The Design and Evaluation of a Valid Dysphagia Screening Tool for Acute Stroke Patients

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Abstract

Screening acute stroke patients for dysphagia (difficulty swallowing) is recommended within 24 hours due to risks of morbidity and mortality. A review of the international literature identified no universal consensus for a valid method of screening. This thesis describes a multi-method Action Research (AR) programme of study focused on the design, development and evaluation of a reliable and valid dysphagia screening tool (the 'Head Dysphagia Screen for Stroke' or HeDSS) for use by Registered General Nurses (RGNs).

As a component of the assessment phase of the AR programme, a survey of dysphagia screening practices in England and Wales highlighted widely varied screening practices. Many of these practices were based on limited research evidence, reflecting the lack of consensus for valid dysphagia screening criteria reported in the literature. The design phase of the AR programme involved the development of the HeDSS tool, which centred on the use of research-based screening criteria. Focus group activity determined nurses' perceptions of the design and subsequent refinement of the HeDSS tool. The intervention and evaluation phases of the AR programme followed three empirical stages. Stage one established the inter-rater reliability of the Speech and Language Therapist Researcher's (SLTR's) clinical dysphagia assessment, which acted as a reference standard against which the validity of the HeDSS tool was to be measured. Clinical judgements for the presence and absence of dysphagia in the same 30 referred patients were compared between the SLTR and a Speech and Language Therapist (SLT) of equivalent experience. Inter-rater reliability was substantial (k = .71). The second empirical stage established inter-rater reliability of the HeDSS measurement outcomes (indicative signs of dysphagia and appropriateness of referral for SLT clinical dysphagia assessment) when employed by two RGNs compared against the SLTR when screening two samples of 20 acute stroke patients. Rater agreement was substantial (k = .71 and k = .79, for detection of signs of dysphagia and k = .79 and k = .87 for appropriateness of referral). The final empirical stage evaluated the concurrent validity of the HeDSS tool measurement outcomes when employed by a second sample of two RGNs compared with the SLTR's clinical dysphagia assessment outcomes in a sample of 100 acute stroke patients. The HeDSS tool measurement outcomes correlated highly with the clinical dysphagia assessment outcomes (sensitivity .88 - .96 and specificity .85 - .88 for detection of dysphagia; sensitivity

.90 - .96 and specificity .84 - .88 for determining patients appropriate for assessment). Correlation coefficient measures confirmed high concurrent validity for the HeDSS tool (Phi ranged between .76 - .82).

This study is the first in the UK to establish a reliable and valid dysphagia screening tool for use with acute stroke patients and has significantly advanced the professional knowledge base within this domain of practice. It is recommended that a multi-centred programme of research be undertaken to replicate this study with a larger nurse and patient sample.

Thesis Summary

Chapter 1 introduces the problem of dysphagia, its associated risks and issues around early identification and management. The lack of consensus for a valid dysphagia screening method is outlined and the potential for determining the validity of a combination of evidence based dysphagia screening criteria into a dysphagia screening tool is explained. The action research framework, which underpins the thesis, is also introduced.

Chapter 2 provides an overview of the salient literature related to normal and disordered swallowing. Dysphagia and its associated risks is described as well as its assessment and management. Screening for dysphagia is further explored and the lack of consensus for a valid dysphagia screening method is described. The need for measuring the concurrent validity of a combination of evidence based screening criteria within a focused dysphagia screening tool is argued.

Chapter 3 describes a survey undertaken to determine dysphagia screening practices within acute hospital Trusts across England and Wales. The variability in dysphagia screening practices and low frequency of use of evidence based dysphagia screening criteria as determined by the literature review is described. The specific research questions to be explored within the thesis are outlined.

Chapter 4 describes the design and planning phase of the research programme with a focus on methodological aspects of reliability and validity.

Chapter 5 outlines the ethical considerations necessary for undertaking the research including setbacks and compromises.

Chapter 6 describes the first stage of the empirical phase of the study; an inter-rater

reliability study which measured the reliability of the Speech and Language Therapist Researcher's (SLTR's) clinical dysphagia assessment to determine whether this was an appropriate reference standard against which to measure the validity of the prototype dysphagia screening tool (the Head Dysphagia Screen for Stroke shortened to 'HeDSS').

Chapter 7 describes the requisite design and evaluation of the HeDSS for use by registered nurses. The outcomes of two focus groups are reported, which were convened to examine the understanding and perceptions of a representative sample of RGNs towards the design and application of HeDSS.

Chapter 8 provides an overview of the design and development of the nurses' dysphagia screening education programme. This includes a description of the potential factors influencing nurse learning and skill acquisition and the specific theoretical and practical components of the education programme.

Chapter 9 describes the second phase of the empirical research process; determining the inter-rater reliability of the HeDSS when employed by a representative sample of registered nurses compared to its use by an expert (the SLTR).

Chapter 10 describes the final phase of the empirical research process; an evaluation of the validity of the HeDSS.

Chapter 11 reflects on the limitations of the study, the action research process underpinning the study, the contribution to new knowledge and the implications of the findings for clinical practice.

An organising framework of the research phases is provided below and is returned to in Chapter 4 where the design and planning of the research is explained in detail.

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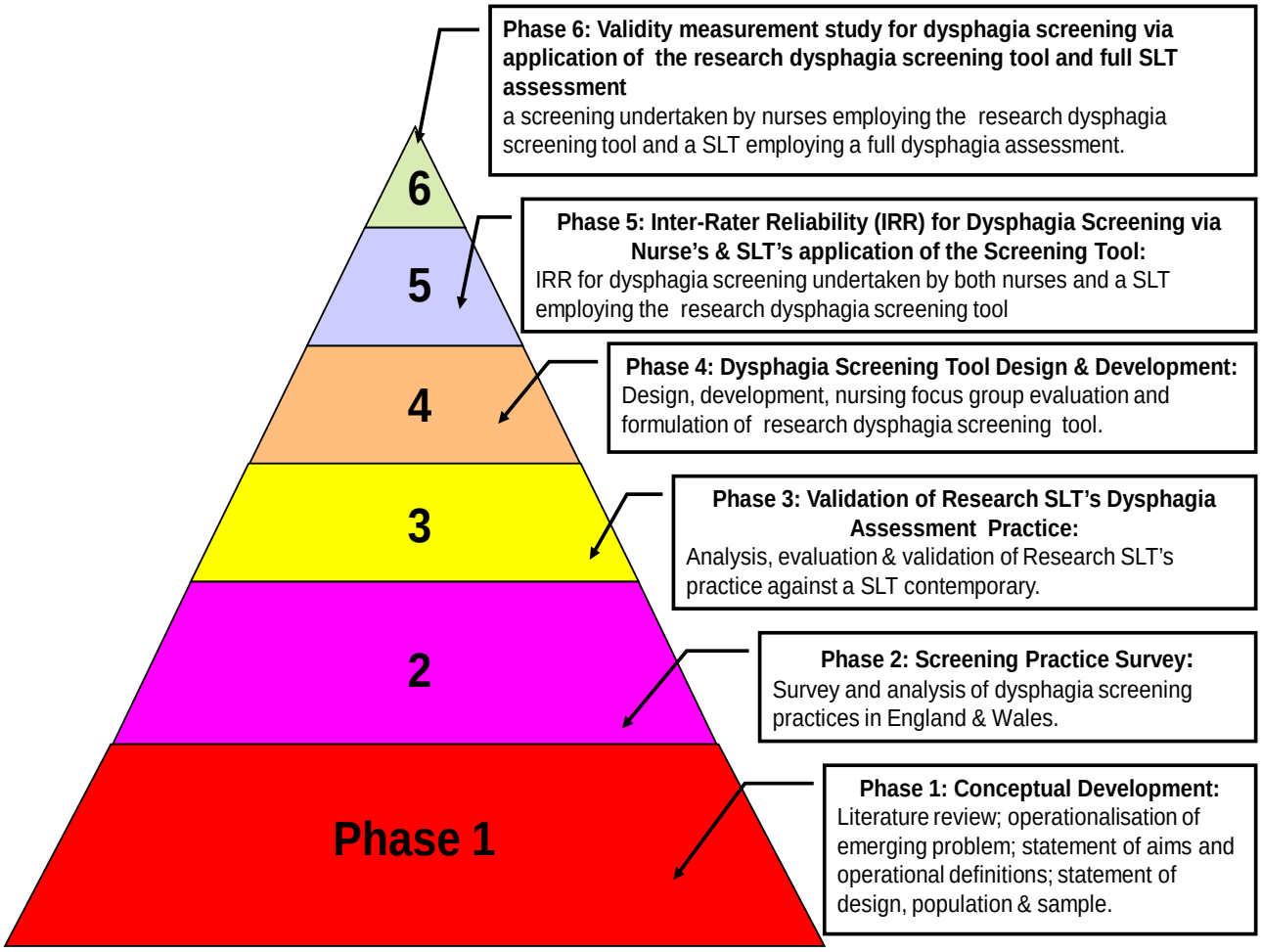


Figure (i) A model of the design phases of the Action Research process for the design and evaluation of a valid dysphagia screening tool

Glossary

ABBREVIATIONS USED IN THIS THESIS:

Asp = Aspiration

FEES = Fibreoptic Endoscopic Evaluation of Swallowing

HeDSS = Head Dysphagia Screen for Stroke

RGN = Registered General Nurse

RRR = Relative Risk Ratio

SLT = Speech and Language Therapist

SLTR = Speech and Language Therapist Researcher

Sw = Swallow

VF = Videofluoroscopy

ASSESSMENT OF RELIABILITY AND VALIDITY (based on Baumgartner *et al.* 2008 and Haynes *et al.* 2005).

Accuracy: The amount the test result reflects the true clinical state. If disease is present, a truly accurate test will always give a positive result, whilst if disease is not present, the test will always give a negative result. This is not the case for all tests.

Sensitivity: Sensitivity is the measure used to report how effective a test is in identifying individuals with a disease. The higher the sensitivity/the proportion of positive results the better.

Specificity: The measure used to report how effective a test is in identifying individuals without the disease. The higher the specificity/proportion of negative test results the better.

Likelihood Ratios: The likelihood that a given test result (e.g. signs of dysphagia present/absent) would be expected in a patient with the target disorder compared with the likelihood that the same result would be expected in a patient without the target disorder.

The likelihood ratio combines information about sensitivity and specificity and indicates how much a positive or negative result changes the likelihood that a patient would have the disease.

Positive predictive value: The proportion of patients with a positive test result who are correctly diagnosed.

Positive Test Result/Positive Outcome: A test result that reveals the presence of a specific disease or condition for which the test is being done.

Negative predictive value: The proportion of patients with a negative test result who are correctly diagnosed.

Negative Test Result/Negative outcome: A test result that fails to show the specific disease or condition for which the test is being done.

Relative Risk Ratio: This measure compares the likelihood of an event e.g. dysphagia, between two groups e.g. acute stroke patients with normal swallowing versus acute stroke patients with dysphagia. The ratio is calculated as the number of events e.g. dysphagia divided by the number of non events (e.g. no dysphagia). For example in a sample of 100, 51 patients are found to have dysphagia and 49 do not display signs of dysphagia, the ratio would be:

$$\frac{\textit{number of patients with dysphagia (51)}}{\textit{number of patients without dysphagia (49)}} = 1.04$$

If the odds of an event are greater than one the event is more likely to happen than not; if the odds are less than one the chances are that the event will not happen (the odds of an impossible event are zero).

Incidence: Incidence is the rate of new (or newly diagnosed) cases of a disease arising within a specified period (e.g. per month, per year). It is often reported as a fraction of the population at risk of developing the disease (e.g. in describing the incidence of stroke per 100,000 or per million population).

Predictive validity: The degree to which one measure can predict performance on a second measure e.g. a person coughing on water may be predictive of aspiration measured on videofluoroscopy.

Prevalence: Prevalence is the actual number of living cases with the disease either during a designated period of time or at a particular date (point) in time (point prevalence). The prevalence of a disease may be recorded as all new cases and all deaths between two dates or may only count cases that are alive on a particular date.

Reliability: Reliability is the degree of consistency of what a test measures i.e. the extent to which a test or any measuring procedure provides the same result on repeated trials. Within the study, reliability is concerned with the consistency of the measurement tool when employed by nurses compared against its use by the SLTR for determining the presence or absence of dysphagia and the appropriateness of referring acute stroke patients to the SLT.

Validity: The extent to which a test accurately measures what it is supposed to measure. Within the research programme, validity is concerned with the measurement tool's success at detecting the presence or absence of signs of dysphagia and the appropriateness of decisions to refer patients for full clinical dysphagia assessment when used by nurses in a given context with the acute stroke population as measured against the 'Gold standard (the SLTR's bedside assessment of swallowing) measure outcomes.

Chapter 1: Background

1.1. Statement of the problem

Dysphagia ('difficulty swallowing') is an associated outcome of neurological disorders with the highest prevalence attributed to stroke affecting up to 78% of stroke patients (Daniels *et al.* 1997, Mann *et al.* 1999, Martino *et al.* 2005). Early identification and management of dysphagia is an international concern due to consequences of aspiration pneumonia, morbidity, mortality and implied costs (Sitoh *et al.* 2000, Smith and Connolly 2003, Smithard *et al.* 2007).

Speech and Language Therapists (SLTs) have had responsibility within the multidisciplinary team for assessment and management of dysphagia since the mid eighties (Logemann 1983, Enderby and Petheram 2002). Currently, it is common practice for patients having a potential for dysphagia (e.g. following stroke) to be kept nil by mouth until assessed by a SLT (Ellul and Barer 1996). However, due to the typical level of SLT service provision, i.e. lack of availability during weekends, evenings and bank holidays, assessment can be delayed for up to six days; having clear implications for malnutrition and thus increased susceptibility to infection and medical complications. Aspiration (entry of food and drink into the lungs) with the possible consequence of pneumonia is an important acute complication of dysphagia, affecting between a third to a half of dysphagic patients (Nakagawa *et al.* 2000, Marik and Kaplan 2003, Ramsey *et al.* 2005).

Dysphagia screening of acute stroke patients is recommended within the first 24 hours of presentation (National Guidelines for Stroke 2004, 2008). This recommendation serves to identify acute stroke patients at risk for dysphagia and to initiate early referral for assessment, management or treatment for preventing adverse dysphagia symptoms and minimizing risks to health (Martino *et al.* 2005). Subsequently, given the typical early and unique contact nurses have with stroke patients, there is an increasing drive for nurses' engagement in dysphagia screening (National Guidelines for Stroke 2004, 2008). Dysphagia screening recommendations aim to improve quality of care amongst this group in two ways: preventing normally swallowing patients being placed 'nil orally' and

preventing dysphagic patients being fed inappropriately, thus incurring the risks of aspiration.

A review of the international professional literature has revealed a number of problems in these recommendations. Currently, due to limitations of contemporary dysphagia test validity, reliability and research study design, no consensus exists on the most predictive test for determining signs of dysphagia and its complications, i.e., no currently available individual test is highly accurate for detecting dysphagia in patients or for ruling it out (Martino *et al.* 2000, Perry 2001a, Ramsey *et al.* 2003). Several studies and systematic reviews have examined the predictive value of individual signs of dysphagia (Martino 2000, Mann *et al*. Hankey 2000, Ramsey *et al.* 2003) and have highlighted a need to evaluate the minimal combination of predictive factors for their ability to detect dysphagia. Until very recently, the potential of combining screening criteria with reported predictive validity into a focussed, non-invasive screening tool for determining the presence or absence of dysphagia and the appropriateness of referral for detailed swallowing assessment had not been explored. The current research study, reported in this thesis, contributes to existing world knowledge by exploring the conceptual basis, development and evaluation of a valid and focused dysphagia screening tool for use by registered nurses within the acute stroke patient population.

1.2. Professional background

I qualified as a registered nurse in 1989 and spent a short time working in an acute stroke unit where I witnessed the effects of dysphagia. These included a spectrum of sequalae, including the psychological and physical effects acute stroke patients suffered in relation to being denied food and drink, through to the effects of complications of dysphagia including aspiration pneumonia and reduced tissue viability. Over time, I became increasingly interested in developing my understanding and skills of how to identify and manage dysphagia and subsequently decided on a career in speech and language therapy.

After graduating as a speech and language therapist (SLT) in 1996, I eventually specialised in the field of dysphagia at a time that saw an increasing national drive for professionals in early contact with acute stroke patients i.e. nurses and doctors, to undertake dysphagia screening. The basis for this was to prevent prolonged and unnecessary nil by mouth status

in patients who had a normal swallow, whilst identifying and prioritising those patients who demonstrate signs of dysphagia and who therefore require full clinical dysphagia assessment by a SLT. I began training nurses in early identification and management of dysphagia but was unable to find a universal dysphagia screening tool or framework to incorporate into the dysphagia screening programme that I was aiming to develop. This was due to a lack of consensus of what screening criteria should be employed within a valid dysphagia screening tool for use by nurses.

Malnutrition is known to be highly prevalent in hospitals affecting up to 60% of inpatients (Elia 2003). One study indicates that around 15% of stroke patients admitted to hospital are malnourished but this increases to about 30% over the first week of hospitalisation (Kelly *et al*. 2000). Subsequently it is evident that steps taken to address the prevention of malnutrition and complications of dysphagia, which include aspiration pneumonia, dehydration, morbidity, mortality and implied costs, are critical (Smithard 1996, Sitoh *et al.* 2000, Smith *et al.* 2000, Smithard *et al.* 2007).

A screening tool should, according to its definition, be able to 'identify disease in an unsuspecting population, detect 'risk' when it is present; and produce negative results where the patient is not 'at risk' (Cochrane and Holland 1971). With this in mind, it was necessary to explore the current body of knowledge on predictive screening criteria. A critical evaluation of the literature around dysphagia screening highlighted that due to limitations of validity, there were no universally agreed dysphagia screening criteria or tools utilised nationally or internationally.

Several studies and systematic reviews have examined the predictive value of individual signs of dysphagia (Martino 2000, Martino *et al.* 2005, Perry 2001, Ramsey *et al.* 2003, Wu *et al*. 2004, Teasell and Kalra 2004). Although a number of valid tests have been identified, these studies and reviews highlighted a need to identify and evaluate the minimal combination of predictive factors for their ability to detect potential dysphagia and aspiration risk and ensure correct management of this patient group.

This study aimed to identify, develop and evaluate the validity of a minimum subset of criteria combined into a focussed bedside dysphagia screening tool designed for use by registered nurses to determine the presence/absence of signs of dysphagia in acute stroke patients and the appropriateness of their referral to SLTs for a clinical dysphagia

assessment.

1.3. Research framework

Undertaking research typically involves a process of systematic inquiry. An action research framework, which is guided by movement through four phases of inquiry, underpinned the research design. Stringer (2008) describes action research as a process of inquiry founded on a partnership between action researchers and participants, all of whom are involved in the change process. The specific research questions posed by the SLTR were anchored in her work as described on pages 2-3. The researcher is a clinician; it was therefore felt important that there should be a connection between the research and the practitioner, with the explicit intention that current practices would be informed or improved. Patton (2002) explains the value of action research further,

> "Action research explicitly and purposefully becomes part of the change process by engaging the people in the program or organisation in studying their own problems in order to solve those problems" (Patton, 2002, p. 221).

The personalised nature of action research allows the researcher to have an applied focus and work with stakeholders to address the research problem. Royer (2002) and Stringer (2008) suggest that action research is a cycle of continuous movement where the researcher identifies and defines the research problem, designs and plans the research, collects and analyses data, communicates outcomes and takes action. Based on reflection, new problems may be identified and new plans created so that the cycle begins anew. These phases are summarized in Figure 1 (page 5).

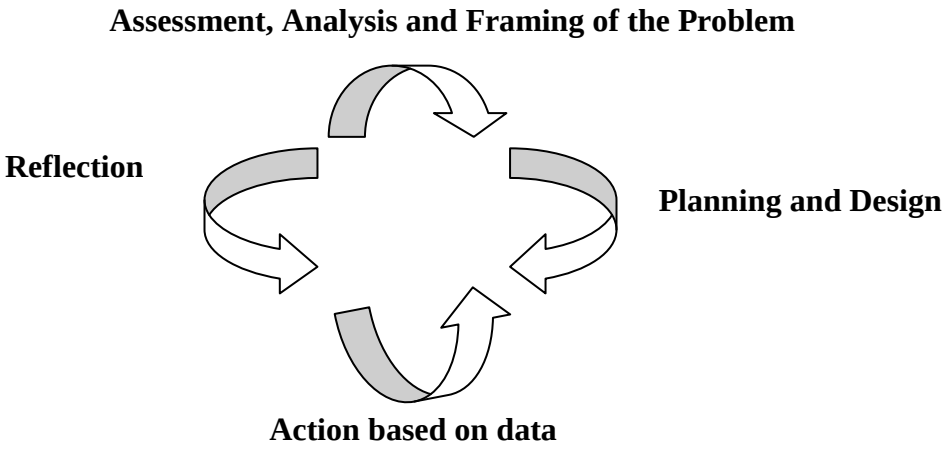


Figure 1: The Action Research Cycle (adapted from Stringer 2008).

1.3a. Phases of the Action Research Cycle

1. Assessment, analysis and framing of the problem

This is a conceptual phase and involves describing and framing the problem and determining the specific research questions which need to be investigated.

2. Planning and design

This phase involves the planning and design of the investigation. Here the method of carrying out the investigation is planned along with determining the specific information needed to answer the research question. Data are organised in a way that makes it useful to identify trends and themes. Further consideration is given to the necessary time allotted to implement the plan of action.

3. Action based on data

Having collected the data, the information from the data collection and review of the literature is used to design a plan of action that enables the research to make a change and to study its effects. These study effects are then reviewed to help answer the research question.

4. Reflection

Here the effects of the intervention are evaluated to determine if improvement has occurred, whether there have been design weaknesses and where improvement is evident, whether the data clearly provides the supporting evidence. A reflection on further actions to be undertaken is determined.

The phases of action research have provided a framework for the organisation of the thesis and are further described in the following chapters.

Chapter 2: Assessment, Analysis and Framing of the Research Problem

Literature Review

2.1 Background

As a starting point to describing and framing the research problem and determining the specific research questions to be investigated, it was necessary to review the current body of literature relating to evidence based dysphagia screening criteria, dysphagia assessment and areas related to this. The first stage of the literature review enabled identification of relevant themes and issues, clarification of other perspectives on the subject area and subsequent scoping of the problem. The literature review was also helpful for determining the stakeholder groups centrally involved or affected by dysphagia screening and issues related to this. The literature search was aided considerably by the use of computer search engines and databases. A summary of these searches and emerging themes is provided below.

2.2 Description of methods used to search, identify and extract evidence from the literature

The search strategies for undertaking a comprehensive literature review have included hand searches of published literature (primary sources). These have included Dysphagia Journal; peer reviewed nursing journals including Nurse Researcher, Clinical Effectiveness in Nursing, Journal of Neuroscience Nursing, American Journal of Nursing; peer reviewed medical journals including Stroke, Cerebrovascular Disease, Medicine Journal, Chest, BMJ, Lancet, Topics in Geriatric Rehabilitation and Respiratory Medicine. Searches have also included peer reviewed Speech and Language Therapy and dietetic journals including Journal of Speech, Language and Hearing Research, International Journal of Therapy and Rehabilitation, American Journal of Speech and Language Pathology, British Journal of Nutrition.

Searches of published data via secondary sources and searches of electronic databases included HOWIS, The Cochrane Database of Systemic Reviews, Cochrane Library (1991-

2008), MEDLINE (1986 through to 2008), ECRI International Health Technology Assessment (IHTA) Database (1990 through July 2007), Embase, Nursing and Allied Health (NAHL) (1988 through April 30, 1998) and Statistics online. The year range has covered 1986-2008. Internet searches of various websites include Department of Health, SIGN (Scottish Intercollegiate Guidelines Network), Royal College of Speech and Language Therapists, Royal College of Physicians, Department of Health, Office of National Statistics, British Nutrition Foundation and Dysphagia online.

Key word and combinations of key word searches included but were not limited to the following areas:

Diagnosis: 'Dysphagia assessment', screening, FEES, ''screening-tools' 'aspiration', 'Manometry', 'videofluoroscopy', 'and 'prevalence'. Searches were also undertaken using combinations of key words. These included dysphagia and stroke, acute and stroke, screening and dysphagia, epidemiology and stroke and aspiration/ pneumonia and stroke, tomography and CT Scans.

Disorder: Swallowing disorders, malnutrition, nutrition (exploded), 'deglutination (exploded), stroke (exploded) and focused, Parkinson's disease, dementia, Motor Neurone, Alzheimer disease; dementia; multiple sclerosis disease, ageing.

Epidemiology: epidemiology; research design; epidemiologic study characteristics; epidemiologic methods; epidemiologic studies; evaluation studies; incidence; prevalence; statistics and numbers; aspiration pneumonia; neurodegenerative diseases (exploded); dysphagia, swallowing disorders, Parkinson disease; silent aspiration; stroke.

Miscellaneous: weight loss; quality of life; QOL; satisfaction, length of hospital stay.

Treatment: speech therapy; speech-language pathology; nursing; management, rehabilitation, geriatric; national guidelines; speech and language; rehabilitation, patients; elderly care.

Other Methods

Other forms of information retrieval included reviews of bibliographies, reference books, research texts and reference lists from peer reviewed journals as well as literature from key government reports. Personal communication has also been made with a number of key

study authors as well as established experts in the field of dysphagia that include Dr Thomas Hughes, Dr Singh Hamdy, Dr Paula Leslie, Dr Rosemary Martino, Mary Heritage and Holly Froud.

2.3 Focus of the literature review

The focus of the literature search was on research-based papers i.e. original, peer reviewed studies relating to the validity, reliability, sensitivity and specificity of dysphagia screening criteria. Areas relating to dysphagia screening including the role of the speech and language therapist, nursing management of dysphagia were also combined and the themes developed as a whole. The criteria for considering papers for the thematic analysis were:

- Randomised controlled trails (RCTs), controlled trials, non RCTs, systematic reviews, literature reviews, quantitative and qualitative studies, policy documents, position papers and opinion papers;
- Foreign studies were accounted for in the literature search but for practical reasons were restricted to papers that were translated into English;
- The following professions were included in the analysis: Speech and Language Therapists/Speech pathologists, Nurses, Dieticians, Physicians, Radiologists, Diagnostic Radiographers, allied health professionals and the multidisciplinary team;
- Papers focussing on dysphagia, stroke, acute and chronic medical conditions such as Parkinson's disease, speech and language therapist as well as nurse roles in feeding and dysphagia management were considered.

A breakdown of search items used, numbers of relevant papers retrieved, total number of hits as well as the original language of the papers is provided in Table 1 (p 10).

Table 1: Literature search: A summary of databases and search items used to inform literature review

Database	Dates covered	Search items used	Hits	Relevant papers obtained and Language/country of origin
MEDLINE	1989-2008	Stroke (stroke, epidemiology, incidence, prevalence, outcomes, treatment, assessment)	453	147 (132 English, 6 Japan, 2 Singapore, 1 French, 1 Russian, 3 German, 1 Spain, 1 Brazil
MEDLINE	1989-2008	Speech and Language Therapy/Speech Pathology (role, dysphagia, assessment, swallowing)	140	68 (60 English, 2 Spain, 3 Japan, 1 Finnish, 1 French, 1 German)
MEDLINE	1989-2008	Dysphagia/Swallowing disorder/deglutination (Stroke, Parkinson's Disease, Dementia, normal, complications, assessment, screening, criteria, diagnosis, Motor Neurone Disease, Aged, videofluoroscopy, FEES, cervical auscultation, manometry, long term conditions, acute, chronic)	1466	127 (121 English, 2 German, 1 Portuguese, 3 Taiwan)
MEDLINE	1989-2008	Epidemiology of dysphagia, prevalence, incidence	8	3
CINAHL	1991-2008	Nurse+role+dysphagia	12	9 (8 English, 1 French)
OVID	1991-2008	Swallow/dysphagia+aspiration pneumonia	14	5 (4 English, 1 French)
		Stroke+ aspiration pneumonia	21	8 (7 English, 1 Spanish)
Cochrane Library	1999-2008	Dysphagia	14	4 (English)

Table 1: Literature search: A summary of databases and search items used to inform literature review (continued)

Database	Dates covered	Search items used	Hits	Relevant papers obtained and Language/country of origin
Cochrane Database	1999-2008	Stroke	153	4 (English)
MEDLINE	1989-2008	Dysphagia + Diagnostic Tests	24	2 ((English)
Embase	1999-2008	Epidemiology	4	1 (English)
OVID	1991-2008	Dysphagia +Definition	5	1 (English)
OVID	1991-2008	Videofluoroscopy	197	28 (25 x English, 2x German, 1 x Japan)
CINAHL	1991-2008	Nurses+Stroke+Dysphagia	20	12 (English)
MEDLINE	1989-2008	Dysphagia +Stroke	453	198 (English x 174, Spain x 7, Japan x 6, Poland x1, China x 2, Singapore x 6, Italy x 2)
MEDLINE	1989-2008	Dysphagia + Malnutrition, Dysphagia and Dehydration	210	18 (9x English, 2x Singapore, 1 Malaysia, 3x Finland, 2x French, 1 Czech)
OVID	1991-2008	Aspiration Pneumonia + swallowing Aspiration pneumonia + Stroke	35	14 (English)
OVID	1991-2008	Statistics + Medicine + diagnostic tests	355	13 (10 English, 1 China, 1 French)
		Totals	**3584**	**662**

2.3a A thematic analysis of the literature:

A robust methodology was used to undertake a thematic analysis of papers reviewed for the thesis. Papers reviewed were colour coded according to the topic areas. This allowed for a subsequent analysis of emerging themes. An overview of these themes is provided in Table 2 below:

Table 2: A thematic analysis of retrieved papers

Definition and analysis of the normal swallow and cough reflex
Definition, analysis and epidemiology of stroke / dysphagia / aspiration
Complications of dysphagia and aspiration
Signs and symptoms of dysphagia and predictive validity for detecting dysphagia
Definition and methods of assessing and measuring dysphagia and aspiration
Benefits and disadvantages of existing methods for assessing and screening for dysphagia and aspiration risk
Role of the SLT in dysphagia assessment
Role of nurses and members of multidisciplinary team involved in dysphagia identification and management
Nurses' knowledge of dysphagia, and the rationale and process for screening
Education programmes employed for teaching dysphagia assessment and screening
Videofluoroscopy as the gold standard
Lack of consensus for a valid dysphagia screening tool-arguments for the need of a valid dysphagia screening tool

After accounting for duplication of articles, reports and reviews, a total of 662 journal articles, systematic reviews, reports and documents were retrieved and considered relevant to the research topic. These themes were further explored and are detailed over page.

2.4. Introduction

In this chapter, normal swallowing, impaired swallowing (dysphagia) and its associated difficulties will be described along with assessment techniques and screening criteria reported in the literature as having predictive validity for detecting patients with suspected dysphagia and aspiration. Problems surrounding the lack of consensus for screening criteria will be discussed and key studies that support the need to redefine dysphagia screening outlined. The potential contribution of a valid screening tool for nurse use that places patients into one of three groups listed below will be argued:

- Those displaying signs of dysphagia requiring SLT assessment;
- Those inappropriate for SLT assessment e.g. due to poor levels of consciousness;
- Those not displaying signs of dysphagia, who may therefore resume normal diet and fluids.

The term dysphagia is used here to describe disorders, which may occur in the oral and/or pharyngeal phases of swallowing (definition taken from RCSLT Guidelines 2006). In order to understand dysphagia and its complications it will first be necessary to describe the process of normal swallowing.

2.5. Aetiology of normal swallowing

Eating and drinking are basic functions which most of us give little conscious thought to, yet the ease with which we perform these tasks belies their highly complex control.

The process of swallowing involves over 40-paired muscles (Rubin and Bradshaw 2000), all of which have specific functions. The oropharynx has a dual role as a conduit for air and for the safe passage of food and drink into the oesophagus. Only one of these actions can occur at a time thus for swallowing to take place, breathing has to be rapidly suspended then resumed within around 1 second (Marks and Rainbow 2001). A number of approaches are available to study swallowing including videofluoroscopy, a dynamic X-ray of the oral and pharyngeal phases of the swallow and nasendoscopy, which permits direct viewing of the pharyngeal phase of the swallow. All have enhanced the

understanding of swallowing anatomy and physiology and are used in clinical practice for objective swallow assessments. These will be dealt with in detail later (pages 42-47).

Swallowing makes use of a series of valves that change the shape and configuration of the system or protect it (Logemann *et al.* 2000, Paik 2002). Valves created by the lips and tongue keep food in the mouth and in place prior to swallowing. The valve created by the cricopharyngeus sphincter at the top of the oesophagus keeps air out of the digestive system during breathing. The soft palate acts as a valve through elevating to prevent food entering the nasal airway during swallowing. Finally, food and drink are prevented from entering the airway during swallowing by valves created by the false and true vocal folds and the epiglottis (Paik 2002). Despite its complexity, normal swallowing is a coordinated and smooth process that most of the population give little conscious thought to unless the intake of food or drink result in choking or coughing.

Four phases of the normal swallow are typically described (Logemann 1998, Logemann *et al.* 2000, Marks and Rainbow 2001). These are the oral preparatory and oral phase, which are under voluntary control and the pharyngeal and oesophageal phases, which are involuntary. A number of authors including Proekt and Weiss (2003), Cichero and Murdoch (2006) highlight an anticipatory or pre-oral stage, which provides the stimulation that entices us to eat. This is dependent on a number of factors including the degree of hunger or thirst of the individual, smell and sight of food, mood and societal demands.

2.5a. Oral preparatory phase

The oral preparatory phase refers to processing of the bolus to prepare it for swallowing. Hughes (2003) describes how each swallow is tailored to the size and consistency of the bolus through the sensory information obtained from the oral mucosa and the teeth along with fine control of the tongue, lips and musculature of the mouth and throat. Thus, information received from a large bolus will result in larger jaw opening, which quickly reduces as the bolus is manipulated and made smaller. The lips, tongue, jaw, palate and cheeks act in harmony with saliva to grind and manipulate the presented food into a soft ball (bolus) and position so that the subsequent phases of swallowing can take place safely and appropriately. Saliva production is essential for the preparation of food to enable swallowing. The water in saliva moistens and binds the food particles into a bolus that can

be easily swallowed. Additionally, saliva is important for the teeth and oral mucosa protection and acts as a buffer for maintaining oral pH (Marks and Rainbow 2001). The important role of saliva for chewing and swallowing has been demonstrated by the recent finding that the time spent chewing as preparation for swallowing significantly increases after experimentally induced oral dryness (Gaviao *et al.* 2004). This finding may have significant relevance to informing clinicians of the importance of ensuring oral hygiene and moistness prior to assessing the integrity of the swallow.

Chewing is necessary to breakdown the solid or semisolid food bolus into a consistency ready for swallowing. Hence teeth or adequately fitting dentures are an important factor for this to occur successfully. Adequate lip seal prevents loss of the bolus from the oral cavity and along with the actions of other 'valves' has a role to play in creating intra-oral pressure.

2.5b. Oral phase

The oral phase involves the propelling of the bolus from the oral cavity into the oropharynx. This begins when the tongue propels the bolus back to the pharynx by pushing against the hard palate. Normal movement of the anterior two thirds of the tongue is essential for carrying out the tasks of the oral stage of swallowing. Marks and Rainbow (2001) describe how lip and jaw closure, increased tone in the cheeks and anterior-lateral tongue seal against the alveolar ridge (behind the upper front teeth), lowers the pressure within the mouth to facilitate bolus transfer.

The posterior one third of the tongue, tongue base and upwards and forward movement of the larynx also plays an important role in the generation of forces that propel a food bolus posteriorly towards the pharynx. As the tongue base retracts, the posterior tongue and soft palate make contact. This action allows the nasal cavity to be sealed off from the oral cavity and helps generate negative pressure to direct the bolus posteriorly. Sequential contractions of the tongue and muscles of mastication are coordinated to enable mixing the food bolus with saliva and transfer backwards towards the pharynx, where the involuntary swallowing reflex is triggered (Hill *et al.* 2004).

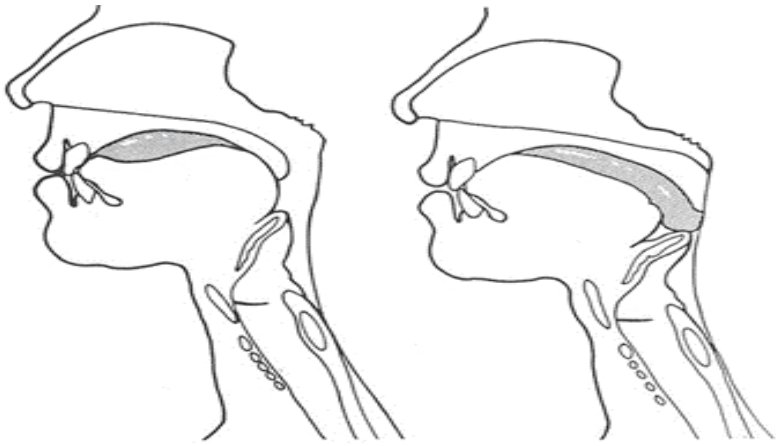


Figure 2: Oral phase of swallowing taken from Logemann (1998)

A number of studies have demonstrated that bolus volume significantly influences the timing and physiology of the normal swallows i.e. the swallow adjusts physiologically according to whether for example the swallow is a single sip from a cup or forms part of continuous drinking (Pelletier and Lawless 2003).

The average volume per swallow for adults is 20mls although there is a large degree of variability ranging from 15-30mls (Adnerhill *et al*. 1989). There are slight gender differences in that men's volumes are slightly bigger on average than women's are, although Pelletier and Lawless (2003) suggest that volumes swallowed by men and women are the same if they are matched for height and weight. Having knowledge of average volume per mouthful has important implications for screening for swallowing difficulties. It may be of little consequence if swallow performance is evaluated using minute volumes of fluid as this is not representative of the typical volume swallowed by the individual per swallow.

2.5c. Pharyngeal phase

During the involuntary pharyngeal and oesophageal phases, safeguard sequences of physiological reflexes are initiated to prevent aspiration i.e. inhalation of oropharyngeal or

gastric contents into the larynx and lower respiratory tract (Irwin 1999).

The pharyngeal phase has two specific functions, transport of the bolus from the mouth to the oesophagus and protection of the airway. Swallowing is considered to occur in a pre-programmed sequence in terms of the timing of average bolus transit and typical swallowing gestures (Marks and Rainbow 2001, Hill *et al.* 2004, Cichero and Murdoch 2006). These gestures are summarised as:

- Closure of the vocal folds, retroversion of the epiglottis and suspension of breathing in a specific sequence is a major mechanism for the prevention of aspiration (Medda *et al.* 2003);
- Contraction of the pharyngeal constrictor muscles in a superior to inferior direction;
- Elevation and tipping forward of the larynx and hyoid bone towards the base of tongue. Thus, the larynx acts as a valve, which in combination with closure of the vocal cords and folding backward of the epiglottis prevent food and drink being misdirected into the airway;
- The upwards and forwards movement of the larynx pulls open the relaxed cricopharyngeal sphincter. The resulting drop in pressure within the cricopharyngeal sphincter pulls the bolus from the tongue base into the lower pharynx and upper oesophagus.

Swallowing makes use of gravity to propel the bolus into the oesophagus hence an upright posture reduces the physiological load for swallowing whilst serving a dual purpose for reducing the risk of material being refluxed back into the pharynx after swallowing (Cichero and Murdoch 2006). The duration of the pharyngeal phase of swallowing is approximately one second although duration and sequencing of this phase does vary on an individual physiological basis (Kendall 2002) as well as with bolus volume and viscosity (Preiksaitis and Mills 1996). Pharyngeal transit time also increases slightly with advancing age (Logemann 1998, Leslie *et al*. 2005). This variability suggests there are multiple levels of input into the coordination of swallowing and must therefore again be factored in to the evaluation of swallowing integrity to prevent misinterpretation of this normal phenomenon for impairment of swallowing.

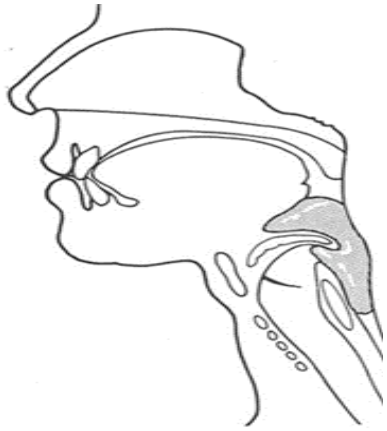


Figure 3: Pharyngeal phase of swallowing (taken from Logemann 1998).

2.5d. Oesophageal phase

Like the pharyngeal phase, the oesophageal phase of swallowing is under involuntary neuromuscular control. During this phase, the bolus is propelled downward by sequential wave like contractions known as peristaltic movement. However, propagation of the food bolus is significantly slower than in the pharynx with transit time decreasing to 3-4 cm/sec (Rubin and Bradshaw 2000). The oesophagus connects the pharynx to the stomach. Anatomically the oesophagus begins at the upper oesophageal sphincter (cricopharyngeal sphincter). The sphincter is tonically contracted and is pulled open by extrinsic musculature during upward and anterior movement of the larynx (Martin-Harris *et al.* 2004, Hill *et al.* 2004). A lower oesophageal sphincter relaxes at initiation of the swallow, and this relaxation persists until the food bolus has been propelled into the stomach. It closes after the bolus enters the stomach, thereby preventing gastroesophageal reflux (Paik and Han 2002). Bolus transit from the point of entering the upper oesophageal sphincter to reaching the stomach lasts between eight and 20 seconds (Logemann 1983).

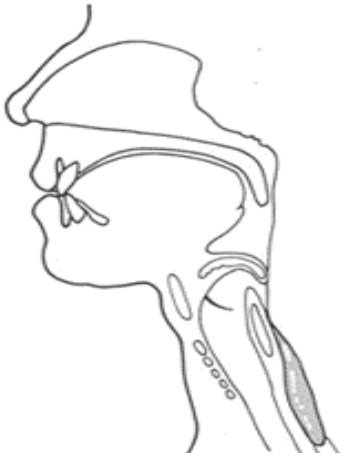


Figure 4: The Oesophageal phase of swallowing (taken from Logemann 1998)

Although this anatomical overview is useful, defining swallowing according to landmark anatomical features may give an inaccurate reflection of its moving, dynamic process. The physiological reality is that these phases are integrally related and overlap with variability between and within individuals (Jean 2001, Satow *et al*. 2004).

2.5e. Brainstem control of swallowing

Control of swallowing derives from swallowing centres within the brainstem. It has long been recognised that the body can sustain swallowing and respiration in the absence of cortical input (Mitchell and Berger 1975, Zheng *et al.* 1991). Several studies have illustrated the ability of animals that have had cerebral functions removed or severed to independently sustain functional swallowing behaviours and respiratory patterns (Mitchell and Berger 1975; Janczewski and Karczewski, 1990). The brainstem is responsible for the involuntary (pharyngeal and oesophageal) phases of swallowing. In recent years, two main theories have been postulated to explain neural control of swallowing. Control centres for both respiration and swallowing have been identified in animals and in humans using methods such as magnetic resonance imaging (MRI), tomography and transcranial magnetic stimulation (TMS). Dodds (1989) put forward the Reflex Chain Hypothesis, which describes how as the bolus moves through the oral and pharyngeal tract; sensory receptors are triggered sequentially allowing the next step in the swallow process to

proceed. Jean (1972, 1990) studied brainstem control of swallowing extensively. Jean (1972) noted swallowing could be elicited reflexively even when there are no connections from higher parts of the brain above the brainstem (e.g. due to surgical removal of the cerebral hemispheres in animals or in infants with anencephaly, where the cerebral hemispheres are congenitally absent). It was therefore assumed that all the necessary neural components for swallowing are present below the level of the midbrain and that sensory input from the surface of the palate, epiglottis, and tongue is sufficient to provide the activation necessary to elicit a swallow. Jean (1972) described a 'Central Pattern Generator' for swallowing which involves two groups of neurones. The first group located in the nucleus of the tractus solitarius and adjacent reticular formation receives sensory information from the periphery and a motor group in the reticular formation. Evidence was provided to support the concept of swallowing being a predetermined brain stem response, which can produce a swallow irrespective of feedback, received from sensory receptors. More recent thinking argues a blending of both hypotheses (Wheeler and Sapienza 2005) suggesting a predetermined swallow programme, which can be modified through sensory feedback in the oropharynx by factors such as the size and consistency of a bolus.

Of the twelve cranial nerves with points of origin within the brainstem, five have a key role in swallowing. An overview of their function and method of assessment of function is provided in Table 3 overpage (adapted from Cichero and Murdoch 2006).

Table 3: Cranial nerves-role in swallowing and methods for testing function (adapted from Cichero and Murdoch 2006).

#	Cranial Nerve	Area of Innervation and Function	Method of Testing Function
I	**Olfactory**	**Sensory**: Transmits the sense of smell	Test response to strong odour e.g. smelling salts (patient should not be able to see the stimulus)
V	**Trigeminal**	**Sensory**: Receives sensation from the face	Touch the face with patient's eyes closed-ask the patient to locate where he/she is being touched.
		Motor: Innervates muscles of mastication, located at the level of the pons. Contains both sensory and motor fibres that innervate the face	Ask the patient to clench his/her jaw and note response
VII	**Facial**	**Sensory:** Receives sense of taste from anterior 2/3 tongue. Important for sensation of oropharynx and posterior 2/3 of tongue	Use a small sample of four tastes bitter/salty/sweet/sour) solution applied to one side of the anterior two-thirds of the tongue using cotton bud saturated in the solution. With the tongue protruded, the patient should indicate from a choice of four which of the solutions they taste.
		Motor: Provides motor innervation to muscles of facial expression contains both sensory and motor fibres	To determine motor damage, ask the patient to smile/raise eyebrows-check for facial asymmetry
IX	**Glossopharyngeal**	**Sensory**: Receives sensation of taste from posterior 1/3 tongue. **Motor**: Provides motor innervation to stylopharyngeus (important for sense of touch, pain and thermal sensation). Contains both sensory and motor fibres. Important for taste to posterior tongue, sensory and motor functions of the pharynx	Assess the gag reflex by gently stroking the soft palate on each side.

Table 3: Cranial nerves-role in swallowing and methods for testing function -continued

#	Cranial Nerve	Area of Innervation and Function	Method of Testing Function
X	**Vagus**	**Sensory**: Receives sense of taste from epiglottis. Important for taste to oropharynx, sensation and for airway protection. **Motor**: Supplies motor innervation to soft palate, muscles of pharynx and larynx (important for vocalization and swallowing). Symptom of damage=dysphagia	Check palatal elevation by having the patient sustain an 'ah'. Check for asymmetry of movement. Swallowing can be assessed by giving the patient a sip of water and observing the swallow. Listen to the patient's speech is there a nasal or hoarse voice quality?
XI	**Spinal Accessory**	**Motor**: Controls muscles of the neck (trapezius and sternocleidomastoid) and overlaps with functions of the vagus. Examples of symptoms of damage: inability to shrug, weak head.	Observe for quickness of shoulder shrug or ability to shrug shoulders against resistance. Ask the patient to turn head to the opposite side against resistance.
XII	**Hypoglossal**	**Motor**: Innervates tongue muscles	Ask the patient to stick tongue out. Problem detected if the tongue is seen to deviate towards weak side

2.5f. Cortical control of swallowing

The cerebral cortex plays a significant role in the initiation of swallowing and along with sub cortical regions of the brain, is an important pathway in the voluntary swallow (Martin 2001; Mosier and Bereznaya 2001, Singh and Hamdy 2006). Mosier and Bereznaya's (2001) study provided compelling evidence for cortical control of swallowing. They identified specific regions that work in excitory and inhibitory loops to facilitate voluntary motor behaviours, sensory feedback of the bolus, motor planning, coordination and processing necessary for swallowing. Further studies using transcranial magnetic stimulation (Martin 2000 and Hamdy 1998) have demonstrated that oral muscles are represented symmetrically between the two cortical hemispheres, while muscles of the pharynx and oesophagus are represented bilaterally but asymmetrically, with most people having a dominant swallowing hemisphere (Hamdy 1999, Martin 2001, Satow *et al*. 2004).

Jean (1990) was one of the first to provide evidence that specific areas (the dorsal and ventral medullary regions) controlling swallowing are represented on both sides of the brainstem and are interconnected. Either side can coordinate the pharyngeal and oesophageal stages of swallowing, however because they are interconnected, normal motor and sensory functioning on each side of the larynx and pharynx depends both sides of the medulla being intact (Hamdy 1997). Jean's work has furthered thinking on swallowing function beyond original models that viewed swallowing as a reflex response evoked through receptors in the oral mucosa, larynx and pharynx. Swallowing is understood to be controlled both through motor input via brain stem responses and through sensory information received peripherally. These findings have enabled practitioners to better understand the changes in swallow function that accompany various neurological disorders such as Motor Neurone Disease and Parkinson's disease.

Hamdy *et al.* (1998) investigated stimulation of the brain using repetitive transcranial magnetic stimulation to measure its effects on swallowing recovery. Analysis of tomographic images revealed marked changes in the unaffected hemisphere in dysphagic patients implying that the brain is re-organising. It was evident within the study that swallowing recruits multiple cerebral regions and activation in the cortex was greater with frequency of swallowing i.e. greater activation if the subject swallowed every three seconds versus every 10 seconds. Further findings suggest different areas of the cerebral cortex are activated according to whether the swallow is volitional or reflexive.

Tomographic images show more brain involvement in the left cortex for reflexive swallowing (the involuntary pharyngeal and oesophageal phases) whilst increased activation is noted in the right cortical hemisphere with volitional swallowing (the voluntary oral phase of swallowing). Martin (2001) further found that swallowing water versus swallowing saliva is controlled by different sides of the cortex (left for water and right cortex for swallowing saliva). Activation was affected by the size of the bolus for water swallowing. This study and others (Hamdy 1998; 1999 and Satow 2004) have been influential in confirming the role of the cerebral cortex in the control of swallowing. The results of these studies have implications for rehabilitation in terms of expediting swallowing recovery, and for how swallow function is assessed or screened.

The studies have been limited by for example small sample sizes e.g. Hamdy (1999) evaluated these activation patterns during swallowing in only ten healthy volunteers. In addition, the changes reported, particularly the lateralisation associated with different swallowing tasks; remain to be fully understood in terms of their clinical relevance. The data showed a preponderance to the left hemisphere for water bolus swallowing, but this does not mean that at an individual level, following a right hemisphere stroke and natural compensation, that an individual can manage water swallowing safely. Despite limitations, the studies provide persuasive arguments against sensorimotor deprivation of swallowing, as may occur when people are placed nil by mouth in terms of overall swallowing recovery and the central nervous system's ability to react and reorganise.

In terms of application of the outcomes to the existing study, it is clear that assessing or screening swallow function according to the patient's ability to manage their saliva may be erroneous if this function is independent of the ability to swallow water. Similarly, determining swallow safety based on a sip or teaspoon of water, which is the starting point for many dysphagia screens, e.g. Staff Swallowing Assessment (SSA) devised by Ellul and Barer (1996) may not be adequate if the cerebral cortex requires a larger bolus to trigger a response. The limitations of existing dysphagia screens in terms of amounts trialled has been an important consideration in the current study. As noted previously, there is a need to tailor bolus trials to reflect an individual's typical swallowing volumes (page 16). Also, research relating to the effects of swallowing water on chest status has not found evidence for adverse health risks (Garon *et al*. 1997), which adds weight to trialling larger volumes of water than current screens permit.

2.6. Control of breathing around swallowing and the normal cough response

Swallowing and breathing share a common aerodigestive tract, entry of the food/liquid bolus into the airway is therefore a hazard. Breathing around swallowing needs to be controlled to prevent remnants of food and drink entering the airway after the pharyngeal phase of swallowing. Typical breathing patterns around swallowing have been described (Selley 1989, Hadjikoutis *et al.* 2000). Breathing is arrested during swallowing, and this arrest is preceded and followed by expiration in most cases. Respiratory distress or abnormal breathing patterns will increase the likelihood of significant aspiration even in the presence of normal swallow function (Hadjikoutis *et al.* 2000). The normal cough response is critical for expulsion of the bolus from the larynx and airway to prevent aspiration pneumonia (Smith and Wiles 1998, Marik and Kaplan 2003, Smith Hammond and Goldstein 2006). The vital protective mechanism is impacted on by various medical conditions such as Parkinson's Disease and Stroke as well as depressed conscious states e.g. drowsiness following a stroke, resulting in complete or partial suppression of the cough reflex (Smith and Wiles 1998, Nakajoh *et al*. 2000). The normal laryngeal cough response involves closing of the larynx, allowing the patient's external abdominal muscles to contract to generate forceful, clearing coughs. In addition, the reflex closing of the larynx during swallowing helps protect the patient from aspirating food or other foreign material into the respiratory airways.

Coughing, like swallowing, is unique as it can be induced voluntarily and reflexively due to higher cortical control (Canning 2006). Receptors located in the airways relays information via sensory feedback to the cough centre in the brain stem (Ludlow 2005). The 'cough centre' then sends information to airway smooth muscles and via spinal nerves to the expiratory muscles to produce coughs (Canning 2006).

Various reports within the literature have found an association between neurological diseases and dysphagia and hence the risk of aspiration (Smith and Wiles 1998; Marik and Kaplan 2003; Canning 2006). Other reports point to a correlation between the presence of pneumonia in the elderly and depression or loss of the cough reflex (Sekizawa 1990; Nakajoh *et al*. 2000, Smith *et al.* 2006). Clearly co-existing morbidities such as pulmonary or cardiovascular disease may complicate the clinical picture. A main reason put forward for the association between loss of the cough response and the development of pneumonia is desensitisation of the mucosa within the pharynx, larynx and/or trachea resulting in an

inability to clear substances from the upper airway or pharynx to prevent their entry into the lungs. Consequently, a number of studies have examined the efficacy of testing the reflex cough as a predictor of aspiration risk (Smith and Wiles 1998; Addington 1999, Nakajoh *et al.* 2000, Addington 2005).

Addington *et al*. (1999) assessed the laryngeal cough reflex in 400 acute patients and 204 patients admitted to a sister rehabilitation hospital within 30 days of their stroke. All patients underwent a reflex cough test (RCT) stimulated by a chemical irritant to assess for the laryngeal cough reflex, followed by a bedside swallowing evaluation and videofluoroscopy. Ten percent of the experiment group had a weak or absent cough response and significantly higher cases of pneumonia. The authors concluded that the presence of a normal laryngeal cough response is an important determinant of adequate airway protection (but not of dysphagia) and its absence or weakness should be seen as a warning sign for the development of pneumonia.

Although the study established the efficacy of using a test to evoke the laryngeal cough response for determining pneumonia risk, it is subject to a number of criticisms. The study was not blinded or randomized therefore confounding variables such as differences in stroke severity and the standard of care provided at the two centres used within the study were not accounted for. No mention of the procedure for the videofluoroscopy was made in the methods and other methodological procedures such as who determined pneumonia is not stated. As a result the outcomes of the study have to be viewed in the context of its design weaknesses.

2.7. The role of conscious levels and posture on swallowing safety

As noted previously, suspension of breathing and glottal closure is an important protective mechanism, which exists in normal swallowing to prevent aspiration. It has long been understood that altered levels of consciousness places the patient at risk for aspiration pneumonia and aspiration pneumonitis and has been identified as an independent predictor for aspiration (Adnet and Baud 1996, Smithard *et al.* 1996, Marik and Kaplan 2003). Depressed consciousness inhibits the cough, gag and swallow reflexes, which normally act to prevent oral bacteria, oropharyngeal and gastric contents entering the lungs (Vergis *et al*. 2001, Dziewas *et al.* 2004, Swaminathan 2008). Aspiration pneumonitis results from

chemical damage to the tracheobronchial tree due to inhalation of gastric contents. In a sample of 224 patients, Adnet and Baud (1996) demonstrated that the risk of aspiration increases with the degree of unconsciousness as measured by the Glasgow Coma Scale. Offering food and drink trials to a drowsy patient represents significant risks for the development of aspiration and airway blockage (Swaminathan 2008).

An upright sitting posture for feeding is an important consideration for the prevention of reflux of swallowed material and to reduce the risk of aspiration/entry of material into the airway. This is due to the effect of gravity on assisting the flow of the bolus through the pharynx and the role gravity has in retaining gastric contents in the stomach (Shaker and Lang 1994, Logemann 1997). Linden *et al.* (1993) identified recumbent posture as predictive for material being inhaled into the upper airway in 2/3 of their sample during videofluoroscopy. Clearly, it is an essential requirement to check for reduced conscious levels and assist the patient into an upright as possible posture before introducing trial boluses to at risk patients. These factors have been addressed in the design of the HeDSS which will be discussed in Chapter 4.

2.8 The normal, ageing swallow

Anatomical and physiological changes occur during the normal ageing process particularly with respect to reduced muscle strength and slowed swallowing (Leslie *et al.* 2005, Kim and Sapienza 2005). A full understanding of the normal ageing swallow is critical to differentiating normal function from dysphagia. Current literature suggests that swallowing slows in individuals over the age of 65 years (Logemann *et al.* 2000, Kendall *et al.* 2004, Leslie *et al*. 2005). Changes in timing of the co-ordination of breathing and swallowing have been reported, specifically relating to increased duration of swallow related apnoea occurring with increased bolus size (Hirst *et al.* 2002).

Leslie *et al*. (2005) suggests these changes may simply be a normal and effective compensation for the natural ageing process. A number of studies point to the increased prevalence of dysphagia amongst the elderly population (Kaplan *et al*. 2002, Thota and Richta 2003, Smithard *et al*. 2007). El Sohl *et al.* (2004) examined the indicators of recurrent hospitalisation for pneumonia in the elderly and found swallowing dysfunction to

be top of their list of hazardous variables, followed by smoking and use of tranquilisers.

Kendall *et al*. (2004) have argued however that studies reporting changes in swallowing function occurring as a consequence of age, are subject to criticism. In their review, many of the key studies failed to control for the presence and impact of diseases common in the elderly population such as arthritis and hypertension. Kendall and colleagues studied 63 elderly subjects with a variety of managed medical complaints and 23 elderly subjects with no medical problems using videofluoroscopy. The timing of the pharyngeal bolus transit was compared between the two groups. The relationship between the presence of medical problems and increased bolus transit times in 60 younger normal controls was also evaluated. Findings indicated (weakly) significant prolonged pharyngeal bolus transit times in the groups with medical problems for a small bolus size (1ml) although not for the larger boluses (20mls) which more closely reflect the typical mouthful of liquid. The authors suggest these differences may be due to decreased sensory awareness with a smaller bolus. Of importance in the findings, is that 64% of the subjects both with and without medical complications had pharyngeal transit times comparative to the young healthy control group. These studies have clear implications for assessing swallowing in the elderly. It is evident that knowledge of the normal ageing swallow is essential for the clinician to not misdiagnose normal swallowing events in the elderly as dysphagia. Indices for normal swallowing which includes average volume and average time per swallow, have been calculated for healthy adults accounting for age, sex and height (Nathadwarwala *et al.* 1992, Hughes and Wiles 1996). These have been addressed in the design of the HeDSS (see Chapter 4).

2.9. Dysphagia-a definition

Dysphagia has Greek origins and literally means difficulty (dys) eating (phagia) (Oxford Dictionary of English 2005). It is a collection of signs and symptoms or consequences of an underpinning pathological condition and is characterized by difficulty in the oral preparation for the swallow and/ or moving material from the mouth to the stomach. Subsumed in this definition are problems in positioning food in the mouth and in the oral manipulation preceding the swallow, including mastication (RCSLT 2006). In recent years, a number of authors have broadened the definition of dysphagia to include

behavioural, sensory and motor aspects of swallowing as well as cognitive awareness and visual recognition of food (Leopold and Kagel 1996, Cichero and Murdoch 2006).

Despite these broader definitions, there continues to be considerable variation and thus confusion in the literature as to what constitutes dysphagia many papers using the terms aspiration (which relates to material entering the airway below the level of the vocal cords (Lim *et al*. 2001) and dysphagia interchangeably. Dysphagia is now recognised as a symptom of disease and is coded under 'symptoms and signs' in the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) which is a coding system for diseases and their signs, symptoms, complaints, social circumstances and contributory causes of injury or diseases, as classified by the World Health Organization (WHO).

Aspiration is therefore a consequence of dysphagia and not its diagnostic marker. Shifrin and Choplin (1996) suggest that as many as 45% of the normal population aspirate oral secretions and gastric contents during sleep and anaesthesia without incurring harm. Therefore, it is clearly erroneous to consider aspiration and dysphagia as synonymous.

2.10 Epidemiology of dysphagia

Dysphagia as an area of research has developed exponentially since the mid eighties when the first textbook on dysphagia titled 'Evaluation and Treatment of Swallowing Disorders' (Logemann 1983) was published. In recent years the World Health Organisation (WHO) has recognised dysphagia as a disability, which has contributed to raising its profile. Studies of prevalence of dysphagia vary according to the techniques used for measurement. An American study carried out by the AHCPR (1999) estimated that approximately 300,000 to 600,000 people each year are affected by dysphagia from neurological disorders. With the exception of 51,000 of these new cases, all were due to strokes. In the UK, Department of Health figures for 2006-2007 record almost 26,000 patients received a primary diagnosis of dysphagia (DoH 2008). This figure is likely to greatly under-represent the true incidence of dysphagia in the acute hospital as dysphagia is more typically recorded as the outcome of disease such as Stroke or Parkinson's disease rather than a standalone primary diagnosis.

Prevalence and incidence of dysphagia is calculated from data describing a broad range of diseases and conditions. These include acquired neurological conditions such as Stroke, Parkinson's disease and Motor Neurone Disease, structural abnormalities, or neuromuscular impairment of the oral cavity, pharynx, larynx, and oesophagus (Murray, Carrau and Eibling, 1999). Many of these conditions occur in the ageing population. The exact prevalence and consequences of dysphagia are yet to be established due to the differing methodology and selection criteria used (Smith and Connolly 2003). Prevalence amongst stroke patients vary from 37% if using screening techniques to almost 78% when using instrumental assessment (Dziewas *et al.* 2004, Martino *et al*. 2005). As noted, dysphagia and aspiration are variously described as the same. This gives a nebulous picture of the true degree of prevalence. A recent survey undertaken by the Standing Liaison Committee of E.U Speech and Language Therapists and Logopedists (CPLOL 2005) indicates as many as 33% of patients in acute care, 66% of patients in long term care and 30% of stroke patients may be dysphagic (CPLOL 2005).

Increased life expectancy and an increase in the aged population have resulted in greater numbers of people at risk of age related illness such as Parkinson's disease, Multiple Sclerosis and Stroke (Leslie 2005; Kubo *et al.* 2005) all of which may cause dysphagia. Decline in saliva production is common in the elderly, which can result in Xerostomia (dry mouth) and subsequently contributes to dysphagia. Between 15% (Wright, 2002) and 33% (Stevenson, 2002) of patients in nursing homes have trouble swallowing medication.

Other studies have examined the effects of ageing on swallowing (Leslie 2005, Loeb *et al.* 2003) and overwhelmingly find that the elderly swallow more slowly than younger people do without necessarily compromising the safety of the swallow. However, these changes may be mis-attributed to impaired swallowing (Leslie 2005).

2.11. Disorders causing dysphagia- Neurogenic dysphagia

Dysphagia develops in almost all patients with degenerative diseases of the central nervous system (Dray *et al.* 1998, Marik and Kaplan 2003). Neurogenic dysphagia is a term that describes a pattern of dysphagia that affects the sensory and motor aspects of swallowing involving oral and pharyngeal phases (Huckabee and Pelletier 1998). Neurological disorders such as Stroke, Parkinson's disease and Myasthenia Gravis can cause weakness

of facial and lip muscles that are involved in coordinated chewing and swallowing. Decreased saliva flow can lead to a dry mouth and to difficulty forming, processing and swallowing the food bolus. In patients with dementia, Motor Neurone Disease and Parkinson's disease, dysphagia usually occurs early in the course of the disease, and the severity of dysphagia does not necessarily relate to the overall severity of the neurological disease (Marik and Kaplan 2003). In other conditions such as Multiple Sclerosis, dysphagia is more common in the later stages of the disease. This and other main conditions associated with acquired neurological dysphagia are described below.

2.11a. Multiple Sclerosis

Dysphagia is common in patients with Multiple Sclerosis (MS) although not a common complaint in the early stages of the disease. A survey carried out by Marchese-Ragona *et al*. (2006) suggests approximately one third of MS patients (particularly those with brainstem involvement) have swallowing difficulties. In their survey, many of the patients were asymptomatic and subsequently the patients infrequently reported dysphagia. They also noted that the incidence of dysphagia increased to up to 50% in the later stages of the disease largely due to a disturbance in the sequencing of the pharyngeal phase of swallowing and progressive weakening of the muscles in this area.

2.11b. Muscular Dystrophy

Muscular dystrophy is the name for a group of inherited disorders in which strength and muscle bulk gradually decline. There are nine types of Muscular Dystrophy generally recognised (http://www.healthline.com). More than 60% of patients may have dysphagia, which usually follows a progressive pattern (Langmore *et al.* 1998). Bolus transit times are longer, and the onset of some swallow gestures is delayed. Abnormal swallowing in Muscular Dystrophy can be due to reduced tongue control; delayed swallow trigger and possible velopharyngeal reflux (Leonard *et al.* 2001).

2.11c. Motor Neurone Disease

Dysphagia is a common feature of Motor Neurone Disease (MND) and is prevalent in up to 70-90% of sufferers (Skelton 1996, Wagner-Sonntag *et al.* 2000). Hughes (2003) describes how the exact mechanism of dysfunction varies between individuals. In pure upper motor neurone syndromes, typical early swallowing problems are encountered with bolus control. As the disease progresses, crude swallowing of soft or pureed diet may be possible however due to preservation of the cough response. Lower motor neurone syndromes on the other hand, cause more muscle weakness of the tongue, pharyngeal and laryngeal muscles which predisposes the patient to pooling and aspiration of swallowed material.

2.11d. Parkinson's disease

Dysphagia is usually a late feature in Parkinson's disease but is sometimes reported by patients in the early stages and may even be the presenting symptom in some cases. Dysphagia occurs in between 50-70% of patients but as a rule, this is mild and has little or no effect on the patient's nutritional status (Park and O'Neill 1994, Langmore 1998). Tremor and speech disturbances have been found to be the main predictors of dysphagia in these patients. (Groher 1997, Bakheit 2001). The swallowing difficulties most frequently associated with Parkinson's disease relate to the oral phase (difficulties with lip closure and tongue movements) and the pharyngeal stage (complaints of food sticking in the throat). On videofluoroscopy these abnormalities are seen as abnormal bolus formation, multiple tongue elevations, delayed swallow reflex, and prolongation of the pharyngeal transit time with repetitive swallows to clear the throat (Dray *et al.* 1998, Bakheit 2001).

2.11e. Dementia

Dementia affects over 750,000 people in the UK (Alzheimer's Society, 2004); Alzheimer Disease being the leading cause of dementia. Oral and pharyngeal swallowing abnormalities, including delayed swallow trigger, poor oral preparation and aspiration, are more prevalent in patients with Alzheimer Disease than in the healthy elderly population (Feinberg *et al.* 1992, Horner *et al.* 1994). In a study of 131 institutionalised elderly patients with advanced dementia, which utilised videofluoroscopy imaging, major aspiration of contrast medium was present in 24% and minor aspiration in 50% of patients

(Feinberg *et al.* 1992).

Difficulties presented around eating and drinking are often complex and will include feeding, positioning, behavioural and psychological problems (Steele *et al.* 1997). Global cognitive deterioration contributes to the loss of independence with eating something that Langmore (1998, 2002) has highlighted as an independent predictor for the development of aspiration pneumonia. Dysphagia and aspiration pneumonia are subsequently common in late-stage Alzheimer Disease; and is a common cause of death in end-stage Alzheimer disease due to a spectrum of difficulties, which include poor nutrition, dysphagia, and depressed host immune response (Kalia 2003).

2.11f. Stroke/Cerebral vascular accident

WHO define stroke as;

> '*rapidly developing clinical signs of focal disturbances of cerebral function, lasting more than 24 hours or leading to death with no apparent nonvascular cause* (WHO 1989 p105).

Stroke is often cited in the literature as the most common cause of dysphagia (Carnaby *et al.* 2006, Singh and Hamdy 2006, Cichero and Murdoch 2006). Circulatory diseases (which include Heart Disease and Stroke) have remained the most common causes of death in England and Wales over the last 90 years among both males and females (The Office of National Statistics (ONS) 2006). It has been estimated that 150,000 people have a stroke in the UK each year (ONS Quarterly Statistics 2001). As a result, stroke patients occupy around 20 per cent of all acute hospital beds and 25 per cent of long term beds (National Audit Office 2005) and accounts for 11% of all deaths in England and Wales (Royal College of Physicians/RCP, National Guidelines for stroke 2004).

Studies on the prevalence of dysphagia range from 25% to 70% in patients who have experienced a new/acute stroke (Perry 2001, Finestone and Greene-Finestone, 2003, Martino *et al.* 2005). These estimates vary because of the method of assessing swallowing function, the timing of swallowing assessment after stroke, and the number and type of stroke patients studied (AHCR 1996, Martino *et al.* 2005, Singh and Hamdy 2006).

Dysphagia in stroke is usually transient. Recovery of swallowing ability occurs in almost 90% of cases within two weeks but this can follow a fluctuating course with 10% to

30% of individuals continuing to have dysphagia with aspiration (Smithard *et al*. 1996). These authors suggest that at six months post stroke, 8% of patients remain dysphagic. One of the main concerns surrounding dysphagia following acute stroke is the reported high incidence of aspiration approximating 50% and the frequency of silent aspiration in this population (Daniels *et al.* 1998; Teasell *et al.* 2002). The risk of dying following an acute stroke within the first 30 days is around 20% (RCP 2004). The causes of death are most often due to the direct effects of the stroke such as coma and raised intracranial pressure. However, deaths from pulmonary complications arising from dysphagia, an impaired cough response and/or immobility, represents around a third of these fatalities (RCP 2004). The most commonly reported symptoms of dysphagia following a stroke include delayed or absent swallow trigger, reduced tongue/oral control, impaired mastication function, reduced pharyngeal pressure and reduced laryngeal excursion (Logemann 1998, Cichero and Murdoch 2006, Kim and Han 2005). A number of factors determine the presence and severity of dysphagia and include:

- Haemorrhagic stroke which accounts for 15% of strokes (Counihan 2004) and is more commonly associated with the development of dysphagia (Paciaroni *et al*. 2004);
- Oropharyngeal dysphagia occurs in up to a third of patients with unilateral hemiplegic stroke (Hamdy *et al*. 1997);
- Paciaroni *et al*. (2004) found that lesion size rather than location was the most predictive factor for determining dysphagia presence.

2.12. Summary of relevant clinical territories necessary for oral feeding

The ability to swallow food and drink safely depends on not only swallowing but respiratory function, general medical health, and environmental factors too. For example, swallow function can be normal but it is known that distractibility places the individual at risk for aspiration or choking, it is similarly possible to have poor oral control yet adequate pharyngeal function and airway protection to permit safe swallowing. It is clear decisions on whether the individual is safe to eat or not, should be based on a number of components related to oral feeding. A composite framework for swallowing is argued and is illustrated

in figure 5 overpage.

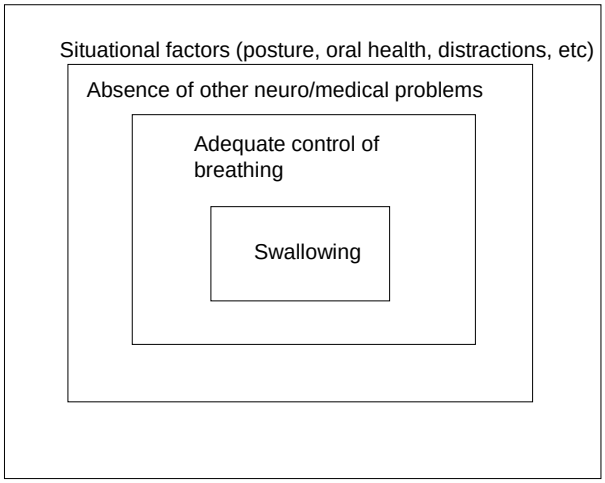


Figure 5: Clinical territories related to oral feeding

2.13. Features associated with dysphagia

Manifestations commonly associated with dysphagia include a number of signs and symptoms that may or may not always be present. These include the following (adapted from Logemann 1998, Kim and Han 2005, Cichero 2006):

- Drooling;
- A feeling that food or liquid is sticking in the throat;
- A need to modify or restrict certain food types;
- Impaired chewing;
- A sensation of a foreign body or 'lump' in the throat;
- Nasal regurgitation of food or drink during swallowing;
- Weight loss and inadequate nutrition due to prolonged or more significant problems with swallowing;
- Coughing or choking during eating and drinking caused by food, liquid, or saliva not

passing easily during swallowing and being inhaled into the lungs;

- Difficulty initiating a swallow;
- Unexplained weight loss;
- Gurgly or wet voice after swallowing.

2.14. Complications of dysphagia

Dysphagia has been identified as an independent predictor of mortality (Smithard 1996, Martino 2005). Martino (2005) further demonstrated an increased risk for pneumonia in patients with dysphagia following stroke and an even greater risk in patients with aspiration. Whilst complications of dysphagia following stroke may partly be accounted for by its relationship with increased stroke severity, dysphagia also exerts an independent effect revealed by the tripling of mortality rates in alert dysphagic stroke patients compared to similar groups with intact swallowing function (Barer 1989).

Teasell *et al.* (2002), in a study of 563 stroke patients admitted to a rehabilitation unit, compared patients with and without dysphagia and noted significant differences with regard to length of hospital stay and the development of pneumonia ($p < 0.05$). More than half of the patients evidencing dysphagia were more likely to develop aspiration pneumonia, and experienced longer hospital stays.

In addition to the known morbidity and mortality complications of dysphagia, there are psychosocial complications too. Mealtimes are a social event; therefore the inability to eat and participate in mealtimes due to associated problems of dysphagia such as excessive drooling and nasal regurgitation, will have a negative effect on mental wellbeing, precluding social enjoyment of eating (Cichero and Murdoch 2006, Nguyen *et al*. 2007). Some of the main complications of dysphagia and pertinent studies relating to these are outlined.

2.14a Malnutrition

Malnutrition literally means ‘bad nutrition’ but may be defined as

> '*a state of nutrition in which a deficiency, excess or imbalance of energy, protein, and other nutrients causes measurable adverse effects on tissue (shape, size, composition), function and clinical outcome* (Malnutrition Advisory Group 2006).'

Dysphagia has a potential for causing malnutrition and dehydration, which further complicates the individual's health by limiting functioning of vital organs, increasing the risk of infection through compromising the immune system, as well as accruing cost burdens to the NHS through prolonged hospital stays (Riensche and Lang 1992, Kelly *et al.* 2000, Elia *et al.* 2005).

Hospital malnutrition remains a major problem in the UK costing in excess of £7.3 billion pounds per year to treat (Bapen 2005). Elia and colleagues (2005) conducted a large-scale study involving over 11,000 patients who were screened for signs of malnourishment. More than one in four adults (28%) of the patients who were screened across hospital and care home settings were found to be malnourished. This problem is complicated by the fact that malnutrition is frequently under-reported as highlighted in a number of key studies which demonstrate that malnutrition in acute hospitals is largely unrecognised and unmanaged in up to 70% of cases particularly amongst the elderly (Elia 2003 and Kondrup *et al.* 2003, Lean and Wiseman 2008). Subsequently, there have been repeated national calls for hospital malnutrition to be addressed as a matter of urgency (Still Hungry in Hospital Report 2000; Age Concern, 'Hungry to be heard' Campaign 2003, Help the Aged 2006, NICE Guidelines 2006).

Baroness Finlay of Llandaff, speaking in Parliament in May 2008, highlighted malnutrition as a serious concern in hospitals in the UK (Lords Hansard text for May 15th 2008 www.publications.parliament.uk). Quoting the findings of Lean and Wiseman (2008) published in the BMJ, she emphasised estimations of more than 130,000 patients were malnourished when they were admitted to hospital in 2007, an increase of 12% on 2006. Patients leaving NHS hospitals in England were even more at risk with estimations that the incidence of malnutrition has increased by 85% in the previous 10 years to almost 140,000 patients in 2006-2007. Around 70-80% of malnourished patients are estimated to enter and leave hospital without action being taken to treat their malnutrition (Kelly 2000, Lean and Wiseman 2008) highlighting that malnourishment is not being fully addressed in hospitals.

This is an important consideration for the management of the dysphagic population

especially following an acute stroke if they are placed nil orally until assessed by a SLT. Yoo (2008) reports an identified risk of developing malnutrition in patients hospitalised for acute stroke acute placing them at increased risk for poorer clinical outcomes. Avoidance of delays in initiating nutrition whether this is orally or through a non-oral route is critical (Malnutrition Advisory Group 2003). Initiatives for screening acute stroke patients for dysphagia alongside screening for undernutrition (RCP 2000, BAPEN 2006, National Institute for Health and Clinical Excellence 2006) can limit unnecessary malnutrition in potentially vulnerable populations.

2.14b. Dehydration

Dehydration is a condition in which a person's body water content is at a dangerously low level (British Medical Association Medical Dictionary 2002) caused by losing too much body fluid e.g. due to vomiting and diarrhoea, not drinking enough water or fluids, or both.

Water is critical for sustaining life; all of the body's cells depend on water being maintained at the correct levels for optimum function (Whelan 2001). The incidence of dehydration has been found to be the highest amongst the elderly population due to a tendency towards a decreased fluid intake and is associated with high mortality rates (Gasper 1999, Whelan 2001). There are a number of predisposing factors that contribute to dehydration in the elderly. The main predisposing factors listed in the literature are decreased sense of thirst, reduced renal function and the prevalence of neurological and physical impairments such as stroke (Gasper 1999, Whelan 2001).

Dehydration may also be a risk factor for pneumonia. Dehydration decreases salivary flow, thereby promoting colonization of bacteria in the oropharynx and increasing the risk of developing aspiration pneumonia by depressing the person's immune response to infection (Palmer *et al.* 2001, Leibovitz *et al*. 2003). According to one recent study, almost 25% of individuals over 70 years of age are dehydrated on admission to hospital, and more than 33% of nursing home residents admitted to hospital are dehydrated (Kedlaya and Brandstater 2002). Dehydration has also been found to be an independent risk factor for the development of ischaemic strokes placing an already vulnerable population at increased risk (Nadev *et al.* 2002). In a retrospective study of 80 hospitalised patients who suffered ischaemic strokes during their hospital admission unrelated to surgical procedures,

Nadav and colleagues found that dehydration was a significant independent risk factor for the development of ischaemic strokes. These findings were echoed in a subsequent study of 102 acute infarct stroke patients where dehydration was demonstrated as independently associated with the development of venous clots as occurs in deep vein thrombosis and pulmonary embolism (Kelly *et al*. 2004). The acute stroke population are at particular risk for dehydration and its associated complications due to age factors and their limited access to water especially in the critical early stages of their hospitalisation.

2.14c. Aspiration and the development of aspiration pneumonia

Aspiration is defined as the mis-direction of oropharyngeal or gastric contents into the larynx and lower respiratory tract (Marik 2001). Its primary cause is impaired airway protection, which can occur in patients with an altered level of consciousness, and/or abnormal swallowing reflexes (Le Conte 2001). The extent and severity of aspiration pneumonia is dependent on a number of factors mainly the volume and acidity of the aspirate (Le Conte 2001, Marik 2001). Within the literature, aspiration is reported as the most prevalent adverse complication of dysphagia (Langhorne *et al.* 2000, Katzan *et al.* 2003; Konstantin *et al.* 2006) and the most common cause of death following a stroke (Henon *et al.* 1995; Konstantin *et al.* 2006). Typical overt signs of aspiration are sudden onset of coughing and shortness of breath associated with eating, drinking, regurgitation, altered mental status, putrid expectorant, chest pain, abdominal pain, anorexia and weight loss (Le Conte 2001). Prevalence estimations of aspiration pneumonia vary depending on the underlying diagnosis, method of detection and expertise of the diagnosing practitioner but it has been suggested that dysphagia carries a sevenfold increased risk of aspiration pneumonia and is an independent predictor of mortality (Singh and Hamdy, 2006). Pikus *et al.* (2003) suggest aspiration pneumonia is the most common form of hospital acquired pneumonia and occurs in approximately four to eight patients of every 1000 hospitalised patients in the USA. Accurate calculations of the prevalence of aspiration pneumonia do however remain challenging in certain groups. Marrie (2000) reported that the elderly who suffer pneumonia often complain of significantly fewer symptoms than their younger counterparts do; it was therefore concluded that pneumonia is commonly under-reported in this population.

Based on data from the stroke literature, the Agency for Health Care Policy and Research (AHCPR 1999) estimated that between 43% to 54% of stroke patients with dysphagia experience aspiration, approximately 37% of these subsequently develop pneumonia and 3.8% of these die of pneumonia if they are not part of a dysphagia diagnosis and treatment programme. In addition to overt signs of aspiration, such as choking or coughing, a substantial number of patients also experience silent aspiration. Silent aspiration is defined as

> *"penetration of food below the level of the true vocal cords, without cough or any outward sign of difficulty"* (Linden and Siebens 1983 p 281)

Detailed clinical swallowing assessments have been shown to under-diagnose or to miss these cases of aspiration (Kidd *et al.* 1993, Terre and Mearin 2006). Walter *et al.* (2007) evaluated clinical predictors of pneumonia in 236 patients with acute ischaemic stroke admitted to a neurological intensive care unit and found dysphagia along with stroke severity were highly predictive for the development of pneumonia (76% sensitivity and 88% specificity). A further complicating factor for the development of aspiration pneumonia is an increased incidence of oral and pharyngeal colonization with respiratory pathogens in the elderly population. Leibovitz *et al.* (2003) suggest aspiration of infected oropharyngeal matter accounts for the main cause of aspiration pneumonia. Colonization of these pathogens is a well-known risk factor for the development of pneumonia (Palmer *et al.* 2001, Yoneyama *et al. 2002*). These changes can occur secondary to decreased salivary production and abnormalities in swallowing which in turn may result in impaired clearance of organisms, allowing pathogenic colonization. In addition to identifying a relationship between aspiration of colonised oral bacteria and the development of aspiration pneumonia, Langmore (1998) further identified other factors from her review including dependency on others for feeding, multiple medical conditions, smoking, tube feeding and dependence for oral care.

A systematic review by Perry and Love (2001) concluded that aspiration alone cannot fully explain the consequent development of pneumonia. An intact immune system is required to clear infectious aspirated matter; a decline in immune function associated with the ageing population may have a greater influence on the development of aspiration pneumonia (Konstantin 2006). Missing teeth and poorly fitted dentures predispose to aspiration by interfering with chewing and swallowing. Infected teeth and poor oral

hygiene further influence the development of pneumonia following the aspiration of contaminated oral secretions (Quagliarello *et al.* 2005, Terpenning 2005). This is supported by further evidence, which suggests providing weekly dental care, and cleaning the elderly person's teeth with a toothbrush after each meal lowers the risk of aspiration pneumonia (Yoneyama, *et al.* 2002).

2.14d. Long term outcomes-Institutionalisation and mortality

Smithard *et al.* (2007) conducted a population-based long-term follow-up of 567 patients with dysphagia following a stroke. Dysphagia was assessed within one week of stroke and patients were followed up at three months and yearly for five years by face-to-face interview. Outcomes indicated residence in a nursing home was more likely to occur in those who failed the swallow test during the first week of their stroke; reaching statistical significance at three months, four years and five years post stroke. There was also a significant association with increased mortality only during the first three months confirming that the presence of dysphagia during the acute phase of stroke is associated with poor outcome during the subsequent year, particularly at three months, and is associated with an increased institutionalisation rate in the long term. Chen *et al.* (2004) found in a cohort of 182 consecutive patients with stroke related dysphagia that advanced age, recurrent stroke, dependency on tube feeding and being wheelchair-confined during follow-up, were independent predictors of long-term survival. Aspiration detected on VF was not predictive for the long-term survival in stroke patients with dysphagia.

2.15. Management of dysphagia in the hospital setting

Having explained dysphagia and its complications, it is now necessary to consider how dysphagia is assessed and managed in the hospital setting. A number of techniques are available to evaluate swallowing function. They vary in their utility in terms of whether they are required to provide a detailed understanding of the anatomy of swallowing, determine the presence or absence of aspiration or listen to patterns of respiration around swallowing. These have informed conceptual frameworks for the swallowing process, which clinicians use as a reference when making diagnostic, and management decisions (Logemann 1998, Singh and Hamdy 2006). The main techniques are described.

2.15a. Instrumental diagnostic tools for determining the presence of dysphagia

Videofluoroscopy

Videofluoroscopy (VF) is a dynamic X-ray study used to study swallowing structures, aspiration and guide dysphagia management. This procedure involves the recording of the patient swallowing bolus trials of varying consistencies mixed with a radio opaque substance such as barium under X-ray conditions. VF has the advantages of visualisation and quantification of barium through the oral cavity as well as the pharynx and oesophagus. The images are evaluated by a SLT and radiologist to determine anatomic and physiological aspects of swallowing and are helpful for differentiating between abnormal physiology, penetration of barium into the airway, and true aspiration (barium entering the airway below the true vocal cords). This procedure is commonly regarded as the gold standard for instrumental detection of dysphagia. There are however a number of limitations to this procedure. Videofluoroscopy requires the patient to stand or sit upright in a specialised chair that is radio translucent to permit imaging. This limits its accessibility to patients who are bedbound or cannot transfer to a chair. The sitting or standing postures that are required to allow imaging do not necessarily replicate normal eating postures thus how far the procedure can be generalised to swallowing situations is questioned. In addition, the procedures for undertaking videofluoroscopy are not standardised in terms of viscosity and amounts of trials offered. Exposure to radiation is a further risk factor which makes frequent repetition of the procedure inappropriate (Ramsey *et al.* 2003).

Increasing evidence shows that radiologically defined aspiration does not necessarily indicate clinical complications or potentially poor long-term outcome; videofluoroscopy should therefore be used to evaluate why and not just if a person aspirates (Marik and Kaplan 2003).

Videofluoroscopy as the gold standard

There remains limited evidence to support the premise that abnormalities detected on videofluoroscopy can determine overall swallow function or predict complications of dysphagia such as pneumonia (Smithard 1996, McCullough 2001a). However, almost all studies reviewed in the literature use videofluoroscopy as the 'gold standard' i.e. the 'true diagnosis' for determining presence and absence of dysphagia or aspiration.

Greenhalgh (2001) notes that a gold standard is only the best diagnosis according to experts at the current time. A number of studies suggest videofluoroscopy is not an ideal tool, because it can yield false-negative and false-positive results (Kuhlemeier *et al.* 1998), has highly variable interjudge reliability for detection of aspiration (Logemann 1999b, Mann and Hankey 2000, McCullough 2001a) and is carried out under artificial conditions that do not reflect normal swallowing (Mann *et al.* 2001., Ramsey *et al.* 2003). Research has shown that inter-rater reliability in assessing physiological deficits on videofluoroscopy is poor ranging from kappa coefficient 0.01 to 0.56 (i.e. just above the level of chance at best) on various oral and pharyngeal swallowing assessment parameters (Logemann 1999b, McCullough *et al.* 2001a, Stoeckli *et al.* 2003).

McCullough *et al.* (2001a) found poor inter-rater reliability for most measures commonly employed for the interpretation of videofluoroscopy for detection of dysphagia. In fact,

> "*interjudge reliability for most measures, with the exception of a binary rating of aspiration, appears to vary among clinicians and is unacceptable"* (McCullough *et al*. 2001a p.117).

Similarly, Stoeckli *et al.* (2003) found that clinicians interpreting videofluoroscopy generally agreed when aspiration was absent, but were unable to agree on the cause of the altered swallow. In contrast to studies evaluating the efficacy of dysphagia management programmes employing clinical dysphagia assessment and screening (AHCPR 1999, Hinchey 2005), no evidence exists to date that detection of dysphagia and aspiration using videofluoroscopy reduces the rate of pneumonia. Teasell *et al.* (1999) measured the association between the frequency of VF and the incidence of pneumonia in 1024 acute stroke patients admitted to two stroke rehabilitation units. In the first hospital, videofluoroscopy was carried out much more frequently after 15 days (17.2% compared to 2% in the second hospital). The authors noted that despite a relatively high use of VF in

the first hospital, there was no commensurate reduction in the rate of pneumonia compared to the second setting, which was otherwise similar.

It is clear that detection of aspiration on videofluoroscopy is not a perfect gold standard for informing the assessment and management of dysphagia and its complications. Assessment of both structural and functional ability such as establishing how much the patient can eat will have more impact on informing patient outcomes than merely determining whether a patient aspirates on videofluoroscopy or not.

Fibreoptic Endoscopic Evaluation of Swallowing (FEES)

FEES is another instrumental procedure used for assessing dysphagia. In this procedure a flexible endoscope, which contains a camera, is passed via the nose into the oropharynx. This enables visualisation of the larynx and pharynx during swallowing of food and fluids (Langmore *et al.* 1988, Kelly *et al.* 2006). An Evidence Report for Stroke published by the Centre for Evidence-Based Practice (2002) provided a review of the literature for studies that evaluated the accuracy of FEES in predicting pneumonia or nutrition problems. Four studies were identified which compared FEES and VF in detecting aspiration in patients who had dysphagia of various aetiologies (25% to 79% had dysphagia resulting from a stroke). The range of agreement between the two tests for detecting aspiration was reported in the individual studies as between 74% to 96%. Although FEES has several advantages, shortcomings have been cited in the literature. Logemann (1998) states that the nasendoscope may be uncomfortable and not well tolerated by certain patients and suggests its presence also interfere with the dynamics of normal swallowing. In addition FEES only allows visualization of the pharyngeal stage of swallowing so information about the oral phases such as bolus preparation is lost. Visualisation of the pharyngeal phases of swallowing is not possible during the swallow so aspiration occurring at this point cannot be determined (Kelly 2005). Lim (2001) conducted a cohort study which evaluated the accuracy of a combination of a 50-ml water swallow test, an oxygen desaturation test, and the combination in both predicting pneumonia and in detecting aspiration on FEES in 50 consecutive acute stroke patients. In this study, FEES was 100% sensitive and 53% specific in predicting pneumonia i.e. pneumonia did not develop in any patient that had a normal FEES.

Cervical auscultation

Cervical auscultation is an adjunct to the clinical swallowing assessment. The procedure involves assessing the sounds of swallowing and swallowing related respiration using a stethoscope (Stroud *et al.* 2002). It permits the therapist to monitor swallowing and the coordination of respiration for swallowing using foods and drink. Disturbance in the normal swallow respiratory cycle such as gasping after the swallow, suggests in-coordination placing the patient at risk of aspiration. Stroud *et al.* (2002) investigated inter and intra-rater reliability of cervical auscultation for detecting aspiration in patients with dysphagia. They found a sensitivity of 86% and specificity of 56%. The SLTs were able to accurately determine genuine occurrences of aspiration however there were a significant number of false positives i.e. the SLTs over-predicted aspiration in its true absence. The therapists were very accurate when determining that aspiration had not taken place (the negative predictive value was 94%). Some of the clinicians had very high intra-rater reliability suggesting that they were using their own internal criteria when differentiating the sounds of aspiration from non-aspiration (Stroud *et al.* 2002). A criticism of the study is that it sought to investigate the clinician's ability to determine aspiration using swallowing sounds isolated from other cues including respiration and pre and post-swallowing events, which some reviewers argue, are necessary cues for the detection of aspiration (Cichero and Murdoch 2006). Leslie e*t al*. (2004) evaluated clinicians' reliability using cervical auscultation interpretation and investigated whether decisions were based on the sounds heard or were influenced by information obtained from other aspects of the clinical assessment, medical notes, or previous knowledge. They sought to determine rater reliability and its impact on the clinical value of cervical auscultation and how judgments compare with the "gold standard": videofluoroscopy. Intra-rater reliability did not correlate with years of experience, practice pattern, or frequency of use and was generally poor. Inter-rater reliability of decisions using cervical auscultation was also poor although from a group of 20 swallowing clips the group consensus correctly identified 17. The authors concluded from this that the swallow sound contains audible cues that should in principle permit reliable classification. Interestingly, there has been research that reports musically talented physicians had better intra-rater reliability for using auscultation than physicians who did not play a musical instrument (Richardson and Moody 2000).

One of the main criticisms of cervical auscultation is that the cause of the swallowing

sounds is not fully understood and to date, no correlation of sounds with specific swallowing events has been proved. The efficacy of using cervical auscultation for assessing for aspiration is therefore questioned (Cichero and Murdoch 2006).

Manometry

Manometry offers quantitative information relating to the measurement of pressure during swallowing. The procedure requires passing a small catheter through the nose and into the oesophagus and stomach. The catheter has multiple electronic pressure probes and measures oesophageal contractions during swallowing. Manometry enables the SLT to determine the strength of pharyngeal pressures as well as the degree of relaxation of the cricopharyngeal sphincter as well as the timing and coordination of pharyngeal pressures. However, manometry detects definitive abnormalities in only 25% of patients with nonobstructive lesions. Its use in disorders of the oropharyngeal upper oesophageal sphincter is not particularly effective, because patients do not tolerate the procedure well. Similarly, due to its technical insertion process it is not widely used by SLTs (Butler *et al*. 2005, Bateman 2007).

Pulse oximetry

Pulse oximetry is a non-invasive measurement of arterial oxygenation using a probe attached to a pulsating vascular bed (Cichero and Murdoch 2006). Its use is based on the assumption that when aspiration occurs, the patient will evidence a decrease in oxygenated blood flow. The evidence base for this technique is mixed. Sherman (1999) investigated the use of pulse oximetry for detecting aspiration in 46 dysphagic patients who underwent simultaneous videofluoroscopy. They found a statistically significant association between decrease oxygenated blood flow and aspiration. It has to be noted however, that this study was based on a small sample size. Smith *et al.* (2000) comparing pulse oximetry results against videofluoroscopy found the test was not sensitive enough to distinguish between aspiration and material that had dropped on the vocal cords but was subsequently moved from the airway (penetration). They found that combining the test with the clinical dysphagia assessment improved the sensitivity to 86% for aspiration and/or penetration.

The problem here is the relevance of penetration for the development of aspiration.

Ramsey *et al.* (2006) sought to refine the investigation of the efficacy of pulse oximetry for detecting aspiration following an acute stroke. They investigated pulse oximetry, clinical dysphagia assessment and videofluoroscopy for detecting aspiration in 189 stroke patients. Results indicated that pulse oximetry during swallowing, whether alone or in combination with a modified swallowing screen, showed inadequate sensitivity, specificity and predictive values for detection of aspiration compared with videofluoroscopy in stroke patients. The variability in the study results for pulse oximetry means that no consensus exists as to its efficacy and hence this assessment is not frequently used in clinical practice within the UK (Bateman *et al.* 2007).

2.15b. SLT clinical dysphagia assessment

SLTs have a pivotal role within the multidisciplinary team for the assessment and remediation of dysphagia (RCSLT 2005). SLTs are skilled in the assessment and remediation of speech and voice disorders arising from structural, neurological and psychological abnormalities; many of these disorders are frequently accompanied by dysphagia (Martin and Corlew 1990; Halper *et al.* 1999). In the U.K. dysphagia used to be seen as a specialist area with training only being delivered at post registration (post qualification) level. In 1999, the RCSLT (Royal College of Speech and Language Therapists) recommended all speech and language therapy-training establishments modify their curricula so that students could gain basic theoretical knowledge and practical skills in dysphagia awareness and assessment during their undergraduate studies. More recently, specific core competencies for the assessment, treatment and remediation of dysphagia have been developed (Inter-professional Dysphagia Framework. Boaden *et al*. 2006).

SLTs use a clinical dysphagia assessment typically performed at the patient's bedside. The assessment evaluates conscious levels, posture, oral sensation, and swallowing performance measured with a range of fluid and diet consistencies. A clinical dysphagia assessment is a critical component of a thorough diagnostic evaluation. The clinical assessment typically begins with a thorough medical history (Logemann 1998, Bateman *et al.* 2007). Establishing information regarding the history of the dysphagia, medical history as well as current medical diagnosis and medications taken is important to be able to make

an accurate judgment regarding the aetiology of the swallowing problem (Logemann 1998, Cichero 2006). The medical history may also include nurses' and carers' observations around the observed dysphagia such as coughing during feeding.

The next phase of the clinical dysphagia assessment is an evaluation of the conscious level and body posture as both are implicated in aspiration risk (refer to Table 5 on page 77). Depending on judgements of conscious level and posture at this point, it may be decided that it is unsafe to proceed with trials of fluid and diet. The assessment of the patient will include an appraisal of the patient's behaviour and communication, respiratory function/endurance, an oral motor/cranial nerve evaluation, and a swallowing evaluation (Logemann 1998). The respiratory function and endurance, as previously discussed, has an impact on a patient's ability to swallow. In order for the pharyngeal phase of swallowing to occur, respiration must cease. This is particularly difficult for the patient who suffers compromised respiration.

The oral motor and cranial nerve examination evaluates weakness, deficits in function and loss of sensation in the lips, tongue and palate (Logemann 1998). Any deficits in the swallowing mechanism are important to acknowledge so that compensatory measures such as modifying fluid and food consistencies or adjusting feeding posture during swallowing can be correctly applied in a treatment programme.

As has been noted, there is no standard method of assessing swallowing at the bedside; however, clinical dysphagia assessment of swallowing typically comprises key components. An overview of these components along with the rationale for their inclusion is presented in Table 4 page 49.

Table 4: Components of the clinical dysphagia assessment (adapted from Logemann 1998 and Cichero & Murdoch 2006)

Prefeeding Observations	Rationale
Review of medical and nursing notes: **Purpose:** Check the patient's current and past medical problems especially those that might cause dysphagia	Helpful in forming dysphagia diagnosis and planning treatment and management
Respiratory status including reports of recent pneumonia	Provides insights into patient's general tolerance of diet and fluids as well as safety of swallow. If the patient is in respiratory distress, it may not be appropriate to proceed with assessment or treatment
Current and recent medications	Certain medications such as those used to treat Parkinson's Disease can impact on swallowing, others cause drowsiness or dry mouth
History and description of patient's swallowing problem	Determine duration and nature of dysphagia, symptoms such as coughing/sensation of food sticking in throat
Ability to follow directions	Important to determine and adapt method of assessment accordingly
Checking Posture and mobility	Sitting in an upright posture in bed is often the safest position for the patient to be in for trialling diet and fluids. A recumbent posture has been linked with dysphagia and aspiration risk (see Table 5 p 80).
Level of alertness or conscious levels- checking if safe to proceed with trial swallows	A reduced level of consciousness or delayed reaction time is linked with unsafe swallowing (see Table 5 p 77).
Patient awareness and control of oral secretions	Gives an indication of the patient's oromotor skills including ability to form a lip seal to stop oral secretions/food/drink escaping from the lips as well as oral sensation
Auditory and visual status	This again provides insight into how food is offered and presented to the patient and for how the clinician will need to augment her communication with the patient in order to enhance understanding

Table 4: Components of the Bedside clinical dysphagia assessment (adapted from Logemann 1998, Nathradawala 1998, Cichero 2006 and Ramsey 2006) -Continued

Caregiver-patient interaction	There may be a requirement for education of the carer to enhance feeding such as placement of food in the mouth or to modify textures. It is also often necessary that the patient is given time to eat and drink and this is done with minimal distractions. Checking caregiver-patient interaction is critical; this may require advice relating to modification of interaction
Oromotor assessment	**Rationale**
Examination of oral function i.e. rate and range and accuracy of movement of the lips, tongue, soft palate and pharyngeal wall	Checks for weakness or reduced function of oral structures. This informs the clinician of damage to the relevant cranial nerves, which innervate muscles of the face; lips, tongue and soft palate (refer to Table 1).
Examination of oral sensation	Checking for facial paralysis, lack of sensation in the tongue/oral cavity rationale as above
Examination of oral hygiene	Check oral hygiene: determine whether the tongue is coated or swollen/ dry. Any of these factors will make swallowing difficult and may need to be remedied with e.g. medication/oral toilet or artificial saliva
Examination of laryngeal function including: **-assessment of gurgly or hoarse voice quality** **-strength of voluntary cough** **-ability to sustain 'ah' i.e. measurement of phonation times**	An examination may reveal impaired cranial nerve innervation (to the vagus nerve in this example) and the patient's ability to protect his/her airway from inhaled or aspirated material
Assessment of Trial Swallows	**Rationale**
Assess with water and a range of food textures (if judged safe to do so)	Determines how the patient tolerates fluid and diet in terms of timeliness and efficiency of swallow trigger.
Use of cervical auscultation or pulse oximetry. (This may be dependent on the therapist as not universally adopted due to lack of consensus on efficacy)	Cervical auscultation may be used as an adjunct to the bedside assessment. It typically involves the use of a stethoscope to assess swallow sounds including respiratory patterns around swallowing. Judgments are then made on the normality or degree of impairment of the sounds. Pulse

Table 4: Components of the Bedside clinical dysphagia assessment (adapted from Logemann 1998, Nathradawala 1998, Cichero 2006 and Ramsey 2006) -Continued

	oximetry measures for drops in the oxygen levels in the blood during swallowing as an indication of aspiration in stroke patients. These two techniques have a limited evidence base and is therefore not universally adopted (Cichero 2006, Ramsey *et al.* 2006)
Digital examination of swallow i.e. feeling for the swallow to occur (refer to glossary for an illustration and full explanation of this technique)	As the patient swallows, the SLT's fingers on the patient's neck can feel for initiation of tongue movement and movement of the hyoid cartilage during the oral phase of swallowing and defines laryngeal movement during the pharyngeal trigger of the swallow. A judgement is made of the promptness and coordination of the trigger of the swallow by comparing the time elapsed between initiation of tongue movement and initiation of movement of the hyoid and laryngeal structures (normal = < 1 second)
Immediately following the swallow, ask the patient to sustain an 'ah' sound for several seconds. Check for a gurgly, wet voice quality	Indicates material sitting on the vocal cords at the entrance of the airway
Estimation of speed of swallowing	For water the average speed of swallowing a given volume of water is 10mls per second (Nathadrawala *et al.* 1998) An increased length of time/lesser average volume swallowed suggests the presence of dysphagia
Estimate oral transit and pharyngeal delay time observation of whether the swallow is absent or delayed.	Swallowing of a water bolus is normally initiated within 1 second. Where the swallow takes longer to be triggered, this can suggest delayed swallowing placing the patient at risk for aspiration (Logemann 1998)
Checking for presence/absence of productive cough during or following swallowing	Determines patient's ability to clear and protect airway

2.16. Reliability and consistency of clinical dysphagia assessment

A number of authors have noted that to date, specific clinical guidelines for dysphagia assessment have not been published (Smith and Connolly 2003, Bateman *et al.* 2007). Smith and Connolly note that a clinical dysphagia assessment is only one component of dysphagia evaluation which includes taking an in depth patient history to determine the nature and onset of the dysphagia. A common complaint levied at clinical dysphagia assessment as noted previously, is their tendency to over predict aspiration i.e. sensitivity for detecting aspiration can be high but specificity for excluding patients without aspiration is low (Smithard *et al.* 1996, Mann *et al.* 2000, Smith *et al.* 2000). A number of reviews (Ramsey *et al.* 2003, Mann and Hankey 2007) highlight that between 8-68% of patients with normal bedside evaluations have been shown to aspirate on VF (i.e. have displayed 'silent aspiration'). However, to date there are no direct data that show that this additional information leads to more accurate prediction of (or prevention of) pneumonia or other complications.

Inter-rater and intra-rater reliability levels for clinical examination vary considerably between studies. McCullough (2001) investigated inter- and intrarater reliability of SLTs' clinical examination of swallowing in adults. Results indicated that fewer than 50% of the measures clinicians typically employ were rated with sufficient inter- and intra-rater reliability. Measures of vocal quality and oral motor function were rated more reliably than were history measures or measures taken during trial swallows. This study was limited by a small sample utilising only three speech and language therapists evaluating 20 swallows. Design flaws were also apparent in that the swallowing assessments were carried out on adjacent days rather than concurrently limiting the reliability of the results. Mann *et al.* (2000) suggests higher consistency and calculated values of $k = .82 \pm .09$ and $.75 \pm .09$ i.e. 'almost perfect' and 'substantial' agreement respectively (please see Appendix 1) for inter-rater agreement on diagnosis of dysphagia or aspiration by two speech pathologists. These results were supported by a subsequent study by McCullough *et al.* (2001b) which evaluated the sensitivity and specificity of clinical dysphagia assessment when compared to VF in 60 stroke patients. An overall measurement of the presence of aspiration as detected by the bedside assessment and confirmed by VF was reliable (.80) and sensitive (.91) but only moderately specific (.47) at the $p < .05$ level of significance.

Kuhlemeier *et al.* (1998) and Karnell and Rogus (2005) suggest that it may be easier for SLTs to agree that a swallow is either normal or abnormal rather than agreeing on what it is that makes it so and this may be due to the confusion as to what constitutes dysphagia. It may be as Smith and Connolly (2003) suggest that clinical dysphagia assessments are themselves a form of screening and inform the clinician of the need for additional instrumental evaluation of swallowing. The lack of specific guidelines for dysphagia assessment means that clinical judgement as to dysphagia presence or absence may be dependent on the experience and expertise of the clinician.

In determining the consistency of clinical dysphagia assessment practices of UK and Ireland SLTs, Bateman *et al*. (2007) found considerable variation. The authors conducted an email survey of SLTs working with dysphagic adults (n=296). Their aim was to determine practice patterns across clinicians, to determine the level of consistency in practice and to compare how the UK findings compared against those previously reported in a US study (Mathers-Schmidt and Kurlinski 2003). The frequency of use of a broad range of components of dysphagia assessment was evaluated, such as use of cervical auscultation, determining secretion management, vocal quality and obtaining the patient's drug history. Low frequency was reported for four components: trials with compensatory techniques, obtaining the patient's drug history, assessment of speech articulation/intelligibility and screening/assessment of mental ability. Variability between therapists was high with inconsistency for 19% of the components evaluated. Only ten out of the 31 components evaluated showed high consistency (i.e. used frequently by 75% or more of respondents). These were: obtaining the patient's medical history, determining respiratory status, judgement of efficiency of oral movements, establishing nutritional status, assessment of ability to manage secretions, adequacy of lip seal, assessment of vocal quality pre and post swallowing, judgement of pharyngeal delay, adequacy of dentition for chewing and adequacy/strength of laryngeal movement. These results were compared to the US study. Differences in practice were noted for the use of cervical auscultation, trials with compensatory techniques, examining the gag reflex, assessment of sensory function and screening/assessment of mental function. Of the components, usually or always used 48% were used by more than 90% of the respondents and all of these are taught within accredited courses. However, assessment of sensory function and trials with compensatory techniques are also taught in accredited courses yet only 56% tested

sensory function and 42% regularly using compensatory techniques. They noted that the use of pulse oximetry and cervical auscultation were rated inconsistently and conclude that this may reflect the lack of consensus within the literature for the efficacy of these components as well as the lack of central guidance within dysphagia training courses for SLTs. The authors further highlight that full literature reviews of the individual components of the clinical dysphagia examination was beyond the realm of their study.

2.17. Dysphagia referrals and their impact on SLT services and patients

Due to the high prevalence of dysphagia following stroke, it is common practice for this population of patients to be kept nil by mouth until their swallow is assessed by a SLT (Ellul and Barer 1996). This places the patient at further risk of malnutrition (Perry and McLaren 2003, Lean and Wiseman 2007).

The National Guidelines for Stroke (2002) state acute stroke patients should have access to an assessment of swallow function by SLTs within 72 hours. However, within the last decade the demand for dysphagia assessments has increased 100 fold without being matched by available SLTs (Petheram and Enderby 2001). Enderby and Petheram (2002) conducted a retrospective study to review the change in number of referrals to speech and language therapy for dysphasia (language difficulties) and dysphagia over one decade. These authors evaluated referral patterns in the UK between 1985 and 1995 and noted that of the 80,000 referrals made to the speech and language therapy service, in 1985 there were 12 times more for dysphasia than dysphagia. By 1995, there were half as many dysphasia as dysphagia referrals made. This pattern of increased numbers of people with dysphagia referred to speech and language therapists (and the effect on the provision of speech and language therapy services) has been increasing throughout Europe *(*Petheram and Enderby 2001; *CPLOL – Prevention Commission* Dysphagia Review 2005). This 'alarming rate' of increased referrals has meant that some services have become so overwhelmed that they no longer have the resources to respond to patients with communication problems (Heritage 2001). The negative impact on the increase in referrals to speech and language therapy services has been echoed throughout Europe *(CPLOL – Prevention Commission* Dysphagia Review 2004-2005) with all European member states revealing concern about the increasing workload due

to referrals of individuals with dysphagia and the need for increasing numbers of SLTs to be competent in the assessment and treatment of dysphagia.

The National Sentinel Audit of Stroke (2006) reports a third of patients with swallowing disorders have not been assessed by a SLT within the recommended Stroke guidelines of 72 hours of hospital admission. These poor figures are however likely to reflect the typical working practices of SLTs i.e. that they do not work evenings, weekends and bank holidays. As noted in the National Sentinel Audit of Stroke 2006 Clinical Audit Report, "the service needs to acknowledge that illness does not recognise days of the week or times of the day" (p53).

Patients requiring swallow assessments can wait up to 6 days (if a referral is received before a bank holiday weekend) and yet SLTs are still working within the recommended standard for two working days (Royal College of Speech and Language Therapists 2006). Research and key reports (e.g. Kings Fund Report 1992; Collaborative Dysphagia Audit 1997; National Audit of Stroke 2006) have identified a need for early identification and management of dysphagia through screening to reduce the number of patients who are fed inappropriately or starved while awaiting clinical dysphagia assessment and who are thus at risk of aspiration pneumonia and malnutrition.

In May 2006, the National Sentinel Audit for Stroke reported that only 55% of patients received screening for dysphagia in Wales compared to 67% in England and 62% in Northern Ireland (Healthcare Commission, 2006). Subsequently, the Department of Health (DoH) published the National Stroke Strategy, *A new ambition for stroke-a consultation on a national strategy* (DoH, December 2007). The strategy, which was developed in partnership with key stakeholders including SLTs and Stroke professionals in the NHS, highlights the importance of screening for dysphagia within the first 24 hours following an acute stroke. In Wales, in January 2008, a Welsh Health Circular was published on improving stroke services to improve standards of care and services for patients who are at risk or who have suffered a stroke. One of the requirements set out meant that by March 2009 all acute stroke patients should be admitted to dedicated beds staffed by a specialist stroke care team. This bodes well for the development of dysphagia screening programmes in terms of the recent attention given to screening. The purpose of screening will be returned to in detail later (see page 59).

2.18. Nurses' role in screening and managing dysphagia

Nurses play a significant role in identifying dysphagia and frequently, the nurse may be the first member of the medical team to detect signs and symptoms of dysphagia (Perry 2001, Ramsey *et al.* 2003). Consequently, nurses are critical to the communication of relevant observations to core members of the team managing the patient's care and may be instrumental in recommending referral to the SLT for a clinical dysphagia assessment. Given the typically early contact nurses have with stroke patients, there is an increasing drive for nurses' engagement in dysphagia screening (Intercollegiate Working Party for Stroke, 2004). These recommendations aim to prevent patients with normal swallows being placed nil by mouth and prevent dysphagic patients from being fed inappropriately and incurring the risks of aspiration. Collaboration with patients and their family members as well as interdisciplinary communication between nurse, medical team members, dieticians, occupational therapist, SLT and other professionals to develop and agree on interventions can improve the patient's hydration and nutrition status as well as avoid life-threatening complications. A number of authors (Perry 2001, Heritage 2001, Miller and Krawczyk 2001, Farneti and Consolmagno 2007) advocate a multi disciplinary approach to the management of dysphagia, including an enhanced role for nurses.

The Nursing and Midwifery Council's Code of Professional Conduct (2004, 2008) stipulates that nurses *'must act to identify and minimise risk to patients and clients'* (p3). Nurses make use of models to guide nursing care. One of the most well known models in the UK is the Roper, Logan and Tierney nursing model (1980, 2000 and 2001). The model is focused on the patient and 12 activities of living which are related to either functions that maintain life (e.g. breathing, eating, sleeping, eliminating) or to increased quality of life (e.g. communicating and personal hygiene). These activities of living are used to inform the initial assessment of the patient upon admission into hospital. Activities that the patient can no longer do or complete are then identified and plans are put in place to guide care. It is clear within the code and models such as that devised by Roper and co-authors, that the RGN has a pivotal role in early identification and management of eating and drinking difficulties and therefore are best placed to

undertake dysphagia screening.

Davies (1999) lists a number of advantages and disadvantages for nurses undertaking the role of dysphagia screening which includes the nurses' availability on a 24 hour basis, the nurses being available to all members of the multidisciplinary team to communicate and advise on the patients' swallowing status, and having responsibility for feeding their patients. He reiterates some of the perceived disadvantages to nurses undertaking dysphagia screening, which include the perception of this role being yet another task thrust upon an already overstretched nurse and the service resource implications for training nurses and keeping these skills updated. A number of studies of dysphagia management policies have demonstrated that when nurses were trained to use a dysphagia screening tool, the proportion of patients with an unsafe swallow in whom no precautions were taken against aspiration, was reduced by one to two thirds (Barer and Davies1999, Dangerfield and Sullivan 1999). These studies highlight nurses' critical role within the multidisciplinary team for identifying and managing dysphagia.

The Royal College of Physicians National Guidelines for Stroke (2004) and the SIGN Guidelines (2004) requires all hospitalized acute stroke patients are placed 'Nil by Mouth' until screened for dysphagia placing increased focus on the need for standardized and robust dysphagia screening procedures. Currently there are no standard guidelines or framework for training nurses to undertake this role. However, the Scottish Intercollegiate Guidelines Network (2004) suggests that training for screening programmes should include:

- Risk factors for dysphagia;
- Early signs of dysphagia;
- Observation of eating and drinking habits;
- A water swallow test;
- Monitoring of hydration;
- Monitoring of weight and nutritional risk.

The Inter-professional Dysphagia Framework (2006) published by the Royal College of Speech and Language Therapists in collaboration with other key stakeholders including National Patients Safety Agency; Royal College of Physicians; and Royal College of Nurses, has identified strategies for developing dysphagia competencies for nurses as

well as SLTs and other healthcare professionals involved in the identification and management of people with feeding and swallowing difficulties. The Inter-professional Dysphagia Framework (IDF) outlines the competencies and knowledge required for professionals to work at defined levels. With regard to nurses, these skills are identified within the 'Assistant dysphagia practitioner' level. Knowledge and skills link to the nurse's care and treatment of individuals presenting with dysphagia including recognising signs of dysphagia, preparing food and drink for dysphagic individuals and providing assistance with feeding. The framework is beginning to inform Speech and Language Therapy undergraduate education programmes training for dysphagia e.g. Marjon University (marjon.ac.uk/clinical/dysphagiahandbook1.pd, 2007) and Manchester Metropolitan University (did.stu.mmu.ac.uk, 2007). Its application to nurses' training programmes has not, to date, been evaluated.

2.19. An interdisciplinary approach to managing dysphagia

Heritage (2000) reporting on her experience of developing nurse screening programmes in the Southern Derbyshire Trust since the late 1990s advocate a collaborative approach to develop dysphagia screening programmes. She noted that for a dysphagia screening programme to be effective there needs to be partnership and commitment from all levels from the outset especially from nurse management. In Southern Derbyshire, two to three registered nurses were trained to screen for dysphagia arising from multiple aetiologies on each ward. The nurses attended from a wide range of fields including mental health, nursing homes learning disability and acute hospital wards. The nurses attended a day and a half training programme for dysphagia awareness and to develop skills in carrying out the "Screening for Dysphagia" tool, which is a four-page algorithm. This enabled the nurses to manage simple and short-term dysphagia in the absence of a SLT service. Dysphagia trained nurses (DTNs) are able to offer peer support to colleagues. Such a programme clearly requires considerable SLT resources and this is acknowledged in both papers. A specialist SLT has been funded to oversee the DTN training programme, which includes additional support via a DTN telephone help line, delivery of regular dysphagia newsletters, establishing training needs and regular audits. In addition, it must be recognised that this specific scheme is more involved than a simple screening procedure that the researcher is advocating in the

current thesis.

Miller and Krawczyk (2001) further identify a number of factors that influence the development of dysphagia training programmes. The first factor relates to how nurses perceive themselves in terms of their role within the multidisciplinary team i.e. as a member of the team who informs dysphagia assessment and management and or as someone who must comply with what is asked of them. This factor also relates to how nurses perceive their role in dysphagia management i.e. they may perceive nurse screening is a 'backdoor' tactic for replacing the SLTs' role in dysphagia assessment. The authors also consider the core differences in how SLTs versus RGNs are taught skills; nurse training is more procedural based whereas the SLT's training places more emphasis on 'finely tuned' observation skills.

Dysphagia training programmes must account for these perceptions and style of learning to ensure nurses are engaged in the training programme from the outset through agreeing objectives at the planning stage, defining and clarifying roles and voicing expectations. A variety of teaching styles is advocated to blend reflective learning, theory and 'hands on' practical application and the emphasis must be placed on team working. These factors will be addressed in the nurses' dysphagia screening education programme within this study.

2.20. Dysphagia screening

Screening identifies patients at sufficient risk of a disorder to justify a subsequent diagnostic assessment or may direct preventative action (Lang and Secic 2006). The purpose of dysphagia screening is to identify people at risk of dysphagia and its associated complications, to determine whether a patient is safe to feed orally and where signs of dysphagia are identified, to initiate early referral to a SLT/clinician competent in dysphagia assessment and treatment. Dysphagia screens take a number of different forms ranging from observing for coughing following swallowing fluid, measures of laryngeal dysfunction such as wet voice after swallowing to tests of pharyngeal sensation. The utility of some of these measures will be described in more detail in Table 5. Regardless of method, the process will typically include interviewing the patient or reviewing the medical notes, observation of swallowing with or without

water, observing for signs of dysphagia such as coughing following ingestion of fluids or delayed swallowing and communication of results and recommendations (Martino 2000, Mann *et al.* 2007). Patients with a positive dysphagia screening outcome (i.e. those who are found to evidence signs of dysphagia) are then maintained nil orally and referred to the SLT for a detailed bedside assessment. The screening procedure should ideally be simple and quick to use and should yield a pass or fail outcome to decide whether the patient can resume eating and drinking or needs to be referred for a clinical dysphagia assessment by the SLT. It has been noted however; that the majority of screening procedures reported in the literature are narrow focused and place their emphasis on identifying overt signs of aspiration as defined by videofluoroscopy (see glossary). These reported procedures are explored later in this chapter.

In describing the benefits of dysphagia screening, Hinchey *et al.* (2005) reported on a national stroke practice study that evaluated the impact of formal dysphagia screening on the incidence of pneumonia following stroke. The authors found that formal screening protocols prevented pneumonia even after adjustment for stroke severity. They further estimated that delivery of formal dysphagia screening procedures saves up to 8,300 lives and prevents around 40,000 pneumonias annually; highlighting the important role they play in acute stroke management.

In order to determine the essential characteristics and development of screening tests, Lang and Secic (2006) suggest that an accurate screening test needs to be highly sensitive, i.e. it identifies most of the people who have the disorder. A screening test also needs to be specific, i.e. it identifies people who do not have the disease. Lang and Secic (2006) further advocate the need to compare the screening test to an appropriate reference or 'gold standard'; which for bedside assessment of swallowing function is the speech and language therapy full clinical dysphagia assessment and for aspiration risk is the modified barium swallow/videofluoroscopy. Sackett *et al.* (1991) suggest specific guidelines for appraising the viability and effectiveness of diagnostic and screening tests. The guidelines have been integral to the whole research programme from the assessment, analysis and framing of the research problem through to the design, empirical and evaluation phases of the research. The criteria are described below in the context of the decision analysis applied to the literature review of salient studies of dysphagia screening tests and criteria (see pages 76-80). The criteria will be returned

to in Chapter 4 to describe the planning and design phases of the study.

2.20a. Eight guiding principles for determining the quality and clinical usefulness of screening studies (adapted from Sackett *et al*. 1991)

1. Has there been an independent, 'blind' comparison with a 'gold standard' of diagnosis?

The reference ('gold') standard i.e. videofluoroscopy for detection of aspiration and clinical dysphagia assessment for determining dysphagia at the bedside must be clearly defined and must be the best available method to definitively assess the presence or absence of dysphagia. The investigators who judge and interpret the features of the test being evaluated should not be aware of the results of the reference standard and vice-versa. This is because knowledge of one test result can influence the interpretation of the other, leading to 'expectation' bias. The comparison of the screening or diagnostic test with the accepted reference standard is usually measured in terms of kappa (see glossary). Kappa is a measurement of the degree of agreement that has occurred between the test and the reference standard over and above that which would be expected by chance alone. Sackett *et al.* (1991) suggests that when the comparison is between a screening test and a reference test, kappa becomes a measure of the tests accuracy.

In terms of the application of this principle to the literature review, only studies which have used a blinded study design and compared the test or screening criterion with an appropriate reference standard to determine its accuracy will be considered for potential inclusion in the decision analysis for specific evidence based dysphagia screening criteria.

2. Has the diagnostic test been evaluated in a patient sample that included an appropriate spectrum of mild and severe, treated and untreated, disease, plus individuals with different but commonly confused disorders?

The test should be applied in the study to patients at different stages of the target disease. This is because the selection of patients can affect the results of the test and in particular, the distribution of the stages of disease may affect the sensitivity and specificity of the test (refer to glossary). This means if studies only used patients

evidencing overt signs of severe dysphagia, one would expect the sensitivity of the test to be artificially high. The value of an accurate dysphagia screening test is its ability to distinguish between people presenting with dysphagia and those presenting with normal phenomena such as slowed swallowing that may be misinterpreted as dysphagia. It is therefore necessary to ensure that patients with a variety of presentations of dysphagia, as well as a variety of symptoms such as normal age related slowed swallowing, have been included in the study sample.

3. Was the setting for this evaluation, as well as the filter through which study patients passed, adequately described?

The setting for conducting the procedures should be described in sufficient detail along with inclusion and exclusion criteria to permit replication of the study.

4. Have the reproducibility of the test results (precision) and its interpretation (observer variation) been determined?

Different observers must ideally agree upon the interpretation of the same test result and the same observer judging the same test on two different occasions should reach the same conclusions. However, it is possible to have different results within and between observers in a certain proportion of cases. Observer variability should be investigated and explained by the authors of the diagnostic or screening study. Attempts to measure observer variability should be made in the study.

5. Has the normal been defined sensibly as it applies to this test?

As described, normal and abnormal swallowing are variously described. In terms of describing normal swallowing, this may be defined differently according to the aims of the study author. For example, normal swallowing could be defined diagnostically as the absence of signs of dysphagia as determined by the application of certain diagnostic criteria, according to risk factors e.g. not carrying risks of developing aspiration pneumonia or percentile such as the percentage of the normal population who may be expected to have for example a slow swallowing rate. Sackett *et al.* (1991) suggest that the reader should be satisfied that the definition used within the study is clinically sensible. Definitions of normal, which are based on diagnostic, or screening test results assumes there is a normal distribution for “normal”. One way of accounting for this is

to calculate the probability of a test outcome being normal or abnormal; otherwise known as predictive values (see glossary). This is calculated by comparing the test outcomes with gold standard test outcomes. As noted, only those studies that compared their test with an accepted gold standard were given credence for their reported outcomes. Checks were made for calculations of predictive values as well as operational definitions (see glossary) for dysphagia and 'normal' swallowing.

6. If the test is advocated as part of a cluster or sequence of tests, has its individual contribution to the overall validity of the cluster or sequence been determined?

This suggests that any single criterion of a screening test should be evaluated in the context of its clinical use. A test that requires significant expertise to implement such as testing pharyngeal sensation may have limited clinical usefulness if RGNs do not feel equipped to carry this out. Literature reporting criteria that required technical skill for implementation were reviewed but excluded from the decision analysis (see page 76).

7. Have the tactics for carrying out the test been described in sufficient detail to permit their exact replication?

The procedures to conduct the screening or diagnostic test should be described in sufficient detail to permit replication of the study. This implies description of issues related to the preparation of patients and to technical aspects of the procedure. The literature was evaluated for these details as a necessary precursor for determining criteria for potential inclusion in the HeDSS.

8. Has the utility of the test been determined?

A diagnostic test must perform well technically to be worth using. The technical precision of a test is measured in terms of sensitivity and specificity; positive and negative predictive values; and likelihood ratios (refer to glossary). These features of the test should be clearly reported in the study or calculated from raw data when not reported by the authors. The perfect screening test will have high sensitivity for determining patients who are dysphagic and moderate to high specificity to determine patients who are not dysphagic. The closer to 100% sensitivity and specificity, the more accurate the test. In reality, however, there is often a trade off between sensitivity and specificity i.e. as the one increases the other tends to reduce (Singh and Hamdy 2006).

Sackett (1991) suggest that the ultimate criterion for a screening test is whether the patient is better off for it, i.e. does the screen help identify a treatable disorder? The risks associated with dysphagia are largely preventable and for this reason, screening in the early, critical stages of an acute stroke is a necessary part of dysphagia management (SIGN Guidelines 2004, Royal College of Physicians: Intercollegiate Working Party for Stroke 2000).

2.21. Limitations of current dysphagia screening procedures

Most screening procedures described in the literature have focused on identifying overt signs of aspiration, not on addressing a simple process for identifying people at risk of dysphagia and associated complications that require referral to a SLT for assessment and treatment. Martino *et al.* (2000) in a systematic review of dysphagia screening, reported that most published clinical dysphagia evaluation methods were related to observation of symptoms and laryngeal signs (63% of the methods evaluated). Martino also found that the screening accuracy of these tools was limited because of poor study design and the predominant use of aspiration as the single diagnostic reference. Nonetheless, they concluded that while the evidence for benefit from dysphagia screening was limited, it did suggest an associated reduction in pneumonia incidence, length of hospital stay, and hospital costs.

A review of the literature has highlighted that there are no universally agreed dysphagia screening criteria or tool utilised nationally or internationally. This is exemplified by studies and reviews carried out worldwide e.g. in Canada (Martino *et al.* 2000), Australia (Mann and Hankey 2001), Singapore (Sitoh *et al.* 2000) and Britain (Ramsey *et al*. 2003). A number of reasons have been cited for this; namely, limitations of validity due to differences in methodologies, limited sample sizes and the lack of randomised controlled trials.

In a systematic review of studies of dysphagia screening tests, Martino *et al.* (2000) reported significant variability in the accuracy of screening tools and tests for dysphagia and aspiration. Some tests were found to be predictive for determining signs of dysphagia presence (i.e. they were sensitive to its presence) but not predictive for ruling out people without dysphagia (i.e. were not specific to its absence), others were found to

be specific but not sensitive, or neither. Only ten articles out of 154 identified as reporting criteria within this domain, employed sufficiently robust methodologies to inform decisions regarding the accuracy of impaired swallow function. Oral, pharyngeal and laryngeal impairment as well as abnormal neurological signs were compared with aspiration seen on videofluoroscopy (a dynamic X-ray of swallow function and the current 'gold standard' for the detection of aspiration and dysphagia). The study designs were generally weak i.e. no evidence of investigator blinding or measurements of reliability was found in any of the studies and very few included operational definitions for either screening tests or outcome values. Statistical power calculations were not used in any of the studies and small sample sizes further weakened any report of evidence for screening accuracy and benefit.

Failure on a 50ml water swallow test; where the patient is observed drinking from 10 ml medical aliquots and impaired pharyngeal sensation were the only tests with reasonable evidence of accuracy for determining signs of aspiration. Severe dysarthria (difficulty with the articulation of speech) had very high specificity for ruling in aspiration (100%) but sensitivity was fairly low (47%). Subsequent studies have not found any link between abnormal pharyngeal sensation and aspiration (Leder 1997, Bastian and Riggs 1999). Furthermore, these findings are flawed by poor study designs e.g. it is unclear whether amounts trialled in the videofluoroscopy condition matched the 50ml water swallow test and both tests only assessed for aspiration (the entry of material below the vocal cords into the airway). This is a relevant point as the significance of aspiration of material into the airway has not been fully established particularly with regards to how much can be aspirated before causing adverse outcomes (Marik 2001). In addition, aspiration of small amounts occurs frequently in the normal population without causing problems (Shifrin and Choplin 1996; Marik and Kaplan 2003).

Ramsey *et al*. (2003); McCullough *et al*. (2005) and Singh and Hamdy (2006) similarly note that the accuracy of reported screening tests is limited due to poor study design, failure to report sensitivity and specificity in some studies, small sample sizes with few exceeding sample sizes of 100 and the predominant use of aspiration detected on videofluoroscopy, as the diagnostic reference. Ramsey *et al.* (2003) conducted a systematic literature review and database search in her evaluation of screening tools and criteria. The sensitivity of the tools evaluated was variable (59% to 91%) but of these,

coughing during swallowing, speed of swallowing and delayed swallowing were the most predictive for dysphagia and its complications. Logistic regression further identified impaired consciousness levels and weak voluntary cough as independent predictors for aspiration. Mann and Hankey (2001) examined the predictive value of criteria associated with impaired swallowing in an attempt to identify independent clinical signs. They noted that an age over 70 years, stroke severity, a male gender, weakness of the palate, inability to clear the mouth after swallowing and coughing or gurgly voice quality were predictive of dysphagia and aspiration risk. However, a recent study of voice quality (Warms and Richards 2000) failed to confirm a link between voice quality and aspiration risk when compared to videofluoroscopy.

Coughing during and following swallowing has been identified as predictive for dysphagia and aspiration by a number of key studies and reviews. Mari *et al*. (1997); Daniels *et al*. (1997) and McCullough *et al.* (2001b) report association of coughing during swallowing can provide a correct diagnosis or positive predictive value in up to 84% and accurately predict the proportion of patients with negative test results who are correctly diagnosed (i.e. the negative predictive value) in up to 78% of patients. In Daniel's study the presence of two out of six clinical features (changes in voice quality, slurred speech/ dysarthria, abnormal volitional cough, cough after swallow, abnormal gag reflex, and voice change after swallow) predicted greater dysphagia severity on videofluoroscopy. Logistic regression identified abnormal volitional cough and cough with swallow as independent predictors of aspiration. The diagnostic accuracy of measuring coughing during swallowing does however depend on the preservation of the cough reflex and sensitivity of the pharynx. This means that some forms of dysphagia that result in an impairment in pharyngeal innervation or silent aspiration are unlikely to be detected by the bedside clinical dysphagia assessment (Bakheit 2001, Galvan 2001). Therefore, the absence of coughing during or following swallowing cannot be taken as an independent measure of swallowing safety.

2.22. Dysphagia screening tools and recent developments

2.22a. Timed Test of Swallowing

One promising test that is reported to be both specific and sensitive for the detection of

dysphagia in the literature is measuring the time taken to swallow a given volume of water known as the 'Timed Test of Swallowing' (Nathadwarawala *et al.* 1992, Hughes and Wiles 1996, Hinds and Wiles 1998 and Wu *et al*. 2004). Nathadwarawala *et al.* (1992) investigated the use of the timed test of swallowing and the indices obtained from the test. The patient is timed drinking a quantified amount of water i.e. 100ml-150ml. A ratio of swallowing performance is determined by the time taken to swallow divided by the volume swallowed. Normative data has been determined for average volume per swallow (ml) and the average swallowing speed or capacity (ml per second) in men and women. A swallowing volume of less than 10 ml per second suggests the presence of dysphagia. Hinds and Wiles (1998) investigated 115 acute stroke patients within 72 hours of hospital admission. Using normative data obtained from a previous study of healthy volunteers, they report sensitivity of speed per swallow as 97% and specificity as 69%. In their study, the test was validated against the decisions of medical and nursing staff to refer patients for assessment and the intervention of the SLT. The authors note that the referrers' prior knowledge of the study taking place on the wards may have influenced the validity of this test. Also the volunteers used for obtaining normative data were healthy and did not report any difficulty swallowing thus they were not necessarily representative of a population drawn from a normal sample i.e. people with age related swallowing difficulties but not necessarily dysphagic. Studies carried out by Nathadwarawala *et al*. (1992) and Hughes and Wiles (1996) report high levels of specificity and sensitivity in their studies but used patients with mixed neurological aetiologies or MND making direct comparison difficult due to the often different presentation of dysphagia in these populations. Wu *et al.* (2004) report the sensitivity of swallowing speed in detecting swallowing dysfunction in acute stroke patients as 85.5% and the specificity as 50%. Specificity increased to 91.7% when the test included choking or wet voice. However, the results of this study are limited due to a small sample size (n=45) and selection bias in that the investigators already knew the reported swallowing difficulties of the patients.

2.22b. Burke Dysphagia Screening Test (BDST)

The BDST (DePippo *et al*. 1994) was designed to identify patients in the rehabilitation phase post stroke at risk for pneumonia, recurrent upper airway obstruction, and death.

The test was used on 139 consecutive stroke patients and seven areas were evaluated for their presence or absence as outlined:

- Bilateral stroke;
- Brainstem stroke;
- History of pneumonia in the acute stroke phase;
- Coughing associated with feeding or during 3 oz (90ml) water;
- Failure to consume one-half of meals;
- Prolonged time required for feeding;
- Non-oral feeding programme in progress.

Presence of one or more of these features is scored as failing the Burke Dysphagia Screening Test. Failing the screen triggers a referral to the SLT for full assessment of swallowing. A fundamental weakness of the design and evaluation of the BDST is that it was not compared with evidence of dysphagia using another method i.e. concurrent validity was not measured. Also, the tool was developed in the rehabilitation setting only with non-blinded raters and no reported measures of reliability. Perry (2001) notes that the development of this test is non-specific and calls into question the replicability, intelligibility and cost benefit for adopting this as a screening tool.

2.22c. Standardised Swallow Assessment

The Standardised Swallow Assessment (SSA) was originally developed as an audit tool by Ellul and Barer in 1993 and has subsequently been evaluated in larger populations (Ellul and Barer 1996, Perry 2001b). The SSA consists of three stages; the first evaluates conscious levels and postural control along with oromotor control including lip and tongue movements, gag reflex, voluntary cough and voice quality. Patients who are sufficiently alert and able to maintain an upright head posture proceed to three teaspoonfuls of water. Observations of laryngeal movement, signs of pooling of fluid around the opening to the airway (‘wet’ or ‘gurgly’ voice) or signs of aspiration (coughing, choking, respiratory distress) are made after each swallow. If the patient manages these teaspoons of water with adequate laryngeal movement and without displaying a wet, gurgly voice or coughing/choking/respiratory distress, the patient

proceeds to the third stage; drinking 60mls of water from a glass. Observations are made for the same signs as in stage two as well as the speed of drinking (although this is not directly timed) and whether the patient is able to finish the glass. A final judgement is made as to whether the patient's swallowing is 'safe', 'possibly unsafe' or 'definitely unsafe'. Outcome measures for the evaluation of this test were based on a relative risk calculation for developing lower respiratory infection as well as referrals to speech and language therapy over a 12 month period. A number of limitations are apparent in the development and evaluation of the SSA. Ellul and Barer's studies (1993, 1996) provide data pertaining to the reliability and validity of the tool but there is no explanation or reference to the statistic techniques used to develop and evaluate the tool.

Perry (2001) further evaluated the SSA and reports sensitivity as 94%, specificity 75%, positive predictive value = .84 and negative predictive value = .89. Limitations were again apparent in the design and evaluation of this study. The performance of the SSA was compared against summative clinical judgements of dysphagia derived from a range of sources including a range of SLTs and doctors rather than a single source blinded to SSA screening results. The data are considered retrospectively rather than making direct comparisons of SSA versus 'gold standard' outcomes, which does not allow for replication. In addition, the data relating to the nurses' use of the tool is measured by recruiting a range of nurses with varying levels of competence in screening from nurses still undergoing supervised practice to fully competent nurses. The range of screening conditions is similarly widely variable. Data used to calculate sensitivity and specificity were gained from a review of medical notes, nursing notes and SLT documentation bringing into question the robustness of the data collection and analysis. The specifics of the training programme are not provided limiting replication and the rationale for why the nurses are trained for a day and supervised undertaking a minimum of five screens is not explained. Davies (2001) notes nurses have debated the practicality of carrying out the SSA. He cites that nurses consider lack of available time limits their ability to perform dysphagia screening using the SSA. The need for a quick and simple screening tool for nurse use is again highlighted.

2.22d. Massey Bedside Swallow Screen

The Massey Bedside Swallowing Screen (Massey and Jedlicka, 2002) is a 14-point

screen that examines alertness, dysarthria, aphasia, oral motor abilities, gag reflex, and incorporates observations of a 1-teaspoon water swallow followed by a 60 cc water swallow. Measurement outcomes of the screen were determined when two research assistants used the tool. Sensitivity and specificity were reported as 100% determined by monitoring the participants' charts for 5 days to track dysphagia indicators. There are a number of fundamental design limitations to this study, the study sample was very small recruited from one site (n= 25) thus affecting the generalizability of the findings. In addition, the measurement properties of the Massey Bedside Swallow Screen were assessed when two research assistants used the tool allowing for measurement bias. Education given to the screeners is not described.

2.22e. The Gugging Swallow Screen (GUSS)

The Gugging Swallow Screen (Trapl *et al.* 2007**)** is a graded bedside screen consisting of four subtests developed as a means to identifying patients at risk of aspiration and dysphagia. The first subtest checks for alertness, sitting posture of 60 degrees or greater and a check that the patient can perceive the tester's face, spoon and food texture. Checks are then made for weak or absent voluntary coughing, drooling/management of saliva, spontaneous coughing before, during or after swallowing and voice change (wet/gurgly voice change). This test differs from other screening tests evaluated in that it starts with semi solid food textures and progresses towards solid textures. The decision to commence with semi solid textures is based on the observation that "stroke patients are better at swallowing semisolid textures diet than liquids". To determine content validity, scores pertaining to deglutination of fluids during FEES were compared to scores relating to scores obtained for the patient swallowing semisolid diet textures. The screen was evaluated with 50 acute stroke patients; 20 patients were seen by two independent therapists to establish inter-rater reliability and thirty were tested by stroke nurses.

Clearly a sample size of 30 is too small to give any credence to the reported high inter-rater reliability between the two raters (kappa = .83) and the 100% sensitivity, 69% specificity and NPV of 100% as an estimation of the tool's predictive validity. The tool was evaluated for its accuracy in detection of aspiration as opposed to its accuracy in

detecting an abnormal/unsafe swallow regardless of aspiration. The logic of starting the screen with semisolid textures assumes that the patient is able to tolerate this consistency with an apparent disregard for oropharyngeal dysphagia/unsafe feeding. To date there is no evidence that aspiration of small trials of water increases a patient's risk of developing complications (Garon 1997) whereas it may be argued that aspiration of semisolid textures may be more difficult to remove from a dysphagic patient's airway particularly where the cough response is suppressed (Marik and Kaplan 2003).

2.22f. Toronto Bedside Swallow Screening Test (Tor-BSST)

The Toronto Bedside Swallowing Screening Test (Martino *et al.* 2009) is a recently validated screening tool which uses criteria based on a systematic review of clinical dysphagia tests (Martino *et al.* 2000). Of the 49 clinical tests reviewed, only four were selected based on reported high likelihood ratios. These were impaired pharyngeal sensation, performance on the 50 ml water test (a water swallow test where water is drunk in 10ml medical aliquots), impaired tongue movements and general dysphonia (split into 'voice before' and 'voice following' a water bolus).

The basis for the validation of the Tor-BSST was the hypothesis that an abnormal finding on Tor-BSST positively relates to an abnormal finding on videofluoroscopy. The tool was validated on 311 consecutively admitted stroke patients recruited from both acute and rehabilitation hospital settings (103 acute stroke patients and 208 stroke patients in rehabilitation settings). The screen evaluates patients for alertness and participation in the test, followed by tests of oral motor function including an evaluation of voice quality and pharyngeal sensation and the presence of coughing during or following swallowing. Small amounts of water are administered using a preset protocol and the patient is monitored for signs of impaired swallowing as determined by coughing during and for one minute following swallowing water and/or a 'wet' or hoarse voice. The test is estimated to take around ten minutes to administer. Inter-rater reliability for the administration of the Tor-BSST by trained nurses screeners was established for the first 50 patients screened (intraclass correlation coefficient = .92). Pharyngeal sensation was subsequently eliminated from the screening tool as it met the exclusion criteria of contributing less than five percent of the total score.

The validity of the screen was measured prospectively over three years, recruiting 27 trained nurses from two rehabilitation hospitals in Ontario, Canada and 28 trained nurses from two acute hospitals. Twenty percent of enrolled patients were randomly allocated to clinical dysphagia assessment and videofluoroscopy assessments administered by separate blinded expert raters. Patients with a positive screen but not randomized were assessed clinically by a blinded expert rater.

Overall comparison of screening with clinical judgments (n=151) derived a sensitivity of 91.7%. However, specificity was found to be only 36.9%. Comparison of 59 screenings with videofluoroscopy judgments derived a sensitivity of 91.3% and specificity of 66.7%. It was concluded that the Tor-BSST offers an accurate method by which to identify stroke patients with dysphagia in the acute and rehabilitation setting with confidence that patients with a negative screening outcome will not have dysphagia.

The Tor-BSST clearly goes a long way to developing a standard validated approach to screening for dysphagia in both acute and rehab settings. Sensitivity of the screening tool is high suggesting that patients with a negative screening result will not have dysphagia. However, measures of specificity yielded a high false positive rate i.e a high number of patients who were screened as dysphagic were not assessed as dysphagic using clinical assessment as well as videofluoroscopy. There is some debate within the literature whether aspiration or any physiological abnormality observed on videofluoroscopy defines dysphagia (see 2.15a and 2.21). Pharyngeal sensation and wet voice quality as an indication of aspiration or dysphagia has not been supported in the literature. Kidd *et al.* (1993) noted abnormal pharyngeal sensation was demonstrated with all patients aspirating on videofluoroscopy but sensation was found to be abnormal in 40% of patients not aspirating. Similarly, Warms and Richards (2000) did not find that a wet voice was indicative of dysphagia or aspiration (refer to Table 5). Only comparing those patients screened as positive with clinical dysphagia assessment allows for threats to external validity i.e. selection bias in that dysphagia is more likely to be assessed as present in patients who have been screened as positive (see Table 8). None-the-less the Tor-BSST offers a sensitive standardised method for identifying stroke patients with dysphagia in the acute and rehabilitation settings.

2.23 Determining evidence based dysphagia screening criteria from the literature: an Action Research process of enquiry

The action research process necessitates systematic, carefully considered phases. Stringer (2008) describes these processes as "Look-Think-Act". The first phase requires gathering information, the second phase requires analysing the information for significant features and the third 'acting' phase necessitates use of the newly formulated information to develop solutions to the research problem. This process was applied during the conceptual phase of the study to determine dysphagia screening criteria that the literature reported as predictive for determining the presence and absence of dysphagia. As noted on pages 10-11, the literature review yielded a large body of literature related to dysphagia and dysphagia screening. A number of papers reported studies of criteria and tests as predictive for determining signs of dysphagia. It was therefore important to undertake a robust critique process before deciding on the utility of the criteria and tests reported.

2.23a. Definition and analysis of validity for determining the development and evaluation of dysphagia screening tests

As a starting point to evaluating the literature for evidence based dysphagia screening criteria, it was important to consider what qualifies screening criteria as 'evidence based'. Lang and Secic (2006) suggest that screening or diagnostic tests need to be reliable and valid. Test reliability and validity are further described below in terms of how these related to a comprehensive review of salient literature for dysphagia screening criteria:

Test Reliability: When measuring a dysphagia screening test's ability to determine the presence or absence of signs of dysphagia, it is important to estimate the consistency or reliability of the measurement. One way to determine this is to have two or more observers rate the same subjects and then correlate their observations. This is an example of inter-rater reliability e.g. the screening decisions as determined by a novice nurse may be correlated with the screening decisions of an expert nurse when using the same screening tool with the same patients. Reliability is a prerequisite for measurement of validity as a screening tool cannot be valid if it isn't reliable. It was therefore a

necessary consideration when reviewing the literature for evidence based dysphagia screening criteria and tools to check that evaluations of the test's reliability had been made.

Test Validity: A test is valid if it truly measures what it purports to measure (Sackett *et al.* 1991). In the context of evaluating dysphagia screening tests, validity was defined as a statistical association of dysphagia screening binary decision scores (dysphagia present =1, dysphagia absent =0) with the same binary decision scores of another objective measure of evaluating dysphagia such as by bedside assessment of swallowing or videofluoroscopy. This is measured using the kappa coefficient (see glossary). Thus, for dysphagia screening, validity is determined in terms of the proportion of all screening results that are correct (based on comparison with an accepted gold standard such as videofluoroscopy).

Construct Validity: This is the term given to a test that measures a construct (here the presence or absence of signs of dysphagia) accurately. There are three components of construct validity; concurrent validity, content validity, and predictive validity:

- **Concurrent Validity.** This is the measurement of a tests ability to distinguish between groups that it should theoretically be able to distinguish between e.g. people with normal age related swallowing and people with dysphagia. In order to determine concurrent validity, the test should be compared with a valid test or accepted gold standard measurement. To assess the concurrent validity of a dysphagia screening test, one would expect to see that the screen had been evaluated with people presenting with dysphagia as well as with people with normal swallows.

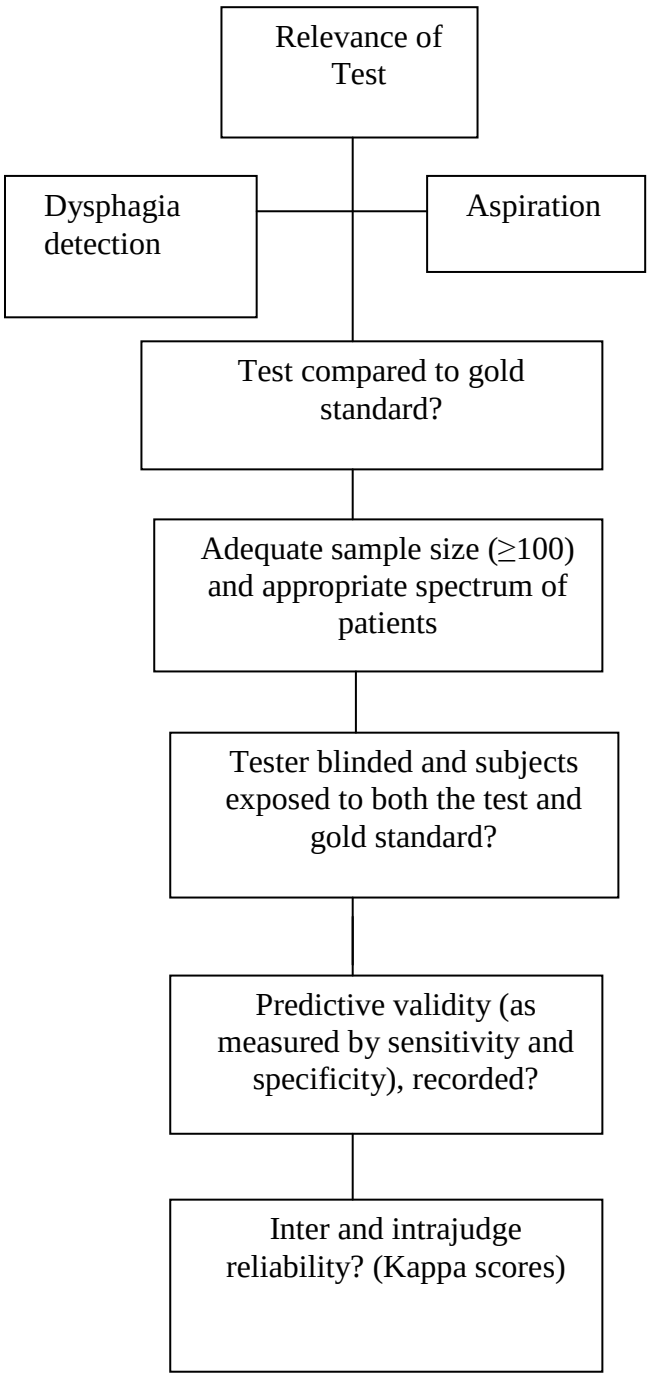
- **Content Validity:** Content validity is the extent to which the questions on a test are representative of the trait, behaviour, or attribute that is being measured. This is more pertinent to tests that assess abstract concepts such as behaviour or knowledge. A related area is face validity which refers to whether a test "looks valid" to the examinees who use the test or experts reviewing it and is therefore as such a non-statistical method. Although this is a useful factor when reviewing the

literature for tests, which purport to determine the presence or absence of dysphagia, it has greatest relevance to the planning and design of a dysphagia screening tool and will be returned to in the following chapter.

- **Predictive Validity:** In order for a test to be a valid screening device for determining dysphagia or the development of aspiration, it must demonstrate predictive validity (see Figure 6). Predictive validity is measured by calculating a correlational coefficient to compare for example, signs of dysphagia determined through screening with a diagnosis of dysphagia assessed independently using a bedside assessment of swallowing. If they are directly related, then a prediction may be made regarding dysphagia prevalence based on the dysphagia screen.

2.24. Determining, evaluating and selecting criteria reported as valid predictors for the presence or absence of dysphagia

In order to determine which criteria were evidence based for inclusion in the research-screening tool, a decision analysis was undertaken (figure 6). This was informed by the eight guiding principles for determining the quality and clinical usefulness of screening studies advocated by Sackett and colleagues (1991) as outlined previously (refer to pages 61-64). The process for the decision analysis was based on recommendations for evaluating studies that purport diagnostic tests adapted from Greenhalgh (2001). The identification of these screening criteria then enabled identification of evidence-based practice. Decisions on inclusion of criteria were made by examining the robustness of the criteria as reported in the literature. These are summarized in Figure 6 and Table 5 on pages 76 to 79.



Inclusion Criteria:

- Non-instrumental screening criteria with reported predictive validity i.e. moderate to high sensitivity and specificity (>0.70) for determining dysphagia & aspiration presence and absence.
- Homogenous sample i.e. acute stroke patients and sample sizes ≥100.
- Criteria tested against reference standard e.g. (videofluoroscopy).
- Sound methodology i.e. investigator blinding, calculation of inter and intra-judge reliability.

Exclusion Criteria

- Interpretation of criteria that requires technical training e.g. pulse oximetry,
- Non homogenous sample i.e. a sample that includes mixed aetiologies
- Reported low sensitivity/specificity for a test criterion i.e. below 0.70
- Small sample sizes (less than 100)
- Poor study design e.g. lack of investigator blinding, criteria not compared with gold standard.

Figure 6: Decision Analysis Tree for evaluating the robustness of studies and the predictive value of criteria for determining the presence or absence of signs of dysphagia

Table 5: An overview of screening criteria reported in the literature as predictive for determining the presence/absence of dysphagia

Screening Criteria	Author/s	Purpose of Test	Sample	Evidence	Concurrent Validity?	Include Criteria? (See Inclusion criteria)
Wet voice	Daniels *et al.* (1997)	Aspiration	59 stroke pts	63% sens 64% spec	VF	Exclude- small sample, moderate sens and spec
	Warms and Richards. (2000)	Aspiration	23 pts with neurological dysphagia	No association between wet voice and aspiration of material after a swallow.	VF	Findings do not support link between wet voice and aspiration but study limited by small sample size.
Voice change post swallow	Daniels *et al*. (1997)	Dysphagia	59 ischaemic stroke pts	Sens 31% Spec 88%	VF	Reject- small sample and low sensitivity
Drooling	Linden *et al.* (1993)	Aspiration	249 mixed neurology	No relationship found	VF	Reject-low sensitivity and PPV
	McCullough *et al.* (2005)	Aspiration	165 acute stroke	23% sens 94% spec PPV 56 NPV 78	VF	Reject-low sensitivity
Pharyngeal sensation	Kidd *et al.* (1993)	Aspiration	60 acute stroke patients	Abnormal sensation demonstrated with all patients aspirating on VF but sensation abnormal in 40% of patients not aspirating	VF	Reject- unreliable findings

Screening Criteria	Author/s	Purpose of Test	Sample	Evidence	Concurrent Validity?	Include Criteria? (See Inclusion criteria)
Dysphonia	Daniels *et al*. (1998) McCullough *et al* (2005)	Dysphagia Dysphagia and aspiration	55 ischaemic stroke patients 165 acute stroke patients	76% sens 68% spec 54% sens 86% spec PPV 54	VF VF	Reject small sample size Reject- low sensitivity
Volitional cough	McCullough *et al* (2005) Daniels *et al* (1997) Smithard *et al.* (1997)	Aspiration Dysphagia Aspiration	165 acute stroke pts 59 ischaemic stroke pts 121 acute stroke patients	Sens 42% Spec 79% PPV 39 NPV 81 Sens 26% Spec 89% k=.56 PPV41 NPV 80 Identified by logistic regression as independent predictor of aspiration	VF VF VF	Reject-low sensitivity Reject small sample size and low sensitivity Consider as a caution sign for screening
Abnormal gag	Daniels *et al* (1997) Ellul *et al.* (1993) Davies *et al.* (1995)	Dysphagia & Aspiration Dysphagia Aspiration	59 ischaemic stroke patients 156 consec stroke patients 140 healthy adults	Sens 54% Spec 67% No relationship demonstrated between gag and outcomes Up to 30% of young adults and 44% of healthy older adults have absent gag reflexes	VF VF VF	Exclude low sensitivity + not supported in literature

Table 5: An Overview of Screening Criteria Reported in the Literature as Predictive for Determining the Presence/Absence of Dysphagia (continued)

Screening Criteria	Author/s	Purpose of Test	Sample	Evidence	Concurrent Validity?	Include Criteria? (See Inclusion criteria)
Dependence for feeding	Langmore *et al* (1998)	Aspiration and dysphagia	189 elderly pts, mixed aetiologies	Sens. 34% Spec. 90% PPV 48%	Prospective clinical outcomes	Mixed aetiologies but important consideration for how to provide trials of water in study
Dysarthria	Martino *et al* (2000)	Aspiration	Systematic review	Severe dysarthria 47% sens 100% specificity	VF	INCLUDE CRITERION
	Logemann *et al* (1999a)	Aspiration	200 adult pts (stroke =69)	64% sens 75% specificity	Consecutive tests (blinded)	
	McCullough (2005)	Dysphagia + aspiration	165 acute Stroke	78% sens 46% spec interjudge reliability 1.0	VF	
Coughing during or after the swallow	Daniels *et al.* (1997)	Dysphagia	59 acute stroke	Identified as independent predictor for aspiration	VF	INCLUDE CRITERION
	Logemann *et al* (1999a)	Aspiration	200 adult pts (stroke =69)	Sens 78% spec 58%	VF	
	McCullough *et al* (2001b)	Dysphagia & aspiration	165 acute stroke	Sens 45% spec 82%		

KEY (Adapted from Lang and Secic 2006)

Construct validity*:* the extent to which the swallowing screening criterion/test, measures the presence/absence of risks for dysphagia and/or aspiration).
Sensitivity*:* the number of patients with a swallowing problem who are correctly identified as having a swallowing problem by the screening procedure.
Specificity*:* the number of patients with no swallowing problem who are correctly identified as having no swallowing problem by the screening procedure.
Positive predictive value*:* the sensitivity of the screening procedure for detecting swallowing difficulty x the true prevalence of dysphagia in the population.
Negative prediction value*:* the specificity of a screening procedure for accurately detecting absence of swallowing difficulty x the true prevalence of a lack of dysphagia in the population.
Likelihood ratios*:* A combination of the sensitivity and specificity of a swallowing screening test that tells you how much a positive or negative result changes the likelihood that a patient would have dysphagia

2.24a. Summary of criteria identified as predictive for the detection of dysphagia and aspiration risk

A decision analysis exercise applied to studies to determine dysphagia screening criteria with reported predictive value for determining signs of dysphagia and risk of aspiration identified five criteria:

- Reduced consciousness;
- Poor/recumbent posture for feeding;
- Speed of swallowing;
- Coughing during and following swallowing;
- Severe Dysarthria/slurred, imprecise speech.

2.25. Conclusion

Dysphagia is a debilitating condition characterised by difficulty in the oral preparation of the swallow and/ or moving material from the mouth to the stomach. It is apparent from the literature review that determining normal and abnormal swallowing is not a straightforward science. This has been complicated by the fact that dysphagia and aspiration are variously described and defined e.g. according to anatomical landmarks, the presence or absence of signs of aspiration as detected on VF or clinical signs such as a wet voice. Dysphagia in the acute stroke population accounts for the highest prevalence in up to 65% of the acute stroke population (Daniels *et al.* 1998, Mann *et al.* 1999, Department of Health 2007). SLTs are the lead clinicians within the multidisciplinary team for the assessment and management of dysphagia. However, increased demands on the service for dysphagia assessment within the last ten years and the typical working patterns of SLTs (i.e. not working weekends, evenings and Bank holidays) has resulted in SLTs not being able to assess swallowing within the recommended 72 hours (Sentinel Audit 2007). This is complicated by the common practice of placing newly admitted acute stroke patients nil orally until the swallow is assessed by a SLT (Ellul and Barer 1996) meaning patients may have to wait for anything up to six days before their swallow is tested. There is emerging evidence that early detection of dysphagia in patients with acute stroke not only reduces complications of dysphagia but reduces related health costs too. This has resulted in national drives for nurses to screen for dysphagia within the first 24 hours of the patient's

hospitalisation using a valid tool. It is clear from the review of the literature that because of weaknesses in study design, there remains limited consensus for what this valid dysphagia-screening tool should be. Although the literature reports there is no single test which can reliably indicate the true absence or presence of dysphagia, the potential for identifying and combining a minimal set of criteria into a dysphagia screening tool for use by nurses had not been explored. A decision analysis applied to papers reporting studies of dysphagia and aspiration screening/assessment criteria was undertaken and subsequently, five screening criteria with reported predictive criteria were identified.

This study focused on the design, development and evaluation of the valid dysphagia-screening tool for use by registered nurses with acute stroke patients. Videofluoroscopy has been a suggested gold standard for the detection of dysphagia but has been shown to have variable inter-rater reliability (Kuhlmeier *et al.* 1998) yielding false positive and false negative results and fails to address the bigger picture of oral feeding failure as highlighted in figure 5. Some individual may for example be seen to aspirate on videofluoroscopy but may have an adequate cough response or immune system for the development of pneumonia to be prevented.

The focus of interest in this study is not for nurses to diagnose dysphagia or aspiration but to determine those acute stroke patients who require a clinical dysphagia assessment from those who demonstrate normal swallowing and therefore do not require assessment of swallowing by the speech and language therapist. According to Stringer (2008), Action Research is not just based on problem solving but is focused on gaining insight to improve practice. The literature review identified screening criteria with reported evidence and predictive value for determining the presence and absence of dysphagia. These criteria fell into the domains for evaluating territories related to oral feeding (see Figure 5) i.e. situational factors (upright posture), control of breathing (coughing during or following swallowing), swallowing (speed of swallowing), neurological problems (poor conscious levels). Having determined these criteria, it was felt necessary to further scope the research problem to determine whether the lack of consensus reported in the literature was mirrored in clinical practice. This required a survey of dysphagia screening practice to determine the frequency of use of evidence based dysphagia screening criteria, which is further described in Chapter 3.

Chapter 3: Assessment, Analysis and Framing of the Research Problem: Identification of the frequency and application of valid screening criteria used in practice settings in England and Wales

3.1. Introduction

As outlined in Chapter 2, a dysphagia screening tool needs to be reliable for measuring the target disorder consistently and valid for predicting its presence or absence when compared to an appropriate reference standard assessment such as the clinical dysphagia assessment performed by a SLT. Sackett (1991) suggests that for an assessment or screening tool to be valid, it needs to demonstrate high sensitivity to detect most of the people with the disease and have moderate to high specificity (see glossary) to detect some people without the disease. Following a comprehensive literature review, the lack of consensus for robust and predictive dysphagia screening criteria was ascertained. A decision analysis undertaken to check papers reporting studies of dysphagia criteria revealed only a small number of dysphagia screening signs with moderate-high sensitivity and specificity and thus validity for determining signs and associated risks of dysphagia (see Table 5). In order to determine whether SLTs are evidence based in their selection of screening criteria, a survey of acute NHS Trusts across England and Wales was undertaken.

3.2 Aims of Survey:

- To compare and evaluate the frequency of use of screening criteria, which the literature reported as having predictive validity for determining the presence of dysphagia;
- To evaluate the degree of variation in screening practice for the earliest point in the screens when decisions are made to place the patient nil by mouth;
- To determine the range of nurse grades screening for dysphagia across NHS trusts in England and Wales.

3.3. Population and sample

Clinical Lead SLTs for dysphagia i.e. SLTs with a minimum of five years experience in dysphagia who take the lead role for dysphagia within their trust. These were selected from 40 acute NHS Trusts falling within the 28 strategic health authorities in England and the 12 acute NHS Trusts in Wales.

3.4. Methods and materials

A survey of 52 acute NHS Trusts in England and Wales was carried out via Emails (see Appendix 3). Twelve acute NHS Trusts in Wales were listed on the NHS Wales Website and 162 acute hospitals Trusts in England were listed on the 'NHS England' web site. A number of the lead SLTs working in England who were initially contacted, indicated that they covered several acute hospital Trusts. Subsequently, to ensure that the screening tools requested came from an even spread of Trusts, a decision was made to contact acute NHS Trusts that fell within the 28 Strategic health authorities in England. Addresses and telephone numbers for each SLT department were made available from the Royal College of Speech and Language Therapists' Practice Register. Where information was not available, telephone numbers were accessed from 'NHS England' and 'NHS Wales' web site listings. Letters were sent to each Trust requesting contact details for the lead therapist for dysphagia. Inclusion criteria were outlined (see Appendix 2) to ensure the survey questions were only answered by a suitably qualified, lead SLT for Dysphagia.

Emails were sent to the lead SLTs working within the 28 strategic health authorities in England (n=40) and the 12 acute NHS Trusts in Wales. The email explained the purpose of the survey and included loosely framed questions and a request for the lead SLTs to provide a copy of their screening tools. A decision was made to use this format rather than multi-choice questionnaires in order to elicit the broadest and most honest responses possible. The questions and the rationale for the same are outlined.

3.4a. Survey questions and rationale

1. Do nurses screen for dysphagia in your Trust? Yes/No. If not please explain why.

Rationale: To determine the number of Trusts in the selected sample that carry out dysphagia screening programmes and to determine possible future barriers to developing a research dysphagia-screening programme including training for nurses.

2. What is the range of nurse grades trained to undertake screening in your Trust? (Please provide a breakdown of the proportion of grades trained).

Rationale: To determine what is happening in clinical practice and to further identify what the representative sample of nurse grades should be for the eventual design and evaluation of the HeDSS.

3. Please could you provide a copy of the dysphagia screen employed within the Trust? (Return in the enclosed stamp addressed envelope).

Rationale: To determine the range and frequency of evidence based dysphagia-screening criteria used in clinical practice.

3.5 Procedure

Trusts indicating that they were not screening were contacted by phone to the explore reasons why. Trusts that failed to respond within one month were contacted a second time. If Trusts indicated that they were not screening and had not explained their reasons for this through their emailed response, they were contacted again by phone to explore these. Raw data were recorded on a database using the double data entry method (see Appendix 1 for definition of terms). Emerging criteria collated from the Trusts were prioritised according to which heading/label best described the way of asking about for example, conciousness (see Appendix 3 for a decription of the sorting exercise 3). The agreed upon criteria headings are detailed later in Figures 9 and 10.

3.6 Results of survey

The survey response rate was 96% (*n* = 49). Eleven Trusts indicated that they were not using dysphagia screening by nursing staff. As noted, the lead SLTs working in these trusts were contacted by phone to explore their reasons for choosing not to screen. A number of reasons were provided (Figure 7).

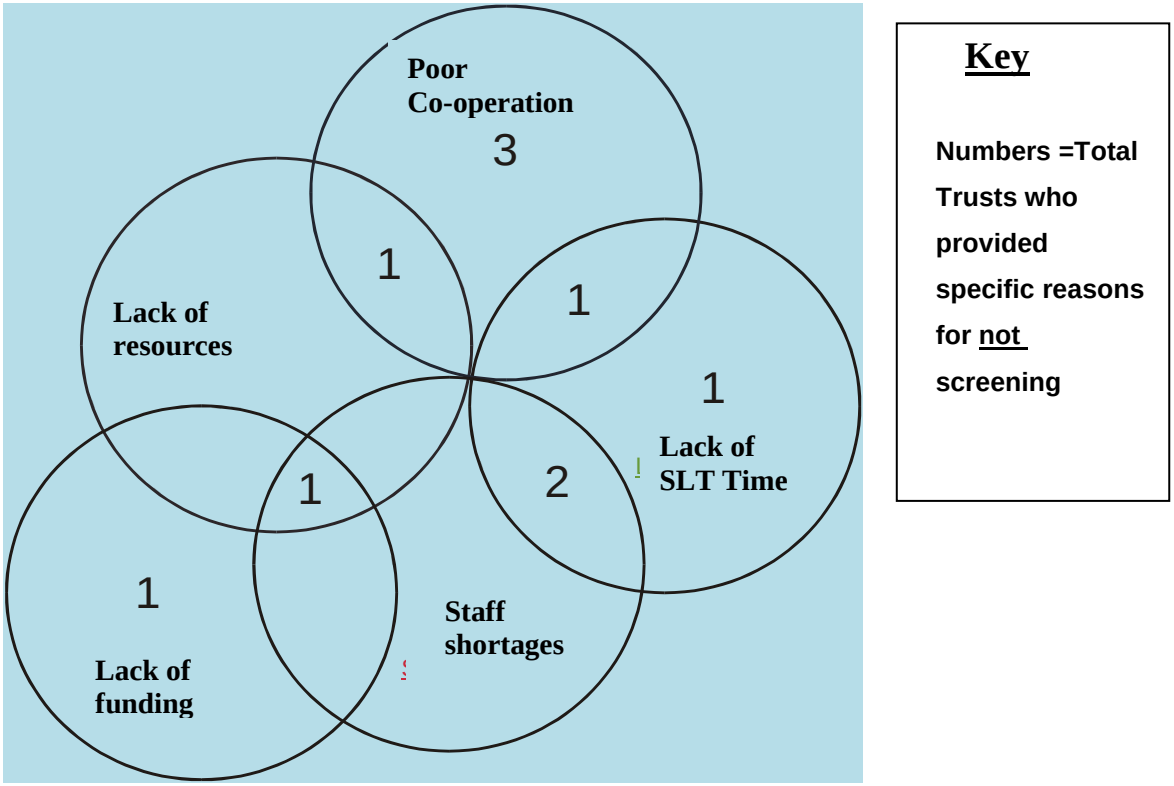


Figure 7: Reasons Provided By Trusts for Not Screening

3.6a. Nurse grades trained

No Trust was able to quantify the proportion of specific nurse grades trained, but gave general information on the range of grades. The typical grade of nurses undertaking dysphagia screening was D grade RGNs (newly qualified) and above accounting for just over 89% (see Figure 8).

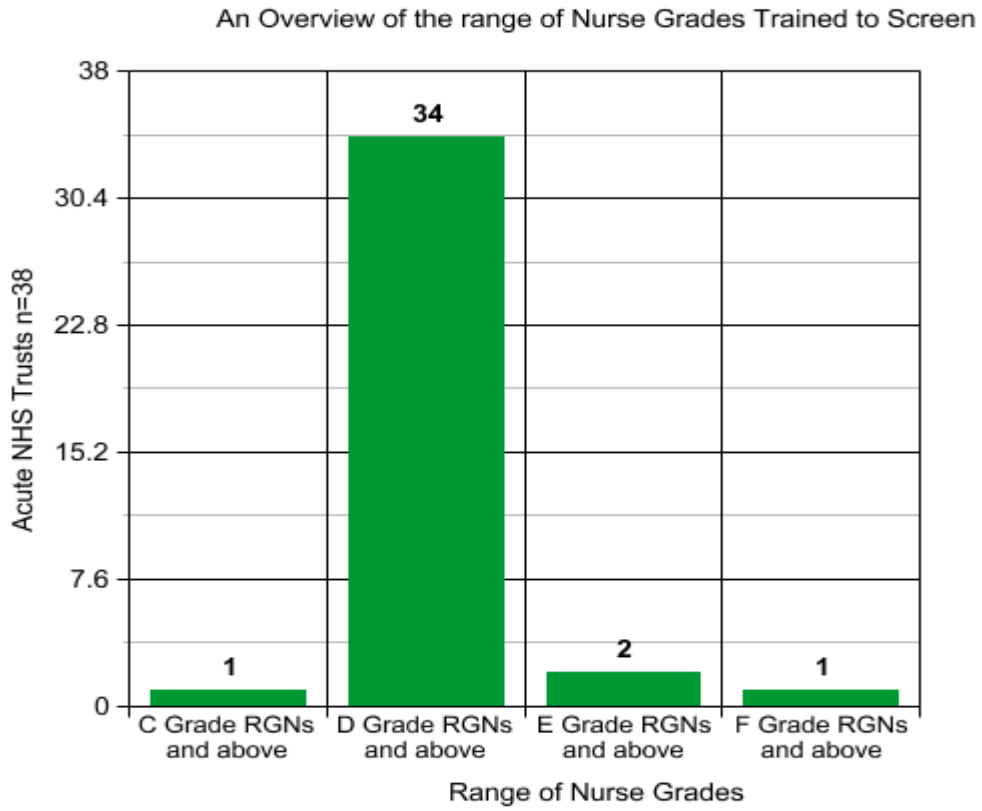


Figure 8: An Overview of the range of nurse grades trained to screen for dysphagia

3.6b. Dysphagia screening training programmes

Although not directly requested or surveyed, a number of lead SLTs provided copies of their dysphagia screening protocols which outlined the dysphagia screening training requirements. Dysphagia screening education programmes (n=14) identified during the survey, differed substantially in both training content and duration. Training programme duration ranged from two hours to three days. This variation was echoed in the literature; Heritage (2001) for example, reported 1½days of training whereas Lees *et al.* (2006) reported half a day of training.

3.6c. Frequency of use of evidence based screening criteria

The frequency of use of evidence-based criteria varied widely across trusts, (Figures 9 and 10). Emerging criteria: A total of 35 out of 38 trusts used voice change/wet voice as a

screening criterion despite a lack of evidence to support this, yet only four out of 38 trusts included speed of swallowing despite support in the literature for its ability to predict dysphagia and aspiration (Table 5*).*

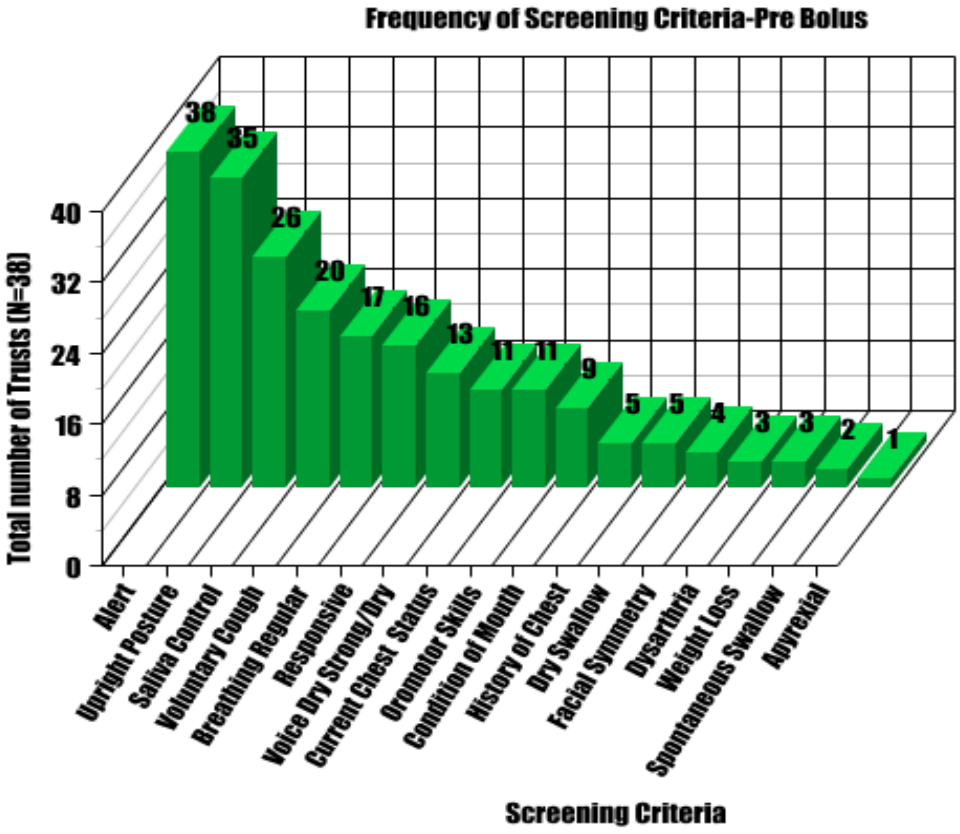


Figure 9: Frequency of screening criteria used pre- bolus trials

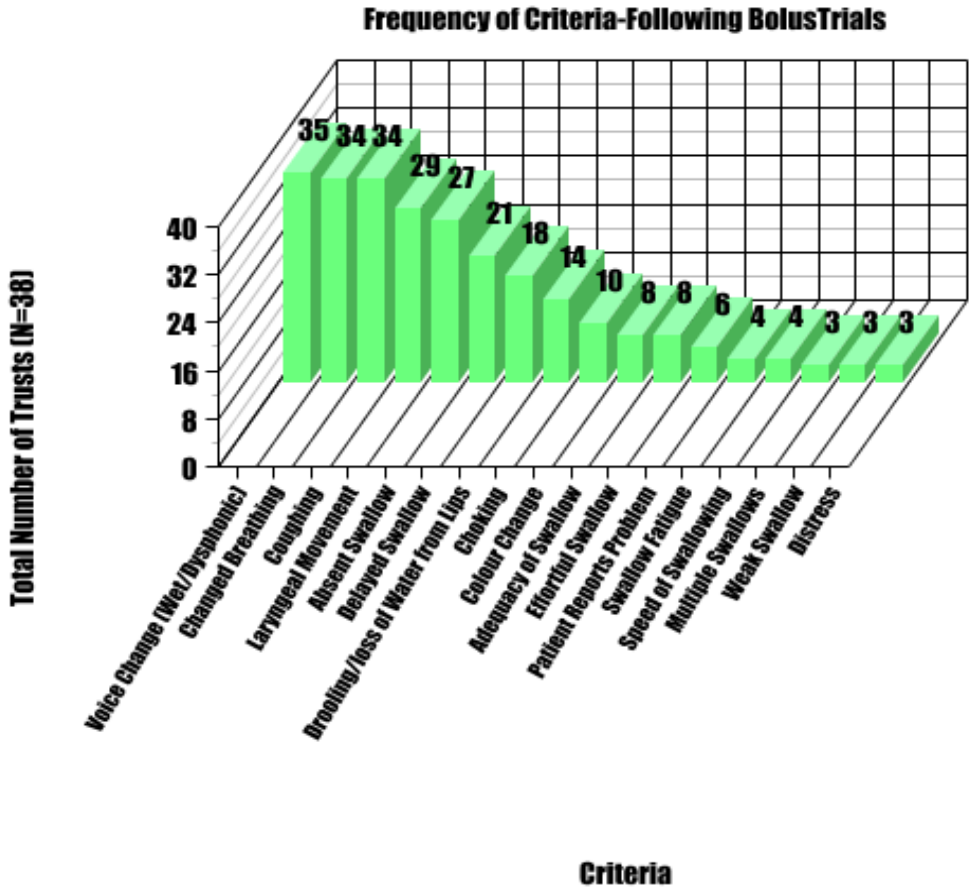


Figure 10: Frequency of use of criteria following the presentation of trial boluses

Criteria varied widely across trusts confirming a lack of consensus for screening criteria and practice as illustrated in Figures 9 and 10.

3.6d. Screening practice and use of nil by mouth

The minimum amount of water trialled before determining nil by mouth status and the emphasis placed upon ‘negative signs’ deemed to indicate unsafe swallowing, also varied widely. Thirty nine percent of tools required nurses to place the patient nil by mouth if coughing, drooling or failure to swallow was noted following one teaspoon of water, 13% made the same decision based on half a teaspoon of water, 2.5% on failure to perform a dry swallow and 5% on failure to elicit a voluntary cough (see Figure 11).

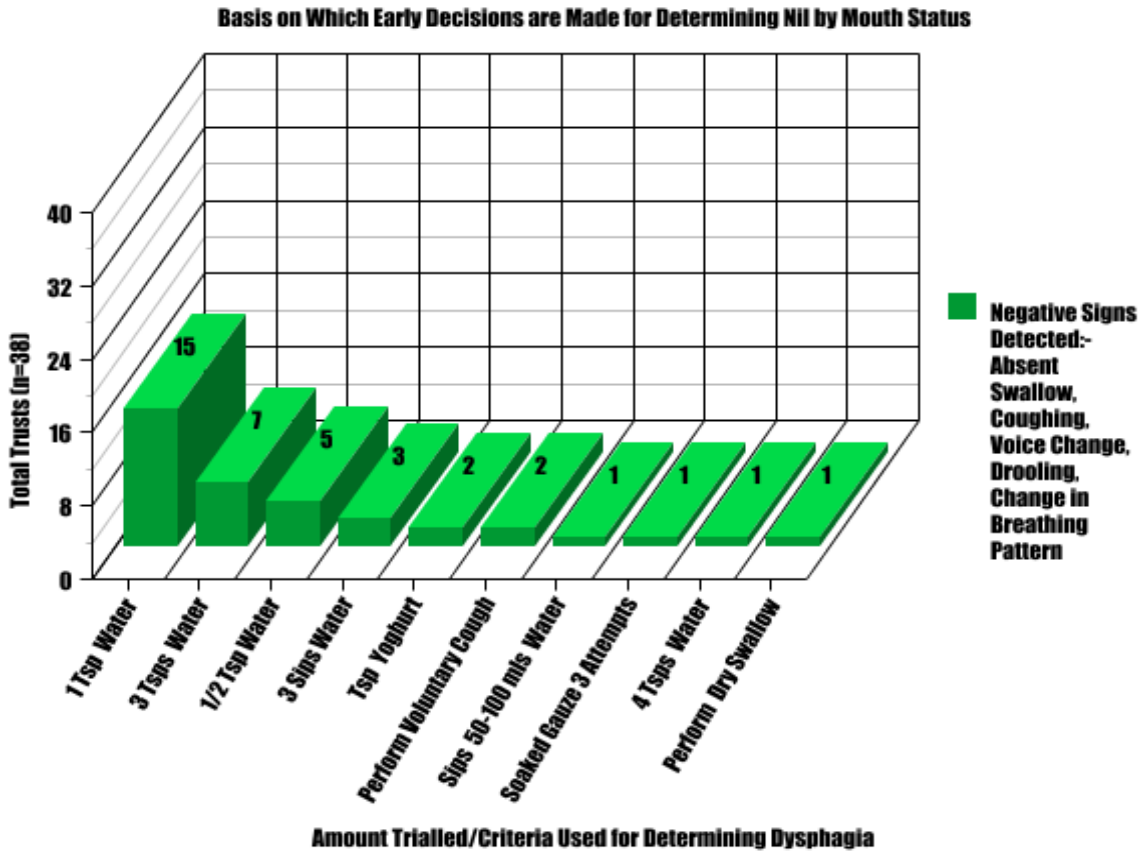


Figure 11: Basis on which early decisions are made for determining nil by mouth status

The popularity of the criteria used in dysphagia screening tools submitted for the survey did not reflect the evidence base for their predictive criteria (See Table 5).

3.7. Discussion

3.7a. Reasons for not screening

Screening for dysphagia is recommended within the first 24 hours of hospitalization. Thirty-eight out of the 49 responding Trusts employed dysphagia screening, however, a significant number (n = 11) did not. This fits in with the national picture; in 2006, the National Sentinel Audit for Stroke reported that only 55% of patients received screening for dysphagia in Wales compared to 67% in England and 62% in Northern Ireland

(Healthcare Commission, 2006).

Reasons cited in this survey for not providing screening programmes highlighted lack of staff time, lack of cooperation and lack of resources. Miller and Krawczyk (2001) interpret the possible reasons for poor uptake of nurse screening training and emphasise the need to define roles in the multidisciplinary team, encourage interdisciplinary working by agreeing common goals and objectives, and to apply theoretical learning to practical situations.

3.7b. Nurse dysphagia screening training

Although not specifically surveyed, nurse dysphagia screening training programmes differed in terms of time and content and the range of nurse grades trained. This potentially reflects the lack of a framework to inform the development of education programmes for training nurses in this domain. The literature commonly reports the need for an interdisciplinary approach in order to overcome barriers to training. This approach embraces 'cultural' factors such as role definition, together with the necessity for education in key areas relevant to dysphagia such as the role of physiological functions that include oral and pharyngeal phases of swallowing (Heritage, 2001; Miller and Krawczyk, 2001). Ultimately there may be a need to:

- Select nurses who are motivated to take on the role of screening;
- Address cultural beliefs of nurses in terms of role definition and expectations;
- Address the logistical and practical considerations of nurses being afforded the time to attend training.

Given that lack of SLT time, lack of resources and poor cooperation were cited as reasons for not screening, the fundamentals of dysphagia screening training may need to be incorporated into pre-registration nurse education programmes. This may potentially encourage nurses to see this role as essential to the nursing care of this patient group.

3.7c. Screening criteria

The frequency of use of evidence-based dysphagia screening criteria, i.e. cough during and following swallowing, speed of swallowing and severe dysarthria, was generally low,

however the frequency of use of certain criteria which the literature does not support for its ability to predict people at risk of dysphagia and its complications was high. Hence based on the survey results, the frequency of the criteria used in dysphagia screening tools does not reflect the evidence base for their predictive criteria (Table 5). The variation in screening criteria employed by NHS trusts surveyed, confirms a lack of consensus with the evidence-based screening criteria and practices identified in the literature review. This suggests that consistency in the design of screening tools is variable. Tools may therefore vary in robustness and their validity in correctly identifying patients in need of referral to the SLT for clinical dysphagia assessment. Further research in this domain is essential to identify and evaluate the validity of a dysphagia screening tool that utilises evidence based screening criteria with swallowing amounts which reflects typical swallowing.

3.8. Conclusion

The results of the survey reflected a lack of consensus for dysphagia screening tools and criteria. There was clear evidence for the requirement for a framework to inform clinicians of minimum amounts of water to trial before decisions can be made to discontinue screening and place the patient nil by mouth. The frequency of use of criteria reported in the literature as having moderate to high predictive validity was relatively low (e.g. 10.5% for speed of swallowing). The converse was true for criteria with reported low predictive validity for determining signs of dysphagia or aspiration (voice change/wet voice 92% and change in breathing pattern 89%).

These findings provide extremely limited evidence of SLTs using evidence based decision making to identify combinations of criteria for screening tool design and construction. A recent study demonstrated that the time taken to initiate swallowing increases significantly with oral dryness (Gaviao *et al.* 2004). There is no evidence within the literature that suggests that aspiration of water is noxious. However, there is a common misconception of aspiration of water being harmful which leads to decisions of unsafe swallowing being made based on minute amounts. Dysphagia management policies appear to adopt the maxim ‘better safe than sorry’ which may result in normally swallowing patients being denied food and drink until assessed by a SLT. The findings highlight the need to explore whether the identification of predictive criteria for determining the presence and absence of signs of dysphagia can improve the accuracy of identification and exclusion of acute stroke

patients requiring clinical dysphagia assessment by the SLT. A detailed summary and analysis of this survey are reported in Head *et al*. (2007).

At the conclusion of the Problem Assessment and Framing Phase of the Action Research Process, the literature review, conceptual framing of the problem and survey of dysphagia screening practices has revealed a problem with the lack of consensus for a dysphagia screening tool for use by nurses. The problem assessment is operationalised below:

3.8a. Operationalisation of emerging problem

- Screening of acute/newly hospitalised first time stroke patients for dysphagia is recommended within the first 24 hours using a valid method (i.e. a method that has been accurately measured to detect the presence or absence of signs of dysphagia and to therefore prioritise patients appropriate for assessment of swallowing by the SLT).

- Due to limitations of validity and design within previous studies, no agreement exists on what this valid method should be. This lack of consensus for a valid method was highlighted in an audit of dysphagia screening practices across England and Wales (Head *et al.* 2007).

- The literature review has revealed no individual sign is highly predictive for determining signs of dysphagia or for ruling dysphagia out. The potential for combining a minimum combination of predictive criteria and measuring their ability to detect signs/absence of signs of dysphagia has not been explored.

3.9. Research questions

The key research problem explored is whether a minimal combination of predictive criteria for determining the presence and absence of signs of dysphagia used within a dysphagia screening tool, can improve the accuracy of identification and exclusion of acute stroke patients requiring clinical dysphagia assessment by the SLT. This was centred on measuring whether the Head Dysphagia Screen for Stroke (HeDSS) is as valid as a clinical dysphagia assessment for determining the presence or absence of signs of dysphagia and whether the patient requires a referral to the SLT for a clinical dysphagia assessment.

If the outcome showed poor agreement, it would be necessary to establish whether this was due to (a) poor reliability of the SLTR's clinical dysphagia assessment (b) due to poor reliability of the nurses' use of the HeDSS or (c) due to weak validity of the screening tool itself. To facilitate this, a number of key research questions needed to be answered in a staged sequence within the Empirical Phase of the Action Research programme:

1. Is the SLTR's clinical dysphagia assessment consistent with another SLT of equivalent knowledge and experience for determining the presence and absence of dysphagia?

Rationale: It is essential to identify the inter-rater reliability between two expert SLT's (one of whom is the SLTR) when undertaking a clinical dysphagia assessment. This assessment will be used as the reference (gold standard) against which evaluation of concurrent validity of the prototype screening tool will be measured in Question 3 (see below).

2. Can RGNs use a newly designed HeDSS in a way that is consistent with an expert using the tool?

Rationale: This will evaluate whether RGNs agree with the SLTR when both are using the HeDSS. This phase will elucidate potential problems with the nurses' training programme and/or design of the tool.

3. Are the clinical decisions made by RGNs using HeDSS, consistent with an expert SLT performing a clinical dysphagia assessment for determining signs of dysphagia and the appropriateness of referring acute stroke patients for swallowing assessment?

Rationale: This will explore whether a nurse assessment using the HeDSS agrees with an SLT assessment using a clinical dysphagia assessment for determining the presence or absence of signs of dysphagia and whether the patient requires clinical dysphagia assessment. A lack of agreement will highlight a weakness in the predictive value of combining the evidence-based criteria.

The following study addresses the need for a robust and valid dysphagia screening method and describes the design, development and evaluation of evidence based dysphagia

screening criteria combined in a screening tool for use by nurses with acute stroke patients.

Chapter 4: Design and Planning Phase

4.1. Determining characteristics essential to the experimental design

In its simplest sense, the proposed research design is a measurement study. There are a number of characteristics essential to measurement without which the development, design and evaluation of a valid screening tool cannot be properly interpreted. These are explored in more detail below:

4.1a. Reliability:

A reliable test measures whatever it measures consistently (Baumgartner *et al.* 2008) e.g. for the Head Dysphagia Screen for Stroke (HeDSS) to be classed as reliable, a patient whose dysphagia status had not changed if screened twice under the same test conditions, would have identical outcomes. It is important to remember that reliability is not measured, it is estimated. A brief description of test reliability in relation to evaluating the literature for evidence based dysphagia screening was made in Chapter 2. Characteristics of reliability and its relevance the study design is further outlined in Table 6.

Table 6: Characteristics of reliability, definitions and relevance to the study design

Test Reliability	Definition	Relevance to Study Design
Inter-rater reliability	Inter-rater reliability refers to the agreement of responses from two or more raters, each evaluating the same endpoint or making the same measurement, in multiple subjects.	This measurement was planned to address ***research question 1*** i.e. to determine whether the SLTR's clinical dysphagia assessment was a reliable standard by which to measure the validity of the Head Dysphagia Screen for Stroke (HeDSS)
Test-Retest Reliability	Used to assess the consistency of a measure from one time to another. Researchers estimate test-retest reliability when administering the same test to the same sample on two different occasions	This measurement was planned to ***address research question 2*** i.e. to determine whether the HeDSS in the hands of nurses was reliable for detecting signs of dysphagia and for determining acute stroke patients appropriate for referral to the SLT for a clinical dysphagia assessment.
Intra-rater reliability	The degree of stability exhibited when a measurement is repeated under identical conditions by the same rater.	This is referred to within the literature review when evaluating the reliability of bedside detection of dysphagia and instrumental assessment of aspiration

4.1b. Validity:

A test is valid if it measures what it is supposed to measure (Baumgartner *et al*. 2008). Test validity and how this related to determining evidence based dysphagia screening criteria from the literature review and decision analysis, was described in Chapter 2. Validity has a number of other strands; many of which have informed the design and planning phases of the present study. These are further described:

Internal Validity: This relates to the extent to which the conclusions about causal relationships are likely to be true. Within the study design, this refers to the degree the outcomes of the HeDSS for determining acute stroke patients appropriate for assessment of swallowing by the SLT, are likely to be true, in view of the measures used, the research setting, and the research design. In order that the conclusions drawn from the study could be measured as internally valid, there was a need to plan and design the research study. Haslam and McGarty (2003) describe nine sources of threat to internal validity. These principles were considered in the research design and are described in Table 8 along with measures taken to prevent or limit these threats.

External Validity: External validity refers to the degree to which the conclusions drawn from the study may be generalised to other study samples and settings at other times. As with internal validity, several components and perceived threats need to be considered. An analysis of external validity is provided in Tables 7 and 8 to elucidate how the design of the research study was planned and measures were undertaken to attempt to prevent or limit design flaws:

Table 7: Characteristics of internal validity, perceived threats and how these were controlled for within the research design (adapted from Haslam and McGarty (2003) Fraenkel and Wallen (2003) and the Cochrane Handbook accessed 2007).

Components of Internal validity	Perceived Threats to Internal Validity	How controlled for within study design
History refers to events occurring previous to or during the study that could alter the outcome of the results.	RGNs could use dysphagia screening criteria previously learnt, to inform their decision making rather than criteria used within the prototype screening tool to determine signs of dysphagia and the appropriateness of referral to SLT.	This was addressed through ensuring that the RGNs recruited for the study met the inclusion criteria for not having been exposed to dysphagia screening previously.
	RGN and Trust SLT participants may have already known the feeding status of the patients if for example, the patients had already been assessed by the Trust SLT and the nurses had accessed this information.	Measures were taken to remove cues relating to the patient's feeding status from the patient's bedside such as bedside signs and jugs of water (refer to research protocol Appendix 8 and ward based protocol Appendix 10).
Maturation pertains to any unanticipated changes that occur in the subjects during the course of the study that might affect the results of the study. These changes may include physiological changes within the patient sample.	Natural recovery of swallowing function or worsening of the patient's condition due to a medical complication could occur if the time period between a patient being screened and subsequently assessed was prolonged. The patients could also have become fatigued if screened and assessed in very close succession.	This was addressed within the research design by ensuring that the patients were screened using the HeDSS and assessed using the reference standard within 1 working day (refer to Appendix 8).

Components of Internal validity	Perceived Threats to Internal Validity	How controlled for within study design
Testing: A threat to the required procedure produced by a previous administration of the same test or other measure.	The patient may have become less sensitised on how to carry out the requests of the screening tool e.g. to drink continuously 50ml of water from a glass. Failure on the first attempt may be due to lack of understanding for the requirements of the test which could have potentially improved on the second screen.	Measures taken to standardize the instructions for the test were made so that all patients received the same instructions. The RGNs were trained and supervised in the administration of the screening tool prior to the data collection phase (refer to Figure 13).
Instrumentation is concerned with the effects on the outcome of a study due to inconsistent use of a measurement instrument.	The conducting of the screening tool and application of the screening criteria could have been carried out differently by the RGNs due to misunderstanding of the criteria/specific language of the screening tool.	Focus groups looking at the way RGNs interpret the specific language and criteria used within the screening tool were carried out. The specific nurse education programme for dysphagia screening was clearly outlined and the criteria and instructions used within the tool were operationalised so that RGNs were clear on its wording and implementation.
Mortality/differential attrition: Loss of participants due to mortality or due to withdrawal from the study.	Patients recruited for the study were acutely ill. This could pose a threat if the patients were approached for their inclusion in the study but not seen for some time later.	Test A and Test B took place within a maximum of 8 hours limiting this effect.

Table 8: Characteristics of external validity, perceived threats and how these were controlled for within the research design

Components of External Validity	Perceived Threats to Validity	How controlled for within study design
Population Validity the extent to which the results of a study can be generalized from the specific sample that was studied to a larger group of subjects	**Patient population:** This would pose a threat if the sample were drawn from an accessible population e.g. all patients referred to the SLT department rather than the target population, (i.e. all acute stroke patients admitted into the hospital). **Nurse population:** The study could recruit RGNs who did not represent the typical grades of nurses i.e. junior through to senior or recruit nurses that were not characteristic of typical nurses working with acute stroke patients e.g. trained in another country, do not usually work with acute stroke patients etc. If the study did not stipulate that RGNs be recruited at representative nurse grades there would be a potential for e.g. senior nurses to perform differently to novice RGNs in their decision-making.	The study population used a convenience sample of referred acute stroke patients. The ward base protocol asked that all acute stroke patients were referred to the SLTR. Exclusion criteria (see Appendix 8) prevented patients such as those who suffered previous strokes from being recruited. The study recruited RGNs at representative grades i.e. a relative novice and an experienced RGN (refer to glossary) as determined by the survey outlined in Chapter 3. Trends in differences in decision outcomes were evaluated during the data analysis.

Explicit description of the experimental treatment: (not sufficiently described for others to replicate)	As SLTR, I could potentially fail to adequately describe how I conducted the study, making it difficult to determine whether the results are applicable to other settings.	The specific steps involved in the quasi experiment are detailed in the chapters relating to the empirical phases.
Hawthorne effect: Subjects perform differently because they know they are being studied.	External validity of the experiment could be jeopardized because the findings might not generalise to a situation in which the researcher is absent e.g., the RGNs could proceed to undertake screening with drowsy patients.	This was accounted for in the nurse education programme for dysphagia screening where the nurses were initially supervised undertaking screening. This allowed the RGNs opportunity to become familiar with this technique.
Novelty and disruption effect (anything different makes a difference).	The screening procedure may be problematic because it is unique to the RGNs.	The training programme was explained in detail, to allow reproducibility.
Experimenter effect (it only works with this experimenter). This also refers to the possibility that an experimenter may sometimes unintentionally influence the performance of participants in a study	The screening may have only 'worked' due to my own intervention such as the way I trained the nurses to use the prototype dysphagia screen.	The use of "blind" data collection procedures was undertaken as a means of minimizing threats to external validity due to experimenter effects.
Specificity of variables is concerned with the extent to which the variables in a study are adequately described and operationally defined. In addition, the description and definition of variables must employ measurement instruments or observational devices that are themselves reliable and valid.	The SLTR may unintentionally influence the performance of the RGNs in their decision making for determining the presence of dysphagia and the appropriateness of referral to SLT I fail to explain the variables of the study in sufficient detail to allow reproducibility.	Operational definitions of variables were provided as a measure to minimise this threat to external validity and to facilitate consistency of use of the HeDSS. The use of widely agreed upon definitions or multiple competing definitions were provided where possible.

4.2. Rationale for research design

Sackett and colleagues (1991) advocate that any study of new diagnostic or screening tests must demonstrate that the new test is accurate in distinguishing patients with the target disorder (here this is dysphagia) from patients without the disorder. They propose that the ideal diagnostic study is a comparative prospective study in which all participants undergo the new test as well as the reference ('gold') standard test and the results are independently and blindly interpreted by at least two assessors. This has informed the decision to employ a validation study design which ultimately compares the HeDSS outcomes for determining signs of dysphagia and the decision to refer patients appropriate for dysphagia assessment against a reference standard for determining signs of dysphagia at the bedside; the clinical dysphagia assessment performed by a SLT. In this study, I refer to my own bedside clinical dysphagia assessment as the 'reference standard'.

4.2a Key aspects of the research design to determine the validity of the HeDSS

Use of consecutively selected patients

Use of consecutively selected patients limits selection bias. Unfortunately within the current research study it was not possible to recruit consecutively referred patients as this would necessitate the researcher being available 24 hours a day, seven days a week. The study population comprised of a convenience sample of hospitalised patients.

Comparison of the 'diagnostic test' with an appropriate reference/ 'gold' standard

The reference gold standard (see glossary) should be clearly defined and be the best available method to assess the presence or absence of the target disease. Clinical dysphagia assessment by the SLT is the accepted reference standard. It is recognized that as with most 'gold standards' this is not perfect (see page 52 for a detailed evaluation).

The diagnostic test and the reference ('gold') standard should be performed on all participants to avoid investigator bias.

It is important that all patients are exposed to the screening tool and the reference standard. If for example the reference standard (the clinical dysphagia assessment) is only performed on patients who have been screened as dysphagic, there would be potential for biasing the outcome.

The test and the reference standard should be measured independently so that the assessor/user of the diagnostic test (here the RGNs) and the reference standard (the clinical dysphagiae assessment as used by the SLTR) are blind to one another's results until all data are collected.

This is addressed in the design of the research programme and is covered in the research protocol (see Appendix 8).

The patient sample should include an appropriate spectrum of subjects (mild and severe; treated and untreated cases).

In order that the information obtained is useful and transferable, the literature suggests that a new diagnostic or screening test should be applied to a minimum of 100 patients with an appropriate spectrum of disease (Baumgartner *et al.* 2008). The screening tool needs to be applied to patients with differing severities and different presentations of dysphagia including those with no obvious swallowing difficulties and those with similar symptoms who do not have dysphagia e.g. normal elderly swallow. This is due to the potential of the distribution of dysphagia severity affecting the sensitivity and specificity of the test i.e. the HeDSS would most likely generate high sensitivity if only tested on patients with obvious signs of dysphagia (e.g. those coughing on own secretions) and would generate low sensitivity if only used on patients who did not display any signs of dysphagia. This has been accounted for in the proposed selection of patients (a convenience sample of 100 hospitalised acute stroke patients).

The methods for performing the diagnostic test should be described in sufficient detail to permit replication

The procedure for the training of the nurses and for conducting the screening tool will be described in sufficient detail to permit replication.

The interpretation of results should be consistent both within and between observers

Variability between observers will be measured and explained within the research programme.

The characteristics of the test should be adequately described

Any diagnostic or screening test must perform well to be considered worth using. The technical precision of a test is measured in terms of sensitivity and specificity; positive and negative predictive values and likelihood ratios (see glossary for an explanation of these terms). These features of the test were calculated through comparison of the HeDSS with the reference standard which is assumed as being correct.

This research used quantitative data i.e. data were collected and analysed in a numerical format. The primary aim of the research was to analyse data from the target sample in order to produce results that may be generalized to a wider population. For quantitative research to be useful, the study needs to address issues of reliability and validity to ensure that any claims made about the generalisability of the results stand up to scrutiny. Having evaluated the various forms of reliability and validity, it is necessary to return to the research questions as outlined in Chapter 2 and consider the hypotheses and variables associated with these questions for the purpose of planning the empirical phase of the research. This is illustrated in Table 9 overpage.

Table 9: Research questions and variables influencing the research process

Research Question	**Independent Variable** **(What I change)**	**Dependent Variable** **(What I observe)**	**Controlled variables** **(What I keep the same)**
1. Is the SLTR's clinical dysphagia assessment consistent with another expert SLT of equivalent knowledge and experience for determining the presence and absence of dysphagia?	Two clinical lead SLT practitioners employing their clinical decision making via a clinical dysphagia assessment on whether signs of dysphagia are present or not	Presence or absence of dysphagia represented as a dichotomous decision: Yes= signs of dysphagia observed; No= No signs of dysphagia observed	Same patients seen by SLTR and contemporary. Patients seen in the same location within 3.5 hours by the SLTR and SLT contemporary
2. Can RGNs use a newly designed dysphagia-screening tool in a way that is consistent with an expert using the tool?	Both the SLTR and RGNs' use of the HeDSS	Presence or absence of dysphagia represented as a dichotomous decision: Yes= signs of dysphagia observed; No= No signs of dysphagia observed Judgement of whether patients appropriate for referral to SLT for a clinical dysphagia assessment	The screen is to be used by the RGNs and SLTR Same patients to be screened and seen in the same location Each patient screened within 8 hours by the RGN and SLTR

Table 9 Research questions an

Research Question	Independent Variable (What I keep the same)	Dependent Variable (What I observe)	Controlled Variables (What I keep the same)
3. Are the clinical decisions made by RGNs using a HeDSS, consistent with an expert SLT performing a clinical dysphagia assessment for determining signs of dysphagia and the appropriateness of referring acute stroke patients for swallowing assessment?	Variation: Clinical decisions made by RGNs use of the screen and clinical decisions of SLTR use of a clinical dysphagia assessment	Presence or absence of dysphagia represented as a dichotomous decision: Yes= signs of dysphagia observed; No= No signs of dysphagia observed Judgement of whether patients appropriate for referral to SLT clinical dysphagia assessment again represented as binary decision Yes= appropriate to refer patient for clinical dysphagia assessment; No= patient is not appropriate to refer for dysphagia assessment	• Same patients to be screened or assessed • Patients seen in the same location • Each patient is screened or assessed within 8 hours by the RGNs and SLTR

4.3. Statement of Design, population and sample

To address the research questions and hypotheses, the study employed a prospective, blinded clinical validation design. An overview of the design phases is represented in Figure 12 below, as an organising framework to the study and thesis.

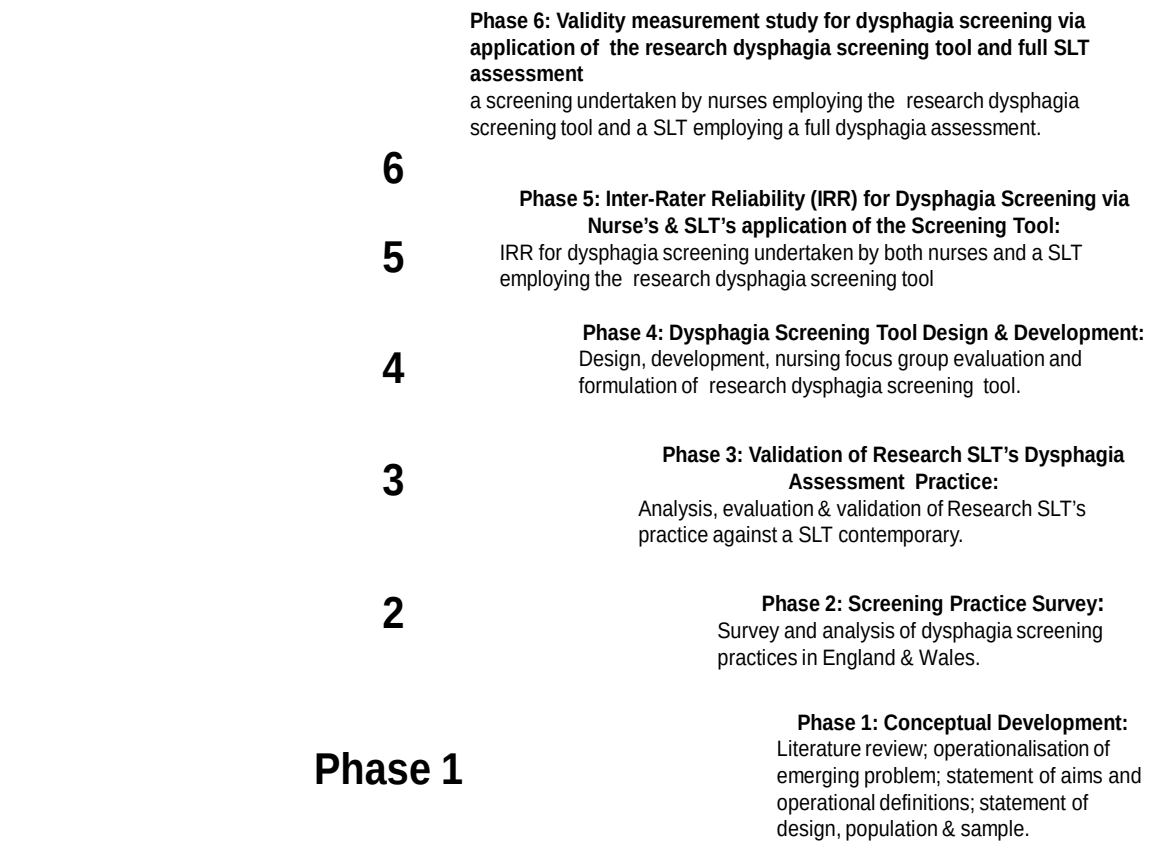


Figure 12: A model of the designs phases of the Action Research process for the design and evaluation of a valid prototype dysphagia screening tool

Having described the conceptual development of the research problem via the literature review and survey of dysphagia screening practices in England and Wales, together with the design and planning considerations for the study, the subsequent chapters detail the empirical and reflective phases of the action research process.

Chapter 5: Ethical Considerations

5.1. Early ethical considerations and university requirements

Within this study as in any research involving human subjects, it was necessary to meet institutional and professional ethical requirements to protect the rights of research participants. This was of particular importance as the research required the recruitment of a vulnerable patient group; subjects who had suffered an acute stroke. The principle of recruiting patients for research requires that people are not exploited or coerced into participating in research and are fully informed of the procedures and risks involved (Mental Capacity Act, 2007). Informed consent must therefore be gained before the subject participates in the research. Ethical standards also require that researchers do not put participants in a situation where they might be at risk of harm because of their participation.

At the outset of the research programme, ethical requirements, which included ascertaining informed consent and protection of research participants from risk of harm, were carefully considered. The research proposal was submitted to the University's Research Proposal Committee (RPC). The RPC's role is to review research proposals to determine ethical implications and any actions needed to address the safety and rights of participants. The RPC also act to protect the university and the researcher against potential legal implications of neglecting to address important ethical issues of participants.

The initial proposal was for a reliability and validity study with a large sample of acute stroke patients. This was not passed on its first submission in February 2005; as it was considered too ambitious an undertaking for the given four year timescale of the PhD. Points raised were taken on board and the study aims and design were made more focused to address the design, development and evaluation of an evidence based dysphagia screening tool.

5.2. Hospital Trusts' research and development ethical requirements

The next phase in the research ethics process was registration of the research with the Research and Development Offices of Trusts one and two. This involved completion of the relevant registration forms, which addressed issues including potential risks to participants and resource implications. These were also accompanied by a research protocol for each site. The Research Risk Review Committee at Trust two reviewed the proposal, registration form and research protocol and provided approval in December 2006 subject to approval from the local Research Ethics Committee. Approval from Trust one where the inter-rater reliability of the SLTR's clinical dysphagia assessment compared to a SLT contemporary was to be undertaken, was more timely. A number of points that required clarification were raised by Trust one's Research Scrutiny Committee and Risk Review Committee. The first related to a request for a copy of the Head Dysphagia Screen for Stroke (HeDSS). It was explained that the tool was not part of the research study to be conducted at Trust one so would have little relevance to the study. Further clarification was sought by the panel to determine why this phase only involved one other SLT for the inter-rater reliability study. It was explained that each Trust only has one SLT fulfilling the role of clinical lead SLT for dysphagia and therefore, there was only one SLT who could act as my contemporary within the Trust. The third point raised was related to why the inter-rater reliability was to be undertaken with a SLT contemporary and not e.g. videofluoroscopy. The need to determine the performance of the SLTR's bedside assessment of swallowing against a contemporary assessing the same patients was defended. It was explained that the SLTR's bedside assessment would be the reference standard by which the validity of the HeDSS in the final phase of the research programme would be measured. This formed the basis for the present study, which was to determine whether it was a reliable and therefore appropriate reference standard by which to measure the validity of the HeDSS. Point four related to data analysis and justification of modified kappa to determine agreement between the SLTR and SLT contemporary's clinical dysphagia assessment. This was outlined in detail with an illustration of the kappa matrix for each SLT's assessment outcome for determining presence versus absence of dysphagia. The final point related to ascertaining capacity to consent and how I would address consent with patients who could not sign their name or clearly verbalise their consent. An explanation of including only

patients who were assessed as competent to consent was provided. I assured the panel that I would adhere to Common Law, which dictates, that provided the patient is over the age of 16 and has been assessed as competent to consent, a witness or next of kin can confirm consent has been given. Consent can also be given non verbally e.g. using a 'thumbs up' gesture, this would be documented as the mode of consent. Approval from both committees was finally obtained in April 2007.

5.3. Research ethics committee requirements

The final phases for ethical approval were through the Research Ethics Committee, which involved two panels representing the two Trusts. This involved scrutiny of the research protocols, the patient, SLT and nurse information sheets and research application. Some minor amendments to documentation were advised such as including the version number of the consent form or correct headings. The original patient information sheet used pictures and simplified language to assist understanding for those acute patients with communication difficulties. It was felt by the SLTR that the template for the research information letter (which is five pages long), provided by the National Research Ethics Service (NRES), would be too difficult to read for an acute stroke patient. A decision was made to make use of a shorter information sheet using Makaton pictures, which would be used to support understanding of the longer NRES template. Makaton symbols are specially designed to support the written word in the same way that signs support speech. The layout and format was based on the Department of Health leaflet on guidelines for obtaining consent from people with learning difficulties (DoH Consent Policy 2001). However, the research ethics committee were concerned that the information sheet deviated too much from the accepted template. Another concern related to the potential of patients being coerced into being screened using the HeDSS or those refusing to be screened being disadvantaged. A request for an explanation of how the sample size was decided upon and to detail statistical advice was further made. Further to this, the committee raised concerns that the GP should be informed of the study and wished for further information on storage and protection of confidential data. Based on these concerns, the initial application was not passed and a request was made to submit a new

application. A decision to appeal this decision was made and the SLTR along with one of her research supervisors met with the committee to defend her application. It was explained that screening for swallowing problems was part of normal clinical management protocols at Trust two. Therefore, nothing over and above standard practice would happen to the patients recruited for the study i.e. their swallows would be screened and subsequently assessed regardless of their participation in the research. There was therefore no inducement for the patients to participate. The information sheet was revised in line with the NRES template (see Appendix 9) with the understanding that it may be necessary to explain its content using simplified language or using pictures for those experiencing difficulty in reading. It was emphasised that patients unable to consent to participation due to communication difficulties would be excluded from the study. With regard to statistical advice and how the decision to use the proposed sample size was determined, full details of the statistical advice received from the research statistician and Power analysis was provided. The panel were also advised that there would be no need to advise the patients GP of the research as they would be hospital inpatients and therefore the medical practitioners responsible for their care i.e. the hospital consultants would be informed of the patients' participation, as explained in the patient information and patient consent sheets (see Appendix 7). The final question relating to storage and subsequent confidential destruction of patient data was further explained. The SLTR explained that data would be stored securely and anonymised using non-patient identifiable codes. The data would be stored on a password protected encrypted computer for the duration of the research. Storage and destruction of data would comply with the Data Protection Act 1998 and in accordance with Research Governance at Trust two i.e. data would be stored for a total of five years and after the stipulated period confidentially destroyed either through shredding of paper copies of data or deleting from stored computer files.

In the initial application, a request was made to include patients too drowsy to assess and therefore provide consent with measures taken to ensure they would be merely observed with no direct participation in the research. The rationale for this was to check the nurses could use the screen to determine patients too drowsy for referral to SLT; drowsiness was after all a screening criterion. Despite reassurances that these patients would only be observed, this was not felt to be appropriate by the NRES committee. It was subsequently

concluded that patients too drowsy to consent were likely to be inappropriate for referral. It was anticipated that a small cohort of patients may present with variable levels of alertness and it would therefore be these patients who presented a challenge to the RGNs in terms of judging their appropriateness for referral to SLT for full assessment of swallowing.

5.4. Conclusion

The time scale for obtaining full ethical consent to proceed with the research began in January 2005 and ended in August 2007 something that was never anticipated when the initial research proposal was submitted. The researcher was cognisant of the need for clear ethical standards and guiding principles but there were times when the need to do accurate research was confined and limited by the need to protect the rights of potential participants and the need to comply with national guidelines and templates. A compromise had to be made in the research process to ensure that participants were not disadvantaged or exposed to risk whilst endeavouring to make a valid and relevant contribution to the body of knowledge on screening for dysphagia.

Chapter 6: Reliability of the SLTR's Clinical Dysphagia Assessment

6.1. Summary

6.1a. Aim

The aim of this phase of the research programme was to investigate the research question relating to determining whether the speech and language therapist researcher's (SLTR's) clinical dysphagia assessment is a reliable reference standard against which to measure the concurrent validity of the Head Dysphagia Sceen for Stroke (HeDSS).

6.1b. Objective

To measure the inter-rater reliability of the SLTR clinical dysphagia assessment as compared to a similarly qualified SLT contemporary's clinical assessment for determining the presence or absence of dysphagia in a prospective sample of 30 acute medical patients referred to the SLT department.

6.1c. Study design

This phase employed a prospective blinded reliability design. A comparison was made of the detection of dysphagia as determined by clinical dysphagia assessment performed by two SLTs assessing the same convenience sample of 30 acute medical patients i.e. patients admitted into acute medical ward settings with medical conditions, which include stroke, acquired neurological disease (e.g. Parkinson's disease, Motor Neurone Disease), and patients admitted with chest infections.

6.1d. Population and sample

- Two Clinical lead SLTs (one being the SLTR) with five years+ postgraduate dysphagia experience and postgraduate training in dysphagia to Masters' level equivalent. Each work in different acute hospital trusts in South Wales henceforth referred to as Trust 1 (contemporary's place of work and site for Phase One of study) and Trust 2 (study site for Phases Two and Three of the research study) to avoid potential bias in assessment.
- Thirty acute medical inpatients referred for clinical dysphagia assessment.

6.1e. Results

Twenty six patients out of 30 patients assessed received the same assessment ratings i.e. dysphagia present or dysphagia absent. The proportion of agreement for the two therapists' clinical dysphagia assessment was calculated as .87. Kappa was calculated as .71 suggesting substantial agreement.

6.1f. Conclusion

A high level of agreement for the presence and absence of dysphagia was obtained within this study. Differences occurred for four patients and despite operational definitions for dysphagia, differences in agreement arose from the SLT contemporary applying management decisions to two of the cases assessed and thus placing a different weight on signs of dysphagia. Differences in agreement were also due to the patients' performance on bedside assessment of swallowing possibly due to slight differences in the timing of assessment. Possible reasons relating to the high level of agreement were further identified.

6.2 Introduction

According to the literature, (e.g. Sackett, 1991), the accuracy of a screening test is best determined by comparing it to an appropriate reference standard. SLT clinical dysphagia assessment remains the cornerstone for clinical detection of dysphagia and in some studies (e.g. Hinchey, 2005), has been shown to demonstrate high sensitivity and specificity for determining signs of aspiration as well as demonstrating a reduction in the incidence of aspiration pneumonia. This was therefore felt to be the most appropriate reference standard against which to determine the concurrent validity of the HeDSS.

As it was decided that the SLTR clinical dysphagia assessment would be utilised in this study, it was important to demonstrate that this professional assessment process was reliable. Reliability refers to the consistency of a measuring instrument and inter-rater reliability estimates the degree to which two or more independent raters/scorers are consistent in their judgments when using a particular instrument (Wisker, 2001). If the SLTR's clinical dysphagia assessment could not be shown to be reliable, then any subsequent correlation of measurement outcomes of the HeDSS with the SLTR's assessment would be potentially attenuated the first research question to be explored was therefore:

Question 1. *'Can the SLTR make clinical judgements on the presence and absence of dysphagia in a way that is consistent with a SLT contemporary?'*

6.3. Research design

This phase used a prospective blinded reliability design. The inter-rater reliability of the SLTR and a SLT contemporary of similar experience carrying out a clinical dysphagia assessment on the same 30 acute hospitalised patients was evaluated. The aim was to determine whether the SLTR's clinical dysphagia assessment demonstrated agreement with another expert SLT and reflected typical assessment outcomes.

A number of variables that may affect reliability were considered and are outlined in figure 13.

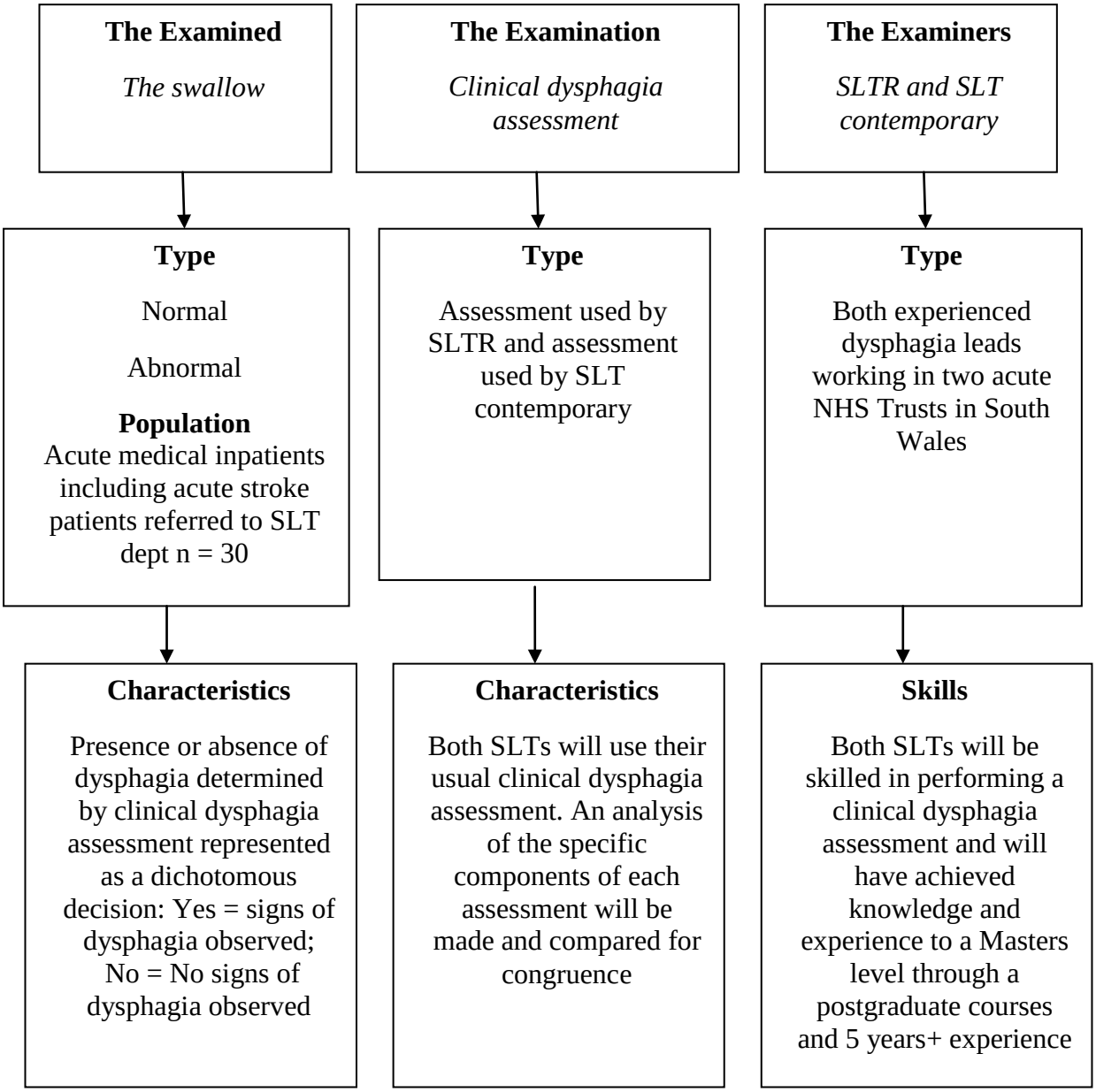


Figure 13: Variables of clinical dysphagia assessment

6.4 Variables of clinical dysphagia assessment

6.4a. The examined; the swallow

This phase of the research programme examined the ability of the SLTR's clinical dysphagia assessment to determine the presence or absence of dysphagia in a sample of 30 acute medical patients as compared to a contemporary performing a clinical dysphagia assessment on the same sample of patients. Dysphagia here was defined as abnormal swallowing physiology of the oral and pharyngeal tract as detected by a clinical dysphagia assessment.

Each swallow assessed was characterised using a dichotomous decision of dysphagia present versus dysphagia absent as determined by signs of dysphagia observed at the bedside (see glossary). Swallowing is a dynamic process and can change according to time and status of the patient. Polit and Hungler (1991) note that reliability of a particular instrument (here the clinical dysphagia assessment) is not the property of the instrument, but rather of the instrument when administered to a certain sample under certain conditions. The patients were seen by both SLTs as closely together as possible although due to working constraints of the SLT contemporary, this was set as within 3.5 hours (the time of the session allocated each week to data collection). As this is a study of inter-rater reliability and recruits patients who have been referred to the SLT department, a number of inherent risks to internal and external validity were evident (refer to Tables 7 and 8). The study sample was patients referred to the SLT department for assessment of swallowing. This meant that the presence of dysphagia would already be high in this population and may therefore artificially inflate the inter-rater reliability (as discussed in Chapter 4). Acute stroke patients whose swallowing had been screened as normal were included in the study sample and measures were taken to prevent both SLTs having access to this information (refer to study protocol Appendix 6). This in part allowed for the inclusion of 'normal' swallowing patients in the study sample.

6.4b. The examination

The clinical dysphagia assessment used in this study by each SLT was not a standardised assessment but the assessment each SLT typically used to assess swallowing. The reason not to adopt a standardised assessment is that in practice, this does not exist. Consideration was given to adopting or drafting a clinical dysphagia assessment for both therapists to use, however it was felt that this could potentially lead to further confounding variables affecting the outcome such as the assessment being novel to both therapists and therefore further lack of standardisation to the way in which this assessment would be normally undertaken. Therefore, it was felt necessary to determine whether, regardless of the order of variables assessed, two SLTs of equivalent experience and knowledge could agree on the detection of signs of dysphagia when assessing the same population of patients under similar study conditions. An evaluation was made of the components of each therapist's assessment to determine the degree of congruence. This is illustrated in Table 10. The evidence base for some of these variables is further explained in Table 5, Chapter 2.

6.4c. The examiner

The examiners were both senior SLT clinicians who have five years minimum working experience of acting as lead therapists for dysphagia in two acute NHS Trusts in South Wales. Each therapist assessed each patient once at the bedside and recorded their decision (i.e. categorical decisions for each swallow) as:

- Dysphagia present, or
- Dysphagia absent

Table 10: Analysis of SLT Researcher and contemporary's clinical dysphagia assessment X=SLTR X = SLT contemporary

Prefeeding Observations	*Oromotor assessment*	*Assessment of Trial Swallows*
Posture and mobility X X	Examination of oral structures-tongue, teeth, lips etc. Check oral hygiene: tongue coated or swollen/ dry? Teeth absent or decayed/Dentures worn? X X	Assess with water only Assessment with water and range of food textures if safe to do so X X
Level of alertness or conscious levels-checking if safe to proceed with trial swallows X X	Examination of oral function i.e. rate and range of oral movements X X	Digital examination of swallow i.e. feeling for the swallow to occur (refer to glossary) X X
Patient awareness and control of oral secretions X X	Examination of oral sensation i.e. checking for facial paralysis, lack of sensation in the tongue/oral cavity X X	Observation of larynx observing for movement of the larynx X X
Cognitive and communicative status i.e. ability to follow directions and answer questions X X Auditory and visual status X X **(ascertained from background history**	Examination of laryngeal function including: -assessment of gurgly or hoarse voice quality -strength of voluntary cough -ability to sustain 'ah' i.e. measurement of phonation times X X	Timing swallowing. Estimate oral transit and pharyngeal delay time observation of whether the swallow is absent or delayed (typically, a swallow is initiated within 0.3 - 1 second) X X Checking for presence/absence of productive cough post swallow X X
Caregiver-patient interaction Respiratory status: Respiratory rate Laboured/wheezy breathing X X Mouth or nasal breathers?		Checking rate and range of oral movements during feeding i.e. is chewing/ observed? Is tongue retraction felt? X X Checking rate and range of laryngeal movements i.e. check the larynx lifted in a timely and safe manner X X

6.5. Methods:

6.5a. Recruitment of a similarly qualified SLT

A SLT experienced in the assessment of dysphagia was recruited from an acute hospital setting here referred to as Trust 1. Prior to approaching the therapist for participation in the study, it was established through discussion that the therapist met the inclusion criteria.

The SLT contemporary was given the SLT information sheet (see Appendix 7) and the research protocol (see Appendix 6) to read which covered the purpose of the study, including operational definitions for what was to be assessed i.e. the presence or absence of signs of oral pharyngeal dysphagia as determined by a clinical dysphagia assessment and the same was discussed. A consent form was subsequently signed.

6.5b. Recruitment of patients for the study

Over a two-month period, a convenience sample of medical patients referred to the speech and language therapy department for a swallowing assessment and who met the inclusion criteria (see Appendix 6) were approached for inclusion in the study. Prior to approaching patients, all relevant medical consultants, nurse managers and directorate managers were informed of the study. Permission was sought from the medical consultants to approach their patients. It was established from the SLT contemporary that dysphagia screening took place on the acute admissions ward and the stroke ward. This would mean that potentially, acute stroke patients screened as having a normal swallow by the dysphagia trained nurses (DTNs) would not be referred to the department. To avoid a potential threat to validity of only having patients referred who displayed overt signs of swallowing difficulties, discussions were undertaken with these wards to request they refer all acute stroke patients to the department regardless of screening outcome and withhold the outcome of the screening from both therapists. Another inherent risk to the design of the study was selection and maturation effects for age and cause of dysphagia. This was controlled for by including a mix of patient ages and causes of dysphagia.

6.5c. Procedure

The research protocol was discussed fully with the SLT contemporary to cover areas of recording of data, preparation of the wards during the study and not sharing clinical dysphagia assessment outcomes with each other until all data were collected. Days and times for undertaking the data collection were agreed upon and a policy of assessing patients newly referred to the department was further agreed. A ward based protocol was discussed with participating wards to ask that during the study, any visible signs of feeding recommendations or the patients feeding status such as jugs of water were removed from the patient's bedside just prior to the SLT's visit. This served to avoid potential bias of the SLTs being exposed to environmental cues to the patient's swallowing status. The SLTR was not given access to the patient's medical notes to prevent potentially viewing feeding/swallowing recommendations made by the SLT contemporary. However, the age and medical diagnosis/medical history were ascertained. Where possible, the patients were seen immediately following the SLT contemporary. However due to limitations of the SLT contemporary's time and hence working practice, some patients were seen within 3.5 hours. The data collection sheets (see Appendix 11) were prepared for each SLT. This contained columns for insertion of the patient's name, an assigned number to allow future anonymising and comparison of data, gender, age, medical diagnosis, two columns for indicating the patient's dysphagia status i.e. 'dysphagia present' and 'dysphagia absent', following the clinical dysphagia assessment and a column for comments such as idiosyncratic behaviours observed and feeding recommendations. A profile of patient characteristics for the patient sample is provided in Appendix 12.

6.5d. Assessment of swallowing function

The SLT contemporary assessed patients using a clinical dysphagia assessment. This was followed within 3.5 hours by the SLTR assessing the same patients using her clinical dysphagia assessment. This included an evaluation of relevant cranial nerve functions for swallowing (see Chapter 1), oromotor function, management of water (i.e. displaying signs of coughing, drooling, choking, delayed or absent laryngeal movement, speed of swallowing) as well as ability to chew and swallow solids. It was ascertained that the two

therapists may not assess swallowing in exactly the same way as is typical of current SLTs' bedside dysphagia assessment (Bateman *et al.* 2007). Reasons for not drafting a clinical dysphagia assessment for both SLTs to use have been explained earlier in this section.

The outcome decision (i.e. dysphagia present or absent) was recorded independently by each therapist on their data recording sheets along with the patient's demographic details and comments as noted previously. It was not known by the SLTR what specific dysphagia assessment criteria were used by the SLT contemporary for assessing dysphagia until after all the data were collected. This was to prevent potential bias of the SLTR towards the contemporary's clinical dysphagia assessment.

6.5e. Justification of methods

The reliability of clinicians' ratings is an important consideration in areas such as diagnosis and the interpretation of examination findings (Sim and Wright 2005). Reliability is applied here to explain the extent to which clinicians agree in their ratings as opposed to the extent to which ratings are associated or correlated.

Inter-rater reliability is the chosen method of analysis because the clinical dysphagia assessment involves subjective judgement as well as clinical expertise, therefore the rater is a potential source of measurement error (refer to Chapter 4). It is important in the evaluation of the reference standard clinical dysphagia assessment that the raters can agree on the presence or absence of observed behaviours. Inter-rater reliability refers to the level of agreement between a particular set of judges using a particular instrument at a particular time. It is recognised within this study that the design and methods do not follow a traditional inter-rater reliability design i.e. the patients were not assessed at the same time by the two therapists using the same clinical dysphagia assessment. This was due to the need for the SLTR and SLT contemporary to be blinded to each other's assessments as well as the issues around each SLT using their own clinical dysphagia assessment as discussed earlier in this chapter.

Agreement estimates tend to be the most useful when data are nominal in nature (here it was ‘dysphagia present’ and ‘dysphagia absent’). Therefore, agreement exists where both SLTs assess dysphagia to be present or absent.

According to the literature (Stemler 2004, Baumgarter *et al*. 2003) a minimum sample size of 30 is necessary to determine inter-rater reliability when nominal data is used.

6.6. Data analysis

Data were entered into the SPSS statistical and data management programme (SPSS 15.0. 2006, SPSS Inc., Chicago IL.). Variables relating to each ‘case’ (patient) i.e. demographic details such as age, gender, medical diagnosis and dysphagia assessment outcome for both SLTs were defined and coded. Frequency counts were generated based on gender type, age range and medical diagnosis. Further data analyses were run to compare the clinical dysphagia assessment results for both therapists using proportion of agreement and kappa to determine level of agreement between the SLTs.

6.6a. Justification of data analysis

Demographic data relating to each patient assessed by the therapists were recorded as a way of identifying any possible trends in the outcome measures e.g. whether differences in rating may be due to the medical condition of the patient or whether agreement was more consistent with elderly patients.

Proportion of agreement is an estimate of consensus of inter-rater reliability and has an important role in descriptive statistics for its ability to provide information on agreement at a practical level (Stemler 2004). The goal of this phase of the research programme was to determine whether raters of similar knowledge and experience could agree consistently on the presence or absence of signs of dysphagia as determined by clinical dysphagia assessment. Proportion of agreement is calculated by adding up the number of cases that received the same rating by both judges and dividing that number by the total number of cases rated by the two judges. The formula for this is provided later in section 6.7. The

proportion of agreement statistic has several advantages; it has a strong intuitive appeal, is easy to calculate, and is easy to interpret (Stemler 2004). It also has limitations in that it does not provide information about prevalence of the finding (here dysphagia), in the subjects studied and fails to adjust for the fact that a certain amount of agreement could occur by chance alone. For this reason, another statistical measurement, kappa, was applied to the data.

The kappa statistic was used as a supporting method of estimating inter-rater reliability. It has been designed to estimate the degree of agreement between two raters after correcting for the amount of agreement that could be expected by chance alone (Cohen 1968, Stemler, 2004). The interpretation of the kappa (*k*) differs slightly from the interpretation of the proportion of agreement. A value of zero on kappa does not indicate that the two judges did not agree at all; rather, it indicates that the two judges did not agree with each other any more than would be predicted by chance alone. Consequently, it is possible to have negative values of kappa if judges agree less often than would be expected by chance. If the raters are in complete agreement then $\kappa = 1$. If there is no agreement among the raters (other than what would be expected by chance) then $\kappa \leq 0$ (please refer to Appendix 1 for an overview and interpretation of kappa).

Within the literature there is considerable debate about the over-reliance and misuse of reporting 'statistical significance' i.e. reporting that the data are unlikely to be supported by a non-random effect (Schmidt and Hunter 2002, Field, 2005, Kraemer 2006). The problems of over-reliance on reporting p values is summarised below :

> "*Significance testing almost invariably retards the search for knowledge by producing false conclusions about research literature"* (Schmidt and Hunter 2002 page 65).

Consequently there is more emphasis on reporting effect size, which measures the strength of the relationship between two variables to facilitate the interpretation of the clinical significance of the finding. A number of different effect sizes for interpreting kappa exist in the literature. The most frequently reported interpretation is offered by Landis and Koch (1977) who suggest that kappa values from .41 – .60 are moderate, values .61 - .80 are substantial and values above this are 'almost perfect'. Kappa is a highly useful statistic

when there is concern that the proportion of agreement statistic may be artificially inflated due to the fact that most observations fall into a single category e.g. 'dysphagia present' (please refer to Chapter 4, page 102). For this reason kappa was included as a method for data analysis. A decision to not focus on reporting p values was determined (although for the purpose of clarity, p values were calculated as less than $p < .01$ i.e. a probability of 1% that the results observed could have happened by coincidence).

6.7. Results

SPSS output for the cases is provided in Appendix 12. A summary of cases and calculation of agreement on assessment ratings follows.

6.7a. Summary of Cases

Gender ratio

There was an equal divide of male and female patients for gender i.e. 15 male and 15 females were recruited for the sample.

Age Range

The majority of cases were aged over 71 (n = 25). Four patients were aged between 61-70 and one patient was aged 35. The distribution of age ranges is similar to those reported in the literature with regard to prevalence of stroke in the elderly population**.**

Aetiologies

Seventeen patients from the total sample of 30 had suffered an acute stroke (Right CVA = 7, Left CVA = 9, 1 hemorrhagic stroke). Thirteen patients had suffered other aetiologies including Parkinson's disease, Trans-ischaemic attack (see glossary), chest infection of unknown cause and chronic pulmonary disease.

6.7b. Proportion of agreement analysis

Calculation of observed frequencies of dysphagia presence and absence is summarised in Table 11.

Table 11: SLTR and SLT contemporary's clinical dysphagia assessment outcomes

		SLTR		
		Present	Absent	Total
SLT contemporary	Present	17 (a)	2 (b)	19 (a + b)
	Absent	2 (c)	9 (d)	11 (c + d)
	Total	19 (a + c)	11 (b + d)	30 (a + b + c + d)

Interpretation of table

The values a, b, c and d in the cells of Table 11 denote the observed frequencies for each possible combination of ratings by the SLTR and the SLT contemporary.

Cell (a) denotes where both the SLTR and SLT contemporary agreed on the presence of dysphagia in the patients assessed (i.e. present/present)

Cell (b) denotes present/absent rater disagreement,

Cell (c) denotes absent/present rater disagreement,

Cell (d) denotes the SLTR and SLT contemporary agreed on dysphagia being absent in the patients assessed (i.e. absent/absent).

The observed proportion of agreement, which is denoted p_o is the number of cases for which the SLTR and the SLT contemporary agree divided by the total number of cases rated by the two judges. That is:

$$\mathbf{p_o = \frac{a + d}{a+b+c+d}} \qquad \mathbf{p_o = \frac{17+9}{17+2+2+9}}$$

$$\mathbf{p_o = 26/30 = \underline{.87}}$$

The proportion of agreement for the two SLTs' clinical dysphagia assessment is therefore **.87** indicating a high agreement of ratings i.e., the SLTs agreed with each other for 87% of the cases assessed.

6.7c. Kappa

Although the proportion of agreement value is useful, taken by itself it has limitations. In order to determine the degree of agreement between the two SLTs beyond what could be expected by chance, kappa was calculated (see Appendix 1). These calculations are set out below.

To compute kappa, the proportion of agreement needs to be calculated. As noted, the proportion of agreement was calculated as $\mathbf{p_o} = \underline{\mathbf{.87}}$

The equation for kappa is: $\boldsymbol{k} = \dfrac{\mathbf{\underline{p_o - Pr\,(e)}}}{\mathbf{1 - Pr\,(e)}}$

$\mathbf{p_o}$ = the observed agreement between raters **.8666*** (* denotes number recurring).

To calculate Pr (e) (the probability of random agreement) it was noted that the SLTR said "yes" to dysphagia presence 19 times and no 11 times. This was the same for the SLT contemporary meaning both SLTR and SLT contemporary said yes 63.33*% of the time and "no" 36.66*% of the time to dysphagia presence. The probability of both the SLTR and SLT contemporary saying yes was .6333 x .6333 = .4011* and for no was .3666 x .366 = .13.

Overall the probability of random agreement was therefore .4011 + .1344* = **.5355***

Kappa is $k = \frac{.8666^* - .5355^*}{1 - .5355^*} = \frac{.3311}{.4644} = .7129 = .71$ (correct to 2 decimal places)

Kappa was calculated as **.71** which using Landis and Koch's (1977) definition, suggests 'substantial' agreement. Although not intentionally calculated, SPSS estimated the results as significant at $p < .01$ exceeding chance levels on measurement outcomes.

6.8. Discussion

6.8a An Evaluation of differences in opinion

What these calculations fail to indicate is the possible reasons for differences in opinion. This was explored with the SLT contemporary following the data collection. Patients 12 and 14 were assessed by the SLTR approximately 3.5 hours after the SLT contemporary. On examination by the SLTR, the patients displayed signs of dysphagia as evidenced by a delayed swallow trigger and multiple swallowing attempts with patient 12, and drooling with patient 14. On discussion with the SLT contemporary, he stated that the patients evidenced difficulty but the patients had been seen to be managing functionally if care was taken to ensure the patient was seated in an upright position and small sips/mouthfuls were taken. In this case, where the patient was managing despite a seemingly effortful swallow, a judgment of 'no dysphagia/normal swallow' was made. This differed to the SLTR's decision that was only based on the clinical signs of apparent difficulty.

The SLT contemporary stated 'on reflection' he "should have coded the patient as dysphagic". This may suggest that his judgment of this patient's assessment outcome was influenced by how he would typically manage the patient. Also, as this study employed a non-traditional inter-rater reliability study design i.e. the patients were not assessed at the same time by the two SLTs, it may be that the patient performed differently. This is discussed in more detail overpage.

For Patients 25 and 29 there was a three-hour time difference in the time assessed. On discussion with the SLT contemporary, it was apparent that these patients performed differently on the two clinical dysphagia assessments. Patient 25 coughed on trials of fluid and diet with the SLTR but had not displayed such signs three hours earlier when assessed by the SLT contemporary. The patient had been generally unwell i.e. she was weak due to a history of dehydration and was emaciated. Clearly factors such as fatigue could play a role in this patient's swallowing performance over time. The reverse presentation was true for patient 29 who appeared to manage all trials when assessed by the SLTR but had coughed and choked with the SLT contemporary. As this patient had a diagnosis of Parkinson's Disease, these differences in performance can occur as a consequence of optimum performance around anti-Parkinson's medication (Parkinson's Disease Society 2007). These findings highlight the effects of maturation (refer to 'Characteristics of Internal Validity', Table 7).

6.9. Study design limitations

A number of design weaknesses are recognized in the current research study and relate to both internal and external validity (see Chapter 4, Tables 7 and 8). These are outlined in more detail below.

Weaknesses in standardization of conditions under which the study is carried out

- As noted previously, the study needed to be blinded. It was not possible for the patients to be assessed at the same time by the two SLTs. There are therefore weaknesses in the study design as the raters were effectively making judgments on two separate trials i.e. the assessment outcomes may have been different as the patient may have performed differently in each of the trials.

- Operational definition of dysphagia: Despite agreeing and operationalising what comprised dysphagia as assessed at the bedside, the definition may not have gone far enough to define what the SLTR and the SLT contemporary were measuring at the bedside. It may have been more useful to define what dysphagia is not i.e. judgments

should not be based on whether the patient may be able to cope at a functional level despite signs of dysphagia being exhibited at the bedside.

- Specificity of variables described-i.e. the extent to which the variables in the study are adequately described and operationalised. A research protocol, SLT information sheet and discussions with the SLT contemporary outlined the operational definition for dysphagia and what 'internal criteria' both therapists used for determining dysphagia in terms of observed signs of dysphagia. Following on from the previous point, it is recognized that in hindsight, the definition for dysphagia detected at bedside could have been better operationalised. Also, minimally the assessment and variables used with each patient should have been described to allow for replication. It is understood that there was a high degree of concordance with the assessments although maybe not all of these variables were assessed for each patient. It would have been advantageous to list each variable assessed for each patient in terms of determining differences in opinion and for replicability.

- Maturation: There were clearly biological and physiological changes that occurred in two of the patients assessed that were not anticipated as part of the study. These related to the potential effect of fatigue on swallowing performance with patient 25 and the possible effects of optimum effects of anti-Parkinsonian medication on patient 29.

In order to repeat this study, it would be advantageous to use an agreed protocol for both SLTs to assess dysphagia at the bedside and ensure clarity for the operationalisation of dysphagia as detected at the bedside. The study would recruit larger numbers of patients who would ideally need to be assessed by both SLTs within a shorter time frame to reduce the likelihood of variations in swallowing performance which can occur over time.

6.10. Conclusion

The extent to which this study may be generalized to the wider population is open to scrutiny, as the study recruited only a small population of acute medical patients and one other SLT. It does however set out the foundations for the subsequent phases of the study.

Dysphagia is multifaceted and any attempt to evaluate its presence and absence may be dependent on a number of variables. A judgment made on the presence or absence of dysphagia may be influenced by the timing of bedside assessment, changes within the patient (e.g. fatigue, posture, performance around medication) as well as differences based on the weight given to 'signs of dysphagia' when considered along with other information such as chest status, medical complications and feeding history. No method of dysphagia assessment can be completely objective if human judgement is involved. Some of the criteria used within the clinical dysphagia assessment are very robust so for example, patients either swallow or do not swallow or cough. Therefore, it may be that these are enough to assess swallowing function and the assessment of other variables such as voice quality merely informs the swallowing assessment. It is possible that there is a high level of intuition or 'gut instinct' involved in dysphagia assessment. As Bateman *et al*. (2007) note, specific guidelines for clinical dysphagia assessment have not been published and subsequently, variability among clinicians undertaking clinical dysphagia assessment can be high. Previous studies evaluating inter-rater reliability of dysphagia assessments (McCullough *et al.* 2001a) indicate that clinicians demonstrate good agreement on overall judgments of whether an individual is dysphagic or not despite poor inter-rater reliability for the specific assessment criteria such as voice quality measures and judgments of aspiration (refer to Chapter 1). Despite differences in the way the therapists may have assessed the patients in this study, there was good agreement reflecting an inherently high inter-rater reliability. A framework for defining and evaluating dysphagia may be helpful in informing the clinician's bedside assessment of dysphagia but will clearly need to embrace the dynamic nature of dysphagia itself in terms of its measurement.

Chapter 7: Evaluating the Design and Implementation of the Head Dysphagia Screen for Stroke (HeDSS)

7.1 Summary

7.1a Objectives

To examine the understanding and perceptions of a representative sample of nurses towards the design and application of the HeDSS

7.1b Design

Two focus group interviews to determine RGN's understanding and perceptions of the specific design and flow of information of the HeDSS and to evaluate understanding of language used within the tool and perceptions towards its use.

7.1c Participants and setting

Two convenience samples of six RGNs representing typical grades of nurses who work with acute stroke patients. The nurses were recruited from acute medical wards in an acute NHS Trust in South Wales ('Trust 2').

7.1d Results

There was support for the algorithmic design of the HeDSS. Themes emerged relating to understanding the specific wording of the tool, determining dysarthria and specific roles and responsibilities for implementing the screen.

7.1e Conclusions

The emergent themes necessitated a need to return to the literature to determine whether severe dysarthria as a screening criterion should remain within the HeDSS. There was also a need to re-draft the specific wording of the HeDSS prior to developing the nurse dysphagia screening training programme.

7.2 Introduction

Action research, as the overarching framework of the research programme, is a recursive, participatory process of problem identification, planning, implementation and evaluation (Stringer 1999, 2008). It is a group activity founded on a partnership between action researchers and participants, all of whom are involved in the change process (Kreuger 1988).

The problem of a lack of consensus for an evidence based dysphagia screen was identified from a review of the literature and survey of screening practices. Criteria potentially appropriate for inclusion in the HeDSS were subsequently determined. This phase of the Action Research process required an initial iterative programme of focus group work with a representative sample of registered nurses to inform the planning and design of the HeDSS.

As nurses would ultimately be involved in measuring the effectiveness of the tool, it was important to assess their needs and preferences towards its design and implementation. Focus groups as a data collection method was selected due to its usefulness in obtaining a relatively large body of information pertaining to the design of the tool from a representative range of nurses. Other research designs such as the Delphi technique were not used because the data collated from the survey had already confirmed that within current screening practices, no consensus exists on dysphagia screening criteria.

A number of definitions of focus groups exist within the literature; Stringer (2008) describes a focus groups as

> "*a group interview, with questions providing a stimulus for capturing peoples' experiences and perspectives*" (p 66).

According to Stewart and Shamdasani (1990), focus groups serve a number of functions that include:

- Diagnosing the potential for problems with a new programme, service or product;
- Generating impressions of products, programmes or other objects of interest;
- Learning how respondents talk about the phenomenon of interest, which may facilitate quantitative research tools.

The focus group method lends itself well to the guiding principles of action research where research participants are an active part of the process of analysis. For this reason, this

method for qualitative data collection was selected for this phase of the research programme.

7.3 Justification for sample size

A review of the literature around conducting focus groups suggests four to eight participants is an optimal number (Greenbaum 2000, Stringer 2008). More than this number is potentially detrimental to group dynamics and to adequately maintaining the focus of the group discussions (Greenbaum 2000, Wisker 2001). Merton *et al*. (1990) suggests that:

> *"the size of the group should manifestly be governed by two considerations...it should not be so large as to be unwieldy or to preclude adequate participation by most members nor should it be so small that it fails to provide substantially greater coverage than that of an interview with one individual"* (p137).

This review informed the decision to select six nurses for each of the planned focus groups.

7.4 Phase 1- An exploratory focus group to determine nurse perceptions of the design and flow of information of the HeDSS

7.4a Aims

To evaluate the paper design of the HeDSS i.e. the aesthetics of the tool, its overall algorithmic design and the flow of information. This served as a preliminary measure to check whether the nurses felt they could understand and use the tool (a copy of the final version of the tool is provided in Figure 14 page 149).

7.4b Methods

During October 2007, I arranged an exploratory focus group with a sample of registered nurses representing the typical range of registered nurses who work with acute stroke patients.

7.4c Sample

A purposive convenience sample of six registered general nurses (RGNs) working on acute medical wards in Trust 2 participated in the exploratory pilot focus group facilitated by the SLT Researcher. The nurses represented a range of registered nurse grades from newly qualified to ward sisters. Some nurses (n=3) had a range of experience of undertaking dysphagia screening whilst the remaining three nurses had no experience. A profile of the registered nurses is outlined in Table 12:

Table 12: Demographic profiles of exploratory focus group participants

Nurse grades	Time qualified	Previous experience of dysphagia screening?
Ward sister	20-25 years	4 years
Senior RGN	10-15 years	3 years
Ward sister	10-15 years	0
Junior RGN	0-6 months	0
Senior RGN	1-5 years	0
Junior RGN	6 months-1 year	6 months

7.4d Procedure

The focus group was convened in an office adjacent to the main ward. The office did not have phones and signs were placed to deter ward staff from disturbing the group. Thirty minutes were set aside for the focus group; the time being determined by the very few questions to be asked as well as practical considerations for the nurses to either be released to cover their wards or leave for home at the end of their shifts. The purpose of the focus

group was explained and informed consent was ascertained from registered nurses. Permission to tape record the meeting was obtained. Basic ground rules were outlined to all the nurses and covered areas of confidentiality, respecting one another's opinions and to talk to each other rather than addressing themselves to me directly as researcher. The nurses were asked to state their first name before speaking for the purpose of identification when later transcribing the data.

The focus groups were led using semi-structured questions (Table 13) designed to encourage group discourse. As SLTR, I acted as the moderator for the focus group interview and was careful to cover all questions outlined whilst ensuring that the entire group participated and a wide range of perspectives were solicited and expressed. Where responses were incomplete, I asked follow-up questions as a way of eliciting more complete information for the question. Field notes were also made during the focus group and expanded on immediately following the discussion.

7.4e Question formats-rationale

Questions focussed on the design of the tool, i.e. its algorithmic design and the flow of information. Stringer (2008) suggests focus groups commence with 'Grand tour questions' i.e. questions that enable people to express their experience and perspectives in their own terms.

Having explained the purpose of the group, the questions asked specifically about the members' views towards the algorithmic design and logical progression of the tool (refer to Table 13, p136).

Sackett *et al.* (1991) suggest that when designing a screening tool it should first and foremost be simple and easy to follow. It was therefore necessary to determine whether the current format fulfilled that function i.e. did the nurses feel they could follow the design of the tool easily and logically or would it be better in a different format?

Table 13: Questions raised for discussion in the exploratory focus group

Questions	Format
1	What are you views on the algorithmic layout of the screening tool?
2	Cochrane suggests a screening tool should progress logically and be easy to follow. Looking at this tool, what are your views on how it meets these requirements?

7.4f Data Analysis

The first step of data analysis involved a transcription of the recorded interviews. Data were subsequently entered onto a database in order to carry out a thematic analysis using the Nvivo (2006 QSR International Pty Ltd) computer programme. This programme analyses data to determine emergent trends and patterns and provides a methodical and systematic framework for eliciting and coding the emergent themes. The themes within this phase related to understanding the design and flow of the HeDSS.

7.4g Findings

Six female nurses participated in the interview. Five were white Caucasian, one was Asian and they ranged in age from 22 to 55 years. Three of the six nurses had been previously trained to screen for dysphagia using the existing trust dysphagia-screening tool. None of the nurses in the exploratory focus group had been trained to screen using the HeDSS.

All nurses actively participated in the focus group and were at times highly animated. The interview lasted just under 25 minutes and was brought to a close to stay within reasonable limits of what had been intended. The following results summarise the responses. Themes are listed and then illustrated with verbatim quotations in italics from the interview.

Question 1. ***What are your views on the algorithmic layout of the screening tool?***

i) Approval for the algorithmic design of the tool

Nurses were unanimous in their approval for the layout of the screening tool, identifying the need for logical directions. RGN 2 explained that she liked the layout because "*it is what we are used to*", RGN4 stated, "*what you need to do jumps out and grabs you"*.

ii) Aesthetics of the tool

The traffic light colour code of warning, stop and go were welcomed, three of the nurses specifically commented on liking the traffic light colour coding (RGNs 4, 5 and 6).

Question 2. ***Cochrane suggests a screening tool should progress logically and be easy to follow. Looking at this tool, what are your views on how it meets these requirements?***

i) Consensus for the logical flow of the screening tool

There was an overwhelming response that the tool's design was logical and easy to follow. "*Practical and straightforward"* were cited by four of the nurses. "*The tool is very straightforward, it's clear what you have to do"* (RGN 6). All other nurses nodded agreement.

ii) Roles and Responsibilities

Two RGNs expressed surprise that the severe dysarthria screening criterion was included in the draft screen: *"Hang on, where does this come in?"* (RGN 3) and *"I like the screening tool but I wonder if here*…" (pointing to the dysarthria question on the screen). "*it becomes a screen within a screen"* (RGN 4).

7.4h Conclusion

The overwhelming support for the algorithmic design and flow of the screening tool suggested its current format was acceptable to nurses. However, concerns were raised about the dysarthria criterion in terms of whether this would complicate the screening process. It was recognised at this point that the nurses had not been exposed to the dysphagia screening training programme that would be tailored to the HeDSS however, the concerns raised were

noted. The next phase of focus group work required a more in depth analysis of the nurses' understanding of the language of the HeDSS and the specific requirements for its implementation.

7.5 Phase 2: A focus group to determine understanding of the specific wording and implementation of the HeDSS

7.5a Introduction

Weeks *et al.* (2001) argue that the notion that knowledge can be transmitted from one person to another by words alone must be challenged. They quote the work of constructivists such as Von Glaserfeld (1987) who argue that words can be interpreted differently according to the prior experiences and internal representations that the person holds. It was therefore important to evaluate how nurses interpreted the specific language of the tool and thus what they needed to do to implement the tool. This data would potentially contribute to the evaluation of the training programme in terms of whether the training programme changed the nurses' understanding of the words and specific requirements of the tool.

7.5b Methods

During November 2007, I arranged a focus group with a convenience sample of registered nurses (n=6) representing the typical range of registered nurses who may work with acute stroke patients. The objective here was to evaluate the nurses understanding of the specific language and hence the requirements for implementing the tool in the absence of dysphagia screening training.

7.5c Sample

A purposive convenience sample of six registered general nurses (RGNs) working on acute medical wards in Trust 2 participated in the pre-training focus group facilitated by the researcher (SLTR). The nurses represented a similar range of registered nurse grades from

newly qualified to ward sisters as in focus group 1 and all worked on acute medical wards within Trust 2. None of the nurses had previous experience of dysphagia screening. A profile of the registered nurses is outlined in Table 14 below:

Table 14: Demographic profile of pre-screening training focus-group participants

Nurse Grades	Time Qualified	Female	Male
1.Ward sister	25 years	X	
2.Junior RGN	1 year	X	
3.Junior RGN	2 Years	X	
4.Mid Grade RGN	6 Years		X
5.Senior RGN/Deputy Sister	18 Years	X	
6.Mid Grade RGN (trained in Asia)	8 Years (2 Years spent in Britain)		X

7.5d Procedure

The focus group was convened in a seminar room away from the main ward. The room was free from distractions such as phones and background noise and a 'meeting in progress sign' was placed on the door to deter other ward staff from disturbing the meeting. Forty five minutes were set aside for the focus group; the time being determined by the nurses themselves who needed to be released to cover their wards or leave for home at the end of their shifts. The purpose of the focus group was explained by the SLTR. Permission was obtained to record the meeting using a tape recorder and informed consent was ascertained and recorded verbally.

As in the initial focus group, ground rules were outlined to all the nurses and covered areas of confidentiality, respecting one another's opinions and to talk to each other rather than directly to me. The nurses were asked to state their first name before speaking for the purpose of identification when later transcribing the data. I led the focus group as moderator using semi-structured questions (Table 15) designed to encourage group discourse. All nurses had a copy of the HeDSS in front of them to refer to as the questions were asked. The HeDSS (in its final format), is illustrated on page 149.

Table 15. Questions raised for discussion in the pre-dysphagia screening training focus group

Questions	Format
1	The tool asks 'Is the patient alert and able to maintain full consciousness for the duration of the screen?' What does that mean to you?
2	Here the tool asks 'Can the patient sit/be sat upright?' What does this mean to you?
3	The tool asks whether the patient's speech on counting to ten is 'severely slurred/unable to understand'. What do you understand this to mean?
4	Here the tool asks you to 'Give 50 mls of water from a glass. Ask patient to drink water as quickly and comfortably as possible. On the prompt to 'swallow' start the stopwatch when the first drop of water touches the lips whilst observing the Adam's apple/larynx for movement' What do you understand by this?
5	The tool asks you to 'Stop if the patient coughs or experiences difficulty' Can you explain what you understand by this statement?
6	What do you understand by the question 'Is prompt, upward movement of the larynx noted?'

Table 15. Questions raised for discussion in the pre-dysphagia screening training focus group (continued)

7	Here the tool asks 'Can the patient drink the water without coughing during or after the swallow'-what do you understand by this?
8	The tool asks 'Can patient swallow 50mls of water within 5 seconds' can you explain what you understand this to mean?
9	Do you have any comments about the overall design of the screening tool?

Field notes were also made during the focus group and expanded on immediately following the discussion.

7.5e Question formats-rationale

The questions were specifically phrased to capture how the nurses interpreted the language and therefore the implementation of the screening tool. This was crucial for determining whether the nurses could interpret and follow the instructions of the tool for its intended purpose. Mis-application of the screening tool could potentially lead to the nurses making inappropriate decisions as to the patient's ability to eat and drink safely or their need for a clinical dysphagia assessment. Where confusion or new themes emerged during discussions, these were explored with the nurses using open ended and probing questioning e.g. 'Can you expand on what you have just said?'

7.5f Data analysis

The recorded interviews were again transcribed then entered into the Nvivo computer programme (2006 QSR International Pty Ltd) to determine emergent themes and patterns. The themes are outlined below:

Questions and Responses (see Appendix 13 for focus group raw data).

Question 1. *The tool asks, "Is the patient alert and able to maintain full consciousness for the duration of the screen?" What does this mean to you?*

Three themes emerged from the nurses' responses to this question:

- **Wakefulness***:* All nurses agreed that this meant the patient can maintain wakefulness 'awake' was cited by three of the nurses.
- **Awareness of surroundings*:*** Two nurses specifically referred to the patient needing to be aware of their surroundings or to "know what is going on" to which two of the other nurses nodded agreement
- **Communication**: Two nurses referred to determining the patients' ability to communicate

  "Can understand what I am saying even though they might not be able to respond because of a speech problem... They can maintain eye contact and show there is some understanding even if it is in their non verbal response" (Nurse 5),

  "*I guess it means if the patient can talk to you and answer questions appropriately*" (Nurse 6).

Question 2. *Here the tool asks, "Can the patient sit/be sat upright?" What does this mean to you?*

All responses related to the patient being able to be positioned upright "sitting posture" was used by two nurses and "90 ^{o}" was used by nurses 1 and 3.

Question 3. *The tool asks whether the patient's speech on counting to ten, is 'severely slurred/unable to understand'. What do you understand this to mean?*

Responses to this question were mixed but an overwhelming theme that emerged was one of confusion as to what constitutes severe dysarthria and concern as to roles and responsibilities for determining severe slurred speech in certain patients.

- **Differentiating between dysarthria and other causes of poor speech.** *"Working out whether someone has severely slurred speech adds another complication for the nurses to consider"* (RGN 1)
  "It might be difficult to work out if the patient is confused or dysarthric" (RGN 3).

- **Slurred speech** RGN 1 and 4 explained the speech would be "*very slurred and difficult to understand"*

- **Misleading wording** RGNs 5 and 6 indicated confusion over the wording of the instruction i.e. they perceived "unable to understand" to mean the patient has comprehension problems as highlighted in RGN 5's response: *"the patient is unable to understand the instructions"*. It was clear that the specific wording of the instruction was misleading and needed to be made more explicit.

- **Role and responsibilities**. The theme of role and responsibilities was raised by RGN 2's response (pointing to the instruction which requires the nurses to determine on counting to ten, whether the speech is severely slurred) *"I don't know whether I'd be qualified to determine that"*.

Question 4. *Here the tool asks you to 'Give 50 mls of water from a glass. Ask patient to drink water as quickly and comfortably as possible. On the prompt to 'swallow' start the stopwatch when the first drop of water touches the lips whilst observing the Adam's apple/larynx for movement' What do you understand by this**?***

- **Clarity for measuring 50 mls water.** All RGNs indicated they understood that they needed to measure 50 mls of water into a glass.

- **Wording not clear** RGNs 1 and 2 expressed concerns relating to the specific wording of the instruction

"I'm wondering if 'finish the drink' would be better than 'completes the drink" I think prompt to swallow makes this confusing. I prefer to leave it at "begin timing when the first drop of water touches the patient's mouth…there is a time lapse between on the prompt to swallow and then actually starting to begin timing". (RGN1)

When prompted to enlarge on her response, RGN 2 complained that drinking without pausing is "*not explicit, it doesn't say without pausing*". Again the specific wording was misleading and needed to be made more explicit to avoid mis-interpretation of the HeDSS.

Question 5. *The tool asks you to 'Stop if the patient coughs or experiences difficulty' can you explain what you understand by this statement?*

All RGNs were clear of the need to stop the screen if the patient coughs or experiences difficulty such as choking.

Question 6. *What do you understand by the question 'Is prompt, upward movement of the larynx noted?*

As with question 5, this instruction was clearly understood and the larynx related to the "*throat area*" (RGN6) or "*Adam's apple*" (RGNs 4, 2, 3)

Question 7. *Here the tool asks 'Can the patient drink the water without coughing during or after the swallow'-what do you understand by this?*

This instruction was clearly understood by all RGNS. RGN 1 clearly differentiated between coughing during or following swallowing as indicating a problem whilst coughing before swallowing may indicate "*they (patients) could be nervous or just need to clear their throat*"

Question 8. *The tool asks 'Can the patient swallow 50mls of water within 5 seconds?' can you explain what you understand this to mean?*

All six RGNs suggested this instruction was 'obvious' in that the patient would be timed drinking 50mls from a glass over 5 seconds. RGN 2 suggested it would be helpful if a note was made in brackets on the relevance of drinking 50mls within 5 seconds i.e. "what is the average for healthy normal people".

Question 9. *Do you have any comments about the overall design of the screening tool?*

- **Lack of clarity for the colour coding system.** An overwhelming theme of lack of clarity over the relevance of the colour coding used on the screening tool was made by all RGNs. Five of the six nurses suggested a key or box to explain the coding of the colours.

- **Algorithmic design of the tool** With regard to the algorithmic design of the tool, RGNs 5 and 6 indicated approval "*I am used to algorithms*" (RGN 5) "*An algorithm is a good idea because it is like a chain of actions.*" (RGN 6).

7.6 Conclusion

In conclusion, the focus groups provided invaluable insight into the nurses' perceptions of the design and logical flow of the HeDSS as well as the understanding of the specific language used within the tool; a necessary precursor to the development of the nurses' dysphagia screening training programme.

As stated in the introduction, a predominant misconception exists that knowledge may be transmitted from one person to another by words alone. These focus groups have highlighted an essential need to involve the users in the development and evaluation of the HeDSS to avoid misinterpretation or misuse in its implementation.

The main themes to emerge relate to the specific wording and nurses' perceived roles and responsibilities in implementing the tool. Using question 1 as an example, it is not the author's intention to exclude people who cannot adequately communicate from having their swallow evaluated yet the tool's instruction to determine that the patient is 'alert' was clearly interpreted as being able to communicate according to two of the six nurses or to be aware of their surroundings. With regard to roles and responsibilities, concern was raised about determining severe dysarthria/severely slurred speech and differentiating this as a criterion from other elements of communication problems. As a clinician, the notion that severe dysarthria is highly accurate for ruling in aspiration risk did not sit comfortably as through experience, I knew of many patients with severe dysarthria who can manage drinks

well without suffering aspiration (as is reported in the literature with regards to the low sensitivity of the criterion). It was therefore felt important to address these themes by returning to the literature to determine the incidence of severe dysarthria, scoping the size of the problem and on the basis of this, making a judgement on whether this criterion could feasibly remain within the HeDSS. There was also a need to re-draft the specific wording of the screening tool prior to developing the training programme.

7.7 Discussion

7.7a Reviewing the design and development of the HeDSS

As noted, focus groups carried out to evaluate the design and specific wording of the HeDSS revealed a number of problems with regard to the use of the severe dysarthria/severely slurred speech criterion and the specific wording. In keeping with the Action Research Framework, the specific data and identified problems that emerged from the focus groups required a period of reflection. A decision was made to revisit the literature and scope out the size of the 'severe dysarthria' problem in terms of its incidence and prevalence within the acute stroke population, the reliability for determining severe dysarthria compared against for example moderate dysarthria and to check the original study on which the basis to include this criterion was made.

7.6b Use of 'Severe Dysarthria' as a criterion within the HeDSS

Incidence

I was unable to find specific data within the literature relating to the incidence or prevalence of severe dysarthria. However, frequencies between 20 and 30% have been reported for dysarthria following stroke (Arboix *et al.* 1990, Melo *et al.* 1992, Warlow 2001) highlighting that dysarthria per se is not a frequent outcome of stroke.

Evaluating dysarthria

In terms of judging its presence, the literature points to the difficulty in evaluating the nature and severity of dysarthria. This is largely due to the fact that the precision of speech production will vary. It can also be difficult to differentiate it diagnostically from other communication disorders. Swigert (1997) highlights the considerable skills required to evaluate dysarthria. Two dysarthria assessments, 'The Dysarthria Test' (Hartelius *et al.* 1993) and the 'Frenchay Dysarthria Assessment' (Enderby 1983) are commonly used to assess the severity of dysarthria and comprise of between six to 11 elements of speech that are tested for the differential description and diagnosis of dysarthria. These include the assessment of respiration, voice loudness and pitch. As is normally the case with evaluation based on subjective criteria, consensus for classification of severity of dysarthria particularly where this relates to intelligibility may be poor even among experts and can vary by around 30% (Carmichael and Green 2003). Hence, from the literature review, practical difficulties of nurses making a judgement on the severity of dysarthria within a bedside dysphagia screening tool are very apparent.

Reviewing the original article from which the decision for including severe dysarthria was made

In the early phases of my research journey, I read many articles relating to the sensitivity and specificity of dysphagia screening criteria. My literature review included review articles by eminent academics in the field of dysphagia. One such review written by Martino *et al.* (2000) which apparently applied strict criteria for conducting a systematic review, helped form my opinion on the decision to include severe dysarthria as a screening criterion. Unfortunately, despite having sought out the original articles for all other potential screening criteria, I failed to do so with this criterion. The article; 'Dysphagia following brain-stem stroke. Clinical correlates and outcome' (Horner *et al.* 1991) was reviewed. The sample size employed in the study was very small (23) thus statistical power calculations were not reported. The study's design was further weakened through its failure to use investigator blinding or reliability testing. Horner's study reported high specificity of 100% but low sensitivity of 47% for severe dysarthria as a predictor of the presence of dysphagia. Mild and moderate dysarthria had relatively poor predictive values (mild = 33% sensitivity, 43% specificity, moderate = 13% sensitivity and 57% specificity) again highlighting its poor predictive ability to determine the presence and absence of dysphagia.

Clearly, Horner's study used a weak study design and methodology. The study's reported predicted values are not strong for moderate dysarthria and having determined through the literature review how difficult it is to evaluate dysarthria, it cannot be justifiably used as a predictor for determining dysphagia presence or absence. Additionally, it was determined that dysarthria is not a frequent outcome of acute stroke to justify a sufficient concern. In view of this new information and reflection, a decision was made to remove this criterion from the HeDSS**.**

The specific wording was reviewed in light of the information gained from the focus groups. This was then further reflected on as the design of the nurses' dysphagia screening education programme was planned as described in the following chapter. The final form of the HeDSS is provided in Figure 14 overpage.

HEAD DYSPHAGIA SCREEN FOR STROKE (HeDSS)

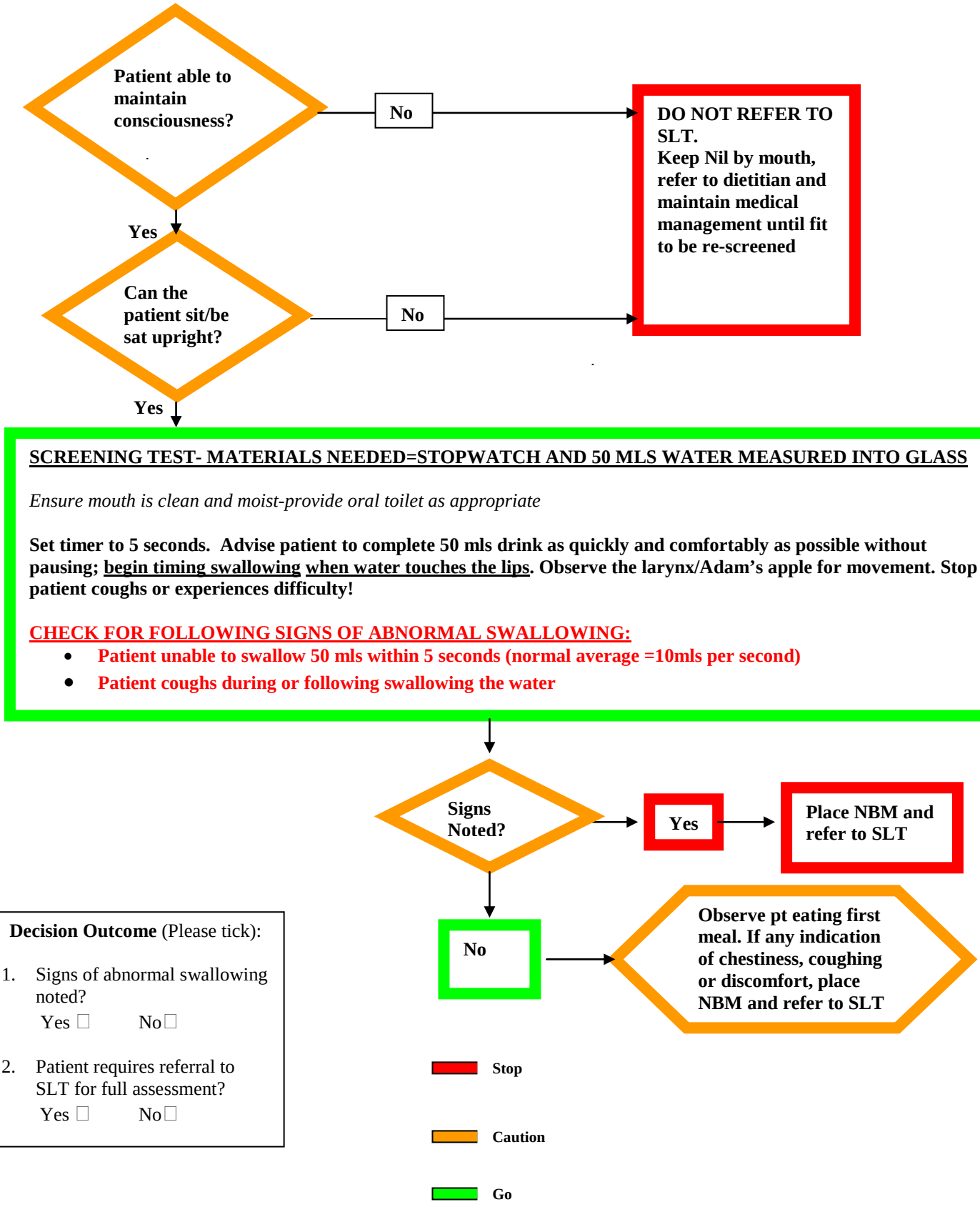


Figure 14: Head Dysphagia Screen for Stroke (HeDSS)

Chapter 8: The Design and Development of the Nurse Dysphagia Screening Education Programme

8.1 Aims

To develop RGNs' understanding and use of the Head Dysphagia Screen for Stroke (HeDSS) to determine the presence and absence of dysphagia and the appropriateness of referral of acute stroke patients for a clinical dysphagia assessment by the SLT.

8.2 Introduction

The focus groups highlighted the importance of nurses' opinions in the designing of the training programme; a programme based on the cyclical processes of action research i.e. planning--acting--observing--reflecting. Stringer (2008) explains that the ultimate objective of data analysis in action research is to understand how people experience and interpret activities that shape their actions and behaviours.

According to the responses elicited from the focus groups, the data indicated a need to define the design of the nurse dysphagia screening education programme. Clear requirements to explain the specific wording used within the tool and its practical implementation as well as to clarify roles and responsibilities were determined. Before considering the design of the nurse dysphagia screening education programme, some time was required to consider the practical implications of the specific skill acquisition required for dysphagia screening and what, if any, factors affect this. Benner's insightful book 'From Novice to Expert; Excellence and Power in Clinical Nursing Practice' (1984) was reviewed in order to identify potential problems that may be anticipated from the point of the RGNs taking on the new role of screening and ultimately to becoming experienced in screening. These implications were considered and addressed in the training programme.

8.2a Nurses' knowledge of dysphagia and its management

In an American study, McHale *et al.* (1998) explored the practical knowledge of expert nurses when they assess and feed patients at risk of dysphagia. In their descriptive, exploratory study, 12 registered nurses who were expert in the care of patients at risk of dysphagia were interviewed. They concluded from the interviews that although some nurses had considerable experiential knowledge of assessing and feeding patients, they had difficulty in articulating the processes involved in carrying out these tasks. The nurses acknowledged their role in feeding patients, providing nutrition and preventing complications such as aspiration but were less clear on their role in determining swallowing status. These findings are supported in subsequent studies such as Colodyn (2001) and Miller and Krawczyk (2001) who identified role perception and lack of knowledge as a key factor for non-engagement in dysphagia screening and management.

8.2b Factors affecting nurse learning and skill acquisition

The conceptual understanding of the acquisition and development of a nurse practitioner's competence from novice to expert was originally described by Benner (1984) describing the results of a qualitative study of nurses, identified five levels of competency in clinical nursing practice, which were based on an earlier model postulated by Dreyfus (1981).

Stage 1: Novice

The novice has had no experience of the situations in which he or she is expected to perform. Novices are taught context free rules, which are used to guide their actions and these tend to be applied universally. The rule-governed behaviour typical of the novice is thereby extremely limited and inflexible.

Stage 2: Advanced Beginner

Advanced beginners demonstrate marginally acceptable performance and begin to perceive either for themselves or with the help of a mentor, meaningful situational insights. These insights require prior experience in actual situations for recognition. Principles to guide

actions begin to be formulated but at this stage, the advanced beginner may miss some critical details from a new situation.

Stage 3: Competent

Competence develops as the practitioner becomes aware of all relevant aspects of a situation. The nurse begins to see his or her actions in terms of long-range goals or plans. For the competent nurse, plans based on contemplation of the problem, establish a perspective of the task. The skills developed at this level help achieve efficiency and organisation but lacks the speed and flexibility of the proficient nurse. The competent practitioner does not yet have enough experience to recognise a situation in terms of an overall picture or in terms of which aspects are most salient or most important.

Stage 4: Proficient

The proficient practitioner perceives situations as wholes rather than in terms of small, defined aspects and performance is guided by rules underpinned by a deeper understanding of the situation. The ability to perceive a situation holistically and from a range of different perspectives is key to this level of competence.

Stage 5: The Expert

The expert practitioner no longer relies on analytical principles to connect understanding of a situation to an appropriate action. Competence at this level is underpinned by wider experience and intuition of each situation and an ability to focus in on the problem. The expert practitioner demonstrates a deep understanding of the whole situation and may account for their decisions to undertake a task as being based on having an instinctive or 'gut feeling' about the task. Performance becomes more flexible and highly proficient but where situations present as novel, the expert will again need to use highly skilled analytical problem solving skills.

8.3 Implications for planning the nurse dysphagia screening education programme

Benner (1984) concludes that nurse skill acquisition requires well-planned educational programmes. It is important to consider the specific components and phases of skill acquisition for the design of the nurse dysphagia screening education programme in terms of planning for experience-based skill acquisition in combination with the necessary theoretical component of the training.

8.4 Planning the design of the nurse dysphagia screening education programme

In designing a training programme, it is accepted that for training to be effective, participants need to be actively engaged rather than simply 'receiving'. There was a need for blended learning, which provides both theory and practice as was borne out in the focus group data and the work of Benner (1984), Stringer (2008) and others. It was therefore useful to consider a flexible approach to developing the nurses' dysphagia screening education programme.

Joyce and Showers (2002) suggest five requisite components necessary for training skill acquisition and these underpinned the nurses' dysphagia screening education programme:

- **Theory**: presentation of the theory that explains the value, importance and use of the skill i.e. the telling or describing portion of training;
- **Demonstration:** demonstration of the skill to be carried out;
- **Practice:** Opportunities for the learners to practice the skill both under the direction of the expert trainer and within more natural e.g. ward based settings;
- **Feedback**: timely and constructive feedback on the learners' practice in order that they understand what they are doing well and what requires further refining;
- **Follow up**: more long term guidance and support so that what is practised within the training programme can be transferred to the workplace.

8.5 Training programme objectives

The objectives of the training programme were;

- For nurses to gain an understanding of normal swallowing, signs of dysphagia, associated risks and basic dysphagia management in the stroke population;
- For nurses to understand the specific language and instructions of the HeDSS as well as the rationale for its inclusion, necessary to conduct dysphagia screening with acute stroke patients;
- To develop the specific competence and confidence of registered nurses to screen swallowing function using the HeDSS in order to determine patients who may or may not demonstrate signs of dysphagia;
- To provide the nurses with the clinical skills sufficient to know when an appropriate referral is required for a full clinical dysphagia assessment carried out by the SLT or when they can initiate oral feeding recommendations in the absence of signs of dysphagia;
- To develop the knowledge and competence of registered nurses to refer patients with an urgent need of a swallowing assessment to the SLT department with a complete and documented swallowing screen.

8.6 Details of the dysphagia screening training education programme

8.6a Theoretical knowledge

Normal versus abnormal swallowing

The first focus of the dysphagia screening education programme was to provide an overview of normal versus abnormal oral and pharyngeal swallowing. The rationale of this was for nurses to understand normal and abnormal patterns of swallowing including those covered by the screening criteria which is outlined in Table 16 page 158. An operational definition of dysphagia was outlined. For the purpose of the study, dysphagia was defined as difficulty in the oral and /or pharyngeal phases of swallowing as determined by an inability to swallow 50 mls of water within five seconds and coughing during or following swallowing. Main causes of dysphagia i.e. neurological, structural, age related, psychological and associated risks including poor conscious levels and poor posture for

eating and drinking were further described. The purpose of this was for nurses to be alerted to at-risk groups and to gain an understanding of how these conditions and risk factors impact on swallowing. Complications of dysphagia including malnutrition, dehydration, aspiration pneumonia, medical complications and death were further described in order that the nurses were cognisant of the full impact of dysphagia and its signs. Finally, chronic signs of dysphagia (refer to glossary) including coughing during and following swallowing and the development of chest infections were explained in order that nurses could identify the differing manifestations of dysphagia.

Drivers for screening, roles and responsibilities

The specific drivers for screening were further outlined. These included the Royal College of Physicians (2004) guidelines for screening acute stroke patients for the presence and absence of dysphagia (see glossary). This was supported by a brief outline of nurses' roles and responsibilities in identifying and managing patients with eating and drinking difficulties in terms of the professional scope of practice (refer to Chapter 2). SLTs' roles and responsibilities in the assessment and management of dysphagia were further described. An emphasis on the difference between dysphagia screening and dysphagia assessment was made as follows:

- Dysphagia screening is a test designed to identify the possibility that dysphagia might be present and to prompt appropriate referral for a detailed assessment of swallowing in patients who screen positive;
- Dysphagia assessment is designed to provide the clinician with some certainty that a disease is present i.e. by providing information on the underlying cause of the condition (please refer to Appendix 1).

The purpose of this was to clarify roles and thereby facilitate engagement in the dysphagia-screening programme; a pre-requisite identified in previous studies (McHale 1998, Colodyn 2001, Miller and Krawczyk 2001).

Understanding and use of the HeDSS

Explanations of the specific wording of the screening tool and the rationale for the same were provided as outlined in Table 16.

Table 16: Operational definitions and rationale for wording of HeDSS

Wording of Screening	Operational Definition	Rationale
Patient able to maintain consciousness?	The patient must maintain wakefulness for the duration of the screen without requiring prompts to stay awake	Reduced consciousness is an independent risk factor for dysphagia and complications of feeding
Can the patient sit/be sat upright?	The patient must able to sit or be sat upright approximating a 90 degree angle before commencing screening	Recumbent posture has been found to be a predictor for dysphagia and complications
Ensure the mouth is clean and moist. Provide oral care to include rinsing/cleaning with normal water	Ensure the tongue is cleaned with a mild solution of oral mouthwash and rinsed with tap water before commencing screening	a) A dry mouth increases oral preparation and swallowing time, which may skew the results of the subsequent timed swallowing of water. b) Cleaning the mouth reduces risks of aspiration of oral bacteria into the airway and subsequent chest complications
Measure 50 mls of water from a medical aliquot into a glass	Measure 50 mls of water from a medical aliquot into a hospital glass	People adjust their swallowing volume according to the size of the drinking vessel. Hence, if taken from a medical aliquot, the patient would be inclined to take very small sips and thereby prolong the swallowing time.
Ensure the timer is set to 5 seconds	Set the digital timer to 5 seconds (this is normally preset but can be set by pressing the second button on the timer)	The patient will be timed drinking the 50mls over 5 seconds. The normal average volume per swallow is around 25-30mls (Adnerhill 2004). An average volume of 10mls per second has been equated with normal swallowing (Hughes *et al.* 1996)
Inform the patient he/she must try to finish the drink as quickly and comfortably as possible without pausing	The patient needs to drink the given volume of water as quickly and comfortably as possible within the 5 seconds	Speed of swallowing a given volume of water is an evidence based screening criterion for determining the presence or absence of dysphagia
Give the patient 50mls of water in a glass and begin timing swallowing as soon as the water touches the patient's	Time the patient swallowing 50mls of water from the point when the water is seen to touch the lips. Normal swallowing should begin almost instantly	Rationale as above. It is important to observe the movement of the larynx as an indicator that swallowing is taking place as the larynx typically elevates then

lips (i.e. press start on the timer). Observe the Adam's apple for movement	as noted from movement of the Adams Apple/larynx	quickly returns to its resting position for each swallow cycle during normal swallowing
Stop if the patient coughs during or following swallowing	Stop the screen and take the water off the patient if coughing occurs during drinking	Coughing during and following swallow has been found to suggest dysphagia and aspiration risk
Check for signs of dysphagia: -Patient unable to swallow 50mls within 5 seconds -Patient coughs during or following swallowing	See points above	See rationale for timed swallowing and coughing during/following swallowing above
Decision outcome 'Signs of abnormal swallowing' 'Patient requires referral to SLT for full assessment	Signs of abnormal swallowing are: reduced consciousness, poor sitting posture, an inability to complete drinking of 50 mls of water within 5 seconds, coughing during and following swallowing. The patient requires referral to SLT only if unable to completely swallow 50 mls of water (i.e. no/limited movement of the larynx is observed) within 5 seconds or coughs during/ following swallowing	It is important to determine whether the nurse and the research SLT agree on two points: a) whether or not the patient displays signs of dysphagia b) whether the patient requires a referral to the SLT for a clinical dysphagia assessment
Observe patient eating first meal. If any indication of chestiness, coughing or discomfort, place nil by mouth and refer to the SLT	The patient should be witnessed by a nurse eating their first meal and a note be made of any coughing, chestiness or discomfort as an indication of whether the patient can cope with diet.	The patient has not been tested with diet therefore, measures should be taken during the patient's first meal to check for any potential signs of difficulty. If difficulties are observed the patient should be placed nil by mouth and referred to SLT as appropriate

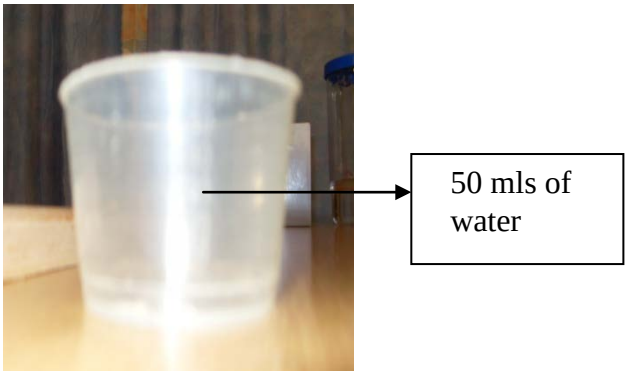
8.6b Practical component of training programme

The practical component of the nurses' dysphagia screening education programme comprised a practical demonstration of the implementation of the HeDSS with trainees and trainer in the training venue. Here nurses were able to observe the trainer (the SLTR) demonstrate use of the HeDSS on herself and the nurses followed by practising use of the tool on each other in order that the nurses could practice screening in the safe environment. This was followed by ward based supervision of the RGNs using the HeDSS with acute stroke patients. Specifically, the ward based practical component comprised:

- Ward based, supervised screening with a minimum of two acute stroke patients. The RGNs were shown the appropriate position for the patient to be in for carrying out the screen, how to determine level of consciousness of the patient and to check the mouth to determine oral hygiene. They were further shown how to set the digital timer, measure 50mls of water from a medical aliquot into a glass and position themselves to check for laryngeal movement during the timed swallowing component of the screen (this is illustrated in Figure 15);
- Documentation of the swallowing screen;
- How to refer to the speech and language therapy department; the referral criteria for referral i.e. RGNs are not to refer patients who are drowsy or who can't sit/be sat upright;
- For the purpose of the research, nurses were shown how to record the outcomes of their screen whilst ensuring that their decisions were not discussed with the SLTR or the other participating RGN to ensure screening or assessment outcomes were not influenced by knowledge of each other's screen. The research protocol for the study was further outlined (see appendices 8 and 10).

Requirements for the timed component of the prototype dysphagia screen

1. Digital timer set to five seconds



2. 50mls of water measured into a medical aliquot and then poured into a hospital glass

3. The nurse positions herself where she can observe movement of the patient's larynx during swallowing. The patient is evaluated continuously drinking 50mls of water over 5 seconds; timing starting as soon as the water touches the lips.

Figure 15: Requirements for carrying out the timed component of the HeDSS

8.7 Conclusion

A clear need for consistency in the interpretation and use of the HeDSS was identified during the design and planning phases of the research programme in order to reduce the risks of threats to internal validity (see Chapter 4). The nurse dysphagia screening education programme was based on the outcomes of the focus groups and a review of the literature for ascertaining typical learning styles and the requirements for communicating how to implement the HeDSS. The RGNs recruited for the empirical phase of the study attended a one hour presentation that covered normal and abnormal swallowing, the understanding and use of the tool and professional aspects of the dysphagia trained nurse and SLT role for the identification and management of dysphagia. An explanation for the rationale and method of evaluating each criterion contained within the screening tool was covered. Determining signs of dysphagia at the bedside and appropriateness for referring the acute stroke patient to SLT for a clinical dysphagia assessment is based on the specific criteria contained within the HeDSS. The decisions made are therefore dichotomous; signs detected?-Yes/no and appropriate to refer to SLT? Yes/no.

Having provided the requisite dysphagia screening training for the four nurses recruited for the two empirical phases, it was necessary to measure its performance in terms of its consistency in use and its ability to accurately determine acute stroke patients appropriate for clinical dysphagia assessment. These measures are described in the following chapters.

Chapter 9: Inter-rater Reliability of the Head Dysphagia Screen for Stroke (HeDSS)

9.1 Summary

9.1a Aim

To investigate whether the HeDSS can reliably determine the presence/absence of dysphagia in acute stroke patients and determine patients appropriate for referral to SLT for a clinical dysphagia assessment.

9.1b Objective

To establish inter-rater reliability of the HeDSS for determining the presence and absence of signs of dysphagia and judging whether the patients screened are appropriate for referral for a clinical dysphagia assessment.

9.1c Study design

Evaluation of the HeDSS performed by two RGNs compared against its use by an expert (the SLTR) when independently screening a sample of hospitalised acute stroke patients.

9.1d Materials and methods

Raters: Two RGNs; one experienced and one novice both of whom worked on acute medical wards with stroke patients in Trust 2. A clinical lead SLT (SLTR) with 12 years+ postgraduate dysphagia experience

Patient sample: A prospective convenience sample of 40 hospitalised acute stroke inpatients (stroke confirmed by CT scan). These formed two groups; the first 20 patients in Group One were seen by the Novice RGN and the SLTR followed by the second 20 patients in Group Two seen by the Experienced RGN and the SLTR.

Methods: Data from the RGNs screening outcomes and the SLTR's screening outcomes using the HeDSS were analysed to determine the level of agreement.

9.1e Results

Kappa showed substantial agreement of measurement outcomes for detection of signs of dysphagia with the SLTR (Novice RGN kappa = .71; Experienced RGN kappa = .79) and for agreement for appropriateness for referral (Novice RGN kappa = .79; Experienced RGN kappa = .87).

9.1f Conclusion

In this study, the HeDSS when employed by registered nurses compared with its use by an expert SLT, was reliable for detecting the presence and absence of signs of dysphagia and for determining patients' appropriateness for referral for clinical dysphagia assessment by the SLT. These findings supported proceeding to the final phase of the research programme, to measure the validity of the screening tool when employed by nurses compared to a clinical dysphagia assessment performed by the SLTR.

9.2. Introduction and basis of inter-rater reliability study

As noted previously, the accuracy of a screening test is best determined by comparing it to an appropriate reference standard (Sackett 1991). Sackett (1991) and Baumgartner *et al.* (2008) note that in order for a measuring device to be valid; it must be first established as reliable. This phase of the research programme therefore explored the inter-rater reliability of the screening tool when employed by two representative grades of registered nurses as established from the audit of dysphagia screening practices (see Chapter 3), compared against its use by an expert (the SLTR). Specifically this phase of the research programme explored research question two:

Question 2. *Can RGNs use a newly designed dysphagia-screening tool in a way that is consistent with an expert using the tool?*

The rationale for undertaking this study was to evaluate whether RGNs agree with an SLT (the SLTR) when both are using the HeDSS. Use of the HeDSS was to be undertaken by both the RGNs and compared with an expert's screening outcomes of the same patients. Poor inter-rater reliability at this stage of the research programme would highlight the potential inappropriateness of the nurse dysphagia screening education programme or of the design features of the screening tool.

9.3. Research Design

This phase used a prospective blinded reliability design. This focussed on an evaluation of the inter-rater reliability of the measurement outcomes recorded by RGNs employing the HeDSS versus those recorded by an expert (the SLTR).

9.4. Methods:

9.4a. Recruitment of Registered General Nurses

Following ethical approval from the Research and Development Department at Trust Two and the Local Research Ethics Committee, a basic grade RGN with one year's experience (here referred to as 'Novice RGN') and an experienced RGN with 15 years

nursing experience (henceforth referred to as 'Experienced RGN') were recruited for this phase of the study. Prior to approaching the nurses for participation in the study, it was established with the ward manager that both nurses met the inclusion criteria for being registered to practice with the Nursing and Midwifery Council and were employed by Trust Two to work on acute medical wards. The research protocol was outlined and the commitment of both nurses for their engagement in the study was discussed i.e. the requirement that each nurse would be required to screen 20 acute stroke patients and ideally be available on weekdays so that both nurse and SLTR could screen the same patients on the same day. Both nurses were given the nurse information sheet to read and a consent form was subsequently signed **(**see Appendix 9).

9.4b Recruitment of patients for the study

Over a three-month period, a convenience sample of acute stroke patients admitted to a medical ward at Trust Two were approached for participation in the study. Prior to approaching patients, all relevant medical consultants, nurse managers and directorate managers were informed of the study. Permission was sought from the medical consultants to approach their patients. It was first established that the patients approached met the inclusion criteria for participation in the study (see Appendix 8). A ward-based research protocol directing the nurses to alert the SLTR of all stroke patients admitted to the ward was given to the ward managers and senior nurses to read and the same was discussed (see Appendix 8). This ensured that all relevant staff were clear about alerting the SLTR of admissions of acute stroke patients rather than only referring acute stroke patients that had failed an existing dysphagia screening test.

The aims and nature of the study were explained to the patients and an accompanying information sheet was either read to the patients or given to the patient to read (see Appendix 9). Patients with accompanying communication difficulties were not excluded from the study provided that the SLTR established that the patient had the capacity to consent as outlined in the Mental Capacity Act (2004). Where communication difficulties existed, care was taken to supplement the information sheet with simple language and pictures as appropriate. Patients who were judged as unable to provide informed consent

were excluded from the study as per exclusion criteria (see Appendix 8). Characteristics and patient demographics were recorded as a method of determining possible reasons for trends in measurement outcomes.

9.4 c. Average age of acute stroke patients recruited

The majority of acute stroke patients recruited for the study fell into the 'over 71' group over accounting for 70% of the sample. The age range of the patients recruited for the study is presented in Table 17:

Table 17: The average age range of acute stroke patients

Age Range	Frequency	Percent
31-40	1	2.5
51-60	2	5.0
61-70	9	22.5
over 71	28	70.0
Total	40	100.0

9.4d. Stroke aetiologies of patients recruited

Stroke aetiologies were recorded as a method of evaluating potential differences or trends in screening results e.g. if due to stroke severity or location of lesion. These are presented in Table 18.

Table 18: Stroke type expressed as frequencies and percentages

Stroke Type	Frequency	Percent
Right CVA	18	45%
Left CVA	17	42%
Mid Cerebral artery	3	7%
Haemorrhage	2	5%
Total	40	100%

9.5 Procedure

The research protocol was discussed with the participating ward to ask that during the study, any visible signs of feeding recommendations or the patient's feeding status such as jugs of water or signs, were removed from the patient's bedside just prior to the SLT and nurse participant's visit. This served to avoid potential bias of the SLT researcher or nurses picking up environmental cues as to the patient's swallowing status. The target number of 40 acute stroke patients provided informed consent to participate in this phase of the study. A profile of their characteristics along with a summary of the SLTR's and RGNs' screening outcomes is provided in Tables 19 and 20.

9.5a Patients excluded from the study

A total of 12 patients were excluded from the study. A breakdown of the reasons for exclusion is shown in Table 19 overpage.

Table 19: Characteristics and reasons for patients excluded from the study

Patient	Age	Medical condition	Gender	Reason excluded
1	>71	Left CVA	Male	Too drowsy
2	61-70	Left CVA	Female	Too drowsy
3	>71	Left CVA	Female	Accompanying neurological disease
4	61-70	Right CVA	Male	Too drowsy
5	61-70	Left CVA	Female	Too drowsy
6	>71	TIA	Female	CVA not confirmed by CT scan
7	>71	Left Trans ischaemic attack (TIA)	Female	CVA not confirmed by CT scan
8	>71	Right CVA-haemorrhagic infarct	Male	Diarrhoea and vomiting
9	>51-60	Right CVA	Male	Too drowsy
10	>71	Left CVA	Male	Unable to consent
11	>71	Right CVA	Female	Too drowsy
12	>71	MCA	Female	Too drowsy

9.6 Justification of methods

The reliability of the HeDSS when employed by both the nurses and expert (the SLTR) clinicians' ratings was a necessary consideration in order to evaluate the robustness of the tool. To summarise;

> '*A reliable test measures whatever it measures consistently. That is, if an individual whose ability is not changed is measured twice with a perfectly reliable measuring device, the two scores will be identically defined in terms of the agreement of raters about the value of a measurement*' (Baumgartner *et al.* 2003, page 114).

If two judges scoring the same individual on the same test cannot be shown to agree on a measurement outcome, the test may lack reliability as well as validity. Inter-rater reliability refers to the level of agreement between a particular set of judges using a particular instrument at a particular time (Stemler 2004). In the ideal study design, the dysphagia screens would be carried out at the same time by three different raters with the same patient. However, this design was not practical due to the need to limit investigator bias. It is therefore acknowledged that the three ratings were based on three swallow performances albeit within a relatively short period of time. Threats to the study design are outlined in Chapter 4 and will be addressed later in this chapter. In this study, it was felt important to evaluate the degree of agreement between two RGNs with different levels of nursing experience and an expert SLT (i.e. the SLTR), when employing the HeDSS. The decision for selecting RGNs with different levels of nursing experience was undertaken to reflect the range of nurse grades that may use a dysphagia screening tool and to evaluate whether any differences in screening outcomes were related to level of nursing experience or confidence in decision making (see Chapter 8).

As recorded previously in the inter-rater reliability study between the SLTR and a contemporary SLT, the data for measuring rater agreement was dichotomous and nominal in nature. Agreement was considered to exist where both the SLTR and RGN judged dysphagia to be present or absent on the first measure; and in the second measure where the RGN and SLTR judged referral to an SLT to be appropriate or not.

According to the literature (Baumgarter *et al*. 2003, Stemler 2004) a minimum sample size of 30 is necessary to determine inter-rater reliability. It would not have been ethical or practical to expose each patient to numerous screens by a number of nurses followed by the SLTR. A decision was therefore made to recruit two RGNs, each of whom would screen a group of 20 acute stroke patients followed by the SLTR screening both sets of patients (a total of 40 patients).

9.7 Data analysis

Results were analysed using proportion of agreement and kappa to determine level of agreement between the SLTs.

9.7a Justification of data analysis

An estimation of consensus of inter-rater reliability was calculated via proportion of agreement. As noted in Chapter 6, proportion of agreement is calculated by adding up the number of cases that received the same rating by both judges and dividing by the total number of cases rated by the two judges. The proportion of agreement statistic was again selected for its strong intuitive appeal, its ease of calculation, and for being easy to explain (Stemler 2004).

The kappa statistic was used as a supporting method of estimating inter-rater reliability. In this phase of the research, the SLTR was again acting as a 'rater' i.e. her rating of dysphagia presence and appropriateness for referral to SLT using the HeDSS was compared against the RGNs' ratings using the same tool. The data analysis was therefore focused on measuring the level of agreement between her screening outcomes and those of the RGNs. The kappa statistic is appropriate for testing whether agreement exceeds what would be expected by chance and can be easily applied to dichotomous decisions (here dysphagia present/dysphagia absent and appropriate to refer/not appropriate to refer to SLT). A detailed description of kappa, its interpretation and how it differs to proportion of agreement is provided in Chapter 6 along with the rationale for not overly focusing on significance testing.

9.8. Results:

A summary of cases assessed by the SLTR and each of the RGNs is provided in Tables 20 and 21.

Table 20: Case summaries for SLTR and RGNs

Pt #	Gender	Age	Stroke type	SLTR Dysphagia present/absent	Novice RGN Dysphagia present/absent	SLTR Refer to SLT?	Novice RGN Refer to SLT?
1	Male	>71	Left CVA	1	1	1	1
2	Female	61-70	Right CVA	0	0	0	0
3	Male	61-70	Right CVA	1	1	1	1
4	Male	>71	Left CVA	0	0	0	0
5	Female	61-70	Left CVA	1	1	1	1
6	Male	61-70	MCA	0	1	0	1
7	Female	51-60	Left CVA	0	0	0	0
8	Female	>71	Right CVA	1	1	0	0
9	Female	>71	Right CVA	0	0	0	0
10	Female	>71	Left CVA	1	1	1	1
11	Female	61-70	Left CVA	0	0	0	0
12	Female	31-40	Left CVA	0	1	0	0
13	Female	>71	Right CVA	1	1	1	1
14	Male	>71	Left CVA	1	1	1	1
15	Female	>71	Right CVA	0	1	0	1
16	Female	>71	Left CVA	0	0	0	0
17	Male	> 71	Right CVA	1	1	1	1
18	Female	> 71	Right CVA	0	0	0	0
19	Female	> 71	Left CVA	0	0	0	0
20	Female	> 71	Left CVA	0	0	0	0

Key: = agreed decisions = disagreed decisions MCA= Mid cerebral artery

1= signs of dysphagia present; and for second measure, referral to SLT appropriate

0= no signs of dysphagia present; and for second measure, referral to SLT not appropriate

Pt #	Gender	Age	Stroke type	SLTR Dysphagia present/absent	Experienced RGN Dysphagia present/absent	SLTR Refer to SLT?	Experienced RGN Refer to SLT?
21	Male	61-70	Left CVA	1	1	0	0
22	Male	>71	Left CVA	1	1	1	1
23	Female	61-70	MCA	0	0	0	0
24	Male	61-70	Left CVA	1	1	1	1
25	Female	> 71	Right CVA	0	0	0	0
26	Female	> 71	Right CVA	1	1	1	1
27	Female	> 71	Right CVA	1	1	1	1
28	Male	> 71	Left CVA	0	1	0	1
29	Female	> 71	Right CVA	0	0	0	0
30	Female	> 71	Right CVA	0	0	0	0
31	Female	> 71	Left CVA	0	0	0	0
32	Female	> 71	Left CVA	0	0	0	0
33	Male	61-70	Right CVA	0	1	0	1
34	Female	> 71	Right CVA	0	0	0	0
35	Female	> 71	Right CVA	0	0	0	0
36	Female	> 71	Right CVA	1	1	0	0
37	Female	> 71	MCA	0	0	0	0
38	Male	> 71	Right CVA	0	0	0	0
39	Male	> 71	Left CVA	0	0	0	0
40	Female	> 71	Left CVA	1	1	1	1

Key: please refer to Table 20

9.8a Estimation of Inter-rater reliability SLTR and Novice RGN

Proportion of agreement calculations are explained in 6.7b and are presented overpage.

9.8a (i) SLTR and Novice RGN: Detection of dysphagia

Table 21: Detection of dysphagia: SLTR versus Novice RGN screening decisions

		SLTR		
		Present	Absent	Total
Novice RGN	Present	8 (a)	3 (b)	11 (a + b)
	Absent	0 (c)	9 (d)	9 (c + d)
	Total	8 (a + c)	12 (b + d)	20 (a + b + c + d)

Proportion of agreement calculated for the contingency table

$$p_o = \frac{a + d}{a + b + c + d} \qquad p_o = \frac{8 + 9}{8 + 0 + 3 + 9} = \frac{17}{20} = .85 \text{ (correct to 2 dp)}$$

The proportion of agreement for the SLTR and the Novice RGN's screening outcomes is **.85** indicating a high agreement of ratings and reflects that they agreed with each other for 85% of the cases assessed.

Kappa calculation for SLTR versus Novice RGN screening decisions for dysphagia detection (please refer to 6.7c for explanation of calculation):

$$k = \frac{p_o - Pr(e)}{1 - Pr(e)} \qquad k = \frac{.85 - .49}{1 - .49} = \frac{.36}{.51} = .71 \text{ (correct to 2 dp)}$$

According to Landis and Koch (1977) a kappa value of .71 suggests substantial agreement (see Appendix 1 for criteria) between the SLTR and Novice RGN's screening measurement outcomes for detection of signs of dysphagia.

9.8a (ii) SLTR and Novice RGN: Determining patients appropriate for referral to SLT

Following the initial proof equation calculated on pages 127-128, all equations provided in this section and throughout the thesis will be rounded to two decimal places (dp) but were in fact calculated to four decimal places. Calculations are reported in Appendix 15. The screening decisions for the Novice RGN and SLTR are reported in Table 22 below.

Table 22: Determining patients appropriate for referral: SLTR versus Novice RGN screening decisions

		SLTR		
		Referral	No Referral	Total
Novice RGN	Referral	7	2	7
	No Referral	0	11	11
	Total	7	13	20

Proportion of agreement: = .90 Kappa = .79

9.8b Estimation of inter-rater reliability: SLTR and Experienced RGN

9.8b (i) SLTR and Experienced RGN: Detection of dysphagia

Table 23: Detection of dysphagia: SLTR versus Experienced RGN screening decisions

		SLTR		
		Present	Absent	Total
Experienced RGN	Present	7	2	9
	Absent	0	11	11
	Total	7	13	20

Proportion of Agreement: = .90 **Kappa = .79**

These results show that there was slightly higher agreement for screening outcomes between the SLTR and the Experienced RGN than with the Novice RGN for the detection of signs of dysphagia. Landis and Koch's (1977) described a kappa value of 0.79 as 'substantial agreement'.

9.8b (ii) SLTR and Experienced RGN: Determining patients appropriate for referral to SLT

Table 24: Determining patients appropriate for referral: SLTR versus Experienced RGN screening decisions

		SLTR		
		Referral	No Referral	Total
Experienced RGN	Referral	5	1	6
	No Referral	0	14	14
	Total	5	15	20

Proportion of Agreement: = .95 **Kappa = .88**

Using criteria defined by Landis and Koch (1977) these calculations suggest 'almost perfect' rater agreement between the SLTR and Experienced RGN for determining patients appropriate for referral to SLT (please refer to Appendix 1 for Landis and Koch's criteria for determining kappa values).

9.9. Discussion

9.9a. An evaluation of differences in opinion between the SLTR and Novice RGN

Differences in opinion between the SLTR and the Novice RGN were noted with patients 6, 12 and 15; these differences were explored with the Novice RGN following collection and analysis of the data.

Both patients six and 15 failed the timed test component of the HeDSS with the RGN but had not done this with the SLTR. Each of these patients had different aetiologies of

stroke; i.e. Patient six had suffered a MCA stroke, patient 12 a left haemorrhagic stroke and patient 15 a right ischaemic CVA. There was therefore no trend in relation to aetiology of stroke. The Novice RGN explained that patient 15 “only just failed the test”. The patient was in her eighties and required assistance to hold the glass when screened by the SLTR but despite this, had passed the screen. Patient 12 was seen an hour apart by the SLTR and the Novice RGN. When seen by the SLTR, patient 12 passed the screen without difficulty. However, when seen later by the Novice RGN, the patient was sleepy and difficult to rouse. As drowsiness is a screening criterion of the HeDSS, the patient failed the screen. The nurse subsequently judged the patient would not require referral to SLT due to his drowsy status as directed by the dysphagia screening tool.

9.9b. An evaluation of differences in opinion between the SLTR and Experienced RGN

Differences in opinion between the SLTR and the Experienced RGN were noted with patients 28 and 33. Both these patients again failed the timed swallowing component of the swallow screen with the RGN but had passed with the SLTR. Both patients were screened by the SLTR first, quickly followed (within 30 minutes) by the Experienced RGN. It is not clear whether there was fatiguing of the swallow by these patients, which may have accounted for the differences in opinion or whether the SLTR’s expertise in swallowing assessment influenced her interpretation of the screen but both these patients drank the 50 ml of water within five seconds without coughing when screened by the SLTR.

9.9c. Potential influences on the interpretation of results

The results of this study suggest that the HeDSS when employed by the representative grade nurses, demonstrated high inter-rater reliability for determining signs of dysphagia and for determining patients appropriate for referral to the SLT for full assessment of swallowing. It is recognised that this was a small study in terms of the number of patients evaluated with the tool. Subsequently while it is recognised that the study should be

replicated with a larger sample, the results nevertheless indicated high rater agreement. Consideration needed to be given to the possibility that dysphagia was artificially high in the sample making its presence easier to detect. However, post screening evaluation of test results revealed that the total number of patients screened as dysphagic by the SLTR was 15 compared to 25 judged not to have dysphagia.

Addressing threats to internal validity, issues of investigator bias were kept to a minimum by ensuring both the SLTR and the RGNs were blinded to each other's screening outcomes. Patients were seen as soon after admission as possible on an acute admissions ward and the SLTR made herself available from Monday to Friday thereby limiting the possibility of another SLT first assessing the patients and documenting findings prior to screening. It is acknowledged that the nurses could potentially access documented SLT swallow assessments to determine whether the patients screened were later assessed as dysphagic or non-dysphagic. However, the patients were admitted onto a ward where patient stay is typically very short term (less than 24 hours) before they are transferred to the stroke ward. This meant that the patients were mainly assessed by the Trust SLT on a different ward. It is interesting to note that the screening outcomes of the SLTR and the Experienced RGN demonstrated higher agreement than those of the SLTR and the Novice RGN. One interpretation for this may be that the novice RGN was potentially using rule governed behaviour as described by Benner (1984) which did not deviate from the screening protocol e.g. in the cases where patients "only just failed" the timed swallowing component. It is possible that the Experienced RGN, may have allowed her experience within the field of nursing to draw upon nuances of the situation which were missed or meaningless to the Novice RGN, to influence her decision making. Although this topic was explored with the RGNs, they both felt they followed the tool rigorously. A need to explore these issues further was identified as a necessary factor within the subsequent phase of the research programme.

9.10. Conclusion

This phase of the study focussed on an evaluation of the inter-rater reliability of the measurement outcomes recorded by RGNs employing the HeDSS versus those recorded

by an expert (the SLTR) when screening the same 40 referred acute stroke patients. Results indicated that within this context, the screening tool was reliable for detecting the presence and absence of signs of dysphagia and for determining patients' appropriateness for referral for clinical dysphagia assessment by a SLT. Subsequently it is argued that these findings supported proceeding to the final phase of the research programme, which was aimed at measuring the concurrent validity of the outcome measures achieved through employment of the HeDSS by nurses, in comparison to the outcome measures achieved during a clinical dysphagia assessment performed by the SLTR.

Chapter 10: Concurrent Validity of the Head Dysphagia Screen for Stroke (HeDSS)

10.1. Summary

10.1a Aim

To investigate whether the HeDSS is a valid tool for determining the presence or absence of signs of dysphagia and judging whether patients screened are appropriate for referral for clinical dysphagia assessment by the SLT.

10.1b Objective

To evaluate the concurrent validity of the HeDSS when employed by nurses, compared to a clinical dysphagia assessment performed by an expert SLT (the SLTR) in determining the presence or absence of signs of dysphagia and judging whether the patients are appropriate for referral for clinical dysphagia assessment.

10.1c Population and sample

- Two RGNs (different from those employed in Phase 2), both of whom worked on acute medical wards with stroke patients in Trust 2. The 'Novice RGN' was a basic grade RGN with 18 months post qualification working experience, the'Experienced RGN' was a RGN with more than 15 years working experience.
- A Clinical lead SLT (SLTR) with more than 12 years postgraduate dysphagia experience and postgraduate training in dysphagia to Masters' level equivalent.
- A prospective convenience sample of 100 hospitalised acute stroke inpatients (stroke confirmed by CT scan).

10.1d Results

The prototype dyphagia screen outcomes measured against the clinical dysphagia assessment performed by the SLTR correlated highly for determining the presence/absence of signs of dysphagia (Novice RGN: sensitivity = .96, specificity = .85, PPV = .88, NPV = .95, Phi = .82; Experienced RGN: sensitivity = .88; specificity = .88, PPV = .88, NPV = .88, Phi = .76). Measurement outcomes of the HeDSS for determining the appropriateness of referral also correlated highly with the SLTR's clinical dysphagia assessment outcomes (Novice RGN: sensitivity = .88, specificity = .95, PPV = .96, NPV = .85 , Phi = .82; Experienced RGN: sensitivity = .88, specificity = .90, PPV = .90, NPV = .88, Phi = .78). The results and their implications are discussed in detail in the following chapter.

10.1e Conclusion

In this study, the measurement outcomes achieved via the HeDSS when employed by nurses was comparable with the measurement outcomes achieved via a clinical dysphagia assessment by an expert SLT, for detecting the presence and absence of signs of dysphagia and for determining patients' appropriateness for referral for clinical dysphagia assessment by the SLT.

10.2. Introduction

In the development and evaluation of any new screening tool, it is necessary to demonstrate that the tool is both valid and reliable i.e. it must be established that the tool measures what it purports to measure and does this consistently (Sackett *et al.* 1991, Lang and Secic 2006). Literature relating to the development and interpretation of screening tests suggest that minimally, criterion-related validity (predictive and concurrent validity) need to be accounted for (see Chapter two). The SLT inter-rater reliability study in Phase One demonstrated that the SLTR's clinical dysphagia assessment was an appropriate reference by which to measure the validity of the HeDSS. Having established that the tool was reliable when employed by representative grades of RGNs in comparison with its employment by the SLTR in Phase Two, the foundations were set for the evaluation of the screening tool's concurrent validity.

It was determined that for the HeDSS to be validated, it would need to correlate well with a clinical dysphagia assessment for (a) detecting patients with and without signs of dysphagia, and (b) determining patients appropriate/not appropriate for clinical dysphagia assessment. Specifically this phase of the research programme explored research question three:

Question 3: *Are the clinical decisions made by RGNs using a HeDSS, consistent with an expert SLT performing a clinical dysphagia assessment for determining signs of dysphagia and the appropriateness of referring acute stroke patients for a dysphagia assessment?*

10.3. Rationale

The overarching focus of the research programme was to determine whether the screening outcomes of a newly designed dysphagia screening tool correlated highly with a clinical dysphagia assessment for determining the presence of or absence of signs of dysphagia and whether the patient requires a referral to the SLT for clinical dysphagia assessment. Having carried out the preparatory studies in Phases One and Two, poor correlation of the screening outcomes with the clinical dysphagia assessment carried out

by the SLTR would highlight a lack of robustness of the specific combination of the screening criteria for detecting signs of dysphagia and determining patients appropriate for referral for assessment by a SLT.

10.4. Research design

This study used a prospective blinded concurrent validity study design. This focussed on an evaluation of the concurrent validity of the HeDSS compared with a clinical dysphagia assessment performed by the SLTR when undertaken with a convenience sample of 100 acute stroke patients.

10.5. Methods:

10.5.a Recruitment of Registered General Nurses

Following ethical approval from the Trust Research and Development Department, Risk Review Committees and the Local Research Ethics Committee, two nurses, different from those recruited in the Phase 2 were approached for participation in the study. These again comprised a basic grade RGN with 18 months nursing experience (here referred to as 'Novice RGN') and an experienced RGN with more than 15 years nursing experience (here referred to as 'Experienced RGN'). As for Phase 2, prior to approaching the nurses for participation in the study, it was established with the ward manager that both nurses met the inclusion criteria for being registered nurses and employed to work in the acute medical field at Trust Two. The research protocol was outlined to the nurses and ward manager and the commitment of the ward and both nurses for their engagement in the study was discussed. As this phase required that both nurses and the SLTR tested the same patients within the same working day, i.e. between 9am to 5pm, a commitment was required for the nurses to be rostered to work together or, minimally, to work the same day. This was agreed by the RGNs and ward manager. It was recognised that the commitment of both RGNs to screen patients on a different ward to which they worked would not be practical, as this would mean that the ward would potentially be left unmanaged. Therefore, the RGNs agreed to screen patients admitted to the ward on

which they worked. The SLTR agreed to make herself available on weekdays 9-5pm for the study with flexibility to work later should this be required. Both nurses were given the nurse information sheet to read **(**see Appendix 9) and the same was discussed. A consent form was subsequently signed.

10.5b. Recruitment of patients for the study

Over an eight month period, a convenience sample of patients admitted to an acute medical ward at Trust Two with a suspected acute stroke were approached for participation in the study. The procedure for approaching the acute stroke patients mirrored that of the Phase Two study in that all relevant medical consultants and nurse managers were informed of the study and their permission was sought prior to approaching the patients. It was first established that the patients approached met the inclusion criteria for participation in the study (see Appendix 8). The criteria included a documented diagnosis of an acute stroke, which was subsequently confirmed by a CT scan. A ward based research protocol directing the nurses to alert the SLTR of all stroke patients admitted to the ward was given to the ward managers and senior nurses to read (see Appendix 10). This ensured that all relevant staff were clear about alerting the SLTR of admissions of acute stroke patients including those deemed to be drowsy.

An explanation of the aims and nature of the study was provided to the patients. Measures were also taken to supplement information with simple language and pictures where necessary to allow any patients with communication impairment the opportunity to consent to participate in the study. A patient information sheet (refer to Appendix 9) was given to the patient to read or this was read out as necessary. Patients who were judged as unable to provide informed consent were excluded from the study as per exclusion criteria (see Appendix 8). A breakdown of patients excluded from the study is provided in Table 25.

10.5c. Procedure

The research protocol was discussed with the participating ward to ask that, during the study, any visible signs of the patient's feeding status such as jugs of water were removed from the patient's bedside just prior to the SLT and nurse participants' visit. This served to avoid potential bias of the SLTR or nurses being exposed to environmental cues as to the patient's swallowing status. The target number of 100 acute stroke patients provided informed consent to participate in this phase of the study. A profile of their characteristics along with a summary of the SLTR's assessment outcomes and the RGNs' screening outcomes is provided in Appendix 15.

10.5d. Patients excluded from the study

A total of 20 patients were excluded from the 120 patients approached for the study. A breakdown of the reasons for exclusion is shown in Table 25.

Table 25: Characteristics and reasons for patients excluded from the study

Pt #	Age	Medical Condition	Gender	Reason Excluded
1	>71	Left CVA	Male	Too confused, unable to provide consent
2	61-70	Left CVA	Male	Too Drowsy
3	>71	? CVA	Female	Stroke not confirmed
4	61-70	Right CVA	Male	Too Drowsy
5	>71	Left CVA	Female	Dementia
6	61-70	Right CVA	Male	Too Drowsy
7	>71	Left CVA	Male	Too confused, unable to provide consent
8	>71	?Left CVA	Male	CVA not confirmed
9	>71	MCA Infarct	Female	Dementia
10	>71	Right CVA	Male	Too Drowsy

Table 25: Characteristics and reasons for patients excluded from the study (continued)

Patient	Age	Medical Condition	Gender	Reason Excluded
11	>71	Right CVA	Male	Too Drowsy
12	>71	Right CVA	Female	Vomiting and Diarrhoea
13	>71	Right CVA	Male	Too Drowsy
14	61-70	Right CVA	Male	Too Drowsy
15	>71	Left CVA	Male	Barratt's oesophagus and alcohol abuse
16	51-60	Right CVA infarct	Female	Too Drowsy
17	51-60	Left CVA	Female	Too Drowsy
18	>71	Left CVA	Female	Unable to provide consent (dysphasic)
19	>71	Left CVA	Female	Too Drowsy
20	51-60	Left CVA	Female	Too Drowsy

Key: Dysphasic = language impairment

As can be seen in the above Table 25, the most frequent reason for excluding patients from the study was that patients were too drowsy to give consent. Drowsiness is a screening criterion used within the HeDSS. As noted in Chapter 5, a compromise had to be reached with the Research Ethics Committee to ensure that only patients who could consent to participation in the study were included in order to protect vulnerable patient groups. Excluding these patients could have potentially affected the estimated validity of the screening tool as discussed in detail in Chapters Two and Four. It should however be noted that for the majority of cases, excluded patients were very obviously drowsy i.e. they were unrousable.

10.5e. Justification of methods

This phase was focused on measuring the performance of the HeDSS compared against an appropriate reference standard i.e. the clinical dysphagia assessment performed by the

SLTR. According to Sackett *et al.* (1991), the ideal methodology for determining the validity of a screening tool is a comparative, prospective study where all participants undergo the new test and also the reference measure using blinded interpretation of results. The suggested methodology was adopted for this phase of the research programme.

Selecting RGNs with different levels of nursing experience was again based on the need to reflect the range of nurse grades that may use a dysphagia screening tool and also to evaluate whether any differences in screening outcomes were due to the level of nursing experience and confidence in decision making. According to the literature (Baumgartner *et al.* 2003, Stemler 2004) a minimum sample size of 100 is necessary to determine validity. The literature search informed the decision to recruit a sample of 100 acute stroke patients. It would not have been ethical or practical to expose each patient to numerous screens by a number of nurses followed by the SLTR's assessment. A decision was therefore made to limit the number of nurses recruited for this phase to two RGNs each of whom would screen a total sample of 100 acute stroke patients followed by the SLTR assessing the same patients using a clinical dysphagia assessment.

10.6. Data analysis

Following completion of the data collection, results were coded and entered onto an SPSS spreadsheet. Results were compared using Phi coefficient to determine the level of correlation between the RGNs' screening results and those of the SLTR clinical dysphagia assessment for determining signs of dysphagia and for selecting patients appropriate for referral for a clinical dysphagia assessment by a SLT. Data were also analysed to calculate the sensitivity and specificity of the HeDSS and the positive and negative predictive values for the 'true presence and absence' of the research variables (please refer to Appendix 1 for a detailed description of terms).

10.6a. Justification of data analysis

In this phase, the SLTR's clinical dysphagia assessment was acting as the reference standard for determining whether signs of dysphagia were present or absent and whether it was appropriate or not appropriate to refer the patients for clinical dysphagia assessment. Phi coefficient is an index of the degree of association between two variables (here the outcome measures of the HeDSS and the clinical dysphagia assessment carried out by the SLTR). This measure is similar to the Pearson correlation coefficient in its interpretation (Zysno 1997). Two dichotomous variables are considered associated if most of the data falls along the diagonal cells of a contingency table. With reference to Table 26, if data fall on the "c-b" diagonal, two variables are considered negatively associated and if most data fall on the "a-d" diagonal, two variables are considered positively associated. If data falls off the diagonal cells low or no correlation is determined. The range of index values of Phi Coefficient is from –1.00 to +1.00. The test or test item is considered a better discriminator as its index moves toward +1.00.

Data for measuring the degree of correlation were dichotomous and nominal; 'dysphagia present' = 1 'dysphagia absent' = 0 for the first measure and 'Referral to SLT appropriate' = 1, 'Referral to SLT not appropriate' = 0 for the second measure. A correlation was determined to exist where both the SLTR using a clinical dysphagia assessment and the RGN using the HeDSS each determined signs of dysphagia to be present or absent and secondly, where both the RGN and SLTR determined referral to SLT to be appropriate or not. Using the parameters presented in Table 26, the equation for calculating Phi-coefficient is

$$\textit{Phi} = (AD - BC) / \text{sqrt}((A+B)(C+D)(A+C)(B+D)) \quad \text{(Warrens 2008).}$$

Interpretation of Phi coefficient as a way of estimating the degree of association between the measurement outcomes was based on Rea and Parker (2005, page 189). These range from .1 to .20 for weak association to .8 - 1.0 for very strong association (refer to Appendix 1). Davenport El-Sanhury (1991) and Zysno (1997) advocate that interpretation of the Phi coefficient should be treated with caution as its maximum value is determined by the distribution of the two variables. If responses are consistent and have

a 50/50 split, the range of Phi will range from −1 to +1 but as the variables are dichotomous i.e. + (positive) versus – (negative), values as extreme as + / - 1 should not be expected.

10.6b. Sensitivity and specificity

It is suggested in the literature that for a screening tool to be accurate it must be highly sensitive, i.e. it identifies most of the people who have the disorder, as well as specific for identifying people who do not have the disorder (Lang and Secic 2006). Singh and Hamdy (2006) note that an inevitable outcome of improving sensitivity in screening and assessment tools which use dichotomous decisions for determining the presence or absence of disease, is a decline in specificity and vice versa. A compromise had to be met whereby an acceptable level was agreed for sensitivity and specificity. Failure to identify patients appropriate for referral for full swallowing assessment can potentially have adverse outcomes for dysphagic patients whereas patients misattributed as showing signs of dysphagia and requiring a full swallowing assessment will theoretically have less adverse outcomes for the normally swallowing patient other than the denial of food and drink until swallowing is assessed by the SLT. The minimum level acceptable for sensitivity and specificity is governed by the degree of risk associated with screening negative when dysphagia is present or screening positive when dysphagia is absent. A test with a higher sensitivity will often sacrifice specificity by increasing its false-positive rate i.e. patients without the disease have a positive screening result (Sackett *et al.* 1991). Given the degree of risk associated with missing dysphagia in an at-risk population, the ideal screening tool would be a highly sensitive test. Sensitivity and specificity are calculated vertically in a 2 x 2 contingency table as illustrated overpage.

Table 26: Calculation of sensitivity and specificity

		Criterion Measure		
		Present	Absent	
Diagnostic Test Result	Present	**a**	**b**	a + b
	Absent	**c**	**d**	c + d
		a + c	b + d	a + b + c + d

Key: Four possible groups of patients, as indicated (a,b,c,d) in the table, may be determined as explained below:
Group **a** = Patients correctly diagnosed/tested as having the target disorder (true positive)
Group **b** = Patients without the target disorder wrongly identified as having the target disorder (false positive)
Group **c** = Patients who have the target disorder but are wrongly identified as healthy (false negative)
Group **d** = Healthy patients correctly identified as healthy (true negative)

From these sensitivity and specificity is determined as follows:

Sensitivity = a / (a + c)

Specificity = d / (b + d)

Sensitivity contains no information about false-positive results, and specificity does not account for false-negative results. This limits the applicability of sensitivity and specificity in predicting disease when the clinician is uncertain about the diagnosis. For this reason, it was necessary to determine predictive values. These are described below.

10.6c. Predictive values

A primary consideration within the study was the degree to which a positive or negative screening outcome reflected the likelihood of the patient truly having or not having dysphagia. Predictive values explore this likelihood based on prevalence of disease (Sackett *et al.* 1991). Positive predictive value (PPV) is an essential consideration for the measurement and interpretation of the validity of the HeDSS. It reflects the probability

that a positive test reflects the underlying condition (dysphagia) being tested for. Negative predictive value (NPV) determines the probability that a negative test result (e.g. no signs of dysphagia detected) reflects not having dysphagia. Predictive values are not stable characteristics of screening tests and are determined by the prevalence of disease among the specific patient population. A low prevalence of dysphagia in the study sample would potentially give rise to a high false positive rate (patients screened as dysphagic when in fact swallowing normally). Negative predictive value decreases when there is a high prevalence of disease in the study population (Sackett *et al.* 1991, Elavunkal 2007).

With reference to Table 26, the calculation for determining PPV and NPV is as follows:
Positive predictive value = a / (a + b)
Negative predictive value = d / (c + d)

Without knowing the disease prevalence in the population of interest, predictive values cannot be accurately estimated (Elavunkal, 2007). However, once prevalence of the disorder is established, positive and negative predictive values are an essential consideration in the development of screening tests. Surprisingly, predictive values were under-reported in the literature review (see Table 5).

10.7 Results:

A summary of cases assessed by the SLTR and the RGNs is provided in Appendix 14. The decision not to focus on reporting p-values is discussed in Chapter 6. Nakagawa and Cuthill (2007) note that Null hypothesis significance testing i.e. assigning a significance level to determine whether the relationship observed is due to chance, fails to account for the size of an observed relationship between two variables (effect size). Nonetheless, all statistical calculations reported are based on $p<.01$ providing strong evidence against chance effects accounting for the data observed (please refer to Appendix 1).

10.7a. Summary of case characteristics

Gender ratio

The gender ratio was calculated as 51 females to 49 males; an almost equal distribution.

Age range:

The majority of patients were aged 71 and over accounting for 67% of the total sample. The spread of age categories is detailed in Table 27 below. The prevalence of acute stroke in the aged supports findings reported in the literature that prevalence of stroke increases with age (please refer to Chapter 2).

Table 27: Age range of acute stroke patient participants

Age Range	Frequency	Percent
31-40	2	2
41-50	3	3.0
51-60	3	3.0
61-70	25	25.0
over 71	67	67.0
Total	100	100.0

Table 28: Average time patients seen for screening and assessment from date of hospital admission

Number of days following admission	Percent
Day of admission	45.0
Second day	32.0
Third day	11.0
Fourth day since admitted	9.0
Fifth day since admitted	3.0
Total	100.0

As noted in Table 28, 45% of patients were seen on the day of hospital admission and 77% were seen within 48 hours of admission. Some of the patients were not screened and assessed by the SLTR and RGNs until several days following admission due to the nurses and SLTR not being available to see them together but were seen by the Trust SLT as part of their standard management.

10.7b. An evaluation of the concurrent validity of the HeDSS

10.7b (i). Correlation of the Experienced RGN's dysphagia screening outcomes and SLTR's clinical dysphagia assessment outcomes

Detection of dysphagia

The Experienced RGN's screening outcomes for determining the presence and absence of dysphagia correlated with the SLTR's clinical dysphagia assessment for 88 cases. Screening outcomes are summarised in Table 29.

Table 29: Detection of dysphagia: Experienced RGN screen versus SLTR's clinical dysphagia assessment

		SLTR Clinical Dysphagia Assessment		
		Present	Absent	Total
Experienced RGN Dysphagia Screen	Present	46 (a)	6 (b)	52 (a + b)
	Absent	6 (c)	42 (d)	48 (c + d)
	Total	52 (a + c)	48 (b + d)	100 (a + b + c + d)

Key: (Refer to Table 26 for key)

Calculation of sensitivity and specificity

With reference to Table 29, the sensitivity and specificity were calculated using a formula described by Sackett *et al.* 1991 as follows:

Sensitivity = a / (a+c) = 46 / (46+6) = 46/52 = **.88**

Specificity = d / (b+d) = 42 / (6+42) = 42/48 = **.88**

These results indicate that 88% of the patients with dysphagia had a positive test result (i.e. screened as dysphagic), while 88% of patients who did not have dysphagia had a negative screening test result.

Calculation of Positive and Negative Predictive values

Predictive values were calculated using formulae described by Sackett *et al*. (1991). Refer to Table 26 to determine what a,b,c and d denote.

Positive predictive value = a / (a+b) = 46 / (46+6) = 46/52 = **.88**
Negative predictive value = d / (d+c) = 42 / (42+6) = 42/48 = **.88**

The scores suggested a high likelihood of an underlying diagnosis of dysphagia in patients who screened positive and of the absence of dysphagia in those patients who the Experienced RGN screened as negative i.e. not showing signs of dysphagia.

Calculation of Phi

The data were arranged within contingency tables with the frequencies of the measurement outcomes of the SLTR and each of the RGNs coded to simplify calculation of Phi as recommended within the literature e.g. Field (2005) and Warrens (2008). Calculation of Phi is as follows (see Table 26).

Phi = (AD - BC) / sqrt ((A+B) (C+D) (A+C) (B+D)).

Phi = (1932-36) / sqrt ((52) (48) (48) (52)) = **.76**

As an estimate of test validity it is argued that a Phi of .76 suggests a strong positive association between measurement outcomes of the HeDSS and the SLTR clinical dysphagia assessment for determining dysphagia (based on criteria for interpreting Phi as suggested by Rea and Parker 2005, page 189).

Determining patients appropriate for referral

Following the initial proof equations calculated on pages 193, all equations provided will be rounded to two decimal places but were in fact calculated to four decimal places. The equations and their calculations are reported in detail in Appendix 16.

Table 30: Determining patients appropriate for referral: Experienced RGN screen versus SLTR's clinical dysphagia assessment

		SLTR Clinical dysphagia assessment		
		Referral	No Referral	Total
Experienced RGN Dysphagia screen	Referral	44	6	50
	No Referral	5	45	50
	Total	49	51	100

Sensitivity = **.90** Specificity = **.88**

PPV= **.88** NPV = **.90** Phi = **.78**

As noted in Table 30, the measurement outcomes of the SLTR and Experienced RGN correlated highly for determining patients appropriate for referral (n = 44) and not appropriate for referral (n = 45). The Experienced RGN screened patients as not being appropriate to refer on five occasions when the SLTR had judged the patients appropriate to refer (false negatives). Whereas the screening outcome for six patients indicated the

patients were appropriate for referral when the SLTR's clinical dysphagia assessment suggested they were not (false positives).

Calculation of sensitivity and specificity

Calculation of sensitivity and specificity indicate that 90% of the patients who were appropriate to refer to SLT had a positive test result (i.e. screened as appropriate to refer), while a specificity of .88 suggests 88% of patients who were not appropriate to refer to SLT had a negative screening test result.

Calculation of Positive and Negative Predictive values

The PPV of .88 suggest a very high likelihood of an appropriate referral (i.e. the patient displays signs of dysphagia can sit upright and is not drowsy) of the acute stroke patient for a clinical dysphagia assessment for patients who screened positive. The high NPV of .90 suggests a high likelihood of patients screened without signs and therefore not needing assessment.

Calculation of Phi

Phi = .78 suggests a strong positive association (refer to Appendix 1) of the HeDSS when used by the Experienced RGN compared against the SLTR's clinical dysphagia assessment for determining patients appropriate for referral to SLT.

10.7b(ii). Correlation of the Novice RGN's dysphagia screening outcomes and SLTR's clinical dysphagia assessment outcomes

Detection of dysphagia

Correlation of the SLTR's clinical dysphagia assessment versus the Novice RGN's screening outcomes was again high with a consensus on 91 of the 100 patients seen. The distribution of screening versus SLTR clinical dysphagia assessment results is detailed in Table 31.

Table 31: Detection of dysphagia: Novice RGN screen versus SLTR's clinical dysphagia assessment

		SLTR Clinical Dysphagia Assessment		
		Present	Absent	Total
Novice RGN Dysphagia Screen	Present	50	7	57
	Absent	2	41	43
	Total	52	48	100

Sensitivity = **.96** Specificity = **.85**

PPV= **.88** NPV = .**95** Phi = **.82**

Calculation of sensitivity and specificity

A sensitivity of .96 indicates that 96% of the patients with dysphagia had a positive test result (i.e. screened as dysphagic), while a specificity of .85 suggests 85% of patients who did not have dysphagia had a negative screening test result.

Calculation of Positive and Negative Predictive values

The PPV of .88 suggest a high likelihood of an underlying diagnosis of dysphagia in patients who screened positive. A NPV of .95 suggests a very high likelihood for the absence of an underlying diagnosis of dysphagia in those patients who the Novice RGN screened as negative i.e. not showing signs of dysphagia.

Calculation of Phi

Phi = .82 suggests a very strong positive association for the performance of the HeDSS when used by the Novice RGN compared against the SLTR's clinical dysphagia assessment for the detection of dysphagia.

Determining patients appropriate for referral

Table 32: Determining patients appropriate for referral: Novice RGN screen versus SLTR's clinical dysphagia assessment

		SLTR Clinical dysphagia assessment		
		Referral	No Referral	Total
Novice RGN Dysphagia screen	Referral	47	8	55
	No Referral	2	43	45
	Total	49	51	100

Sensitivity = **.96** Specificity = **.84**

PPV= **.85** NPV = .**96** Phi = **.81**

The measurement outcomes of the SLTR and Novice RGN correlated highly for determining patients appropriate for referral (*n* = 47) and not appropriate for referral (*n* = 43). The Novice RGN screened patients as not being appropriate to refer on two occasions when the SLTR had judged the patients appropriate for referral (false negatives). Whereas the Novive RGN's screening outcome for eight patients indicated the patients were appropriate for referral when the SLTR's clinical dysphagia assessment suggested they were not (false positives).

Calculation of sensitivity and specificity

Calculation of sensitivity and specificity indicate that 96% of the patients who were appropriate to refer to SLT had a positive test result (i.e. screened as appropriate to refer), while a specificity of .84 suggests 84% of patients who were not appropriate to refer to SLT had a negative screening test result.

Calculation of Positive and Negative Predictive values

The PPV of .85 suggest a very high likelihood of an appropriate referral of the acute stroke patient for a clinical dysphagia assessment by the SLT in patients who screened positive. The NPV of .96 also suggests a very high likelihood of patients screened with negative signs not needing assessment.

Calculation of Phi

Phi = .81 suggests a very strong positive association (see Appendix 1) for the performance of the HeDSS when used by the Novice RGN compared against the SLTR's clinical dysphagia assessment for determining patients appropriate for referral to SLT.

10.8 Discussion

10.8a. An evaluation of differences in opinion between the SLTR and Experienced RGN

Differences in opinion for detection of signs of dysphagia between the SLTR and the Experienced RGN were noted and are detailed in Table 33.

Table 33: Differences in opinion for SLTR assessment versus Experienced RGN's Screen

Patient number (#) Gender, Age and stroke	SLTR's Assessment Outcome and Reason	Experienced RGN's Screening Outcome and Reason
# 10 (F) >71 Left CVA	**Dysphagia** Mild oral dysphagia, difficulty controlling bolus resulting in a slightly delayed swallow trigger	**No Dysphagia** Patient completed drink with Experienced RGN
#12 (F) >71 Left CVA	**No Dysphagia** Prompt complete swallowing	**Dysphagia** Patient only taking sips therefore failed timed component
#20 (F) >71 Right CVA	**No Dysphagia** Prompt, complete swallowing	**Dysphagia** Failed timed component "just outside 5 seconds"
#22 (M) >71 MCA	**Dysphagia** Patient intermittently drowsy	**No Dysphagia** No signs detected
#23 (F) >71 Right CVA	**Dysphagia** Very mild, oral dysphagia	**No Dysphagia** No signs detected
#40 (M) >71 Right CVA	**No Dysphagia** Oral thrush noted	**Dysphagia** Oral thrush, some wincing taking sips only
#43 (F) 61-70 Left CVA	**Dysphagia** Unusual presentation with solids, regurgitation of bolus	**No Dysphagia** No signs detected
#68 >71 Right CVA	**Dysphagia** Mildly delayed swallow trigger	**No Dysphagia** No signs detected, completed drink within 5 seconds
#71 (F) 61-70 Left CVA	**Dysphagia** Mild, oral phase difficulties affecting bolus manipulation	**No Dysphagia** No signs detected, completed drink without coughing
#78 (M) 61-70 Left CVA	**No Dysphagia**	**Dysphagia** Patient taking sips therefore failed timed component of screen
#80 (F) >71 Left CVA	**No Dysphagia**	**Dysphagia** Failed timed component "just outside five seconds"
#91 (F) >71 Left CVA	**No Dysphagia**	**Dysphagia** Drowsy at time of screen therefore not appropriate for referral to SLT

The SLTR assessed patients 10, 22, 23, 43, 68 and 71 as dysphagic however; the Experienced RGN's screening outcomes suggested that these patients did not indicate signs of dysphagia. As noted four of these patients were judged to have mild oral phase difficulties by the SLTR which would have resulted in the patients being advised to have a soft diet. In essence, it may have been likely that these patients would not have attempted the more challenging textures of a normal diet i.e. they were coping at a functional level. Patient 22 was drowsy when assessed by the SLTR but was fully roused later in the day when screened by the Experienced RGN. It later transpired that the patient had had a difficult night and had taken sedatives in the early hours of the morning to assist sleep. Patient 43 could not swallow solids and subsequently required an ENT referral for a suspected stricture. These difficulties were very apparent with solids as the patient was seen to regurgitate.

In relation to those patients who the SLTR judged as not dysphagic but were screened as dysphagic, all patients failed the timed component of the screen. All but one of the six patients who failed the screen with the Experienced RGN were aged over 71. The effects of age on the speed of swallowing have been described in Chapter 2 and it may be a variable that affected the accuracy of the screen. Some of these patients were judged by the Experienced RGN to have failed the timed component of the screen only just outside the five seconds. It may be that a larger volume of water such as 100mls advocated by Nathadwarawala *et al.* (1992) and Hughes and Wiles (1996) is required to allow for the normal degree of compensation which occurs when swallowing larger volumes.

10.8b. An evaluation of differences in opinion between the SLTR and Novice RGN

Differences in opinion for detection of signs of dysphagia between the SLTR and the Novice RGN were noted with patients 22, 34, 39, 40, 43, 49, 78, 80, 91 and 98. Again, these differences were explored with the Novice RGN following collection and analysis of the data. The reported reasons for these differences are detailed in Table 34.

Table 34: Differences in opinion for SLTR assessment versus Novice RGN's Screens

Patient number (#) Gender, Age and stroke	SLTR's Assessment Outcome and Reason	Novice RGN's Screening Outcome and Reason
#22 (M) >71 Right MCA	**Dysphagia** Patient Drowsy unable to assess fully and therefore not appropriate for referral to SLT	**No Dysphagia** Patient completed drink with Novice RGN
#34 (F) >71 Right CVA	**Dysphagia** Oral and pharyngeal dysphagia referral appropriate	**Dysphagia** Patient drowsy with Novice RGN therefore screened as evidencing a 'sign of dysphagia' but due to drowsiness, referral not appropriate
#39 (M) >71 Right CVA	**No Dysphagia** Prompt, complete swallowing	**Dysphagia** Failed timed component "just outside 5 seconds"
#40 (M) >71 Right CVA	**No Dysphagia** Oral thrush noted	**Dysphagia** Oral thrush, some wincing taking sips only
#43 (F) 61-70 Left CVA	**Dysphagia** Unusual presentation with solids, regurgitation of bolus	**No Dysphagia** No signs detected
#49 (F) >71 Right CVA	**No Dysphagia** Prompt swallowing	**Dysphagia** Physically weak, coughed on drink
#78 (M) >61-70 Left CVA	**No Dysphagia**	**Dysphagia** Patient taking sips therefore failed timed component of screen
#80 (F) >71 Left CVA	**No Dysphagia**	**Dysphagia** Failed timed component "just outside five seconds"
#91 (F) >71 Left CVA	**No Dysphagia**	**Dysphagia** Failed timed component-small sips taken
#98 (F) >71 Left CVA	**No Dysphagia**	**Dysphagia** Failed timed component-"took 6 seconds to complete drink"

Key: M = Male F = Female MCA = Mid cerebral artery

Patients 22 and 43 were assessed as dysphagic with the SLTR but were screened as not showing signs of dysphagia with the Novice RGN. Patient 22 was drowsy when assessed by the SLTR but there was a time difference of two hours when the Novice RGN screened the patient as she was working a different shift to the Experienced RGN. Patient

43, as described previously, had a specific problem swallowing solids that subsequently required an ENT referral. As with the Experienced RGN, six of the seven patients who failed the screen did so on the timed component and all but one of these were aged over 71. A number of patients were described as 'only just failing' the timed component by both RGNs and it was interesting to note that this happened almost exclusively in the elderly cohort of patients aged over 71 years. Again, this may relate to reports of slower swallowing which occurs as a natural consequence of ageing (refer to page 27). There was no trend in relation to aetiology of stroke amongst patients who had different screening outcomes to the SLTR's assessment; i.e. five had left sided strokes and five had right sided strokes. There was also no particular trend with gender; six were female and four patients were male.

10.8c. An analysis of potential reasons for higher validity outcomes with the Novice RGN

The correlation of screening versus assessment outcomes with both RGNs and the SLTR is high. It is interesting to note that there was a higher correlation of the Novice RGN's screening outcomes with the SLTR's assessment outcomes than with the Experienced RGN. One interpretation for this may be that the Novice RGN was more governed by rule based behaviour (see page 151) than the experienced RGN. The HeDSS makes use of an algorithmic, rule based design. The focus within the design of the tool was for it to be minimally interpretive using a dichotomous yes/no decision response. Studies that make use of more interpretive tools such as videofluoroscopy, can potentially present a greater challenge for measuring concurrent validity due to the high level of analytical skills required for their interpretation (see page 42). It may be that the signs of dysphagia were clearly discernible as a pass or fail and therefore the less flexible actions typical of the novice learner as described by Dreyfuss (1981) lent themselves well to undertaking screening with the HeDSS. If using Dreyfuss's model, it could be argued that the Experienced RGN was more guided by her broader knowledge of the clinical context as is typical of the competent practitioner. She would therefore have a deeper contemplation

of problems of missing or detecting signs of dysphagia but not yet be experienced enough to extrapolate the more subtle nuances of the situation (refer to page 152).

There were however, clear differences in the performance of some of the patients screened which accounts for differences in screening or assessment outcomes. These include drowsiness and slower swallowing performance/taking sips (refer to Tables 33 and 34). In these cases, the judgements made by the RGNs at the time of screening were appropriate and were based on clinical signs determined at the time of screening. Similarly, some of the patients who were judged as not showing signs of dysphagia were assessed by the SLTR as having very mild dysphagia, which may in principle have meant the patient could cope functionally with taking small sips, or eating slowly. Nonetheless, in the main, there was a high correlation of results.

10.9. Conclusion

The results of the validity study suggest that the HeDSS had high concurrent validity for detecting signs of dysphagia and determining patients appropriate for referral when compared to the decisions of an expert SLT (the SLTR) performing a clinical dysphagia assessment. It is recognised that this study only utilised two RGNs who worked in the same hospital Trust as the SLTR. This may account in part, for why the results were high. The Phi coefficient was used to determine the degree of association between the HeDSS and the clinical dysphagia assessment for determining signs of dysphagia and for determining patients appropriate for referral for a full clinical dysphagia assessment. Baumgartner *et al.* (2008) warn that when interpreting Phi, high values should not be expected due to the fact that Phi is the correlation between two dichotomous variables (page 189). An acceptable value of a validity coefficient is determined by a number of factors such as whether it is based on concurrent or predictive validity (please refer to Glossary) and the degree of risk associated with lack of agreement on the variables measured. The effect size conveys whether observed outcomes are substantively important. In Chapter 6 it was argued that Null hypothesis testing and estimating *p*-values can be misleading in measurement studies such as this due to its tendency to assess

whether a relationship could be due to chance, regardless of the strength of the apparent relationship in the data. It is however worth noting that p values were computed and compared to a significance value set at $p < .01$ to estimate the probability that a relationship observed in the data occurred only by chance. The correlation of measurement outcomes as determined by Phi suggested a strong to very strong positive association for the concurrent validity of the HeDSS when used by the RGNs compared against the clinical dysphagia assessment of the SLTR highlighting the clinical meaningfulness of the data.

Chapter 11: Final Discussion

11. 1. A reflection on the phases of the Action Research Process

The outcomes of the study suggest the Head Dysphagia Screen for Stroke (HeDSS) is valid for identifying a high number of acute stroke patients who were dysphagic and appropriate for referral for a clinical dysphagia assessment as well as a high number of patients who did not evidence signs of dysphagia and therefore did not require referral. The risks associated with failing to detect the true presence of dysphagia are high due to serious consequences to health including aspiration pneumonia, malnutrition and death. The development of a dysphagia screening tool that evidences high accuracy is therefore especially important. The Action research framework is an iterative process of systematic enquiry focussed on providing the practitioner with new knowledge and understanding. It is therefore important here to reflect on the extent to which the outcomes of the research have addressed the issues investigated.

11.1a Conceptual phase: Determining consensus for a valid dysphagia screening tool

The literature review described a range of bedside procedures, which are designed to determine dysphagia and aspiration risk including cough provocation and testing pharyngeal sensation. Other procedures were focused on describing overt signs of difficulty during trial swallows of water. A lack of consensus nationally and internationally for a valid dysphagia screening tool was determined. The survey of dysphagia screening practices within acute Trusts in England and Wales provided a dearth of evidence of SLTs using evidence based decision making to identify combinations of criteria for screening tool design and construction. The survey outcomes further confirmed a lack of consensus on valid dysphagia screening criteria and ultimately provided the incentive to develop a valid dysphagia screening tool for use by nurses.

11.1b. Conceptual phase: Operationalisation of dysphagia and the implications of the HeDSS measurement outcomes

The conceptual phase of the inquiry process required an evaluation of pertinent dysphagia literature to determine the current body of knowledge for identification and evaluation of dysphagia. The primary problem was rooted in how normal and abnormal swallowing is described. It was clear from the literature review that dysphagia and aspiration are described vicariously i.e. dysphagia may be defined by landmark features such as reduced tongue control or by the degree of aspiration. Furthermore, the definition of normal swallowing is not clear either. This is due to the phenomenon of slowed swallowing in the elderly which may be misinterpreted as dysphagia and the problem of false positives and negatives for determining the presence and absence of dysphagia using various assessment methods including clinical dysphagia assessment and videofluoroscopy and also when using various screening criteria as outlined in Chapter 2. The purpose for which the present study was undertaken necessitated a clear operational definition of what is and what is not dysphagia. The implicit complexities of this were highlighted in the inter-rater reliability study between the SLTR and the SLT contemporary. Here, dysphagia was defined as 'abnormal swallowing physiology of the oral and pharyngeal tract as detected by a clinical dysphagia assessment'. The specific requirement for using this definition was outlined prior to the data collection and each swallow that was assessed was characterised using a dichotomous decision of dysphagia present versus dysphagia absent as determined by signs of dysphagia observed at the bedside (see glossary). Although the SLTR attempted an operational definition of dysphagia, it is acknowledged that the definition did not go far enough to describe what dysphagia is not. Subsequently, the SLT contemporary began to introduce clinical management decisions to determine the presence and absence of dysphagia i.e. based on the decision of whether functionally, the patient could cope with the trials of water or diet. The importance of defining dysphagia for the purpose of the study was further apparent when planning the design of the HeDSS particularly the specific wording used within the tool. The tool asks the nurse to decide whether, based on the presence or absence of criteria determined by the literature review, signs of dysphagia are detected. Normal versus abnormal swallowing is therefore based on the presence or absence of these specific signs. Normal

swallowing shares certain physiological components to permit clearance of the bolus from the oral cavity and pharynx with no residue and with adequate protection of the airway. However swallowing is a dynamic process and changes according to many factors including the volume swallowed, viscosity of the bolus or whether the bolus is measured using a single sip or continuous drinking. Swallowing can also differ according to the population described e.g. the elderly. It is therefore important to emphasise that a screening outcome of 'no dysphagia detected' does not necessarily mean that the patient has a 'normal' swallow. It may, however, mean that the swallow has the necessary physiological components to permit clearance of the bolus without compromising the patient's health. The importance of considering swallowing as one component of the ability to manage food and drink was emphasised in Chapter 2 and illustrated in Figure 5, (page 35). Measuring the prevalence of clinical outcomes such as chest infections or dehydration in patients screened as dysphagic as well as in those screened as having no dysphagia detected would be a necessary consideration to further determine the utility of the HeDSS.

11.1c. Reflection on the design and planning phase

Guidelines for designing a swallowing screening programme and evaluating its accuracy, suggest that it is important to consider the performance of the screening tool on the following methodological aspects:

- **Construct validity**
- **Sensitivity**.
- **Specificity**

These methodological aspects were applied to the conceptual phase during the evaluation of studies and reviews within the literature and were further applied during the design, planning and empirical phases of the research. The sensitivity for the HeDSS for determining acute stroke patients with dysphagia and appropriate for referral to SLT was found to be high i.e. ranging from .88 sensitivity for detection of dysphagia and .90 for determining patients appropriate for referral. The ideal screening tool will provide

positive results for all patients who have the disorder and return negative results for all patients who do not have the disorder. It is however, rare to achieve this level of accuracy due to the tendency for most tests to have some measure of error associated with them i.e. false positives and false negatives (please refer to the glossary). The most significant function of a screening tool is that it identifies most of the people who have the target disorder i.e. it is shown to be highly sensitive. Specificity has more relevance to diagnostic tests as here, the emphasis is on the test identifying most of the people who do not have the disease. As noted previously, an acceptable threshold had to be determined in terms of the level of risk associated with a screening tool missing dysphagic patients.

The literature review detailed in Chapter 2 indicated few screening procedures that were reviewed evidenced high sensitivity and specificity and even fewer demonstrated acceptable levels construct validity due to weaknesses in study design such as the failure to compare the new test with an accepted gold standard. Also, many procedures used subjective criteria e.g. determining vocal quality after swallowing which may rely on the practitioner's skill and experience for its interpretation. Of the papers reviewed and considered within the decision analysis (see page 76), only four screening criteria/tests were found to have acceptable concurrent validity. The potential for combining those criteria with reported high levels of sensitivity and specificity into an evidence based dysphagia screening tool was identified. The design and planning phases of the action research programme were focused on ensuring robust methodology. This included determining the performance of the screening tool against a reference standard for determining the presence or absence of signs of dysphagia. The method of data collection and analysis to measure the sensitivity and specificity of the HeDSS and the strength of association between the measurement outcomes of the HeDSS and those of the clinical dysphagia assessment carried out by the SLTR were also important considerations.

A limiting factor for the design and evaluation of the HeDSS was the Ethics Committee's requirement to exclude patients too drowsy to provide informed consent from the study sample. Drowsiness is a criterion used within the HeDSS for determining the presence of dysphagia. Excluding these patients (totalling seven out of 12 excluded in the reliability study and 11 out of 20 patients excluded in the validity study) thereby limited the nurses'

exposure to this specific screening criterion. If these patients had been included in the original study sample for measuring the validity of the HeDSS there would almost certainly have been an increase in the total number of patients judged as dysphagic thereby positively affecting the reliability and validity outcomes. It is therefore argued that the data provided for determining the reliability and validity of the HeDSS is an underestimate for what would have been reported if the study sample had included drowsy patients as originally intended. It may be argued that for most cases, these patients were very obviously drowsy so would not have presented as a challenge to the nurses. It is those patients who present with variable levels of alertness due to the variable response to the stroke or due to effects of their medication that may provide the greater challenge.

It is acknowledged that to claim a test is valid implies that the accuracy of the test as reported in the study has accounted for necessary test conditions (see Tables 7 and 8). These include comparing the test with a reference standard/'gold standard' and recruitment of a broad spectrum of patients with and without dysphagia and demonstrating a range of severities including conditions potentially mistaken as dysphagia e.g. age related slowed swallowing. The study design attempted to account for these requirements as far as possible from identification and scoping of the research problem through to the design and evaluation of the HeDSS. A test's validity will of course vary according to the purpose for which the results are being provided and the range of patients tested. Given that it has been developed and evaluated with acute stroke patients, it is proposed that the HeDSS is only used with acute stroke patients in the acute hospital setting by registered nurses. It would be necessary to ascertain its validity and reliability with a broader range of patients and nurses in multiple settings before advocating the use of the tool in other contexts.

11.1d. The Empirical phase: The SLTR's clinical dysphagia assessment as a reference standard

The HeDSS is designed as an algorithm and only permits a dichotomous pass/fail outcome. It may therefore be argued that the tool is minimally interpretive and works to capture patients who present with or without signs of dysphagia without offering an in-depth analysis. The ideal scenario may have been to test all patients with videofluoroscopy as well as the SLTR's clinical dysphagia assessment and perform a retrospective evaluation of the medical notes to determine the presence of medical complications including chest infections, dehydration and malnutrition. The design would have been improved further if the study was multicentred using a larger number of nurse and patient participants. However, this was beyond the scope of the present study. The purpose of the screening tool is to determine patients appropriate for clinical dysphagia assessment by the SLT whilst enabling those patients who do not present with signs of dysphagia to resume earing and drinking. The screening process is not designed to replace the SLT's clinical dysphagia assessment as it is only a pass/fail procedure. The SLT's assessment is a more comprehensive measurement and yields more specific information such as that relating to the level of severity and specific location of impairment.

The SLT clinical dysphagia assessment remains the cornerstone of a hospital assessment of dysphagia and for this reason it was felt to be an appropriate reference standard against which to assess the performance of the HeDSS. As with any gold standard, clinical dysphagia assessment is not perfect and has been demonstrated in previous studies to vary in terms of inter-rater reliability and validity when compared against videofluoroscopy. These studies have, however, focussed on the SLT clinical dysphagia assessment of swallowing detecting silent aspiration at the bedside (see page 52). There may be a need to move away from how well clinical dysphagia assessment compares with instrumental assessments of swallowing such as videofluoroscopy and fibreoptic endoscopic evaluation of swallowing (FEES) for detection of aspiration and focus more on how well bedside clinical dysphagia assessment predicts the presence or absence of complications of dysphagia such as the development of aspiration pneumonia. It has been

determined that a formal dysphagia assessment and management protocol decreases the incidence of pneumonia. In contrast, it is not yet known whether aspiration detected on videofluoroscopy is predictive for the development of pneumonia. It is therefore argued that the concurrent validity of the HeDSS was determined using an appropriate reference standard; the SLT clinical dysphagia assessment. It was necessary within the design and planning phases to consider at the outset, measurement of the inter-rater reliability of the SLTR's bedside clinical dysphagia assessment when compared to that of a contemporary. This was due to the potential design flaw of the SLTR's bedside assessment not being reflective of typical SLT bedside assessment. This was addressed and is described in Chapter 6. The outcomes of this study suggested that despite slight differences in the specific criteria assessed at bedside, there was high agreement between the SLTR and her contemporary for determining the presence and absence of dysphagia in the 30 patients assessed. The SLTR's clinical dysphagia assessment may not be the perfect gold standard for determining dysphagia. However, for the purpose of the research, it represented the definitive 'answer' for whether or not dysphagia was present and whether those patients identified as evidencing signs of dysphagia, were appropriate for referral for a clinical dysphagia assessment by a SLT.

11.1e. Empirical phase: Prevalence of dysphagia in the study sample and the implications of screening outcomes

A potential difficulty with the evaluation of the validity of the HeDSS is that is designed to be used with patients who have a high pre-test probability of dysphagia i.e. prevalence of dysphagia following stroke has been estimated to be as high as 65% (Mann *et al.* 1999, Department of Health 2007). The starting point of any screening or diagnostic process is the patient, presenting with a myriad of symptoms and signs. Each screening variable is a test that either increases or decreases the probability of the presence of dysphagia. Patients presenting with for example, coughing on swallowing, may exert a major influence on the screening process leading to a high pre-test probability for detection of dysphagia.

The accuracy of any screening test is dependent on the prevalence of disease. A study sample with a high proportion of dysphagic patients and a low proportion of 'normals' will potentially inflate the level of sensitivity. It was noted that following data collection for the validity study, the distribution of dysphagic and non-dysphagic patients, according to the SLTR's assessment, were relatively evenly spread i.e. 52 patients were assessed as dysphagic and 48 patients were assessed as not dysphagic. It is therefore possible to deduce from this that the prevalence of dysphagia in the study sample would not account for inflating the sensitivity value.

Calculations of positive and negative predictive values were a necessary consideration for interpreting the outcomes of the HeDSS applied to clinical practice. This is of significance to the evaluation of the study as these values are not dependent on the prevalence of dysphagia within the population. If the screen was to be used in a population where the prevalence is known to be less high such as Parkinson's disease, its potential to detect the true presence of dysphagia and to determine patients appropriate for referral to SLT may not be so robust. In its present form, if the HeDSS was introduced for use by nurses with acute stroke patients, up to 12% of the patients who were screened as demonstrating signs of dysphagia and requiring referral to the SLT would potentially be maintained nil by mouth (false positives). Up to 10% of the total patient sample would be screened as not having dysphagia when in fact they did (false negatives). It should be born in mind that HeDSS directs the user to observe the patient eating their first meal after a negative screen. Additionally, the nurse education programme alerts the nurse to monitor the patient for complications of dysphagia such as chestiness and temperature spikes. Collectively, there would be safeguards in place to potentially capture dysphagic patients who have been screened as not presenting signs of dysphagia (false negatives). Although not 100% perfect, these results of the studies provide robust evidence for an accurate screening procedure for determining the presence of signs of dysphagia and determining patients appropriate for referral for a full swallowing assessment.

An important issue for evaluating the significance of the results is the degree to which the results may be generalised for use in clinical practice. The HeDSS has been developed

and evaluated on registered nurses screening acute stroke patients. It is argued that providing the HeDSS is used in similar settings i.e. acute stroke wards, with patients who meet the inclusion crtiteria used within the study (i.e. patients whose admitting physician suspects an acute stroke) the results may be generalisable for application in clinical practice. The ultimate criterion for the usefulness of a screening test is whether it adds information beyond that otherwise available, and whether this information leads to a change in management that is ultimately beneficial to the patient. Failure to identify dysphagia incurs significant risks to the patient's health. It is known that early detection of dysphagia is critical to prevent dehydration and malnutrition complications, aspiration, to improve the patient experience and reduce expenditure to the NHS. The HeDSS is easy and quick to perform (around 1-2 minutes if the patient is already sitting upright) and does not incur significant costs for its implementation. It is among the first in the UK to evidence high sensitivity and specificity as well as construct validity using an appropriate reference standard, the SLT clinical dysphagia assessment.

11.2. Implications for practice

This work examined the action research process for the identification, design and evaluation of a valid dysphagia screening tool for use by nurses. The study analysed the evolution of the research process from the conception of the research problem through to exploring and reflecting on the validity of the HeDSS. It has demonstrated the complex nature of defining normal and abnormal swallowing and the importance of engaging stakeholders throughout the research journey.

The study has empirically and explicitly identified a valid combination of dysphagia screening criteria within a minimally invasive dysphagia-screening tool, which can be used by registered nurses. The design and planning phases as well as the empirical phases of the action research process suggest that the HeDSS is relatively easy to administer. Potentially, the algorithmic pass/fail format allows the tool to be administered in a standardised way with consistent interpretation to determine the presence and absence of dysphagia and further identify patients appropriate for a clinical dysphagia assessment.

Evidence reported within the literature indicates that early detection of dysphagia among acute stroke patients reduces the risk of pneumonia, mortality, average length of hospital stay and therefore reduces health costs (Hinchey *et al.* 2005, Smithard 2007). It remains the responsibility of the SLT to assess swallowing to determine the cause of the dysphagia and to safeguard against complications. SLTs are however, continuing to struggle to meet the recommended target of undertaking a full swallowing assessment within 72 hours of the patient's hospitalisation. This is largely due to the influx of referrals for dysphagia assessment. Dysphagia management necessitates interprofessional collaboration. An evidence based, valid dysphagia screening tool as described in this study can empower nurses in their management of acute stroke patients through fast tracking at-risk patients and potentially minimising risks to the patient. Implementing an action research framework has been helpful in demonstrating how engaging stakeholders in decision-making can potentially improve clinical practice.

11.3 Future research

Outcomes of implementing the screening programme using the HeDSS are measurable in terms of evaluating frequencies of complications of dysphagia and average length of hospital stay. Measuring these outcomes has been beyond the scope of the current study but would be recommended for further study. It is further recommended that the validity of the screening tool is evaluated with a broader range of nurses or medics across a range of centres.

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APPENDIX 1

OPERATIONAL DEFINITIONS OF TERMS USED WITHIN THE THESIS

Operational Definitions

Acute care: Short-term medical treatment, in a hospital, for patients having an acute illness such as stroke.

Aspiration: A severe outcome of dysphagia involving entry of foreign material into the airway beyond the vocal folds (such as liquid bolus). The primary outcome of interest is pneumonia, defined by abnormal lung status detected from clinical testing.

Predictors of aspiration, as reported in the literature are outlined below:

Predictors of Aspiration Risk as Reported in the Literature

Predictor	Definition
Dysphonia	A voice disturbance in the areas of vocal quality, pitch or intensity
Dysarthria	A speech disorder resulting from disturbances in muscular control affecting the areas of respiration, articulation, and resonance or prosody
Abnormal gag reflex	Absent or weakened velar or pharyngeal wall contraction, in response to tactile stimulation of the posterior pharyngeal wall
Abnormal volitional cough	A weak response, or lack of response when given the command to cough
Cough after swallow	Cough immediately or within one minute of ingestion of 50 mls of water
Voice change after swallow	Alteration in vocal quality following swallowing of calibrated volumes of water

Blinding: The blind method means hiding information about the treatment/test from the patients, their carers and any health care professional that interacts with the patients. It is used to prevent research outcomes from being influenced by observer bias. Within this research programme, the method involved removing all cues from the bedside prior to data collection for all patients seen and ensuring the SLT researcher and nurse and Trust SLT participants were not privy to one another's screening/assessment outcomes until all data were collected for each phase.

Bolus: A small, soft lump or mass, of chewed food or an accumulation of liquid which is held between the tongue and hard palate and then propelled posteriorly into the pharynx.

Caregiver: The individual(s) entrusted with the care of the patient, this may be nurse, family member or clinician.

Cervical Auscultation: Cervical auscultation is an adjunct to clinical or other instrumental assessment and serves to detect abnormal acoustic sounds of the pharyngeal swallow for helping to identify the physiological basis of impaired swallowing.

Choking: The overt physical response of the patient to obstruction of breathing following foreign material such as food or drink entering the airway.

Clinical dysphagia assessment: The clinical assessment serves to evaluate both the structure and function of the swallow to determine the overall nature and cause of impairment at the oral and pharyngeal stages of swallowing. Clinical assessment as carried out by the research speech and language therapist includes the following:

- Reviewing the medical and nursing notes to determine relevant medical history and background to swallowing difficulties (such as medical diagnosis, the patient's nutrition and hydration status, observed swallowing difficulties, current medication and chest complications);
- Interview with the patient and/or caregiver to establish past and present swallowing difficulties, swallowing symptoms and to determine the patient's cognitive and communication status;

- Oral motor and sensory assessment (such as the structure, function and sensation of lips, tongue, palate, etc.). This involves checking the relevant cranial nerves involved in swallowing using a normal and texture-modified liquid and solids (an overview of cranial nerve assessment is provided in Chapter 2);
- Direct observation of signs and symptoms of oropharyngeal swallowing difficulties during oral feeding. Swallowing efficiency and behavioural characteristics are monitored;
- Where an evaluation of airway protection is required in more detail, cervical auscultation may be used to evaluate the sounds of associated with swallowing;
- Trials of swallowing strategies (such as various textures, volumes, postures, manoeuvres, etc.);
- Education and feedback to the patient and/or caregiver(s) regarding assessment results and recommendations.

Cohort: A group of people who have a similar background in terms of age and experiences such as stroke diagnosis.

Contingency table: A contingency table represents data two dimensionally to illustrate association between two categorical variables (please refer to table shown under ‘Reference Standard’ page 244).

Correlation: The degree of relationship between two or more variables.

Correlation coefficient: A statistical value that represents the degree of similarity between two numerical variables. Correlation coefficients range between a maximum of +1 and a minimum of -1. A value of +1 means that the two variables are perfectly similar. A value of -1 means the opposite. A value of 0 means there is no relationship between the two variables.

CT Scan: A CT scan (computerised tomography) is a specialised X-ray test which provides pictures of the soft tissues of the body. The most commonly performed CT scan is of the brain to determine the cause of a stroke.

Data: here refers to the collection of information relating to the presence or absence of signs of dysphagia as determined by the screen or clinical dysphagia assessment.

Dependent variable: The variable measured or observed by the experimenter (here, the presence or absence of dysphagia).

Diagnosis is an essential process in medical care to determine whether or not a disease is present. A truly accurate test will **always** give a positive result, whilst if disease is not present, the test will always give a negative result. Test accuracy is measured in terms of sensitivity and specificity (see definitions below).

Doctor: here refers to an individual licensed under the Royal College of Physicians professional code to practice medicine.

Double data entry method: This is a process of increasing the accuracy of keyed data by entering it twice. The two versions of the keyed data are then compared to determine any discrepancy between the two.

Dysphagia: Any abnormality in swallowing physiology or mechanics of the oral, pharyngeal areas as detected from clinician testing including screening, clinical bedside, or instrumental tests.

Empirical: Related to knowledge from observation

Experimental hypothesis: The claim or proposition that a researcher intends to test using research methods. The experimental hypothesis is formulated so that all terms are defined. The experimental hypothesis is not directly tested. Instead, the experimenter formulates a contrast version of the hypothesis (a null hypothesis). Data are collected in an attempt to falsify the null hypothesis. If the null hypothesis is rejected, then the data are regarded as consistent with the experimental hypothesis

Experimental Method: A method for determining the relationship (if any) between an independent variable manipulated by the experimenter (the HeDSS) and a dependent variable (presence/absence of signs of dysphagia) measured by the experimenter.

Experimenter bias occurs in research where the outcome of an experiment tends to be biased towards a result favoured by the experimenter. This could have occurred in the study if the nurses or SLT researcher had been aware of the screening/assessment outcome of the patients before engaging in screening/data collection.

False negative test: The prototype dyphagia screening outcomes fails to identify dysphagia in patients who have dysphagia

False positive test: The prototype dysphagia screening results indicate dysphagia in patients who do not have dysphagia

Feeding: The act of transporting food toward the mouth in preparation for swallowing.

FEES: An adjunct to clinical assessment which directly visualises the structure and swallow physiology of the oral, pharyngeal, and laryngeal areas in order to determine impairment and possible compensatory strategies that enhance the safety and efficiency of the swallow.

Gold standard/reference standard: the best available method for establishing the presence or absence of the target condition (here dysphagia).

Hypothesis: A claim or proposition about the world that may or may not be true.

Independent variable: The variable manipulated by the experimenter.

Informed consent: The ethical process by which participants in an experiment are given sufficient information regarding the experimental procedure to make an informed judgment for whether to participate in a study.

Instrumental Assessment: Instrumental assessment is an adjunct to clinical assessment and serves to determine impairment in the structure and function of the oral, pharyngeal,

laryngeal and upper oesophageal swallow physiology, and compensatory strategies that enhance swallowing safety and efficiency (such as videofluoroscopy, FEES, etc).

Kappa: Kappa measures the degree of agreement that has occurred between one measure (in the study, this was the contemporary SLT's assessment or the RGN's screening outcomes, and the central line (here the gold standard SLTR's bedside assessment of swallowing) over and above that which would have occurred by chance alone. Sackett (1991) states that when the comparison is between a test and a gold standard, kappa becomes a measure of accuracy. Landis and Koch (1977) suggested the following table, based on personal opinion, for interpreting κ values.

κ	**Interpretation**
< 0	Poor
0.0 — 0.20	Slight agreement
0.21 — 0.40	Fair agreement
0.41 — 0.60	Moderate agreement
0.61 — 0.80	Substantial agreement
0.81 — 1.00	Almost perfect agreement

Management: SLT intervention intended to compensate for the impaired structure and physiology of the swallow for the purpose of improving the safety, efficiency and effectiveness of the oropharyngeal swallow.

Mastication The act of breaking down solid food in preparation for forming a bolus and subsequent swallowing.

National Clinical Guidelines for Stroke (2008) National evidence based guidelines for stroke care published by the Intercollegiate Working Party Stroke (2008) for Stroke third edition 2008 http://www.rcplondon.ac.uk/pubs

National Sentinel Audit: National audit at a specific point in time to identify levels of practice and service provision across the country

Null Hypothesis: A null hypothesis assumes that any kind of difference or significance observed in a set of data is due to chance. It is presumed to be true until statistical evidence nullifies it for an alternative hypothesis. Here, the experimental hypothesis was that a minimum combination of evidence based dysphagia screening criteria within a HeDSS was as valid as a full clinical dysphagia assessment performed by the SLTR for determining patients appropriate for assessment of dysphagia. The null hypothesis claims that the correlation of the measurement outcomes of the screening tool and the clinical dysphagia assessment is due to chance alone and not due to a systematic cause.

Nurse/Registered General Nurse/RGN: means in the context of this study, a nurse who is registered or licensed to practice with the Nursing and Midwifery Council.

Oropharyngeal Dysphagia: Same as 'dysphagia' but limited to oral and pharyngeal areas versus entire oesophagus

P-Value: The probability value (p-value) of obtaining a statistical hypothesis test statistic as extreme as or more extreme than that observed by chance alone, if the null hypothesis H0, is true. Small p-values suggest that the null hypothesis is unlikely to be true. The smaller it is, the more convincing is the rejection of the null hypothesis. The maximum power a test can have is 1, the minimum is 0. Ideally, a test's p-value is close to 1. A p value of 0.05 means that this result would have arisen by chance on less than one occasion in 20. Standard scientific practice, which is entirely arbitrary, usually deems a p value of less than 1 in 20 (expressed as $p<0.05$, and equivalent to a betting odds of 20 to 1) as "statistically significant" and a p value of less than 1 in 100 ($P <0.01$) as "statistically highly significant."

Patient: The individual who receives the dysphagia service.

Penetration: Bolus entry into the airway to the level of the opening of the larynx but not below the vocal folds.

Phi coefficient: A measure of the degree of association between two dichotomous variables. Phi was used within the concurrent validity study to test categorical decision agreement i.e. dysphagia present versus dysphagia absent and referral appropriate versus referral not appropriate. This measure is similar to the correlation coefficient in its interpretation and is calculated from a contingency table (see definition). Its value varies from -1 (total disagreement) to +1 (total agreement). The value 0 means agreement just by chance and the closer the value is to 1.0 the stronger its positive association. As Phi is the correlation between two dichotomous variables, Baumgartner *et al.* (2008) warns that high values should not be expected (page 104).

The equation for Phi is: Phi = (AD - BC) / sqrt ((A+B)(C+D)(A+C)(B+D)). (Taken from Warrens 2008).

Rea and Parker (2005) suggested the following criteria for interpreting Phi

Phi	**Interpretation**
0-< .10	Negligible association
.10 and under .20	Weak
.20 and under .40	Moderate
.40 and under .60	Relatively strong
.60 and under .80	Strong
.80 — 1.00	Very strong

Rea and Parker (2005) p. 189.

Power calculation: A statistical calculation used to estimate the number of subjects

required to take part in the experiment. The number of subjects needed in an experiment depends on a number of factors including the statistical significance level and the number of raters used (here, three in the validity study).

Pulse Oximetry: A device, which measures oxygen saturation in the blood.

INTERPRETING THE SENSITIVITY AND SPECIFICITY OF SCREENING AND DIAGNOSTIC ASSESSMENT TESTS

Reference Standard: A method which determines if a subject has the condition that the test is attempting to identify. The reference standard should be independent of the test being evaluated. It is also assumed that the reference standard identifies the condition more accurately than the test being evaluated. To be useful in calculating sensitivity and specificity, a reference standard has to have specified diagnostic criteria to determine if a person does or does not have the condition. This is illustrated below:

	Have disorder	**Do not have disorder**	
Test is positive	**a** true positive	**b** false positive	a + b
Test is negative	**c** false negative	**d** true negative	c + d
	a + c	b + d	a + b + c + d

Reference Standard- Based on descriptions from
http://www.poems.msu.edu/EBM/Diagnosis/SensSpec.htm

Sensitivity: The percentage of all patients with the condition (dysphagia in the current study) who are correctly identified as having the condition, based on the reference standard. The sensitivity of a test is the percentage of all patients with the condition who have positive tests that correctly identify the condition (the positive rate).

Specificity: The percentage of all persons who do not have the condition (according to the reference standard) who are correctly identified by the tests as being free of the condition. The specificity of a test is the percentage of all persons who do not have the condition who have negative test results (the true negative rate).

Calculation of sensitivity and specificity based on descriptions from http://www.poems.msu.edu/EBM/Diagnosis/SensSpec.htm

Definition	Formula
Sensitivity: The percentage of those who have the disorder, as determined by reference standard, and have positive tests	[a/(a + c)] [x100]
Specificity: The percentage of those who do not have the disorder as determined by reference standard, and have negative tests	[d/(b + d)][x100]

Reliability: The degree to which a measurement (here, the use of the HeDSS), produces consistent results

Screening: Screening here refers to dysphagia screening. It serves to identify patients at risk for dysphagia and initiate early referral for assessment, management or treatment for the purpose of preventing distressful dysphagia symptoms and minimising risks to health.

Significance Level: The criterion used for rejecting the null hypothesis. Traditionally, experimenters have used either the 0.05 level / 5% level or the 0.01 / 1% level, the lower the significance level, the more the data must diverge from the null hypothesis to be significant. Therefore, the 0.01 level is more conservative than the 0.05 level

Stroke: A stroke is the sudden death of brain cells due to a problem with the blood supply. When blood flow to the brain is impaired, oxygen and important nutrients cannot be delivered. The result is abnormal brain function. Blood flow to the brain can be disrupted by either a blockage or rupture of an artery to the brain and neurological signs and symptoms such as limb weakness persist longer than 24 hours. A stroke is also

referred to as a cerebrovascular accident or CVA. Within the study, a CT scan confirms this diagnosis.

Supervision: Watching over a registered general nurse (RGN), whilst the nurse engages in conducting dysphagia screening of the stroke patient for the purpose of developing the nurses competency in this procedure

Swallowing The act of ingestion of foods or fluids from the oral cavity to the stomach

Treatment An intervention intended to change the physiology of the swallow for the purpose of improving the safety, efficiency and effectiveness of the oropharyngeal swallow and maintaining nutrition and hydration.

The following books, journals and websites were consulted for the above definitions:

http://www.rcplondon.ac.uk/pubs

http://www.poems.msu.edu/EBM/Diagnosis/SensSpec.htm

Baumgartner, T., Jackson, A., Mahar, M. and Rowe, D. (2008). Measurement for evaluation in physical education and exercise science (8th ed.). Boston, MA: McGraw-Hill

Benson, J. (1998). Developing a strong program of construct validation: A test anxiety example. Education Measurement:Issues and Practice, 17, 10–22.

Elavunkal, J. (2007) Screening and Diagnostic Tests
http://emedicine.medscape. com/article/

Fang, Y., Wit, E. (2008). Test the Overall Significance of p-values by Using Joint Tail Probability of Ordered p-values as Test Statistic. ADMA, volume 5139 Lecture Notes in Computer Science, 435-443. Springerlink

Field, A. (2005). Discovering statistics using SPSS, second edition, London,Sage publications.

Landis, J.R. and Koch, G.G. (1977). The measurement of observer agreement for categorical data. Biometrics, 33(1), 159-174.

Sackett, D.L., Haynes, R.B., Guyatt, G.H., Tugwell, P. (1991) Clinical Epidemiology: A Basic Science for Clinical Medicine. Boston, Mass: Little, Brown, and Company

Sim, J. and Wright, C. C. (2005) "The Kappa Statistic in Reliability Studies: Use, Interpretation, and Sample Size Requirements" in Physical Therapy. Vol. 85, pp. 257--268

APPENDIX 2

SURVEY OF DYSPHAGIA SCREENING PRACTICES:

LETTER AND EMAIL TEMPLATES

April 2005

Dear highly specialist speech and language therapist for dysphagia,

Re: Dysphagia Screening Tool for Nurses

I am a research speech and language therapist (SLT) at the University of Glamorgan conducting research into the development of a rigorous, evidence based dysphagia screening tool for nurses. In the literature, there appears to be no agreement on the most effective screening tool or criteria for predicting the presence or absence of abnormal swallowing. Given that there is no consensus, one of the objectives of this research will be to design and validate a dysphagia screening tool for nurses.

As part of my research, I would like to establish what tools or criteria are being used across England and Wales for screening patients at risk of abnormal swallowing (dysphagia). For the purpose of this study, screening refers to a procedure designed to detect any clinical indication of potential swallowing difficulty. In many NHS trusts registered nurses working in the acute hospital setting screen patients suspected of having suffered a stroke. They will have undertaken a training programme to identify those patients who may have swallowing difficulties and would normally require a referral to a SLT for a more detailed assessment of swallow function.

The research will comprise the following:

1. All adult speech and language therapy services across England and Wales will be contacted to establish whether or not a dysphagia screening tool is used in the acute hospital setting by registered nurses.

2. I wish to further establish the range of recruitment criteria used for the selection of nurses onto screening training programmes as I will need a representative sample of RGNs for the validation process.

3. A copy of the tool currently used in your trust will be needed and will form the basis of the qualitative component of the research.

Your involvement in this research is entirely voluntary and is much appreciated. Although the questions are general in nature, you need not answer any questions which you are unhappy with. Please be assured that any information you provide will be treated confidentially and anonymity will be protected. I plan to email you in two weeks.

This study has received ethical approval through the University of Glamorgan. If you have any questions or would like additional information to assist your decision for participating in the study, please feel free to contact me on 01443 483108 or e-mail me at: **khead@glam.ac.uk**

Thank you in advance for your interest in this project

Yours sincerely,

Kathryn Head
Research Speech and Language Therapist

From: Kathryn Head [mailto:Kathryn.head@[redacted]
Sent: 14 September 2005 14:12
To:
Subject: A survey of dysphagia screening tools/screening criteria used by nurses

Dear_____,

I am a specialist speech and language therapist for dysphagia at [redacted]in Wales and as preliminary work for planned research, I aim to establish what dysphagia screening tools/criteria are being used across NHS Trusts in England and Wales. I also need to identify the range of nurse grades undertaking screening. My primary objective is to evaluate whether the screening criteria and the sequencing of the criteria within the screening tools vary widely across England and Wales and evaluate the range of criteria used within the tools measure against the evidence base.

I would be very grateful if you could let me know the following:

Does your Trust undertake dysphagia screening? (If no please explain why).
What are the grades of nurses trained to undertake dysphagia screening in your Trust? (please, if possible provide a breakdown of the grades trained)
Please provide a copy of the dysphagia screen that nurses use within your Trust (I can send a stamp addressed envelope if you are unable to attach the screen in your response).

Your involvement in this survey is entirely voluntary and is much appreciated. Please be assured that any information you provide will be treated confidentially and anonymity will be protected. Feedback on the outcome of the survey will be provided.

If you have any questions or would like additional information to assist you in your decision to participate, please feel free to email me at:Kathryn.Head@[redacted] or phone[redacted].

My address is as follows:
Kathryn Head
Speech and Language Therapy Department
[redacted]
Thank you in advance for your interest in this project

Yours sincerely
Kathryn Head

APPENDIX 3

PRIORITISATION EXERCISE FOR DETERMINING APPROPRIATE SCREENING CRITERIA HEADINGS

EMERGING CRITERIA COLLECTED FROM SURVEY OF NHS TRUST SCREENING CRITERIA

Establishing Expert Consensus for Emerging Criteria Headings

Criteria headings taken verbatim, were collated from the survey of dysphagia screening practices across England and Wales (see Chapter 3). These were grouped under broad headings of what the criteria related to e.g. consciousness, posture, delayed swallowing and whether the criterion is checked 'before giving the patient anything to swallow' or 'after/during a swallow'. A copy of the criteria headings is enclosed overpage.

In order to ensure expert consensus with the headings the criteria were grouped under, three lead SLTs for dysphagia from three acute NHS trusts in Wales were recruited to perform a sorting exercise. The lead SLTs were requested to rank the statements under the category headings assigned e.g. consciousness. 'Don't know' responses were not allowed. A 75% agreement level was set. If no agreement was made then this was taken to indicate no expert agreement on the criteria, indicating a need to eliminate the criteria from the research-screening tool. The second phase required the SLTs to independently prioritise the statements under each category in order of most fitting, in order to ensure that the criteria headings selected was the best way for asking about e.g. consciousness. The process was repeated until agreement between the four SLTs was ascertained. Agreement (80%) was met for all criterion headings and these are detailed in Figures 9 and 10 (pages 86 and 87).

APPENDIX 4

PUBLISHED PAPER AND PRESENTATION AT NATIONAL SCIENTIFIC CONFERENCE

APPENDIX 5

ETHICS PROCESS

APPENDIX 6

RESEARCH PROTOCOL TRUST 1

INTER-RATER SLTR RELIABILITY STUDY

APPENDIX 7

SLTR RELIABILITY STUDY: LETTERS, INFORMATION SHEETS AND CONSENT FORMS

APPENDIX 8

RESEARCH PROTOCOL TRUST 2

APPENDIX 9

RGN VS SLTR INTER-RATER RELIABILITY AND VALIDITY STUDY TRUST 2: LETTERS, INFORMATION SHEETS AND CONSENT FORMS

Dear _____,

Re: The design, development and evaluation of a valid dysphagia screening tool for use by nurses-Phase 1 reliability of Speech and Language Therapists undertaking clinical dysphagia assessments

Ethical approval Number: 07/WSE03/44

I am a research Speech and Language Therapist studying for a PhD at the University of Glamorgan. I would like to collect data from the speech and language therapist at _____Hospital beginning on the _____2007.

New acute stroke patients who are inpatients at RGH will have a Speech and language Therapist dysphagia assessment as part of their normal management. This will categorise patients as having a normal or abnormal swallow. Phase 1 of this study will test whether Speech and Language Therapists agree on this categorisation. I want to retest patients who have had this assessment from the Gwent Speech and Language Therapist.

This study has had ethical approval from Gwent Research Scrutiny Committee (3rd May 2007 Reg: RD/564/07), Gwent Risk Review Committee (17th April 2007) and South East Wales Research Ethics Committee (3rd July 2007 REC Ref number: 07/WSE03/44). I have an Honoury Contract for the duration of the data collection from Gwent R and D department.

If you have any questions or concerns please feel free to contact me on 01685 728451 Email: Khead@glam.ac.uk. If I do not hear from you by 2nd August, I will assume you are happy for me to proceed.

Yours sincerely

Kathryn Head

Research Speech and Language Therapist

APPENDIX 10

TRUST 2

WARD BASED PROTOCOL

APPENDIX 11

TRUST 2

DATA COLLECTION SHEETS

PATIENT IDENTIFIER NUMBER	PT NAME	DOB	MED CONDITION	SLT DECISION (DYSPHAGIA PRESENT/ABSENT)	NURSE SCREENING DECISION (DYSPHAGIA PRESENT/ABSENT)	COMMENTS
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

APPENDIX 12

CASE SUMMARIES FOR SLTR VS CONTEMPORARY SLT

INTER-RATER RELIABILITY STUDY

	Gender	Age	Stroke type / Provisional Diagnosis	SLTR assessment	SLT Contemp'y assessment
1	Female	over 71	Other	No dysphagia	No Dysphagia
2	Male	over 71	Right CVA	No dysphagia	No Dysphagia
3	Female	61-70	Right CVA	Dysphagia	Dysphagia
4	Male	over 71	Other	Dysphagia	Dysphagia
5	Male	over 71	Other	Dysphagia	Dysphagia
6	Male	over 71	Left CVA	Dysphagia	Dysphagia
7	Male	over 71	Right CVA	No dysphagia	No Dysphagia
8	Female	over 71	Other	Dysphagia	Dysphagia
9	Female	over 71	Other	Dysphagia	Dysphagia
10	Female	over 71	Left CVA	No dysphagia	No Dysphagia
11	Male	over 71	Left CVA	Dysphagia	Dysphagia
12	Male	31-40	Left CVA -Hemorrhage	Dysphagia	No Dysphagia
13	Female	over 71	Left CVA	Dysphagia	Dysphagia
14	Male	over 71	Right CVA	Dysphagia	No Dysphagia
15	Female	over 71	Right CVA	No dysphagia	No Dysphagia
16	Female	over 71	Other	Dysphagia	Dysphagia
17	Male	over 71	Other	Dysphagia	Dysphagia
18	Male	over 71	Other	No dysphagia	No Dysphagia
19	Male	over 71	Right CVA	Dysphagia	Dysphagia
20	Female	over 71	Left CVA	Dysphagia	Dysphagia
21	Female	over 71	Left CVA	Dysphagia	Dysphagia
22	Female	61-70	Hemorrhage	Dysphagia	Dysphagia
23	Male	61-70	Other	Dysphagia	Dysphagia

24	Male	61-70	Left CVA	No dysphagia	No Dysphagia
25	Female	over 71	Other	No dysphagia	Dysphagia
26	Male	over 71	Right CVA	Dysphagia	Dysphagia
27	Female	over 71	Other	Dysphagia	Dysphagia
28	Female	over 71	Other	No dysphagia	No Dysphagia
29	Male	over 71	Other	No dysphagia	Dysphagia
30	Female	over 71	Left CVA	No dysphagia	No Dysphagia

APPENDIX 13

CALCULATIONS FOR DETERMINING INTER-RATER RELIABILITY OF THE HEAD DYSPHAGIA SCREEN FOR STROKE (HeDSS)

SLTR and Novice RGN: Determining patients appropriate for referral to SLT

SLTR versus Novice RGN screening decisions for determining patients' appropriateness to refer

		SLTR		
		Referral	No Referral	Total
Novice RGN	Referral	7	2	7
	No Referral	0	11	11
	Total	7	13	20

Proportion of agreement calculated for the contingency table

$$p_o = \frac{a + d}{a + b + c + d} \qquad p_o = \frac{7 + 11}{7 + 2 + 0 + 11} = \frac{18}{20} = .90$$ **(correct to 2 dp)**

Kappa calculation for SLTR versus Novice RGN screening decisions for determining patients' appropriateness to refer (please refer to 6.7c for explanation of calculation):

$$k = \frac{p_o - Pr(e)}{1 - Pr(e)} \qquad k = \frac{.90 - .52}{1 - .52} = \frac{.38}{.48} = .79$$ **(correct to 2 dp)**

Estimation of inter-rater reliability SLTR and Experienced RGN

SLTR and Experienced RGN: detection of dysphagia

SLTR versus Experienced RGN screening decisions for dysphagia detection

		SLTR		
		Present	Absent	Total
Experienced RGN	Present	7	2	9
	Absent	0	11	11
	Total	7	13	20

Proportion of agreement calculated for the contingency table

$$p_o = \frac{a + d}{a + b + c + d} \qquad p_o = \frac{7 + 11}{7 + 2 + 0 + 11} = \frac{18}{20} = .90 \text{ (correct to 2 dp)}$$

Kappa calculation for SLTR versus Novice RGN screening decisions for dysphagia detection (please refer to 6.7c for explanation of Pr (e) calculation):

$$k = \frac{p_o - Pr(e)}{1 - Pr(e)} \qquad k = \frac{.90 - .52}{1 - .52} = \frac{.38}{.48} = .79 \text{ (correct to 2 dp)}$$

SLTR and Experienced RGN: Determining patients appropriate for referral to SLT

SLTR decision versus Experienced RGN for appropriateness for referral

		SLTR		
		Referral	No Referral	Total
Experienced RGN	Referral	5	1	6
	No Referral	0	14	14
	Total	5	15	20

Proportion of agreement calculated for the contingency table

$$p_o = \frac{a + d}{a + b + c + d} \qquad p_o = \frac{5 + 14}{5 + 1 + 0 + 14} = \frac{19}{20} = .95$$ **(correct to 2 dp)**

Kappa calculation for SLTR versus Experienced RGN screening decisions for referral decision:

$$k = \frac{p_o - Pr(e)}{1 - Pr(e)}$$

Pr(e) = SLTR Refer? 'Yes' = 0.25 Experienced RGN 'Yes' = 0.35

'No' = 0.75 Experienced RGN 'No' = 0.65

Pr(e) = 0.25 x 0.35 + 0.75 x 0.65 = 0.087 +0.487 = 0.57

$$\text{Kappa} = \frac{0.95 - 0.57}{1 - 0.57} = \frac{0.38}{0.43} = 0.88$$

APPENDIX 14
RAW DATA FOR FOCUS GROUP INTERVIEWS

Focus group interview- Raw Data

Nurse E

1. **The tool asks 'Is the patient is alert and able to maintain full consciousness for the duration of the screen?' What does that mean to you?**
   "Right, that the patient is awake and knows what is going on and on top of that is able to keep on knowing what is going on…can concentrate for a certain amount of time"

2. **Here the tool asks 'Can the patient sit/be sat upright?' What does this mean to you?**
   "So the patient cn either do it themselves that is get themselves upright or will be assisted into an upright posture at something approaching 90 degrees"

3. **The tool asks whether the patient's speech on counting to ten is 'severely slurred/unable to understand'. What do you understand this to mean?**
   "Speech is very slurred, I understand that the words would be very difficult to understand"

4. **Here the tool asks you to 'Give 50 mls of water from a glass. Ask patient to drink water as quickly and comfortably as possible. On the prompt to 'swallow' start the stopwatch when the first drop of water touches the lips whilst observing the Adam's apple/larynx for movement' What do you understand by this?**
   "Give 50 mls of water, that is totally clear..I'm wondering if finish the drink would be better than 'completes the drink' I think 'prompt to swallow' makes this confusing, I prefer to leave it at 'begin timing when the first drop of water touches the patients mouth'.." there is a time lapse between on the prompt to swallow and then actually starting to begin timing"

5. **The tool asks you to 'Stop if the patient coughs or experiences difficulty' Can you explain what you understand by this statement?**
   "I think that's clear enough, I would need to stop the screen if the patient begins coughing or choking or experiences discomfort in some way"

6. **What do you understand by the question 'Is prompt, upward movement of the larynx noted?'**
   "Just that,…do I see prompt movement of the larynx..I don't know what else to add really"

7. **Here the tool asks 'Can the patient drink the water without coughing during or after the swallow'-what do you understand by this?**
   Can the patient drink the water without coughing or choking during or after the swallow'

8. **The tool asks 'Can patient swallow 50mls of water within 5 seconds' can you explain what you understand this to mean?**
   "Self explanatory- I would be timing the patient and checking the he can finish the glass of 50 mls of water within 5 seconds"

9. **Do you have any comments about the overall design of the screening tool?**
   "I am not sure what is going on with the colours but I like the fact it is colour coded the green is the instructions of what to do….Oh, its traffic lights... I think that needs to be clearer maybe a box or key?"

Nurse N

1. The tool asks 'Is the patient is alert and able to maintain full consciousness for the duration of the screen?' What does that mean to you?

"So the patient needs to be fully awake or roused without their eyes closing or drifting off for the duration of the test"

2.Here the tool asks 'Can the patient sit/be sat upright?' What does this mean to you?

"Ensuring the patient is not slouching almost 90 degrees"

3.The tool asks whether the patient's speech on counting to ten is 'severely slurred or is unable to understand'. What do you understand this to mean?

"Unintelligible, listening out to the quality of the speech. I guess if I couldn't understand the speech I would need to put the patient nil by mouth"

4. Here the tool asks you to 'Give 50 mls of water from a glass. Ask patient to drink water as quickly and comfortably as possible. On the prompt to 'swallow' start the stopwatch when the first drop of water touches the lips whilst observing the Adam's apple/larynx for movement' What do you understand by this?

"So you need to get 50 mls of water and start timing when the water touches the patients lips. I would be looking to see that the throat area rises as the patient swallows"

5.The tool asks you to 'Stop if the patient coughs or experiences difficulty' Can you explain what you understand by this statement?

"I would need to stop if the patient begins coughing or choking

6.What do you understand by the question 'Is prompt, upward movement of the larynx noted?'

"Does the Adam's apple area move quickly and in an upward direction?"

7. Here the tool asks 'Can the patient drink the water without coughing during or after the swallow'-what do you understand by this?

I agree with Elaine, its pretty obvious really… can the patient drink or swallow the water without coughing

8.The tool asks 'Can patient swallow 50mls of water within 5 seconds' can you explain what you understand this to mean?

"Again I think this is obvious.. can the patient drink 50mls within 5 seconds"

9.Do you have any comments about the overall design of the screening tool?

"I like the design, I didn't get the traffic light idea immediately, I would like to see a box explaining the coding of the colours"

Nurse A

1. The tool asks 'Is the patient is alert and able to maintain full consciousness for the duration of the screen?' What does that mean to you?

I guess it means if the patient can talk to you and answer questions appropriately and stay awake for the duration of the screen"

2.Here the tool asks 'Can the patient sit/be sat upright?' What does this mean to you?

(Nods agreement with E)

3.The tool asks whether the patient's speech on counting to ten is 'severely slurred or is unable to understand'. What do you understand this to mean?

Yes.. I think it means if the patient's speech is very difficult to understand because it is slurred

4. Here the tool asks you to 'Give 50 mls of water from a glass. Ask patient to drink water as quickly and comfortably as possible. On the prompt to 'swallow'

start the stopwatch when the first drop of water touches the lips whilst observing the Adam's apple/larynx for movement' What do you understand by this?

"I agree with what's been said.. I would give the patient 50 mls of water to drink and start timing how long the patient takes to complete the glass to see if this is within 5 seconds"

5.The tool asks you to 'Stop if the patient coughs or experiences difficulty' Can you explain what you understand by this statement?

"So in the process of swallowing if the patient experiences difficulty and begins to cough you have to stop"

6.What do you understand the question 'Is prompt, upward movement of the larynx noted?'

"So the process of swallowing has started and the throat is moving upwards and quickly"

7.Here the tool asks 'Can the patient drink the water without coughing during or after the swallow'-what do you understand by this?

"So if the patient basically coughs during or after the process of swallowing they have a problem. If they cough before they could be nervous or just need to clear their throat"

8.The tool asks 'Can patient swallow 50mls of water within 5 seconds' can you explain what you understand this to mean?

"Well, they can drink 50 mls of water within 5 secs. I think it would be helpful if in brackets you explained the relevance of this…what is the average for healthy normal people".

9.Do you have any comments about the overall design of the screening tool?

"It looks pretty good..a key would probably help for people to understand. I think its a good idea because it is like a chain of actions..

Nurse L

1. The tool asks 'Is the patient is alert and able to maintain full consciousness for the duration of the screen?' What does that mean to you?

Yes, like everyone else says…are you able to complete the assessment without the patient drifting off. Alert and conscious are fairly explicit really

2.Here the tool asks 'Can the patient sit/be sat upright?' What does this mean to you?

Can they sit upright, vertical or at a 90 degree angle either independently or with pillows

3.The tool asks whether the patient's speech on counting to ten is 'severely slurred or is unable to understand'. What do you understand this to mean?

Same as everyone else.. that you are unable to understand the person counting to 10 or if the patient is able to understand.

4.Here the tool asks you to 'Give 50 mls of water from a glass. Ask patient to drink water as quickly and comfortably as possible. On the prompt to 'swallow' start the stopwatch when the first drop of water touches the lips whilst observing the Adam's apple/larynx for movement' What do you understand by this?

A measured glass of water..50mls.. that's self explanatory, to drink it quickly (prompt:) without pausing? Well that's not explicit it doesn't say without pausing

5.The tool asks you to 'Stop if the patient coughs or experiences difficulty' Can you explain what you understand by this statement?

Yes.. stop if the patient coughs or chokes

6.What do you understand the question 'Is prompt, upward movement of the larynx noted?'

Well, in response to the patient swallowing water, do you see prompt upward movement of the adam's apple

7.Here the tool asks 'Can the patient drink the water without coughing during or after the swallow'-what do you understand by this?

I agree with everyone else

8.The tool asks 'Can patient swallow 50mls of water within 5 seconds' can you explain what you understand this to mean?

Nods agreement

9.Do you have any comments about the overall design of the screening tool?

Why the colours?… I think you need a key at the bottom to explain this.

Nurse M

1. The tool asks 'Is the patient is alert and able to maintain full consciousness for the duration of the screen?' What does that mean to you?

Nods, yes self explanatory

2.Here the tool asks 'Can the patient sit/be sat upright?' What does this mean to you?

Sit up at 90 degrees.

3.The tool asks whether the patient's speech on counting to ten is 'severely slurred or is unable to understand'. What do you understand this to mean?

If the speech is very slurred like what you expect with people following a stroke and maybe so slurred understand that I can't understand what the patient is saying?

4. Here the tool asks you to 'Give 50 mls of water from a glass. Ask patient to drink water as quickly and comfortably as possible. On the prompt to 'swallow' start the stopwatch when the first drop of water touches the lips whilst observing the Adam's apple/larynx for movement' What do you understand by this?

No I wouldn't have twigged that the patient shouldn't pause

5.The tool asks you to 'Stop if the patient coughs or experiences difficulty' Can you explain what you understand by this statement?

Yeah, (laughs) stop if the patient coughs, chokes or whatever

6.What do you understand the question 'Is prompt, upward movement of the larynx noted?'

Nothing else to add.. I would be looking for prompt upward movement of the Adam's apple

7.Here the tool asks 'Can the patient drink the water without coughing during or after the swallow'-what do you understand by this?

Can the patient drink without coughing?

8.The tool asks 'Can patient swallow 50mls of water within 5 seconds' can you explain what you understand this to mean?

Self explanatory. Think you should explain relevance of drinking that amount within 5 seconds

9.Do you have any comments about the overall design of the screening tool?

Yeah, I like the design, it fits in with what nurses are used to using

Nurse J

1. **The tool asks 'Is the patient is alert and able to maintain full consciousness for the duration of the screen?' What does that mean to you?**

I am looking at someone who is aware of their surroundings, can understand what I am saying to them even though they might not be able to respond because of a speech problem..so how do I know if the patient is fully conscious? They can maintain eye contact and show there is some understanding even if it is in their non verbal responses

2.Here the tool asks 'Can the patient sit/be sat upright?' What does this mean to you?

Whether the patient can sit up of their own accord or if they need someone to help them sit upright, they can maintain that posture (prompt: how upright is upright to you?) Upright to me is in a sitting posture almost sitting forward

3.The tool asks whether the patient's speech on counting to ten is 'severely slurred or is unable to understand'. What do you understand this to mean?

That the patient is unable to understand the instructions. .the patient is unable to form words

4.Here the tool asks you to 'Give 50 mls of water from a glass. Ask patient to drink water as quickly and comfortably as possible. On the prompt to 'swallow' start the stopwatch when the first drop of water touches the lips whilst observing the Adam's apple/larynx for movement' What do you understand by this?

Asking them to put 50 mls of water into their mouth on prompt to swallow begin observing the larynx

5.The tool asks you to 'Stop if the patient coughs or experiences difficulty' Can you explain what you understand by this statement?

Agree with them

6.What do you understand the question 'Is prompt, upward movement of the larynx noted?'

Nothing else to add.. I would be looking for prompt upward movement of the Adam's apple

7.Here the tool asks 'Can the patient drink the water without coughing during or after the swallow'-what do you understand by this?

I think I understand that..coughing during or after water is being swallowed

8.The tool asks 'Can patient swallow 50mls of water within 5 seconds' can you explain what you understand this to mean?

Nods agreement with E and M.. yes.. swallow 50 mls within 5 seconds

9.Do you have any comments about the overall design of the screening tool?

I'm used to algorithms, I am more used to going downward rather than across, I didn't initially get the colours and agree you would benefit from a key to explain it

APPENDIX 15

TRUST 2: CONCURRENT VALIDITY STUDY

RAW DATA CASE SUMMARIES

Case Summaries for SLTR and RGN Stroke Participants for the Validity Measurement Study

	Male/Female	Age	Stroke type	SLTR Assessment outcome	RGN1 (Novice) Screening outcome	RGN2 (Experienced) Screening outcome	SLTR: Referral appropriate?	RGN1: Referral appropriate?	RGN2: Referral Appropriate?	Days since admission
1	Female	over 71	Right CVA	0	0	0	0	0	0	Second day
2	Female	over 71	Right CVA	0	0	0	0	0	0	Second day
3	Female	over 71	Right CVA	1	1	1	0	0	0	Day of admission
4	Male	over 71	Mid Cerebral artery	0	0	0	0	0	0	Third day

5	Male	over 71	Right CVA	0	0	0	0	0	0	Day of admission
6	Male	61-70	Left CVA	0	0	0	0	0	0	Day of admission
7	Female	over 71	Left CVA	1	1	1	1	1	1	Second day
8	Male	51-60	Right CVA	1	1	1	1	1	1	Fourth day since admitted
9	Female	over 71	Right CVA	0	0	0	0	0	0	Day of admission
10	Female	over 71	Left CVA	1	1	0	1	1	0	Fourth day since admitted
11	Male	over 71	Left CVA	1	1	1	1	1	1	Second day
12	Female	over 71	Left CVA	0	0	1	0	0	1	Day of admission

13	Female	over 71	Right CVA	1	1	1	1	1	1	Day of admission
14	Female	over 71	Left CVA	0	0	0	0	0	0	Day of admission
15	Male	61-70	Mid Cerebral artery	0	0	0	0	0	0	Second day
16	Male	over 71	Left CVA	0	0	0	0	0	0	Fifth day since admitted
17	Female	over 71	Right CVA	0	0	0	0	0	0	Day of admission
18	Male	over 71	Right CVA	1	1	1	1	1	1	Day of admission
19	Male	over 71	Right CVA	1	1	1	1	1	1	Second day
20	Female	over 71	Right CVA	0	0	1	0	0	1	Second day

21	Female	over 71	Left CVA	1	1	1	1	1	1	Second day
22	Male	over 71	Mid Cerebral artery	1	0	0	0	0	0	Fourth day since admitted
23	Female	over 71	Right CVA	1	1	0	1	1	0	Second day
24	Male	61-70	Right CVA	1	1	1	1	1	1	Second day
25	Female	over 71	Left CVA	1	1	1	1	1	1	Day of admission
26	Male	over 71	Left CVA	0	0	0	0	0	0	Day of admission
27	Female	over 71	Left CVA	1	1	1	1	1	1	Third day
28	Male	over 71	Right CVA	0	0	0	0	0	0	Third day

29	Male	over 71	Left CVA	1	1	1	1	1	1	Second day
30	Male	over 71	Left CVA	0	0	0	0	0	0	Day of admission
31	male	over 71	Right CVA	1	1	1	1	1	1	Day of admission
32	Female	over 71	Right CVA	1	1	1	1	1	1	Day of admission
33	Female	over 71	Left CVA	1	1	1	1	1	1	Fourth day since admitted
34	Male	over 71	Right CVA	1	1	1	1	0	1	Day of admission
35	Male	61-70	Mid Cerebral artery	1	1	1	1	1	1	Day of admission

36	Female	over 71	Left CVA	1	1	1	1	1	1	Second day
37	Female	61-70	Left CVA	0	0	0	0	0	0	Day of admission
38	Male	over 71	Right CVA	1	1	1	1	1	1	Fourth day since admitted
39	Female	over 71	Right CVA	0	1	0	0	1	0	Third day
40	Male	over 71	Right CVA	0	1	1	0	1	1	Fifth day since admitted
41	Female	61-70	Left CVA	1	1	1	1	1	1	Second day
42	Male	over 71	Right CVA	1	1	1	1	1	1	Day of admission
43	Female	61-70	Left CVA	1	0	0	1	0	0	Day of admission

44	Female	61-70	Left CVA	0	0	0	0	0	0	Second day
45	Male	over 71	Left CVA	1	1	1	1	1	1	Day of admission
46	Male	51-60	Left CVA	1	1	1	1	1	1	Day of admission
47	Male	over 71	Right CVA	0	0	0	0	0	0	Second day
48	Female	over 71	Left CVA	0	0	0	0	0	0	Fourth day since admitted
49	Female	over 71	Right CVA	0	1	0	0	1	0	Fifth day since admitted
50	Male	over 71	Left CVA	0	0	0	0	0	0	Second day
51	Male	over 71	Right CVA	1	1	1	1	1	1	Day of admission

52	Male	over 71	Left CVA	1	1	1	1	1	1	Day of admission
53	Female	41-50	Left CVA	0	0	0	0	0	0	Third day
54	Female	over 71	Mid Cerebral artery	1	1	1	1	1	1	Second day
55	Female	over 71	Left CVA	0	0	0	0	0	0	Day of admission
56	Male	over 71	Left CVA	1	1	1	1	1	1	Second day
57	Female	over 71	Left CVA	1	1	1	1	1	1	Day of admission
58	Male	over 71	Right CVA	1	1	1	1	1	1	Second day
59	Male	61-70	Right CVA	0	0	0	0	0	0	Day of admission

60	Female	over 71	Right CVA	1	1	1	1	1	1	Fourth day since admitted
61	Female	over 71	Left CVA	0	0	0	0	0	0	Second day
62	Female	61-70	Right CVA	1	1	1	1	1	1	Day of admission
63	Male	61-70	Left CVA	1	1	1	1	1	1	Day of admission
64	Female	61-70	Left CVA	0	0	0	0	0	0	Second day
65	Female	31-40	Right CVA	0	0	0	0	0	0	Day of admission
66	Female	over 71	Left CVA	0	0	0	0	0	0	Second day
67	Male	61-70	Left CVA	0	0	0	0	0	0	Second day

68	Male	over 71	Right CVA	1	1	0	1	1	0	Second day
69	Female	over 71	Right CVA	1	1	1	1	1	1	Third day
70	Male	51-60	Right CVA	0	0	0	0	0	0	Second day
71	Female	61-70	Left CVA	1	1	0	1	1	0	Fourth day since admitted
72	Female	over 71	Mid Cerebral artery	1	1	1	1	1	1	Day of admission
73	Male	61-70	Left CVA	0	0	0	0	0	0	Day of admission
74	Male	61-70	Right CVA	0	0	0	0	0	0	Second day
75	Male	61-70	Right CVA	1	1	1	1	1	1	Day of admission

76	Male	61-70	Left CVA	1	1	1	1	1	1	Day of admission
77	Male	61-70	Left CVA	0	0	0	0	0	0	Third day
78	Male	over 71	Left CVA	0	1	1	0	1	1	Second day
79	Male	61-70	Right CVA	0	0	0	0	0	0	Day of admission
80	Female	over 71	Left CVA	0	1	1	0	1	1	Third day
81	Male	61-70	Right CVA	0	0	0	0	0	0	Second day
82	Female	over 71	Right CVA	0	0	0	0	0	0	Day of admission
83	Female	over 71	Left CVA	0	0	0	0	0	0	Second day
84	Female	61-70	Left CVA	1	1	1	0	1	1	Day of admission

85	Female	over 71	Left CVA	0	0	0	0	0	0	Day of admission
86	Male	61-70	Left CVA	0	0	0	0	0	0	Day of admission
87	Female	over 71	Right CVA	1	1	1	1	1	1	Second day
88	Female	over 71	Left CVA	1	1	1	1	1	1	Third day
89	Male	31-40	Right CVA	1	1	1	1	1	1	Day of admission
90	Male	61-70	Left CVA	0	0	0	0	0	0	Day of admission
91	Female	over 71	Left CVA	0	1	1	0	1	0	Second day
92	Male	61-70	Mid Cerebral artery	1	1	1	1	1	1	Day of admission
93	Female	over 71	Right CVA	1	1	1	1	1	1	Third day

94	Male	41-50	Left CVA	0	0	0	0	0	0	Day of admission
95	Female	over 71	Right CVA	0	0	0	0	0	0	Day of admission
96	Male	41-50	Mid Cerebral artery	1	1	1	1	1	1	Second day
97	Female	over 71	Left CVA	1	1	1	1	1	1	Third day
98	Female	over 71	Left CVA	0	1	0	0	1	0	Fourth day since admitted
99	Female	over 71	Right CVA	1	1	1	1	1	1	Day of admission
100	Male	over 71	Right CVA	1	1	1	1	1	1	Day of admission

KEY: Dysphagia present=1 **Dysphagia absent=0**

Referral to SLT appropriate =1 **Referral to SLT not appropriate=0**

APPENDIX 16

CALCULATIONS FOR DETERMINING THE CONCURRENT VALIDITY OF THE HEAD DYSPHAGIA SCREEN FOR STROKE (HeDSS)

APPENDIX 16: Calculations for Determining the Concurrent Validity of the HeDSS

Experienced RGN's dysphagia screening outcomes vs SLTR's clinical dysphagia assessment outcomes: dysphagia presence and absence

		SLTR CLINICAL DYSPHAGIA ASSESSMENT	
		Dysphagia Present	**Dysphagia Absent**
EXPERIENCED RGN SCREENING TOOL	**Dysphagia Present**	46 a	6 b
	Dysphagia Absent	6 c	42 d
Total		a + c = 52	b + d = 48

Key: (Refer to Table 32 for key)

Calculation of sensitivity and specificity for the HeDSS when used by the Experienced RGN

With reference to the above table, the sensitivity and specificity were calculated using a formula described by Sackett *et al.* 1991 as follows:

Sensitivity = a / (a+c) = 46 / (46+6) = **.88**

Specificity = d / (b+d) = 42 / (6+42) = **.88**

Calculation of Positive and Negative Predictive values of Experienced RGNs screening outcomes

Predictive values were calculated using formulae described by Sackett *et al*. (1991). Refer to Table 32 to determine what a,b,c and d denote.

Positive predictive value = a / (a+b) = 46 / (46+6) = **.88**

Negative Predictive value = d / (d+c) = 42 / (42+6) = **.88**

The scores suggested a high likelihood of an underlying diagnosis of dysphagia in patients who screened positive and the absence of dysphagia in those patients who the Experienced RGN screened as negative i.e. not showing signs of dysphagia.

Calculation of Phi- For Detection of Signs of Dysphagia

Applied to the Experienced RGN dysphagia screening outcomes versus the SLTR clinical dysphagia assessment outcomes for the detection of signs of dysphagia, calculation of Phi is as follows (please refer to Table 36 for explanation of codes).

Phi = (AD - BC) / sqrt ((A+B)(C+D)(A+C)(B+D)).

Phi = (1932-36) / sqrt ((52) (48) (48) (52)) = **.76**

Correlation of the Experienced RGN screening and SLTR assessment for appropriateness of referral of patients for clinical dysphagia assessment

Experienced RGN versus SLTR's Clinical Dysphagia Assessment

		SLTR CLINICAL DYSPHAGIA ASSESSMENT	
		Referral	**No referral**
EXPERIENCED RGN SCREENING TOOL	**Referral**	44 a	6 b
	No referral	5 c	45 d
		a+c	b+d

Calculation of Sensitivity and Specificity- appropriateness of referral to SLT

Sensitivity = a/ (a+c) = 44 / (44+5) = **.90**
Specificity = d/ (b+d) = 45 / (6+45) = **.88**

Calculation of Positive and Negative Predictive values – appropriateness of referral

Positive predictive value = a / (a + b) = 44 / (44 + 6) = .**88**
Negative predictive value = d / (d + c) = 45 / (45 + 5) = **.90**

The predictive values suggest a very high likelihood of an appropriate referral of the acute stroke patient for a clinical dysphagia assessment by the SLT in patients who screened positive and a high likelihood of patients screened with negative signs not needing assessment.

Using the calculation and coding of the contingency table as presented in Table 37

Phi = (AD - BC) / sqrt ((A+B)(C+D)(A+C)(B+D)).

Phi = (1980-30) / sqrt ((50) (50) (49) (51)) = **.78**

Correlation of the Novice RGN's dysphagia screening outcomes and SLTR's clinical dysphagia assessment outcomes for dysphagia presence and absence

Novice RGN screen versus SLTR's Clinical dysphagia assessment

		SLTR CLINICAL DYSPHAGIA ASSESSMENT	
		Present	**Absent**
NOVICE RGN SCREENING TOOL	**Present**	50	7
		a	b
	Absent	2	41
		c	d
		a + c	b + d

Key: (Refer to Table 32 for key)

SLTR Assessment versus Novice RGN's Screen: Calculation of Sensitivity and Specificity

Sensitivity = a/ (a+c) = 50/52 = **.96**

Specificity = d/ (b+d) = 41/ 48 = **.85**

Calculation of Positive and Negative Predictive values for Novice RGN screen

Positive predictive value = a / (a + b) = 50 / (50 + 7) = **.88**

Negative Predictive value = d / (d + c) = 41 / (41 + 2) = **.95**

Phi = (AD - BC) / sqrt ((A+B)(C+D)(A+C)(B+D)).

Phi = (2050-14) / sqrt ((57) (43) (52) (48)) = **.82**

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Correlation of the Novice RGN screening and SLTR assessment for determining appropriateness of referral of patients for full swallowing assessment

Novice RGN's Screen versus SLTR's Clinical Dysphagia Assessment

		SLTR CLINICAL DYSPHAGIA ASSESSMENT	
		Referral	**No referral**
NOVICE RGN SCREENING TOOL	**Referral**	47	8
		a	b
	No referral	2	43
		c	d
		a+c	b+d

Calculation of Sensitivity and Specificity for decisions on appropriateness of referral to SLT

Sensitivity = a / (a + c) = 47 / (47 + 2) = **.96**
Specificity = d / (b + d) = 43 / (8 + 43) = **.84**

These results indicate that 96% of the patients appropriate for referral to SLT had a positive test result (i.e. screened as appropriate for referral), while 84% of patients who were not appropriate for referral to SLT had a negative screening test result.

Calculation of positive and negative predictive values for Novice RGN

Positive predictive value = a / (a + b) = 47 / (47 + 8) = **.85**
Negative predictive value = d / (d + c) = 43 / (43 + 2) = **.96**

The predictive values suggest a very high likelihood of an appropriate referral of the acute stroke patient for a clinical dysphagia assessment by the SLT in patients who screened positive and a high likelihood of patients screened with negative signs not needing assessment.

Calculation of Phi = .81 (see 10.7i for explanation of calculation of Phi).

Phi = (AD - BC) / sqrt ((A+B)(C+D)(A+C)(B+D)).

Phi = (2021-16) / sqrt ((55) (45) (49) (51)) = **.81**