration for stroke patients through measurement of patient outcomes. This could be done by a before and after intervention case-matched cohort study or a cluster randomised controlled trial; and
- determine barriers and facilitators to the uptake of clinical guidelines for hydration for stroke patients through translational research.

Concluding Remarks

As author of this thesis, I have enjoyed working with my patients and my colleagues in pursuit of practice improvements in stroke care. I believe this thesis has addressed many of the questions that arose from clinical practice and were posed in the introduction (Chapter 1). Specifically, the collective findings of this research highlight the need for clinicians to question any blanket prescription of thickened fluids as the default position for an individual they suspect has thin fluid aspiration. By highlighting the high prevalence of dehydration in the stroke population, particularly for individuals with dysphagia reliant on thickened fluids as their only source of beverages, this thesis obligates clinicians to consciously balance aspiration risk against risk of dehydration. Rather than prescribing thickened fluids with the sole intention of keeping patients safe from aspiration, they need to be mindful of the additional risk this recommendation may bring to other areas of patient's health. On a wider scale, hydration and health outcomes must be monitored and alternatives to improving hydration must be a high priority for the interdisciplinary team. Even patients without dysphagia post stroke, especially those who are older, more dependent and have poorer mobility, are at high risk of dehydration. Ultimately, it is hoped that the findings of this research will have an impact on health policy. To this end, publication of these studies is timely, as the National Stroke Foundation in Australia has just launched a comprehensive review of its stroke guidelines (L. Wright, personal communication, 20/08/2015).

Implementation of water protocols provides one promising alternative to improving hydration and other health outcomes. While previous studies of the effectiveness of water protocols have focussed on the outcome of fluid intake, this thesis, through its direct measurement of hydration, has uniquely demonstrated that even a small amount of water per day may positively influence hydration, despite no overall increase in total intake. This finding is particularly promising given that the trend is for hydration status to deteriorate the longer a patient is institutionalised, including for patients without dysphagia.

The revelation that patients do not dislike thickened fluids as much as previously thought should lead clinicians to modify their own perceptions and attitudes. It appears to be the dysphagia itself that precludes greater fluid intake; this is the issue where clinicians need to focus when determining management. As in all fields of clinical practice, in dysphagia management post-stroke we must think holistically and problem solve creatively. And, of course, we need to continue to collect evidence to guide our practice, a pursuit to which I am committed.

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Ethics committee	Study involved	Date of approval	Approval number
Royal Adelaide Hospital Research Ethics Committee	RCT and Cohort study	29 June 2009 Amendment approved 8 July 2011	090430 090430c
Southern Adelaide Health Service / Flinders University Human Research Ethics Committee	RCT and Cohort study	8 June 2010 Amendment approved 17 March 2011	73/10
Human Research Ethics Committee (TQEH/LMH/MH)	RCT and Cohort study	20 December 2010 Amendment approved July 2011	2011002
Royal Adelaide Hospital Research Ethics Committee	Retrospective audit	6 March 2012	090430c
Southern Adelaide Clinical Human Research Ethics Committee	Retrospective audit	15 March 2012	91.12
Human Research Ethics Committee (TQEH/LMH/MH)	Retrospective audit	12 April 2012	2011002
Social and Behavioural Research Ethics Committee Flinders University	Survey	21 September 2012	5767
SA Health Human Research Ethics Committee	Incidence study	7 November 2012	HREC/12/SAH/78

Appendix 1 Ethics Committee Approvals

International Journal of Speech-Language Pathology, 2013; Early Online: 1-9

informa

Intake of thickened liquids by hospitalized adults with dysphagia after stroke

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¹Faculty of Health Sciences, Flinders University, Adelaide, Australia, and ² Hampstead Rehabilitation Centre, Adelaide, Australia

Abstract

There is widespread concern that individuals with dysphagia as a result of stroke do not drink enough fluids when they are prescribed thickened liquid. This paper details a retrospective audit of thickened liquid consumption of 69 individuals with dysphagia following stroke in acute and rehabilitation hospitals in Adelaide, South Australia. Hospitalized individuals with dysphagia following stroke drank a mean of 781 ml (SD – 507 ml) of prescribed thickened liquids per day, significantly less in the acute setting (M – 519 ml, SD – 305 ml) than in the rehabilitation setting (M – 1274 ml, SD – 442 ml) (t(67) – 8.34, p < .001). This daily intake of thickened liquids was lower than recommended standards of fluid intake for hospitalized adults. Fluid intake could be increased with definitive protocols for the provision and monitoring of consumption of thickened liquids, by offering more fluid via food or free water protocols or by routine use of non-oral supplementary routes. Future research into the effectiveness of such recommendations needs to evaluate not only the impact on fluid intake but also on health outcomes.

Keywords: Deglutition disorders, fluid intake, thickened liquids, stroke, dehydration.

Introduction

Dysphagia, or difficulty swallowing, is a common consequence of stroke, with incidences reported to be between 37-78% of adults post-stroke (Martino, Foley, Bhogal, Diamant, Speechley, & Teasell, 2005). There is concern that individuals with dysphagia may be at risk of malnutrition and dehydration as a result of decreased food and fluid intake (Foley, Martin, Salter, & Teasell, 2009). Malnutrition and dehydration have an enormous impact on physical and cognitive function, recovery, and quality-of-life, with greater susceptibility to low blood pressure, falls, pressure ulcers, infection, and organ failure (Weinberg, Minaker, & American Medical Association Council on Scientific Affairs, 1995). Furthermore, dehydration has a known negative impact on hospitalization rates, length of stay, and ultimately on healthcare costs (American Medical Directors Association, 2001, Reviewed 2007). Following stroke, dehydration may affect the ischaemic penumbra, induce neurological deterioration, influence the evolution of the stroke itself (Britton, de Faire, & Helmers, 1980), and is strongly associated with an increased risk of venous thromboembolism (Kelly, Hunt, Lewis, Swaminathan, Moody, & Seed, 2004), and stroke mortality (Bhalla, Sankaralingam, Dundas, Swaminathan, & Wolfe, 2000).

Stroke is more prevalent in the elderly (National Centre for Monitoring Cardiovascular Disease, 2004) and they may be particularly vulnerable to the effects of dysphagia following stroke due to the agerelated changes to swallowing, termed presbyphagia (Logemann, Pauloski, Rademaker, & Kahrilas, 2002; Logemann, Pauloski, Rademaker, Colangelo, Kahrilas, & Smith, 2000; Robbins, Duke Bridges, & Taylor, 2006). Dysphagia also compounds the sensory and physiological changes experienced by people who are getting older, e.g., reduced perception of thirst, a lower percentage of total body water, and a reduced ability of the kidneys to concentrate urine (Bennett, 2000), increasing the risk for dehydration. In addition, some elderly people have a greater use of medications affecting water losses, particularly diuretics, sedatives, antipsychotics, tranquilizers, and nonsteroidal anti-inflammatory drugs (Lavizzo-Mourey, Johnson, & Stolley, 1988). External factors such as the environmental temperature, amount of physical activity, and even involuntary activity due to tremors and dystonias may also affect hydration status (Grandjean, 2005). For these reasons, the fluid requirements for each individual to maintain an adequate degree of hydration vary considerably.

Despite these concerns for the hydration status of the elderly, healthy and independent older

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Appendix 3 Published Paper

Journal of Evaluation in Clinical Practice



Journal of Evaluation in Clinical Practice ISSN 1365-2753

A survey of thickened fluid prescribing and monitoring practices of Australian health professionals

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Keywords

data collection, deglutition disorders, dehydration, drinking, fluid balance, thickened liquids

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Abstract

Rationale, aims and objectives This study aimed to describe (1) how thickened fluids are supplied to clients with dysphagia; (2) how clients' consumption of thickened fluids and hydration status is monitored; and (3) the impact of institutional factors on thickened fluid intake and hydration in Australian health care settings.

Methods Speech pathologists, dictitians and nurses working in Australian health care settings were asked to voluntarily participate in an online survey that was advertised through their respective professional associations. The questions required a self-report of their practice with respect to thickened fluids.

Results Few health care facilities (17%) monitored thickened fluid consumption routinely even though, in the opinion of 51% the respondents, clients on thickened fluids at their facility do not drink enough. Palatability of the thickened fluid products and patients' dependence on others for drinking were thought to have a major impact on fluid intake. Respondents also highlighted institutional factors such as inadequate assistance from staff and inconsistent systems for monitoring fluid intake and signs of dehydration. The most common way to address inadequate intake was for nurses to 'push fluids' (87%). Free water protocols were used only 14% of the time and setting small oral fluid targets throughout the day was the least common strategy (11%).

Conclusions There is a need for Australian health care facilities to educate all clinical staff about the risks of dehydration and develop clinical pathways for clients with dysphagia, which include routine monitoring of oral fluid consumption and dehydration and timely intervention.

Introduction

Hospitalized individuals with dysphagia (difficulty swallowing) are at greater risk of malnutrition and dehydration than those without dysphagia [1,2]. Speech pathologists commonly prescribe thickened fluids when patients present with dysphagia for thin liquids, with the aim of providing a safe oral form of fluid intake. However, there is widespread perception by dysphagia clinicians that patients do not consume enough when prescribed thickened fluids and the literature confirms that this is a valid concern for many clinical populations [3–6]. Furthermore, studies have demonstrated that hospitalized individuals with dysphagia are at high risk of dehydration [7,8].

Stroke guidelines specifically recommend the screening of nutrition and hydration for all patients hospitalized following

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stroke [9,10]. Screening for malnutrition is becoming more prevalent with 78% of all hospitals surveyed across Australia in 2008, indicating they implement nutritional screening processes [11]. However, screening for dehydration is less prevalent perhaps because of the complex nature of dehydration and the lack of a standard assessment protocols [12–14]. Given this lack of routine screening for dehydration in hospitals, even patients at known risk for dehydration could remain undiagnosed. Patients with dysphagia who are reliant on the oral intake of thickened fluids and food as their only source of hydration, that is, those whose diet is not supplemented by enteral feeding, may be particularly at risk of dehydration.

Previous opinion surveys around the issue of thickened fluid consumption have focused on the preparation of thickened fluids and internal patient factors for non-compliance [15–17]. To date,

Appendix 4 Published Paper

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Routledge Taylor & Francis Group

Original Research

A Descriptive Study of the Fluid Intake, Hydration, and Health Status of Rehabilitation Inpatients without Dysphagia Following Stroke

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Adequate hydration is important for all people, particularly when hospitalized with illness. Individuals with dysphagia following stroke are considered to be at risk of inadequate fluid intake and, therefore, debydration, but there is little information about the fluid intake or bydration of individuals without dysphagia poststroke. This cohort study measured the average beverage intake, calculated the urea/creatinine ratio as a measure of bydration, and documented specific health outcomes of 86 people without dysphagia poststroke who were inpatients in rehabilitation centers. Participants drank on average 1504 ml per day (SD 359 ml), which typically represented 67% of their estimated daily requirement. Approximately 44% of the participants in the sample were debydrated based on a blood urea nitrogen/creatinine ratio >20:1. Sixteen percent of participants were diagnosed with one or more of the health outcomes of debydration/bypernatremia,

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Appendix 5 Published Paper

Dysphagia (2016) 31:424-433 DOI 10.1007/s00455-016-9694-x

ORIGINAL ARTICLE

CrossMark

Does a Water Protocol Improve the Hydration and Health Status of Individuals with Thin Liquid Aspiration Following Stroke? A Randomized Controlled Trial

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Abstract The benefit of water protocols for individuals with thin liquid aspiration remains controversial, with mixed findings from a small number of randomized controlled trials (RCTs). This study aimed to contribute to the evidence of the effectiveness of water protocols with a particular emphasis on health outcomes, especially hydration. An RCT was conducted with patients with known thin liquid aspiration post stroke randomized to receiving thickened liquids only or a water protocol. For the 14 participants in rehabilitation facilities whose data proceeded to analysis, there was no difference in the total amount of beverages consumed between the water protocol group (mean = 1103 ml per day, SD = 215 ml) and the thickened liquids only group (mean = 1103 ml, SD = 247 ml). Participants in the water protocol group drank on average 299 ml (SD 274) of water but offset this by drinking less of the thickened liquids. Their hydration improved over time compared with participants in the thickened liquids only group, but differences between groups were not significant. Twenty-one percent of the total sample was diagnosed with dehydration, and no participants in either group were diagnosed with pneumonia. There were significantly more diagnoses of urinary tract infection in the thickened liquids only group compared to the water protocol group ($\chi^2 = 5.091$, p = 0.024), but no differences between groups with regard to diagnoses of dehydration ($\chi^2 = 0.884$, p = 0.347) or constipation ($\chi^2 = 0.117$, p = 0.733). The findings reinforce evidence about the relative safety of water protocols for patients in rehabilitation post stroke and provide impetus for future research into the potential benefits for hydration status and minimizing adverse health outcomes.

Keywords Drinking · Deglutition · Deglutition disorders · Stroke · Water · Water-electrolyte imbalance

Introduction

Dysphagia (swallowing difficulty) is a common consequence of stroke [1]. The oral and pharyngeal phases of swallowing are commonly affected, in particular with regard to oral control of liquids and timely initiation of the pharyngeal swallow response [2, 3]. Consequently, individuals with dysphagia as a result of stroke are more likely to aspirate thin liquids compared with thicker or more solid bolus consistencies [3–5]. The compensatory strategy of prescribing thickened liquids is, therefore, common practice when thin liquid aspiration is suspected [6]. The premise is that thickening a liquid makes it more cohesive and dense, reducing its flow rate. This enables many patients to better control the bolus intra-orally, thereby reducing aspiration risk before and during swallowing [7, 8].

There has been growing concern, however, about the blanket prescription of thickened liquids for a number of reasons: (i) not all who aspirate thin liquids will develop pneumonia, and prescription of modified diets can be unnecessarily restrictive [9, 10]; (ii) patients may not like drinking thickened liquids and are, therefore, frequently non-compliant [11-13]; (iii) there is a potential for increased aspiration risk of thickened liquids post-swallow

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Appendix 6 Audit Tool for Consumption of Thickened Fluids by Stroke Patients in SA Hospitals

Consumption of Thickened Fluids by sti	oke inpatie	nts					
	1						
Date of Audit							
Hospital							
Auditor's name							
Patient initials and MR no.							
Admission diagnosis of stroke (infarct,							
haemorrhage, subarachnoid haem) Y/N							
Diagnosis of dysphagia Y/N							
Prescribed thickend fluids at any point during							
admission Y/N							
Gender M/F							
Age in years							
Stroke severity (NIHSS score or Admission FIM)							
Thickened fluid consumption from FBC	Date	Date	Date	Date	Date	Date	Date
Amount in mls							
Supplementary non-oral feeding on same days as	Date	Date	Date	Date	Date	Date	Jate
V/N							

Appendix 7 Survey Questionnaire

Thickened fluid prescribing and monitoring practices by Australian speech pathologists

Thank you for agreeing to participate in this questionnaire. This is a multidisciplinary survey involving speech pathologists, dietitians and nursing staff. Your answers will help to give a snap-shot of current practice of the provision of thickened fluids and the monitoring of their consumption in acute and rehabilitation hospitals and residential facilities around Australia.

Because this survey is multi-disciplinary, some questions will be easier/harder for you to answer than others. If you are unsure of any answers, feel free to indicate "I don't know" and move on to the next question.

By all means, pass this link on to other health professionals in your workplace to complete the survey.

- What is your profession?
 Speech pathologist
 Enrolled nurse
 Registered nurse
 Dietitian
- 2. In which state or territory do you work?

Qld NSW ACT Vic Tas SA WA NT

- In which location do you work?
 Capital city
 Regional city
 Rural
 Remote
- 4. In which inpatient setting do you work? Acute hospital Rehabilitation centre Low level of care residential facility High level of care residential facility Other
- 5. Does your hospital/facility have thickened fluids available for dysphagic patients?

Yes

No

- 6. How does your hospital/facility supply thickened fluids to the patients? (select each answer that applies)
 Pre-packaged containers of commercially available thickened drinks (eg Flavour Creations, Resource)
 Hospital's food services prepare from thickening powder in bulk either in a jug or individual cups
 Drinks individually prepared with thickening powder by staff as required (one cup at a time)
 I don't know
 Other
- 7. Where are thickened fluids provided to the patient? (select each answer that applies)At bedsideIn the dining room

On mobile drink trolleys On individuals' meal trays In therapy areas Other I don't know

- 8. How often are thickened drinks delivered to patients throughout the day?
 Only once (ie 1x per day)
 Mealtimes only (ie 3x per day)
 Mealtimes and snack times (ie 6x per day)
 Available and accessible all day
 Anytime at patients' request
 I don't know
 Other
- 9. How much thickened fluid would be offered/ provided to each patient per day (ie in one 24 hour period)?
 1 litre
 1.2 to 1.4 litres
 1.5 to 1.7 litres
 1.8 to 2 litres
 Greater than 2 litres
 Calculated individually based on patient's clinical presentation and need
 I don't know
 Other
- 10. Does the treating clinical team monitor the consumption (intake) of thickened fluids by patients?

Yes, routinely for all patients on thickened fluids

Yes, but only when a clinical need is recognised (ie on a case by case basis) No

I don't know

- 11. How is thickened fluid consumption monitored by the treating clinical team? (select each answer that applies)
 Individual patient fluid balance charts (FBC)
 Other individual patient chart (food and fluid intake)
 Calculation from wastage (fluid not consumed)
 Sample auditing
 I don't know
 Other.....
- 12. In your opinion, do patients on thickened fluids at your hospital/facility drink an adequate amount? Yes, the majority do No, the majority don't Varies from patient to patient I don't know Other
- 13. In your opinion, what are the major barriers to a patient drinking an adequate amount of thickened fluids? (select each answer that applies)
 Patients don't like the taste
 Patients don't like the texture/feel in the mouth
 Not enough thickened fluid is provided/offered per day
 The patient's dysphagia itself
 Patient's intake isn't monitored closely enough
 I don't know
 Other
- 14. How is hydration monitored by the treating clinical team? (select each answer that applies)

Regular nursing observations of blood pressure, pulse, respiration rate, O_2 sats

Clinical signs eg dry mouth, skin turgor, headaches, colour of urine Urine analysis Biochemistry results from blood sample I don't know Other.....

15. What processes are put in place if thickened fluid intake/hydration is considered inadequate? (select each answer that applies) Request medical assessment Referral to Dietitian Supplementary non-oral hydration (i.e. sub-cutaneous fluids, IVT, NGT) Free Water Protocols implemented Additional thickened fluid ordered Alternative flavours of thickened fluids offered Additional food high in fluid content ordered Nursing staff asked to "push fluids" or "encourage fluids" Patient and family education provided as to the importance of drinking/hydration Family asked to supply naturally thick fluids eg apricot juice Smaller targets set for each part of the day with increased monitoring e.g. 300ml at lunchtime Patient upgraded to thin fluids with recognised and agreed risk I don't know Other.....

Appendix 8 Patient Data Form

Sex	Male/Female	
Age	in years	
CVA classification	Infarct/ICH/SAH	
	Cortical/Subcortical/Brainstem/Cerebellar	
	L/R/Bilateral	
Date of CVA	dd.mm.yy	
Stroke Co-morbidities	Mobility-bed bound incl cloud chair	
(Y/N)	Mobility-predominantly sitting	
	Mobility-exerting to mobilise (walk or w/c)	
	Independent for oral hygiene	
	Self feeding	
	Independently able to pour fluids	
	Independently able to drink from a cup	
	Aphasia	
	Apraxia of speech	
	Motor/Ideational apraxia	
	Dysarthria	
	Cognitive impairment	
Significant past medical	Previous CVA	
history (Y/N)	GORD	
	CCF	
	Renal impairment	
	Smoker	
Admission FIM		
Admission weight		

Appendix 9 Clinical Dysphagia Assessment

<u>Clinical Signs of Aspiration/Penetration Checklist</u>

Symptoms dur	ing OMA	Obse	rved			Unab	e to
		Yes		No		Assess	6
Impaired palatal	Impaired gag	Com how:	ment				
response	Palatal weakness or asymmetry						
Impaired or no s secretions	swallowing of						
Weak Voluntary	/ Cough						
Dysphonia	Wet						
during speech	Hoarse						
	Harsh						
	Breathy						
Tremulous							
Swallow Trials (Observed Y/N)		Food (solid semi-	bolus l or solid)	Thick flui (mildly/m	d bolus oderately)	Water	
		Yes	No	Yes	No	Yes	No
Impaired Swallow	Delayed swallow initiation						
	Abnormal or absent hyo-laryngeal elevation						
Pharyngeal response –	Effective Reflexive cough						
Cough	Throat clear						
	Weak Reflexive cough						
	Wet Reflexive cough						
	No cough but wet voice						
	No cough but wet breath sounds						

(Patient Sticker)

Incomplete bolus clearance from the oral cavity (oral residue).			
* Total no. of symptoms present			
† Dysphagia rating (NAD, mild, mod, severe)			
‡ Aspiration rating (NAD, mild, mod, severe)			

* Count total no. of "Yes" answers in the OMA section then <u>add</u> this number to the total number of "Yes" answers in <u>each</u> of the 2 or 3 swallow trial consistencies columns.

res answers in <u>each</u> of the 2 of 5 swanow that consistencies

† and *‡* see over for severity descriptors.

Severity Descriptors

Perry, A. & Skeat, J. (2004) AusTOMs for Speech Pathology

† Dysphagia Severity

Profound	Unable to manage own secretions (if tracheostomy is in situ, it is cuffed). Unable to safely manage any oral intake. Requires full alternative (e.g. PEG, NGT) nutrition.
Severe	Can sometimes manage own secretions with prompts (if cuffed tracheostomy is in situ, may be deflated). May sometimes safely take small practice amounts of modified consistencies. Requires mainly alternative or supplementary nutrition (e.g. PEG, NGT).
Moderate/Severe	Can manage own secretions safely and independently (if tracheostomy is in situ, it may be uncuffed). Safe on a limited range of consistencies, requires strategies and full supervision to manage oral intake. Some alternative/supplementary feeding (e.g. PEG, NGT).
Moderate	Can manage a diet of modified consistencies. Some supervision/strategies may be required. No alternative or supplementary feeding (e.g. PEG, NGT) required.
Mild	Can manage most consistencies, may require some restrictions in range of consistencies. Independent using strategies, with no supervision required. May eat/drink slowly.

‡ Aspiration Severity

Profound	Absent swallow. No or weak cough. Unable to manage secretions. Wet breathing.
Severe	Present but significantly delayed or abnormal hyo-laryngeal excursion. No cough or weak reflexive cough. Wet voice. Needing prompts to swallow secretions.
Moderate/Severe	Delayed or abnormal hyo-laryngeal excursion but managing own secretions safely. Always has wet voice after eating or drinking and requires full supervision for prompts to clear with cough or throat clear.
Moderate	Delayed hyo-laryngeal excursion. Occasional wet voice after eating or drinking. Requires occasional reminders to clear. Good reflexive cough.
Mild	Infrequent gurgliness mainly on thin fluids. Strong reflexive cough or throat clear spontaneously initiated.

Appendix 10 Timed Water Test

150ml Water Swallow Test

Hughes, T.A and Wiles, C.M (1996) Clinical measurement of swallowing in health and in neurogenic dysphagia. *Quarterly Journal of Medicine;* 89: 109-116

To measure

- Average volume per swallow V/S
- Average time per swallow T/S
- Swallowing capacity V/T

Methodology

Patient seated comfortably

Patients to hold the cup to their own mouth

Asked to drink a cup of water (150ml) as quickly as is comfortably possible

Observe patient from the side

Stopwatch started when water first touches the bottom lip

Count the number of swallows by observing movements of the thyroid cartilage

Stopwatch stopped when the larynx comes to rest for the last time (usually accompanied by other signs such as exhalation, phonation or opening of the mouth)

Note any coughing during or coughing, drooling or altered voice quality after the test

If the patient is unable to complete the test, calculate the volume swallowed from that left in the cup

Patient Data			
# Swallows	Time taken (secs)	Volume drunk (mls)	Coughing, drooling, altered voice (Y/N)
V/S	T/S	V/T	

V/S= total volume (mls)/# swallows

T/S=time (secs)/#swallows

V/T=total volume (mls)/total time taken (secs)

Normative	data						
Sex	Age	V/S	Range	T/S	Range	V/T	S/D
	19-34	37.5	25-50	1.2	1-1.3	31.9	9.5
Male	35-55	30	21.4-37.5	1.2	1-1.4	24.8	7.8
	56-73	23.2	20.8-30	1.3	1.2-1.4	18.7	5.2
	74+	20	15.7-25	1.5	1.3-1.8	14.6	5.9
	19-34	18.8	15-30	1.1	1-1.3	18.7	6.0
Female	35-55	16.7	13.6-21.4	1.3	1.1-1.7	13.6	4.8
	56-73	16.7	13.6-21.4	1.5	1.1-2.1	12.3	4.9
	74+	10.6	9.1-13	1.5	1.4-1.8	7.5	3.3

Appendix 11 Oral Health Assessment

Oral Health Assessment Tool (OHAT) for Dental Screening modified from Kayser-Jones et al. (1995) by Chalmers (2004)

Patient:		Completed by:		Date:	<u> </u>
Scores: The final unhealthy). While individually. Sym *If any category h	score is the sum of the cumulative sco ptoms that are und as a score of 1 or 2	scores from the eight categ ore is important in assessing erlined require immediate att please arrange for the patie	ories and can range from 0 (ver oral health, the score of each i ention. ent to be examined by a dentist	ry healthy item shou t.	y) to 16 (very uld be considered
Category	0 = healthy	1 = changes *	2 = unhealthy *		Category scores
Lips	Smooth, pink, moist	Dry, chapped, or <u>red at corners</u>	Swelling or lump, <u>white/red/ulcerated</u> bleeding/ulcerated at corners	l patch;	
Tongue	Normal, moist, roughness, pink	Patchy, fissured, red, coated	Patch that is <u>red and/or white, ulcerated</u>	d. swollen	
Gums and tissues	Pink, moist, smooth, no bleeding	Dry, shiny, rough, red, swollen, one <u>ulcer/sore spot under dentures</u>	Swollen, bleeding gums, ulcers, whi patches, generalized redness or ulcer dentures	<u>ite/red</u> rs under	
Saliva	Moist tissues, watery and free-flowing saliva	Dry, sticky tissues, little saliva present	Tissues parched and red, very little/n- present, saliva very thick	o saliva	
Natural teeth Yes/No	No decayed or broken teeth/roots	1-3 decayed or broken teeth/ roots or teeth very worn down	4 or more decayed or broken teeth/ro fewer than 4 teeth, or very worn dow	<u>oots</u> , or n teeth	
Dentures Yes/No	No broken areas or teeth, dentures regularly worn	1 broken area/ tooth or dentures only worn for 1-2 hrs daily, or loose dentures	More than 1 broken area/tooth denture missing or not worn, needs denture adhesive	<u>.</u>	
Oral cleanliness	Clean, no food particles or tartar in mouth or on dentures	Food particles/ tartar/ plaque in 1-2 areas of the mouth or on small area of dentures or bad breath	Food particles/tartar/plaque in most are mouth or on most of dentures or so halitosis (bad breath)	eas of the evere	
Dental pain	No behavioral, verbal, or physical signs of dental pain	Verbal &/or behavioral signs of pain such as <u>pulling at face,</u> <u>chewing lips</u> , not eating, aggression	Physical signs such as <u>facial swelling</u> , gum, broken teeth, large ulcers, and and/or behavioral signs such as pulling <u>chewing lips</u> , not eating, aggress	sinus on verbal o at face. sion	
Arrange for Patient or f Review this	r patient to be exam amily/guardian refu s patient's oral heal	nined by a dentist. Ises dental treatment. Ith again on (date):/_/	_		TOTAL SCORE: 16

Chalmers J, Johnson V, Tang JH, Titler MG. Evidence-based protocol: oral hygiene care for functionally dependent and cognitively impaired older adults. J Gerontol Nurz. 2004 Nov;30(11):5-12.

Appendix 12 VFSS Research Protocol

Stroke Patients who Aspirate Thin Liquids – a Comparison of Current and Emerging Practice

Modified Barium Swallow – Research Protocol

Patient ID Sti	cker:
Examiner:	
Rater:	
Date:	Day Of Study:
Preparation of	f Materials and Equipment
Metric teaspoo	on measures
Metric jug for	water
Flavour Creat	ions pre-thickened drinks; mildly thick 185ml and moderately thick
185ml	
Commercially	available pureed fruit
EZHD barium	sulphate
Empty EZHD	container to mix the water/barium solution
For all fluids (water, mildly thick, moderately thick): 185ml fluid: 3 level teaspoons
$+ \frac{1}{2}$ level teas	poon of EZHD
For smooth pu	reed: 10 level teaspoons pureed fruit: 2 level teaspoons of EZHD

Instructions to patient

Give the patient these instructions at the beginning of the study. Specific instructions for each bolus are on subsequent pages.

"You will be asked to drink and eat some food that contains barium so we can see what happens when you swallow. If you are having difficulty at any stage, feel free to cough or spit out what's in your mouth"

If the patient penetrates or aspirates on any one bolus, do not give a command to cough until he/she aspirates on 2/2 or 2/3 boluses.

Reliability

Each of the single bolus consistencies has 3 swallows to ensure reliable results. If the patients aspirates on the first bolus, please proceed to the second bolus. If aspirating on the second, cease assessment of this consistency and move on according to the protocol.

Analysis of Penetration or Aspiration

Use the ASPEN SCALE (Rosenbek et al, 1996) to rate each swallow ie what happens spontaneously when the patient swallows. Rate only the spontaneous swallow for the purposes of the research, not what happens after a command to cough.

Use of Strategies

Use of strategies, positions, manoeuvres is not formally part of the research protocol. If you wish to determine the effectiveness of swallow strategies and remediation techniques for various consistencies during the MBS, this should be done as an adjunct to the research protocol <u>after</u> the research protocol is completed in its entirety.

Outcome for study

Use flowchart on page 9 to determine whether the patient is to be included or excluded in the study based on their MBS and to which group they are to be allocated.

Water

i. Single swallow via normal cup x3

Instructions to patient: "Take your usual size mouthful and swallow when you're ready" Instructions to Radiographer: "Screen in real time"

	Swallow 1	Swallow 2	Swallow 3
Penetration/Aspiration 1			
Material does not enter airway			
PENETRATION (material falls into laryngeal	vestibule)		
Penetration/Aspiration 2			
Material remains above TVC Patient senses and expels it			
Penetration/Aspiration 3			
Material remains above TVC Patient does not sense it			
Penetration/Aspiration 4			
Material falls to TVC Patient senses and expels it			
Penetration/Aspiration 5			
Material falls to TVC Patient does not sense it			
ASPIRATION (material falls below TVC)			
Penetration/Aspiration 6			
Patient spontaneously expectorates material			
Penetration/Aspiration 7			
Patient tries to expel it but is unsuccessful			
Penetration/Aspiration 8			
Patient makes no attempt to expel it			

If patient <u>aspirates</u> on 2 out of 3 trials, proceed to mildly thick fluids (page 4). Omit consecutive swallow (page 3). If patient does <u>NOT aspirate</u> on 2 out of 3, proceed to consecutive swallows (page 3).

Water

ii. Consecutive Swallows via normal cup

Instructions to patient: "Take 3 or 4 mouthfuls like you do if you are thirsty" Instructions to Radiographer: "Screen in real time"

Swallow 1

Penetration/Aspiration 1

Material does not enter airway

PENETRATION (material falls into laryngeal vestibule)

Penetration/Aspiration 2

Material remains above TVC Patient senses and expels it

Penetration/Aspiration 3

Material remains above TVC Patient does not sense it

Penetration/Aspiration 4

Material falls to TVC Patient senses and expels it

Penetration/Aspiration 5

Material falls to TVC Patient does not sense it

ASPIRATION (material falls below TVC)

Penetration/Aspiration 6

Patient spontaneously expectorates material

Penetration/Aspiration 7

Patient tries to expel it but is unsuccessful

Penetration/Aspiration 8

Patient makes no attempt to expel it

If patient <u>aspirates</u>, proceed to mildly thick fluids (page 4). If patient does <u>NOT aspirate</u> water proceed to smooth pureed consistency (page 8). Omit trials with thick fluids (pages 4-7).

Mildly Thick Fluid

i. Single swallow of mildly thick fluid from normal cup x3

Instructions to patient: "Take your usual size mouthful and swallow when you're ready" Instructions to Radiographer: "Screen in real time"

	Swallow 1	Swallow 2	Swallow 3
Penetration/Aspiration 1			
Material does not enter airway			
PENETRATION (material falls into laryngeal	vestibule)		
Penetration/Aspiration 2			
Material remains above TVC Patient senses and expels it			
Penetration/Aspiration 3			
Material remains above TVC Patient does not sense it			
Penetration/Aspiration 4			
Material falls to TVC Patient senses and expels it			
Penetration/Aspiration 5			
Material falls to TVC Patient does not sense it			
ASPIRATION (material falls below TVC)			
Penetration/Aspiration 6			
Patient spontaneously expectorates material			
Penetration/Aspiration 7			
Patient tries to expel it but is unsuccessful			
Penetration/Aspiration 8			
Patient makes no attempt to expel it			

If patient <u>aspirates</u> on 2 out of 3 trials, proceed to moderately thick fluids (page 6). Omit consecutive swallow of mildly thick fluids (page 5). If patient does <u>NOT aspirate</u> on 2 out of 3, proceed to consecutive swallows of mildly thick fluids (page 5).

Mildly Thick Fluid

ii. Consecutive swallows via normal cup

Instructions to patient: "Take 3 or 4 mouthfuls like you do if you are thirsty" Instructions to Radiographer: "Screen in real time"

Swallow 1

Penetration/Aspiration 1

Material does not enter airway

PENETRATION (material falls into laryngeal vestibule)

Penetration/Aspiration 2

Material remains above TVC Patient senses and expels it

Penetration/Aspiration 3

Material remains above TVC Patient does not sense it

Penetration/Aspiration 4

Material falls to TVC Patient senses and expels it

Penetration/Aspiration 5

Material falls to TVC Patient does not sense it

ASPIRATION (material falls below TVC)

Penetration/Aspiration 6

Patient spontaneously expectorates material

Penetration/Aspiration 7

Patient tries to expel it but is unsuccessful

Penetration/Aspiration 8

Patient makes no attempt to expel it

If patient <u>aspirates</u>, proceed to moderately thick fluids (page 6) If patient does <u>NOT aspirate</u> mildly thick fluids proceed to smooth pureed consistency (page 8). Omit trials with moderately thick fluids (pages 6 and 7).

Moderately Thick Fluid

i. Single swallow of fully thick fluid from normal cup x3

Instructions to patient: "Take your usual size mouthful and swallow when you're ready" Instructions to Radiographer: "Screen in real time"

	Swallow 1	Swallow 2	Swallow 3
Penetration/Aspiration 1			
Material does not enter airway			
PENETRATION (material falls into laryngeal	vestibule)		
Penetration/Aspiration 2			
Material remains above TVC Patient senses and expels it			
Penetration/Aspiration 3			
Material remains above TVC Patient does not sense it			
Penetration/Aspiration 4			
Material falls to TVC Patient senses and expels it			
Penetration/Aspiration 5			
Material falls to TVC Patient does not sense it			
ASPIRATION (material falls below TVC)			
Penetration/Aspiration 6			
Patient spontaneously expectorates material			
Penetration/Aspiration 7			
Patient tries to expel it but is unsuccessful			
Penetration/Aspiration 8			
Patient makes no attempt to expel it			

If patient <u>aspirates</u> on 2 out of 3 trials, patient is EXCLUDED from the study. Proceed to smooth pureed (page 8) only if clinically relevant. If patient does <u>NOT aspirate</u> proceed to consecutive swallows of moderately thick fluids (page 7).

Moderately Thick Fluid

ii. Consecutive swallows from normal cup

Instructions to patient: "Take 3 or 4 mouthfuls like you do if you are thirsty" Instructions to Radiographer: "Screen in real time"

Swallow 1

Penetration/Aspiration 1

Material does not enter airway

PENETRATION (material falls into laryngeal vestibule)

Penetration/Aspiration 2

Material remains above TVC Patient senses and expels it

Penetration/Aspiration 3

Material remains above TVC Patient does not sense it

Penetration/Aspiration 4

Material falls to TVC Patient senses and expels it

Penetration/Aspiration 5

Material falls to TVC Patient does not sense it

ASPIRATION (material falls below TVC)

Penetration/Aspiration 6

Patient spontaneously expectorates material

Penetration/Aspiration 7

Patient tries to expel it but is unsuccessful

Penetration/Aspiration 8

Patient makes no attempt to expel it

If patient <u>aspirates</u>, patient is EXCLUDED from the study. Proceed to smooth pureed (page 8) only if clinically relevant. If patient does <u>NOT aspirate</u> moderately thick fluids proceed to smooth pureed (page 8).

Smooth Pureed

Dessert spoon of smooth pureed fruit x3			
Instructions to patient: "Take you usual sized Instructions to Radiographer: "Screen in real	l spoonful of this a time"	nd eat it"	
	Swallow 1	Swallow 2	Swallow 3
Penetration/Aspiration 1			
Material does not enter airway			
PENETRATION (material falls into laryngeal	vestibule)		
Penetration/Aspiration 2			
Material remains above TVC Patient senses and expels it			
Penetration/Aspiration 3			
Material remains above TVC Patient does not sense it			
Penetration/Aspiration 4			
Material falls to TVC Patient senses and expels it			
Penetration/Aspiration 5			
Material falls to TVC Patient does not sense it			
ASPIRATION (material falls below TVC)			
Penetration/Aspiration 6			
Patient spontaneously expectorates material			
Penetration/Aspiration 7			
Patient tries to expel it but is unsuccessful			
Penetration/Aspiration 8			
Patient makes no attempt to expel it			

If patient <u>aspirates</u>, patient is EXCLUDED from the study. Cease MBS. If patient does <u>NOT aspirate</u> this is also the end of the study. Proceed to Outcome (page 9).

OUTCOME (tick appropriate box)



Appendix 13 RAH Water Protocol

Royal Adelaide Hospital Water Protocol For Dysphagic Patients

The Speech Pathologist will assess each patient individually and make a recommendation about the consumption of water for those dysphagic patients who are assessed as aspirating thin fluids.

The patient may cough when they drink the water. This is the body's normal protective reflex. The patient should not be stopped from drinking more unless they are showing signs of distress.

We know that this patient is at risk of aspirating the water into the lungs but water itself is thought to be harmless and is quickly absorbed by the body if aspirated. However certain precautions need to be taken.

- When providing water to patients the following protocols should be observed:
 - ➤ Water is permitted any time between meals.
 - Water is <u>not</u> allowed at mealtime or with food as the food may be aspirated along with the water.
 - Water intake is unrestricted prior to a meal but is <u>not allowed</u> for 30 minutes <u>after</u> a meal. The period of time following the meal allows spontaneous swallows to clear any pooled residue.
 - Patients for whom compensations are recommended such as chin tuck, head turn should be encouraged to use these compensations while drinking water.
 - Medications are never given with water as these may be aspirated with the water. Tablets should be crushed or given whole in a spoonful of yogurt, jam or thickened liquid (depending on the Speech Pathologist's recommendations).

- Routine oral care should be provided to those patients who are unable to clean their own teeth and mouths so that pathogenic bacteria are less likely to contaminate secretions.
- Patients who are independent in teeth cleaning should be monitored to ensure their oral hygiene routine is adequate.

Royal Adelaide Hospital Speech Pathology Department 2005 Adapted from Frazier's Rehabilitation Center Water Protocol (K. Panther, 2003)

Appendix 14 Oral Hygiene Protocol

Oral Hygiene Protocol

A healthy mouth is vital to the patient with dysphagia. The inactivity of the mouth and tongue after a stroke can lead to a build up of bacteria in the saliva. A dry mouth (xerostomia) can also lead to bacteria build up. In addition to the effects of the stroke, many patients have pre-existing xerostomia and poor dentition.

A coated, overgrown tongue can result from inactivity of the mouth. If the patient's tongue is not constantly moving in their mouth having contact with their teeth or food, the papillae on the surface of the tongue can become overgrown. These papillae can harbour bacteria from the food debris and plaque which results in a yellow/browny coloured and odorous tongue.

Bacteria build-up can potentially lead to pathogenic saliva which, when mixed with food or fluid or normal secretions, can lead to pneumonia if aspirated.

To reduce the risk of complications, a good oral hygiene routine is required.

Many stroke patients will need assistance to maintain oral hygiene post-stroke for all sorts of reasons: fatigue, reduced activity of the mouth and tongue, poor oral sensation, tube feeding, poor sitting posture and balance, reduced dominant upper limb activity, reduced insight, medications causing dry mouth etc. (Langmore, et al., 1998).

General Principles

- Nurses should apply Universal Precautions when assisting with oral hygiene.
- In the context of "rehabilitative nursing" nurses should encourage the patient to attend to their own oral hygiene, but provide close monitoring and intervene and assist if necessary to ensure the task is thoroughly completed.
- Assess whether the patient is independent / needs partial assistance / needs full assistance.

Equipment

Gloves	Toothbrush (small head, soft bristles)
Safety glasses	Fluoride toothpaste for patients with teeth
Mask	Soap and water is adequate for dentures
Gauze	
Cotton swab	

Technique

Dentures

Remove dentures and rinse mouth after every meal.

Clean dentures after each meal with soap and toothbrush.

Avoid regular toothpaste as this is abrasive.

Remove all food and plaque from both surfaces of the denture

especially the surface that rests against the tissues.

Remove dentures nightly to allow gums to breathe.

Soak dentures in water or denture cleaning agent overnight.

For ingrained stains soak in ¹/₂ vinegar and ¹/₂ water solution.

Partial dentures with metal parts should only be soaked for 30 minutes.

Teeth

Rinse mouth after every meal to remove food residue.

Brush teeth morning and night.

Place toothbrush at 45 degree angle to the gums.

Gently brush teeth and gums in a circular motion.

Brush back and forth over chewing surfaces.

Work systematically around the mouth spending about

5 seconds on every tooth.

Standing behind the patient to brush their teeth may be easier.

Using another toothbrush to hold back the cheeks may be useful.

Tongue

Using a soft toothbrush scrape the coated area of the tongue.

Use a sideways or forward sweeping motion of the brush for 4 to 5 second.

If necessary tongue cleaning can be done in 2 or 3 stages to avoid eliciting the gag response.

General Mouth Hygiene

For unwell patients, do regular mouth toilets with warm damp gauze

or cotton swabs rubbed around the mouth's surfaces about 4 times a day.

An antibacterial rinse or gel can be used. The rinse can be put into labelled spray bottles and sprayed directly onto the teeth or soft tissues then these can be wiped over with damp gauze. Ensure all mouthwashes are ethanol or alcohol free.

Moisten the mouth / lips 4 times per day

Langmore SE, Terpenning MS, Schork A, Chen Y, Murray J, Lopatin D, Loesche W (1998) Predictors of aspiration pneumonia: How important is dysphagia? Dysphagia 13:69-81
Appendix 15 Example of Completed Fluid Balance Chart



Appendix 16 Medical Checklist

Dysphagia Research – Medical Checklist

1. Classification of stroke (circle the nature and location of the stroke)

Infarct	Left	Cortical
Intracerebral Haemorrhage	Right	Sub-cortical
Subarachnoid Haemorrhage	Bilateral	Brainstem
		Cerebellar

2. Chest Examination / Pneumonia (circle most appropriate)

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
Date							
	Clear						
Chest	Abnormal						
exam	but no infection	but no infection	but no infection	infection	but no infection	but no infection	infection
	Pneumonia suspected						
	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13
Date							
	Clear						
Chest	Abnormal						
exam	but no						
	infection						
	Pneumonia suspected						

	Day 14	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
Date								
	Clear							
Chest	Abnormal							
exam	but no							
	infection							
	Pneumonia							
	suspected							

3. Chest Xray

Date				
Chest	Clear	Clear	Clear	Clear
Xray	Abnormal but no pneumonia	Abnormal but no pneumonia	Abnormal but no pneumonia	Abnormal but no pneumonia
	Pneumonia Confirmed	Pneumonia Confirmed	Pneumonia Confirmed	Pneumonia Confirmed

4. Urea/Creatinine Ratio (circle most appropriate)

	Day 0	Day 7	Day 14	Day 21
Date				
Urea Value				
Creatinine Value				
Calculated Ratio				

Appendix 17 Patient Satisfaction Survey

SATISFACTION SURVEY

Date:

Name: _____

We want to know how you feel about the water you've been allowed to drink.

Please mark your response to these questions. Put a cross on the face that matches your feelings.

1. How much did you cough when you were drinking water?



2. If you coughed, did the coughing worry you?



3. How did you like the taste?



4. How did the water feel in your mouth?



5. Did the water quench your thirst?



6. Which drink did you prefer? Water \Box or Thickened drinks \Box

Appendix 18 Results of One Acute Patient

Age	80years
Hospital site	FMC
Stroke Type	Infarct
Stroke Location	Brainstem
Stroke Lateralisation	Left
Time post stroke	31days
Weight	83.4kg
Stroke co-morbidities	Not exerting to mobilize (bed-bound)
	Dysarthria
	Dependent for oral care
	Dependent for feeding
	Dependent for pouring drinks
	Dependent for drinking from a cup
Past medical history	Previous stroke
	GORD
Severity of dysphagia for thin fluids	Moderate
Severity of aspiration of thin fluids	Moderate
Diet	Minced and Moist
Fluids	Mildly thick
Oral health /25	Day 0=8, Day 7=6
Group allocation	Thickened fluids only
Average daily beverage intake	787ml
U/Cr ratio	Day 0=148.84, Day 7=141.18
Adverse events diagnosed	Pneumonia, Dehydration, Constipation, UTI