Improving the evidence base for oral assessment in stroke patients

By

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Abstract

Oral care is essential in maintaining oral hygiene and oral health. When oral care is neglected individuals are at risk of oral and systemic complications affecting general health. Stroke patients are one group who are at risk of poor oral health due to their physical and cognitive dependency. Providing oral care is normally the responsibility of the nurses, and currently there is little evidence to support oral care provided. Through a series of studies this thesis aims to explore oral care in hospitalised stroke patients with the aim of developing an oral assessment to inform oral care.

An integrative literature review examining oral assessments developed for use in a dependent population, identified that an oral assessment for use in stroke patients did not exist. The majority of oral assessments had been developed using the empirical literature and/or expert opinion, with a focus to assess oral health and cleanliness. Those assessments that were selected for review were found to be of a poor quality both in development and testing of psychometric properties. Where agreement had been tested, both within and between raters, agreement was variable across all items. The information gathered from the review was used to aid the design of a qualitative study to explore stakeholder's views of oral care in stroke patients, and the development of a new oral assessment for use in stroke patients.

An interpretive approach was utilised to explore the views and experiences of experts in oral health and stroke; health professionals'; patients' and carers'. Two different methods were used to capture this data: one to one interviews for the experts in oral health and stroke, patients and carers; and focus groups for the health professionals. Eight experts were interviewed, five patients, five carers and the two focus groups with six/seven health professionals. The findings illustrated that oral care is complex, and assessment is only one component of this process. Five concepts relating to oral assessment were identified by all the groups: ability to attend to oral care; oral health and cleanliness of the oral cavity; comfort of the oral cavity; contributing factors; assessment format and layout.

The findings from the qualitative interviews, focus groups, and the literature review, were presented to an expert panel that contained a representative from the oral health experts, stroke experts, health professionals, patients and carers. This group reviewed the data and, using a systematic approach, developed the new oral assessment; the Comprehensive Oral Assessment Tool for Stroke (COATS). Following development, the COATS was tested for within and between rater agreement, and diagnostic accuracy, in 82 stroke patients on an acute stroke unit. Agreement was tested, in registered and unregistered nurses, and ranged from

fair to very good. The registered nurse showed better agreement than the unregistered nurse. The COATS also demonstrated in this initial testing that it could correctly identify a high proportion of patients either with or without a problem.

This thesis has provided some novel findings that will contribute to the existing knowledge of oral care in a stroke and dependent population. It has provided an overview of the quality of oral assessments available to nurses looking after acutely ill patients as well as highlighting all the potential issues that need to be considered when implementing a new oral assessment into clinical practice.

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Abbreviations

AGNB	Aerobic Gram Negative Bacteria
APB	Adapted Passos and Brand
BOHAT	Burns Oral Health Assessment Tool
BOHSE	Brief Oral Health Status Examination
BuSH	Built, Sport and Health schools ethics committee
CASP	Critical Appraisal Skills Programme
COM-B	Capability, Opportunity, Motivation, Behaviour system
COATS	Comprehensive Oral Assessment Tool for Stroke
COSMIN	COnsensus based Standards for the selection of health Measurement Instrument
CT	Computerised Tomography
CI	Confidence Interval
DOHA	Daily Oral Health Assessment
DH	Department of Health
GOHAI	General Oral Health Assessment Index
HCA	Health Care assistant
HR-PRO	Health-Related Patient Reported Outcomes
K	Kappa
Kw	Weighted Kappa
ICC	Intra-Class Correlation Coefficient
ICSWP	Intercollegiate Stroke Working Party
IQR	Inter-Quartile Range
IRC	Inter-Rater Coefficient
M	Medical Intervention
MCAT	Mouth Care Assessment Tool

MeSH	Medical Subject Heading
MM	Mucous Membrane
MOAG	Modified Oral assessment Guide
NA	Not Applicable
NAO	National Audit Office
NG	Nasogastric
NHS	National Health Service
NOAG	Neurosciences Oral Assessment Tool
NPV	Negative Predictive Value
NVG	National Vocational Qualification
O	Oral care intervention
OAG	Oral Assessment Guide
OAIT	Oral Assessment and Intervention Tool
OAVAS	Oral Assessment Visual Analogue Scale
OCAT	Oral Cavity Assessment Tool
OEG	Oral examination Guide
OHAT	Oral Health Assessment Tool
OHR-QoL	Oral Health Related Quality of Life
OHIP	Oral Health Impact Profile
PB	Passos and Brand
PEG	Percutaneous Endoscopic Gastrostomy
PPMC	Pearson Product Moment Correlation
PPV	Positive predictive value
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analysis
QUDAS-2	QUality assessment of Diagnostic Accuracy Studies
QUOROM	QUality Of Reporting Of Meta-analysis
RDeWalt	Revised DeWalt

RCN	Royal College of Nursing
RCT	Randomised Controlled Trial
RND	Round
RMBMAT	Rattenbury Mooney Baron Mouth Assessment Tool
RN	Registered Nurse
ROAG	Revised Oral Assessment Guide
SDD	Selective Decontamination of the Digestive tract
SF-16	Short Form health survey
SIGN	Scottish Intercollegiate Guidelines Network
SSEF	Stroke Specific Education Framework
SSNAP	Sentinel Stroke National Audit Programme
STARD	Standards for Reporting of Diagnostic Accuracy
TDF	Theoretical Domains Framework
THROAT	The Holistic and Reliable Oral Assessment Tool
TOAT	The Oral Audit Tool
U	Unable to assess
UK	United Kingdom
USA	United State of America
VAP	Ventilator Associated Pneumonia
WHO	World Health Organisation

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Chapter one

Oral health and hygiene

1.1 Introduction

Oral care is essential in maintaining a healthy oral cavity and preventing complications such as caries, gingivitis, periodontitis and tooth loss. Having a healthy, clean and fresh oral cavity also contributes to a person's sense of well-being (Locker and Slade 1997). One method of maintaining oral health is an oral care regime. The current recommendations are: to clean the oral cavity twice daily with a toothbrush and fluoride toothpaste for two minutes with no rinsing; and flossing once daily (Department of Health (DH) 2009). Today's lifestyle exposes individuals to a high sugary diet, increasing the need for effective cleaning of the oral cavity, including access to fluoride and regular dental health checks (Petersen 2003). For the majority of healthy adults attending to their oral care and accessing regular dental health checks, oral health is not an issue. However, a proportion of adults may struggle to perform effective oral care due to physical and/or cognitive difficulties. When an individual is unable to maintain their oral care it is often a carer or family member who would assist them (DH 2007). However, in some instances oral care may be neglected, which impacts on the person's oral and general health as well as their psychological well-being (Petersen 2003).

One group of individuals at increased risk of oral disease impacting on their general health are those with an acute illness in hospital. Many of these individuals may have existing dental problems before becoming acutely unwell; tooth decay, gingivitis, and these may be exacerbated further by ill health. A number of factors such as a reduced ability in attending to oral care, side effects of medication, oxygen therapy, a compromised immune system, medical comorbidities such as diabetes and age all increase the risk of oral complications. Research has also suggested possible associations between oral health and both respiratory infections (Scannapieco 1999) and cardiac conditions such as endocarditis (Lockhart et al. 2009). Maintaining oral health in acutely unwell patients is essential, not only for their oral and dental health, but possibly for their general health.

In a hospital setting the oral care pathway is multi-faceted and involves assessing, planning, implementing and evaluating evidence based care. There are also organisational issues impacting on care provision. Nurses have limited education and training regarding the provision of evidence based oral care (Wardh et al. 1997). Oral care is viewed as low priority in the hierarchy of care (Wardh et al. 2000; Adams and Bond 2000) and there is a lack of guidance and protocols (Talbot et al. 2005).

Stroke patients are one particular group whose oral care may be challenged due to a number of factors, identified by the British Society of Gerodontology, as being likely contributors to increase the risk of poor oral health:

- Physical and/or cognitive problems;
- Older age;
- Pre-existing comorbidities,
- Medication and oxygen therapy leading to xerostomia (dry mouth)

(British Society of Gerodontology 2010).

Furthermore, a systematic review of oral care in stroke patients identified that there was a lack of evidence to support and guide best care for stroke patients (Brady et al. 2010). Consequently, this thesis will focus on oral health and care in stroke patients. The thesis will present a series of studies focussing on assessment in stroke patients. The first study will review the current literature for existing oral assessments, critically appraising their methodological quality and content. The second study will use the information gathered from the literature review to inform an interview spine and focus group questions, which will explore the views and experiences of the "experts" in the field regarding oral care provision in hospital and gain an understanding of the issues for implementation of a new assessment into clinical practice. "Experts" in the field are defined as those who have theoretical and/or clinical expertise (professionals in oral health and stroke), those who provide oral care (health professionals), those who receive oral care (patients), and those who are carers and advocates for patients who receive oral care but have communication or cognitive difficulties (carers). In the third study, information gained from the literature review and the qualitative study will be synthesised. The synthesised information will be presented to a stakeholder group to inform the development of an oral assessment for use in stroke patients, the Comprehensive Oral Assessment for Stroke (COATS). The COATS will then be tested for validity and reliability in stroke patients.

This chapter will define the terms oral hygiene, oral care, and oral health and will focus on one particular concept of oral health; oral hygiene. The oral structures and mechanisms that contribute to oral hygiene will be described, followed by a brief description of how oral bacteria cause tooth decay and how gingival disease may impact on general health and well-being. The chapter will then examine stroke and how it may impact on a person's oral health and care, specifically examining the processes of oral care and the evidence supporting hospital care in stroke patients. Finally the structure of the thesis will be presented.

1.2 Oral health

Oral health is

> *"A state of the mouth and associated structures where disease is contained, future disease is inhibited, the occlusion is sufficient to masticate food and the teeth are of a socially acceptable appearance."*

(Yewe-Dyer 1993 pp.225)

Although social and environmental factors have been considered, this definition focuses on the oral cavity and an absence of disease. A more inclusive definition provided by Dolan (1993) incorporates oral health and the person:

> *"A comfortable and functional dentition which allows individuals to continue in their desired social role."*

(Dolan 1993 pp. 37)

Oral health is conceptually an anomaly. In general, health is associated with the person and does not necessarily focus on any one body part. Therefore, the concept of oral health relates to the individual and how oral disease, oral conditions, or oral disorders affect the person's health, well-being or quality of life (Locker and Slade 1997).

For the purpose of this thesis the term oral health will relate to the definition provided by Dolan (1993) where the oral cavity is comfortable and functioning without affecting the person's health and well-being.

Different terminology is used throughout the literature to describe different concepts of oral health such as the process (the cleaning of the oral cavity) and the outcome (the cleanliness

of the oral cavity). The term oral hygiene is used interchangeably to describe the process and the outcome, creating a lack of clarity. For the purpose of this thesis, oral care is the term that will be used to describe the process of cleaning the oral cavity (the care provided) and oral hygiene to describe the outcome of the care (the cleanliness of the oral cavity) (Figure 1-1).

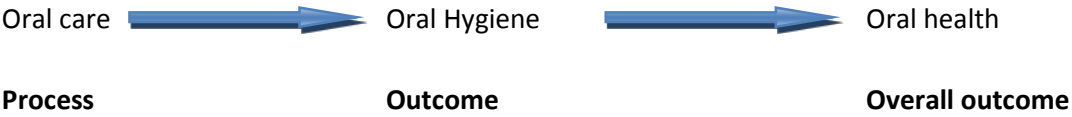


Figure 1-1 Defining oral care and oral hygiene

The Oral cavity

The oral cavity has several structures: teeth and the supporting alveolar bone, hard palate, cheeks, gingivae, soft palate, tongue, and floor of the mouth. Each structure is categorised as either being hard or soft tissue (Table 1-1) and plays an important role in the functions of the oral cavity. All the hard and soft tissues are covered by the mucous membrane except teeth. The mucous membranes and saliva work in partnership with the teeth, gingivae and the tongue to preserve oral health.

Table 1-1 Hard and soft tissues in the oral cavity

Hard tissue	**Soft tissue**
Teeth	Cheeks
Alveolar Bone	Gingivae
Hard palate	Soft palate
	Tongue
	Floor of the mouth

Mucous membranes

The structures within the oral cavity are covered by mucous membranes which are stratified squamous epithelium and are either keratinised or non-keratinised tissue. Keratinised tissues have a harder outer layer, made of dead stratified squamous cells full of keratin. These tissues are perfectly designed to protect against abrasion and are found on the

dorsum aspect of the tongue, hard palate, attached gingivae, and the outer surface of the lips. Non-keratinised tissues are softer with no hard outer layer and cover the remaining part of the tongue, lips, soft palate, cheeks and floor of the mouth. In order to prevent damage and abrasion the membranes are kept moist and lubricated by secretions from a large number of major and minor salivary glands.

Saliva

There are three pairs of major salivary glands, the parotid, submandibular and sublingual. Within each there are two types of cells, 1) Serous, which produce a watery secretion and 2) Mucous which produce a viscous secretion (mucoid). The parotid glands secrete a more serous secretion, the submandibular glands produce a mixture of serous and viscous secretions, whilst the sublingual produce mainly a viscous secretion. Together these secretions lubricate the mucous membranes allowing food to pass through the oral cavity without causing damage by breaching the membranes integrity.

Saliva is 99.5% water, whilst the other 0.5% is composed of salivary proteins, inorganic ions (ammonium, potassium, magnesium, calcium, and phosphate), gases and other constituents. Saliva possesses antibacterial properties that impact on the rate sugar and acids are cleared from the oral cavity and helps maintain a healthy pH balance within the oral cavity. The salivary proteins, for example glycoproteins bind with micro-organisms to form a pellicle, which is a biofilm that acts as a protective layer on the tooth surface. Other proteins such as lactoferrins also produce an antibacterial effect by binding with ferric ions, which are essential microbial nutrients. Saliva also contains lysozymes capable of breaking down bacterial cell walls, leading to destruction of the bacteria and so contributing to controlling the bacteria population. Other proteins such as sialoperoxidase neutralise the overall products of bacterial metabolism, and histains inhibit the growth of *Candida albicans*.

One of the main threats to the integrity of tooth structure is dissolution of their mineralised tissues (enamel, dentures and cementum). This occurs when the pH of the oral cavity decreases becoming more acidic. Demineralisation is prevented when the teeth are surrounded by a solution that is rich in minerals such as calcium phosphate (saliva). When the oral pH is normal (6.5), saliva is saturated with calcium phosphate providing the minerals required to maintain the mineralised surfaces. However, calcium phosphate is only part soluble and can become solid again. Saliva contains both statherin and proline-rich proteins

which both inhibit the calcium phosphate from crystallising on the tooth surface. Saliva's role in maintaining a healthy oral cavity depends on all the constituents of saliva working.

The Tongue

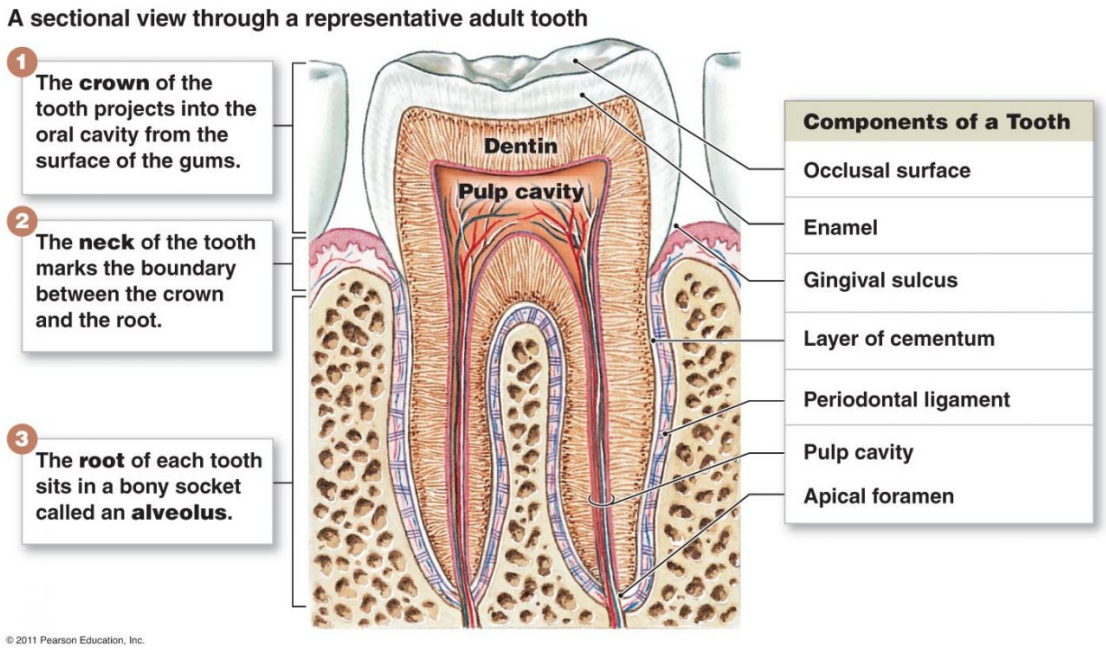
The tongue is a large muscle which aids communication, chewing, taste, swallowing and also explores the oral cavity, cleaning the tooth surfaces. The tongue movements are able to manoeuvre saliva around the oral cavity washing excess food off the teeth. The tongue also provides important sensory feedback such as how clean or comfortable the oral cavity feels (Ireland 2006).

Teeth

The teeth are the main structures in the oral cavity, and a healthy adult would expect a compliment of 32. They are used to aid speech, chewing and also make contributions to a person's appearance and well-being. Each tooth is divided into two areas, one third exposed and two thirds un-exposed. The exposed area is known as the crown, sitting outside the gingivae (gum) (Figure 1-2). The crown has an outside layer of enamel which protects the tooth and its inner layers. The enamel needs to be tough enough to withstand chemical and physical assault from acid and chewing.

The root is normally un-exposed, and is covered in cementum and embedded mainly in the alveolar bone covered by the gingivae (Figure 1-2). The main body of the tooth is dentine, which lies beneath the enamel and cementum running the full length of the tooth, beneath which the pulp can be found where the tooth's neurovascular system is situated (Figure 1-2).

Cementum, alveolar bone and periodontal ligaments make up the periodontal tissues that provide anchorage of the tooth to the alveolar bone and the gingivae (Figure 1-2). The periodontal ligaments attach themselves between the cementum and alveolar bone securing the tooth in position (Figure 1-2).



(Human Anatomy Ped.net 2015)

Figure 1-2 Anatomy of the tooth

The relationship between oral bacteria and the oral structures

Oral flora

The oral cavity has its own commensal population of micro-organisms (e.g. bacteria, fungi, protazoa) and in healthy hosts no harm will occur. These commensals are a diverse population of multiple species of bacteria, existing in a symbiotic relationship with the host. When the host's health conditions alter, this changes the symbiotic relationship, which may lead to dental disease (tooth decay) (Marsh and Percival 2006). The conditions in the oral cavity can be affected if:

- The individual's general health deteriorates, for example develops diabetes mellitus;
- There is a reduction in nutritional intake reducing the individual's immune response;
- The individual has increased sugar intake;
- There is reduced or absent oral care regime;
- Salivary flow is reduced;
- The individual has a high alcohol intake;
- The individual smokes;
- The individual takes certain medication;

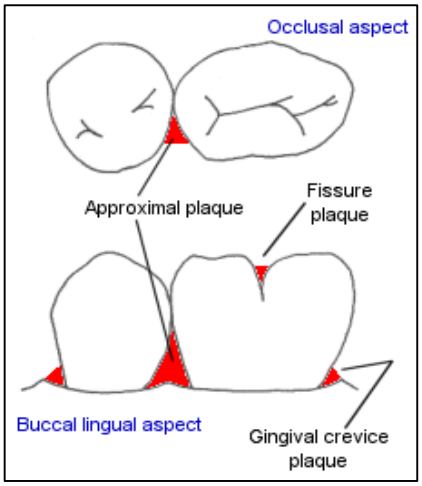
- The individual is ageing. (Marsh and Percival 2006).

When the conditions change and the symbiotic relationship is disrupted, the balance of oral bacteria may change allowing an increase in harmful bacteria. Pathogenic bacteria are the opposite of commensals in that they cause disease if allowed to grow in large quantities.

Dental plaque

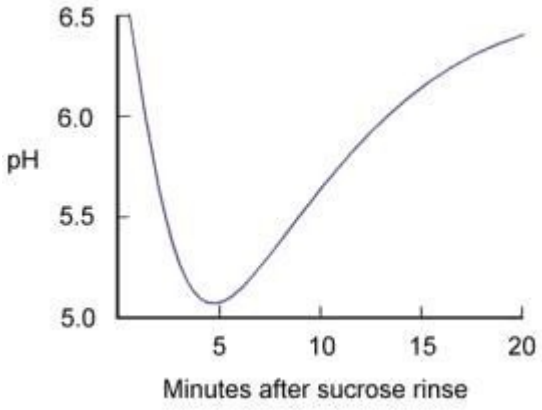
All teeth are covered by a pellicle. This is a layer of salivary and bacterial proteins, which form a protective layer over the tooth surface after the teeth are cleaned, the pellicle will quickly form pioneer bacteria which attach themselves to the pellicle and attract other bacteria to join them forming plaque (Kolenbrander et al. 2002). Plaque contains over 700 known micro-organism species and is found on nearly all teeth. Initially when the bacteria attach themselves to the pellicle they are unstable and vulnerable and can be dislodged by saliva being washed around the oral cavity with the aid of the tongue creating a sheer velocity as it washes over the teeth. However, there are certain areas in the oral cavity, the surfaces between adjacent teeth (approximal), gingival sulci (gingival crevice) and molar fissures, where the sheer force of the saliva is reduced and the bacteria is more sheltered and able to attract more bacteria creating a more stable structure. Plaque formation is therefore seen more readily in these areas (Figure 1-3). If left undisturbed the bacteria continues to attract more bacteria and slowly a more stable structure is formed, which starts to build around the tooth.

The bacteria in dental plaque metabolise fermentable carbohydrates (e.g. sucrose and glucose) in many foods. The end product is acid, which is released into the oral cavity changing the resting pH from 6.5 to 5. This acidic environment creates a chemical attack on the tooth surface promoting demineralisation and subsequent tooth decay. Calcium phosphate in saliva plays a major role in bringing the pH balance forward to 6.5. However, the Stephan curve shows that from the moment plaque is exposed to fermentable carbohydrates the oral cavity pH drops rapidly. It then takes approximately 20-40 minutes for salivary pH to reach resting levels and promote remineralisation of the tooth surface (Figure 1-4) (Edgar 1976).



(Chenhizhem 2010)

Figure 1-3 Plaque sites



(Chenhizhem 2010)

Figure 1-4 Stephan curve

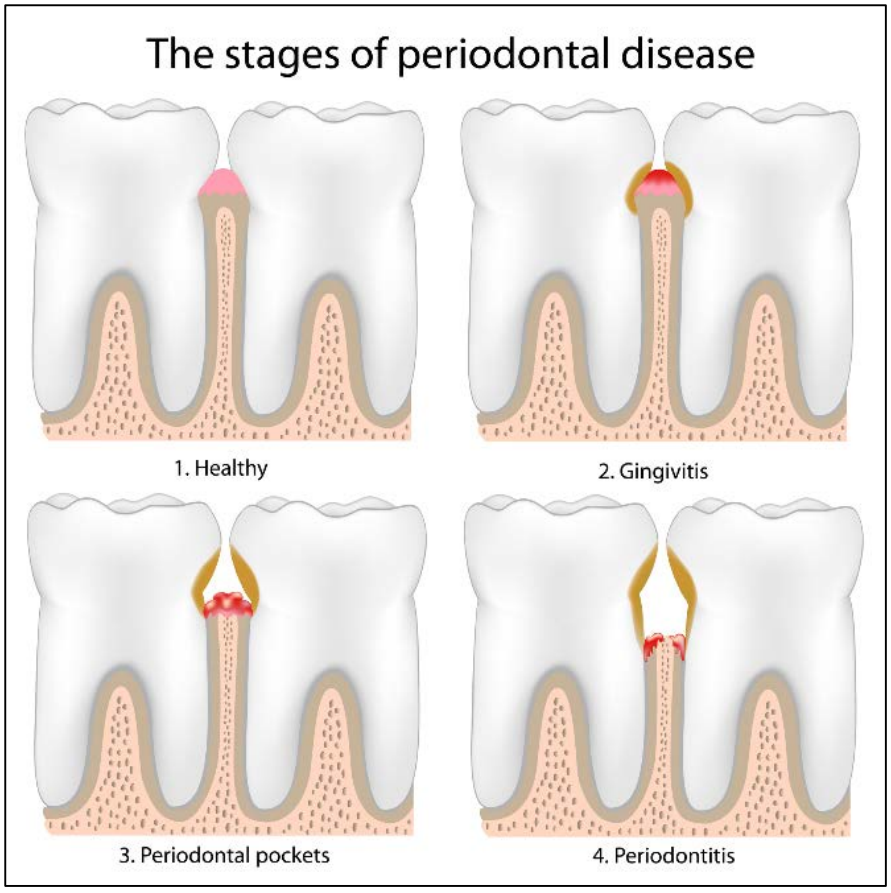
Plaque also poses challenges to the health of the gingival tissues. The release of bacterial toxins and acids are known to irritate the outer sulcular epithelial gingival layer. This constant attack eventually causes ulceration leading to bacteria infiltrating deep into gingival tissue, initiating an acute inflammatory response. This has the potential to become chronic if plaque levels remain high.

The inflammatory response involves proliferation of activated macrophages, which reside within the gingival tissues. Macrophages are able to recognise intruder organisms (pathogenic bacteria), and break them down to harmless protein fragments. During this process they release cytokines (e.g. 1L-6, 1L-1), causing the local blood vessels to dilate (vasodilation) increasing the gingival blood supply. The increased blood supply brings an influx of immune based cells and antibodies programmed to counteract effects of the pathogenic bacteria. Five characteristics of acute inflammation can be observed over time: redness (local infiltration of blood into the blood vessels); heat (increased blood supply to

the area); swelling (extra fluid in the tissues); pain (swelling compresses the nerve endings); and loss of function (severe swelling prevents movement of the tissues) (Ireland 2006).

This continued inflammatory response in the gingivae is known as gingivitis. Many of the adult population (50-90%) have some degree of gingivitis (Oliver et al. 1991), which is potentially reversible through the effective removal of dental plaque. A twice daily oral care regime of brushing and flossing teeth is the recommended method of plaque removal (DH 2009). If however, such a regime is not followed and plaque is not removed, it may eventually form a calcified hard exterior known as tartar. This hardened exterior traps and protects the underlying pathogenic bacteria allowing them to continue metabolising fermentable carbohydrates, releasing toxins, and cytokines increasing the inflammatory response. However, some of these cytokines may activate an enzyme called collagenase, which can break down the protein bonds in gingival connective tissue, leading to recession of the gingivae tissue (Ireland 2006) (Figure 1-5). Once the gingivae starts to recede a small space (periodontal pocket) forms, exposing the structures that support the tooth in the gingivae (Figure 1-5).

Once a periodontal pocket has formed, plaque and food particles are then able to lodge in the depths of the pockets, making it difficult for the individual to remove them with normal brushing. As the inflammatory response cycle continues the gingivae may be destroyed resulting in exposure of the underlying periodontal structures. Damage to the periodontal ligaments reduces the integrity of the anchorage holding the tooth in the alveolus. The tooth may in time become mobile risking eventual tooth loss (Ireland 2006). Once the periodontal structures become affected this is known as periodontitis. Although those individuals who have gingivitis and poor oral care are at risk of developing periodontitis, it is only present in 30% of the population (Kornman et al. 1997).



(Cotswald Periodontal Centre 2013)

Figure 1-5 Gingivitis and periodontitis

The effect of oral bacteria effect on the systemic system

Inflammation within the gingivae and periodontal tissues provides the bacteria with access to periodontal blood vessels and then the systemic circulation. This increases the risk of bacteraemia (bacteria entering the circulation system) and possible systemic inflammatory disease (Bahekar et al. 2007). When bacteria access the circulatory system an inflammatory response causes vasodilation of the gingivae tissues. The gingivae then becomes swollen and rounded, making them more vulnerable to trauma and bleeding (Oliver et al. 1991). Bleeding gingivae indicate the vulnerability of the circulatory system to oral bacteria both commensal and pathogenic. The blood, like the tissues in the body, produces monocytes cells that detect and destroy intruder cells that are regarded as non-self. Like macrophages in the gingival tissues, monocytes in the blood absorb and break down the bacteria, reducing their ability to do harm.

In most cases, bacteraemia is managed by the individual's own immune system resulting in no harm. However, in some cases the bacteria can overwhelm the immune response and travel through the circulatory system, giving access to general tissues, for example arterial wall leading to atheroma formation (Bahekar et al. 2007; Beck et al. 2001). The atheroma plus a supportive environment provide an ideal location for the bacteria to multiply and colonise. A significant body of evidence shows that oral bacteria very commonly causes >50% endocarditis when the bacteria settles on the endocardium (e.g. heart valves) and causes vegetation (thickening) (Lockhart et al. 2009). In addition, there has also been suggestion that certain oral bacteria (*streptococci*) promote platelet aggregation, predisposing thrombus formation (Genco et al. 2002). At present, this is only an association and there is no cumulative evidence; but over the last 15 years several studies have suggested that poor oral health is linked to heart disease and stroke (D'Aiuto et al. 2004; Loesche et al. 1998; Mattila et al. 1989; Syrjanen et al. 1989).

Further to these studies a systematic review examining the associations between periodontal disease and risk of atherosclerosis, cardio vascular disease and stroke found that periodontal disease may be modestly associated with cardiovascular disease and stroke (Scannapieco et al. 2003). Randomised controlled trials, longitudinal, cohort and case controlled studies were included and a total of 31 were analysed. Participants in the study included those with atherosclerosis, myocardial infarction, stroke and peripheral vascular disease. Those studies that were included were retrospective and the review identified that the heterogeneity of the oral assessments used in the studies meant meta-analysis of the results could not be performed. The review highlighted the need for an internationally accepted standardised protocol for oral assessment of oral health. The review concluded there was moderate evidence to support periodontal disease is associated with cardiovascular disease and stroke, although the reason for this association is unclear. There was insufficient evidence to support that the treatment of periodontal disease reduces the risk of heart disease. Although there is modest evidence supporting the association between periodontal disease, cardio vascular disease and stroke, it is unclear whether this association may be due to other confounding factors such as smoking (Dietrich and Garcia 2005)

There has also been increasing evidence suggesting an association between high colonisation of oral pathogenic bacteria and chest infection or pneumonia in individuals who

are medically ill, immuno-compromised, or dependent on others to attend to their oral care (Lam et al. 2012; Sellars et al. 2007; Li et al. 2000; Scannapieco 1999; Bonten et al. 1994).

Oral health and its impact on well-being

Oral disease impacts on a person's psychological well-being as well as their general health, and has been explored using oral health-related quality of life questionnaires in several studies (Schimmel et al. 2009; McMillan et al. 2005; Locker et al. 2002; Locker et al. 2000). The oral health-related quality of life questionnaire measures a person's perspective of oral health through four domains: physical, psychological, social and activities of daily living. Locker et al. (2000) carried out a longitudinal observational cohort study to identify if oral health affects psychological well-being in an older adult population.

Participants were aged 50 or over and were assessed at baseline and then at three and seven years post recruitment. This was a large study that recruited 907 participants at baseline, 611 were followed up at three years and 435 completed a telephone interview of which 334 also completed a self-assessment psychological questionnaire. The study did perform analysis that adjusted for confounding factors. An association was found between the person's perceived oral health, pain, disability, psychological well-being and life satisfaction. Those subjects who perceived they had poor oral health, also reported low morale and experienced more life stresses (Locker et al. 2000).

There were limitations to this study. The participants who took part in the seven year follow up were healthier than those participants who were assessed at baseline, they were more likely to be dentate, and actively accessing dental services, and were from a higher socio-economic group. This potential difference between the two groups could mean the results from those participants who were still actively involved in the research at seven years were potentially not representative of a normal population. The true extent of poor oral health on quality of life and well-being is therefore difficult to quantify. It could be suggested that the impact of oral health on quality of life may be higher because those participants who are at greater risk of oral health problems in a lower socio-economic group (Patrick et al. 2006), were underrepresented. An adequately powered study which includes a representative sample is required.

A similar study in elderly, medically ill patients found this population had oral problems such as missing teeth, dry mouth and limited chewing ability which affected their oral health-related quality of life (Locker et al. 2002). This study included 225 patients who were

deemed medically compromised and lived in a long term care setting. Quality of life was measured using a shortened form of the oral health impact profile (OHIP-14). This study also showed similar associations were seen between those who reported poor oral health and low morale and life satisfaction.

In terms of a stroke specific population, a study in Hong Kong identified in a small number of patients that although they were medically fit for discharge from a rehabilitation ward they had significantly impaired quality of life scores compared to healthy community dwellers of a similar age (McMillan et al. 2005). Quality of life was measured using the Short Form health survey (SF-16) and the General Oral Health Assessment Index (GOHAI). This study does not report statistically powering the study and so the results have to be viewed with caution. Those patients who were included in the study were also cognitively well and patients who had a severe stroke or swallowing difficulties were excluded so the participants in this study may not be representative of a normal stroke population.

Another exploratory study examined the impact of reduced oral function in stroke patients on Oral Health-Related Quality of Life (OHR-QoL) (Schimmel et al. 2009). A total of 55 patients were recruited, this included 31 stroke patients in the intervention group and 24 healthy matched controls. The OHR-QoL was examined using a self-report questionnaire already developed and validated, the Oral Health Impact Profile (OHIP). The OHIP examines function limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The OHIP showed that the stroke patients OHR-QoL was significantly reduced in the hospitalised stroke patients which was closely related to oral function and chewing (Schimmel et al. 2009). However, this is one small exploratory study that only recruited small numbers from a stroke rehabilitation ward. Patients with cognitive problems were excluded and so does not represent a normal stroke population. Although both of these studies were small they do suggest that disturbances or change in the oral cavity after stroke affects a person's quality of life. A larger study is required, that includes all stroke patients, to fully examine the impact stroke has on oral health related quality of life.

1.3 Maintaining oral hygiene

Conserving satisfactory oral health is important in preventing dental and possibly systemic diseases alongside maintaining a sense of well-being (Locker 1997). As stated by Yewe-Dyer (1993), oral health should be maintained in order to contain and inhibit the spread of

diseases. Humans have their own intrinsic mechanism of controlling oral bacteria. However, changes in extrinsic factors such as lifestyle and diet may increase the bacterial assault on the teeth and the oral cavity and need to be balanced alongside the person's intrinsic mechanisms if oral health is to be maintained (Petersen 2003).

The World Health Organisation (WHO) recommends that health policies need to encourage the prevention of oral disease by focussing on health promotion, such as a healthy diet, because this not only helps prevent stroke and heart disease but also helps with oral health (Petersen 2009). The current Department of Health (DH) guidance, "Choosing Better Oral Health", focuses on eight factors that contribute to oral disease, recommending dentists and oral health practitioners should assess and manage all eight areas not only to maintain oral health but general health and well-being as well (DH 2005).The eight areas are:

- Diet and nutrition
- **Oral hygiene**
- **Exposure to fluorides**
- Tobacco
- Alcohol consumption
- Trauma
- **Medical disease**
- **Medication**

(DH 2005)

Although all eight factors play a role in the maintenance of oral and general health, only certain risk factors (medical diseases and medication) and oral care (oral hygiene and exposure to fluorides) will be discussed in depth in the thesis. This is because these are the main factors that nurses and other health professionals could influence for those patients who are acutely ill in a hospitalised setting.

Co-morbidities and medication

Existing medical diseases, and or their treatment through medication, may increase a patient's risk of developing oral disease. For example, patients suffering from diabetes mellitus or those receiving corticosteroids may become immuno-compromised. Consequently, in these groups of individuals, the inflammatory response is less effective resulting in more aggressive periodontal disease. This can lead to further stress on the immune system possibly affecting general health and well-being of the person. Patients with diabetes have been shown to be at greater risk of developing periodontal disease. However, there is a suggestion that periodontal disease may predispose people to diabetes (Li et al. 2000), indicating the possibility that oral health may contribute to systemic disease.

The management of diseases such as diabetes, cardiac disease, respiratory disease, auto immune-diseases, depression, renal disease and pain management relies heavily on medication that can alter the condition within the oral cavity. This change alters the balance of bacterial growth, predisposing the oral cavity to a more pathogenic bacterial population with the consequences of oral health deteriorating.

Medications such as diuretics, analgesics, anti-hypertensives, antidepressants, proton pump inhibitors, bronco dilators, anticonvulsants and anti-parkinsonian drugs may all cause xerostomia. This leads to a reduction in the oral cavities' predisposed defences against even commensal oral bacterial growth. Other medications, for example cough linctus and antibiotics, have to be delivered in a syrup format containing high levels of fermentable carbohydrates (sucrose and glucose), to make the medication palatable. Oral bacteria can then metabolise the sugar, releasing acid into the oral cavity, dropping the pH and increasing the risk of demineralisation of the tooth and decay (Ireland 2006).

Fluoride and oral hygiene

A systematic review found that fluoride in toothpaste, mouthwash and the water supply was important in preventing tooth decay because the fluoride helps decrease demineralisation of the tooth and increase remineralisation (Marinho et al. 2003). Further to this, a Cochrane systematic review of 79 studies which included 73,000 children found that toothpaste containing at least 1000ppm fluoride was associated with a reduction in tooth decay (Walsh et al. 2010). Another systematic review also examined the impact brushing techniques, using manual toothbrushes, would have on oral health and found a small but significant

reduction in gingivitis (Van der Weijden and Hioe 2005). Both reviews have contributed to current dental guidance that recommends brushing teeth twice a day with fluoride toothpaste using a circular brushing motion for two minutes (DH 2009). The evidence to support these recommendations are from robust high grade studies.

Although robust evidence is available to support these recommendations, oral disease is still prevalent in underdeveloped countries, and in vulnerable groups such as the elderly and those with physical or learning disabilities (Petersen 2009). Further guidance has been produced by the DH for those who have physical and learning disabilities. For these groups, access to oral health care becomes more complicated due to physical needs, lack of communication skills, and lack of ability to attend to oral health needs (DH 2007). The DH recommends that the guidance for individuals with disability should be used in conjunction with the guidance for healthy adults to aid commissioning and service provision for vulnerable groups.

When examining oral hygiene in these challenging groups, it became apparent that functional factors also influenced oral hygiene and oral health. Function/ability is not included in the eight factors that contribute to maintaining oral health (DH 2005), and people with disabilities or those who are acutely unwell often require assistance from others to attend to their oral care. Therefore, a person's functional ability needs to be considered and managed when attempting to maintain their oral health.

When considering the eight factors that are related to oral disease (DH 2005), it might be assumed at first glance that an equal relationship exists between all the factors. While all of the other factors plus function contribute to supporting oral health and are independent of each other, oral hygiene has a pivotal role in maintaining satisfactory oral health. For example, you can address the risk factor smoking, and it does not necessarily affect a person's diet or fluoride intake. If oral health is visualised as an arch and smoking was removed the structure would fall in and would no longer be a whole (Figure 1-6). The arch however, is missing a keystone to hold the items together. Oral hygiene would be the keystone, the supporting factor that keeps the arch in place, because it has a relationship with all the other factors (Figure 1-7). For example, using fluoride toothpaste is beneficial on its own but good oral care practices are still required daily. Avoiding smoking can help prevent staining and damage to the tissues, but maintaining oral hygiene is still required. Assessing medication and treating any side effects such as a dry oral cavity helps restore the

body's own defences, but oral care is still required. Although each factor improves oral health, oral hygiene is also required to ensure the symbiotic relationship is maintained and pathogenic bacterial growth is controlled.

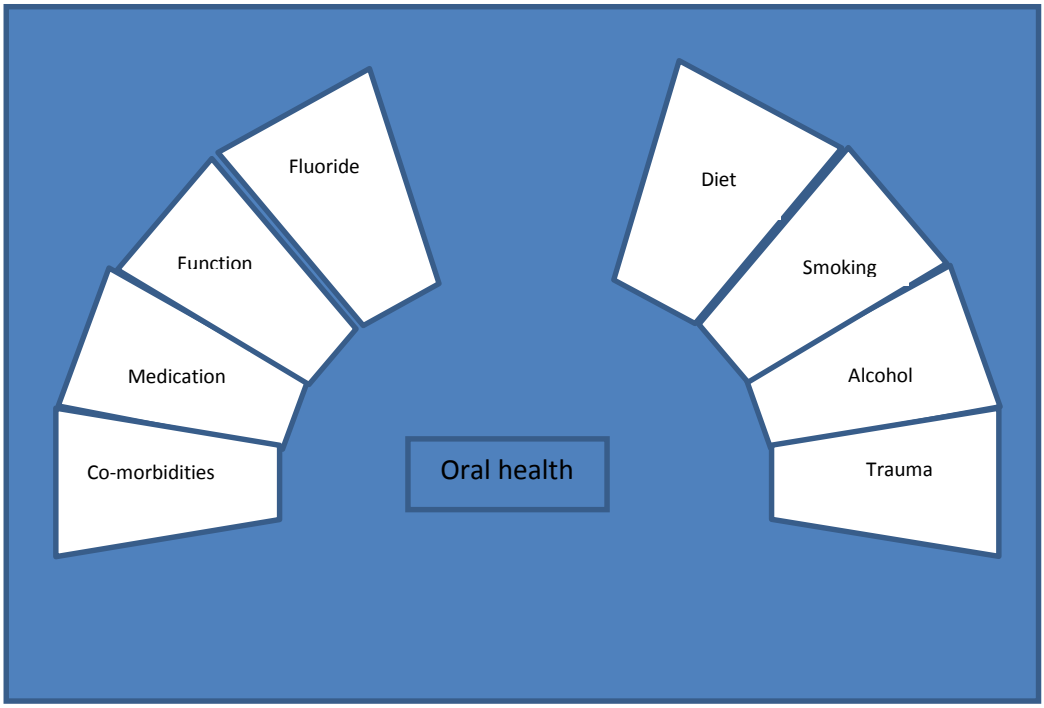


Figure 1-6 Incomplete oral health

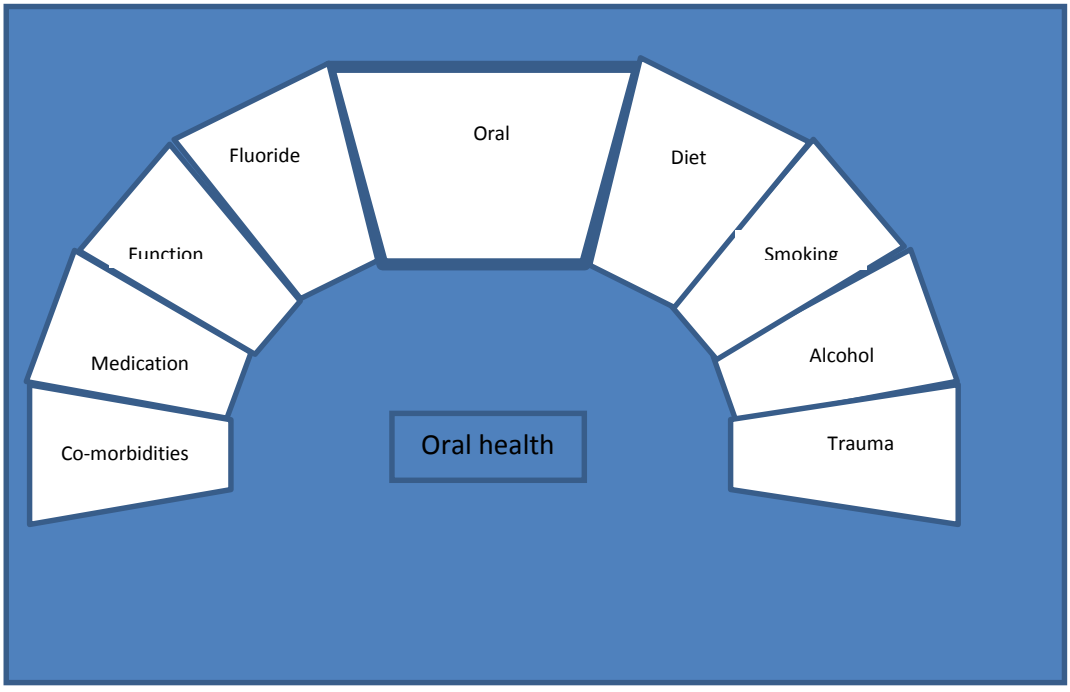


Figure 1-7 Complete oral health

1.4 Stroke

Stroke is one example of a disease where patients may have difficulty attending to their oral care due to physical and cognitive impairments, reduced conscious level and other contributing co-morbidities (Hunter et al. 2006). In the United Kingdom, it is estimated that stroke affects 152,000 people every year (Townsend et al. 2012), is the fourth most common cause of death and leading cause of adult disability (National Audit Office 2005). Between 2005 and 2015 the prevalence of people has increased by 28% (DH 2014), this therefore places a significant burden on health services, with the direct cost estimated at approximately £4.5 billion per year (Saka et al. 2009). One fifth of acute hospital and a quarter of long term beds are occupied by stroke patients. The wider annual cost of stroke, which includes informal care costs, are estimated at £8 billion (National Audit Office 2010). If oral care is not managed effectively this may result in further systemic complications placing an extra burden on health services.

The need for oral care in stroke patients is both physiological and psychological. Many stroke patients are at risk of xerostomia caused by reduced saliva production, oxygen therapy, mouth breathing, dehydration and side effects of medication. In addition, between 19% and 81% may have swallowing difficulties (dysphagia), due to muscle weakness and reduced saliva flow, making it difficult to manoeuvre food or fluids through the oral cavity towards the pharynx (Meng et al. 2000; Barer 1989). Therefore, food may not be cleared adequately from the oral cavity becoming lodged in the cheeks or on the teeth surfaces. A reduced saliva flow and large quantities of food debris lying in the oral cavity disrupts the bacterial population, increasing the risk of oral disease.

Stroke patients have an increased risk of infections (Langhorne et al. 2000) and reduced nutritional intake which places extra demands on the patient's ability to activate an immune response (Dirnagl et al. 2007). Nutrition is important in maintaining a healthy immune system and if nutrition is depleted this affects the production of the immune defences, such as macrophages, to initiate an antibody response to infection. At the same time, if infections occur this increases the body's metabolic rate and the body's general consumption of calories, reducing the calories available to produce immune defences (Keusch 2003). Many stroke patients have been shown to suffer from malnutrition following their stroke, compromising their ability to mount an effective immune response (Davalos et al. 1996). As more demands are made on the immune system, the stroke patient's ability to activate an effective inflammatory response against pathogenic bacteria and against fungal

infections may be reduced (Budtz-Jorgensen et al. 2000). This in turn will reduce the body's own natural defences within the oral cavity in preventing gingival disease and infections, so effective oral care is therefore essential if the accumulation of bacteria associated with these problems are to be avoided.

Several studies have identified that there may be an association between oral bacteria and chest infection and pneumonia in medically ill patients (Li et al. 2000; Scannapieco 1999). In an acute stroke population, it has been demonstrated that dependent stroke patients are more at risk of developing a chest infection in the first few weeks following their stroke (Langhorne et al. 2000), especially those with swallowing problems (Martino et al. 2005; Teasell et al. 1996). A recent systematic review found that 10% of stroke patients develop a chest infection in hospital (Westendorp et al. 2011). The systematic review had its limitations, the data was collected from published studies and stroke registers and so those hospitals that do not take part in research or keep stroke registers were excluded. The excluded population may be a different population to those included and so the results may not be representative of all stroke patients. Those studies that were included in the review did not use a uniform definition for infection and in some cases the reporting of certain characteristics was absent. Due to this lack of information the researchers pooled information which potentially diluted the results. Although these techniques were used the results suggest that chest infection is prevalent post-stroke, the reason for this remains unclear.

Zhu et al. (2008) and (Millns et al. 2003) suggest a higher pathogenic bacterial count exists in the oral cavity of stroke patients during the acute phase, potentially increasing their risk of infections. Both these studies were performed in stroke patients, however, they had very small sample sizes and limited inferences can be made from the studies. Zhu et al. performed a small prospective study that examined the presence of oral yeast and bacteria in 56 stroke patients from admission to 6 months post stroke. These were mainly male (75%), retired and living with their family. The population was also from one ethnic group and so may not be representative of a white British stroke patient both in stroke risks and oral health risks. The paper does not report what clinical characteristics the patients had, such as dysphagia, however, they did report the dependency of the group. Eighty percent of the patients did have difficulty with manual dexterity so were unable to brush their teeth in the acute phase but by 6 months this was greatly improved. The study reported high oral yeast and bacterial count in the acute phase which reduced during the recovery phase. This

was thought to be related to manual dexterity. This study was a small, and although high counts of yeast and bacteria were found it is unclear if this was different to a normal population. Similarly, Millns et al. (2003) performed a prospective study comparing 50 acute stroke patients, 25 stroke patients in rehabilitation, 50 acutely ill medical patients and 25 healthy volunteers. The paper does not report patient characteristics in detail so it is difficult to ascertain if they are representative of their population. There is no indication that the study was adequately powered or analysis was performed to adjust for confounding factors. The results identified half of the stroke patients had an unsafe swallow and one third of the stroke group had bacteria present that cause pneumonia. Evidence to support the theory that oral bacteria in stroke patients increases the risk of pneumonia remains weak and further research is required.

The link between oral cleanliness, bacterial load and pneumonia remains unknown, however for some clinicians it is felt that the risk of pneumonia may be increased if the bacterial load in the oral cavity is not managed. A large prospective cohort study of 412 participants aimed to identify risk factors for serious infections such as pneumonia after stroke (Sellars et al. 2007). This study found five factors were independently associated with pneumonia after stroke, older age, speech loss, severity of post stroke disability, cognitive impairment and failed water swallow test. This study did examine oral health and the presence of oral bacteria and although an increase in bacteria was seen in stroke patients, the link between a high presence of oral bacteria and pneumonia remains weak. There were several limitations to the study. The study was statistically underpowered because 500 participants were required to meet a prediction rate of 85%; and it was performed in an area of high social deprivation and therefore included patients with multiple social determinants for stroke and oral health problems. A larger multi-centre study would be required to see if these results would be reproduced.

Although there is no conclusive evidence to support that a high colonization of oral bacteria increases the risk of pneumonia, two studies have explored this theory further by examining the effect of a standardised oral care regime on the incidence of pneumonia in a dependent population (Lam et al. 2012; Fields 2008; Gosney et al. 2006a; Yoneyama et al. 2002). An initial study examining oral interventions in an institutionalised dependent population in reducing pneumonia took place in Japan (Yoneyama et al. 2002). This was a longitudinal randomised cohort study that used multiple centres. Four hundred and seventeen patients were selected from 11 nursing homes. The residents were randomly allocated to receive

oral care or no oral care. The residents who were receiving oral care also had intervention from the dentist or dental hygienist once a week if required for plaque and calculus removal. Pneumonia was diagnosed using a set criteria of: a new infiltrate on x-ray; and a temperature above 38 ^{o}C. Plaque scores were also measured as well as cognitive and physical ability. The study found a significant reduction in febrile days, pneumonia, and death due to pneumonia, in those patients who received oral care (Yoneyama et al. 2002). The study concluded that oral care maybe beneficial in reducing pneumonia in dependent patients.

Although this study reports promising results it has several limitations due to poor methodology. The paper does not report if the sample size was adequately powered to detect a change between both groups not due to chance. All the facilities had two floors but only those residents on one floor were selected to participate. The participants were randomly selected but it is not clear from the paper how this was performed and what informed the random selection. Only those patients who could provide informed consent were included and patients who had existing pulmonary disease or were on tube feeding were excluded. The inclusion and exclusion criteria therefore meant that only those patients who were well both physically and cognitively were included and so may not totally represent a dependent population. The intervention was being performed by the carers on the same floor and so they were not blinded to group allocation. Although the paper reports the carers were not asked to assist the normal care group with oral care, carer biases were still a possibility.

The results from this study are not generalizable to an acute hospital population because the residents are medically well, and the carer's' workload and priorities are different. Other factors in an acute hospital environment may contribute to the risk of pneumonia such as; oxygen therapy drying the mouth and affecting saliva flow, acute swallowing difficulties, poor nutritional intake, and reduced immunity. The residents in the study also received extra dental support and it is not clear if it was the oral intervention by the carers and/or the dentist that was responsible for the reduction of pneumonia. Currently, there is very little dental support in acute hospitals with regard to oral care and dental health (Talbot et al. 2005). The provision of extra support, at present, would not be sustainable in an acute hospital setting.

A prospective randomised placebo controlled trial examined if Selective Decontamination of the Digestive tract (SDD) would reduce the colonisation of Aerobic Gram-Negative Bacteria (AGNB) and reduce pneumonia and mortality in acute stroke patients (Gosney et al. 2006a). The study recruited 203 patients from 3 centres, recruitment took place within 24 hours of admission. Patients were randomised to receive SDD or placebo. Of the 203 patients recruited 20 died while in hospital and 19 withdrew, 164 were therefore analysed. No significant difference were found between the participants who received the SDD and those that received placebo. Although no significant difference was found the results showed a reduction in AGNB and documented pneumonia in those patients who were treated with SDD in the first few weeks, however mortality was not changed. This study was conducted in a small number of patients and it is unclear from the paper if the study was adequately powered to detect any significant change. The patients included in the study were reported as having less dependency and dysphagia than a normal stroke population affecting the generalisability of the results. Patients were blinded to their treatment but it is not clear if those collecting or analysing the data were also blinded to group allocation reducing bias. Eight patients were diagnosed with pneumonia and seven of these were patients with swallowing problems, however, clinical signs and symptoms of pneumonia as documented in the case notes was accepted as a diagnosis of pneumonia which was a subjective measure rather than an objective measure. This study highlights that SDD may be effective in reducing the colonisation of bacteria in the first few weeks and has the potential to reduce pneumonia but a larger powered study is required to ascertain if this effect is significant and not by chance.

Another study examined timed oral care interventions in preventing Ventilator Associated Pneumonia (VAP) in stroke patients on a neurologic and medical intensive care unit (Fields 2008). When this study was performed there was growing evidence to support the use of an oral care bundle in reducing VAP in intensive care patients (Berry et al. 2007; Grap and Munro 2004; Munro and Grap 2004). This study was specifically examining the role of tooth brushing in reducing VAP. Specific instructions were given to the staff about the tooth brushing technique to be used. Target recruitment was 200 patients or 2000 ventilation days. The study recruited 345 patients of which 200 patients had complete data sheets and were included. Although the study started as a randomised controlled trial the control group was disbanded when the VAP rate had dropped from 6.49% pre-trial to 0.62% in the treatment group and 4 patients had developed VAP in the control group. All patients were therefore given the intervention. Although, this study was performed in stroke patients the

development of pneumonia in this group is related to decreased conscious level, inability to protect airways, and prevention of the body's own natural defences in preventing the colonisation of bacteria. Very few stroke patients are actually treated in intensive care units with the majority being treated on stroke units or medical wards (IntercollegiateStroke Working Party 2015). This study highlights the importance of oral care in stroke patients especially those who require intensive care intervention. However, the transferability of this evidence into acutely ill patients on a stroke unit or medical ward is unclear.

Following on from Fields (2008) a further study was conducted in Hong Kong, examining the effect of three oral interventions in reducing oral pathogens in stroke patients and potentially reducing the development of pneumonia (Lam et al. 2012). This was a randomised study and a total of 102 patients were recruited and allocated one of the three treatment groups. Group one involved professional instruction in the use of an electric tooth brush, group two involved a corsodyl mouth rise twice daily for 3 weeks and group three received the corsodyl mouth wash and assistance with tooth brushing twice a week for 3 weeks. Only 81 patients data were analysed because seventeen patients were lost to early discharge, 2 patients transferred to another hospital, 1 patient was non-compliant with the mouth rinse and 1 patient self-discharged. The study found that 72.8% of the patients had anaerobic Gram-negative bacilli in the oral cavity however, the level of these bacteria remained stable throughout the study and no significant differences were found between the groups (Lam et al. 2012). A secondary outcome was to monitor the development of pneumonia during hospital stay and no new cases of pneumonia were found.

There are several limitations to the study; the study did not reach the required number of participants in each group to be able to detect a reduction in plaque score by 0.3. The study was therefore statistically underpowered and any difference that may have been present between the groups could have gone undetected. The aim of the study was to reduce the bacterial load in the oral cavity and reduce the risk of chest infections in stroke patients. The patients who were recruited were not acutely ill and were up to seven days post stroke and so do not represent the acutely ill stroke patient who may be at greatest risk of chest infections in the first week after stroke (Langhorne et al. 2000). Although there were several limitations to the study the authors acknowledged these and reported this was as an exploratory study to inform further research. The authors do recommend that further research in required to fully explore the effectiveness of oral care interventions against opportunistic bacteria in the oral cavity of stroke survivors.

At present there is insufficient evidence to support an association between oral pathogens and pneumonia/chest infections in acutely ill patients and to date the studies that have been conducted have been poorly designed and under-powered. However oral care in an acutely ill population remains important for dental health and psychological well-being. Although there is increasing interest in the relationship between a high colonisation of pathogenic bacteria in the oral cavity and potential systemic infections, oral care is important in the first instance, in maintaining a healthy oral cavity (DH 2009). Maintaining oral hygiene is the key to maintaining oral health (see Figure 1-7) and following a stroke, many patients may have difficulty attending to their oral care. Physically, they may suffer from weakness in one side of their body, impairing movement and control. Patients can therefore have difficulty preparing their toothbrush and toothpaste, holding and manoeuvring the equipment effectively around the oral cavity and spitting out excess toothpaste. Cognitive difficulties can include incorrect processing of information, disorientation to time and place, and being unable to recognise the need for oral care. Patients may have difficulty recognising objects such as toothbrushes and their function. This can lead to little or no oral care. For this group of patients, the nurses become a key link in assisting them in their oral care needs.

Often, if oral care is not attended to, other symptoms occur such as bad breath, and the feeling of an unclean oral cavity. Many individuals feel embarrassed, worried and anxious about these, in addition to having an uncomfortable feeling in their oral cavity. These issues subsequently impact on well-being and quality of life and possibly their overall recovery (Schimmel et al. 2009). Providing oral care is therefore essential in stroke patients. Providing evidence based care is the ideal, and up to 2006, oral care provision remains under researched and ad hoc in stroke units (Talbot et al. 2005).

A Cochrane review, examined staff-led interventions for oral hygiene in stroke patients (Brady et al. 2010). The main aim of the review was to identify, from the literature, which interventions were available to guide the care nurses provide to maintain oral hygiene in stroke patients. These interventions could be oral assessments, the use of equipment, and the use of agents and or staff training. Initially, eight studies were identified, seven sampled 'elderly' patients and it was not possible to separate out stroke specific data from the total dataset so these studies were excluded. The remaining study that was included in the review examined the effectiveness of an oral health care education programme aimed at care assistants working in a nursing home (Frenkel et al. 2001).

Frenkel et al. (2001) performed a cluster randomised controlled trial in nursing homes examining the effect of an oral health care education training programme on oral health. Twenty two nursing homes were randomised to receive either education on oral care or usual care. Six hundred and seven potential residents could be included, of which 127 were excluded due to cognitive problems, and a further 49 who had no dentures or teeth so could not be included. Of the remaining 431 residents eligible to take part 412 patients provided consent of which 67 had a diagnosis of stroke. Dental and denture plaque were the primary outcome and were quantified using objective measures. Gingivitis and denture stomatitis were secondary outcomes. The amount of plaque on teeth was not significantly different between the intervention and control group at six months. However there was a significant reduction in denture plaque in the intervention group after one month and this was still evident at six months. There was no statistical difference found for gingivitis or denture induced stomatitis. The number of stroke patients is low and although a power calculation was performed this was not aimed at meeting stroke specific outcomes. The intervention was provided by a dental health promoter which is not reflective or current clinical practice. The study did show a lasting effect even though there was a large turnover of staff.

Brady et al. (2010) suggests that education continues between the existing staff and new staff. Although specific measures were used to measure plaque the study did not assess other aspects of oral health. The Cochrane review concluded that an education programme targeted at nursing home health care staff had a positive impact on reducing denture plaque within a small group of stroke patients, and staff's knowledge and attitude to oral care significantly improved. This review was updated in 2011 and two more studies were included, Gosney et al. (2006a) and Fields (2008). As discussed earlier there were limitations to these studies and the reviews recommendations remained the same, suggesting there was a distinct lack of randomised controlled trials investigating staff led oral care interventions for stroke patients. Further research is still required to support oral care provision in stroke patients, in all areas: assessing oral hygiene; interventions and treatment; and equipment because there was a paucity of high quality evidence.

This Cochrane review has provided some robust evidence to support current national clinical guidelines for stroke which recommended that:

"All stroke patients, especially those who have difficulty swallowing, and are tube fed, should have oral and dental hygiene maintained (involving the patient or carers) through regular (at least 3 times a day); brushing of teeth with a toothbrush, and dentures and gums with a suitable cleaning agent (toothpaste or chlorhexidine gluconate dental gel); removal of excess secretions.

B All patients with dentures should have their dentures: put in appropriately during the day; cleaned regularly; checked and replaced if ill-fitting, damaged or lost.

C Those responsible for the care of patients disabled by stroke (in hospital, in residential and in home care settings) should be trained in: assessment of oral hygiene; selection and use of appropriate oral hygiene equipment and cleaning agents; provision of oral care routines; recognition and management of swallowing difficulties."

(Intercollegiate Stroke Working Party (ICSWP) 2012 pg 102).

Further guidance has also been provided by The Scottish Intercollegiate Guidelines Network (SIGN) for management of dysphagia in stroke. They recommend:

"Good oral hygiene should be maintained in patients with dysphagia, particularly in those with PEG (percutaneous endoscopic gastrostomy) or NG (nasogastric) tubes, in order to promote oral health and patient comfort."

(Scottish Intercollegiate Guidelines Network (SIGN) 2010 pg 5).

The evidence described in Brady et al. (2010) support guidelines A and C. Whereas guideline B was developed from consensus of opinion. The evidence to support the Intercollegiate Stroke Working Party guidelines is limited with only one systematic review examining oral care in stroke patients (Brady et al. 2010). The guidelines recommend the brushing of the teeth or dentures at least three times a day, which is different to the DH guidance (2009) that recommends, twice daily for healthy individuals. However, Fields (2008) provided oral care bundle three times a day. Although this study was not statistically powered and terminated early this is the only study available to the stroke clinicians at present.

Maintaining oral health is essential in all individuals, especially those individuals who are acutely unwell, those who are unable to maintain their own oral care, and those who are at risk of oral health problems due to other factors such as co-existing medical conditions and medication. Oral care is a complex care need that requires support from an organisational level, nursing level and patient care level. Nursing staff have also reported they received little or no support from the organisation regarding accessibility to equipment and education to support and enhance the care they provide (Talbot et al. 2005; Preston et al. 2000; Weeks and Fiske 1994). Suggesting oral care was not seen as a high priority by the organisation. Whist nurses view oral care as important (Wardh et al. 1997), in the hierarchy of nursing care it is given low priority (Royal College of Nursing (RCN) 2012; Wardh et al. 2000; Wardh et al. 1997). Patient factors can also affect oral care in a hospital environment. Patients may have difficulty cooperating with the nurse who are providing oral care because of cognitive problems or a reduced conscious level. For patients in hospital who are acutely unwell and unable to attend to their daily needs (e.g. washing, dressing, and oral care) it becomes the responsibility of the nursing team to assist or attend to these needs.

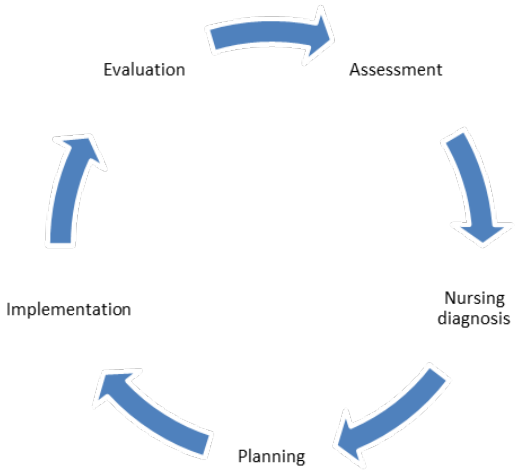
Much of the literature examining oral interventions has concentrated on reducing oral plaque, bacterial growth, which will ultimately reduce complications such as chest infections. Although the evidence remains limited regarding which intervention will provide the best outcome oral care still needs to be provided at least twice daily. This is to ensure normal homeostasis of the oral cavity is maintained, dental disease is prevented (DH 2009) and quality of life and well-being are impacted upon (Locker et al. 2002). The evidence available to nurses to guide the care that they provide also remains limited (Brady et al. 2010). As a nurse, providing evidence based nursing care that has an impact on patient wellbeing and outcome, is paramount. Oral care is a basic fundamental daily need for many patients and providing the opportunity and facilitating oral care for patients is important.

Henderson defines nursing as:

> *"Nursing is primarily helping people (sick or well) in the performance of those activities contributing to health or its recovery (or to peaceful death) that he would perform unaided if he had the necessary strength, will or knowledge"*
>
> (Henderson 2006 pp. 26)

Nursing therefore continues the functions that the person would normally perform themselves to maintain general health and well-being. Nursing care is underpinned by the

Nursing Process, a framework that aims to provide an organised, systematic approach to providing effective evidence-based care. The nursing process is cyclical, containing five stages: assessment, diagnosis, planning, implementation, and evaluation (Henderson 1960) (Figure 1-8).



(Henderson 1960)

Figure 1-8 Nursing process

Assessment, the first stage, gathers the information required to make a decision as to what the problem may be (diagnosis) or to identify risk (Ackley and Ladwig 2008). Several methods can be used to make an assessment: a simple checklist, an interview to obtain information (e.g. clinical history), a clinical examination, laboratory tests, and self-reporting questionnaires (de Vet et al. 2011). During an assessment more than one method may be used to gain the information required. The assessment of oral care is multifaceted and involves assessing:

- Risk factors for oral complications;
- Current clinical condition;
- Oral care needs;
    - Ability to attend to oral care;
    - Oral cleanliness and health;
- Equipment required.

Risk would be assessed by identifying those factors (medication, oxygen therapy, co-morbidities) that increase the likelihood of oral problems (dry mouth, reduced saliva flow).

Identification of the oral care needs of a patient is through reviewing the individual's current clinical condition, their ability to attend to their oral care and examination of the oral cavity.

Following a diagnosis of risk and oral care needs, the next phase is planning the appropriate care required with clear goal setting. This may involve prescribing the equipment required (e.g. toothbrush), frequency of care, degree of assistance required, treatment (e.g. toothpaste, saliva substitute), and finally the time at which evaluation will take place. Once the plan for oral care has been prescribed, the next phase would be implementation of the care. In the implementation phase the nurses would complete the care as prescribed. This may be cleaning the individual's teeth or dentures twice daily, providing moisture, or simply helping the individual to the bathroom so they can clean their own teeth. Following implementation of oral care, the nurse would complete the cycle by evaluating both the care prescribed and the oral cavity. Evaluation occurs at the time point specified in the planning stage and is specific to the care needs of an individual. Evaluation involves the nurse reviewing the whole process of oral care that was planned, and implemented. At the evaluation stage, the nurse decides whether the prescribed care is sufficient and whether to continue with the care plan that is in place. If the plan of care is deemed not to be sufficient then the cycle starts again and oral care is re-assessed, a diagnosis is made, care is planned, implemented and re-evaluated.

Evidence available to support each of these nursing phases is lacking. The researcher's interest in oral care developed because as a nurse they were unable to effectively assess and treat oral problems. Assessment, being the first stage is a crucial phase in the nursing process, however there is a lack of effective assessment tools and guidance to support oral care. Assessment needs to be specific, meaningful and structured (Wade 2002). A comprehensive assessment is crucial if nurses are to identify, plan and implement best oral care, which could prevent pathogenic bacterial growth, resulting in oral and systemic disease. Stroke patients are at risk of oral health problems, as discussed earlier in this chapter, and so assessing the oral cavity is an essential aspect of nursing care for this patient population. A lack of a standardised assessment led the researcher to investigate this process further and through a master programme an oral assessment was developed in medically ill patients (Dickinson et al. 2001). This was a small student study which had many limitations. The aim of the thesis is to explore the current literature, identifying if an oral assessment already exists that can be modified for use in stroke patients with a view to

developing a new oral assessment specific to stroke patient's needs. In order to address this aim several questions will need to be answered.

1) Is there an oral assessment that has been developed for use in stroke patients?
2) If an oral assessment does not exist that is specific to stroke, can an oral assessment that has been developed for use in dependent patients be modified for use in stroke patients?
3) If an oral assessment does not exist that can be modified and a new oral assessment is required for stroke patients, what items should be considered for inclusion in this oral assessment?
4) Is the newly developed oral assessment valid and reliable in a stroke population?

In order to answer these questions a review of the current literature will be performed to identify if any oral assessments have previously been developed for use in a stroke or dependent population. If any assessments are identified, they will be critically evaluated for their content, methodological quality, and applicability to a stroke population. Should no suitable assessment be identified then a new measure will need to be developed. The new assessment will be developed from the literature identified in the review and through seeking the views and experiences of those who are deemed "experts" in the field (Rycroft-Malone 2004). In terms of oral care these are: clinical and academic experts in oral health and stroke; health professionals; patients; and carers.

1.5 Structure of the thesis

Chapter One has presented an overview of oral health, including the intrinsic and extrinsic factors that are important in maintaining oral health. The chapter then described the importance of oral care and the factors that need to be considered if oral health is to be achieved. The chapter then considered oral hygiene, specifically exploring the importance of oral hygiene in a stroke population, and the nursing process with regards to oral care.

Chapter Two will outline what an assessment is, and the steps that need to be considered when developing an assessment. This chapter will provide definitions of the terminology and methodology used throughout the thesis.

Chapter Three will describe an integrative review of the existing literature examining the development of oral assessments in dependent populations. The review will examine the measurement properties of the assessments and whether they are suitable to be used in a

stroke population. The chapter concludes with a summary of the findings and how these findings will inform the development of an oral assessment for use in a hospitalised stroke population.

Chapter Four will present the methods of a qualitative study exploring the views and experiences of oral care in clinical and academic experts in oral health and stroke, health professionals', patients', and carers'.

Chapter Five will present the results from the interviews described in Chapter Four. The results are presented for each group, providing a small pen portrait of each participant which will be followed by a summary of the main findings from that group. The chapter concludes with an overall summary of the results, relating them to the current literature and how they can be used in the development of an oral assessment for stroke patients.

Chapter Six provides an overview of the methodology used to develop an oral assessment. The chapter progresses through the different steps required when developing an assessment from construct development through to pilot testing. The final oral assessment is presented and discussed in relation to the existing oral assessments identified in Chapter Three.

Chapter Seven will present a study that examines the validity and reliability of an oral assessment when used by three nurses. The findings from this study are described and discussed in relation to the stroke population, and the current literature.

Chapter Eight is the concluding chapter for the thesis. This chapter brings together all the information gathered from the three studies and discusses them in the context of clinical care and the current literature. The chapter discusses the overall limitations to the research described within this thesis and makes suggestions for taking the research forward.

1.6 Summary

This chapter has laid the foundation for the thesis, outlining the importance of oral hygiene and oral health, specifically in a hospitalised stroke population. Chapter Two will provide further background to assessment and its role in the oral care process, as well providing the reader with background information to oral assessment development and testing.

Chapter Two

Defining the methodology and terminology

2.1 Introduction

Chapter One has laid out why oral care is important, focusing on the needs of an acutely ill, dependent population. Assessment was identified as an important stage in identifying problems and guiding care provision. The assessment process involves the gathering of information to inform the next step in the care process (Wade 2002).

> *"Assessment is an analytical process that depends upon and includes obtaining information."*
>
> (Wade 2002 pp. 348)

In the clinical setting, assessments are used routinely to aid in the identification and classification of particular problems (de Vet et al. 2011). Different methods of data collection can be used to gather this information such as simple observations, physical examination, laboratory or clinical tests, and history taking through face to face interviews (de Vet et al. 2011). In order to provide consistency some information may be collected and documented using specifics such as questionnaires, a clinical measure/assessment, or formatted questioning. Having a clear idea of what data are required and how it will be used is therefore important (Wade 2004).

Many members of health care staff come into contact with patients when accessing and/or collecting data. Through using validated assessments, data are collected and recorded in a systematic way, making it accessible to all members of staff caring for that patient (Wade 2004). These tools need to be competent in their purpose, provide a level of certainty, be able to detect change or difference, be practical, and any data that are collected need to be understood by others (Wade 2004). Such tools should therefore be developed in a systematic way to ensure uniformity and methodological rigor.

This chapter will therefore describe the aspects to be considered when developing an assessment, providing definitions for the different terms and methods that will be used throughout the thesis. The chapter will look specifically at the development process and the psychometric testing of an assessment, exploring the different methodologies and properties required. This chapter will take a general view of the development of an assessment, with Chapter Six describing how the methods and principles have been used when developing an oral assessment for stroke patients. Throughout the literature different terms such as measurement, instrument, and assessments are used to describe the measure used to collect the data. This can be confusing, so the term assessment will be used throughout the thesis when referring to oral measures.

2.2 Assessment properties

Although assessments are developed in many different areas, for different populations and disciplines, the need for methodological accuracy remains the same. Before a researcher can examine the methodological quality of assessments, they need to have an understanding of the development process and what the assessment aims to measure. de Vet et al. (2011) have recommended six steps to guide the development and statistical testing of an assessment (Figure 2-1). Before commencing the development of a new assessment a pre-development stage is recommended: a review of the literature. This is to identify if any existing assessment could be adapted for the population of choice (de Vet et al. 2011). This pre-developmental stage will be described in Chapter Three. The remainder of this chapter will explore the six steps set out by de Vet et al. (2011).

Step 1	Definition and elaboration of the construct intended to be measured
Step 2	Choice of measurement method
Step 3	Selecting and formulation of items
Step 4	Scoring issues
Step 5	Pilot-testing
Step 6	Field-testing

(de Vet et al. 2001 pp. 31)

Figure 2-1 Six steps in the development of an assessment of a measurement instrument

2.3 Step 1: Definition and elaboration of the construct intended to be measured

The first step in developing an assessment, involves identifying what it is you want the assessment to measure (construct), in whom, and for what purpose. In order to answer these questions, the researcher needs to be specific about the construct they want to measure, as this will guide the content and layout of the assessment. A construct is defined as:

> *"A well-defined and precisely demarcated subject of measurement."*
>
> (de Vet et al. 2011 pp. 8)

Consideration also needs to be given to: who will be carrying out the assessment (clinician or patient) because this may impact on the format of the assessment; whether the assessment is objective or subjective in nature. If an assessment is objective, it does not involve any personal judgement by either the assessor or the patient. A subjective assessment however can potentially be influenced by the assessor and/or the patient. Although many assessments are considered to be objective, some subjectivity is often present when interpretation is required by the person at some point during the assessment (Guyatt et al. 1992). If it is known that subjectivity is part of an assessment, it is important to try to reduce this subjectivity as this alters the accuracy of the assessment (measurement error). For example, in the case of clinical examinations, subjectivity may be reduced through specific training or providing clear written guidance for all assessors. In some assessments subjectivity is reduced through statistically testing the properties of the assessment. This can be a continuous process where the assessment is revised and retested until agreement is sufficient and the subjectivity has been reduced enough that it is not affecting the outcome (de Vet et al. 2011).

Other issues such as age, gender and severity of disease also need to be considered, as they may affect the content and layout of an assessment. For instance, young children or older adults with cognitive difficulty may not be able to answer questions or write their responses. In these instances, visual scales may need to be used. Severity of disease may also change the symptoms that patients report. These aspects therefore need to be considered if the assessment is to inform the identification of a problem.

2.4 Step 2: Choice of measurement method

Once the construct to be measured has been identified, the developer then needs to decide how they are going measure it. To measure what someone can do, may be through asking them to do the task or testing their ability. If you wish to seek people's views or opinions, interviews or questionnaires may be used. Once the method for gathering the specific information has been identified, the next step is to decide if the construct can be measured using a single-item measure (one question) or a multi-item measure (multiple questions). Again it is important to think about what it is you want to measure, for some constructs, a single-item measure does not provide sufficient information and a multi-item measure is required (Sloan et al. 2002). Single-item measure may be considered when the construct is not the main focus of the study but the information is required to provide global information, for instance weight, or height (Sloan et al. 2002). A multi-item measure may be more useful if the construct under investigation is complex, for example: functional ability; or depression where there is more than one reason or answer; or the assessment is seeking the person's opinions or views (de Vet et al. 2011; Sloan et al. 2002).

Multi-item assessments should be underpinned by a conceptual framework that will define the development and testing of the assessment in the future. A conceptual framework describes the relationship between the items in the assessment. This relationship can be either reflective or formative (Edwards and Bagozzi 2000). In a reflective model, there is a relationship between a construct (something that does not physically exist) and each item, so the items make up the construct. An example of this may be the construct of anxiety which has several items such as worrying thoughts, panic and restlessness. If a person is anxious, then this impacts on all of the items, increasing worrying thoughts, panic and restlessness (de Vet et al. 2011. p14). In a formative model, the items are independent and contribute to a construct. An example of this may be the construct of life stresses with items such as job loss, death in the family and divorce. In this case, divorce will increase life stresses but does not affect job loss or death in the family (de Vet et al. 2011. p14).

2.5 Step 3: Selecting and formulation of items

Items are often selected following a review of the literature and from experts' knowledge in the field (de Vet et al. 2011; Streiner and Norman 2008). Examining the existing literature helps to

identify what items have been used in similar assessments, and whether these items can be used with adaptions to meet the requirements of the new assessment (Fayers et al. 1997).

An expert is defined as:

> *"A person with extensive skill or knowledge in a particular field."*
>
> (Oxford University Press 1989).

Expert knowledge in the field can be obtained either from clinicians in the area of interest or from the target population at which the assessment is directed. Clinicians are able to provide clinical information and knowledge at a high level regarding symptoms, characteristics of the construct being measured, and a clinical understanding of the consequences of the disease or construct (de Vet et al. 2011; Streiner and Norman 2008). The target population are key informants who provide information regarding symptoms and experiences, and an explanation as to why they are important to them (de Vet et al. 2011; Streiner and Norman 2008). Interviews and focus groups are often the methods used to gather this information from the "experts" in the field. Once the information has been obtained from the literature and key informants, items can then be deliberated for inclusion in the new assessment. The new items need to be comprehensible, specific and not have multiple meanings such as "fair" (can mean good or not bad). Negative wording should also be avoided.

2.6 Step 4: Scoring issues

Once the items have been identified, a scoring system needs to be established that quantifies the information required. Four different types of scoring systems can be used and are reflected in the different types of data: nominal; ordinal; interval; and ratio.

- Nominal data often have two categories: yes/no or present/not present. In nominal data there is no hierarchy or order between the scores and if only two scores exist, these are known as dichotomous data. However, more than two categories are possible, for example eye colour (blue, brown, green).
- Ordinal data can have several categories, and there is an order to the scores (mild, moderate, severe). Scores can move in order from lowest to highest, or normal to severe, although the distance between each score is unknown. For example, if we know that a

score of 1 represents normal, and a score of 4 represents severe disease, we know that a person with a score of 1 has less severe disease than a person with a score of 4. However, the person scoring 4 is not 4 times as bad as someone scoring 1. Ordinal scores therefore measure severity, but do not make any distinction about the distance between 1 and 4.

Nominal and ordinal data use classification and they are known as categorical data.

- Interval data normally involve numbers that quantify the result, such as blood pressure, temperature, or blood result. With interval data, the distance between each score is known because the numbers are along a continuum. For example, we know the distance between a temperature of 37 and 37.5 and that 37.5 is midpoint between 37 and 38.
- Ratio data are similar to interval data, except in this case there is a true zero point of which the data continuum starts (age or organ size). Ratio data therefore defines the distance between two scores, for example someone scoring 10 is considered twice as bad as someone scoring 5.

Interval and ratio data are known as continuous data.

2.7 Step 5: Pilot-testing

In step five, the first draft of the assessment is piloted in a small number of patients (30-50) to test its clarity, relevance, feasibility and acceptance (de Vet et al. 2011). The assessment not only has to be acceptable to the user but also to those who are being assessed.

Feasibility

The pilot phase should also examine the feasibility of the assessment. For instance, if the assessment takes 20 minutes to complete, this may not be feasible to the nurse or doctor as they do not have the time to perform such an assessment. For the assessment to be meaningful, the user needs to understand how to use it and how to interpret the results. Both the user and patient also need to understand any questions that are being asked. After piloting the assessment, adaptations are made. The whole process of piloting and adapting can be repeated a number of times to ensure comprehensibility, acceptability and feasibility before formally pilot testing the assessment in the population of choice (de Vet et al. 2011; Streiner and Norman 2008).

2.8 Step 6: Field-testing

de Vet et al. (2011) describes pilot testing as gaining insight into the structure of the data and item reduction in those measures that are multi-dimensional. It is at this stage that items are taken away if they do not add anything to the assessment. This phase is only relevant in measures that are multi-dimensional and where the items are not observable. Measures that are single-item or that measure observable constructs would miss this stage and progress to the testing of the assessment's psychometric properties.

2.9 Psychometric tests

For any assessment to be useful clinically, it needs to be reliable and valid. Psychometric testing is the term used to describe whether the assessment is measuring what it should be measuring (validity), and that multiple raters achieve the same result when using the assessment independent of each other but at the same time (reliability) (Streiner and Norman 2008).

Validity

Validity is concerned with examining the scores to identify if they are measuring what they say they are measuring. There are three main types of validity that can be measured: content, criterion, and construct validity.

Content validity

Content validity is the extent to which the assessment adequately measures the construct under investigation (de Vet et al. 2011). The first aspect of content validity is face validity, which is assessing the overall view of the assessment, and has been defined as:

> *"The degree to which (the item of) an instrument, indeed looks as though it is an adequate reflection of the construct to be measured."*
>
> (Mokkink et al. 2010a pp.743)

There is no standardised method of measuring face validity. Face validity is assessed through asking "experts" in the field to assess, on first impressions, if they feel the assessment reflects the construct under investigation (Mokkink et al. 2010a).

The second aspect of content validity is to assess the content of the assessment and ascertain whether the assessment represents the construct under study, and if each item measures what it purports to measure. Again, this is not measured through statistical testing but relies on judgement of experts who will be using the assessment (Mokkink et al. 2010a). The experts are provided with a clear outline of the construct to be measured and asked if, in their opinion, all the items are relevant and comprehensive, refer to specific aspects and fully assess the construct (de Vet et al. 2011).

Criterion validity

Criterion validity measures the scores of the new assessment against the best existing assessment known as a reference standard. The reference standard is an assessment that is deemed to provide the best measure (accurate measure) for the item (Streiner and Norman 2008). Often, if a reference standard exists, then there is no requirement for another assessment. However, depending on time to administer, experience, resources available and the population, a new assessment may need to be developed (Streiner and Norman 2008).

Criterion validity is divided into two areas: concurrent and predictive. Concurrent validity compares the new assessment against the reference standard in the chosen population. Predictive validity is calculated when the reference standard (criterion) is not known yet. For example, students' admission test results to college are used to predict their final results in the future, and would be the reference standard (de Vet et al. 2011; Streiner and Norman 2008). Concurrent validity is therefore tested in those assessments that evaluate or diagnose a problem and predictive validity is tested in those assessments that predict outcome (de Vet et al. 2011; Streiner and Norman 2008).

Construct validity

Construct validity is used when no reference standard is available and has been defined as:

> "The degree to which the scores of a measurement instrument are consistent with the hypothesis, e.g. with regards to internal relationships, relationships with scores of other instruments or differences between relevant groups."
>
> (Mokkink et al. 2010a pg 743)

As there is no reference standard to compare the new assessment with, construct validity examines the relationship between each item and tests to see if the scores are those you would expect using existing knowledge. Factor analysis is the statistical method used to determine how many items strongly relate to one another, and identifying those items that do not contribute to the assessment and can be discarded (de Vet et al. 2011).

Sample size for validity

The sample size for validity needs to be adequate enough to provide sufficient data for each item. For validation studies examining criterion or construct validity a sample size of 50 is recommended, but over 100 is preferred if correlations are to be calculated (de Vet et al. 2011). Validation studies with dichotomous scores require a larger sample to ensure there is an adequate number of scores in both categories.

Analysis for Validity

Diagnostic accuracy is one method of assessing validity using sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) (Parikh et al. 2008). This allows the researcher to explore the value of using the assessment in diagnosing presence or absence of a disease/problem. No indicator of diagnostic accuracy would be perfect, so by considering the intended use of the measure and the implications of the assessment over or under diagnosing a problem that gives a suggestion as to usefulness of the assessment in clinical practice.

Sensitivity and specificity

Sensitivity is the proportion of true cases (those with the problem) that are correctly diagnosed by the test, for example if the test was assessing plaque on teeth, sensitivity would be the number of true cases the test diagnoses as positive.

Specificity is the proportion of true non-cases (those without a problem) that are correctly identified by the test. Using the example of plaque on teeth, specificity would be the number of true non-cases the test diagnoses correctly. Sensitivity and specificity are not affected by the prevalence of the problem.

Positive and negative predictive value

Positive predictive value is the likelihood that if the test is positive the patient actually has the problem. That is, the number of cases that test positive are actually positive (have the problem). The remaining cases that test positive are known as false positive because they are diagnosed as having the problem but actually are negative.

Negative predictive value is the likelihood that if the test is negative they don't have the problem. Again this is the number of cases that test negative who actually are negative. Therefore, those cases that have the problem and are diagnosed as negative are false negatives.

The overall accuracy of the test is efficiency. These tests allow the researcher to see how many true positives and true negatives the new assessment is identifying and so testing whether the new assessment is as accurate as the reference standard.

Reliability

Reliability is defined as:

> *"The degree to which the assessment is free from measurement error."*
>
> (Mokkink et al. 2010a pg 743).

Reliability is concerned with reducing the amount of error between raters and therefore reducing the subjectivity and bias that makes the assessment less accurate. When an assessment is being used as a diagnostic or as an outcome measure the clinicians/researchers want to know that the assessment is accurate and can be used by multiple users. This is agreement between raters (inter-rater reliability). The reviewer also want to know that each individual rater is consistent within themselves and can repeat the assessment coming up with the same outcome, this is agreement within rater (intra-rater reliability). Assessing the stability of the assessment is also important and this is through test-retest to ensure the construct has not changed between assessments (Mokkink et al. 2010a; Streiner and Norman 2008). When reviewing reliability, the degree of agreement between raters needs to be considered alongside the intended use and outcome of the assessment because the degree of agreement may never be perfect due to assessment and rater subjectivity.

Sample size for reliability

Guidance with regards to sample size required for reliability studies is limited, however a sample size of ≥60 is recommended (de Vet et al. 2011).

Analysis for reliability

Agreement between raters can be partly due to chance and so to adjust for this and ensure chance is taken into consideration statistical testing is applied. If the data collected are categorical, reliability would be tested using the Cohen's Kappa statistic (K) (Cohen 1960). If the data are continuous, Intra-class Correlation Coefficients (ICC) would be used (Shrout and Fleiss 1979).

The Kappa statistic is one method of examining agreement between raters using a nominal or ordinal scale. Agreement has traditionally been calculated using percentage agreement. That is the percentage cases that are correct. However, this does not distinguish between actual agreement and agreement by chance (Brennan and Silman 1992). The Kappa statistic aims to identify total agreement, correcting for agreement by chance. The kappa statistic compares the observed amount of agreement against the expected amount of agreement (agreement by chance). In a scale where there are two possible options available and two raters, chance agreement is 50% of the ratings.

The kappa values can range between -1 and 1, where 0 is the expected agreement by chance and the value of 1 is when total agreement is achieved. The closer the value is to 1 the better the agreement. In order to make sense of the Kappa values and provide some guidance as to their relevance and interpretation a classification system was devised by Landis and Koch (Landis and Koch 1977). This classification system can be used when examining the results of agreement between and within raters (Table 2-1).

The Kappa statistic was originally developed for 2x2 tables, where agreement was between two observers measuring a positive or negative score. The Kappa has been developed further to consider scales that have more than two categories. In these scales the risk of error and disagreement increases as the number of categories increase. To overcome this issue a weighted Kappa statistic (Kw) is used (Brennan and Silman 1992). The weight can be between 0 and 1 and the researcher has to decide the seriousness of the disagreement between the categories. For example with categories of normal, mild and severe, agreement between normal and mild may be

seen as partial agreement and agreement between normal and serious seen as total disagreement. A weight of 0.25 may then be placed on those cells that show partial agreement and a weight of one placed on those cells where total agreement is found.

Table 2-1 Classification of Cohen's Kappa values

0.81 -1	Very good
0.61-0.80	Good
0.41-0.60	Moderate
0.21-0.40	Fair
<0.20	Poor

(Landis and Koch 1977)

Measurement error

Measurement error can occur for many reasons: variations in the assessment itself, the person performing the assessment may influence those being assessed, the person undergoing the assessment may change their performance, or the circumstances in which the assessment is given may change (de Vet et al. 2011). All of these issues relate to the reliability of the assessment and measurement error is assessed through testing agreement between and within raters.

Internal consistency

Internal consistency is tested in multi-item assessments that have used a reflective conceptual model that there is a relationship between each item with one affecting the other. Internal consistency examines the relationship between all the items to identify those items that are similar in nature and therefore do not contribute anything new to the total score. These items become redundant and can be removed as they do not add to the reliability of the measure (Streiner and Norman 2008).

Responsiveness

Responsiveness is the ability of the measure to identify change over time (Mokkink et al. 2010a). In medicine detecting change in the disease or health status of patients is important and having measures that are able to assess this change is essential. Responsiveness is viewed as one aspect of validity (de Vet et al. 2011). The responsiveness of an assessment would be tested when it is expected that in some subjects the construct being measured would improve or deteriorate over time. If this was the case measures would also be taken at different time points to detect any change and therefore measure the responsiveness of the assessment. Responsiveness is often tested in longitudinal studies.

Interpretability

Interpretability is the understanding of the scores or change scores and what they mean (de Vet et al. 2011). When examining interpretability the distribution of the scores also needs to be considered because it shows how well the scores have been distributed over the whole score range. This is important because a lack of variability may cause artificially low or high reliability assessment values. Variability of scores is also important if the assessment is designed to detect change. Some assessments have too few items at the lower or higher end of the scale to detect change and these are known as floor and ceiling effects. Interpretability is used to detect if an assessment has a floor or ceiling effect, which clinicians and researchers would need to consider when selecting an appropriate assessment to use. Finally, through examining the scores or change score of different sub groups within the study population the researcher can attempt to define what is normal and what is abnormal, providing meaning to the scores.

2.10 Summary

This chapter has outlined the importance of assessment, what issues need to be considered when developing an assessment and some of the statistical tests necessary to examine the assessment properties. Certain terms and methodologies have been explained that will be used throughout the thesis, allowing the reader to refer back to them when required. The next chapter will describe the first of three studies and will examine the literature identifying existing oral assessments, developed in a dependent or stroke population.

Chapter Three

An Integrative literature review of oral assessments developed for use in a dependent population

3.1 Introduction

Chapter Two has provided definitions for terms and methodologies that will be used throughout the thesis. This chapter will attempt to answer the first question of identifying if an oral assessment has been developed for use in stroke patients and contribute to answering the second question that if an oral assessment does not exist can another oral assessment developed for a dependent population be modified for use in a stroke population. This will be through an integrative literature review.

The oral care process in hospitalised patients is complex, with many contributing factors such as physical function, diet, medication and pre-existing co-morbidities needing to be considered. The intervention studies, described in Chapter One examined the reduction in bacteria growth and medical complications using outcome measures that are dependent on specific laboratory tests and examination techniques that may not be accessible in every day practice. Whilst these outcomes are important in identifying if interventions have an effect they are not usable in a clinical setting. Within the clinical setting an assessment is required that can be used by the bedside and can inform decisions about care and potentially reduce the risk of oral and systemic complications. Nursing care uses such assessment and observation to inform their decision making regarding diagnosis and treatment prescribed (Ackley and Ladwig 2008). This is a bedside assessment and does not require specific tests that measure bacterial or plaque scores. Having a meaningful assessment that can inform oral care is imperative if effective evidence-based care is to be prescribed and administered. An assessment also provides standardised documented evidence that is available to the whole team (Wade 2002). At present it is not clear if any such assessment exists that can be used in a stroke population. The aim of this chapter is to review the current literature for existing oral assessments that could be used in a stroke population in a

hospitalised setting. Those assessments identified will be reviewed for the quality of the assessment's content and layout, scoring system, and measurement properties as well as quality assessment of the study. Once the review has been completed a decision will be made as to whether there is an oral assessment already developed that can be used in a stroke population. If no oral assessment exists then the information gathered will be used to inform the development of a new oral assessment for use in stroke patients.

3.2 Integrative review

Prior to considering the development of a new oral assessment a review of the existing literature is essential. The review allows the researcher to: examine the properties of existing oral assessments that measure the construct in question, examine the content of existing oral assessments, and to identify that no oral assessment exists that can be converted for use in the population of choice (de Vet et al. 2011). Different types of review are available to the researcher (narrative, qualitative, systematic and meta-analysis, and integrative) and each have their own advantages and disadvantages.

Narrative reviews are when an expert writes about a specific disease, condition or treatment. A narrative review is a compilation of different evidence to support the statements that the author is writing. Narrative reviews therefore make it harder for the reader to decipher if the recommendations are based on the authors clinical experience or the literature (Garg et al. 2008).

Qualitative reviews have only recently been developed in the last decade (Whittemore 2005; Adams 1999). The aim of qualitative reviews is to syntheses the information gathered in the qualitative studies reporting on a specific topic to ultimately broaden the understanding and generalizability of the topic. This is often a complex process and due to the nature of qualitative studies it can be difficult to syntheses the information. This type of review is still developing with regards to its methodology and scientific rigor and the demand for information regarding one phenomena is growing (Booth 2001).

Systematic reviews are a review of effectiveness and use a process to identify primary research studies that have examined a specific question. Traditionally the systematic review has been seen as the gold standard, the review of choice as the risk of bias is reduced due to the strict criteria in which the review is performed. Typically in a systematic review one specific question is being

answered through examining one particular methodology. Within a systematic review a protocol is set out so the reader can follow the explicit decisions of the reviewers and make informed decisions about the quality and potential biases of the review. The methods are appraised and results reviewed with key findings being presented. The strength of this type of review is the collation of the key findings from all the primary studies allowing the reader to review the current evidence to inform their clinical practice. Systematic reviews are also seen as being robust often informing policy and clinical guidelines (Kirkevold 1997). The transparency of the process also allows the readers to clearly see what biases are present.

Within certain reviews meta-analysis of the results allows all the data from all the studies to be combined and re analysed to identify benefit or harm. For meta-analysis to take place the studies need to have similar if not the same research design and hypothesis. Through pooling the results of studies that have shown no significant difference and those that have shown a significant difference, efficacy can be shown. An example of this is a Cochrane review examining if stroke units save lives (Trialists Collaboration 2007). Before this review the evidence to support the effectiveness of stroke units was unclear. By pooling all the primary studies and performing meta-analysis the review identified that if patients were cared for in an organised stroke unit they had more favourable outcomes at one year post stroke. Disadvantages to systematic reviews are the original biases in the design and recruitment cannot be removed and they remain the same. There is also the risk that by pooling rigorous studies with those studies whose design was not favourable may weaken the efficacy of the treatment (Garg et al. 2008).

The reader also needs to be mindful that just because a review has systematic in the title it does not mean that the review was performed and reported with due rigor. Due to the nature of systematic reviews they only include those studies that have followed a specific methodology to answer one specific question therefore the information they provide relates to that question and does not always answer more complex questions (Petticrew 2015; Kirkevold 1997). This type of review is effective if helping clinicians quickly identify the most effective interventions available and inform national guidelines and policies regarding best care (Booth 2001). However, systematic reviews are limited at present in how they can answer complex questions relating to care. Within the care setting many questions remain unanswered because the simple focused question of a systematic review only answers one aspect of that care and more complex questions need to be asked (Petticrew 2015). This requires examining information from broader

methodologies, exploring more about what has happened previously, and how the effects came about (Petticrew 2015).

One such review that can explore a more complex question is an integrative review which provides a summary of the past evidence regardless of study design to provide maximum knowledge about the phenomenon or problem under investigation (Broome 2000). This type of review is a more comprehensive review that allows the inclusion of experimental and non-experimental studies. Within nursing there is a view that integrative reviews can build the evidence base to improve nursing practice and clinical care (Kirkevold 1997). Integrative reviews have only started to appear in nursing research in the last decade, this is partly due to an increase in nursing research activity and an increase in the recognition that an accumulation of knowledge is essential for developing nursing research (Kirkevold 1997). Nursing is a diverse discipline and in an attempt to improve nursing knowledge and science there has been a greater move towards integrative review because of its inclusiveness of diverse methodologies. This may include randomised controlled trials, surveys, and reports, to capture the full context, process and subjectivity of the phenomenon under study. This is not an attempt to disregard other types of reviews but to embrace them all to enhance nursing science (Whittemore and Knafl 2005). In the past, reviews in nursing have not always followed specific frameworks or structure, opening themselves to criticism from the empirical and theoretical researchers (Whittemore and Knafl 2005). The development of the integrative review therefore allowed nursing to examine the whole of the literature relating to the phenomenon of interest using a systematic process to ensure bias is minimised and rigor maintained. With any review it is important the review is able to answer the questions. Different types of integrative reviews can take place: resume, critical, synopsis and synthesis.

In order to answer the research question of identifying if an oral assessments exist that can be applied in an acute stroke population, a synthesis review was chosen. This type of review synthesises isolated pieces of information from different studies to create a better understanding of the topic of choice. The disadvantages to an integrative review is the potential for bias and reduced rigor because of the complexity and challenges relating to the resources, expertise, transparency and interpretation of the data when combining data from multiple methodologies (Evans 2007; Whittemore 2005; Beck 1999). In order to reduce this risk of bias a systematic process has been developed which has five stages, problem identification, literature search, data evaluation, data analysis and presentation (Whittemore and Knafl 2005).

Currently the evidence available for oral care in stroke is limited (Brady et al. 2010). This systematic review carried out by Brady et al (2010) asked a specific question comparing the effectiveness of staff led interventions with usual care for ensuring oral hygiene in individuals after stroke. Through using this approach the question was narrow and only included randomised controlled trials that evaluated one or more interventions aimed to improve oral health. This review identified a lack of randomised control trials evaluating oral intervention in stroke. Within this review oral assessment was identified as an oral intervention however no randomised controlled trials examining oral assessments were identified. With little evidence available from the systematic review and to ensure duplication did not occur (Petticrew 2015) an initial review of the current literature was undertaken to explore what oral assessment were available. This identified a range of different studies that had developed oral assessments using different methodology, however, due to the different methodologies and research designs used these would not have been captured in the systematic review. In order to search the literature for all potential studies that have developed an oral assessment in stroke or dependent patients and to answer a more complex question, an integrative review was chosen so as to allow the inclusion of diverse methodologies, capturing as much of the current knowledge and evidence regarding the content of oral assessments and their properties.

3.3 Aim

The review will:

- Identify those papers that describe the development and/or validation of oral assessment for use in those who require assistance with their oral care, either in stroke or dependent patients in hospital/institutionalised care;
- Identify items within the assessments that reflect oral health and cleanliness;
- Examine the measurement properties of the oral assessments;
- Examine the quality of the studies in which the oral assessment was developed.

3.4 Methods

Inclusion criteria

Papers were included if they developed an oral assessment and all four inclusion criteria were met:

- A stroke population or dependent population (was defined as patients who required assistance to perform oral care. This could be from preparing equipment through to providing total oral care);
- Hospitalised or institutionalised setting;
- Papers where oral health and cleanliness was assessed;
- Papers written in English and published in a peer reviewed journal.

Exclusion criteria

Papers were excluded if any of these criteria were met:

- Sample was aged under 18;
- Paper did not fully describe the content and layout of the oral assessment;
- Paper was developed specifically for cancer patients.

Non-English papers and papers where an English version was not available were excluded due to limited financial resources to access an interpreter.

Search Strategy

A well-defined search strategy is essential to maintain rigour, reduce bias and ensure an accurate result is reached (Cooper 1998). A search strategy was developed from reviewing search terms already identified in a previous systematic review for stroke (Brady et al. 2010) and from Medical Subject Heading (MeSh) identified from an initial search. Multiple search strategies were used for different databases to evaluate the quality of the primary sources. The search strategy was originally developed to search Ovid from 1946 to December 2013 (Appendix 1), and adapted for

use in CINAHL (1946-December 2013) (Appendix 2), and Cochrane (1946–December 2013) databases.

Identification of papers to include in the review took place in two stages. Stage one screened the title and abstract of the papers using a piloted data extraction sheet (Appendix 3). In order to maintain validation and reduce bias a second reviewer should be used (Broome 2000). However, due to limited resources the second reviewer's time was limited therefore a random sample of 200 (15.5%) papers were reviewed by both reviewers in stage one. This process of validation is essential to increase the rigor of the literature review, reducing reviewer bias and ensuring all potential papers are selected (Broome 2000). The title and abstract of the randomly selected papers were reviewed by both reviewers to ascertain if the inclusion criteria were met. On completion both reviewers conferred over the results. Both reviewers discussed those papers where disagreement arose until a decision was made as to whether the paper should be included. Those papers where agreement was made and where the inclusion criteria were met were selected for inclusion in stage two. Papers with insufficient information to ascertain inclusion or exclusion were also selected for review in stage two. The remaining 1091 papers were then reviewed by the researcher and where there was any concern or the researcher was not clear if they should include the paper the title and abstract was sent to the second reviewer who then reviewed the information. Both the researcher and the reviewer then met to discuss the outcome.

In stage two the papers that had been identified for inclusion from stage one were retrieved and read in full. Again for validation purposes a second reviewer assessed a random sample of papers independent of the researcher and both reviewers discussed their results. Those papers that did not meet the inclusion criteria or who met the exclusion criteria were discarded.

Data extraction

Data relating to the population and sampling, content and layout, scoring and the measurement properties of the assessments were collected. The literature review aimed to assess the diagnostic accuracy of the assessments identified in the literature and to assess the quality of the study in which it was developed. Several different tools exist that allow researchers to measure the quality of the studies such as: Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) (Moher et al. 2009); Critical Appraisal Skills Programme (CASP) diagnostic check list

(Critical Appraisal Skills Programme (CASP) 2014); the Standards for Reporting of Diagnostic Accuracy (STARD) (Bossuyt et al. 2003); the QUality assessment of Diagnostic Accuracy Studies (QUDAS-2) (Whiting et al. 2011); and the COnsensus based Standards for the selection of health Measurement INstruments (COSMIN) (Mokkink et al. 2010a). All these tools were reviewed by the researcher to assess their appropriateness in assessing the diagnostic qualities of the oral assessment identified in the review and the quality of the studies included. Assessing both the measurement properties of the assessment and the quality of the study is important to quantify bias and limitations of the review.

In order to answer the first question of identifying the quality of the measurement properties of the assessment the COSMIN was chosen because this assessment allowed the reviewer to calculate an overall methodological quality score for each measurement property (Terwee et al. 2012). Whereas, PRISMA, CASP, STARD and QUADAS-2 focus more on assessing the quality of the reporting of the studies included. These tools would therefore be considered to answer the second question of assessing the quality of the studies included in the review.

Diagnostic accuracy of the measurement properties

The COnsensus based Standards for the selection of health Measurement INstruments (COSMIN) was carried out to provide some standardisation of reporting an assessment's measurement properties (Mokkink et al. 2010a). COSMIN produced a checklist that allows the researcher/clinician to examine the methodological quality of instruments measuring differing aspects of health (Mokkink et al. 2010b). The checklist has several sections that examine:

- content validity;
- criterion validity ;
- reliability;
- measurement error;
- internal consistency;
- responsiveness;
- interpretability;

The checklist was initially developed for use in Health-Related Patient-Reported Outcomes (HR-PRO); and aimed to provide a consensus around which measurement properties were considered

important, which terms and definitions should be used and how the measurement should be assessed (study design, statistical methods) (de Vet et al. 2011). The COSMIN checklist also grades the quality of the measurement properties as excellent, good, fair and poor. In each section of the checklist there are several questions with a grade. To help guide the reviewer each possible grade has a descriptor, which the reviewer then chooses for each question. Within in that section the reviewer will then have several grades. In order to say if that section is excellent, good, fair or poor the lowest grade allocated for any one question is chosen, as shown in Table 3-1 (Terwee et al. 2012). In the example in Table 3-1 the grades allocated for each question is highlighted in yellow and because question 6 has the lowest grade of poor this is the overall grade given to the section of reliability (Terwee et al. 2012). This grading allows clinicians and researchers to quickly identify the methodological quality of the assessment, highlighting those studies where the methods used were not rigorous as well as identifying the quality of the assessment measurement properties (Terwee et al. 2012).

Table 3-1Example of COSMIN checklist grading

Box B. Reliability: relative measures (including test-retest reliability, inter-rater reliability and intra-rater reliability)					
		excellent	**good**	**fair**	**poor**
Design requirements					
1	Was the percentage of missing items given?	Percentage of missing items described	Percentage of missing items NOT described		
2	Was there a description of how missing items were handled?	Described how missing items were handled	Not described but it can be deduced how missing items were handled	Not clear how missing items were handled	
3	Was the sample size included in the analysis adequate?	Adequate sample size (≥100)	Good sample size (50-99)	Moderate sample size (30-49)	Small sample size (<30)
4	Were at least two measurements available?	At least two measurements			Only one measurement
5	Were the administrations independent?	Independent measurements	Assumable that the measurements were independent	Doubtful whether the measurements were independent	measurements NOT independent
6	Was the time interval stated?	Time interval stated		Time interval NOT stated	
7	Were patients stable in the interim period on the construct to be measured?	Patients were stable (evidence provided)	Assumable that patients were stable	Unclear if patients were stable	Patients were NOT stable
8	Was the time interval appropriate?	Time interval appropriate		Doubtful whether time interval was appropriate	Time interval NOT appropriate

Although the COSMIN checklist was originally developed for patient-report health measures, the manual states that the checklist can be used to assess the methodological quality of any health measure because the COSMIN assesses measurement properties that are relevant to all measures (Mokkink et al. 2010b).

The researcher extracted data into an Excel spread sheet that included setting, sampling method; sample size; demographic information (age, sex); the assessment developed, the study aims, the country where the study took place and the COSMIN checklist. If that particular item was not tested in the study then not applicable was recorded. The structure, content and reported feasibility of the assessments was also examined and compared (Appendix 4). The data was then analysed using the methods described in Chapter Two, page 39.

Quality of the studies included in the literature review

The quality of the studies in which the oral assessments were developed was also assessed. The CASP, STARD, QUADAS-2 and PRIMA all assess the quality of the studies included in reviews. PRISMA is a revised version of the QUality Of Reporting Of Meta-analysis (QUOROM), developed to guide those undertaking and reporting a systematic review (Moher et al. 2009). The PRISMA evaluates the reporting of a systematic review or meta-analysis and so was not considered for use in this review because the aim was to assess the quality of individual studies rather than a systematic review. The CASP appraisal tool was developed for educational purposes to allow clinicians and patients to develop the skills to critically appraise research, assessing its risk of bias and whether the research could impact on clinical practice (CASP 2014). Although the CASP is a recognised tool that provides information with regards to the quality of the study it does not grade the quality and it was therefore discarded at this point. The STARD checklist was developed to improve the quality of reporting of diagnostic studies (Bossuyt et al. 2003). For each study the reviewer has to go through the checklist and decide the relevance, potential bias, and limitations of the study applicability. This is a precise checklist which is reliant on the reviewer's judgement and does not provide an overall quality of the study. The STARD was therefore discarded at this point.

The Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) (Whiting et al. 2011) was developed to examine the quality of studies selected for inclusion in a Cochrane systematic review for diagnostic studies. Although this was not a systematic review and several methodologies may

be used the QUADAS-2 was deemed the most appropriate tool to use because it assesses bias and applicability of the studies that have developed a diagnostic measure, providing an overall score of the study quality (Whiting et al. 2011). Risk of bias is assessed using four domains, patient selection, the index test, reference standard, and flow and timing. Data was extracted into a table that contained specific questions relating to each domain (Appendix 5). For each question the reviewer recorded yes, no or unclear. Yes indicates low risk and the issue has been reported, no indicates a potential for bias because this was not reported and unclear represents insufficient information to make a judgement. Applicability is assessed using three domains, patient selection, index testing and referencing. The reviewer makes a judgement about whether applicability is low risk, high risk or unclear in each domain. If all the risk of bias and applicability domains are rated as low risk then the study was judged as low risk of bias or low concern regarding applicability. Where there was a score of high risk or unclear risk in one or more domain then the study was judged as being at risk of bias or having concerns about applicability. The overall quality score for the study was therefore calculated similar to the COSMIN. In order to reduce reviewer bias another researcher independently applied QUADAS-2 to all the papers in the review. Both the researcher and second reviewer then met to discuss their results and any disagreements were resolved through discussion.

3.5 Results

From the electronic search 1291 papers were identified. Two hundred papers were reviewed by both reviewers, of which 5 papers showed disagreement or the reviewer was unsure and wanted clarification. The researcher discussed a further 10 papers with the second reviewer where clarification was required. Following screening of the title, abstract and full reading 21 papers met the inclusion criteria, as shown in Figure 3-1. Papers were discarded at the title and abstract screen because: they did not assess oral health/oral care, the population was not a dependent population; and no oral assessment was developed.

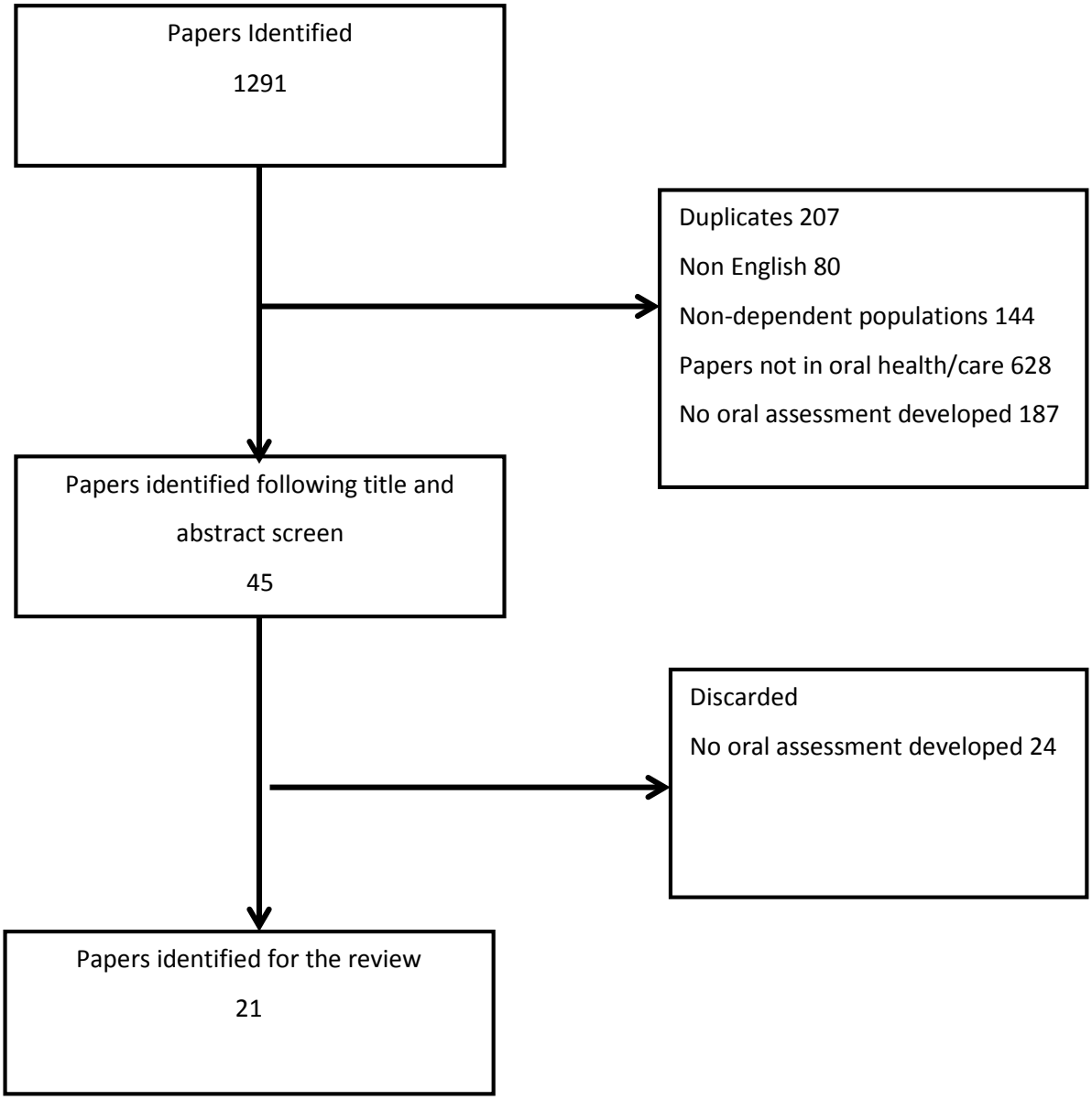


Figure 3-1 Identification and inclusion/exclusion of review papers

Location of papers and types of participants

The 21 papers that developed an oral assessment are summarised in Table 3-2 and Table 3-3. The majority of papers were from the UK (N=9) and the USA (N=7), with the remaining papers from Sweden (N=2), Australia (N = 2) and Ireland (N=1). No oral assessments were developed specifically in a stroke population. Just under half (48%) of the assessments were developed in acutely medically ill, and one third (33%) in those in residential care.

The assessments were categorised as to the purpose of the assessment and what they were measuring:

- The oral health and cleanliness of the oral cavity;
- The risk of oral complications;

Sixteen (77%) of the assessments measured oral hygiene (Table 3 1) and two (9%) assessments measured risk alone. The remaining three (14%) oral assessments measured both oral hygiene and risk (Table 3 2). The three assessments that assess oral cleanliness and risk will be presented in Table 3-3. The quality of the papers selected was poor with all papers having a high risk of bias (Table 3-2, Table 3-3).

Table 3-2 Oral assessments developed to assess oral health and oral cleanliness of the oral cavity in a dependent population

Study	Setting	Sampling	Sample size	Age Mean	Male Sex (N)	Purpose of Study	Assessment	Study Quality (QUDAS-2)
Andersson et al. 1999 Sweden	Acute cancer care	Convenience	16	60.7	Unknown	To evaluate the oral status of patients with haematological malignancies (who were receiving chemotherapy treatment) using the MOAG. The study also tested the reliability of the MOAG.	Modified Eilers Oral Assessment Guide (**MOAG**)	High risk of bias
Andersson et al. 2002 Sweden	Rehabilitation wards	Consecutive	66	81	48	To assess the agreement between raters for the ROAG in an elderly population.	Revised Oral Assessment Guide (**ROAG**)	High risk of bias
Beck 1979 USA	Acute Cancer Treatment	Consecutive	47	58	23	Examine changes in oral cavity following treatment using an oral care protocol.	Oral Examination Guide (**OEG**)	High risk of bias
Burns 2012 UK	Residential care	N/A	N/A	N/A	N/A	To provide an overview of the common oral problems in older people, describing an oral assessment to guide oral care.	Burns Oral Health Assessment Tool (**BOHAT**)	High risk of bias
Chalmers et al. 2005 Australia	Residential care	Cohort	455	82	N/R	To investigate: the development of dental health policies; and test the validity and reliability of the newly developed OHAT.	The Oral Health Assessment Tool (**OHAT**)	High risk of bias
DeWalt 1975 USA	Residential care	Random	48	78.5	16	Effects of timed oral hygiene measures on state of the oral cavity.	**DeWalt**	High risk of bias
Dickinson et al. 2001 UK	Acute Hospital	Convenience	41	84	24	To develop and test an oral assessment for reliability in an older hospitalised population.	The Holistic and Reliable Oral Assessment Tool (**THROAT**)	High risk of bias
Eilers et al. 1988 USA	Acute cancer care	Convenience	20	N/R	10	To develop and test an oral assessment that can identify oral complications in cancer patients following chemotherapy.	Oral Assessment Guide (**OAG**)	High risk of bias
Fallon et al. 2006 Australia	Residential care	Convenience	113	N/R	N/R	To pilot the implementation of evidence based oral hygiene practices in patients with dementia in residential care.	The Oral Audit Tool (**TOAT**)	High risk of bias
Freer 2000 UK	Neurosciences	Convenience	N/R	N/R	N/R	To report the development of oral guidelines and an oral assessment to improve oral care.	Neurosciences Oral Assessment Tool (**NOAT**)	High risk of bias

N/R = Not Reported; N/A = Not applicable because the study does not test in assessment in a sample population

Table 3-2 Oral assessments developed to assess oral health and oral cleanliness of the oral cavity in a dependent population - continued

Study	Setting	Sampling	Sample size	Age Mean (range)	Sex Males	Purpose of paper	Assessment	Study Quality (QUDAS-2)
Huskinson and Lloyd 2009 UK	Acute hospital	N/A	N/A	N/A	N/A	To provide an overview of oral care enabling nurses to undertake an assessment of the mouth and provide appropriate care.	Mouth Care Assessment Tool (**MCAT**)	High risk of bias
Kayser-Jones et al. 1995 USA	Residential care	Convenience	100	82	50	To develop and test an oral health assessment that could be used by nursing staff to assess oral health status in nursing home residents.	A Brief Oral Health Status Examination (**BOHSE**)	High risk of bias
Longman 1986 USA	Residential care	Unknown	30	N/R	N/R	To test if nursing assistants could use oral assessments.	Revised DeWalt (**RDeWalt**)	High risk of bias
Passos and Brand 1966 USA	Intensive care unit	Convenience	66	N/R	N/R	To evaluate and compare the effectiveness of three agents for oral hygiene nursing care in dependent patients.	Numerical rating of the condition of the mouth (**PB**)	High risk of bias
Rattenbury et al. 1999 UK	Acute hospital	Unknown	N/A	N/A	N/A	To discuss the importance of oral care in acutely ill patients and present an oral assessment for use in this population.	Rattenbury, Mooney, Bowen Mouth Assessment Tool (**RMBMAT**)	High risk of bias
Ridley 2008 UK	Intensive care	N/A	N/A	N/A	N/A	To discuss the steps required to conduct an oral assessment in intensive care in the prevention of ventilator acquired pneumonia and present an oral assessment that meets the needs of intensive care patients.	Daily Oral Health Assessment (**DOHA**)	High risk of bias
Roberts 2001 UK	Acute Hospital	N/A	N/A	N/A	N/A	To develop and implement an oral assessment for use in an older population.	The Oral Assessment and Intervention Tool (**OAIT**)	High risk of bias
Stout 2009 Ireland	Acute Hospital	Unknown	N/R	N/R	N/R	To update the oral care policy and assessment tool currently being used in an acute hospital.	Oral Cavity Assessment Tool (**OCAT**)	High risk of bias
Van Drimmelen and Rollins 1969 USA	Residential care	Random	136	(76-90)	38	To evaluate the effectiveness of lemon juice and glycerine as an oral hygiene agent.	Adapted from Passos and Brand (**APB**)	High risk of bias

N/R = Not Reported; N/A = Not applicable because the study does not test in assessment in a sample population

Table 3-3 Oral assessments developed to assess the risk of oral complications

Study	Setting	Sampling	Sample size	Age Mean (range)	Sex Males	Purpose of Study	Assessment	Study Quality (QUDAS-2)
Freer 2000 UK	Neurology	Convenience	N/R	N/R	N/R	To report the development of oral guidelines and an oral assessment to improve oral care.	Neurosciences Oral Assessment Tool (**NOAT**)	High risk of bias
Jenkins 1989 UK	Intensive care unit	Unknown	N/R	N/R	N/R	To improve oral care through discussing the role of the nurse in providing oral care and describes the creation of an "at risk" calculator.	Jenkins at risk calculator (**Jenkins**)	High risk of bias
Lockwood 2000 UK	Acute hospital	Unknown	N/R	N/R	N/R	To develop an oral assessment that is evidence based to improve oral care in the acutely unwell adult.	Lockwood's oral assessment (**Lockwood**)	High risk of bias
Roberts 2001 UK	Acute Hospital	N/A	N/A	N/A	N/A	To develop and implement an oral assessment for use in an older population.	The Oral Assessment and Intervention Tool (**OAIT**)	High risk of bias
Stout 2009 Ireland	Acute Hospital	Unknown	N/R	N/R	N/R	To update the oral care policy and assessment tool currently being used in an acute hospital.	Oral Cavity Assessment Tool (**OCAT**)	High risk of bias

N/R = Not Reported; N/A = Not applicable because the study does not test in assessment in a sample population

Content and layout of the assessment

The assessments were categorised as per what they were measuring, oral health and cleanliness (oral hygiene) or the risk of oral complications in a given population, and then placed in chronological order to enable the reviewer to compare item selection and if this changed over time for each category (Table 3-4).

Oral assessments measuring oral hygiene

The 19 assessments measuring oral hygiene examined anatomical features in the oral cavity such as: lips, mucous membrane, gingivae, teeth, dentures, saliva, swallow, voice, palate, pain, smell and taste (Table 3-4). Teeth, lips and mucous membrane were used in all 19 assessments and appear to be seen as the most important indicators of oral health. Gingivae, tongue and saliva were also reported in 74-94% of assessments (Table 3-4). Palate and swallow were included in just over a third of assessments and voice, smell, pain, food debris and airways (including nares) were reported in less than four assessments (Table 3-4).

Assessments measuring the risk of oral problems

The five assessments measuring risk examined items such as: nutritional state, oral condition, and physical ability in all five (100%) assessments and mental well-being, pain and specific risk factors were cited in three (60%) of the assessments (Table 3-5). Other factors such as mastication ability, age and airway were only cited in two or fewer papers (20-40%).

Table 3-4 The contents of oral assessments measuring oral health and cleanliness

Study	Assessment	Teeth	MM*	Lips	Gingivae	Tongue	Saliva	Denture	Palate	Swallow	Voice	Pain	Smell	Nares	Food debris	Airway
Passos and Brand 1966	PB	✓	✓	✓	✓	✓	✓		✓				✓	✓		
Van Drimmelen 1969	APB	✓	✓	✓	✓	✓			✓					✓		
DeWalt 1975	DeWalt	✓	✓	✓	✓	✓	✓		✓							
Beck 1979	OEG	✓	✓	✓	✓	✓	✓	✓		✓	✓					
Longman 1986	RDeWalt	✓	✓	✓	✓	✓	✓	✓	✓							
Eilers 1988	OAG	✓	✓	✓	✓	✓	✓	✓		✓	✓					
Kayser-Jones 1995	BOSHE	✓	✓	✓	✓	✓	✓	✓	✓						✓	
Andersson 1999	MOAG	✓	✓	✓	✓	✓		✓		✓	✓					
Rattenbury 1999	RMBMAT	✓	✓	✓	✓	✓	✓	✓								
Freer 2000	OAT	✓	✓	✓		✓	✓	✓								
Dickinson 2001	THROAT	✓	✓	✓	✓	✓	✓	✓	✓				✓			
Roberts 2001	OAIT	✓	✓	✓	✓	✓	✓	✓		✓						
Andersson 2002	ROAG	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓				
Chalmers 2005	OHAT	✓	✓	✓	✓	✓	✓	✓				✓				
Fallon 2006	TOAT	✓	✓	✓	✓	✓	✓									
Ridley 2008	DOHA	✓	✓	✓	✓	✓	✓	✓		✓		✓				
Huskinson 2009	MCAT	✓	✓	✓	✓	✓	✓			✓	✓					
Stout 2009	OCAT	✓	✓	✓	✓	✓	✓	✓	✓							✓
Burn 2012	BOHAT	✓	✓	✓	✓		✓	✓				✓			✓	
Total		19 (100%)	19 (100%)	19 (100%)	18 (94%)	18 (94%)	17 (89%)	14 (74%)	8 (42%)	7 (37%)	5 (25%)	4 (21%)	2 (10%)	2 (10%)	2 (10%)	1 (5%)

*MM = Mucous Membrane

APB-Adapted Passos and brand, BOHAT-Burns Oral Health Assessment, BOHSE-Brief Oral Health State Examination, DeWalt–DeWalt, DOHA-Daily Oral Hygiene Assessment, MCAT-Mouth Care Assessment , MOAG-Modified Oral Assessment Guide, NOAT-Neurosciences Oral Assessment , OAG-Oral Assessment Guide, OAIT–Oral Assessment and Intervention , OCAT - Oral Cavity Assessment , OEG-Oral Examination Guide, OHAT–Oral Health Assessment , PB–Passos and Brand, RDeWalt – Revised DeWalt, , RMBMAT – Rattenbury, Mooney, Bowen Mouth Assessment , ROAG–Revised Oral Assessment Guide, THROAT–The Holistic and Reliable Oral Assessment , TOAT-The Oral Assessment

Table 3-5 The contents of oral assessments measuring risk

Study		Nutritional status	Oral condition	Physical ability	Mental well-being	Pain	Special risk factors	Mastication ability	Age	Airway
Jenkins 1989	Jenkins	✓	✓					✓	✓	✓
Lockwood 2000	Lockwood	✓	✓	✓	✓		✓	✓		
Freer 2000	OAT	✓	Table 3-6		✓	✓	✓			
Roberts 2001	OAIT	✓	Table 3-6	✓	✓	✓				
Stout 2009	OCAT	✓	Table 3-6	✓		✓	✓			
Total		5 (100%)	5 (100%)	3 (60%)	3 (60%)	3 (60%)	3 (60%)	2 (40%)	1 (20%)	1 (20%)

OAT-Oral Assessment, OAIT-Oral Assessment Intervention, OCAT-Oral Cavity Assessment.

Scoring systems

Different scoring algorithms have been used to measure the construct (health/cleanliness and risk) under investigation and are presented in Table 3-6. Seventeen (81%) of the assessments used an ordinal scale and four (19%) a nominal scale. Ten ordinal scales (48%) used three categories (normal, moderate, severe) and seven (33%) used four categories (normal, mild, moderate, severe). Three (14%) of the assessments using a nominal scale used a simple yes/no and one used a multiple rating nominal scale, which consisted of numerous independent options for each item. For example, for the appearance of tongue the choices were dry, moist, coated, red, pink and other (Longman and DeWalt 1986).

Having an assessment that is quick and easy to use may be one of the measurement properties required in the clinical setting, aiding the implementation and use of an assessment. However, only two (10%) assessments reported how long it took to complete the assessment and both reported an average time of eight minutes (Table 3-6).

Table 3-6 Scoring system and delivery of oral assessments

Study		Number of items	Score options	Total score	Frequency of oral assessment	Time (Min.)
Ordinal scale						
Passos and Brand 1966	PB	8	1-3	Yes	NR	NR
Van Drimmelen et al. 1969	APB	7	1-3	Yes	NR	NR
DeWalt 1975	DeWalt	9	1-3	No	NR	NR
Beck 1979	OEG	9	1-4	Yes	Daily	NR
Eilers et al. 1988	OAG	8	1-3	Yes	Twice daily	NR
Jenkins 1989	Jenkins	5	1-4	Yes	Constantly	NR
Kayser-Jones 1995	BOSHE	9	0-2	Yes	NR	8
Andersson et al. 1999	MOAG	7	1-3	Yes	Daily	NR
Freer 2000	NOAT	9	1-4	Yes	Alternate days	NR
Lockwood 2000	Lockwood	6	1-4	Yes	Weekly	NR
Dickinson et al. 2001	THROAT	9	0-3	No	NR	NR
Andersson et al. 2002	ROAG	8	1-3	No	Admission	NR
Chalmers et al. 2005	OHAT	8	0-2	Yes	Baseline, 3, 6 months	8
Fallon et al. 2006	TOAT	6	1-4	Yes	NR	NR
Ridley 2008	DOHA	8	0-4	Yes	Daily	NR
Huskinson and Lloyd 2009	MCAT	8	1-3	Yes	Daily	NR
Stout 2009	OCAT	13	1-4	No	Twice daily	NR
Nominal scale						
Longman and DeWalt 1986	RDeWalt	9	Multiple	No	NR	NR
Rattenbury et al. 1999	RMBMAT	6	Y/N	No	Individual basis	NR
Roberts 2001	OAIT	12	Y/N	No	Admission + as required	NR
Burns 2012	BOHAT	10	Y/N	No	Admission + as required	NR

NR= Not reported

Diagnostic accuracy of the measurement properties

Only nine (43%) assessments had their measurement properties assessed because the paper does not report how the assessment was developed. The quality of assessment of measurement properties varied. Internal consistency was only reported in one (5%) paper, validity in five (24%) and reliability in nine (43%) (Table 3-7).

The testing of content validity was limited to four papers (Table 3-7). The extent of testing varied depending on the reporting methods in the paper. Using the COSMIN checklist two papers were classified as having poor testing (DeWalt 1975), one paper was classified as having fair testing (Kayser-Jones 1995) two papers were classified as having good testing (Dickinson et al. 2001; Eilers et al. 1988).

Criterion validity was only reported in one paper (Chalmers et al. 2005) and was classified as excellent on the COSMIN checklist (Table 3-7). The OHAT was compared to other measures that were deemed to be the reference standards for assessing that item. Percentage agreement and Pearson's correlation were reported. There was complete agreement found for lips, with an agreement of 95.2% for tongue, 85.7% for gums and mucous membranes, and 86.6% for tooth decay, 92.3% for denture cleanliness and 85.7% for dental pain. Poor agreement was found for saliva (57.1%) and oral cleanliness (42.9%). The correlation was significant for lips (1.0), tongue (0.80), gums and mucous membranes (0.60), teeth (0.88) and dentures (0.94).

Table 3-7 Overall quality of diagnostic measurement properties ratings as per the COSMIN

Study		Cosmin rating			
	Assessment	**Internal consistency**	**Criterion Validity**	**Content validity**	**Reliability**
Passos and Brand 1966	PB	•	•	•	•
Van Drimmelen 1969	APB	•	•	•	Poor
DeWalt 1975	DeWalt	•	•	Poor	Poor
Beck 1979	OEG	•	•	•	•
Longman 1986	RDeWalt	•	•	•	Poor
Eilers 1988	OAG	•	•	Poor	Poor
Jenkins 1989	Jenkins	•	•	•	•
Kayser-Jones 1995	BOSHE	•	•	Fair	Fair
Andersson 1999	MOAG	Poor	•	•	Fair
Rattenbury 1999	RMBMAT	•	•	•	•
Freer 2000	NOAT	•	•	•	•
Lockwood 2000	Lockwood	•	•	•	•
Dickinson 2001	THROAT	•	•	Good	Poor
Roberts 2001	OAIT	•	•	•	•
Andersson 2002	ROAG	•	•	•	Fair
Chalmers 2005	OHAT	•	Excellent	Good	Poor
Fallon 2006	TOAT	•	•	•	•
Ridley 2008	DOHA	•	•	•	•
Huskinson 2009	MCAT	•	•	•	•
Stout 2009	OCAT	•	•	•	•
Burns 2012	BOHAT	•	•	•	•

• Not tested

Of the nine papers that reported reliability four reported using a reference standard, of which three used a dental hygienist (Andersson et al. 2002a; Dickinson et al. 2001; Andersson et al. 1999), and one used a dentist (Kayser-Jones 1995). Reliability was measured using several statistical methods such as the Kappa and weighted Kappa statistic, Pearson product moment correlation or Intra-Class Correlation (ICC) (Table 3-8). Three papers did not disclose what test they had used and only presented the results as either an overall percentage agreement (DeWalt 1975) or as a reliability coefficient (Longman and DeWalt 1986; Van Drimmelen and Rollins 1969).

Reliability for each item in the assessments varies across the papers from slight agreement to almost perfect agreement. The biggest variations were seen in mucous membranes, gums and saliva (Table 3-8). The spread of data makes it difficult to conclusively say that any one assessment or any one item was shown to be reliable between raters and this could be due to the small sample sizes of less than 50. The ROAG (Andersson et al. 2002b) and OHAT (Chalmers et al. 2005) are the only assessments that show good reliability and had a sample size of 66 and 455 respectively. Intra-class correlation coefficients were used when examining the total scores in two papers (Chalmers et al. 2005; Kayser-Jones 1995) however, it is not clear why they reported total scores other than it allows the reader to identify that there was correlation between the total scores. Fourteen (64%) of the scales did not report any testing for reliability (Table 3-8); therefore it is unknown whether the results of these assessments are reproducible in the same population. Reliability within raters to show stability of the rater and assessment was only reported in two papers as shown in Table 3-7 (Chalmers et al. 2005; Dickinson et al. 2001). Reliability was shown to be similar for teeth and dentures. Differences between the assessments were evident for mucous membrane, lips, gingivae, tongue and saliva. Only one study reported the 95% confidence intervals of the reliability ratings indicating the precision of the result representing the true population (data not shown in the table) (Dickinson et al. 2001).

Table 3-8 Reliability scores

Agreement between raters	Study	Scale	Test	Teeth	MM*	Lips	Gingivae	Tongue	Saliva	Denture	Palate	Swallow	Voice	Pain	Total
	Van Drimmelen 1969	Ordinal	Unknown												0.96
	DeWalt 1975	Ordinal	Unknown												0.92
	Longman 1986	Nominal	IRC												0.86
	Eilers 1988	Ordinal	PPMC												0.91
	Kayser-Jones 1995	Ordinal	K	0.52	0.10	0.32	0.45	0.25	0.12	0.74	0.10				
	Andersson 1999	Ordinal	K	0.31	0.20	0.21	0.55		0.85	0.31		0.76	0.56		
	Dickinson 2001	Ordinal	Kw	0.56	0.75	0.78	0.71	0.69	0.69	0.58	0.80				
	Anderson 2002	Ordinal	K	0.46	0.58	0.68	0.67	0.52	0.53	0.46		0.84	0.45		
	Chalmers 2005	Ordinal	K	0.66	0.57	0.48	0.57	0.53	0.48	0.65				0.62	
Agreement within raters	Dickinson 2001	Ordinal	Kw	0.76	0.94	0.96	0.92	0.87	0.69	0.73	0.81				
	Chalmers 2005	Ordinal	K	0.70	0.71	0.52	0.71	0.61	0.51	0.70				0.66	

*MM=Mucous Membranes, PPMC-Pearson product moment correlation, IRC-Inter rater coefficient, K-Kappa, Kw-weighted Kappa, ICC Intra-Class correlation coefficient.

Kappa rating (Landis and Koch 1977)	Very Good	Good	Moderate	Fair	Poor
	0.81-1	0.61-0.80	0.41-0.60	0.21-0.40	≤ 0.20

In order to reduce measurement error and improve reliability, education was provided in five of papers that tested reliability (Table 3-9). A further four papers reported providing education but did not carry out any reliability testing. The quantity of education provided varied, from unknown to three hours. The type of education also varied from simple instruction on how to use the assessment to more in-depth information about the anatomy and physiology of the oral cavity and potential oral problems that could occur if oral hygiene is neglected.

Table 3-9 Methods used to reduce measurement error

Study	Assessment	Reliability Tested	Education	Time (Hours)	Description of education provided
Passos and Brand 1966	PB				
Van Drimmelen 1969	APB	Yes	None		
DeWalt 1975	DeWalt	Yes	None		
Beck 1979	OEG				
Longman 1986	RDeWalt	No	Yes	N/R	
Eilers 1988	OAG	Yes	Yes	N/R	In service training Trialled assessments
Jenkins 1989	Jenkins				
Kayser-Jones 1995	BOSHE	Yes	Yes	2	Anatomy and physiology Clinical examination of the oral cavity How to use the assessment
Andersson 1999	MOAG	Yes	Yes	2	How to use the assessment
Rattenbury 1999	RMBMAT				
Freer 2000	NOAT				
Lockwood 2000	Lockwood	No	Yes	N/R	How to use the assessment
Dickinson 2001	THROAT	Yes	None		
Roberts 2001	OAIT				
Andersson2002	ROAG	No	Yes	3	Oral health problems Oral assessment on 5 patients
Chalmers 2005	OHAT	Yes	Yes	3	How to use the assessment
Fallon 2006	TOAT	No	Yes	3	Education pack
Ridley 2008	DOHA				
Huskinson 2009	MCAT				
Stout 2009	OCAT	No	Yes	N/R	How to use the assessment
Burns 2012	BOHAT				

Quality of the studies included in the literature review

Using the QUADAS-2 to assess the quality of the studies in which the oral assessments were developed, all 21 papers were rated as having a high risk of bias and only three papers were identified as having low concern regarding applicability (Table 3-10). Thirteen (62%) of the studies did not provide sufficient information to complete the QUADAS-2 suggesting a high risk of bias and concerns regarding applicability. Nine studies were discussion papers, in which the author discussed the importance of oral care and suggested the format and layout of an oral assessment. Six studies were intervention studies where an oral assessment was developed as an outcome measure for the study. Only four reported testing reliability (Table 3-7). The remaining six studies were diagnostic studies that developed and tested an oral assessment for its diagnostic properties. Overall the quality of the studies identified for the review was poor. Only one study showed the potential to have low risk of bias if their reporting of patient selection had been better (Kayser-Jones 1995)

Table 3-10 Assessment of quality: QUADAS-2 results

Study	Study Design	Risk of Bias					Applicability			
		Patient selection	Index test	Reference standard	Flow and timing	At Risk of Bias	Patient selection	Index text	Reference standard	Applicability Concerns
Passos and Brand 1966	I	☹	?	?	?	☹	☺	?	?	☹
Van Drimmelen and Rollins 1969	I	?	?	?	?	☹	?	?	?	☹
DeWalt 1975	I	?	?	?	?	☹	?	?	?	☹
Beck 1979	I	?	?	?	?	☹	?	?	?	☹
Longman 1986	I	☹	☺	?	?	☹	?	?	?	☹
Eilers et al. 1988	DA	☹	?	?	?	☹	?	?	?	☹
Jenkins 1989	DP	?	?	?	?	☹	?	?	?	☹
Kayser-Jones et al. 1995	DA	☹	☺	☺	☺	☹	☺	☺	☺	☺
Andersson et al 1999	DA	☹	☹	☹	☹	☹	☹	☹	☹	☹
Rattenbury et al. 1999	DP	?	?	?	?	☹	?	?	?	☹
Freer 2000	DP	?	?	?	?	☹	?	?	?	☹
Lockwood 2000	DP	?	?	?	?	☹	?	?	?	☹
Dickinson et al. 2001	DA	☹	☹	☺	☹	☹	☹	☺	☺	☹
Roberts 2001	DP	?	?	?	?	☹	?	?	?	☹
Andersson et al. 2002	DA	☺	?	☹	☹	☹	☺	☺	☺	☺
Chalmers et al. 2005	DA	☹	?	☺	☹	☹	☺	☺	☺	☺
Fallon et al. 2006	I	?	?	?	?	☹	?	?	?	☹
Ridley 2008	DP	?	?	?	?	☹	?	?	?	☹
Huskinson and Lloyd 2009	DP	?	?	?	?	☹	?	?	?	☹
Stout 2009	DP	?	?	?	?	☹	?	?	?	☹
Burns 2012	DP	?	?	?	?	☹	?	?	?	☹

I=Intervention, DA = diagnostic accuracy, DP= discussion paper, ☺ = Low risk, ☹ = High risk, ? = Unclear/Not reported

3.6 Discussion

This review has examined the literature for existing oral assessments developed for use in dependent populations. Each of the oral assessments selected was reviewed for their content and layout, scoring system, and measurement properties, using the COSMIN check list (Mokkink et al. 2010b). Quality of assessment development was also assessed using QUDAS-2 (Whiting et al. 2011). The review found that the majority of assessments had been developed in a residential or acute hospital population, with two thirds being developed in an elderly population. The quality of the development of each assessment was variable and only one third of the assessments attempted to test measurement properties of their tool. The variations in the quality and testing of the assessments makes it difficult to identify if any one oral assessment could be adapted for use in a stroke population in a hospital setting.

Limitation of the review

The literature was reviewed using a systematic approach to identify if an oral assessment existed that could be used in a stroke population. The search strategy was developed from MeSH terms identified in the scoping review and from exploring the terms used in a Cochrane review that explored oral care in stroke patients (Brady et al. 2010). This review focused on identifying oral assessments that had been developed for use in hospitalised or dependent patients and excluded studies that were not in English. Through excluding non-English studies there is a risk that studies may have been missed that have developed an oral assessment for use in stroke patients. Another limitation is the literature review only included studies relating to hospitalised or dependent patients and this may also have excluded studies that had developed an oral assessment for other populations which potentially could be used in a stroke population.

When performing a literature search it is important to ensure bias is reduced and validity is maintained. It is recognised that systematic approach should still be followed in an integrative review (Whittemore and Knafl 2005). The ideal is to have two reviewers extracting the data using a data extraction form to ensure validation and reduce the risk of error (Deeks et al. 2009; Higgins and Green 2008). In this review two reviewers analysed a random selection of title and abstracts. This was a pragmatic decision because there were not the resources to support a second reviewer screening 1291 papers. Therefore, 15% of the papers were reviewed by both reviewers. The percentage of agreement was high (98%), so it was deemed that the researcher was including all

the appropriate papers. The researcher had access to the second reviewer to discuss any papers they were unsure of to ensure error was kept to a minimum. Due to only 15% of papers being reviewed by both reviewers there is the possibility that not all papers were included in the review. The first reviewer was an experienced nurse researcher who had undertaken reviews before with an interest in the topic area and the second reviewer was an experienced researcher in both quantitative and qualitative research who had experience in performing literature reviews. Having a reviewer that is topic specific and a second reviewer that has methodological expertise is recommended (Higgins and Green 2008) and this was achieved in this review. In the data extraction stage both reviewers did extract data from all 21 papers to ensure validation and reduce the risk of error.

Population and sample

When developing a new assessment it is important to consider the population in whom the assessment is to be used, the specific issues that may impact on the content of the assessment, and how the assessment is to be administered (de Vet et al. 2011). Issues such as: the person's physical ability, (for example their ability to open their oral cavity, or clean their teeth); or their cognitive ability (for example their ability to obey commands or answer questions) needs to be considered. The population and sample of choice informs the content and layout of the assessment, how the assessment will be performed, who will complete the assessment (patient or health professional), and how the information would be best collected (self-report or clinical examination). Potential users of assessments also want to know if the assessment is usable in their population of choice.

The review did not identify any oral assessments that had been developed specifically for stroke patients. However, some oral assessments had been developed in an elderly population who may also have difficulty attending to their oral care due to similar cognitive and physical disabilities, as well as other factors such as age, medication and multiple co-morbidities.

If an oral assessment is to be considered for use in clinical practice it is important to know that it can be used by multiple users and that it measures the information required. In order to determine whether the assessment is reliable and valid an adequate sample size is required to ensure that all parts of the assessment are tested, and to remove the possibility that agreement between raters occurred by chance. For the nine papers which assessed the measurement

properties of the assessment, the sample size varied from 16–455 participants. The recommended sample size for testing reliability is 60 or more participants and for validity it is 50 or more, although 100 is optimal (de Vet et al. 2011). Four of the nine papers recruited an adequate sample for testing reliability (Chalmers et al. 2005; Andersson et al. 2002a; Kayser-Jones 1995; Van Drimmelen and Rollins 1969). One assessment tested the criterion validity and had an adequate sample size (Chalmers et al. 2005). All these assessments could potentially be considered for further testing in a stroke population.

Content and layout

The content and layout of the oral assessment is shaped by the construct under examination; the items the assessment is designed to measure; and the individual who will be administering the assessment (de Vet et al. 2011). Oral health is a complex construct which is influenced by many factors. In the review two types of assessment were identified, those that measure the oral health and cleanliness and those that measure the risk of oral complications. In some cases the assessments measured both health and risk.

Traditionally oral hygiene and health have been reviewed by dentists and dental practitioners with specialist training, using dental assessments that examine the plaque levels and the health of the gingivae, teeth and periodontal structures (Silness and Loe 1964; Loe and Silness 1963; Greene and Vermillion 1960). However these are not useful in a clinical nursing environment because these assessments require specialist knowledge and training and specific positioning in order for the clinician to view the oral cavity to provide a valid and reliable assessment. The assessments identified in this review were those that could be used by non-dental personnel and also measured the issues relevant to a dependent hospitalised population. These assessments concentrated on assessing the health and cleanliness of specific areas in the oral cavity and so will help for the basis of the development of a new assessment within this thesis. This will be discussed further in Chapter Six. In medically ill patients, factors such as dehydration, reduced physical and cognitive ability, medical co-morbidities and reduced immune defences all contribute to changes in the health and cleanliness of the oral cavity. These factors reduce an individual's own natural defences in maintaining oral health, increasing their risk of oral complications such as coating on the tongue, dry lips, and reduced saliva flow (Dirnagl et al. 2007; DeWalt and Haines 1969). In considering these factors, the oral assessments in the review have included dental

disease and the impact on teeth and gingivae, as well as the health and cleanliness of other structures within the oral cavity.

Risk assessments examined the factors that increase the risk of developing oral complications, indicating a need for increased oral care (Lockwood 2000; Jenkins 1989). Factors such as: increased age, decreased chewing ability, certain co-morbidities and some medications. It could be argued that oral assessment needs to be a step-wise process where oral health and cleanliness and risk need to be considered on initial assessment, but reviewed at different time intervals thereafter. For instance, risk factors such as age and co-morbidities may not change from day to day so there is no clinical need to assess risk daily, rather weekly or when the patient's medical condition changes. Only one of the risk assessments advised weekly reviews, the frequency of which could be increased if the clinical picture changed (Lockwood 2000). The two assessments that combined assessing risk with oral hygiene status advised more frequent assessments and one possible reason is because oral hygiene can change very quickly over a few hours and so frequent assessment would be required to inform care and detect deterioration (Stout et al. 2009; Freer 2000).

The health and cleanliness of the oral cavity can change rapidly in a short space of time if there is reduced cleaning of the oral cavity or a reduction in saliva production. Reviewing the health and cleanliness of the oral cavity would therefore be recommended daily rather than weekly in an acute setting. This not only helps the carer decide how much care to provide but also if the care is sufficient. The evidence to support the frequency of assessing oral hygiene and oral risk is still not available, and so the recommended frequency of assessment remains an unanswered question. At present frequency of assessment is recommended from consensus of opinion, clinical need and time available.

When considering the content and layout of the assessment the developer needs to consider who will be completing the assessment and the realistic time they have available to collect the information required. Having an oral assessment that measures precisely everything that is required but takes a long time to complete might not be accepted into clinical practice and therefore it would not inform clinical care. Having an assessment that is quick and easy to use and provides the information required is much more practicable and is more likely to be accepted into clinical practice informing oral care. Only two papers commented on the length of time it took to complete the assessment; this was eight minutes in both cases (Chalmers et al. 2005; Kayser-Jones

1995). Both of these assessments were developed to assess the oral health of residential patients because there was a lack of dental review in this population. Eight minutes in a residential setting, where time and care pressures are different may be acceptable. However, in an acute hospital setting eight minutes could be viewed as a long time, taking the nurses away from the other clinical roles that are viewed as more important. When examining the barriers to care provision, which includes oral care, time pressures are one factor that is frequently reported (Brown and Kalaitzidis 2013; RCN 2012; West et al. 2005). With the time pressures nurses face, decisions are made as to what care has a greater priority (RCN 2012) of which oral care is seen as low priority (Wardh et al. 2000). Due to the time pressures it is important therefore to have an oral assessment that is quick and easy to use taking only a few minutes to complete. Although no oral assessment was identified as being quick and easy to use, there is no reason why the two assessments that take eight minutes to complete (OHAT and BOSHE) could not be considered for modification to meet the clinical needs of the patients and the demands of the nursing team.

Scoring

When developing an assessment it is important to consider the scoring system with regards to the type of data that will be collected, for instance whether the data are categorical (nominal or ordinal) or continuous (interval or ratio). In some clinical situations having two categories identifying whether there is a problem or not is sufficient. In other situations being able to classify whether the problem is mild, moderate or severe is required and in research, a more sensitive measure may be required with multiple categories to show the effect of interventions or change over time (de Vet et al. 2011). In the review, the majority of assessments used an ordinal scale to categorise the severity of a problem, with only four assessments using a dichotomous system where the problem was either evident or not (Table 3-6). As well as considering how the data are to be collected, the assessor also needs to be able to make the distinction between the different scores for each item, and have an understanding of the relevance of the scores (de Vet et al. 2011). Being able to interpret the scores accurately is important when diagnosing a clinical problem.

Thirteen of the oral assessments also report using a total score which would indicate that the assessment was developed using a reflective model. That is, there is a relationship between all the items and the construct and all the items contribute to a total score which can also be categorised to normal, mild, moderate or severe depending on the score. Although thirteen

papers have reported a total score it is unclear if the assessment was developed with a reflective model in mind.

Measurement properties

Reviewing the measurement properties of an assessment identifies if the assessment measures what it purports to measure and that it is reliable between and within multiple raters. Data from the assessment can be analysed to test for validity and reliability. Just over a third (43%) of the studies in the review included any testing of the assessment's measurement properties.

Internal consistency

Internal consistency identifies items in the assessment that may measure similar aspects and therefore do not add anything new to the total score. The items that do not add to the total score become redundant and can be removed as they don't add to the reliability of the measure (Streiner and Norman 2008). Internal consistency is usually tested in those assessments where items may relate to each other and the construct and hence contribute to a total score. Although 13 of the 21 papers report a total score only one study reports the testing of internal consistency of their assessment, the MOAG (Andersson et al. 1999). The internal consistency for the MOAG was reported as high but the paper does not describe how this was tested and if any items were discarded to improve the assessment's reliability. None of the studies identified if the assessment was developed using a formative or reflective model, making it difficult to ascertain if internal consistency should have been carried out.

Reliability

Having an assessment that is reliable within and between different raters is important in a clinical and research setting. By testing the reliability of an assessment the clinician can make an informed decision as to whether the assessment will lead to the same clinical judgements when used by other clinicians. There are different methods used to improve the reliability of an assessment. Education is one method used to reduce subjectivity and increase reliability (de Vet et al. 2011). Five out of the nine who tested for reliability used education to increase agreement, however it was not clear from all the papers what the content, method of delivery and duration of the training was (Chalmers et al. 2005; Andersson et al. 2002a; Andersson et al. 1999; Kayser-Jones 1995; Eilers et al. 1988). Only four of the five papers reported the duration of the education, which varied from 2 to 3 hours. In one study support was provided, if required, and this was by a

dental expert (Andersson et al. 2002a). From the information reported from the studies it is unclear if education had any impact on the agreement between raters.

Education is an important aspect of increasing reliability; however, in clinical practice very little time is allotted for providing and receiving education which may increase the assessment reliability. In the current clinical climate in the NHS, sending staff to three hours of training may not be seen as a good use of the nurse's time, especially if oral care is not viewed as high priority. Therefore, developers of new assessments need to consider how best to provide education to increase reliability with the time constraints available. One such method of providing education that is not dependent of staff leaving the ward is to have instructions on the reverse side of the assessment. Another method is having one nurse who has the extended training and therefore is the expert on the ward. This nurse would then be responsible for cascading the evidence and training to the other staff in the ward area.

The reported agreement between raters for the oral assessments was variable with comparisons made difficult because of different methodologies used to test reliability. When examining agreement, different statistical methods are recommended depending on the data collected. All the studies in the review had nominal or ordinal scales but only five of the nine reported reliability using the Kappa statistic (Table 3-8). The remaining four reported reliability using a form of correlation coefficient with little explanation as to how the reliability scores were calculated (Eilers et al. 1988; Longman and DeWalt 1986; DeWalt 1975; Van Drimmelen and Rollins 1969). The majority of the studies did not perform any reliability testing and yet five of these were introduced into the clinical environment (Stout et al. 2009; Ridley and Pear 2008; Roberts 2001; Rattenbury et al. 1999; Jenkins 1989). It is therefore very difficult to ascertain if they are clinically adequate to measure what is required.

Validity

The final area examined in the review was the validity of the oral assessments. Having a valid oral assessment informs the clinician that the assessment is correctly measuring the construct of interest. Different types of validity can be assessed: content and face validity were only reported in four (18%) of the studies (Chalmers et al. 2005; Dickinson et al. 2001; Eilers et al. 1988; DeWalt 1975), and criterion validity was only examined in one study (Chalmers et al. 2005). For the remaining studies there was no information provided as to whether validity was tested. The one assessment (OHAT) that was tested for criterion validity against a reference standard showed

significant correlations for lips, tongue, gums, teeth and dentures. This would suggest that these items were measuring the same as the reference standard. Chalmers et al. (2005) found there was less agreement in those items (saliva, oral cleanliness and pain) where the assessor had to make a more subjective assessment. However, Chalmers et al. (2005) recommended that further research was required to increase agreement in all areas.

Quality studies included in the review

Using the QUADAS-2 the overall quality of the studies incorporated in the review was poor. Only one assessment showed the potential to be of moderate quality (Kayser-Jones et al., 1995). The high incidence of bias found in these studies highlights the lack of diagnostic studies available that have assessed the measurement properties of the newly developed oral assessment. Having an oral assessment that demonstrates a low risk of bias is important. A high risk of bias would suggest the assessment results are not a true representation and therefore affect its diagnostic value. This can have significant implications for clinical practice. To ensure good evidence based care is provided, good quality assessment need to be available. The review has highlighted a lack of oral assessments that have been developed using robust methodology and tested for their diagnostic accuracy. In order for clinicians to assess the applicability of an oral assessment to their clinical area they need to be able to identify potential limitations and the risk of bias (Whiting et al. 2011).

Only six papers were identified as diagnostic studies and their reporting of risk of bias was poor. One possible reason for this is development of research methods and reporting with regards to diagnostic assessments (Deeks et al. 2009). Some of the studies describe the development of an oral assessment for use in clinical practice. However, these studies describe a change to service through review of the literature with no testing of the assessment validity and reliability. For these studies it is difficult to ascertain if the assessment measures what it purports to measure and whether in deed it does have any diagnostic properties. For example the OCAT, OAIT, Lockwood, RMBMAT and Jenkins (Stout et al. 2009; Roberts 2001; Lockwood 2000; Rattenbury et al. 1999; Jenkins 1989).

Although the quality of the oral assessments was low, the information from the literature review can provide the foundation to aid the development of an oral assessment for stroke patients. Further research should explore which elements should be incorporated and to ensure the

development of the assessment meets the quality standards required and can be measured by the QUADAS-2.

3.7 Conclusion

Oral health is a complex construct, of which oral hygiene is just one component. Examining the properties of assessments is essential if an assessment is to be used in an environment where multiple raters (e.g. nurses) attend to one patient's care during the day. The review has identified 21 oral assessments for use in a dependent population. Of the 21 studies only one (the OHAT, Chalmers et al. 2005) had an adequate sample size and had tested the validity and reliability of the assessment. Potentially this assessment could be tested in a stroke population. However, the OHAT was developed for use in a residential population with the aim of providing dental screening because there was a lack of regular visits to the dentist by the residents. This meant the assessment focused more on oral and dental health, looking for tooth and gum disease rather than oral cleanliness and comfort. The OHAT also took 8 minutes to complete which could be deemed as too long for an acute ward in a hospital environment where there are a lot of competing care pressures. The OHAT could potentially be adapted or aspects from the assessment could be used to develop a new assessment for use in stroke patients.

The review has identified that there is still a need for an assessment that will aid in the identification of oral problems and evaluate care in a dependent population in an acute hospital setting. There are many items within all the assessments that should be considered when developing a new oral assessment. Items such as teeth, dentures, lips, tongue, gingivae, mucous membrane and saliva have been identified as the main items that have been included in assessments measuring oral health. Although items such as the palate, swallowing, voice, smell and airways are less commonly included they should still be considered before they are discounted. Although a person's ability to attend to their oral care was considered in those assessments that assessed risk, it was not seen as an essential element of a daily assessment. Another aspect of asking the patient how their oral cavity felt and if they had any pain was only present in six of the oral assessment of which three may only be used once or weekly. When considering the elements to include in an oral assessment it is important to consider what the needs of the population are and what information the clinician is hoping the assessment will provide. The selection of items for a new oral assessment will be presented in Chapter Six (6.2.3, page 178). When developing the new assessment and to enhance its reliability methods such as

training, time to complete and delivery of the assessment needs to be considered as this will inform the format and layout of the assessment.

3.8 Summary

This chapter has summarised the oral assessments identified in the integrative literature review to be of poor quality. The review identified 21 assessments that had been developed for use in a dependent population. The testing of these assessments robustness (validity and reliability) was limited. Only one assessment (OHAT) had sufficiently undergone robust testing of its measurement properties, but this assessment was initially developed as a dental screening tool. Therefore, an oral assessment that assesses the specific issues relevant to stroke, still needs to be developed and tested. This assessment will inform nursing care which may help reduce oral and systemic complications such as candida or pneumonia. Chapter Four will now go on to describe the first phase of the development of an oral assessment, examining patients', carers', clinical and academic experts in oral health and stroke, and health professionals' views of oral care and oral care practices and what aspects they feel are important.

Chapter Four

Exploring the views and experiences of the "experts" in the field

4.1 Introduction

It has been established that oral health is important and impacts on general health and psychological well-being (Locker et al. 2002). For those individuals with physical and cognitive dependencies, maintaining oral health and care can be challenging, as care is often required from others (e.g. nurse, relative, or carer). Having an assessment to guide oral care in a hospital would aid in the identification of oral problems. The review in Chapter Three, explored the current literature, identifying oral assessments that have been developed for use in a dependent population. Following the review, only one assessment was shown to be a valid and reliable oral assessment, the OHAT; however, it was developed to screen for dental problems in residents in institutionalised care (Chalmers et al. 2005). So far, research has not explored the use of the OHAT in hospitalised stroke patients or other hospitalised acutely ill patients. Stroke patients have many factors that can impinge on oral health so it was important to have a comprehensive oral assessment. It would need to allow for assessment of the patients cognitive and physical dependencies and be able to assist in identification of problems that would require nursing action. The oral assessment would then have the potential to inform action to improve patient well-being, dental oral health and to prevent complications; oral and systemic infections.

Prior to the development of any new assessment or measure, it is imperative to review the literature to ensure there is a need for a new assessment, and to understand what constructs need to be measured (de Vet et al. 2011). There has been a move towards seeking patients' views when developing health services including involving them in the development of a new assessment because they are the experts of their own disease and care needs. Participation requires patients to work in collaboration with health professionals, becoming active participants in, rather than being a passive recipient of, research and health care (Donabedian 1992). Health service policies have driven patient involvement in research and health service development, encouraging an open and democratic process (Boote et al. 2002). Consulting patients about

services and care is important in all stages of care development and essential if the healthcare is to meet their care needs and expectations (Damschroder et al. 2009; Rycroft-Malone 2004).

It is also important to explore the views of health professionals who will use the oral assessment, as well as clinical and academic experts in oral health and stroke if the assessment is to be meaningful and usable in clinical practice (de Vet et al. 2011). The information gathered from the literature review and from exploring all the stakeholders (academic, professional and users) views should inform the layout and content of the assessment (de Vet et al. 2011). Understanding the barriers and facilitators to implementation can assist in embedding the assessment in clinical practice following pilot testing (Damschroder et al. 2009; Rycroft-Malone 2004).

For the purpose of this thesis the expert groups were defined as those: who had clinical and expert academic knowledge in oral health and stroke; who provided oral care for stroke patients (health professionals); who received oral care from others and who were able to express their own thoughts and feelings (stroke patients); and who were advocates for patients receiving oral care and who were unable to voice their concerns and preferences (relatives/carers).

The aim of this study was to explore the views and experiences of all the stakeholders (clinical and academic experts in oral health and stroke, health professionals, patients and carers) using qualitative methodology to inform the development of an oral assessment. This chapter will describe the methodological approach used to underpin sampling, data collection, and data analysis. The chapter will then set out the study's aims and objectives. In order to reduce the risk of repeating the same information for each stakeholder group the core methods used will be described, followed by a description of sample selection, and how data were collected for each objective. Finally, a short summary will be provided before presentation of the findings in Chapter Five.

4.2 Methodology

There are two main approaches that govern how data are collected in research, quantitative or qualitative. Each method has been developed from different origins and models, and they are tailored to investigating the research questions in different ways. A quantitative approach is the most traditional method used and is often the favoured approach. It is based in a "positivist paradigm". In quantitative approaches the researcher believes in universal laws and objectivity, and as such it is testing theories and hypotheses (Creswell 2007; Holloway and Wheeler 2002). A

positivist approach sees the social world in an objective way believing there are no influences from the person. The gold standard of quantitative methodology is the Randomised Controlled Trial (RCT) which attempts to remove as many biases (subjectivity) as possible (Holloway and Wheeler 2002).

A qualitative approach, on the other hand, uses an interpretive or descriptive style which is rooted in philosophy, history and anthropology (Holloway and Wheeler 2002). Researchers using qualitative approaches assume that humans do not live in a vacuum that is objective, and want to explore people's subjective lived experiences of the social world and their interactions within it. With a qualitative approach, the views and values of the researcher as well as the participants can become part of the research, neither is excluded, but limitations should be acknowledged (Silverman 2010).

Within the hierarchy of research methodology quantitative research has been seen as the gold standard, the driver of testing theory and hypothesises (Carr 1994). Qualitative methods have struggled to be accepted in the research fraternity due to the methods being seen as subjective and open to bias (Carr 1994). However, quantitative approaches cannot always answer all of the research questions posed. In order to develop a service or treatment it is often necessary to perform an exploration of the person's lived experience of that disease (Thorne et al. 1997) as well as health professionals perceptions of barriers and facilitators to delivering the oral care needed. Thus a qualitative approach was considered the best methodology to explore patients', carers', health professionals' and clinical and academic experts in oral health and stroke' views and experiences of oral care and so a qualitative approach was considered to be the best methodology.

Within qualitative research there are different forms of inquiry which all interpret social reality and describe people's lived experiences. Traditionally, three main methods exist, ethnography which explores the patterns of cultural and social relationships, phenomenology which explores the interpretative meaning of an experience and grounded theory which develops theory (Holloway and Wheeler 2002). Initially, nursing adopted these methods to build nursing research and any deviation from these methods was deemed as poor research (Morse 1991; Leininger 1985). All too often nurse researchers report the use of traditional methodologies because they were concerned about maintaining methodological integrity. In reality, variation from the traditional methods was being used to answer specific clinical and research questions

(Sandelowski 2000) and it was felt that many nurse researchers were in fact performing research using an interpretive approach but this method had not been formally named (Morse and Chung 2008). In recognition of traditional methods not meeting the needs of nurse researchers there has been a move towards identifying a method that would fit with nursing's own epistemological position (Thorne et al. 1997).

> *"…build methods that are grounded on our own epistemological foundations, adhere to systematic reasoning of our own discipline, and yield legitimate knowledge for our practice."*
>
> (Thorne et al. 1997)

Interpretive description was therefore developed and has been described by Thorne et al. (1997) as one such method that facilitates nursing in gaining a greater understanding of people's experiences of health and illness to inform clinical understanding (Thorne et al. 1997). Although Interpretative description has been available for many years its value in nursing has not been acknowledged due to nursing researchers being concerned about this new method's research integrity and rigor (Sandelowski 2000). However, many nursing scholars felt the traditional methods were not meeting the needs of nursing research and so pursued a move towards this new method to allow exploration of the meaning for common life practices (Lopez and Willis 2004) to create credible disciplinary knowledge (Thorne et al. 2008). Interpretive description is seen to provide: a logical structure; and a philosophical rationale for the decisions made (Thorne et al. 2008). Underpinning interpretative description is some common philosophies found in traditional methods but allows:

1) Realities to be studied holistically because they are complex, contextual and subjective. This involves exploring indicial experiences but comparing and contrasting how these experiences contribute to the commonality of the subjective experience (Thorne et al. 2008; Lopez and Willis 2004);
2) The researcher and participants are inseparable. The researchers own views and knowledge do interact with the participants. The researcher makes meaning from the data to describe what the individual is saying and how this contributes to the whole group's experience of the reality. This is a process where blending of the ideas and thoughts of both the participants' and realities and the focus of the researcher is brought together (Lopez and Willis 2004).

3) *A priori* knowledge is part of the research process and is viewed as contributing to the inquiry. In fact, the researcher guides the inquiry and makes the research a meaningful undertaking (Koch 1995). It is the researcher knowledge that leads the inquiry in order to produce useful knowledge that can be used in the clinical setting (Lopez and Willis 2004).

The use of *a priori* knowledge, both theoretical and clinical, draws together interpretation of the lived experience and knowledge that is already known (Neergaard et al. 2009; Thorne et al. 1997). In the more traditional methods, such as grounded theory, any previous knowledge or theories the researcher may have with regards to the topic of inquiry has to be discarded or "bracketed" so as not to bias or influence the data collection and analysis (Strauss and Corbin 1998). The researchers existing knowledge is viewed as a bias because the researcher is attempting to gather new data from which to develop theory and this existing knowledge could contaminate the findings through influencing the collection and analysis of the data. In methodologies where theory is being created the researcher is attempting to build theory from the participants lived experiences and should be attempting to report the "truth" as described by the participant. If the researcher does not approach the analysis with a clear mind (bracket their previous experience) any existing knowledge they may have can therefore influence how and what data is collected and analysed.

In nursing research it is often difficult for the researchers to truly leave behind any pre-existing knowledge or information to enable them to conduct research in the traditional methodologies (McIntyre 1988). With interpretive description, the nurse researcher is encouraged to use their pre-existing knowledge, whilst acknowledging that this knowledge is a precursor, and a foundation to which the new inquiry will add to the interpretation of the data and allow new theory to be developed (1988). One of the aims of interpretive description is to provide nursing with information that can be applied to clinical care (Thorne et al. 2008). The researcher's knowledge is an important part of the process as it informs the inquiry direction to provide specific knowledge that can be applied to nursing phenomenon.

With any new research, foundation work developing and exploring the research question is undertaken providing the researcher with new knowledge. During this phase the researcher is processing the newly acquired information within the context of their existing knowledge and often it can be very difficult to actually "bracket" this information, and to know that it has not biased the collection and analysis of the data. In the case of this thesis, a literature review was

undertaken to identify where new inquiry was required. The researcher also had both clinical and scientific knowledge and this *a priori* knowledge was viewed as important in providing the foundations for the qualitative inquiry, and so it was essential that it was not lost. Interpretive description was therefore chosen so as to use this knowledge to inform the research rather than it being seen as a bias or a factor that could corrupt the data. Interpretive description is no different from any other qualitative research where the researcher needs to acknowledge the potential bias they may be introduced during collection and analysis of the data (Creswell 2007).

The researcher's aim was to explore the patient's experience of oral care and to use these experiences to inform the development of an oral assessment for use in clinical practice. The aim was not to develop new theory (Grounded theory), provide thick description of cultural and social relationships (ethnography) or provide in-depth interpretation and meaning of a lived experience (phenomenology). The research question was to explore what issues were deemed to be important, not only to the patient and carers, but also to those who provide oral care, and those who have the expertise in oral health and stroke. Interpretative description is a pragmatic design that would allow the researcher to explore the experiences of all those involved in receiving or providing oral care. This in turn will allow the researcher to examine all the experiences of all parties from a personal and an organisational perspective, so as to inform the development of an oral assessment that would be usable and meaningful in a clinical setting to stroke patients and health professionals.

4.2.1 Subjects and Sampling

The purpose of the study is to explore peoples' views and experiences of oral care using qualitative methodology. This would involve individual interviews with the clinical and academic experts in oral health and stroke, patients and carers and focus groups for the health professionals. Within qualitative research the sample is often determined by saturation of ideas or a sample that captures those participant's experiences (King and Horrocks 2010). A potential sample size was therefore identified and will be presented for each objective.

In qualitative research different sampling techniques are used because the aim is not to make statistical generalisations (King and Horrocks 2010), but to identify the experiences and views of the participants. Although sampling in qualitative research is different, a sampling strategy still needs to be used that relates to the people, the setting, and the topic of interest (King and

Horrocks 2010). Sampling is also guided by the underpinning methodology, which in this case is interpretative description.

Within Interpretative description purposive sampling is recommended (Neergaard et al. 2009; Sandelowski 2000). Purposive sampling was therefore chosen to identify the participants. This sampling technique enables the researcher to deliberately select participants in a non-random fashion to purposively inform the research question (Creswell 2007). The sample is chosen so that it represents particular aspects of the characteristics of the phenomenon, and setting that the researcher wishes to explore (Holloway and Wheeler 2002; Thorne et al. 1997). Several types of sampling strategies can be used in purposive sampling. One strategy is maximum variation sampling, which allows the researcher to set criteria that differentiates between the sites or participants, increasing the chance of different perspectives being identified and therefore increasing the richness of the data (Creswell 2007; Patton 1990). Although the researcher makes the decisions about sampling early in research design, this process should be as objective as possible to ensure rigor in sampling selection and a representative sample is identified (Ritchie et al. 2013).

The researcher wanted to differentiate between the groups and settings and so maximum variation sampling was used in the identification of the patients, carers and health professionals. In order to capture experiences from different areas, patients and carers were recruited from the acute admission on a combined acute and rehabilitation stroke unit and a rehabilitation stroke unit. To be able to explore the views and experiences of the health professionals, from different disciplines, who provide care to stroke patients, a focus group from the combined acute and rehabilitation stroke unit and a focus group from the rehabilitation stroke unit were convened. The clinical and academic experts in oral health and stroke were identified using snowball sampling. Snowball sampling is another strategy used in purposive sampling, and identifies potential participants through one or two key personnel. The researcher uses the key personnel to identify or contact other possible participants who are not known to the researcher and who fulfil the inclusion criteria (Creswell 2007). This strategy is useful in accessing groups that are not known to the researcher, or are difficult to access due to the nature of the topic of inquiry (Kaplan et al. 1987).

4.2.2 Data collection

In qualitative research several data collection methods can be used to gather the information required to answer the research question. These methods are: observation, one to one interviews (structured, semi-structured or unstructured), group interviews (focus groups) or documentary evidence. Using multiple data collection methods is advised because this helps create a more comprehensive study, which completely describes the whole experience, not only the participants' thoughts and feelings but that of the social world (Sandelowski 2009). However, due to time constraints in the programme of study, one-to-one and focus group interviews were the data collections methods used to gain as wide of knowledge as possible of the experiences of others (Neergaard et al. 2009; Sandelowski 2000).

One-to-one interviews

One-to-one interviews are a method of gathering information and knowledge that explain people's views, experiences and thoughts of a particular phenomenon in the lived world (Kvale and Brinkmann 2008). Interviews can either be in-depth, exploring a person's most lived experiences of a phenomenon; semi-structured, exploring a person's experiences through open ended questions, probing for more information; or structured where the questions are often closed (Ritchie and Lewis 2003). Semi-structured interviews are a combination of both structured and unstructured interviews, allowing the researcher to explore a specific topic using a spine (list) of questions to guide the interview. If the researcher has a set topic they wish to explore this is an ideal approach; it allows the researcher to explore the specific topic, gaining the participants' views, and at the same time ensuring all the issues are explored to answer the research question (Silverman 2010).

However, with all methods the researcher has to be mindful of areas where bias can be introduced and should attempt to ensure that objectivity is maintained at all times as far as is possible (Silverman 2010; Nunkoosing 2005). Qualitative interviews are dependent upon interaction between the interviewer and interviewee and the data production is dependent upon the interviewer's skill (Kvale and Brinkmann 2008). The relationship between the interviewer and interviewee should be equal, where the interviewer is the expert exploring the topic and the interviewee is the expert with topic knowledge and experience. Maintaining this balance is

important and neither the interviewer nor interviewee should overpower the other (Nunkoosing 2005). Often the researcher is described as being part of the research and their own views and ontological position (their nature of being) are taken into account (Ritchie and Lewis 2003). One of the main aims of qualitative research is to gather the "truth" of a person's experiences. When recounting experiences from memory the "truth" can become distorted and change so it can be difficult for the researcher to know if the "truth" has been expressed.

> *"Truth should be termed as authentic at that time as the person themselves believe that was the "truth" at that time point."*
>
> (Nunkoosing 2005)

One-to-one semi-structured interviews were chosen as the best method to capture the patients' and carers' thoughts and feelings, providing a safe environment and privacy for participants to communicate their thoughts and feelings at their pace and ability. Focus groups were not chosen for patients and carers because it was felt participants may feel exposed and vulnerable due to their physical, concentration and communication problems. Patients may feel embarrassed about their situation making participation in a group difficult, preventing dialogue and discussion of their personal views. Focus groups could therefore make participants feel isolated and have a negative impact on them.

Semi-structured interviews were also chosen as the method of data collection for academic and clinical experts in oral health and stroke. This was because the dental and stroke experts were recruited from around the country and there were no resources available to arrange a focus group and bring the participants together. Semi-structured interviews could therefore take place either face-to-face or over the telephone and enable the researcher to capture the information required.

Group interviews – focus group

With group interviews (ideally about 6-10 people) the individuals all have a shared experience and they come together to discuss a particular phenomenon (King and Horrocks 2010; Morgan 1997). A focus group creates discussion between the participants and allows each participant to clarify their views, review their position on the topic and amend their position throughout (King and Horrocks 2010). Focus groups take a non-directive approach, but should be guided by a specific topic and led by the group themselves. It is normal to have a moderator who introduces the topic

for discussion, facilitates interaction between the participants and encourages discussion and expression of views. Also present is a scribe to take notes of the participants' comments and interactions (Kvale and Brinkmann 2008).

However, focus groups may not work in all situations. In some situations the participant may feel overwhelmed by the experience, or a hierarchy already exists between potential participants inhibiting dialogue and expression of views. The dynamics of the group therefore needs to be considered to ensure it is balanced, allowing all participants to feel able to take an active part. If this balance is not maintained open dialogue and exploration of the subject is reduced preventing a richness of data being collected (Happell 2007). In order to keep this balance, the researcher needs to be able to facilitate the discussion and ensure all participants feel equal within the group (Happell 2007).

Focus groups were chosen to collect the views of health professionals working in stroke units because the researcher was interested in the health professionals' views of oral health and oral care. A focus group would enable the researcher to explore how oral care is viewed as a team and how each professional group (e.g. nurse, physiotherapist, occupational therapist) perceived their role in providing oral care, as well as observing the interaction between the professional groups. The information gathered would hopefully provide a greater understanding of the issues that stroke teams face when providing oral care, which in turn would inform the development of the oral assessment that could be used by all members of the team in clinical practice.

Interview spine

Within interpretive research the researcher guides the data collection in order to answer a specific question. Using their *a priori* knowledge and information gathered from the literature review interview spines were developed to enable information to be gathered that would help answer the research question and objectives. The interview spine was developed so as to explore each of the stakeholders groups' experiences of oral care in a hospital setting. Once the interview spine had been developed it was piloted and refined to ensure all the aspects the researcher wanted to explore were captured as well as allowing the participants to discuss their thoughts and feelings. The same interview spine would be used for each of stakeholder groups.

4.2.3 Data analysis

Transcription

All the patient and carer interviews and the focus groups were transcribed by the researcher. The expert interviews were transcribed by an independent transcriber working for the university. All interviews and focus groups were transcribed verbatim and were then checked by the researcher for accuracy. Field notes were also kept to aid in the analysis process. Intonations, such as laughing, crying or the participants being upset, were recorded alongside the dialogue in brackets. All names or identifiers were removed and replaced with an alternative, for example their role (DR) or a title (Mr X). This was to maintain data protection and confidentiality.

The participants who took part in an interview were asked if they wanted to receive a copy of the transcript to check its accuracy. Those participants who took part in the focus group were offered a copy of the key issues rather than the whole transcript to maintain confidentiality and anonymity. All participants who requested a copy of the transcript or the key issues were asked to send any comments back to the researcher within four weeks of receiving the transcriptions/key issues. Once all transcripts had been checked for accuracy they were loaded into ATLAS ti and analysed using Framework Analysis, as described on page 98.

Validity and reliability

Validity

Ensuring validity and trustworthiness of the final results is as important for qualitative research as it is for quantitative research (Mays and Pope 1995). Creswell (2007) describes eight strategies for validation that can be employed by researchers to ensure their results are accurate and it is recommended that at least two of these strategies should be used. Not all strategies will be used by every researcher. The strategies are: prolonged engagement and persistent observation, negative case analysis, rich, thick description, external audits, triangulation, member checking, peer review or debriefing, and clarifying researcher bias.

Triangulation involves the researcher using different evidence to support the choice of code from different sources so triangulates the evidence with what has been found. Although the researcher did not actively use this approach their *a priori* knowledge and literature research may have provided some triangulation in the interpretation of the results. Member checking is another

form of validation, which involves the researcher going back to the participants with a summary of the findings for them to confirm if they are accurate. Each participant was invited to clarify if the transcript was a true reflection of the interview. Member checking was also used later in Chapter Six when an expert panel consisting of representatives from each of the stakeholder groups (academic and clinical experts in oral health and stroke, health professionals, patients, carers) were presented with the results to aid the development of a new oral assessment. At this point content validity was assessed.

Validation methods used for the qualitative interviews were peer review or debriefing and clarification of researcher bias. Peer review or debriefing involves an external check of the research process. The process involves the external reviewer asking the researcher questions around the meaning and interpretation of their research with the aim to keep the researcher honest. Notes of the session should also be kept. Peer review or debriefing was provided through the researcher's supervision meetings and interaction with other experienced researchers. The second method of validation was clarification of researcher bias. Researcher bias should be set out from the start of the study and should be documented so that it is clear to the reader the researchers own position, describing any biases or assumptions that may impact the inquiry. This has been reported on page 113.

Reliability

Reliability in the interpretation of the data and results can be achieved through different methods. Obtaining quality tape recordings, and transcriptions will add to the reliability of the data. This includes transcribing pauses, emotion, and overlaps (Silverman 2010; Creswell 2007). To ensure reliability of the findings a second reviewer would be used to analyse a sample of transcripts following the same process as the researcher. The researcher and second reviewer would analyse 20% of the scripts coming together to discuss their findings and decide upon common themes. This process ensures the outcome is what other researchers would find.

4.2.4 Analysis methodology

The research question in this study was to examine the stakeholder's group's views and experiences of oral care with a particular focus on oral assessment in a hospitalised setting. In order to answer this question it is important that the analysis is able to answer the research question (Hsieh and Shannon 2005). In qualitative research the analysis process involves

understanding of the data through immersion of the texts, synthesising the meaning, theorising the relationship and presenting the data in a meaningful manner (Morse 1990). This analysis process can follow varying formats. In those studies where ethnographic, narrative or phenomenological methodology is used to explore language and how it is used in social interaction, narrative, conversation analysis or discourse analysis may be used. These forms of analysis examine the structure of words and language in relation to an event (Holloway and Wheeler 2002). Other methodologies such as grounded theory focus on developing theory from open coding using a constant comparative approach. This allows saturation of the categories or themes identified and aims to tell a story through connecting the themes together ultimately developing theory (Creswell 2007). Many of these analysis approaches are closely linked to specific methodologies and are underpinned by philosophical ideas that shape the analysis process (Gale et al. 2013).

Interpretive description can use a range of analytical approaches available in qualitative research (Thorne et al. 2008) with the aim of answering the research question. A thematic or content analysis format was chosen to search for patterns to develop theory. Data collection methods (interview spine) were developed using a deductive approach because the literature and the researcher's *a priori* knowledge were involved in forming the semi structured questions. The questions were also designed using an inductive approach to allow emergence of new themes through the participants telling their story. It was therefore important to choose an analysis method that would be versatile in allowing both inductive and deductive analytical methods. Approaches such as narrative, constant comparative, and discourse analysis only use an inductive approach so would not be appropriate in this piece of research. Another approach Framework analysis was chosen. This is a systematic approach which is flexible and can be adapted to many qualitative approaches with an aim to generate themes (Gale et al. 2013). Framework analysis identifies commonalities and differences in qualitative data and can be used both inductively and deductively (Gale et al. 2013). The timeframe for completing this research was also an issue and often with inductive analysis time is required to allow the researcher the ability to fully immerse themselves in the data. Framework analysis allowed the researcher to use this systematic approach to maintain rigor of the research in the constricted time period available (Gale et al. 2013). The researcher was using an inductive approach to discover what issues were important in oral care that related to assessment of oral health. As with any qualitative analysis there are limitations and a risk of bias. It is essential that the researcher maintains reflexivity throughout.

Framework analysis uses an approach where the data is placed in a matrix format using spreadsheets and there is the risk that inexperienced researchers may feel the need to quantify the information rather than describe the commonalities and difference between different participants (Gale et al. 2013).

Framework analysis

Framework analysis was initially developed in applied social policy research, which investigates the views of those who would be affected by new policy (Ritchie and Spencer 1994). Social policy research sets out to answer a specific question for a chosen population, within a set timeframe, using *a priori* knowledge (Srivastava and Thomson 2009). In applied social policy the researcher is interested in gaining some insight and explanation of the population's social world under investigation and using this information to drive social policy (Srivastava and Thomson 2009). Although this method was originally developed for social policy research it has more recently been used in health research to explore the views of those receiving and/or providing the care under investigation, and to inform the development of care protocols and guidelines (Srivastava and Thomson 2009; Ritchie and Lewis 2003).

Ritchie and Spencer (1994), reported that framework analysis is grounded in the original data, open to change or amendment and has a systematic process allowing full review of the data collected. The approach allows easy retrieval of the original data between and within case analysis, is accessible to others, and the researcher is able to move forwards and backwards through the data, allowing change and addition. The analysis process is a systematic approach of sifting, sorting and charting a wealth of data into key issues and themes. When using framework analysis you can analyse different groups' views and experiences either together as one large group or as individual groups. In the case of this study the groups were analysed separately to identify the different themes and issues specific to that group.

Framework analysis is broken down into five stages Figure 4-1:

- Familiarization;
- Identifying a thematic framework;
- Indexing;
- Charting;
- Mapping and interpretation.

Familiarisation

Familiarisation is the first step of the analysis process. The researcher reads each transcription making observational notes down the side of the transcript, becoming immersed in the data. This first stage enables the researcher, who has been involved in the data collection and who had probably made some observations, to gain a feel for the whole of the information gathered. The initial notes are crucial, because they form the basis of the next stage, identifying a thematic framework. Familiarisation is repeated a couple of times before the researcher becomes fully acquainted with the content.

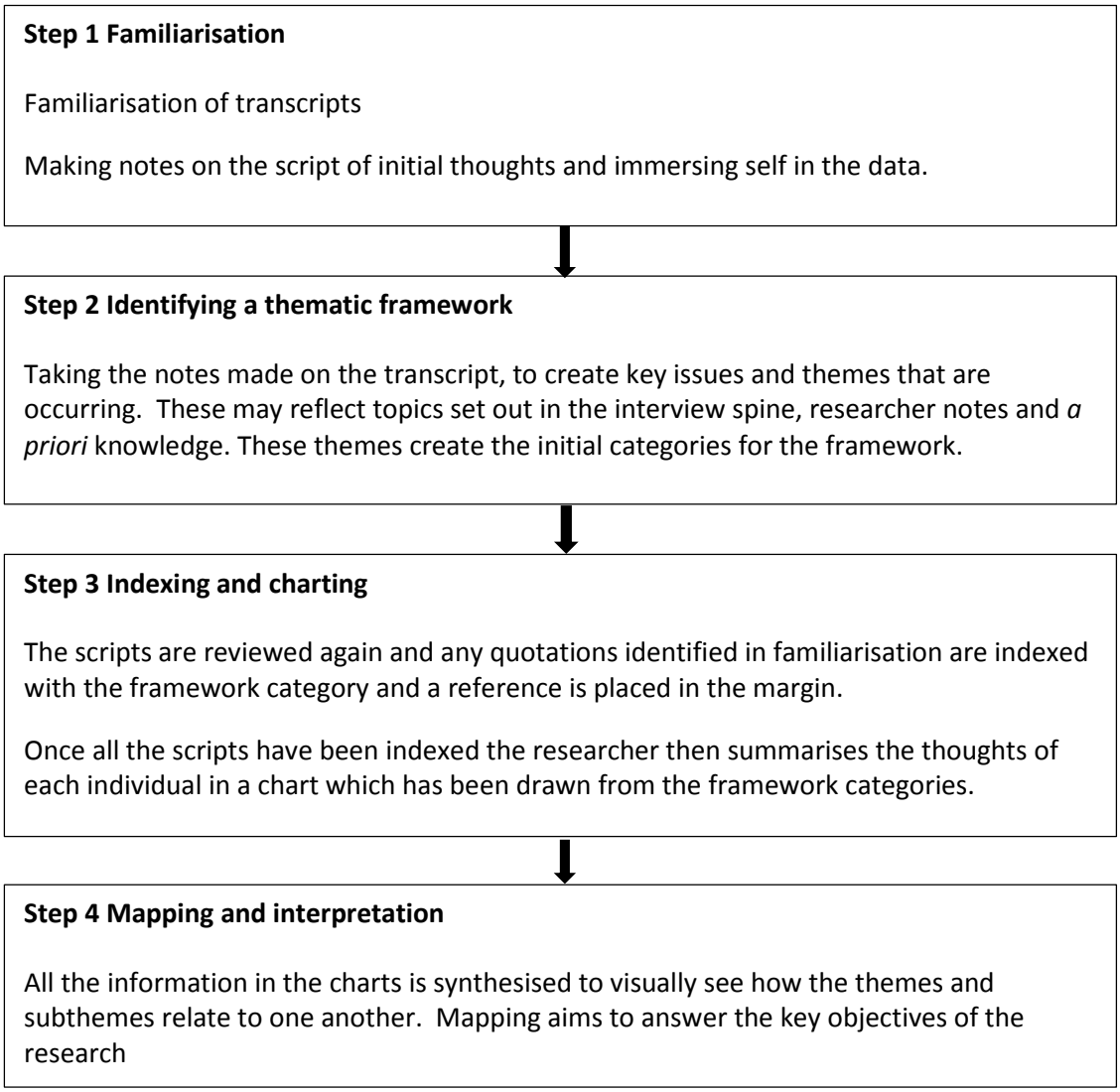


Figure 4-1 Framework analysis process

Identifying a thematic framework

Step two involves identifying a thematic framework. In this next stage, the researcher is beginning the process of conceptualisation, formulating concepts. The notes made in the margin in the familiarisation stage are used to identify key issues and themes that may be emerging. These key themes are then used to create the categories of the Framework. When constructing the Framework, the researcher uses a combination of their *a priori* knowledge, emerging issues from the transcripts and any themes that appear to be emerging across the respondent's experiences (Figure 4-2). Often, the first framework can be described as descriptive and disjointed, but it becomes refined throughout the process of analysing each transcript (Ritchie and Spencer 1994). In this conceptualisation phase, Ritchie and Spencer (1994) describe the researcher as:

> *"Using logical and intuitive thinking; making judgements about meanings and experiences; and showing how these meanings and experiences may relate with one another throughout the process."*

The categories emerging may reflect the topics set out in the semi-structured interview spine, researcher's notes and the responses made by the participants. This new information is critical in contributing to new knowledge. In order to ensure validity and reliability a sample of the scripts were independently reviewed by a second reviewer. The researcher and the reviewer then came together to discuss the developing themes they had identified. A core theme was then created that both reviewers agreed upon.

Interview spine	**Transcripts**	**Research Notes**
Demographic information Prior knowledge Importance Telling the story (Process) Process Evaluation of care process: In hindsight	Themes occurring following familiarisation of the respondent's response	Information noted post interview or focus group

BOX 3 Framework (Index) categories

Theme 1	**Theme 2**	**Theme 3**
1.1 Sub theme	2.1 Sub theme	3.1 Sub theme
1.2 Sub theme	2.2 Sub theme	3.2 Sub theme
1.3 Sub theme	2.3 Sub theme	3.3 Sub theme
	2.4 Sub theme	

Figure 4-2 Development of the framework

Indexing and charting

Step three is indexing and charting. In this stage the newly developed framework is systematically applied to the data. The researcher goes back through each transcript, indexing each quotation (section of text) and allocating it to a specific theme (category) in the framework. A reference to mark the quotation with the theme would be placed in the margin. In this study, the data were initially indexed in ATLAS ti (Friese 2013). Once indexing has been completed, charting can begin.

Charting allows abstraction and synthesis of the data. This allows the researcher to view any associations and relationships that may be occurring within and between the partner groups. In charting, the researcher reviews each section of indexed text and summarizes the experiences and thoughts of the individual into the chart. Each summary is then given a reference to catalogue which part of the original text the summary relates (Table 4-1). Depending on the research, several major subject charts may be developed. The charts have headings and sub-headings that are drawn from the framework, *a priori* knowledge, or from how the research will be written up

(Ritchie and Spencer 1994). Charting can be carried out in two ways: using a thematic approach (themes across all respondents); or by case (each respondent across all the themes). For the purpose of this thesis a thematic approach was used for each group.

Table 4-1 Example of charting using Framework categories

	Theme/Category				
Participant	**Sub category 1**	**Sub category 2**	**Sub category 3**	**Sub category 4**	**Sub category 5**
P1	Summary of the quotation plus index reference (P1:100)	Summary of the quotation plus index reference (P1:290)	Summary of the quotation plus index reference (P1:40)		
P2	Summary of the quotation plus index reference (P2:40)		Summary of the quotation plus index reference (P2:89)		Summary of the quotation plus index reference (P2:4)

Mapping and interpretation

Step four is mapping and interpretation. This stage brings all the key themes and characteristics together in order to map out and interpret the data as a whole.

Mapping provides a visual view of how the themes and sub themes relate to one another and aid interpretation of the data and the phenomenon under study. In mapping, the researcher returns to the key objectives of qualitative research in order to interpret the data to seek patterns and associations, and to provide explanations as to why these patterns and associations may exist. The key objectives of qualitative research that may be explored are:

> *"Defining concepts; mapping the range and nature of the phenomena; creating typologies; finding associations; providing explanation; developing strategies."*
>
> (Ritchie and Spencer 1994).

The researcher may attempt to answer any of these objectives depending on the research question. Mapping provides an explanation of the key findings and how they relate to the research question. In this research, how the findings would contribute to the content, layout and format of an oral assessment.

4.3 Aim

To explore the views and experiences of oral care in clinical and academic experts in oral health and stroke, health professionals, patients and carers using qualitative methodology.

4.3.1 Objectives

1. Explore clinical and academic experts in oral health and stroke views and experiences of oral care in stroke patients;
2. Explore health professionals views and experiences of providing oral care to stroke patients in hospital;
3. Explore stroke patients views and experiences of oral care while in hospital;
4. Explore carers, of patients who require assistance with oral care, views and experiences of the oral care their relatives received while in hospital.

4.4 Methods

4.4.1 Design

Using a qualitative approach the views and experiences of patients, carers, clinical and academic experts in oral health and stroke and health professionals was explored using semi-structured interviews and focus groups.

4.4.2 Setting

The research took place in two Stroke Units in the North West, one a combined unit (acute and rehabilitation) and one a rehabilitation unit. Two separate settings were chosen, acute stroke care and rehabilitation care, to enable exploration of oral care experiences across the whole stroke pathway, while in hospital.

4.4.3 Ethical and Research Governance considerations

Ethical approval was sought from the local NHS Research Ethics Committee (Appendix 6) and BuSH, the University Research Ethics Committee (BUilt, Sport and Health schools) (Appendix 7). In addition, research governance approval was sought from the Research and Development departments at each hospital (Appendix 8). The supervisory team also ensured that governance was maintained throughout the study through regular supervisory meetings with the researcher.

4.5 Core methods

Core methods were used for each objective and these will be presented followed by the specific methods used for each objective. This is to prevent repetition throughout this section. The researcher performed individual interviews with the clinical and academic experts in oral health and stroke, patients and carers and facilitated two focus groups with the health professionals.

Consent

The potential participants were approached by the researcher who explained the project in more detail and answered any questions. Once the potential participant wished to take part in the research, consent was obtained. For face-to-face interviews the researcher obtained written consent before the interview took place. For telephone interviews verbal consent was obtained over the phone prior to the interview, and the participant was advised they would receive a consent form through the post to sign and return to the researcher in the prepaid envelope provided. A copy of the signed consent form was given to all the participants and the original consent form was then stored at the University of Central Lancashire. For those participants who were patients in hospital at the time of the research, a copy of the consent form was also filed in their case-notes.

Interviews and focus groups

Location/Environment

The interviews took place at a time and place that was convenient to the participant. Face-to face interviews occurred in a quiet room in the hospital or the university, and interviews over the phone were performed in a quiet room in the university. In the situation where patient participants were unable to leave their bed the interview took place by the bedside with the curtains drawn. The researcher wanted to provide an environment that would make the participants feel comfortable and at ease and able to express their thoughts and feelings. The focus groups were in a room large enough to accommodate 6-10 people comfortably and where the participants were less likely to be disturbed. Having the correct environment is important to allow both the interviewer and interviewee to feel comfortable, allowing a relationship to build quickly to enable as much rich data as possible to be collected (Silverman 2010).

Interview/focus group core principles

At the start of every interview/focus group the interviewer set out certain core principles which were to:

- Reaffirm participant consent to interview or focus group;
- Reaffirm consent to digitally recording the interview or focus group;
- Gain agreement to the interviewer taking notes throughout the interview or focus group;
- Reaffirm that the interviews or focus groups would be confidential and all names would be removed from the transcription and the transcription would only have the participants unique identifier;
- Reaffirm that the interview recordings would be treated confidentially by the researcher and research team;
- Advise the participant/s they could stop the interview or focus group at any time and they did not have to provide a reason for this;
- Advise the participant/s interviewee they could ask for the digital recorder to be stopped at any time;
- Advise the participant/s the approximate length of the interview.

Interview structure

At the start of all interviews introductions took place and the interviewer established how the participants would like to be addressed. The interviewer then confirmed the rules as set out above. Once the rules had been agreed each interview followed a similar format as set out in the interview spines developed for each group of participants (Appendices 6, 9, 10). The interviews followed a structure where the participant's prior knowledge of oral care and oral health were explored as well as their normal oral care routine. This was followed by asking the participants to describe their oral care experiences or the experiences of others. This experience could be receiving oral care, providing oral care or describing the oral care they perceived their relatives had received. The interviewer would attempt to elicit the participant's thoughts and feeling in more depth as well as asking the participants to describe what aspects hindered or improved oral care. The interviewer then asked the participants to think about one particular aspect of oral care, assessment, and explored their views regarding the importance of an oral assessment and what this assessment should measure. Finally the interview was brought to a close with a summary of

the information provided. All the participants were asked to rate their experiences of oral care and invited to add anything else they felt was important but had not been covered. All participants were asked if they wanted a copy of the transcription to check the content.

Format of focus group

For each focus group there was a facilitator and a scribe present alongside the participants. The sessions started with introductions and the facilitator described the purpose of the focus group and reconfirmed consent. The core principles were presented and agreed. Each participant was asked to introduce themselves and their grade. This not only helped describe the group but also allowed the facilitator to identify the different voices when transcribing the focus group. Using the focus group questions (Appendix 8) to guide the session the facilitator started the discussion by asking the group to describe their own prior knowledge of oral care. Following on from this discussion the group were asked about how important they viewed oral care and to describe the oral care process in their working environment and their role in the provision of oral care. The group was then asked about their views regarding oral assessments and what the content of an oral assessment should be. The focus group was brought to a conclusion through the facilitator summarising the group's thoughts and feelings. All participants were asked if they wished a copy of the summary of the focus group. Throughout the focus group the facilitator attempted to involve all participants encouraging rich discussion.

Equipment/software

All interviews and focus groups were digitally recorded. The interviews and focus groups were then transcribed and analysed using an appropriate qualitative software package, ATLAS ti (Friese 2013).

4.5.1 Objective One

To explore the views and experiences of clinical and academic experts in oral health and stroke on oral care in stroke patients

Sample

A heterogeneous purposive sample of clinical and academic experts in oral health and stroke were recruited. The sample were identified using a snowball technique (as described in section 4.2.1),

where the researcher and their supervisory team identified initial possible participants through networking and known contacts. (Figure 4-3)

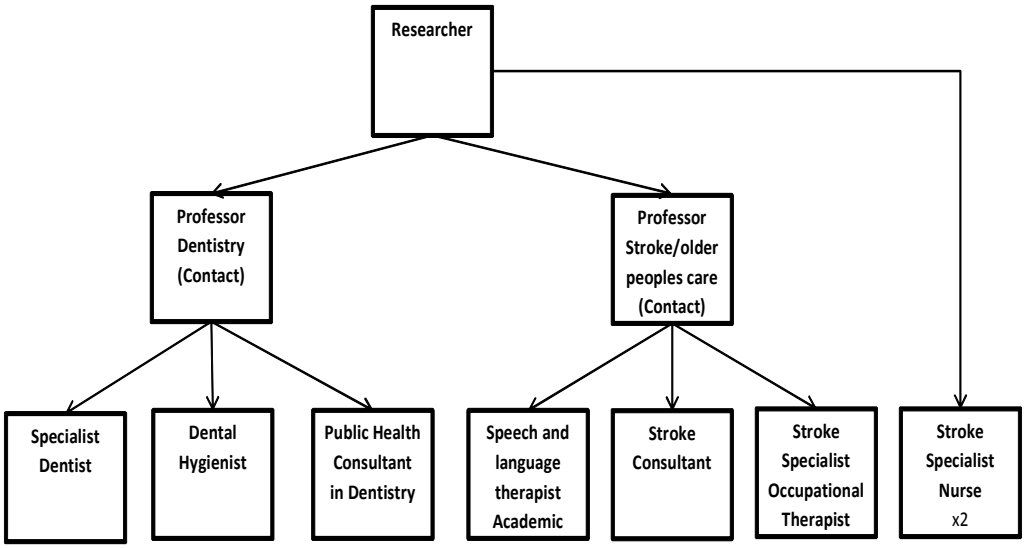


Figure 4-3 Flow chart of expert sampling

Expert Inclusion Criteria:

Clinical or academic experts in stroke care and or oral health.

Procedure

Potential participants were contacted by the researcher, via a letter or email, and were invited to take part in the research. The consent process was undertaken as per the consent section on page 104. Once consent had been obtained the researcher identified whether the interview would be face to face or over the telephone and arranged the interviews at a time (and place if face-to-face) suitable to the participant. The interviews followed the format described in section 4.5 using an interview spine (Appendix 9). At the start of all the interviews the participant was asked to describe their job, role (e.g. academic, clinical) and background (e.g. stroke, dental).

4.5.2 Objective Two

To explore health professionals views and experiences of providing oral care in stroke patients.

Sample

Two focus groups were facilitated with health professionals were recruited from two sites, a combined stroke unit and a rehabilitation stroke unit. A focus group took place on each site and was populated from health professionals working on that unit. The health professionals were randomly selected using a sampling frame (Appendix 10). This was to avoid bias selection by the researcher or the health service managers. Using Excel the sampling frame was populated with the health professional's grade (e.g. band 5) and job role (e.g. Nurse, Occupational Therapist).

Randomisation process

The names of all the health professionals were entered into a list in Excel (column A). In the cell adjacent to each person the following formula was entered: "RND ()" (column B). This gave a random number (between 0 and 1) for each potential participant. The random numbers were then cut and moved into an adjacent empty cell. These numbers were then copied back into column B using the 'paste special', 'values' options. Within each role and band a sort was performed on the copied random number values. The potential participants with the lowest value were invited to take part in the focus group. If they did not wish to take part the next number was contacted and invited to take part.

Inclusion criteria

- Nurses, physiotherapist, speech and language therapist and occupational therapist of all grades working on the stroke unit in each chosen site.

Procedure

The ward manager contacted all members of staff informing them about the possibility that they may be contacted by a researcher to take part in a research project exploring health professionals' views of health care. A copy of the information leaflet was also attached to the email. The researcher contacted the staff who had been selected using the sampling frame. Each potential participant was provided with an invitation to take part in the focus group alongside information explaining the purpose of the project. If the potential participant was interested in taking part the consent was obtained. A copy of the signed consent form was given to all the participants and the original consent form was then stored at the University of Central Lancashire. Both focus groups were arranged by the researcher at a time and place (within the Trust) that was convenient for all

the participants. The focus groups were then conducted following the format described on page 93, using an interview spine to guide the focus group (Appendix 11)

4.5.3 Objective Three

To explore stroke patient's views and experiences of oral care while in hospital.

Sample

A convenience sample of patients was recruited from the combined and rehabilitation stroke units.

Patient Inclusion Criteria:

- Aged 18 years and above;
- Admitted to a stroke unit with a diagnosis of stroke;
- Able to participate in an interview; (patients with expressive communication problems could participate if able to make their wishes known)
- Those who required some assistance with oral care.

Patient Exclusion Criteria:

Medically unstable (as judged by the clinical team);
Unable to consent for themselves (as judged by the clinical team).

Procedure

Potential participants were screened by the clinical team to establish if they met the inclusion criteria. A member of the clinical team (doctor, registered nurse, or therapist) used their clinical judgement to decide if the patient had capacity to consent. A member of the clinical team explained to the potential participant that a research project was taking place and provided them with an information leaflet and that taking part was voluntary. Potential participants were advised to inform the clinical team if they were interested in taking part. Those expressing an interest in taking part in the study were introduced to the researcher by the clinical team. The researcher then arranged to meet the potential participant to further explain the project and answer any questions. During this meeting the researcher identified if the participant was able to provide informed consent by ensuring they fully understood the research project, what it involved, that it

was voluntary and that they could withdraw consent at any time without it affecting patient care. Potential participants were given at least 24 hours to consider the project. Once verbal consent had been given the researcher obtained written consent before any interviews took place. A copy of the signed consent form was given to all the participants as per the process described on page 104. Once consent had been obtained, a semi-structured interview, using an interview spine (Appendix 12), took place at a time and place that was suitable to each participant (as described in section 4.5).

4.5.4 Objective four

To explore carers, of patients who require assistance with oral care, views and experiences of the oral care their relatives received while in hospital.

Sample

A convenience sample of carers was recruited from the combined and rehabilitation stroke units.

Carer Inclusion criteria:

Carer/relative for a patient who has cognitive and/or communication problems and who:

- Has a confirmed diagnosis of stroke;
- Requires assistance with oral care.

The carer has to be:

- Aged 18 years and over.

Carer exclusion criteria:

- Carers unable to participate in an interview;
- Carers unable to provide informed consent.

Procedure

A member of the clinical team approached the potential participants and explained the research project, providing them with an information leaflet and that taking part was voluntary and would not affect their relatives care. If the potential participant was interested in taking part, they were

introduced to the researcher by a member of the clinical team. The researcher would then arrange to meet the potential participant to explain the project and answer any questions. During this meeting the researcher identified if the participant was able to provide informed consent by ensuring they fully understood the research project, what it involved, that it was voluntary and the potential participant could withdraw consent at any time without it affecting their relatives care. Potential participants were given at least 24 hours to consider the project. Once verbal consent had been given the researcher followed the process outlined on page 104. Once consent had been obtained, a semi-structured-structured interview took place at a time and place that was suitable to each participant, as described in section 4.5, using an interview spine (Appendix 13). Minimum data relating to the patients was collected: their dentition, severity of stroke using the Oxford classification for stroke (Bamford et al. 1991). Total anterior circulation stroke were classed as severe and partial anterior circulation strokes were classed as moderate.

4.6 Summary

This chapter has outlined the methodology chosen to underpin study two. A description of the study aims and objectives have been provided alongside the study methods for collecting and analysing the data. The findings from the study will be presented in Chapter Five. Exploring the views and experiences of all the "experts" in the field is essential in the development of a new assessment to ensure the assessment is relevant to the population of choice, measures what is required and is usable in the clinical setting.

Chapter Five

Exploring the views and experiences of the stakeholders: The results

Chapter 5: Exploring the views and experiences of the "experts" in the field: The results.

5.1 Introduction

Chapter Four provided an outline of the methodology used to underpin the qualitative interviews and focus groups, and the methods used for data collection and analysis. This chapter will present the analysis process and the findings from the interviews and focus groups, starting with describing the researcher's background and *a priori* knowledge. Traditional qualitative findings are presented with a summary of the participant's demographic information (age, sex, medical information) followed by a summary of all the participant's data and this is what will be presented here. However, with this form of reporting the sense of who the participants are and their experiences are lost (Kvale and Brinkmann 2008). The reader is not able to make a mental picture of who this person is and why the issue is of importance to them. It has been suggested that at the reporting stage the subjects existing stories have:

"Been butchered into atomistic quotes and isolated variables."

(Kvale and Brinkmann 2008 p269).

Although the former quote appears harsh, the results can appear quite cold and impersonal and do not provide the reader with a picture of those they are representing. The identity of the person is lost and little credit is given to the information provided by the participants, and to the time they have allocated to being part of the research. In order to provide the participants with some identity their particular thoughts and feelings are presented in the charts (Appendix 14-Appendix 40). This format will hopefully provide a snap shot of the person, the interview, and people's thoughts and feelings. This allows the participants to retain their identity and not be lost in the coldness of analysis (King and Horrocks 2010).

At the same time, when presenting qualitative data it is important that the individuals are represented without affecting their anonymity. Therefore, the researcher has to make every

attempt to ensure anonymity is maintained when bringing people's experiences to a wider audience. Each participant has therefore been given a pseudonym.

Reflexivity

In qualitative research, it is important that the researcher is reflective throughout their analysis acknowledging their own life experiences, views and standpoints in relation to the issues under investigation (Creswell 2007; Pope et al. 2000). This allows the reader to see the personal and intellectual biases the researcher may bring to the analysis and interpretation of the data.

The researcher is a registered nurse of twenty three years, who has worked clinically in elderly medicine and stroke care. As a specialist nurse in stroke care, she was involved in research, service development, and education provision. Throughout her career she has become interested in both quantitative and qualitative research with an interest to enhance patient care and experiences. Her research interests to date have included oral care of all patients but especially stroke patients, the psychological impact of stroke on the person and exploring stroke patients' experiences and their coping strategies (Watkins et al. 2007; Dickinson et al. 2001).

The researcher's own beliefs of their role as a nurse may also influence the research (Creswell 2007). Nurses aim to make a difference through providing evidence-based care. As a nurse, the researcher considered their role was to provide assistance where it was needed and at the same time to promote independence in self-care abilities. The researcher's interest in oral care is not only from a personal perspective, but also from a nursing perspective; promoting well-being and comfort, as well as preventing potentially avoidable complications for hospitalised patients. All too often in clinical practice the researcher would be confronted with dry and even unclean oral cavities with painful, damaged mucous membranes. During this time, the researcher felt that health professionals were ill-equipped both in the terms of their own knowledge, but also in the availability of evidence to inform provision of effective oral care (Brady and Furlanetto 2009; Brady et al. 2010). Often registered nurses prioritise other care, with oral care being left for the unregistered staff to attend to (Wardh et al. 2000). As part of their ongoing development, the researcher had to perform a small piece of research for their Master's thesis. As a clinician the researcher was frustrated about the lack of evidence to support the oral care that nurses provide and wanted to compare two cleaning agents with a view to improving oral care. At the developmental stage of the research it was apparent that there was not a suitable outcome

measure that would reflect the effects of the intervention. The researchers focus therefore changed to developing an oral assessment that was specific to nursing and could assess changes in the oral cavity (Dickinson et al. 2001). However, this was only a small study and did not fully investigate all the aspects of assessment development.

The researcher has had more experience of quantitative than qualitative research but they have performed semi-structured interviews and focus groups in the past. The researcher has a strong view that to thoroughly explore care/practice issues within nursing both quantitative and qualitative research is required to gain a full understanding. For this particular piece of research the researcher was aware that their own beliefs and thoughts regarding oral care, both personally and professionally, were to be acknowledged during the research. Oral health is very important to the researcher who considers that having a fresh, clean oral cavity is important. They believe that to maintain oral health a routine of cleaning teeth twice a day, flossing and visiting the dentist 6 monthly for routine oral health checks is essential. This belief and point of view has potentially influenced the researcher's own professional practices with regard to providing oral care for others. Throughout the research, the researcher was very aware of these and every attempt was made to analyse the scripts without bringing these biases in.

This chapter will present the findings for each stakeholder group (objectives 1-4). The findings will be presented in the order as presented below using descriptive text:

1. Explore clinical and academic experts in oral health and stroke views and experiences of oral care in stroke patients;
2. Explore health professionals views and experiences of providing oral care to stroke patients in hospital;
3. Explore stroke patients views and experiences of oral care while in hospital;
4. Explore carers, of patients who require assistance with oral care, views and experiences of the oral care their relatives received while in hospital.

Due to the extensive amount of data generated for each objective the charts will be presented in the Appendix and summaries of the main themes and sub-themes identified through charting (step 3) will be presented with some examples of quotations from the raw data. The final stage of interpretation will then be presented using a visual map description of how the map was created (step 4).

5.2 Results

5.2.1 Objective one: To explore the clinical and academic experts in oral health and stroke views and experiences of oral care in stroke patients

Eight clinical and academic experts in oral health and stroke were recruited via a snowball sampling technique (as described in section 4.2.1, page 90). Two were experts in oral health, four were experts in stroke care, and two had expertise in stroke and/or oral health (Table 5-1). Although the clinical and academic experts in oral health and stroke were from varying professional backgrounds their views were very similar.

Table 5-1 Characteristics of the clinical and academic experts in oral health and stroke

Name	Field of expertise	Years of experience	Special interest
Wendy	Dental consultant in public health developing dental services	20	stroke patients in institutionalised care access to dental services
Pam	Dental hygienist Working in private and NHS services	15	Older peoples oral health in institutionalised care
Claire	Registered Nurse Stroke specialist Nurse	22	Stroke
Ruth	Registered Nurse Stroke specialist Nurse	16	Stroke
Robina	Occupational therapist in stroke care	28 (14 in Stroke)	Stroke
Robert	Geriatrician Stroke physician	35 (15 in Stroke)	Stroke
Emma	Speech and language therapist Director of research	15	Stroke and oral health
June	Registered consultant dentist in specialist care	30	Specialist dentistry

Familiarisation – Step1

Each transcript was uploaded to Atlas ti and read several times. Initial notes and comments were annotated in the review pane (margin) (Figure 5-1). This process was also completed by a second reviewer for several transcripts from each group. Once the scripts had been reviewed and the researcher and reviewer had immersed themselves into the data they met to discuss their initial ideas. Both the researcher and the reviewer were making the same or similar comments and so where they had used different descriptors a discussion took place as to the "truth value" that accurately presents the participant's perspective.

Line	Interview with Expert 1	Initial notes
112	I How would you rate the importance of oral hygiene or mouth care?	
113	R I'd rate it very high, and that's only be, now the main reason behind that is **I'm quite obsessive with my own mouth and teeth,** and it drives me absolutely mental if I've not brushed them for several hours	Own preferences
116	I Mmm.	
117	R Erm, so, and I think it's quite high, because when you see the patients with it caked on, **and even you can only take a couple of hours to do that especially on oxygen**, it would drive the patient mad, and that's why I think it's quite high	Contributing factor
118	I Mmm.	
119	R I**t would drive me mad, it's one of my obsessions.**	Own preferences
120	I Right so, so for you it's very important?	
121	R Yeah	
123	I So how important do you think it is for a hospitalised patients?	
124	R **I think, I think I think it's definitely top, one of the top priorities, but erm. I'm not sure what other nurses think on an acute busy medical ward…**	Priority
125	I right okay	
126	R stroke unit, but I think it's a **high priority**, and it's part of **what you do, it's not something that you go in and do differently, it's part of you know the general thing that you do with a patient when you're with them**	Part of the nurses role

Figure 5-1 Step 1 - An example of familiarisation of a transcript

Development of thematic framework – Step 2

Themes and sub-themes were developed from the discussions regarding the initial coding creating the thematic framework. For pragmatic reasons the second reviewer was not available to read all the scripts, when a new idea was found by the first reviewer the second reviewer would be asked to repeat the above process to ensure the findings of the first reviewer accurately reflected the participants perspective. Following familiarisation and the development of the thematic

framework, 7 main themes were identified as follows: Attitude to oral health; Oral care received while in hospital; Factors affecting the oral cavity and oral care in hospital; Impact on the patient and carer; Facilitators; Assessment content and Assessment format. Within each theme was several sub themes (Figure 5-2).

Framework (Index)	
Attitude to oral health	**Impact on the patient**
1.1 Medical importance	4.1 Well-being
1.2 Importance of oral care	4.2 Physical
1.3 Own beliefs	4.3 Assessing impact
1.4 Nursing importance	**Facilitators to oral care**
1.5 Importance to the patient	5.1 Correct resources
Oral care received while in hospital	5.2 Frequency
2.1 The provider of oral care	5.3 Oral care process
2.2 Oral assessment	5.4 Assessing individual need
2.3 Frequency of care	5.5 Multi-disciplinary
2.4 Oral care process	5.6 Knowledge
Factors affecting the oral cavity and oral care while in hospital	5.7 Interventions
3.1 Patients own beliefs and motivation	**Assessing content**
3.2 Ability	6.1 Ability
3.3 Patient factors	6.2 Assessment of need
3.4 Staff's knowledge/attitude	6.3 Areas within the oral cavity
3.5 Priority of care	6.4 Scoring
3.6 Oral care process	**Assessment format**
3.7 Multi-disciplinary	7.1 Layout
3.8 Organisational factors	7.2 Length
3.9 Resources	7.3 Implementation
3.10 Medical factor	7.4 Evaluation
3.11 Physical and cognitive changes caused by the stroke	

Figure 5-2 Step 2 – The development of the thematic framework

The framework themes were then used to index the quotations already highlighted on the script (Figure 5-3). A number was given to show who the participant was and what line of the transcript the quotation was on. Each quotation was indexed with a framework theme and sub theme if this had not already been given from the initial analysis. Seven charts were then developed in Excel

using a thematic approach where each participant was charted across the theme. Each annotation was then synthesised and summarised in the chart (Figure 5-4).

Line	Interview with Expert 1	Initial notes	Indexing
112	I How would you rate the importance of oral hygiene or mouth care?		
113	R I'd rate it very high, and that's only be, now the main reason behind that is **I'm quite obsessive with my own mouth and teeth,** and it drives me absolutely mental if I've not brushed them for several hours	Own preferences	1.3 Own Beliefs (E1, 113)
116	I Mmm		
117	R Erm, so, and I think it's quite high, because when you see the patients with it caked on, **and even you can only take a couple of hours to do that especially on oxygen**, it would drive the patient mad, and that's why I think it's quite high	Contributing factor	1.1 Medical Importance (E1, 117)
118	I Mmm.		
119	R I**t would drive me mad, it's one of my obsessions.**	Own preferences	1.3 Own beliefs (E1, 119)
120	I Right so, so for you it's very important?		
121	R Yeah		
123	I So how important do you think it is for a hospitalised patients?		
124	R **I think, I think I think it's definitely top, one of the top priorities, but erm I'm not sure what other nurses think on an acute busy medical ward…**	Priority	1.4, Nursing importance 3.5 High priority (E1, 124)
125	I right okay		
126	R stroke unit, but I think it's a **high priority**, and it's part of **what you do, it's not something that you go in and do differently, it's part of you know the general thing that you do with a patient when you're with them**	Part of the nurses role	1.4 nursing importance 2.1 Provider of own care

Figure 5-3 Step 2 - An example of indexing of a transcript

Chart 1 Attitude to oral health					
	1.1 Medical importance	**1.2 Importance of oral care**	**1.3 Own beliefs**	**1.4 Nursing importance**	**1.5 Importance for patients**
Wendy	Oral care is important due to the risk of dental disease (E2:40)	Important for the health of the mouth (E2:58)	Clean teeth regularly, remove dentures to clean them and use fluoride toothpaste.(E2:52)		
Pam	Important because can prevent other medical complications (E5:423)		Not cleaning teeth is a foreign concept (E5:203) Important aesthetically (E5:438-441)		
Claire	Some patients are at greater risk of medical complications due to treatments such as oxygen (E1:117)	Oral care should occur across the whole pathway (E1:112)	Obsessive about own oral health (E1:113)	Should be part of everyday nursing care (E1:119)	
Ruth	Preventing complications (E6:115)			Nurses knowledge of oral care and techniques (E6:115) Part of the nurse's role (E6:430)	
Robina	Important to care for the gums and teeth to enable effective communication and allow adequate nutrition (E3:45)	An important everyday function (E3:165)			

Figure 5-4 Step 3- An example of charting; (E2:58) = Index link to direct quote

Charting – Step 3

The information gathered from the charts is presented below for each category with a copy of the charts in the appendix for the reader to see the summary of the participant's responses. Only those examples from the charts that best describe the ideas will be presented using the original quotations rather than the summary in the chart.

Attitude to oral health (Appendix 14).

During the interviews the importance of oral care was explored and this was influenced by peoples own attitudes and beliefs about oral care. Five sub themes emerged, the importance of oral care in preventing medical complication; the importance of oral care in general; the person's own beliefs about oral care; the importance from a nursing perspective and importance to the patient. These will be summarised and annotated with quotes from the participants below.

Medical importance, such as preventing oral disease and potential systemic infections, was discussed by all the group. Maintaining oral care and oral health was viewed as essential in preventing other diseases and causing ill health.

> *"So important because so much can be prevented if you get the oral hygiene right." (Pam, dental hygienist)*

Oral care was viewed as important to maintain the health of the oral cavity and that it was an important every day function.

> *"It is really important for the health of the mouth and the soft tissues" (Wendy, Public health dentist)*

Many had their own personal beliefs about oral care and this appeared to be linked to their professional role.

> *"It's the maintenance of regular oral health, brushing teeth twice a day at least…caries free and absence of pain and adequate function." (June, Dentist)*

Oral care was viewed as an important part of the nurse's role because there would always be a need to provide oral care for certain patients.

"There are always going to be patients who need that input while they're in-patients especially if they are here for several weeks" (Ruth, Stroke specialist nurse)

The group also suggested oral care was not only important from a dental and medical perspective but also important for the person's quality of life, comfort, and well-being.

"Oral care is really important, impacts on quality of life, nutrition, systemic issues, comfort, pain and social interaction." (Emma, Stroke researcher, Speech and language therapist)

Oral care received while in hospital (Appendix 15).

Four sub themes were identified within this theme: providers of oral care; oral assessment; the frequency of oral care; and a description of the oral care process. The clinical and academic experts in oral health and stroke all agreed that it was very much the registered nurse's role to provide oral care. However, more recently oral care provision had been devolved to the health care assistants and so perhaps those who performed oral care may not have had the same training as those who traditionally attended to oral care. This potentially could have affected the quality of care received.

"I think a lot of these jobs are left to the care assistants now, because the qualified nurse's job is very much more acute, and clinical you know as in doing blood pressure, giving drugs cos of the way things are at the minute." (Claire, Stroke specialist nurse)

Some of the clinical and academic experts in oral health and stroke described oral care being the responsibility of the whole multidisciplinary team and that other members of the team have an important role in maintaining oral care.

"All disciplines yeah it's a multi-disciplinary issue really because anybody who's dealing with a patient should know how to give basic oral care. (June, Dentist)

Assessment of the oral cavity and frequency of care were discussed and seen as an integral part of the oral care process. One expert acknowledged that the nurses are performing assessments every day without realising and what they do observe or prescribe is not documented and so information observed by one nurse is not always passed on. This can ultimately affect patient care.

"Nurses are very often assessing and doing these things all the time in their day to day work. They may not always be aware of it and don't always document this but they will be aware of changes in the patients' ability to care for their own mouth and adjust their input accordingly." (Emma, Stroke researcher, Speech and language therapist)

The experts felt that standards of care within hospitals varied between wards and one expert thought oral care provision in their hospital was to a higher standard on the rehab wards compared to the acute wards.

"I think in terms of mouth care the mouth care standards are probably quite good and patients will be encouraged to wash brush their teeth and everything more so than on the acute wards" (Ruth, Stroke specialist nurse)

Factors affecting the oral cavity and oral care while in hospital (Appendix 16)

There were many factors identified that were viewed as affecting the provision of oral care in hospital. Nine sub themes were identified that affected the oral care provision: Patients own beliefs and motivation to perform oral care; patients ability to attend to oral care; difficulty accessing the oral cavity; the staff's knowledge and attitudes; priority placed upon oral care; oral care processes on the ward; the multidisciplinary team; external factors; and resources available.

The experts felt that the patient's own personal beliefs about the importance of oral care determined whether they engaged with oral care practices or asked the nurses to assist them with their oral care.

"I do accept that some people just don't bother … very low on their priorities I think it depends on … your self-esteem, your self-awareness (Pam, Dental hygienist)

The patient's own ability to attend to oral care was highlighted as affecting the health of the oral cavity. Also assumptions were made as to what a patient's ability may be.

"What ability does that person have to enable them to begin to take control of that aspect of their care" (Robina, Occupational therapist)

"Patients with even arthritic hands you know were struggling, and couldn't debride their teeth." (Wendy, Public health dentist)

Issues were raised relating to difficulty accessing the oral cavity. These included the patients not allowing access due to cognitive difficulties and positioning of the patient to allow good access to clean their teeth.

> *"If you've got a stroke victim it can sometimes be quite difficult, and sometimes patients can fight you which basically means you're less keen to sort of you know to try, but I always found that with stroke victims spitting is always quite difficult or mouth rinsing is quite difficult as well……there's the fact that actually it's quite difficult to brush somebody's teeth if their lay, if their laid on a on a bed sort of a supine position, it's very difficult to get at the right angle (Wendy, Public health dentist)*

The staff's own knowledge and skills was questioned. It was thought that many staff would report they did not have a lot of knowledge regarding oral care.

> *"I don't think they have a lot of knowledge but I do think you know if you spoke to them that they do have some knowledge." (June, Dentist)*

Several of the group also describe the lack of knowledge and the staff's attitude influenced their own beliefs regarding oral care which in turn affected the care they provided.

> *It's this thing about cleaning isn't it, I think some people that feel a bit ooh funny about cleaning dentures and we'd hope not too many but I'm sure there's bound to be some people (Ruth, Stroke specialist nurse)*

> *It's a bit personal, some people that I know staff and patients and carers don't like teeth, it's a bit like people have an aversion to eye care or you know or something like that managing somebody's eye, but there are people that find that very difficult, and find it quite unpleasant to clean somebody's dentures and teeth (Robina, Occupational therapist)*

Priority was also affected by other competing care needs and the priorities of the organisation.

> *"I think it's like so many things isn't it … where is it on the list of priorities within an organisation, where is it on the list of priorities of the nurse looking after the patient, where is it on the list of priorities for the ward manager in a particular ward who has a lot of influence on how their staff work on the unit, … and then where does the Trust sit with this in priority I'm not aware of it" (Robert, Stroke consultant)*

Several issues were raised that affected oral care. Dentures would be removed and not replaced, time affected oral care provision, and oral care was often delegated to the unregistered nurse.

> *"I think a lot of these jobs are left to the care assistants now, because the qualified nurse's job is very much more acute, and clinical you know as in doing blood pressure, giving drugs cos of the way things are at the minute." (Claire, Stroke specialist nurse)*

> *"Dentures, if dentures are taken out, they might not be put back in, and it's, and I'm not even convinced that they're actually taken out and cleaned that often." (Ruth, Stroke Specialist Nurse)*

Certain members of the multi-disciplinary team reported oral care is not seen as an essential part of their role.

> *Medical staff could do better by actually paying more attention to it … and then bringing it to the attention of nursing colleagues because I don't think the doctors spend much time thinking about it or doing anything about it. (Robert, Stroke consultant)*

Also if oral problems were identified there was a lack of communication with the professionals who were specialist in that area and if this could be improved oral health may improve for hospitalised patients.

> *"I mean it's I think it would really help the profession … you know sometimes I think the dentist and the medics are not talking to each other enough" (Pam, Dental hygienist)*

External factors that may influence whether the nurse can perform oral care were issues such as time, and workload.

> *"I think it's, it's sadly probably a time factor that there are lots of patients with high levels of need to be met, and they've all to be seen within a specific time frame." (Robina, Occupational therapist)*

Access to the correct resources and using the appropriate resources for the task was also perceived as affecting oral care provision.

> *"Also lack of support for nurses, they limited access to formal training, often don't have access to appropriate equipment." (Emma, Stroke researcher, speech and language therapist)*

Impact on the patient (Appendix 17).

The clinical and academic experts in oral health and stroke did express that oral care impacts on the patient's physical and psychological well-being. They were unable to speak on the patient's behalf and so discussed this issue in reference to their own personal and clinical experiences. Three sub themes emerged, the impact on: patient well-being; a person physically; and assessment of impact. The experts in oral health and stroke thought that having a clean and fresh oral cavity could only have a positive impact on the patient.

> *"I actually think if you've got a fresh clean mouth as well you feel better you know." (Wendy, Public health dentist)*

Having an unclean oral cavity therefore had the opposite effect.

> *"Yeah, when we all had ... a period when we have … … for whatever reason you know we are dry in the mouth or not manage to brush our teeth or for whatever reason we don't particularly like the way our mouth feels to us so it must be the same for our patients" (Robert, Stroke consultant)*

The physical consequences of the stroke may also affect the patient's ability to control food and saliva and so impact on the person's psychological well-being. The group felt that patient were self-conscious of their breath and their inability to keep saliva in the oral cavity. Other factors

such as a reduction in saliva and drying of the oral cavity could increase the risk of dental disease and systemic infections which would impact on the patient and their recovery.

> *"All about body imaging as well isn't it. Body image and how they feel psychologically." (Ruth, Stroke specialist nurse)*

> *"If people can eat and drink if the mouth care is poor then obviously that is going to cause difficulty in chewing and drinking and swallowing and they get soreness of the mouth all that's going to have an effect on … one's health, primarily through the affect that people normally eat and drink properly." (Robert, Stroke consultant)*

They identified that for some patients having an oral cavity that felt uncomfortable and dry may affect their ability to communicate. This would make it difficult to assess if there was any problems and also prevent the patent from reporting they had a problem with their oral cavity.

> *"Some of the stroke patients can't speak they may not be able to express how they feel about it they may be reluctant about something as private as mouth care but you ask for something to deal with it and they may not know something can be done about it." (Robert, Stroke consultant)*

Facilitators to oral care (Appendix 18)

To be able to consider the format and content of the oral assessment it was important to review what aspects would help to improve oral care provision. Six sub themes were identified in this theme: having the correct resources; frequency of care; oral care process; assessing individual need; multi-disciplinary; and knowledge.

Having fluoride toothpaste, the correct size toothbrush and access to other equipment could only enhance oral care.

> *"So brushing fluoride toothpaste you'd then need some sort of inter-dental cleansing….floss or brushes ideally as well." (Pam, Dental hygienist)*

Cleaning the patient's teeth twice a day was seen as the minimum frequency for care. This was also the clinical recommendations for healthy adults.

> *"Having that at least one to two hourly and along with twice daily teeth and gum brushing." (Ruth, Stroke specialist nurse)*

Actually providing oral care that would contribute to patient well-being was seen as important. Care strategies were mentioned by some of the experts because they felt that this was important.

> *"I think having every, having it as part of the rehab package or a care package would be really helpful because from what I tend to see is that … if an item of care is listed in a care pathway it tends to be seen and acted upon." (June, Dentist)*

Increasing education and knowledge; assessing the patient's individual needs with regards to cleaning the oral cavity and having a evidenced based oral care protocol with the correct resources were seen as the greatest facilitators to oral care provision.

> *"I think I think the knowledge that they need is a need to understand about how quickly it can happen, how quickly the tongue can get caked basically, because I think people think if they maybe do it once a day or twice a day that's enough probably not knowing that you go away for an hour, and especially somebody's that on oxygen, and they can come back and the mouth the mouth's a mess." (Claire, Stroke specialist nurse)*

> *"Ask the patient if there's any bad taste or bad smell because that could indicate either an early gum problem or maybe an abscess." (Pam, Dental hygienist)*

Assessment content (Appendix 19)

Many issues were raised by the group with regards to assessment. Throughout the interviews different issues relating to oral care were highlighted. Those that were seen as important and essential by the group were considered for assessment content. Four sub themes were identified: ability; assessment of need; areas within the oral cavity; and scoring; Ability was identified as an important factor that should be assessed before oral care could be prescribed or provided. Through assessing ability, the nurses would be able to identify which patients required assistance and in what capacity.

> *"Part of the assessment I think, the patient's ability to carry out their own oral hygiene is important." (Wendy, Dentist)*

As well as assessing patient's ability, other factors were deemed important in informing oral care. Assessment of normal routine, how often they clean their teeth, complication following the stroke that may affect oral care and the health of the oral cavity.

"I think it would start with an initial assessment … by gather information about that patient, normal routines, whether they have dentures or not, whether they have known dental problems……..assessing whether the patients able to participate in their own care or do it independently or whether they're going to need the nursing team to support that should be part of that initial assessment." (Ruth, Stroke specialist nurse)

When exploring what should be included in an oral assessment all the experts focused on specific areas in the oral cavity. These areas were perceived to reflect oral health and cleanliness. Areas such as teeth, gums, mucous membrane, and palate. Other factors were also thought to be important such as asking the patient how their oral cavity feels because clinical examination may infer a healthy oral cavity but the patient may feel it is uncomfortable and dry.

"I suppose initially the condition of the mouth, is there any problem with the teeth, the tongue, the lips you know their inner mouth the pallet, is there anything wrong there, so I suppose initially picking that up." (Robina, Occupational therapist)

One expert reported that they did not feel nurses should get too concerned about how they scored the problem, it was more important to identify there was a problem through taking a history or examining the oral cavity.

"I see patients and I think God they've not got a lot of saliva, does your mouth feel dry, "no" that's fine you know or they've got a really moist mouth and they say "oh my mouth's really dry" you know so I would go with what the patient says I think I would honestly keep it, big picture and basic … and that would have the biggest impact rather than getting into fine detail." (Wendy, Dentist)

Assessment format (Appendix 20)

The final category was the layout and format of the assessment. Within this category four sub themes were created: the layout; length; implementation; and evaluation. The clinical and academic experts in oral health and stroke suggested the assessment should be short in length, potentially one page of A4 and should add to care without increasing the workload. The assessment should be stroke and nursing specific, and be able to be used by registered and unregistered members of staff. The logistics of implementing the oral assessment would also have to be considered to ensure it was not onerous and could be embedded in day to day working.

"You are more likely to succeed with such a tool providing it's not going to add an enormous amount of time to peoples work … and I you can do things differently and not necessarily add to the workload." (Robert, Stroke consultant)

Overall the clinical and academic experts in oral health and stroke focused on oral cleanliness and the prevention of complications to oral and general health, suggesting that identification of a problem should lead to an action plan or treatment.

Mapping and interpretation – Step 4

The final stage of the analysis involved printing out all the charts and mapping and interpreting what factors and issues were associated with oral assessment to inform the development of a holistic meaningful oral assessment specific to stroke patient's needs. During this process many maps and associations were made until the final map and interpretation to answer the research objective is met. Different formats of the map were created and re formatted leading to the final map.

In order to show the difference between the stakeholders and to see the map developing the maps will be presented as follows:

- All the new ideas/concepts will be presented in uppercase bold text;
- Any ideas/concepts previously identified by a previous group but mentioned by the group being presented will be presented in Italic bold font;
- Any existing ideas/concepts not identified by the group being presented will remain in normal font.

Oral care is complex with many factors contributing to the health and cleanliness of the oral cavity. The researcher had to keep returning to the research question and the objectives of seeking the views of those in the clinical field. During the interviews and focus groups a lot of information was provided so during the process the researcher had to hone down to discover what particular aspects were important in identifying problems in the oral cavity that would inform oral care and oral care processes. Five core concepts emerged these were split into two different categories:

- Those that would inform the content of the oral assessment: assessing the patient's ability to clean their teeth, oral cleanliness, and oral comfort;

- Those that would contribute to the format, layout and implementation of the assessment: contributing factors to oral care, and the format and layout of the oral assessment.

The core themes for the clinical and academic experts were mapped (Table 5-2). Within the map the first concept was assessing the patient's ability to: clean teeth; communicate their needs; to attend to their oral care. This concept was thought to be the initial assessment a nurse should make to identify if the patient's ability was contributing to their oral health and cleanliness. Through assessing ability the nurse would also be able to identify at this stage how much care they may need to provide.

Throughout the interviews those factors that contributed to oral care provision were mentioned and so the fourth concept related to contributing factors. During interpretation it was apparent that these factors were either patient related or organisation related and so two sub categories were formed: patient factors and organisational factors. Patient factors such as: swallowing difficulties; risk of infection; and other co-morbidities or medication that may cause xerostomia needed to be considered. This would allow the nurse to gain a holistic picture of possible causes that may exacerbate oral problems. The organisational factors related more to the provision of oral care, of which the assessment is one part of that process. Organisational factors were: the resources available; the staff's knowledge and training; workload and how nurses prioritise oral care; and that it should be everybody's responsibility. These factors impacted on oral care provision and so need to be considered when developing an assessment to be used by an already stretched workforce. The fifth concept was the format and layout of the assessment. Format and layout are especially important when considering introducing a new assessment into practice. The assessment needs to be user friendly, acceptable to the user, inform care and practice.

Table 5-2 Mapping clinical and academic experts in oral health and stroke views of oral assessment content and format

ABILITY	ORAL HEALTH AND CLEANLINESS	
ABILITY TO CLEAN TEETH	**TEETH AND DENTURES**	**HARD**
ABILITY TO COMMUNICATE	**FOOD DEBRIS**	**SOFT TISSUES**
COGNITIVE ABILITY	**PLAQUE**	**PALATE**
	LIPS	**SALIVA**
	TONGUE	**HALITOSIS**
	GUMS	**HYDRATION**
		SWALLOWING
COMFORT	CONTRIBUTING FACTORS	
ASK THE PATIENT	PATIENT	ORGANISATIONAL
PAIN	**THE WHOLE PERSON**	**EQUIPMENT**
COMFORT	**DENTITION**	**EDUCATION**
CRACKS	**SWALLOWING**	**WORKLOAD**
COATING	**NUTRITIONAL STATE**	**PRIORITY**
TASTE	**RISK OF INFECTIONS**	**TIME**
SELF-REPORTING	**OTHER CO-MORBIDITIES**	**EVERYONE'S**
	MEDICATION	**RESPONSIBILITY**
FORMAT AND LAYOUT		
SHORT	**ST/'ROKE SPECIFIC**	
NOT IN DEPTH	**FOR ALL GRADES OF STAFF**	
ADD TO CARE NOT WORKLOAD	**FREQUENCY (1-2 HOURLY, ADMISSION THEN DAILY)**	
INCREASE PRIORITY	**REFERRAL TO SPECIALIST**	
NURSING SPECIFIC	**INDICATE TREATMENT OPTIONS**	

BOLD FONT UPPER CASE=new ideas

Specific factors that related to format and layout were: the length of the assessment; that it should add to care but not the workload; the assessment should be stroke and nursing specific and aid in increasing the priority given to oral care. All health professionals should be able to perform the same assessment which should be performed at least once daily or up to 2 hourly.

The clinical and academic experts in oral health and stroke were the first group analysed and so the information gathered would form the foundation of the map. This map would be built upon during the mapping phase for each subsequent objective. Once the final maps, consisting of all

the interpretations from all the groups, had been made an overall conclusion was drawn and these interpretations will be discussed in section 5.3.

5.2.2 Objective two: To explore health professional's views and experiences of providing oral care in stroke patients.

Two focus groups explored the views and experiences of the health professionals. Focus group one included eight health professionals from the combined stroke unit; one male and seven females. The experiences in this group ranged from band two through to band seven. Focus group two included six health professionals from the stroke rehabilitation ward; one male and five females. The experience of the staff ranged from band two through to band six (Table 5-3).

Table 5-3 Health professionals recruited to the focus groups

Participants	**Focus group one (Band)**	**Focus group two (Band)**
Registered nurse	Penny (6)	Phil (6)
Registered nurse	John (5)	Joanne (5)
Health care assistant	Lynn (2), Amanda (3), Catherine (2)	Jessie (2)
Occupational therapist	Julie (7)	Alison (6)
Therapy practitioner	Patsy (4)	Jo (4)
Speech and language therapist		Marion (6)
Physiotherapist	Tom (7)	
	Total 8	**Total 6**

Familiarisation, development of thematic framework

The same analysis process was used for this group and subsequent groups. During the familiarisation and development of the thematic framework all the transcripts were read and

notes made. Although no new core themes were identified during this stage, new sub themes were identified and will be described in the results below.

Charting

The information from the transcripts was summarised and placed in the charts based on the thematic framework developed from analysing the clinical and academic experts. If new sub ideas and thoughts were identified that had not been identified before a new sub theme was created.

Attitude to oral health (Appendix 21)

Within this theme no new sub themes were identified. The health professionals thought that maintaining oral health in stroke patients was important because it could potentially prevent oral complications, general health problems and impact on a patient's well-being. Oral care was viewed as a basic daily activity that should be available to all. Focus group one felt that oral care was an important aspect of the nurses' role in promoting general health and recovery.

> *"To us it's quite important obviously to have a clean mouth for a number of different reasons. I think it's important particularly for our patients with swallowing problems because they might not be able to apply the oral hygiene as well as say patients who haven't had a stroke. In terms of saliva management some of our patients have difficulties managing their saliva and difficulties swallowing it. So therefore they are more at risk of aspirating it. But it's whether that saliva's clean or not. If they're not having that oral hygiene potentially they're aspirating saliva that could contain bacteria. (Focus group two)*

Oral care received while in hospital (Appendix 22)

Five sub themes were identified, three were existing subthemes: who provided oral care; frequency of oral care; the oral care process. Two were new sub themes: location of the patient in the hospital; and the priority of oral care.

The health professionals describe oral care as being part of everyday care provided by the nurses but other members would provide oral care if it was deemed necessary when they were with the patient.

"The OT's sometimes do it. Speech and language may do it but it is more nurses and OT's." (Focus group one)

Overall, oral care was described as occurring regularly. However, they did not always define regular (that is how often in a specified timeframe). Focus group one reported frequency was dependent on other care priorities rather than patient need. Whereas focus group two quite clearly reported the patients' teeth were cleaned twice a day. Some of the health professionals felt that even if the frequency of oral care has been recommended in the patients' notes this was not always followed.

"Sometimes when a speech and language therapist has done their recommendations for swallowing and textured foods they sometimes put on there about how regularly oral hygiene needs to be in the medical notes. And sometimes times I heard a nurse say it must be hourly or before and after food. (Focus group one)

There was some variability between the two hospitals with regards to the oral care process. Focus group one reported that toothbrushes and toothpaste were not routinely used due to fear of aspiration, and the culture on the ward was to send the dentures home to prevent them getting lost. Whereas, focus group two routinely provided oral care twice a day using toothbrushes and toothpaste.

"We do use toothbrushes sometimes but tend not to use toothpaste as they tend to aspirate on the tooth paste. So we use the mouth wash. Which we just rinse the tooth brush in rather than have all the bubbles. (Focus group one)

"False teeth are often sent home as people are worried they are going to lose them but this can affect communication and other issues. I feel this is due to the culture of items being lost in the hospital so send them home for safe keeping." (Focus group one)

"We do it or the night staff does it in the morning and then the night staff do it at night when they're going round as well so it's definitely done unless obviously they refuse and they don't want to you know." (Focus group two)

Some health professionals perceived that the condition of the oral cavity was different between acute care and rehabilitation suggesting oral care provision may be different in different areas.

Patients in rehabilitation appeared to have less severe problems than those in acute care but they did not provide any possible explanation for this.

> *"In acute, patients sometimes seem to have worse mouths not sure if that changes over into rehab." (Focus group one)*

> *"We do it on this ward I haven't I don't know if it is done on any other wards but stroke wards we do do it." (Focus group two)*

The staff in the focus groups reported that those patients who have dysphagia, or who are physically dependent, would definitely receive oral care. Although the groups could identify how they provided oral care they did not describe a formal protocol that they worked to.

> *"If they are not maybe eating especially you know and doing things and……..peg feeds and that would be a top priority even." (Focus group two)*

Factors affecting the oral cavity and oral care while in hospital (Appendix 23)

The focus groups identified many factors that affected oral care provision in hospital. Eight sub themes were identified: ability; difficulty accessing the oral cavity; staff knowledge and attitude; priority of care; the oral care process; multidisciplinary team; organisational factors and medical factors. Medical factors was a new sub theme. These were grouped into patient factors and staff factors. Dysphagia preventing the patient from eating and drinking normal diet and fluids was seen as an important barrier because patients were unable to flush the oral cavity or gain moisture through eating and drinking. The groups also described an altered sensation in the oral cavity as affecting the patient's ability to recognise if any food remains lodged in their cheeks, increasing the risk of complications.

> *"Barriers are patients clamp and stop nurses from going into the mouth. Patients fighting us." (Focus group one)*

Staff factors were: the staff's attitude to oral care; and the ward culture seeing oral care as low priority. Both of these staff factors impacted on the quality and quantity of care received. Some nurses openly reported they did not like cleaning dentures and other staff reported a reduced confidence in providing oral care due to a lack of knowledge and training. The lack of knowledge and training were identified as a large barrier to oral care.

"Oh I'd die and sometimes when I'm brushing them am I doing you all right, am I doing it because you know yourself how far back ….not sure where to put the pressure on ….and you're scared aren't you." (Focus group two)

The health professionals also suggested that nurses often make a decision about who requires oral care from the medical information. They do not formally make an assessment that involves asking the patient if they require help. Organisational factors were identified as contributing to oral care provision. Staffing levels and workload potentially influenced the decisions made by health professionals causing them to choose other care priorities over oral care. Both focus groups view was that organisational priorities took precedence over oral care because oral care was not seen as high priority by the organisation.

"Time is a big one. And I suppose the number of staff that are on. In any one shift and that kind of interlinks with time. And time as in the opportunities to carry it out but also the time as in how long it might take to carry out the procedure and perhaps like you say it is a bit of a grey area and having it at the forefront of your mind actually this is important and perhaps prioritising it over other things." (Focus group two)

Impact on the patient (Appendix 24)

Only two existing sub-themes were identified by the health professionals: patient well-being; and physical impact. The health professionals acknowledged that they could only imagine the impact oral care has on patients by describing their own personal experiences. Many described their oral cavities feeling uncomfortable if they have not cleaned their teeth. Others describe the potential for other problems occurring if the oral care is not maintained.

"It must be pretty horrible if you have got stuff all round your mouth all the time that you can't physically get rid of …well its comfort I suppose as well if your mouth isn't right it can affect other parts of the person." (Focus group one)

The health professionals also discussed the impact of halitosis, on the person and others, and how it could affect a person's confidence making them feel self-conscious when communicating. Another issue was the impact of not being able to control your own saliva and dribbling. This was deemed to affect the patient's confidence when interacting with others.

"Yeah, yeah it affects your confidence you don't want to speak to anyone because you're worrying about your breath." (Focus group two)

The health professionals felt that a lack of oral care provision affected the patient's well-being and general health. Having a dry oral cavity was perceived as feeling uncomfortable and poor oral care provision would only exacerbate the problem. The health professionals thought taste would also be affected because the oral cavity was unclean patients would not be able to taste the food. All these factors may affect the person's well-being and mood and ultimately affect the patient's engagement in rehabilitation.

"Well apart from the usual relatives don't like it, it makes you feel better before you start on anything, less infections and I think it makes your taste better doesn't it if you have got a clean mouth. So therefore they are eating better because their mouth is clean and they feel better because they have got clean I know I do." (Focus group one)

Facilitators to oral care (Appendix 25).

The health professionals throughout the interviews identified several points that could potentially facilitate oral care provision. These related to the sub-themes of: having the correct resources; frequent care; assessing need; multi-disciplinary; and knowledge.

During the interviews there was a lot of reference to the fact that the nurses did not always have the correct resources available to provide effective oral care. If evidence based oral care was to be provided then having access to the correct resources was essential.

"Not all patients have the correct equipment and often toilet bags have everything in them other than toothbrush and toothpaste. Often equipment not available on the ward for the staff to use. (Focus group one)

Providing regular oral care was viewed as important. One suggestion of facilitating regular oral care was for relatives to be encouraged to become involved in providing oral care with the support of the nursing staff.

"Well any person, family members." (Focus group two)

"Carers should get involved at an early stage it is about engaging the family in the process and explaining to them what their role is." (Focus group one)

Education and training for the health professionals was viewed as essential and this training should involve oral care interventions that can be used, the correct equipment and frequency of care. One member of the team felt better assessment, better documentation of the problems identified and the care prescribed would ensure effective communication between team members and ultimately better oral care provision

"Yeah definitely it's all about education and heightening awareness. Like I said before I don't think there's anything out there that does. That I can think of. So I think education is kind of key and not just for qualified nurses it's for everybody." (Focus group one)

"We met during dressing practise and if someone's like on thickened and we've mentioned it to speech therapy haven't we about having some training around you know what that's all involving your mouth and you know should we be cleaning it first are we allowed to use you know that sort of thing really." (Focus group two)

Assessment content (Appendix 26)

No new sub themes were identified by the health professionals: ability; assessment of need; areas within the oral cavity; and scoring were discussed. Assessment was viewed as being the responsibility of the whole multidisciplinary team and not just the nursing staff. The health professionals identified that it was important to first assess the patient's needs and their ability to attend to oral care because in the past assumptions had been made as to who required oral care and often this was incorrect.

"Feel that it is a team approach and when doing care it should involve physio and OT if that is what is required in the therapy session. Look at the patient holistically and their needs." (Focus group one)

"So I were thinking are they cognitively aware to, do we need to prompt the patient to do it…….see if they are able to do that." (Focus group two)

Assessment of the teeth, tongue, gums, lips, and cheeks were identified by both groups. The assessment should also include looking for signs of infection, lesions, halitosis and assessment of

pain in the oral cavity. There was no definite consensus about how these should be scored but descriptive terms such as red, inflamed, coated and moist were suggested.

> *"Signs of infection, if it's moist enough, secretions, halitosis." (Focus group one)*

> *"Whether their gums are red or inflamed…furry tongue...if there's any ulcers or yeah, oh the teeth as well keep the false teeth clean." (Focus group two)……*

> *"Well the cleanliness the surface of the mouth, everything the teeth the lips, the gums all part of I mean once one of them deteriorates it all kind of follows. …. yeah it's the whole picture." (Focus group one)*

Assessment format (Appendix 27)

The layout and format of the assessment was harder for the groups to discuss. The sub themes layout; length; and evaluation were identified. Both focus groups felt that the assessment needs to be easy to use and no more than one piece of A4 paper. One member of the focus group one felt the format should be standardised and others felt that maybe using a tick box approach would be more acceptable in a busy ward environment.

> *"Yeah yeah I think it's good to have something like you said tick box and it's evidence based isn't it then that the patient as actually had their mouth care, sometimes we can presume that they've had done as well can't we." (Focus group two)*

> *"Oral assessment would be useful if it is standardised and not just another piece of paper. It was felt that this would make is acceptable into practice." (Focus group two)*

There was some discussion with regards to the frequency of oral assessment and although the groups felt nurses should assess the oral cavity before oral care, the focus groups thought this was unrealistic in the current clinical climate and suggested twice daily was a more realistic and achievable target for the oral assessment to be completed.

> *"Well every time that you go there you should be yeah." (Focus group one)*

Mapping and interpretation

The charts from the health professionals were then printed so the researcher could begin interpreting the data. This process was the same as the process used in the clinical and academic experts for stroke. Similar concepts were emerging and a similar picture was being identified. At this stage, and to aid with synthesis of the data, the concepts were mapped onto the initial map created in objective one. The initial map was changed to sentence case normal font. Any new ideas were added in capitals using bold font and if ideas were identified by the health professionals that were already on the map (existing) these were placed in bold italics. This would allow for comparison between the two groups (clinical and academic experts in oral health and stroke, health professionals). No new concepts were identified but new ideas were added to the map that had not been considered by the clinical and academic experts in oral health and stroke (Table 5-4). The health professionals also identified ability as a concept that needs to be considered. The focus was about nurses having a formal assessment they could make so as not to make assumptions about the patient's ability to attend to oral care, both physically and cognitively. This information would also enable the nurses to consider exactly what assistance they need to provide. Within oral health and cleanliness the health professionals identified several areas that had already been identified by the clinical and academic experts in oral health and stroke. New areas such as assessing the throat, looking for lesions on the mucosal membrane were added. Patient comfort was discussed and controlling saliva was added to the map. Assessment of pain was also suggested but it was an idea already present on the map.

The health professionals believed the assessment should be a holistic review encompassing all factors that could contribute to oral health. Other new concepts that were viewed as contributing to oral care were the culture of sending dentures home and asking relatives to assist in oral care provision. Education and training was also a large contributor to the quality of oral care provision. The health professionals felt that frequency of assessment would have an impact on the layout and format of the assessment. When developing the assessment the developers should consider the nurses' workload, and time, ensuring the assessment is easy to use, within the current skills of the nursing team and informs care.

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Table 5-4 Mapping health professionals' views of oral assessment content and format

ABILITY	ORAL HEALTH AND CLEANLINESS	
Ability to clean teeth	***Teeth and dentures***	***Palate***
Ability to communicate	***Food debris***	Saliva
Cognitive ability	Plaque	Halitosis
CO-OPERATION	***Lips***	Hydration
ASSUMPTIONS ABOUT ABILITY	***Tongue***	Swallowing
	Gums	**THROAT**
	Hard and soft tissues	**LESIONS**

COMFORT	CONTRIBUTING FACTORS	
Ask the patient	PATIENT	ORGANISATIONAL
Pain	The whole person	***Education***
Comfort	Dentition	Workload
Cracks	Swallowing	Priority
Coating	Nutritional state	Time
Taste	Risk of infections	Everyones responsibility
Self-reporting	Other co-morbidities	**HOLISTIC REVIEW**
CONTROLLING SALIVA	Medication	**SENDING DENTURES**
	Equipment	**HOME**
		RELATIVES ASSISTING

FORMAT AND LAYOUT	
Short	Frequency (1-2 hourly, admission then ***daily*****, x2 daily**,)
Not in depth	Referral to specialist
Add to care	Indicate treatment plan
Workload	**NURSES TIME**
Increase priority	**EDUCATION**
Nursing specific	**STAFF ATTITUDE TO ORAL CARE**
Stroke specific	**ONE PAGE**
For all grades of staff	**EASY TO USE**

Key: **BOLD FONT UPPER CASE**=new ideas; **Bold italicised font, sentence case=** ideas already present; Normal font, sentence case=existing ideas not discussed.

5.2.3 Objective three: To explore stroke patients' views and experiences of oral care.

Ten patients were identified by the nursing staff as being able to participate in an interview and who were or had received oral care. Five patients were recruited from a combined acute stroke and rehabilitation unit (CASRU) and five patients from a stroke rehabilitation unit (SRU). The median age was 78 years (Inter Quartile Range (IQR) 68-85). Nine (90%) patients were female. Four patients had a left sided hemiparesis, five a right sided hemiparesis and one patient only had swallowing difficulties. Patient characteristics are presented in Table 5-5.

Familiarisation, development of thematic framework

During familiarisation and immersion of the transcripts no new themes were identified so the same thematic framework was used. The transcripts were then indexed and charted as per the description in objective one (Pg.109-110) and seven charts were created. Several new sub themes were identified.

Charting

Attitude to oral health (Appendix 28).

The patient's attitude to oral health identified three sub-themes: medical importance; own beliefs; and importance for patients. Three patients felt that oral care was important to prevent bacteria from within the oral cavity causing other health problems. Two patients also described oral care was important to maintain oral health and if oral care did not take place then there was a risk that complications could occur that may impact on the person's ability to chew and swallow, potentially affecting their recovery.

> *"Well I think it's very important for the simple reason if you don't look after your mouth the germs are going right through your body." (Rose)*

Table 5-5 Patient characteristics for combined acute stroke and rehabilitation unit

Location	Patient	Age (Sex)	Dentition	Stroke severity	Side of body affected	Mobility difficulties	Swallowing difficulties	Speech difficulties
CASRU	Rose	85 (F)	Endentulous	Moderate	No obvious weakness	Walking around with the aid of a Zimmer	Severe dysphagia NG feed plus trials of soft diet and thickened fluids	
	Madge	82 (F)	Endentulous	Moderate	Left arm and leg	Walking around the ward with the help of 1 nurse	Dysphagia NBM NG tube	Slight slurring of words
	Grace	81 (F)	Dentate	Moderate	Right arm and leg	Immobile, 2 nurses to transfer from bed to chair	Dysphagia NG tube	Expressive dysphasia
	Jane	83 (F)	Dentate and Partial dentures	Moderate	Left arm and leg	Immobile, 2 nurses to transfer from bed to chair	Dysphagia Now on normal diet and fluids Difficulty controlling saliva	
	Elsie	80 (F)	Endentulous	Severe	Right arm and leg	Bed bound	Dysphagia Now on normal diet and fluids Difficulty controlling saliva	

NG = Naso-Gastric tube, NBM = Nil by Mouth

Table 5-5 continued

Location	Patient	Age (Sex) Sex	Dentition	Stroke severity	Side of body affected	Mobility difficulties	Swallow difficulties	Speech difficulties
SRU	Cathy	71 (F)	Dentate	Mild	Left face, arm and leg	Walking	Dysphagia, normal diet and fluids, difficulty controlling saliva	None
	Con	78 (M)	Dentate and partial dentures	Moderate	Right arm and leg	Walking plus 1 nurse and a stick	Dysphagia, normal diet and fluids, difficulty controlling saliva	
	Ada	54 (F)	Dentate and partial dentures	Moderate	Left arm and leg	Needs a wheelchair to mobilise around the ward	Normal	
	Mary	84 (F)	Dentate	Severe	Right face, arm and leg	Needs a wheelchair to mobilise around the ward	Dysphagia, was NBM and on NG feed. Now normal diet and fluids	Expressive dysphasia Difficulty with sentence formation
	Carol	68 (F)	Dentate and partial dentures	Severe	Right arm and leg	Bedbound, transfers with a hoist	Normal	Expressive dysphasia

NG = Naso-Gastric tube, NBM = Nil by Mouth

Many of the patients believed it was important to have a good oral care regime and visit the dentist regularly. This was especially true for people who are ill and at greater risk of oral problems. Some patients found it difficult to express their beliefs because they were unsure what oral care and oral hygiene were.

> *"What you got to do, need is a proper dentist." (Jane)*

> *"Well I think it is very important I suppose when you are really ill, I suppose it really matters." (Grace)*

All patients reported cleaning their teeth or dentures was an important part of their daily routine and for some, regular visits to the dentist was an integral part of their oral care regime.

> *"Two or three times a day…….certainly after food. Very important because I smoke…..the brushing, the flossing, the mouthwash, the gargling. (Carol)*

Oral health was also viewed as important from a personal perspective. The patients reported that having a clean fresh mouth made people feel better, improved well-being and prevented problems such as halitosis.

> *"I think it is very important, I mean you don't want bad breath do you…….to make them look good and feel good." (Elsie)*

Oral care received while in hospital (Appendix 29)

No new sub-themes were identified for this theme. The sub themes were: providers of oral care; oral assessment; frequency of care; and the oral care process. The provision of oral care was reported as fragmented. Some patients were unable to remember what care they had received in the first few days on the acute stroke unit. Others reported poor oral care provision in the acute stroke unit and better oral care provision in the rehabilitation ward. In some cases it was the nurses who provided oral care, for others, their relatives provided oral care. One patient felt it was the responsibility of the patient to attend to their own oral care needs not the nurse.

> *"They just said have you got toothpaste in the morning when we were getting up and I said yeah. Right we'll set it all out for you. Right when you've had a wash give me shout, we'll come a get a bowl for cleaning your teeth, just totally different." (Ada)*

"Sometimes my daughter she comes at night time……yeah as the fellows (nurses) do no they were doing it initially yeah (in the morning)." (Mary)

"I think you should be able to clean your own teeth. It doesn't take a minute even if you've got no tooth paste you can brush them with cold water." (Jane)

The patients did not report nurses assessing the oral cavity as part of the oral care regime, but two patients did highlight that the nurses made some decision about who required help and who did not. One patient felt that patient dependency was the key to the nurses' decision making and this assessment lead to the nurses attending to the oral care needs of patients who were bed bound or unwell.

"I think I wasn't as severe as most of them it was only as sort off a mild stroke…….I don't think anybody actually cleans people unless they are absolutely immobile I don't think anybody, nobodies cleaned my teeth." (Cathy)

Only one patient mentioned the frequency of care when she was describing how often she attended to her own oral care, which was 2 hourly. Another patient reported she would prefer to have oral care more frequently however, she did not want to disturb the nurses.

"I don't know whether it's because I don't want to bother them, ask them say can I clean my teeth again I don't know." (Ada)

Factors affecting the oral cavity and oral care while in hospital (Appendix 30)

Within this theme, five sub-themes were identified that had already been created: ability; oral care process; external factors; resources and medical factors. The patient's describe difficulty in attending to their oral care and so oral care did not occur or was to a low standard. Patients felt that nurses made assumptions about who required oral care which also meant that many patients did not receive oral care because the nurses thought the patient could attend to it themselves.

"I could never understand why they never asked you to clean your teeth at Blackburn. Unless it was I was so, I was so poorly then I couldn't do much at all then at the time." (Ada)

Normal routine appeared to be that dentures were sent home because of a fear of losing them. One patients reported sending her dentures home because she thought she would not require

them due to her being NBM and not eating and drinking. However, this raised anxiety around whether the dentures would fit again because of changes she noticed in her oral cavity.

> *"No as I say they took them home with my clothes because I did not need them." (Rose)*

The patients perceived that the nurses were too busy and did not have time to attend to oral care because they had more important jobs to attend to. One patient even felt patients should not expect nurse's to carry out oral care because they had more important tasks to attend to.

> *"No not then no, no ….nothing I can do will have to get on with it, well they hadn't people to look after people….too many people too many to do this." (Mary)*

Four patients highlighted a lack of the resources they were familiar with, such as their own toothbrushes and cleaning equipment. This lack of equipment impacted on the quality of oral care they could provide or receive.

> *"No it's mine. But unfortunately I didn't pack to come here so I'm missing various articles." (Carol)*

The patients also reported that many of the physical problems associated with their stroke such as dysphagia, changes in the muscles and sensation of the oral cavity also impacted on their oral health and hygiene. The loss of the oral muscle definition was described as affecting the wearing of dentures and the patient's ability to control food. Wearing no dentures and being aware of food being lodged in the cheek made the oral cavity feel uncomfortable. Patient felt self-conscious about having no or loose fitting dentures and this affected their communication with others.

> *"My mouths alright but the teeth drop down now…….I can't speak properly without them in." (Madge)*

Impact on the patient (Appendix 31).

Within this theme all three sub themes were charted: patient well-being; physical; assessing impact. The patients mainly refer to the impact on their well-being. Two patients make reference to how oral care impacts on how the oral cavity feels from a physical perspective and one patient

describes assessing the level of uncomfortableness. The patients described the physical impact of not receiving oral care using words such as dry, uncomfortable, nasty, and horrible.

> *"Well you know when you are so dry I just didn't like it, it was uncomfortable…it has been horrible." (Elsie)*

The patients reported that having an uncomfortable oral cavity had a big impact on how they felt and their well-being. They described this uncomfortable feeling affecting their morale and mood. Many patients perceived they had problems such as halitosis because they had not received oral care and their oral cavity felt unclean and uncomfortable. They feared their visitors would be able to smell the halitosis and were very conscious about this issue. Other patients felt self-conscious because they did not have any dentures in situ.

> *"It's just cause otherwise you get smelly breath and when you're talking to people it's embarrassing….horrible Yeah it did cause I kept saying to my husband is my tongue white ." (Ada)*

Facilitators to oral care (Appendix 32)

Patients identified several issues that could enhance oral care provision and this spread across four of the sub themes: correct resources; frequency; oral care processes; and interventions. Interventions was a new sub theme found in this group. Having the correct resources available to clean teeth as well as having access to resources that would promote independence in the bathroom was important. Some patients felt that if they had the opportunity to access equipment this would enhance oral care provision.

> *"A perching stool in the bathroom. To make sure you can get to the sink easily." (Carol)*

Frequency of oral care was important to the patients because this was seen as relieving some of their symptoms. Patients reported they would prefer having oral care as frequently as possible but three times a day was preferable.

> *"Everyday…once is practicable, three times though". (Grace)*

Having the opportunity to clean their teeth, rinse their mouths out and for some for the nurse to perform this for them would improve oral care.

"Just make sure that everybody is aware when they are washing a patient that they give them the opportunity to having it done you know having their teeth cleaned and their mouth washed." (Cathy)

Through providing opportunity and frequency of care the patients believed this would help ensure they had a fresh oral cavity making it feel comfortable. Many patients reported experiencing a dry mouth whether they were NBM or not. Once patients were able to drink the first drink was perceived as having the greatest impact on their oral cavity. Applying moisture therefore had a large impact on the patient.

"Oh do you know it was like heaven. The first drink of water and I don't drink water and the first drink of water that I had oh it was like winning the lottery." (Mary)

Assessment content (Appendix 33)

When exploring assessment content the patients focused on particular areas in the oral cavity and two patients discussed assessing need.

One patient felt that the nurses should assess well-being and how the patients felt. Another patient thought the nurses should ask the person to check how their oral cavity felt by running their tongue around the mouth and teeth. This would help provide the nurse with information about how the oral cavity felt and if there were any problems that could not be observed on clinical examination.

"You're rubbing your tongue over your teeth there is that one thing you do to check if your teeth are clean. Yeah, yeah, yeah. Sometimes they can feel … especially after you've eaten bits of food --and what have you." (Con)

The patients drew on their personal experiences quoting those areas that they felt reflected oral health and cleanliness. The most common areas cited relating to the oral cavity were: lips; tongue; teeth; as well as breath; and food being lodged in the cheeks.

"Well, all of it really I mean your mouth your tongue and then around your gums you know all round there …..Yeah that bit. Cause I know I have no teeth up there so I know I have a lot of gum and food tends to stick to it, you up there." (Cathy)

Assessment format

With regards to the format of the assessment the patients did not offer any ideas about how the assessment may be presented.

Mapping and interpretation

The mapping and interpretation phase identified that although the patients identified many ideas that were similar to the clinical and academic experts in oral health and stroke and the health professionals the main points raised related to: the opportunity to attend to oral care; how individual oral care needs could be met; and the psychological impact of oral care on the person (Table 5-6). The patients identified little or no oral care occurred in the acute phase and better care provision in the rehabilitation phase. Two possible causes for the difference in oral care between these two phases are time available and how the nurses assessed patient ability. The patients also identified new ideas that related to the health and cleanliness of the oral cavity. Examining the oral cavity for signs of infection, bleeding gums as well as assessment of the whole oral cavity. The impact on the patient was discussed at great length with many patients concerned about halitosis, loose fitting dentures and not being able to wear their dentures due to changes in their oral cavity following the stroke. For many of the patients the contributing factors to oral care were organisational factors: having the opportunity to attend to oral care; and the frequency of oral care provided. The patients did not add any more information regarding the format and layout of oral assessment.

Table 5-6 Patients' views of oral assessment content and format

ABILITY	ORAL HEALTH AND CLEANLINESS	
Ability to clean teeth	***Teeth and dentures***	***Halitosis***
Ability to communicate	***Food debris***	Hydration
Cognitive ability	Plaque	Swallowing
Co-operation	***Lips***	Throat
Assumptions about ability	***Tongue***	***Lesions***
ABILITY TO GET TO THE	***Gums***	**SIGNS OF INFECTION**
BATHROOM	Hard and soft tissues	**BLEEDING GUMS**
ABILITY TO REMOVE FOOD	Palate	**THE WHOLE ORAL CAVITY**
	Saliva	

COMFORT	CONTRIBUTING FACTORS	
Ask the patient	PATIENT FACTORS	ORGANISATIONAL FACTORS
Pain	The whole person	Workload
Comfort	Dentition	Priority
Cracks	Swallowing	Time
Coating	Nutritional state	Everyone's responsibility
Taste	Risk of infections	Holistic review
Self-reporting	Other co-morbidities	***Sending dentures home***
Controlling saliva	Medication	**FREQUENCY OF CARE**
DENTURES THAT FIT	***Equipment***	**OPPORTUNITY**
HALITOSIS	Education	

FORMAT AND LAYOUT		
Short	Stroke specific	Education
Not in depth	For all grades of staff	Staff attitude to oral care
Easy to use	Referral to specialist	One page
Workload	Indicate treatment plan	**EASE OF USE**
Increase priority	Frequency (1-2 hourly, admission then daily**,** x2 daily,)	
Nursing specific	***Nurses' time***	

Key: **BOLD FONT UPPER CASE**=new ideas; **Bold italicised font, sentence case=** ideas already present; Normal font, sentence case=existing ideas not discussed.

5.2.4 Objective four: To explore carers, of patients who required assistance with oral care, views and experiences of the oral care their relatives received

Six carers of five patients were recruited; two participants were carers for one patient. Three carers were recruited from the combined acute stoke and rehabilitation unit and three carers from the stroke rehabilitation unit. The median age of the carers was 51.5 years (IQR 45-53.5). Five of the carers were female, of which four were daughters, and one was a spouse. The male carer was a son. Carers' and the patients' characteristics are presented in Table 5-7.

Familiarisation, development of thematic framework

During this stage no new themes were identified. During charting only one new sub theme was identified in the theme facilitators to oral care. The new sub theme was carer involvement.

Charting

Attitude to oral health (Appendix 34)

Charting identified the sub-themes of: medical importance; own beliefs; and importance for patient. Two of the carer's highlighted oral care was important for medical reasons such as preventing heart conditions and providing moisture to maintain a healthy oral cavity.

> *"Yeah cause I think that that means if you have bad oral hygiene then you can get infection or things like thrush or er if you have gum disease. All these things well I mean people used to die of gum disease in ancient times cause nobody was doing anything about the teeth....it's just gets progressively worse." (Jenny)*

The carers had strong views about the importance of oral care in sick patients. Many were surprised about how quickly oral health can deteriorate and other felt it was a quick and simple task.

> *"Again mouth care is making sure the mouths clean, you know as best could be. It's like your own oral hygiene you know you look after that so why can't it be looked after in a sick patient……I feel disgusted at the way, I'm not disgusted that's a wrong word, surprised, very surprised, I never thought somebodies mouth could go like that through lack of care." (Dot).*

Table 5-7 Characteristics of the carers and their relative

	Carer characteristics			Patient characteristics							
Location	**Carer**	**Relation-ship**	**Age**	**Patient**	**Sex**	**Dentition**	**Stroke severity**	**Side of body affected**	**Mobile**	**Swallow**	**Speech**
CASRU	Dot	Daughter	54	Agnes	F	Endentulous	Severe	Right face, arm and leg	Immobile, requires two to transfer from bed to chair	Severe dysphagia NBM PEG tube	Expressive and receptive dysphagia
	John and Elaine	Son Daughter	50 48	James	M	Endentulous	Moderate	Left, face arm and leg	Immobile, requires two to transfer from bed to chair	Dysphagia NBM NG tube	None
SRU	Jenny	Daughter	47	Bert	M	Dentate	Severe	Right face, arm and leg	Immobile, requires hoist to sit out	Dysphagia NBM NG tube	Expressive and receptive dysphasia
	Jean	Daughter	54	Ann	F	Dentate	Severe	Right face, arm and leg	Immobile, requires two to transfer from bed to chair	Dysphagia NBM NG tube Starting trials of thickened diet and fluids	Expressive and receptive dysphasia
	Sue	Wife	64	Barry	M	Dentate and partial dentures	Severe	Left face, arm and leg	Immobile, requires two plus a hoist to transfer from bed to chair	Dysphagia NBM NG tube Thickened diet and fluids	None

NBM = Nil by Mouth, PEG = Percutaneous Endoscopic Gastronomy, NG = Naso-Gastric

Some relatives described oral care as being very important to their relatives because they had long established oral care routines, which included regular cleaning of the teeth and visits to the dentist and so these need to be maintained.

> *"She was very clear about her mouth hygiene she was very, we all are in the family, very strict……Yes, all her own teeth and she's 84. ...No but she is, erm, but er very strong on cleaning teeth you know. In fact she was told by the dentist once not to brush so hard. (Jean)*

Oral care was also important from a psychological perspective. Simple things such as not being seen without dentures in-situ and keeping the mouth fresh. However, one patient's carers felt that oral care was potentially not high priority for their relative because they had other issues which they deemed more important.

> *"For us it's important but I think when you start getting to his age I think he's got too many other issues that are more important than his mouth." (Elaine and John)*

Oral care received while in hospital (Appendix 35).

The carers reported a mixture of oral care provision. Three sub themes were found to be described by the carers: providers of oral care; frequency of oral care; and the oral care process. In some instances the carers reported they provided the oral care and in one case the carer felt that they were the only ones providing oral care and the nursing staff were not continuing this between their visits. Others reported the nurses were providing oral care.

> *"We had a meeting here last Friday with a member of the staff and Dr (Name) registrar over the discussion about mum going into a nursing home. And I brought up the oral hygiene and again this staff nurse said well yeah it does get done. So I said well we can put so many of those swabs in a pot and we can go back and the same amount of swabs will be in the pot. So she said well the nurses takes their own trolley around with the swabs on. So we don't know." (Dot)*

Frequency of oral care was discussed by one carer who reported the speech and language therapist had prescribed oral care 2 hourly for her relative. Otherwise there was no specific reference to frequency of oral care.

> *"The speech and language therapist said she needed oral hygiene every two hours". (Jean)*

Oral care provision in the acute phase was limited compared to the rehabilitation phase. In the acute phase one carer assumed oral care was occurring because there was equipment in their relative's locker for cleaning teeth, which suggested they were receiving oral care. Unfortunately, this was not the case. One carer highlighted that oral care was difficult in the acute phase due to issues such as dysphagia and the risk of aspiration. For most of the relatives, oral care in the rehabilitation setting was perceived to be better with more resources and equipment available.

> *"In the latter stages they've dealt with it very well in the initial stages in the acute stages … I think it could have been improved …. Improved quite easily really with not a great deal of resources would have made life a lot better for him." (Jenny)*

The relative reported using a variety of methods for cleaning the oral cavity, gauze swabs dipped in mouth wash, toothbrush and tooth paste and swilling of the mouth after a meal.

> *Well he cleans, when he's had his dinner and his tea, I take him to clean his teeth after because I'm quite aware that his food catches and stays and cause he can't feel it he doesn't know it's there so we make sure we get rid of all the bits and everything. But he does spend a lot of time swilling his mouth out with a lot of water after he's cleaned his teeth." (Sue)*

Factors affecting the oral cavity and oral care while in hospital (Appendix 36)

The carers identified that many factors affected their relative's oral cavity and oral care while in hospital. These thoughts covered six sub-themes: ability; priority of care; oral care process; external factors; medical factors and patients factors. Patient factors were a new concept. The largest factor was the impact the stroke had on the patient physically, which affected their ability to maintain a healthy moist oral cavity and prevent complications.

> *"Especially in somebody elderly like my dad I suppose the nurses almost have to do it for him because he's not capable at the moment." (Elaine and John)*

One carer suggested that one possible reason why oral care provision was lacking was because it was seen as low priority by the nursing and medical teams.

> *"It's not seen as the most important thing is it?" (Sue)*

Another carer felt that oral care provision was poor in general and one carer even challenged the nurses about the frequency of her mother's oral care.

Complications following the stroke that required certain treatment options were seen as causing problems for the patients, affecting their oral cavity. Being Nil by Mouth, being on oxygen and mouth breathing all appeared to increase the drying of the oral cavity. Also those patients who had swallowing difficulties appeared to have reduced oral care due to a fear of aspiration.

Organisational factors such as the nurse's time and workload were viewed as having a large impact on oral care provision. The carers felt the nurses did not have enough time to dedicate to oral care.

> *"Only that they are very busy isn't it…..Busy ward." (Elaine and John)*

Finally patients themselves were reported to not ask for oral care or would not alert the nurses that their oral cavity was uncomfortable. The carers felt that this was linked to the nurse's time and patients not wanting to take the nurse away from other tasks.

> *"Barry won't ask for anything….. No, no he'll ask me but he won't ask anybody else, he won't ask anybody else." (Sue)*

Impact on the patient and carer (Appendix 37)

Three sub themes were charted: a person's well-being; physical; and assessing impact. Receiving oral care was viewed as having a positive impact on well-being because the patients appeared to enjoy having their oral cavity freshened up. Having a dry or unclean oral cavity was viewed as having a negative impact affecting mood, also contributing to the feeling of being unwell.

> *"So what it must feel like for somebody who's in hospital and is able to take nothing by mouth that build up must be massive." And I think also obviously your teeth are, it's a pet thing of mine if somebody smiles at me and erm and there's no oral hygiene obvious then I have to back away." (Jean)*

The condition of the oral cavity not only impacted on the patient but on the relatives too. One carer in particular reported how the condition of the oral cavity affected her emotionally. She describes wanting to reassure her father through a loving kiss but due to the condition of his oral cavity she was hesitant and felt she was unable to convey this. This made her feel guilty.

> *"You could see like a real like yellowing filmy stuff over his teeth then sort of white patchy scaly bits on his tongue and sometimes it was very very dry so it was like a you know snakes skin handbag type of thing it was really cracked and hard. His tongue yeah and ….you know round his gums and that sort of thing and you know your wanting to go and give him a kiss to reassure him and give him a love but …at the same time kind of thinking hmm no, no (And it's awful because it's your dad and you shouldn't have to feel like that." (Jenny)*

The relatives described how the physical changes they observed such as thick saliva, dry cracked lips and a thick coating on the tongue could affect communication, preventing the patient from making their needs known as well as causing distress to the patient.

> *"It must be terrible just lying there and it not feeling clean." (Sue)*

The carers reported they assessed the impact oral care had on the patient through the patient's reactions. Which in most cases was a positive reaction.

> *"No she just appreciates when we do do it. ….By her reaction she goes mmm….You know it's like you might as well have given her a drink of water." (Dot)*

Facilitators to oral care (Appendix 38)

Within this theme, four sub themes were identified: correct resources; frequency; oral care process; and multi-disciplinary. One carer thought that resources were scarce and that patients needed the relevant equipment to perform effective daily cleaning of the teeth. The carer felt that this should be provided by the hospital.

> *"I don't know how much hospitals provide but I firmly believe everybody should be given the means to clean their teeth even if they don't bring their own in." (Sue)*

As well as receiving oral care it was important that oral care was provided at regular intervals. Suggestions of regular intervals was 2-3 hourly.

> *"You know it's something that could do with doing several times a day really. As often as can be fitted in. I would say it could really be done every couple of hours at least." (Jenny)*

One carer thought that assessment should start as soon as patients are admitted to hospital. This assessment should include nurses identifying if patients are able to clean their teeth. For those patients who can clean their teeth nurses should assess if they have actually cleaned their teeth. Patients should also be given every opportunity to attend to their oral care or have their oral care attended to.

> *"I think for me as soon as somebody comes into hospital very ill I think oral hygiene should be taken over straight away before anything has a chance to build up." (Jean)*

The carers identified that many people come into contact with the patients while they are in hospital and so there was the potential for each person to provide oral care. This would increase patient contact and interaction as well as increase oral care provision. Carer involvement was highlighted by three of the carers. They thought that this was a missed opportunity and resource that was underutilised.

> *"I mean the only other thing would have been in the early stages would have been you know sort of being told about the oral hygiene so that visitors as a family could have helped more and do it more because I mean if we can save a nurse doing a job then that's something we are quite happy to do but we weren't really advised about it or told about it .....so the only thing I can think would be in a similar situation would be to you know advise families that they can assist. That in ways they can help the family, you feel the need to do something to help them and if it's just a tiny thing that you can do. (Jenny)*

Assessment content (Appendix 39).

Carers had a slightly different focus regarding assessment, and reported frequency of assessment was important. They felt that performing an assessment of the oral cavity is simple and quick, and should be part of routine oral care. For the carers, assessment was essential if problems were to be identified and treated appropriately. This would include assessing the whole of the oral cavity and checking for food debris.

> *"The tongue because yeah that's always coated in a white fur. And again that can be quite gloopy underneath the, all around the underneath of the top lip right round the bottom lip and the inside of the cheeks." (Dot)*

Assessment format (Appendix 40)

Only one carer made any reference to the format of an oral assessment, specifically when oral care should be assessed. They suggested the oral cavity should be assessed daily.

> *"At least once a day. Cause it's only a case of saying open up isn't it." (Sue)*

Mapping and interpretation

During mapping and interpretation it was felt the carers had identified those issues they witnessed and thought significantly affected their relatives while in hospital. These issues tended to be around the provision and frequency of oral care and the impact this had on the patient and the carer. They identified many areas within the oral cavity that related to oral health and cleanliness that had already been mapped. One new area, the cheeks, was added. Patient comfort was also discussed and the relatives added patient well-being and having a fresh oral cavity as new ideas. A lack of oral care or reduced oral hygiene was seen as a contributing factor to the patient's relationship with their relative, which could affect well-being. Another contributing factor was the lack of communication between the relatives and the health care team in promoting relatives providing oral care during visiting. Applying moisture to the oral cavity regularly was seen as the biggest factor that impacted on patient comfort. Although frequency had already been mapped the carers felt better documentation of oral care was essential (Table 5-8).

Table 5-8 Carer's views of oral assessment content and format

Ability	**Oral health and cleanliness**	
Ability to clean teeth	***Teeth and dentures***	Hard and soft tissues
Ability to communicate	***Food debris***	***Throat***
Cognitive ability	Plaque	***Lesions***
Co-operation	***Lips***	***Hydration***
Assumptions about ability	***Tongue***	***Swallowing***
Ability to get to the bathroom	***Gums***	***Signs of infection***
Ability to remove food	***Palate***	Bleeding gums
	Saliva	***THE WHOLE ORAL CAVITY***
	Halitosis	**CHEEKS**
Comfort	**Contributing factors**	
Ask the patient	**Patient factors**	**Organisational factors**
Pain	The whole person	Equipment
Comfort	Holistic review	***Education***
Cracks	Dentition	Workload
Coating	Sending dentures home	Priority
Taste	*Swallowing*	Time
Controlling saliva	Nutritional state	Everyone's responsibility
Self-reporting	Risk of infections	***Frequency of care***
Dentures that fit	Other co-morbidities	***Opportunity***
Halitosis	Medication	***Relatives assisting***
WELL-BEING	**Relationships**	**APPLYING MOISTURE**
MOUTH FRESH		**AID COMMUNICATION**

Format and layout		
Short	Stroke specific	Nurses' time
Not in depth	For all grades of staff	Education
Add to care	Referral to specialist	Staff attitude to oral care
Workload	Indicate treatment plan	One page
Increase priority	***Frequency*** (***1-2 hourly***, admission then ***daily,***	Easy to use
Nursing specific	x2 daily,)	**DOCUMENTATION**

Key: **BOLD FONT UPPER CASE**=new ideas; **Bold italicised font, sentence case=** ideas already present; Normal font, sentence case=existing ideas not discussed.

5.3 Discussion

Five concepts relating to oral assessment were identified by all the groups: ability; oral health and cleanliness; comfort; contributing factors; assessment format and layout. The experts provided a foundation for all the concepts which were built upon throughout the analysis by all the groups. Each group however, focused on certain concepts more than others. The clinical and academic experts in oral health and stroke and health professionals focused on specific areas in the oral cavity that represent oral cleanliness and health and other contributing factors that may impact on oral hygiene such as the lack of education, time and workload. The patients and carers cited the impact a lack of oral care has on the person's self-esteem and well-being and that the nurses should review a patient's ability and provide them with the opportunity to attend to their oral care.

5.3.1 Trustworthiness of the data

Qualitative research seeks to understand the world from the perspective of others. If the data is incorrect or misinterpreted then this could undermine the findings and research conclusions (Silverman 2010; Creswell 2007). Several methods were used within this study to ensure validity of data and findings, clarifying researcher bias and peer review and debriefing. Each researcher brings a different combination of subjective knowledge, skills and values to the research. It is therefore important for the researcher to know their unique characteristics and understand how their own subjectivity affects the conduct and results of their research. Peshkin (1988) reports that "subjectivity can be virtuous, for it is the basis of researchers' making a distinctive contribution, one that results from the unique configuration of their personal qualities joined to the data they have collected (Pg. 19)." Within the research the researcher examined their subjectively and re visited this throughout. The researcher has previous research experience and so was aware of the potential bias they themselves may have on the data collection and how their own views and experiences may have influenced their decision making and interpretation of the data (Creswell 2007). In order to reduce researcher bias and maintain validity the researcher used impartial peers, from multiple perspectives, to develop the research methods, data collection, analysis and interpretation of the data. These included a non-medical-nursing researcher and a medical and nursing researcher. During the collection of data the researcher attempted to maintain a neutral position, openly exploring the patient's experiences.

Peer review and debriefing was one method that was used. Many writers support the use of debriefing to enhance trustworthiness and credibility of qualitative research (Spillett 2003; Lincoln and Guba 1985). The researcher met with their supervisory team every two months providing peer review and debriefing. The views of the non-medical and medical and nursing personnel were impartial to the study and assisted in the analysis of the transcripts as well as making the researcher aware of their own views and biases regarding the data. The non-medical peer was an outsider with little or no exposure to the topic and had a different professional background. The medical and nursing peers were insiders with a nursing background and some experience of the topic being studied. Through using impartial peers to debrief the methods are strengthened and it allows for probing, interpretation and questioning of the findings providing accuracy and completeness of the data (Spillett 2003). The insider peers required fewer explanations regarding the field of study so were more likely to identify erroneous data, but they may have habitual thinking. This outside peer was able then to challenge some of the researchers thinking because they questioned more due to being disassociated from the field.

During analysis of the data the researcher also sought peer review from another researcher who was not involved in this research. Although this is the method of ensuring reliability of the data it is also providing trustworthiness of the data. The focus is not to train a second reviewer to evaluate the data but to challenge assumptions about the data and manage subjectivity of the research, providing alternative interpretations (Barber and Walczak 2009). The second reviewer has a nursing and qualitative research background and provided a check against biases within the analysis and added to consistency, credibility and reliability in order to maintain the trustworthiness of the research. However, because both reviewers were from similar professional backgrounds this may have prevented a more impartial interpretation of the data being drawn out. The findings were challenged further by the impartial peers in the supervisory sessions with the researcher providing some impartial interpretation. A limitation of the methodology employed was that the second reviewer was unable to review 20% of all the transcripts due to time and ideally a researcher would be able to review all the transcripts until saturation of ideas occurred. In another study examining peer debriefing twenty percent (four) of the scripts were analysed by both reviewers (Barber and Walczak 2009).

Member checking is another method that can used to assess the trustworthiness of the data, with the literature advocating this is as the most critical technique in assessing the credibility of the findings (Lincoln and Guba 1985). This method involves taking the findings and conclusions back

to the participants so they can judge its accuracy (Creswell 2007). On the other hand it has been argued that member checking can cause confusion rather than confirmation because the participants may have changed their mind (Angen 2000). Member checking was not used in this study due to ethical approval not allowing the researcher to return to the participants. The patients and carers situation may have changed in the time between the interviews taking place and presentation of the findings and conclusions. There was also a risk that between these times the patient was no longer in the acute phase of their illness and so their memory and importance of the topic may have changed. Also some patient's conditions may have changed due to the nature of their illness where it would be inappropriate to contact relative and patients. Through not using member checking, inaccuracies in the findings may not be identified and the participant's views may be misidentified by the researcher (Burke 1997). The findings were however presented to a group of individuals who represented all the different stakeholders groups who took part in the qualitative interviews and focus groups. This group were the expert panel who developed the new oral assessment.

5.3.2 Exploring the views and experiences of the stakeholders in the field

The interviews and focus groups identified the complexity of the oral care process. Multiple dimensions were raised, such as assessment of ability, assessment of risk, having the correct resources, identifying problems, effective communication between the patient and nursing staff, and the provision of quality oral care. Although guidance is available to inform oral care in healthy individuals and stroke patients: "Delivering Better Oral Health" (DH 2009), "National Clinical Guidelines for Stroke" (ICSWP 2012), "SIGN 119 Management of dysphagia for stroke" (SIGN 2010), "Guidelines for the Oral Health care for Stroke Survivors" (British Society of Gerodontology 2010). The oral care process described by the participants and their carers is ad-hoc and lacking in guidance and co-ordination. The nursing literature also promotes the importance of assessment in acute care (Potter et al. 2005). However, oral assessment is still lacking in the clinical setting (Heath et al. 2011; Chalmers et al. 2004; Pearson and Chalmers 2004; Nuttall et al. 2001). This may be because the evidence available to underpin the stroke guidelines are weak and are supported by only one Cochrane review (Brady et al. 2010) and consensus of opinion.

The first stage of oral care is assessment, allowing the nurse to identify potential problems and prescribe care. Through assessment and monitoring of the oral cavity, oral health can potentially be maintained, preventing medical complications as well as increasing patients' well-being and

outcome (British Society of Gerodontology 2010; DH 2009; Petersen 2003). Through exploring all the stakeholders views and experiences information can be gathered to inform the development of a meaningful assessment that assesses oral health and is usable for implementation into clinical practice. The final map of the interviews and focus groups is presented in Table 5-9 and each concept will be discussed in relation to assessment and to the literature.

Table 5-9 Suggested oral assessment content and format

ABILITY	ORAL HEALTH AND CLEANLINESS	
Ability to clean teeth	Teeth and dentures	Hard and soft tissues
Ability to communicate	Food debris	Throat
Cognitive ability	Plaque	Lesions
Co-operation	Lips	Hydration
Assumptions about ability	Tongue	Swallowing
Ability to get to the bathroom	Gums	Signs of infection
Ability to remove food	Palate	Bleeding gums
	Saliva	The whole oral cavity
	Halitosis	Cheeks
COMFORT	**CONTRIBUTING FACTORS**	
Ask the patient	**PATIENT FACTORS**	**ORGANISATIONAL FACTORS**
Pain	The whole person	Equipment
Comfort	Holistic review	Education
Cracks	Dentition	Workload
Coating	Sending dentures home	Priority
Taste	Swallowing	Time
Controlling saliva	Nutritional state	Everyone's responsibility
Self-reporting	Risk of infections	Frequency of care
Dentures that fit	Other co-morbidities	Opportunity
Halitosis	Medication	Applying moisture
Well-being		Aid communication
Mouth fresh		Relatives assisting
		Relationships

FORMAT AND LAYOUT		
Short	Stroke specific	Nurses time
Not in depth	For all grades of staff	Education
Add to care	Referral to specialist	Staff attitude to oral care
Workload	Indicate treatment plan	One page
Increase priority	Frequency (1-2 hourly, admission	Easy to use
Nursing specific	then daily, x2 daily)	Documentation

Ability to attend to oral care

Ability was reported many times during the interviews and focus groups. All groups identified that many patients had physical and cognitive difficulties that affected their ability to attend to oral care. The health professionals also suggested that they did not perform any standardised assessment to assess a patient's oral care needs. Routine practice involved the nurses making assumptions about a patient's ability and whether they required assistance with their oral care. This would often lead to patients potentially not receiving oral care. The patients confirmed this by expressing that at times they were missed because the nurse assumed they could attend to their own oral care. The patients thought assessment of their functional needs was important and should be part of routine assessment. However, only one assessment in the literature review assessed physical ability (Lockwood 2000). Lockwood's assessment reviewed the patient's ability to access facilities and their ability to attend to oral care, indicating this was not seen as an important issue in the other oral assessments.

The patient's cognitive ability was also reported as important. This was identified by those who worked with stroke patients or who had extended knowledge of stroke patient's needs. The impact of cognitive ability ranged from the understanding of what the equipment was for, to un-cooperative behaviour. The literature review only identified two assessments that reviewed cognitive ability, and these assessments measured the risk of oral problems occurring (Lockwood 2000; Freer 2000). However, assessing functional and cognitive ability informs the nurse of the patients oral care needs. This allows the nurse to then prescribe care that will help maintain a healthy oral cavity. It appears that although all the groups identified assessing ability as important, it still was not formally assessed. Although there is guidance on oral care in people with disabilities, its primary focus is on the impact physical disability has on oral health rather than the need to determine ability and care required (British Society of Gerodontology 2010; DH 2007). In contrast to this guidance, the groups highlighted the importance of assessing the patient's cognitive and physical ability; the requirement for prompting oral care provision, and the maintenance of oral health. Once ability has been established, then assessing oral health and cleanliness would be the next step, which would then inform what treatment would be required, and the frequency with which it should be given.

Oral health and cleanliness

The interviews and focus groups identified areas within the oral cavity that represented oral health and the groups identified similar areas to those identified in the literature review as described in Table 3-4. These included teeth, dentures, lips, tongue and gums. Although many of these areas were identified by all the stakeholder groups, the dental experts focussed much of their discussions on areas that represented oral health and cleanliness and the prevention of disease. Other areas were identified such as the throat, cheeks, hard and soft palate, and saliva. However, teeth, gums, tongue, and lips were reported more frequently by the patients. These areas have also been identified most often as representing oral health in the existing oral assessments (Table 3-4). Patients and carers also suggested checking for food debris lodged in the cheeks, halitosis, lesions (e.g. ulcers), signs of infection and bleeding gums as important.

Oral health is important and this has been measured in the past using dental assessments that specifically measure gingival disease and plaque levels (Greene and Vermillion 1964; Silness and Loe 1964; Loe and Silness 1963). However, these assessments do not provide nursing specific information that will guide care. Exploring the views of the stakeholder groups has therefore enabled the researcher to confirm or deny those areas that are deemed important to reflect oral health and cleanliness. Many patients judged how healthy their oral cavity was through sensory feedback. If their oral cavity felt dry or unclean (coating on the tongue, plaque on teeth) they would report this as unhealthy or unclean. Patients describe oral comfort as being part of oral health and cleanliness. How comfortable their oral cavity felt, not only alerted them to a potential problem with their oral health but also affected their self-esteem and well-being.

Comfort

Throughout the interviews and focus groups the impact of oral care on the patient was referred to by the patients and carers more frequently than the health professionals and clinical and academic experts in oral health and stroke. The patients reported that the comfort and cleanliness of the oral cavity affected their self-esteem and well-being. The health professionals also suggested that if patients had low self-esteem this affected the patient's recovery. Comfort was therefore very much an indicator of perceived cleanliness, oral problems and impacted on well-being. The effects of the lack of oral hygiene are often underestimated and rarely seen as part an assessment of oral

health. Only two assessments in the literature review assessed comfort and this was through assessing pain (Burns 2012; Ridley and Pear 2008)

Well-being is one concept that contributes to overall health,

> *"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."*
>
> (World Health Organisation (WHO) 1946).

Well-being is viewed as a personal concept that is subjective and relates to feelings of pleasure, happiness and wellness with the avoidance of pain (Deci and Ryan 2008). During the interviews and focus groups, all groups referred to the psychological impact that oral care has on a person; in particular on their mood. However, patient and carers specifically referred to well-being throughout the interviews, describing the positive and negative aspects of oral care. Having little or no oral care was perceived as causing an unclean oral cavity which affected mood negatively (e.g. unwell). In contrast, receiving oral care affected mood positively (e.g. wellness, happiness and positivity). Deci and Ryan (2008) report that increasing one's happiness also increases one's well-being.

Oral health has a major impact on well-being and needs to be considered throughout the oral care process (Sheiham 2005). Several studies have examined the relationship between oral health and quality of life that is the impact that oral health and physical functioning has on a person's well-being (Schimmel et al. 2009; Locker et al. 2002; Locker et al. 2000). The patients in this study described that reduced oral functioning, such as the ability to remove food, chew and control saliva all impacted on their well-being. This lack of control made the patients feel anxious and distressed about their appearance and communication with others. Similar findings were reported in hospitalised stroke patients who associated oral pain, discomfort and reduced ability to chew, with reduced well-being and low morale (Schimmel et al. 2009). Other studies that have examined oral health and quality of life in medically compromised patients found similar issues relating to missing teeth, inability to chew and a dry mouth all impacted on a person's quality of life (Locker et al. 2002). The impact of oral care on well-being is often underestimated and oral health does have a major impact on patients, physically, psychologically and socially (Locker et al. 2002; Locker et al. 2000). Well-being and comfort therefore needs to be considered when assessing oral health.

From the perspective of the patients and carers it appears that well-being and comfort needs to be included in an oral assessment.

Contributing factors

Other factors were also highlighted that potentially could be considered for inclusion in an oral assessment, such as assessing: the patient holistically; swallowing difficulties; nutritional status; and other co-morbidities. These factors reflect those that have been incorporated in previous oral assessments and inform the risk of oral problems rather than oral cleanliness and health (Lockwood 2000; Freer 2000; Jenkins 1989). Process issues were also highlighted, such as equipment, opportunity, frequency of care, applying moisture, and including relatives in the provision of care. Both the risk factors that contribute to oral health and the process issues that were emerging from the data potentially need to be considered when developing an oral assessment to inform oral care. However, these issues would be addressed at other points in the oral care pathway not particularly at the assessment stage.

Education was reported as a major barrier to the provision of quality care. The health professionals suggested that a lack of education affected the care they provided and how they approached care. The literature also supports this notion that a lack of knowledge affects oral care (Miegel and Wachtel 2009; Binkley et al. 2004). Education is important to improve oral care provision and contributes to better reliability when using an assessment for use by multiple nurses (de Vet et al. 2011). Education is also essential when implementing a new care intervention (Damschroder et al. 2009; Rycroft-Malone 2004). Several studies have shown that education has improved awareness and provision of oral care (Peltola et al. 2007; Fallon et al. 2006; Frenkel et al. 2002; Isaksson et al. 2000). However, the benefit of the education was not sustained and improvements to oral care reduced considerably in the weeks following the training, suggesting that continual training and updates are required (Preston et al. 2006; Frenkel 2003). Although education and training is essential in maintaining the quality of care, education sessions tend to be two-three hours long and away from the ward. Staff are often not supported in attending education sessions. Possible reasons for this is because at an organisational level oral care is not seen as important (care viewed as low priority). At ward level other competing care needs, workload and time constraints prevent the nurses from identifying oral care and education as important (Wardh et al. 2000). Potentially the lack of importance and priority placed on oral care is due to the lack of empirical evidence to support the need and interventions required.

The health professionals and clinical and academic experts in oral health and stroke suggested a proportion of nurses did not enjoy providing oral care for others, and that many nurses lacked confidence and feared harming the patients. This lack of confidence has been attributed to limited education and training (Binkley et al. 2004; Wardh et al. 1997; Adams 1986). Also oral care is often seen as a "*dirty task"*, which are those tasks that are the role of the workers in lower social standing; in this case those who have not had the adequate training to do the roles perceived to have a higher priority (Lawler 1991). Avoiding "*dirty tasks"* can be common for some registered nurses (Lawler 1991). The health professionals did report passing oral care to the unregistered staff because it was not deemed an important task when they were prioritising care.

Knowledge varied across the expert groups, with the clinical and academic experts in oral health and stroke having a greater knowledge of: the importance of oral care; and the current evidence and guidance. The patients', carers' and health professionals' knowledge appeared more superficial in nature. During the focus groups the health professionals did not refer to the evidence that supported the oral care they provided. In fact, the health professionals reported a lack of knowledge which was viewed as one of the main contributing factor for ad hoc care practices.

Assessment format

When considering the format of the assessment, several issues were highlighted, generally by the health professionals. Issues regarding the length of the assessment and its ease of use, the time it would take to complete the assessment, and how frequently the assessment would need to be completed. These issues need to be considered when developing the assessment, and consideration also needs to be given to implementation of the assessment into clinical care where time and perceived usefulness are important aspects which may affect implementation (Rycroft-Malone 2004; Rycroft-Malone et al. 2004).

Some of the health professionals thought that a new assessment should be simple, quick and easy to use, to ensure it was accepted in clinical practice. However, others were concerned that an oral assessment would be another piece of paperwork preventing the nurses from providing quality oral care. Workload, time, organisational priorities, were all identified as factors that contribute to whether a new intervention would be accepted into clinical practice. Relevance of fit with the organisational and practice issues all need to be considered when developing a new intervention

to enhance the chances of it being accepted into normal clinical care (Rycroft-Malone et al. 2004). Time appeared to be an important factor. The patients frequently said the nurses did not have enough time to provide care. Having an oral assessment that was not too onerous was deemed a more favourable option. The literature review identified two assessments that examined the time it would take to complete the assessment, this was approximately eight minutes for both (Chalmers et al. 2005; Kayser-Jones 1995). These assessments were developed for use in a residential care setting where work pressures are reduced and eight minutes may not be seen as too long. However, in an acute setting, eight minutes may be deemed too long when nurses are making decisions about what work needs to be completed in the timeframe available.

Health professionals themselves reported oral care was given low priority and other tasks were seen as higher priority and given precedence over oral care. When registered nurses are faced with workload management, they make cognitive decisions regarding the priority and importance of the care task (Potter et al. 2005). Often, this means that those tasks such as oral care, are given a lower priority as they are not seen as causing immediate harm (Potter et al. 2005). Priority is a major factor that impacts on the care received, and assessment is part of the care process (Ackley and Ladwig 2008). A recent Royal College of Nursing report identified that nurses reported oral care was not carried out in 48% of patients due to workload and prioritising of care (Royal College of Nursing (RCN) 2010). Often, when there are other competing pressures, nurses will devolve those jobs that are not seen as important to unregistered staff (Wardh et al. 2000). The health professionals also voiced that oral care was often devolved to health care assistants. If oral care is a fundamental part of routine clinical care, then consideration needs to be given to the oral assessment's feasibility (e.g. ease of use, time to complete) if it is to be considered by the clinical team.

The clinical and academic experts in oral health and stroke and health professionals suggested the assessment should be nursing specific and should include items that are relevant to stroke patients. The risk to oral health in stroke patients is exacerbated due to stroke patients experiencing dysphagia and dehydration. This leads to a reduction in the patient's saliva flow and nutrition affecting the patient's own intrinsic defences against oral bacteria and potentially increases their risk of chest infections and post-stroke complications (Sellars et al. 2007). Also many stroke patients may be at risk of oral complications due to increased oral pathogens (Gosney et al. 2006b; Ding and Logemann 2000).

Many of the issues that stroke patients may experience such as reduced physical ability, reduced cognitive ability, swallowing problems and communication problems could also be experienced by any acutely ill patients and so may not be seen as stroke-specific. The clinical and academic experts in oral health and stroke felt the assessment should relate to the needs of stroke patients, as well as informing oral care. Previously developed oral assessments have concentrated on examining specific areas in the oral cavity with a view to reducing oral disease rather than combining this with the oral care provision which is more relevant to acutely ill stroke patients being cared for by nurses.

As well as the assessment being stroke and nursing specific, the frequency of assessment was also discussed. The carers suggested oral assessment and care should be done every couple of hours. In many cases this was because they witnessed unhealthy and unclean mouths. Some health professionals recommended that oral assessments should ideally be every time oral care is given, other health professionals reported that daily assessment was probably more realistic. The literature identified multiple time points, as shown in Table 3-6 page 67, for assessing oral care. Time pressure and workload were reported as the factors that influenced care provision and so this needs to be taken into consideration when developing other oral assessments. At present there is no definitive recommendations as to the frequency of oral assessment and current guidance is produced from consensus of opinion.

5.4 Summary

This chapter has described the findings of four different stakeholder groups' experiences of oral care in hospital. The information gathered has identified the constructs to be considered for inclusion in an oral assessment, as well as the issues that need to be considered to inform the format, layout and implementation of the assessment. Ability was seen as a very important aspect of the oral care process informing care. Areas such as teeth, gums, mucous membrane, tongue, palate and saliva were reported as representing oral health and should be considered for inclusion. Patient comfort and well-being was also highlighted as important, therefore assessing pain and oral comfort could enhance the assessment by revealing problems that cannot be seen on the clinical examination. The findings from the qualitative interviews will aid in the development of an assessment that can meet the needs of the service users, clinical needs and is usable for those performing the assessment. Chapter Six will describe in more detail the

development of an oral assessment using the data gathered from the literature review as described in Chapter Three and the qualitative interviews described in Chapter Five.

Chapter Six

Development of an oral assessment

6.1 Introduction

Chapter Three identified that an oral assessment did not exist that specifically captured the nursing and oral health issues of hospitalised stroke patients. Chapter Five presented the findings of the views and experiences of the clinical and academic experts in oral health and stroke, health professionals, patients and carers. Within the interviews and focus groups many patient and staff factors that influence oral care in a hospital setting were identified:

Patient factors

- The patient's risk of oral problems, such as other co-morbidities, their nutritional state, medication, risk of infections, dysphagia, and dehydration;
- The patient's ability to attend to their oral care, this includes physical and cognitive ability to access facilities, attending to oral care and use of the cleaning equipment;
- The cleanliness of the oral cavity; including examining areas such as the lips, teeth, tongue, gums and cheeks;
- Oral comfort, including how their oral cavity felt and any experiences of oral pain.

Health professional factors

- The health professional's training and knowledge, confidence and skills at attending to oral care;
- Health professional's perceived priority of oral care versus time allocated to providing oral care;
- Registered verses unregistered nurses skills in providing oral care;
- The need for an integrated oral care pathway.

The information gathered from the literature review and qualitative interviews were synthesized to aid the development of a new oral assessment for use in stroke patients.

6.2 Developing an oral assessment

When developing an assessment it is important that bias and subjectivity are kept to a minimum. In order to reduce bias and ensure impartiality it is important that the assessment is developed by a panel of experts rather than a single researcher (Streiner and Norman 2008). If the researcher develops the assessment independently there is a risk the researcher's own interest and knowledge of oral care may influence the content of the assessment. The expert panel also provides content and face validity for the constructs being measured (de Vet et al. 2011; Streiner and Norman 2008).

6.2.1 Expert panel

An expert panel should represent those who are experts in the area being researched (de Vet et al. 2011). For this particular research it was important to involve experts in oral health and cleanliness, and experts in providing or receiving oral care. A group of individuals were identified by the researcher through their supervisory group, clinical contacts and previous networking. These individuals were contacted by email or phone and were invited to take part in the expert panel. All potential participants were provided with information explaining the purpose of the group, what their involvement would be, and how much time commitment would be required. If a potential participant declined the offer to join the panel they were asked if they could recommend another person of the same discipline. The final expert panel consisted of a stroke specialist nurse, a healthcare assistant, a staff nurse (band 5), an occupational therapist (band 6), a physiotherapist (band 7), a stroke patient, a carer, a dentist, a research nurse and the researcher.

The researcher arranged for the expert panel to meet. At the first meeting the researcher presented the results from the literature review, and the findings from the qualitative interviews. Over the course of three meetings the expert panel worked through de Vet's (2011) steps developing a new oral assessment that could potentially be used in stroke patients.

Characteristics of the measurement

At present in clinical practice the majority of oral care is provided by the nursing team. The expert panel discussed which health professionals could potentially perform an oral assessment.

Although currently in many areas this was seen as the responsibly of the nurse it was decided that oral care was the responsibility of all health professionals in the stroke team. This was reflected in the responses from the health professionals in the focus groups. Although the expert panel perceived that the registered nurses would probably be the clinicians who would perform the oral assessment, it was acknowledged that in clinical practice unregistered nurses may also assess the oral cavity and provide oral care prescribed by the registered nurse. Even though this was current clinical practice the expert panel wanted to develop an assessment that had the potential to be used by registered and unregistered health professionals (health care assistants, physiotherapists, occupational therapists and speech and language therapists).

Assessments can either be objective or subjective in nature. The expert panel identified that, in the case of an oral assessment, there will always be an element of subjectivity because the assessor will be making an interpretation of what is observed or asked. This interpretation is influenced by their own views, clinical knowledge and background as well as by the responder's interpretation of any questions asked during the assessment (de Vet et al. 2011; Streiner and Norman 2008). Subjectivity is always a concern when developing a new assessment and designing the assessment following the six steps set out by de vet et al. (2011) the expert panel hoped to control for this.

6.2.2 Definition and elaboration of the construct intended to be measured.

In order to develop a meaningful oral assessment the expert panel needed to identify what the construct is that they wanted to measure, in what population, and to establish the purpose of the measurement.

Construct

Three main areas were identified from the literature and qualitative interviews and these were assessment of: patient's ability to attend to their oral care; the health and cleanliness of the oral cavity; and oral comfort. The assessment would therefore be multi-dimensional assessing three different sections which would provide information regarding the construct of oral health and cleanliness.

Patient's ability was chosen because the qualitative interviews suggested this had a large impact on whether patients received oral care and ultimately affected their oral health. Patients who

have difficulty attending to their own oral care, are at increased risk of oral complications (Yoneyama et al. 2002) and a reduction in oral comfort affecting their self-esteem and well-being (Schimmel et al. 2009). The expert panel agreed that assessing ability was essential and that currently, within the clinical setting, assessment of ability was very ad hoc with limited, or no, documentation that the assessment had taken place. The expert panel discussed the importance of documented evidence and the transfer of important information from one health professional to another. They agreed on the importance of communicating how much, and the type of, assistance that needed to be provided to enhance patient care and experiences.

The second area to be included was assessment of the health and cleanliness of the oral cavity. The literature review identified multiple areas in the oral cavity that were viewed as providing information about the health and cleanliness of the oral cavity. Areas such as: lips; teeth; tongue; gingivae; mucous membrane; palate; and saliva. Many of these areas were also reiterated in the qualitative interviews and so were considered for selection by the expert panel in the assessment. How each item was selected will be discussed in more detail later in the chapter.

The final area identified was oral comfort. The qualitative interviews identified that oral comfort and personal well-being were very important to the patients and this is supported in the literature (Locker et al. 2002). Oral comfort and well-being was an area that was under-assessed in the pre-existing oral assessments identified in the literature review. The qualitative interviews highlighted the importance of assessing oral comfort through asking the patient how their oral cavity felt because observed characteristics may not reflect the pain and discomfort the patient may be experiencing. This then has an impact on the care the health professional would prescribe and patient's perception of their oral health and well-being.

Target population

When developing the assessment, the expert panel needed to consider the target population and how the information would be gathered. The target population was to be stroke patients aged 18 years and above, who may or may not have physical and or cognitive difficulties. The patients may also be medically ill, so may have other confounding factors that could potentially affect their oral health such as: oxygen therapy, taking medications that caused xerostomia, swallowing difficulties, nutritional problems or other comorbidities (e.g. diabetes). Communication may also be a problem for some stroke patients impacting on how information can be gathered to populate

the assessment. For example, some patients may be unable to obey commands and open their mouths for the assessor to perform a clinical examination. Some patients may also have difficulty answering questions appropriately due to their expressive dysphagia. The expert panel discussed all these aspects to ensure the assessment was designed to allow all the relevant information to be gathered in the same way, in as many patients as possible.

After much discussion it was decided that the new oral assessment would gather information for the oral assessment through questioning and a clinical examination (de Vet et al. 2011). Although questioning was chosen as one of the methods the expert panel acknowledged that in some cases the patients will not be able to communicate their answers. Ideally, testing of different methods such as: Coop charts, which have been used to assess oral health quality of life (Westbury et al. 1997); or a visual analogue scale for pain (Seymour et al. 1985) should be developed for use with the new oral assessment. However, due to limited resources and time constraints this was not developed at this stage. The expert panel did suggest that at the implementation stage of the oral assessment the researcher could further develop methods for collecting information from patients who had communication problems. For this particular research the expert panel suggested that for those patients where the information could not be obtained through questioning or clinical examination the health professional should record that item as unknown or not assessable unless the information could be gathered from the medical notes.

Choice of measurement method

The type of measurement method is influenced by whether the assessment is uni-dimensional or multi-dimensional and whether the relationship between the items that make up the assessment are reflective or formative. The new assessment was identified as multi-dimensional by the expert panel and there was much discussion regarding the relationship between each item in the assessment. The expert panel felt that a person's ability to clean their oral cavity may affect cleanliness and comfort showing a reflective relationship because each item contributes to the overall outcome of an unhealthy oral cavity. The relationship between items such as the teeth, tongue, and gums may also be reflective because the cleanliness of the patient's teeth may influence the cleanliness of their tongue and gums. If a reflective relationship exits, then the scores from each item can also be added together to provide an overall score because each item contributes to the overall outcome (Goldberg 1992). Using the total score the presence or absence of a disease or problem can be identified and if a problem does exist the severity of the

problem can be identified. For instance if the total score is nine and the presence of a problem is anything from 3 up to 9 then the patients with a score under three would be classed as having no problem.

If a formative relationship is used each item is independently considered as contributing to the outcome and an overall score is not used. For instance, if an oral cavity was assessed and the tongue was the only area where a problem was identified the score would be 1/9. If a total score method was used to categorise care, the care prescribed may be usual care of twice daily cleaning, but in fact more frequent care is required to rectify the problem with the tongue. The expert panel felt that using a reflective model may increase the risk of the nurses prescribing care for the overall score rather than the particular problem identified. The aim of the oral assessment is to identify the presence or absence of any oral problems and to inform the planning of oral care. Therefore, clinically, a formative model was chosen to reflect the needs of the patient and the clinician (Figure 6-1).

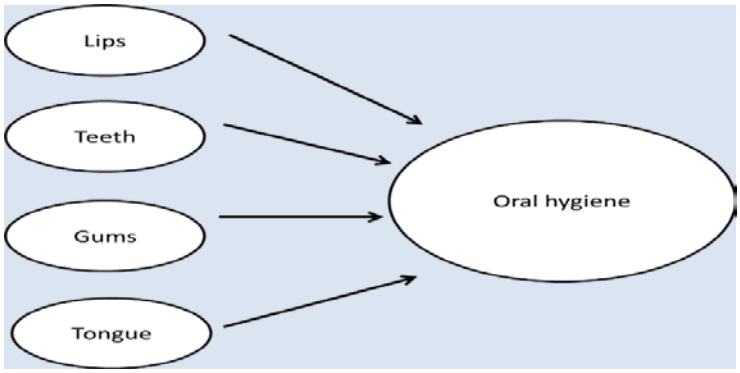


Figure 6-1 Example of COATS formative framework

6.2.3 Selecting items

From the data collated in the literature review and qualitative interviews there were certain aspects that would be important in terms of the implementation of the new assessment but these would not necessarily be seen in the content of the new assessment. Factors such as education and training, priority given to oral care, resources, and layout and frequency. All factors were therefore considered as they may impact on content and format. Items in an assessment are often selected following a review of the literature and from experts' knowledge in the field (de Vet et al. 2011). The information gathered from the literature review and the qualitative interviews relating to ability to attend to oral care, oral health and cleanliness and oral comfort were

presented to the expert panel. The expert panel discussed each section in detail and agreed upon what items should be included in each section. The expert panel included items that would inform oral assessment as opposed to implementation. These are presented in Table 6-1. The expert panel felt strongly that assessing specific areas in the oral cavity relevant to stroke patients was essential in ensuring the correct care was prescribed.

Table 6-1 Sub-division items

Ability	**Oral cleanliness**	**Oral comfort**
Can the patient get to the bathroom? Can they attend to their oral care? Do they attend to their oral care?	Lips Teeth/denture Gums Tongue Cheek Roof of the mouth Saliva	Pain Comfort

Ability

On reviewing the literature, assessment of physical or cognitive ability was present in two oral assessments developed to assess the risk of oral problems (Roberts 2001; Lockwood 2000) and two assessments that assessed both risk and oral health and cleanliness (Stout et al. 2009; Freer 2000). The expert panel felt strongly that although physical and cognitive problems caused by the stroke may not change, the patient's general medical condition could change on an hour by hour or day by day basis impacting on their ability to attend to their oral care. Assessment of ability was therefore important and seen as a daily assessment by the expert panel. The three main aspects of ability highlighted in the qualitative interviews were: assessing the person's ability to access the bathroom; their ability to attend to their own oral care; and whether the person attends to their oral care when they have ability. Assessing the patient's ability to access the bathroom to attend to their oral care would highlight what assistance, if any, the health professional needs to provide to allow the patient the opportunity to attend to their oral care. Assessing the patient's ability to attend to their oral care would identify how much assistance the health professional may need to provide in order to support the patient in achieving optimal oral care. This assistance could be from helping to get the equipment ready for cleaning their teeth to

actually performing the whole task. Finally, if the patient was able to attend to their oral care, are they actively performing this task and if not why not? For example, if the patient is physically and cognitively able to clean their teeth but they lacked the motivation to do so. The expert panel felt that through assessing these specific issues this would aid the nurses in making a formal assessment of the patients ability to attend to their oral care and identify what the health professional's role would be in assisting the patient to complete this task.

Cleanliness

The literature review and qualitative interviews data identified areas that represented oral health and cleanliness such as: lips; teeth/dentures; gums; cheeks; tongue; roof of the mouth; and saliva. The expert panel were presented data on the variability in the research methodology and testing of the studies. Therefore, when considering which items to include, they had information on the quality of the studies and the amount of agreement found between and within raters on particular items. Although agreement varied across the studies all items were considered by the expert panel for inclusion.

Lips were included in 100% of the oral assessments identified in the literature review and were mentioned throughout the qualitative interviews by various experts. Patients reported dry, cracked lips caused pain discomfort and made the patient feel their oral cavity was unclean. Assessment of lips may also help identify dehydration or reduced saliva flow which could contribute to reduced oral health (Turner and Ship 2007). The expert panel felt lips were easily viewed and could provide a lot of essential information, so consensus of opinion was that an item on lips should be included in the new assessment.

Teeth and dentures were deemed important in the literature, by the academic and stroke experts, because a build-up of plaque or food on the teeth provides an ideal environment to harbour bacteria increasing the risk of dental disease (Ireland 2006; Kornman et al. 1997; Edgar 1976). Teeth were included in 100% of the oral assessments, but dentures were only included in 74%. Currently, clinical guidance advocates that cleaning teeth is essential in preventing dental disease and should be part of everyone's daily life (DH 2009). The expert panel agreed that the cleaning of teeth will potentially maintain a normal oral flora and help maintain the body's own immune defences in controlling pathogenic bacteria in the oral cavity. It was felt that maintaining cleanliness and controlling bacterial load in the oral cavity was especially important in stroke patients who may have compromised immunity due to acute illness and may also have reduced

nutritional intake (Keusch 2003; Davalos et al. 1996). The expert panel also felt that cleaning someone's teeth could have a profound impact on the patient's sense of well-being and their engagement with others and this was highlighted by the patients and carers in the qualitative interviews.

Alongside the teeth is the gingivae. If plaque is not removed from the teeth then the gingivae can be affected increasing the risk of gingival disease. In the long term, gingival disease can contribute to systemic problems such as heart disease and stroke (D'Aiuto et al. 2004; Scannapieco et al. 2003). The gingivae was identified in 94% of the assessment in the literature review, potentially because disease of the gingivae is seen as a good indicator of oral health. However, rater reliability in the literature review was variable. Gingivae was discussed at length by the expert panel. They felt that assessing the gingivae was a complex task that may require extra training due to a lack of knowledge, skill and ability. Some of the panel also had concerns about what guidance would be given if gingival problems were identified, because the access to dental services in many hospitals is limited (Talbot et al. 2005). The dental expert in the group felt that assessing the gingivae was essential and one the best indicators of oral problems. Through identifying problems with the gingivae early this will help prevent long term complications. This area, after much debate was therefore included in the assessment.

The mucous membranes cover the cheek area and the inner side of the upper and lower lips. Mucous membranes were included in all (100%) of the assessments in the literature review and were deemed important in identifying any abrasions or breaks that could potentially increase the risk of infection both orally and systemically. The qualitative interviews also highlighted the importance of food becoming lodged in the cheek area of the mucous membranes, this was distressing to the patient and many patients had difficulty removing this food to clean the oral cavity.

The expert panel agreed that the main problem patients experienced was food being lodged in the cheek area. The constant presence of food in the cheeks will cause the pH of the oral cavity to remain acidic increasing the risk of gingival disease (Edgar, 1976). Through examining the cheeks, and removing any food debris, the oral cavity's pH can return to normal allowing oral flora to defend against pathogenic bacteria (Edgar 1976). Other problems that can occur with the mucous membrane is abrasions or ulcers. Although abrasions could occur, the expert panel thought that examining the mucous membranes could be difficult for staff, especially in those patients where it

is difficult to position them to gain a clear view of the mucous membrane. However, the panel did recognise that some patients will be able to report if they have an abrasion. The expert panel decided that the focus of the assessment should be to examine the mucous membranes for any food debris that has become lodged rather than abrasions. This lead to a discussion regarding the term that should be used in the new assessment to represent this item. The expert panel all agreed that mucous membrane was not a term all health professionals were familiar with and so decided the term that would be used for this item was cheek. It was felt that this was more of a universal term and clearly identified which area of the oral cavity the assessment was referring to.

The tongue also featured in over 90% and the palate in 42% of the oral assessments described in the literature review that assessed oral health and cleanliness. Clinically, the tongue and the palate are areas that are affected by acute illness (Carrilho Neto et al. 2011; Andersson et al. 2004). The tongue and palate were two areas that the expert panel suggested should be included because changes in these two areas occur. When patients become dehydrated, have reduced secretions, and are not able to flush the oral cavity with food or fluid due to swallowing problems this increases the risk of problems occurring. The patients described the tongue as providing information about how clean and comfortable their oral cavity feels. The health professionals and academic clinical experts in oral health and stroke also identified that this was one area that was easily seen and could indicate if oral care was required. The expert panel suggested that, for those patients in whom examining the oral cavity was difficult, the tongue was one area health professionals may be able to view as this was a large area. Examining the tongue could therefore provide some vital information about the health and cleanliness of the oral cavity and was therefore included.

Saliva has an important role in helping protect against bacteria, dental disease and to provide moisture. Just fewer than 90% of the assessments in the literature review included assessment of saliva, and the qualitative interviews highlighted that having excess or no saliva can cause distress and discomfort for the patient. Saliva has an important role in maintaining oral health as it contains enzymes that control the proliferation of pathogenic bacteria (Ireland 2006). As well as the protective measures saliva has, the expert panel felt that the quantity and quality of saliva was a good indicator of hydration. Too little saliva may impact on the patient's own ability to defend against pathogenic bacteria; and protect the mucous membrane from abrasions. Too much saliva can be difficult for the patients to control causing dribbling which is distressing to the patient affecting their well-being and quality of life (Schimmel et al. 2009). The qualitative interviews

highlighted the impact excess or no saliva had on the patient's well-being making the patients feel self-conscious and anxious. Saliva was therefore deemed an important item and was included in the assessment.

Although the throat was one area identified in the literature review and mentioned in the qualitative interviews the expert panel felt that problems of a dry throat may occur due to other factors such as dehydration, oxygen therapy or mouth breathing. These factors increase the risk of dryness in the oral cavity and potential problems with the throat. The throat was not seen as one of the areas that would be cleaned and it was seen by the expert panel as being part of the pharyngeal phase of the gastrointestinal tract. The nurses on the expert panel also expressed concern regarding difficulty in examining the throat in stroke patients who may have cognitive difficulties and who may be unable to obey commands. They also suggested that problems that occur with the throat of stroke patients, such as fungal infections (Budtz-Jorgensen et al. 2000), are often diagnosed after the patient has reported pain. Ultimately, the expert panel decided that examining the throat to inform oral care was not appropriate, but nurses should investigate any problems that may be described by the patients with regards to the throat.

Several other areas were included in the oral assessments identified in the literature review and the qualitative data: swallow; voice; smell; nares; food debris; and airways. The expert panel did discuss all of these area, but they were discounted for the following reasons: swallow and airways were seen as a separate clinical assessments, voice and nares were not seen as being part of the oral cavity, the evidence to support the inclusion for smell was limited (Dickinson et al. 2001; Passos and Brand 1966) and food debris was to be included within the assessment of the cheeks.

Comfort

The final area identified for consideration was oral comfort. The literature review identified that items such as pain and comfort were only present in a third (33%) of the studies and only three of the assessments used pain as an indicator of oral health and cleanliness. Although pain was only cited in three assessments the qualitative interviews highlighted that oral discomfort and pain had a large impact on the patient's well-being. Patients perceived that they must have severe problems due to the discomfort they were feeling in their oral cavity. The qualitative data also highlighted that what patients felt was a problem such as dryness may not be observed on clinical examination and so there is always the risk that health professionals will only provide care for problems that can be seen on examination rather than problems the patient describes.

Assessment of pain and comfort were therefore deemed an important part of the assessment of oral health and cleanliness providing invaluable information that may otherwise be missed.

The expert panel discussed many ways of assessing oral comfort and decided the best method of gathering meaningful information was through asking the patients how their oral cavity felt. The expert panel were aware that this may potentially exclude some patients from completing this section of the assessment, such as patients with cognitive or communications problems. Discussion about how to capture as many patients as possible with communication and cognitive problems resulted in the expert panel suggesting the use of Coop or visual analogue scales. These scales are an alternative method in gathering information in patients who may have communication problems. However, due to time constraints it was not possible to explore this in the thesis. This consideration would be taken forward in future studies relating to the implementation of the assessment. Two questions assessing comfort were decided upon: Do you have any pain? How does your oral cavity feel? The final oral assessment would therefore have three sections, assessment of: patient's ability; oral cleanliness; comfort.

6.2.4 Scoring of items

The new oral assessment was being developed using a formative model and therefore needed a scoring system to reflect this model. Within the three sections identified for inclusion in the assessment (ability, health and cleanliness, and comfort) interpretation of the information is required. The literature review reported that ordinal scales had been used in the majority of assessments. This is where the assessor makes a rating based on a category, for example: mild; moderate; or severe. In order for the rater to make this assessment, certain criteria need to be met and in previous oral assessments these criteria has been presented as descriptors of signs and symptoms of severity. Initially a classification system was chosen by the expert panel which included three categories: normal; moderate; and severe. However, following discussion, the expert panel thought that knowing the severity of the problem would not necessarily change nursing or medical intervention and it was more important to assess whether an oral problem was present or absent. A dichotomous scoring system was therefore chosen rather than a classification system. However, the expert panel also felt it may be important to give staff some indication of whether a problem was present or not for some items.

It was felt that ability could be assessed using questions or clinical information and required a yes/no answer. Oral health and cleanliness could be assessed through clinical examination of the oral cavity and for each item a descriptor was required to aid the health professional with their decision making and to help increase rater agreement. The researcher provided the expert panel with a list of descriptors that had been reported in the oral assessments described in the literature review (Appendix 43). For each item the expert panel discussed the purpose of assessing that item, what information was required and who would be completing the assessment. The descriptors should help guide the assessor as to what is deemed healthy/no problem and unhealthy/a problem. Through providing descriptors it was felt this would contribute to inter and intra-rater agreement. The descriptors were therefore developed from the literature and consensus of opinion to provide the assessors with enough information to guide their decision making of what was normal, and what was abnormal.

The expert panel identified that clinical examination and questioning were the best methods of collecting the information which would inform the assessment. However, choosing these methods would mean that some items in the oral assessment may not be able to be assessed due to the patient's inability to communicate and follow commands and/or allow clinical examination. The expert panel thought it was important that all patients had a full assessment and if the nurses were unable to assess any item they could score a "U" for unable to assess. This would inform other health professionals that an assessment has been made but the information could not be obtained, and that it was therefore unknown if there was a problem for that item. The expert panel thought this would prompt the next assessor to try to assess the item again. The expert panel also discussed the need to document an action plan regarding the type of action taken. This would not be a care plan but an indication of whether an action to initiate additional nursing care or medical care was required. The expert panel decided that this should be in a simple format where the health professional could tick a box by each item indicating whether a nursing action (oral care) or medical action was required and was taken. A letter would be placed in the relevant box with an "O" for oral care prescribed by the nurse or other health professional and/or an "M" which would indicate that medical review of an oral problem is required (Figure 6-2). The oral care plan (intervention) was felt to be another part of the process and was beyond the remit of this thesis but prescribed care should be documented in the patient's care plan.

Comprehensive Oral Assessment Tool for Stroke COATS

Date **Patient Name** **D.O.B**

Pre Screening: Please circle each statement to assess need. If any of the responses are red please complete the COATS.

Can the patient go to the bathroom (to do their oral care)?	**Yes**	**No**
Can the patient attend to their own oral care?	**Yes**	**No**
Does the patient attend to their oral hygiene?	**Yes**	**No**

Action **Oral care (O)** **Medical Intervention (M)**

Area: Score **0, 1** or **U** (unable to assess) for each one, plus **O** for oral care or **M** for medical intervention

			Score						
Area	**0**	**1**	Day 1	Day 2	Day3	Day4	Day5	Day6	Day 7
Lips	Smooth, pink	Dry cracked, red at the corners, broken, ulcerated							
Teeth/ Dentures	No plaque	Visible plaque on teeth, food debris							
Gums	Pink, moist	Swollen red edges							
Cheeks	No food	Bolus of food in cheeks							
Tongue	Pink, moist	Coating on the tongue, abrasions on the tongue, swollen tongue							
Roof of mouth	Pink, moist	Red areas, thick mucus covering, broken, ulcerated areas							
Saliva	Normal saliva, free flowing	Dry sticky saliva, no saliva, oral cavity dry							
Pain	No pain	Pain							
How does the oral cavity feel	Clean, fresh	Not clean, dirty							

Figure 6-2 First draft of the COATS - obverse

Supporting information

Equipment

Small headed toothbrushes are essential to clean teeth and dentures. The toothbrush should preferably be a paediatric/small headed toothbrush with soft bristles to ensure ease of getting into the patients mouth and reducing trauma. Electric toothbrushes can also be used. If a patient does not have access to a toothbrush an alternative (sponges on sticks, gauze on a finger or large cotton buds) can be used however these are not as effective in removing plaque. Care needs to be taken with sponges and they should not be left in the cleaning solution and should be discarded after every use.

Cleaning teeth for patients who have no swallowing difficulties

Place a small amount (pea size) of fluoride toothpaste on the toothbrush. Place the toothbrush at 45 degree angle on the tooth surface and using a circular motion brush away from the gum line. Gently brush the inside, outside and chewing surfaces of each tooth. Encourage the patient to spit out any excess toothpaste. Avoid rinsing if possible. Teeth should be cleaned at least twice daily.

Cleaning dentures

Remove dentures from the patient's mouth and clean all surfaces with a small amount of fluoride toothpaste using the same techniques as above. Rinse and replace dentures in the mouth.

Cleaning the teeth of Nil By Mouth (NBM) Patients / Patients with Dysphagia

Patients who are NBM and/or patients who have dysphagia can still receive oral care. Liaise with speech and language therapist if required. When cleaning the teeth use non–foaming toothpaste (ask your pharmacist).

Place a small amount (pea size) of fluoride tooth paste on the toothbrush. Place the toothbrush at 45 degree angle and brush away from the gum line in a circular motion. Gently brush the inside, outside and chewing surfaces of each tooth. Remove any excess saliva and toothpaste using suction (if trained to do so) or using gauze on a gloved finger or a sponge on a stick or large cotton swabs. If the patient is unable to open their mouths place the toothbrush inside the cheek and clean the front surfaces of the teeth.

For those patients who will not allow the nurse to clean the tongue, roof of the mouth, inside and chewing surfaces of the teeth ensure oral care is attempted at every visit.

Dental referral

If a dental referral is required and there is no dental service in your hospital, consider contacting a dentist who will do domiciliary visits to ascertain if they will come and assess the patient in hospital.

Figure 6-2 (continued) – reverse

6.3 Layout and format

When considering the layout of the assessment, issues that impact on the provision of care and implementation of the assessment into clinical practice need to be considered (de Vet et al. 2011). For instance, the length of time taken to complete the assessment and how often the assessment is to be used. The qualitative interviews identified many barriers that would need to be overcome if the assessment was to become an integral part of clinical care; barriers such as staff time and workload. The nursing staff felt strongly that the assessment should be simple and easy to use, standardised, require very little training, and be meaningful to clinical practice. The expert panel used the information identified in the qualitative interviews to plan the layout of the assessment. As time and workload were a consideration, having one piece of A4 paper that could record seven days' worth of assessments was viewed as important. This would save time, and allow the nurses to review previous assessments informing their decision about future care.

The layout of the assessment also had to take into account the frequency of the assessment. The qualitative interviews identified having a sheet for each day would mean multiple pieces of paper, which would need to be collated would be onerous and so may be a barrier to the health professional completing and documenting an oral assessment. Workload and time also has a large impact on whether oral care is performed due to oral care being viewed as low priority (RCN 2012; Wardh et al. 2000). The qualitative interviews suggested several times that oral assessment should be completed every time oral care is performed up to three times daily. The literature also identified multiple time points when the assessments were completed (Table 3-6), this varied from twice daily to weekly. Ideally, the expert panel felt that a formal assessment should be the precursor to oral care being provided. However, they felt that this was probably not practicable and they did not want an assessment that was onerous which could potentially be a barrier to oral care. On the other hand if an oral assessment was completed once daily this could prompt nurses to provide oral care. The expert panel finally agreed that once daily was a reasonable time frame that would take into account workload, changes in the patient's medical condition, and would ensure identification of problems and help guide the nurses as to what care could be prescribed for that day.

Essentially, the assessment needed to be able to identify an oral problem, oral cleanliness, and inform care provision in a timely fashion. One factor that was raised throughout the qualitative interviews and is supported in the literature was the lack of knowledge and education (Wardh et

al. 2000). Education and training is important for several reasons: to improve the rater's self-efficacy in performing the assessment and care; to improve agreement between and within raters. In the qualitative interviews the health professionals felt their lack of knowledge affected their confidence in performing oral care and understanding the implications if oral care did not occur. The literature review found that up to three hours of training had been provided to improve the agreement between raters (Table 3-6). The expert panel all agreed that education and training was important and wanted to ensure that what they decided would be accessible and have the desired impact.

The expert panel's aim was to increase staff knowledge and increase agreement when using the new assessment. They were aware that in the current clinical climate there is difficulty in releasing staff for education beyond mandatory training. The expert panel therefore felt that releasing staff for 1-2 hours training, over and above mandatory training, for an issue that is viewed by the clinical team as low priority would probably be difficult. Providing some education was essential and one method of doing this was to place information on the reverse side of each A4 sheet. The information would contain current clinical guidance on what equipment to use, how to clean the oral cavity for patients with or without dysphagia and when to refer to dental services. Following all these discussions the first draft of the Comprehensive Oral Assessment Tool for Strokes (COATS) was developed (Figure 6-2).

6.4 Pilot testing

Having considered the first four steps for developing an oral assessment (de Vet et al. 2011), the next step is to pilot test the first draft of the new oral assessment in a small group of the target population. This phase is repeated a number of times to assess the comprehensibility, acceptability and feasibility of the oral assessment before formally pilot testing the assessment (de Vet et al. 2011; Streiner and Norman 2008). The first pilot testing will be presented in Chapter Seven.

6.5 Summary

This chapter has presented the development of the COATS by an expert panel that followed the first five steps presented by the COSMIN group (de Vet et al. 2011). Information gathered in the literature review, the qualitative interviews, and their clinical knowledge and experiences were

used to guide their discussion and decision making. The expert panel decided the COATS would have three sections, assessment of:

- The patients' ability to attend to their oral care, determining if assistance is required;
- The health and cleanliness of specific areas in the oral cavity, determining the type of oral care or medical intervention required;
- Oral comfort and how the oral cavity feels.

Throughout the discussion it was clear that each of the experts on the panel focused on those areas that were important to them in their role as either a provider or receiver of oral care. The health professionals were concerned about ensuring all patients had the opportunity to attend to oral care. They were also concerned about how and when an oral assessment would fit into their already busy day. This impacted on the decisions they made. The dental expert focused on the prevention of disease and was very insistent that those areas that are important in dental health were included. This decision to include an item was still made regardless of the reliability that was found in the literature review such as cheeks and gums. The patients and carers were concerned with ensuring they had every opportunity to perform or receive oral care. Those with a professional role felt that the reliability of the assessments was varied and many of the studies were shown to be of a poor quality therefore, there was insufficient data to support or reject including them in the new assessment.

A dichotomous scoring system was decided upon because the aim of the assessment was to identify whether a problem in the oral cavity was present or absent. It was also important that the assessment could measure oral hygiene from a nursing perspective rather than a dental perspective because nursing staff do not have specialist training in assessing oral hygiene. In addition, the assessment should be quick and easy to use. There are disadvantages of using a dichotomous system in that it does not categorise the severity of the problem. However, due to nurses' limited knowledge of the oral cavity and their inexperience in assessing plaque and gingival scores it was felt the assessment needed to meaningful and useful in the clinical setting. Essentially, the assessment needed to be able to identify an oral problem, oral cleanliness, and inform care provision in a timely fashion. A lack of education and training impacts on how health professionals prioritise oral care as well as on ensuring reliability is maintained between and within raters when an assessment is being used by multiple members of the team. The expert panel thought that providing education was important but wanted to ensure this could be

maintained. They therefore decided to add supporting information to the assessment so that nurses and health professionals could access the information required to inform and support their decision making. Having an oral assessment that was reliable with minimal education was deemed more useful than having an oral assessment that was only reliable with extensive education out of the ward area, which may not occur.

The first draft of the COATS was therefore agreed upon and the next step in the development of the COATS was to pilot test it in a stroke population to measure its validity, reliability, and feasibility of use. This will be presented in Chapter Seven.

Chapter Seven

Pilot testing the Comprehensive Oral Assessment for Stroke (COATS).

7.1 Introduction

The previous chapter outlined the first five steps of the development of the COATS. This chapter will present the final step of pilot testing of the COATS. Pilot testing allows the researcher to identify if the assessment is measuring what it should be measuring (valid) and the degree to which the assessment can be used accurately by multiple raters (reliable). The chapter will outline the measurement properties that will be tested in the COATS, the methods used to test its measurement properties, and then the results will be presented. The chapter will conclude with a discussion of the results, relating these to the current literature.

The COATS has been developed so that potentially any health professional would be able to use it in the clinical setting. Ideally this would mean testing the COATS using multiple disciplines. However, the practicalities of doing such a study were beyond the scope of this thesis. Currently, nurses are the main professional discipline who provide oral care so the first stage of field testing the COATS will be in the nursing profession.

7.2 Measurement properties testing

Content and face validity

Face and content validity were initially provided by the literature review and the clinical and academic experts in oral health and stroke, health professionals, patients, and carers. The expert panel also provided further confirmation of content and face validity. This has therefore been discussed in Chapter Six.

Criterion validity

Ideally each item in the COATS would be compared with an independent scale/assessment that could be considered a reference standard. In the testing of the assessments identified in the

literature review the reference standard used was a dental examination performed by an expert in the field under investigation (Chalmers et al. 2005). For example, the reference standard for oral cleanliness could potentially be a clinical examination by an oral health expert such as a dentist who would use a number of recognised measures: the gingival Index (Loe and Silness 1963) and the Plaque Index (Silness and Loe 1964). The aim of the COATS was to measure oral cleanliness in a hospitalised setting using nurses' knowledge and skills. Currently, there is no reference standard available that represented nursing assessment of the oral cavity. The only reference standards available are those in dental medicine that require the expertise of a dentist to perform the examination. Currently, it is beyond the scope of this thesis to utilise a dentist as a reference standard. Therefore, in order to assess the potential diagnostic accuracy of the COATS, a decision was made that a nurse considered to be an expert in oral care would be the expert and their scores on the COATS would act as the reference standard.

Agreement (Reliability)

Agreement was tested in the target population of stroke patients. The researcher assessed agreement between registered and unregistered nurses because oral care is provided by all levels of nurses in clinical practice. Potentially unregistered nurses have had less formal training in oral care than registered nurses (Talbot et al. 2005) so it was important to assess agreement between the different levels of nursing staff who provide oral care.

Feasibility

Assessment of the feasibility and clinical relevance is recommended in pilot testing (de Vet et al. 2011). Although the expert panel had discussed many of the issues relating to feasibility when developing the COATS, issues such as the time it takes to complete, and the ease of use (including making the assessment and recording the information) had not been tested in the clinical setting or in the target population. Feasibility regarding the use, layout, format of the COATS was therefore assessed in the pilot study phase.

7.3 Aim

To explore the validity, agreement and feasibility of an oral assessment for use in stroke patients by:

1) Estimating the diagnostic accuracy of the COATS;
2) Assessing the agreement between registered and unregistered nursing staff and the reference standard when using the COATS;
3) Assessing the feasibility of the COATS.

7.3.1 Design

Using a quantitative approach, validity, agreement and feasibility of the COATS were examined in a patient population.

7.3.2 Setting

An acute stroke unit, in an NHS Trust from the North West of England.

7.3.3 Ethical and research governance considerations

Ethical approval was sought from the local NHS Research Ethics Committee (Appendix 41) and the Built, Sport and Health (BuSH) schools University Research Ethics Committee (Appendix 42). In addition, research governance approval was sought from the Research and Development department at the NHS Trust (Appendix 43). The supervisory team also ensured that governance was maintained throughout the study through regular supervisory meetings with the researcher.

7.4 Methods

7.4.1 Subjects

A convenience sample of patients, were recruited from an acute stroke unit between 25 February 2013 and 26 June 2013. All patients present on the ward, on the days of recruitment, were considered for the study. Recruitment took place when all three raters could meet on two consecutive days. This could be once or twice a week. Patients were eligible if all the inclusion criteria were met and none of the exclusion criteria were met.

Patient Inclusion Criteria

- Admitted to the acute stroke unit with a clinical diagnosis of stroke;
- Aged 18 years and above.

Patient Exclusion Criteria

- Deemed medically unstable by the clinical team;
- Unable to cooperate with the assessment;
- Unable to consent and where there was no identified consultee to provide consultee declaration.

7.4.2 Sample size

The proposed sample size for 3 raters was calculated as 82 patients. This would enable agreement to be estimated using the Kappa statistic to within ±0.15 if the true Kappa was 0.8 (or larger) or within ±0.17 if the true Kappa was 0.6 (or larger) with 95% confidence, assuming a prevalence between 25% and 75%. For pairwise agreement between raters, the corresponding precision would be within ±0.16 if the true Kappa was 0.8 (or larger) and within ±0.20 if the true Kappa was 0.6 (or larger).

7.5 Procedure

Participant identification and recruitment

All stroke patients admitted to the stroke unit were approached and screened for inclusion into the study by a member of the clinical team. If the clinical team deemed patients not to have the capacity to consent, the clinical team identified and approached a consultee. The clinical team then provided the potential participant/consultee with a copy of the information sheet and provided an explanation as to the purpose of the research. If the potential participant/consultee was interested in taking part, a member of the clinical team introduced them to the researcher. A meeting was arranged between the researcher and the potential participant/consultee where the researcher explained the project in more detail and answered any questions. If the potential participant/consultee agreed to take part, the researcher obtained written consent (participant/witnessed consent for patients with capacity or consultee declaration for a patient deemed to have little or no capacity) before any assessments took place. Once consent had been

obtained, a copy of the consent form was given to the participant, the original was stored at the University of Central Lancashire, and a copy was filed in the patient's case-notes. Consent was re-affirmed before any assessment of the oral cavity took place (Figure 7-1).

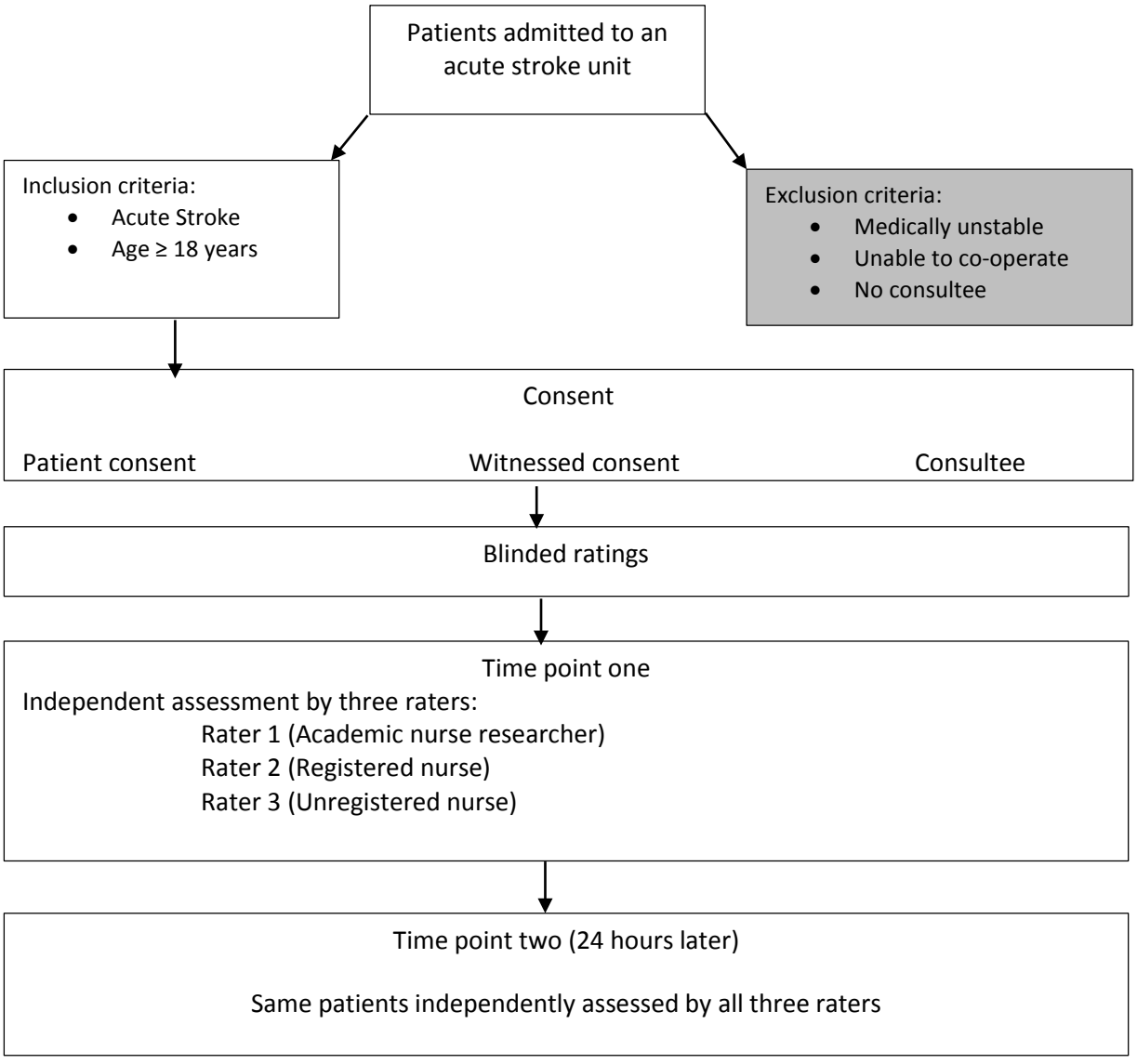


Figure 7-1 Flow chart for validity and reliability testing

The raters

There were three raters:

Rater 1– an academic nurse researcher (registered, post-graduate degree student, principle investigator)[reference standard];

Rater 2 – a registered nurse, band 6 (RN);

Rater 3 – a health care assistant (HCA) (unregistered nurse), band 2.

Rater 1 was an experienced registered nurse who had worked in stroke care for 22 years. They had developed their oral care knowledge and skills to a high level and had an interest in improving the knowledge and evidence to support oral care in stroke patients. For the purpose of this study, Rater 1 was considered the reference standard. Rater 2 was a registered nurse who had been registered for eight years working in acute stroke care, initially as a registered nurse on the acute stroke unit and currently as a stroke research nurse. Rater 2 also had a keen interest in improving stroke care and had been involved in multiple research projects. They classed their knowledge of oral care of a similar level to other registered nurses on the stroke unit. Rater 3 had worked on the stroke unit as a HCA for five years. They had gained their National Vocational Qualification (NVQ) level three in nursing care. Rater 3 reported having some knowledge of the oral cavity because they had just recently completed an internship with the university, examining oral flora in stroke patients. However, with regard to oral care they had not received any formal training.

The nurses were purposively chosen because oral assessment and oral care falls into the remit of all grades of nursing staff on the ward. Having an oral assessment that could be used by all members of staff, registered and unregistered would be more likely to be beneficial to clinical care because all nurses provide oral care. Therefore, it was important to measure agreement between registered and unregistered members of the nursing team. Both raters were also selected for pragmatic reasons. Releasing nursing staff's time on the stroke unit to support the study was not a viable option. Both rater 2 and rater 3 were working on research projects in the trust and it was more practicable for them to be allocated time to support the study.

Training

Training was discussed at length and although several studies have shown that education and training increased agreement and oral care (Clarke 2009; Fallon et al. 2006; Frenkel 2003; Charteris and Kinsella 2001) this did not reflect current practice. Education and training for oral

care is not routinely provided (Wardh et al. 1997) and this was also reiterated at the qualitative interviews. When examining current practice and the available resources, releasing staff for training is not always possible so it was important to explore if an assessment could be introduced into clinical practice with little training and still be reliable between and within raters.

A minimum of training was therefore provided to all raters that covered:

- How to use the COATS;
- The scoring system;
- Clarification was also provided regarding the descriptors in the score if required.

The initial training was given by the researcher who was also the expert nurse. The training was informal, and involved an explanation of the COATS, what each part was measuring, the descriptors and the scoring system. The raters were asked to read through the COATS and ask any questions they may have. This training took 20 minutes. A small pilot study examining their understanding of how to use the COATS was then performed. All three raters were provided with a series of photographs of oral cavities that had been obtained from a previous study (Dickinson et al. 2001). Each rater independently assessed the oral cavities in the photographs using the COATS. The raters then compared their scoring, discussing both agreements and disagreements to ensure the same criteria were being used and that even where they did agree, it was for the same reasons. Where disagreement was found this was discussed until a consensus of opinion was reached. Agreement between the raters was good, with a 90% match.

Oral assessments

The COATS was re formatted into a design that could be used for the purpose of the research (Appendix 44). Each participant was approached and had their oral cavity assessed at two time points 24 hours apart. The assessments were carried out, between 10am and 12 midday or 2pm and 4pm. This was to standardise the times of the assessments and to take into account meal times, and when oral care may take place. All the raters performed their assessments within minutes of each other and the order of raters was ad hoc. With each new participant, one rater would take the lead and co-ordinate the assessment, communicating with the patient. This was to provide continuity for the patients and reduce the patient's burden and stress.

Time point one: Testing Agreement between raters, up to three researchers.

All raters wore non-sterile gloves for each assessment. Consent was re-confirmed and the lead researcher would ask each patient the pre-screening questions in order. For those patients who were unable to answer these questions the researchers would ask the nurse responsible for the patient's care if they could provide the information from their clinical knowledge of the patient. Before the assessment took place, to preserve dignity, the curtains would be drawn. The lead rater would ask the patient to remove any dentures and open their mouths. Each rater independently looked inside the oral cavity using a torch, and a tongue depressor if required. For those participants who had difficulty opening their oral cavity, one of the raters would move the upper and lower lips to expose the teeth and gums and each rater would carry out an assessment. On completion of the examination/observation the lead researcher asked the patient if they were in any pain and how their oral cavity felt. The raters, independently, without discussion, recorded their oral assessment on the dedicated recording sheet for each patient (Appendix 44). Once the raters had recorded their assessment, the sheets were placed in an envelope and sealed. Throughout this process the patients could request to stop the assessment at any time.

Time point two: Testing agreement within raters, three researchers.

The same raters returned 24 hours after the first assessment and reassessed the patients' oral cavity, following the procedure set out in time point one. Twenty-four hours was deemed a reasonable length of time between the two assessments, taking into account construct stability (risk of changes occurring in the oral cavity between assessments) and rater bias (raters remembering the previous day's assessment).

Each rater also completed a questionnaire at the end of the study assessing the feasibility of the COATS (Appendix 45).

Patient data collection

Age, sex, functional ability, (assessed using the Barthel Activities of Daily Living index (Mahoney and Barthel 1965), scored from 0: dependent to 20: independent), date of admission and date of stroke were collected from the case-notes, the clinical team and/or nursing notes at time point one (Table 7-1). These data would enable the researcher to describe the participants and their level of dependency.

Table 7-1 Data collection and time points

Data	*Time point one*	*Time point two*
Age	✓	
Sex	✓	
Date of stroke	✓	
Days since stroke	✓	
Barthel Index	✓	
COATS	✓	✓

Reliability and diagnostic data

The date and time of the assessment, the rater, and COATS scores were recorded for each rating on each patient. Rater agreement comparisons were made between rater 1, and Raters 2 and 3, and between Raters 2 and 3. Within rater agreement comparisons were made within each raters score on the two days (Table 7-2).

Table 7-2 Reliability and diagnostic testing

	Rater 1	Rater 2	Rater 3
Rater 1	Agreement within rater	Validity	Validity
Rater 2	Agreement between raters	Agreement within rater	Agreement between raters
Rater 3	Agreement between raters	Agreement between raters	Agreement within rater

7.6 Analysis

Descriptive statistics will be analysed to provide median and Interquartile ranges (IQR) and percentages. For agreement Rater 1 was considered to be the reference standard. All the other raters were compared to Rater 1 as well as each other. The pairs of rater's assessments were analysed using Kappa (K) statistic (as described in section 43); approximate 95% confidence intervals (CI) for Kappa (K) were obtained using non-parametric bootstrapping. Non-parametric bootstrapping allows the statistical test to be completed in data that are not normally distributed. Intra-rater agreement for Raters 2 and 3 was assessed using patients where Rater 1 had rated the same for that item at both time points. The results have been interpreted using the classification system as described in Table 2-1 on page 44, where a Kappa of 0.81-1 is very good agreement, 0.61-0.80 is good agreement, 0.41-0.60 is moderate agreement, 0.21-0.40 is fair agreement and <2 is poor agreement (Landis and Koch 1977). The sensitivity, specificity, positive predicative value, negative predicative value and diagnostic accuracy were estimated by comparing Rater 2 with Rater 1. Data from the feasibility questionnaire was used to inform and potentially refine the content and design of the COATS.

7.7 Results

Two hundred and twenty four patients were admitted to the stroke unit between 25 February 2013 and 26 June 2013, of which 82 (37%) of patients were recruited into the study. The number of patients assessed by each rater on each day is shown in Table 7-3. Although the target was to recruit 82 patients for all three raters, Rater 1 was the only rater who achieved 82 patients. Rater 2 achieved 61 on day one and Rater 3 achieved 60 on day one. The difference in the number of patients rated by each rater is due to staff holidays, sickness and working patterns. This meant the target of 82 was not met within the time constraints of the study.

Table 7-3 Number of patients assessed by each nurse at each time point

Assessment time point	Number of patients assessed		
	Rater 1	Rater 2	Rater 3
Day 1	82	61	60
Day 2	69	52	44

The demographics of the sample are shown in Table 7-4. Just over half of the patients (54%) were dependent in grooming (which includes attending to their oral care), and 50% were dependent on others to assist with mobilising (Table 7-4).

Table 7-4 Demographic information for the population

Demographics	
Median age (IQR)	76 years (IQR 65-84)
Sex	38 (46%) female
Median Total Barthel score (IQR)	9.5 (IQR 1-16)
Dependence with grooming n (%)	44 (54%) dependent 38 (46%) independent
Assistance required to mobilise n (%)	42 (51%) dependent 24 (29%) require assistance 16 (20%) independent

Patients were assessed between 0 and 40 days from onset of stroke; the median time from onset of stroke was 4 days (Inter quartile range [IQR] 2-8). Seventy-five percent of patients were assessed in the first eight days after stroke. Five patients were assessed 21 or more days after their stroke, four only became medically stable at this time point and one patient was transferred into the unit from another country (Figure 7-2).

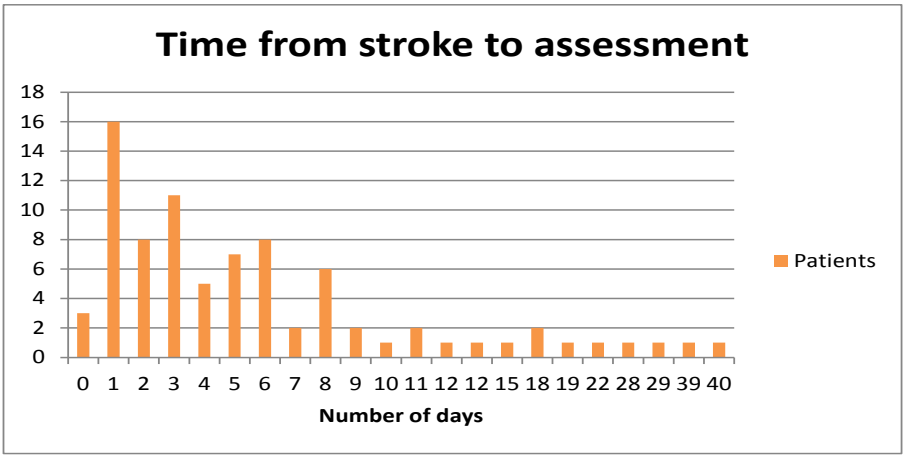


Figure 7-2 Time from stroke to assessment

The pairs of assessments were taken at 25 different time points over the four months. The median number of assessments performed at each time point was 3 for both time point one and time point two (IQR 2-4) (Figure 7-3).

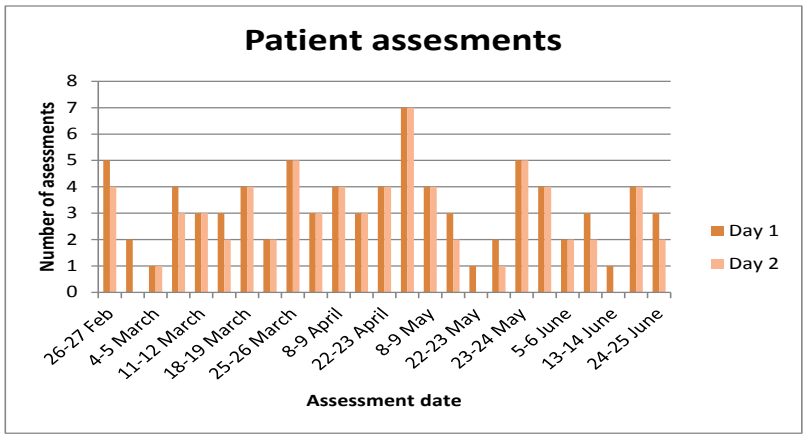


Figure 7-3 Number of assessments at each time point

7.7.1 Agreement between raters

Agreement between Rater 1 and Rater 2 and 3 are presented in Table 7-5. Rater 2 and 3 did not achieve all potential ratings for areas on the COATS due to missing data or inability to obtain the data at the time of the assessment. Raters 2 and 3 are presented in Table 7-6. No results have been presented for dentures because five or fewer patients provided data.

Ability

Rater 2 and Rater 3 had good to very good agreement with Rater 1 for all areas of ability with agreement ranging from 0.75 (CI 0.58-0.92) for patients attending to their oral care to 0.88 (CI 0.74-1) for ability to access the bathroom. Similar agreement was found between Rater 2 and Rater 3.

Oral Cleanliness

Agreement between Rater 1 and the other raters varied across all items. Rater 2 and Rater 3 showed fair agreement with Rater 1 for gums and cheeks and Rater 2 had slightly better agreement with Rater 1 than Rater 3 for teeth and roof of the mouth (Table 7-5). Agreement between Raters 2 and 3 was poor for gums and teeth, fair for tongue, roof of the mouth and saliva and moderate for cheeks (Table 7-6).

Comfort

Agreement for both pain and comfort was very good between Rater 1 and Rater 2 and good between Rater 1 and Rater 3 (Table 7-5). Agreement between Raters 2 and 3 was very good to good (Table 7-6).

Table 7-5 Agreement between Rater 1 and Raters 2 and 3 for the COATS

		Rater 2					Rater 3			
Rater 1	**Ability**	**N**	**K**	**Lower CI**	**Upper CI**		**N**	**K**	**Lower CI**	**Upper CI**
	Can the patient access the bathroom	60	0.80	0.65	0.95		49	0.88	0.74	1
	Can the patient attend to oral care	58	0.86	0.71	1		46	0.87	0.73	1
	Does the patient attend to oral care	58	0.75	0.58	0.92		44	0.77	0.80	0.96
	Oral cleanliness									
	Lips	60	0.54	0.33	0.71		59	0.50	0.27	0.70
	Teeth	51	0.56	0.30	0.76		50	0.28	0.02	0.51
	Gums	60	0.30	0.08	0.50		60	0.35	0.16	0.53
	Cheeks	61	0.31	0.05	0.56		60	0.26	-0.05	0.55
	Tongue	61	0.50	0.09	0.78		60	0.54	0.26	0.75
	Roof	61	0.70	0.51	0.86		60	0.52	0.30	0.71
	Saliva	61	0.52	0.30	0.73		60	0.47	0.25	0.69
	Comfort									
	Pain	61	0.96	0.85	1		59	0.93	0.78	1
	Comfort	61	0.84	0.71	0.95		60	0.76	0.58	0.89

N=Number of patients, K=Kappa, CI=Confidence Interval.

Kappa rating (Landis and Koch 1977)	Very Good	Good	Moderate	Fair	Poor
	0.81-1	0.61-0.80	0.41-0.60	0.21-0.40	≤ 0.20

Table 7-6 Agreement between Rater 2 and Rater 3 for the COATS

		Rater 3			
Rater 2	**Ability**	**N**	**K**	**Lower CI**	**Upper CI**
	Can the patient access the bathroom	31	0.86	0.68	1
	Can the patient attend to oral care	29	0.80	0.58	1
	Does the patient attend to oral care	29	0.86	0.66	1
	Oral cleanliness				
	Lips	39	0.43	0.61	0.69
	Teeth	36	0.26	-0.017	0.536
	Gums	39	0.20	-0.02	0.40
	Cheeks	39	0.49	-0.02	0.87
	Tongue	39	0.39	-0.054	0.79
	Roof	39	0.36	0.07	0.60
	Saliva	39	0.25	0.001	0.54
	Comfort				
	Pain	38	0.89	0.67	1
	Comfort	39	0.76	0.54	0.91

N=Number of patients K=Kappa, CI=Confidence Interval.

Kappa rating (Landis and Koch 1977)	Very Good	Good	Moderate	Fair	Poor
	0.81-1	0.61-0.80	0.41-0.60	0.21-0.40	≤ 0.20

7.7.2 Agreement within rater

Agreement within rater was examined for Rater 1 (Table 7-7). Agreement was variable across all items showing potential change in the oral cavity. Rater 1 rated 57 patients the same on both days. These patients provided the sample for testing intra-rater agreement for Raters 2 and 3. Agreement within raters ranged from fair to very good (7-8).

Ability

Rater 2 had very good agreement for all areas of ability with Rater 3 having total agreement for assessing patients getting to the bathroom and good agreement for patient's ability to attend to their oral care (Table 7-8).

Oral Cleanliness

Rater 2 had better intra-rater agreement than Rater 3. Rater 2 only had fair agreement with themselves for gums, and moderate agreement for saliva; all other areas showed good to very good agreement. Rater 3 only had fair agreement with themselves for gums, cheeks, tongue, and moderate agreement for lips, roof of the mouth, and saliva, good agreement for teeth. Both Raters 2 and 3 showed fair agreement for gums and moderate agreement for saliva (Table 7-8).

Comfort

Rater 2 had very good agreement for pain and good agreement for comfort, whereas Rater 3 only had moderate agreement for pain and good agreement for comfort (Table 7-8).

Table 7-7 Agreement Rater 1

Agreement within rater	Rater 1 (N)	K	Lower CI	Upper CI
Ability				
Can the patient access the bathroom	67	0.63	0.45	0.82
Can the patient attend to oral care	66	0.73	0.56	0.89
Does the patient attend to oral care	65	0.66	0.48	0.84
Cleanliness				
Lips	68	0.24	0.02	0.49
Teeth	59	0.19	-0.04	0.42
Gums	69	0.38	0.19	0.58
Cheeks	69	0.41	0.18	0.65
Tongue	69	0.19	-0.06	0.47
Roof	69	0.52	0.04	0.69
Saliva	69	0.51	0.27	0.72
Comfort				
Pain	69	0.49	0.23	0.71
Comfort	69	0.41	0.23	0.60

N=Number of patients K=Kappa, CI=Confidence Interval.

Kappa rating (Landis and Koch 1977)	Very Good 0.81-1	Good 0.61-0.80	Moderate 0.41-0.60	Fair 0.21-0.40	Poor ≤ 0.20

Table 7-8 Agreement within rater for Rater 2 and Rater 3 using the COATS

Agreement within rater	R2 (N)	K	Lower CI	Upper CI		R 3 (N)	K	Lower CI	Upper CI
Ability									
Can the patient access the bathroom	39	0.90	0.76	1		19	1.00	1	1
Can the patient attend to oral care	39	0.90	0.76	1		19	0.89	0.69	1
Does the patient attend to oral care	39	0.84	0.67	1		19	0.61	0.24	0.98
Cleanliness									
Lips	33	0.80	0.55	1		26	0.44	0.08	0.79
Teeth	23	0.61	0.28	0.90		15	0.75	0.28	1
Gums	34	0.28	-0.02	0.61		24	0.26	-0.06	0.57
Cheeks	38	0.87	0.38	1		28	0.38	0.00	1
Tongue	38	0.73	0.00	1		27	0.32	-0.06	0.74
Roof	40	0.65	0.41	0.86		28	0.41	0.09	0.68
Saliva	43	0.42	0.16	0.69		31	0.44	0.10	0.74
Comfort									
Pain	44	0.93	0.71	1		27	0.59	0.12	0.92
Comfort	33	0.78	0.56	0.95		21	0.66	0.24	1

N=Number of patients, R=Rater, K=Kappa, CI=Confidence Interval.

Kappa rating (Landis and Koch 1977)	Very Good 0.81-1	Good 0.61-0.80	Moderate 0.41-0.60	Fair 0.21-0.40	Poor ≤ 0.20

7.7.3 Diagnostic accuracy of the COATS

Diagnostic accuracy was assessed using rater 2 and the reference standard (Rater 1). The sensitivity for ability presented in Table 7-9 ranged from 86.1% (CI 70.5%-95.3%) to 91.3% (CI 70.5%-98.7%) and specificity ranged from 85.7% (CI 69.7%-95.2%) to 96.7% (CI 69.7%-100%) The PPV ranged from 80.8 % (CI 60.6%-93.4%) for whether the patient actually attended to their oral care to 96.9% (CI 83.7%-99.9%) for the patient's ability to get to the bathroom. The NPV ranged between 82.1% (CI 63.1%-93.9%) for the patient's ability to get to the bathroom and 93.8% (CI 79.2%-99.2%) for whether patients actually attended to their oral care. The overall efficiency of diagnosing patients with problems with their ability to attend to their oral care ranged from 87.9% (CI 76.7%-95%) to 93.1% (CI 76.7%-98.1%) (Table 7-9)

Table 7-9 Sensitivity, specificity, PPV, NPV and Efficiency for the assessment of ability by Rater 2 compared with Rater 1

R1 vs. R2, Time point 1	Successes	Failures	Total	Proportion	Lower CI	Upper CI
Can get to the bathroom						
Sensitivity	31	5	36	86.1%	70.5%	95.3%
Specificity	23	1	24	95.8%	78.9%	100%
PPV	31	1	32	96.9%	83.7%	99.9%
NPV	23	5	28	82.1%	63.1%	93.9%
Efficiency	54	6	60	90.0%	79.5%	96.2%
Can attend to oral care						
Sensitivity	25	3	28	89.3%	71.8%	97.7%
Specificity	29	1	30	96.7%	82.8%	99.9%
PPV	25	1	26	96.2%	80.4%	99.9%
NPV	29	3	32	90.6%	75.0%	98.0%
Efficiency	54	4	58	93.1%	83.3%	98.1%
Does attend to oral care						
Sensitivity	21	2	23	91.3%	72.0%	98.9%
Specificity	30	5	35	85.7%	69.7%	95.2%
PPV	21	5	26	80.8%	60.6%	93.4%
NPV	30	2	32	93.8%	79.2%	99.2%
Efficiency	51	7	58	87.9%	76.7%	95.0%

R=Rater, CI=Confidence Interval

The sensitivity for cleanliness ranged from 0% (CI 0%-0.31%) for cheeks to 90.6% (CI 0%-98.3%) for the tongue and the specificity ranged from 40% (CI 5.2%-85.3%) for the tongue to 95.6% (CI 5%-99.5) for the cheeks (Table 7-10). Lips, teeth, roof of the mouth and saliva showed sensitivity above 70% and specificity above 75% and PPV above 54% and NPV above 69%.

Whereas the tongue shows high sensitivity of 90.6% (CI 79.3%-96.9%) but has a low specificity of 40% (CI 5.2%-85.3), with a PPV of 94.1% and a NPV of 28.6% (3.7%-71.0%) diagnosing 71.4% as false negatives. The sensitivity and specificity of for gums were lower than the other areas, and the cheeks were shown to have a low sensitivity and high specificity, with PPV of 0% and a NPV 81.9% (CI 68%-90.6%) (Table 7-10).

Table 7-10 Sensitivity, Specificity, PPV, NPV and Efficiency for cleanliness

R1 vs. R2, Day 1	Successes	Failures	Total	Proportion	Lower CI	Upper CI
Lips						
Sensitivity	15	5	20	75%	50.9%	91.3%
Specificity	32	7	39	82.1%	66.5%	92.5%
PPV	5	7	22	68.2%	45.1%	86.1%
NPV	32	5	37	86.5%	71.2%	95.5%
Efficiency	47	12	59	62.7%	67.2%	89.0%
Teeth						
Sensitivity	18	7	25	72%	50.6%	87.9%
Specificity	16	5	21	76.2%	52.8%	91.8%
PPV	18	5	23	78.3%	56.3%	92.5%
NPV	16	7	23	69.6%	47.1%	86.8%
Efficiency	34	12	46	73.9%	58.9%	85.7%
Gums						
Sensitivity	11	8	19	57.9%	33.5%	79.7%
Specificity	20	9	29	69%	49.2%	84.7%
PPV	11	9	20	55%	31.5%	76.9%
NPV	20	8	28	71.4%	51.3%	86.8%
Efficiency	28	20	48	43.8%	29.5%	58.8%
Cheeks						
Sensitivity	0	10	10	0%	0%	0.31%
Specificity	43	2	45	95.6%	84.9%	99.5%
PPV	0	2	2	0%	0%	84.1%
NPV	43	10	53	81.1%	68.0%	90.6%
Efficiency	43	12	55	78.2%	65.0%	88.2%
Tongue						
Sensitivity	48	5	53	90.6%	79.3%	96.9%
Specificity	2	3	5	40%	5.2%	85.3%
PPV	48	3	51	94.1%	83.8%	98.8%
NPV	2	5	7	28.6%	3.7%	71.0%
Efficiency	50	8	58	86.2%	74.6%	93.9%
Roof of the mouth						
Sensitivity	17	5	22	77.3%	54.6%	92.2%
Specificity	30	4	34	88.2%	72.5%	96.7%
PPV	17	4	21	81%	58.1%	94.6%
NPV	30	5	35	85.7%	69.7%	95.2%
Efficiency	47	9	56	83.9%	71.7%	92.4%
Saliva						
Sensitivity	13	2	15	86.7%	59.5%	98.3%
Specificity	33	11	44	75%	72.5%	86.8%
PPV	13	11	24	54.2%	58.1%	74.4%
NPV	33	2	35	94.3%	69.7%	99.3%
Efficiency	46	13	59	78%	71.7%	87.7%

R=Rater, CI=Confidence Interval

Comfort had high Sensitivity Specificity, PPV and NPV. The number of false positives was between 0% and 5.9% and false negatives between 0% and 5.7% (Table 7-11).

Table 7-11 Sensitivity, specificity, PPV, NPV and efficiency for pain and comfort

R1 vs. R2, Day 1	Successes	Failures	Total	Proportion	Lower CI	Upper CI
Pain						
Sensitivity	6	0	6	100%	54.1%	100%
Specificity	45	0	45	100%	92.1%	100%
PPV	6	0	6	100%	54.1%	100%
NPV	45	0	45	100%	92.1%	100%
Efficiency	51	0	51	100%	93.0%	100%
Comfort						
Sensitivity	16	1	17	94.1%	71.3%	99.9%
Specificity	28	2	30	93.3%	77.9%	99.2%
PPV	16	2	18	88.9%	65.3%	98.6%
NPV	28	1	29	96.6%	82.2%	99.9%
Efficiency	44	3	47	93.6%	82.5%	68.7%

R=Rater, CI=Confidence Interval.

Feasibility

Raters 2 and 3 completed the feasibility questionnaire and their responses have been collated and presented in Table 7-12. Overall the nurses thought the COATS highlighted problems in the oral cavity that may otherwise be missed if a structured assessment was not available. During collection of the pre-screening data it became apparent that if a nurse was delayed and had to ask the questions independently to the other researchers the patient may provide different information to each researcher. Although the assessment was easy to use, small changes were suggested. Minor wording changes to some of the descriptors for the tongue, gums and cheeks were recommended, specifically adding broken area and ulcerated area to the cheeks and gums. Some of the issues identified related to the patient's willingness to cooperate, not allowing the nurses to examine the oral cavity, or remove dentures to enable a full oral assessment. However, the nurses thought that this issue had been taken into account with the "unable to assess" option. The nurses thought that knowing that an assessment had been performed, but was unsuccessful in obtaining information was useful to inform any subsequent assessments and decisions. One nurse suggested the raters should document the reason why an assessment could not take place. Overall the COATS was described as user friendly, and quick and easy to administer. One nurse

stated that having an oral care protocol alongside the assessment to guide the oral care and its frequency was required.

Table 7-12 Feasibility responses

	Question	Summary of the responses
1.	Is the COATS easy to read? If no please state why.	The COATS was reported as easy to use.
2.	Can you follow the instructions for the COATS? If not please state why.	All the elements are straight forward. Yes you can follow the instructions.
3.	Are the descriptors for each item clear? If no please state why?	The descriptor for the tongue could be elaborated but no suggestion given. All descriptors were fine. Need to add in ulcers or broken areas for the cheeks. Pain should be specific to oral pain.
4.	Are the actions clear?	All actions were clear. It was felt a protocol was needed to guide care. If care was initiated how would it be carried forward to others?
5.	Could you use the COATS with every patient? If no please state what stopped you using it in every patient.	The COATS could be used in everyone. Although it could not be completed fully in all patients, mainly unwell patients or those with cognitive problems. Patients not always willing to remove their dentures.
6.	Is the lay out clear? If no please state why.	The layout was clear allowing a systematic assessment.
7.	How often do you feel the COATS should be used? Please circle one.	**Once a day/twice a day/after every meal/ Four times a day** The COATS should be administered once daily ideally. Although it was acknowledged that, ideally the COATS should be administered several times a day, however, they did not think this was practicable.
8.	What aspects would you change if any and why?	The simplistic nature of the COATS lends the assessment to be used by more staff. If a problem is highlighted and awareness has been raised in all staff, this is better than a few staff with specialist knowledge.

7.8 Discussion

The aim of the study was to test the validity, reliability and feasibility of a newly developed oral assessment. The assessment was developed to assess three main areas: ability, oral health and cleanliness, and oral comfort in acute stroke patients. Agreement between registered and unregistered nurses ranged from fair to very good. The registered nurse showed better inter-rater-agreement than the unregistered nurse. The sensitivity and specificity for ability and comfort was high, indicating the assessment was able to identify a high percentage of cases with the problem or without the problem, with less than 20% being falsely diagnosed. Sensitivity for oral cleanliness was variable and ranged between 0-90 percent. The COATS showed good sensitivity and low specificity for the tongue indicating it was very sensitive in diagnosing those with a problem and greater difficulty in diagnosing those without a problem, with 71.4% being diagnosed as false negatives. Cheeks did not have a full range of data for those with problems and so sensitivity could not be calculated.

Sample

The sample chosen was a convenience sample of stroke patients rather than consecutive patients admitted. Although using patients who were admitted would potentially reduce patient selection bias and provide a more representative sample, this method of sampling was not possible due to the working patterns of the three raters. The sample was therefore those patients who were available when the raters could all meet on two consecutive days. Using this sampling method meant that there was a risk that the sample may be skewed towards a more dependent population because they have a longer stay in hospital and those patients who have a milder stroke may be missed due to being discharged after one day. This potentially meant the full range of scores may not have been tested (Streiner and Norman 2008). The patients selected could potentially not be representative of a normal stroke population in whom the assessment will be used, therefore affecting the internal validity of the study through sample bias (Leeflang et al. 2008). The study was concerned with assessing the agreement of multiple raters using the COATS and so having a random sample was not necessarily essential, but having a sample that was likely to reflect scoring across the full range of the assessment was important. The sample recruited had a median age of 76 years (IQR 65-84) and 38 (46%) were female which is similar to the national population described in the Sentinel Stroke National Audit Programme (SNNAP) (IntercollegiateStroke Working Party 2015). In a previous study performed by the researcher the

sample selected were more independent due to inclusion criteria so a full range of dependence was not included and the assessment could not be fully tested (Dickinson et al. 2001). This sample included patients across a whole range of dependency and so increased the potential for the whole range of scores to be tested. However, not all items had their potential scores assessed due to a lack of patients with dentures, or limited accessibility to certain areas in the mouth. Recruiting a percentage of dentures wearers would need to be considered in future studies when considering sample size and percentage of agreement.

Sample size is important to provide information about the precision of the study, which will show whether or not the findings could have occurred by chance. The sample size was calculated using a specific formula to reduce the risk of chance (random error) (Deeks et al. 2009). de Vet et al. (2011) recommends a sample size of 50 patients is a starting point when comparing two raters, however using a statistical formula to address random error for three raters a sample size of 82 was produced. In this study the sample size was not reached and so there is a risk that chance (random error) has contributed to the study results. Although the results have to be interpreted with caution, especially the agreement within rater results where only 31 patients were examined, the study shows the potential of the COATS to be a reliable assessment for use in the clinical area.

The patients themselves can also introduce subjectivity and bias. This can be through their understanding and reporting of any questions that they may be asked (de Vet et al. 2011). In an attempt to reduce the risk of change in patient responses and measurement error, all raters performed their assessment at the same time. One rater co-ordinated the assessment session and took the lead in communicating with the patient during the assessment. Some patients were unable to participate in answering the questions due to cognitive problems or would not allow the researchers to access the oral cavity making the examination difficult. Although there was a set format for performing the COATS assessment, this was not without its risk of bias. Whilst each rater approaches the patient from the same angle it cannot be guaranteed that the patient will keep their mouths open to the same size while each rater performs their assessment. In some cases, the patient was unable to open their mouth for the full time to allow all three raters to perform the assessment and so had to be asked to open their mouths again and again. When the patients had to open their mouths on multiple occasions there was a risk that the same view was not always available to each rater. This patient bias could affect the rater's interpretation of what they observed therefore affecting potential agreement between raters.

Performing the assessment at the same time, listening to the same response and examining the oral cavity at the same time has the potential to improve rater agreement (Streiner and Norman 2008) and reduce patient burden. If the ratings were performed independent of each other a different result may have occurred. In this study there were some occasions when this occurred due to rater availability. A rater would assess a patient's oral cavity after the other raters. When this occurred there was the risk that the patient may give a different response, open their mouths to a lesser or greater degree and so may increase the risk of bias and differences in agreement. One advantage of performing the assessment independently is that it is a true reflection of clinical practice and will provide a "true" reflection of agreement in clinical practice. Using a pragmatic approach in future research would allow a truer reflection of agreement in clinical practice.

Reference standard

Ideally the reference standard would be the best available measure at that time, performed by an expert in the field. In this particular study, the reference standard for oral health and cleanliness would potentially be assessments such as the gingival index score (Loe and Silness 1963) and the plaque index score (Silness and Loe 1964), which were developed for dental health and are usually performed by a dentist, who is deemed an expert in their field. The researcher was unable to access a dental expert who could perform the assessment due to limited resources. Furthermore, the preferred method for completing these oral examinations is to lie the patient flat with their head tilted so the examiner could gain a good view. In a hospital clinical setting nurses are not able to position stroke patients in this way due medical concerns, the impracticable nature of the examination, a lack of space, and current clinical guidance for stroke patients regarding positioning (ICSWP 2012). There is also the time it would take for the nurses to get the patients into this position for a simple oral assessment. The way in which the reference standard therefore assesses the patient needs to be representative of nursing practice and nursing skills.

The researcher was unable to assess the COATS against a reference standard such as an objective measure like the plaque score. A limitation to the study was COATS was used as the reference standard to assess diagnostic properties. This was the assessment being tested for agreement and whose psychometric properties had not yet been formally tested. The expert using the reference standard was Rater 1 (the academic nurse researcher). An assumption was made that the researcher was the expert, and that all their answers were 100% sensitive and specific (Deeks et al. 2009), this meant the other raters were compared for their ratings against the researcher, this

is known as verification. Verification bias is an issue in this research because we know the researcher is an expert in oral care and nursing but not necessarily an expert in oral examination. The reference standard could in fact over or underestimate the COATS accuracy affecting agreement.

Using the researcher is not ideal because the research is being steered by them and they have an invested interest in the results of the study (individual bias). This bias may therefore impact on the accuracy of their assessments, affecting the results. Using the researcher as the reference standard may also affect the performance of the other raters, causing then to respond in such a way so as to satisfy the researcher. The registered nurse and unregistered nurse may feel obliged or under pressure to perform well for the researcher causing them to either over or under estimate the results (Streiner and Norman 2008). Ideally, using a nurse expert who was not part of the research management team should be considered as this would reduce the risk of systematic error and bias, and should be considered for future studies.

Raters

The researcher wanted the raters to reflect those who currently work on an acute stroke unit and who provided oral care, rather than research staff employed specifically for the project. Using raters who were more representative of the nursing practice was seen as a true reflection of how the COATS would be used by the clinical team in practice. The qualitative interviews and the literature also identified that unregistered nurses performed the majority of oral care. Therefore, a strength of this study is that both the registered and unregistered nurses performed the assessments to measure agreement (Table 7-13). The agreement between raters was variable and ranged from poor to very good which is in line with another study that compared agreement between registered and unregistered staff in a residential care home (Kayser-Jones 1995).

Table 7-13 Comparing reliability scores between registered and unregistered nurses

Agreement between raters	Study	Scale	Test	Teeth	MM*	Lips	Gingivae	Tongue	Saliva	Denture	Palate	Swallow	Voice	Pain	Total
	Kayser-Jones 1995	BOSHE	K RN	0.52	0.10	0.32	0.45	0.25	0.12	0.74	0.10				
			K URN	0.38	0.26	0.26	0.34	0.26	0.20	0.54	0.26				
	Dickinson 2013	**Nominal**	**K Rater 2**	**0.56**	**0.31**	**0.54**	**0.30**	**0.50**	**0.52**	**1**	**0.70**			**0.96**	
			K Rater 3	**0.28**	**0.26**	**0.50**	**0.35**	**0.54**	**0.47**	**0.60**	**0.52**			**0.93**	

*MM=mucous membrane

PPMC-Pearson product moment correlation, IRC-Inter rater coefficient, Kw-weighted Kappa, ICC Intra-Class correlation co-efficient

Kappa rating (Landis and Koch 1977)	Very Good 0.81-1	Good 0.61-0.80	Moderate 0.41-0.60	Fair 0.21-0.40	Poor ≤ 0.20

Rater 2 was not working on the acute stroke unit at the time of the assessments but they had worked in acute stroke care prior to being a stroke research nurse and continued to work bank shifts on the acute stroke unit. Therefore, Rater 2 was deemed to reflect the knowledge and skills of nurses of a similar grade who worked on the stroke unit. The unregistered nurse Rater 3, was a health care assistant who had worked on the acute stroke unit and therefore had similar knowledge base as the health care assistants who may potentially use the assessment on an acute stroke unit. The advantages of using the two raters chosen was their flexibility which meant they were available at certain times to perform the assessments with the other raters, however, they were not from the core nursing team. Furthermore, there is also the risk that they may have developed a greater knowledge of oral care through working in stroke research and their exposure to other research projects regarding oral care. This may have increased their baseline knowledge, making it greater than other nurses of a similar grade.

However, there were practical issues as to why the nursing team from the clinical area were not utilised. Completion of oral assessments by all raters (nurses) needed to be completed in the same patient within a reasonable time frame to ensure the condition of the oral cavity had not changed between ratings. If the clinical team had been utilised this may not have occurred due to: workload issues; and a lack of understanding of the research methods and the importance of timely completion of the assessment. In order to test the COATS using all the nursing staff on an acute stroke unit, different methodology would need to be considered. Potentially an action research design which would engage the staff, provide them with ownership over the research which may help to reduce rater bias, un-blinding, and potentially improve implementation into clinical practice if the assessment is shown to be valid and reliable (Holter and Schwartz-Barcott 1993; Titchen and Binnie 1993). Choosing nurses who have had some research experience and had a better understanding of the research process and the importance of blinding may have reduced the risk of un-blinding and was a potential strength within the study design. The researcher was also present at every rating which helped discouraged discussion throughout and ensure all ratings were placed into an envelope and sealed. This ensured data blinding was maintained throughout the study. Although the raters were provided with an explanation as to why they should not discuss the results with each other the researcher did not know if the raters adhered to this between ratings.

Total blinding was difficult to achieve in the study due to the practical constraints of collecting the data. Ideally each rater would go to the patient independently to rate the oral cavity. However, in

previous studies the burden on the patient lead to subsequent refusal of repeated assessments which affected overall recruitment and completed data set (Dickinson et al. 2001). In order to maintain a good recruitment rate, and reduce patient burden all three raters were present at the same time. One rater took the lead to ask the questions required and co-ordinate the researchers being able to assess the patient's oral cavity. Throughout this process the researchers did not discuss their assessments with each other, however, it is recognised that there was risk the risk of collusion.

During data collection it became apparent that different methods were used by each lead rater and this may have affected the response from the patient answering the question. This was because there was no objective measure for assessing ability other than asking the raters to keep to script. However, some patients may require a more detailed explanation and this could create leading questions. When answering a question the person has to cognitively interpret this information and their response will depend on several factors. Whether they have understood the question, if they are able to recall the behaviour, making an inference or estimation of the quality of quantity required to answer the question, being able to map their response to the options provided, and potentially changing their answer (Schwarz and Oyserman 2011; Streiner and Norman 2008). As patients following a stroke may be unwell and unable to cognitively process the data, at each of these points there is the potential for bias. How the rater communicated the question may have affected the patient's interpretation of the question and their response. Furthermore, as the clinician sometimes responded on behalf of the patient, where there were significant cognitive and communication problems, patient recall of an event or ability may be different to the nurse's clinical knowledge of the patient need. Agreement for ability and comfort was very good to good and it could be argued that it was affected by the patient only being asked the question once and all raters hearing the response together. Therefore, there was less risk of patients interpreting the questions differently.

Assessment of oral health and cleanliness in the COATS relies on the rater interpreting their observations. This involved the rater cognitively deciding which category to place the score and therefore increase subjectivity and rater bias (Streiner and Norman 2008). The strength of the COATS was its dichotomous scoring system. This was chosen to try to reduce rater interpretation and increase agreement. Descriptors were also provided to help support the decision regarding what is healthy/clean or unhealthy/unclean, thus reducing the risk of bias and subjectively.

Rater knowledge of the construct can also increase subjectivity and affect rater agreement (de Vet et al. 2011). An assumption was made at the start of the study that all the raters would have the same knowledge base of oral health and cleanliness. Although both raters did not report having any specific training in oral health and assessing oral problems the registered nurse would have knowledge and experience from their professional training and development which may have enhanced their decision making (Tanner 2006).

Reliability

One method of enhancing rater agreement and reducing subjectivity is through education and training on the construct being measured and the assessment (de Vet et al. 2011). Several studies identified in the literature review that showed good agreement had used education to increase agreement and reduce subjectivity (Chalmers et al. 2005; Andersson et al. 2002a; Kayser-Jones 1995; Eilers et al. 1988). However, from the data collected it is impossible to tease out if the education given had a direct impact on rater agreement because there was not a before or after test of agreement. Furthermore, the studies did not report if education had any impact on maintaining agreement over time. Although providing education can impact on increasing reliability, providing education to all members of the nursing team can be time consuming and may not be feasible in a clinical setting. Therefore a strength of the COATS is that it required minimal training and appeared to have similar agreement both between and within raters to the other oral assessment developed using education, apart from cheeks and gums (Table 7-14). Therefore the COATS may be more practical and easier to implement into the clinical setting (Damschroder et al. 2009; Rycroft-Malone 2004).

Table 7-14 Comparing reliability scores of the COATS with those identified in the literature

	Study	Scale	Test	Teeth	MM*	Lips	Gingivae	Tongue	Saliva	Denture	Palate	Swallow	Voice	Pain	Total
Agreement between raters	DeWalt 1975	DeWalt	Unknown												0.92
	Longman 1986	RDeWalt	IRC												86.13%
	Eilers 1988	Eilers	PPMC												0.912
	Kayser-Jones 1995	BOSHE	K RN	0.52	0.10	0.32	0.45	0.25	0.12	0.74	0.10				
			K URN	0.38	0.26	0.26	0.34	0.26	0.20	0.54	0.26				
	Andersson 1999	MOAG	Kappa	0.31	0.20	0.21	0.55		0.85	0.31		0.76	0.56		
	Dickinson 2001	THROAT	Kw	0.56	0.75	0.78	0.71	0.69	0.69	0.58	0.80				
	Anderson 2002	ROAG	Kappa	0.46	0.58	0.68	0.67	0.52	0.53	0.46		0.84	0.45		
	Chalmers 2005	OHAT	Kappa	0.66	0.57	0.48	0.57	0.53	0.48	0.65				0.62	
	Dickinson 2013	**Nominal**	**K Rater 2**	**0.56**	**0.31**	**0.54**	**0.30**	**0.50**	**0.52**	**1**	**0.70**			**0.96**	
			K Rater 3	**0.28**	**0.26**	**0.50**	**0.35**	**0.54**	**0.47**	**0.60**	**0.52**			**0.93**	
Agreement within raters	Dickinson 2001	Ordinal	Kw	0.76	0.94	0.96	0.92	0.87	0.69	0.73	0.81				
	Chalmers 2005	Ordinal	Kappa	0.70	0.71	0.52	0.71	0.61	0.51	0.70				0.66	
	Dickinson 2013	**Nominal**	**K Rater 2**	**0.61**	**0.87**	**0.80**	**0.28**	**0.73**	**0.42**		**0.65**			**0.93**	
			K Rater 3	**0.75**	**0.38**	**0.44**	**0.26**	**0.32**	**0.44**		**0.41**			**0.59**	

*MM=mucous membrane

PPMC-Pearson product moment correlation, IRC-Inter rater coefficient, Kw-weighted Kappa, ICC Intra-Class correlation co-efficient

Kappa rating (Landis and Koch 1977)	Very Good 0.81-1	Good 0.61-0.80	Moderate 0.41-0.60	Fair 0.21-0.40	Poor ≤ 0.20

Fair agreement was found for gums for both the registered and unregistered nurses. This was lower than the moderate agreement found in a previous studies examining agreement between registered and unregistered nurses in a residential care facility (Chalmers et al. 2005; Kayser-Jones 1995). Both Chalmers et al. (2005) and Kayser-Jones (1995) had a sample size of 100 which may have minimised the impact of random error, thus reducing bias. Both these studies also used education, and so for gums where there is a potential for more subjectivity in the assessment education may increase reliability. The agreement for cheeks between studies was variable. The COATS showed better agreement for cheeks (mucous membrane) than the BOSHE (Kayser-Jones 1995) and MOAG (Andersson et al. 1999) but worse agreement than the THROAT (Dickinson et al. 2001), ROAG (Andersson et al. 2002a) and OHAT (Chalmers et al. 2005). However, it is difficult to make comparisons between the agreement of the BOSHE, MOAG, THROAT, ROAG, and OHAT and the COATS because the assessments were not measuring the same parameters. The BOSHE, MOAG, THROAT, ROAG and OHAT have all assessed the mucous membrane for healthy tissue (pink, red, inflamed) whereas the COATS has specifically focused on assessing cleanliness (presence of food debris).

Overall gums had the worst agreement for between and within raters and cheeks had poor agreement for between raters. This reduced agreement may be due to descriptors not being explicit enough to identify if there was a problem. Also gums and cheeks are difficult areas to view in patients who are lying down in a semi-prone position. In dental health, clients are positioned in a chair with their head tilted back to allow the dentist to gain a good view of all areas in the oral cavity. Nurses do not have the same ability in the clinical setting to position the patient in order to gain a good view of the oral cavity.

Agreement within a rater needs to be undertaken in a short enough time frame so that the items that are being measured are stable and have not changed, but long enough that the rater cannot remember the previous assessment made on that subject (de Vet et al. 2011). Identifying the time period to complete the re-test can be difficult. Twenty four hours between assessments was deemed a reasonable amount of time to allow raters to forget the previous day's ratings, but on average only three patients were assessed at each time point; there was the potential that with such few numbers the raters could remember their previous assessments. However, due to the patients being medically unwell and the risk of changes occurring in the cleanliness of the patient's oral cavity between assessments, 24 hours was considered the longest amount of time between ratings before changes may occur in the oral cavity.

Criterion Validity

Diagnostic accuracy

The diagnostic accuracy of the COATS was variable. Lips, teeth, and roof of the mouth showed good sensitivity and slightly better specificity. The COATS was able to identify a high proportion of cases correctly as not having a problem. Gums showed lower sensitivity and higher specificity indicating the COATS potentially had difficulty diagnosing the presence of a problem. The COATS was only able to diagnose 55% of patients with gum problems indicating a higher proportion were diagnosed as false positives. The COATS appeared to be very sensitive in identifying patients who had a problem with their tongue, only diagnosing 8.4% as false positives; however, the actual number of patients who did not have a problem was low making it difficult to ascertain the COATS' true diagnostic value. This was similar for gums where there were not enough patients with the problem. The gums and cheeks are also difficult areas to assess and some variability may have occurred due to changes in the patient's ability to co-operate. There is also the possibility that the COATS was not sensitive enough to diagnose problems in these areas.

The fact that the COATS is identifying a large proportion of patients as positive when in fact they are negative could have an impact on workload, incorrectly causing an increase in the number of patients who have a problem and need care. As already described, time is limited and so increasing workload would not be appropriate. If the COATS had low specificity and negative predictive value it would under diagnose patients who do have the problem, identifying more as false negatives. This would mean the COATS was missing patients who had the problem, and this could potentially increase the risk of further problems. This may reduce workload in the short term, but increase it in the long term. Therefore a balance needs to be reached as to what would be clinically acceptable for diagnostic accuracy in an oral assessment.

For an oral assessment to be meaningful in the clinical setting it is required to be valid, have good agreement between raters, and have good diagnostic accuracy. During this first phase of pilot testing the COATS has shown it has the potential to diagnose those with problems with their ability, their lips, teeth, roof of the mouth, pain and comfort and further work is required to improve the diagnostic accuracy of the cheeks, gums and tongue. Variability in the target population and a small sample size means that a larger study is required to fully test the validity and reliability of the COATS.

Limitations

This was a postgraduate research study with no funding which posed several issues. Due to time constraints of the study the sample recruited was not large enough to fully test all the items, to be confident that the agreement between raters was not due to chance. Although the sample recruited was representative of the population in which the assessment will be used (Whiting et al. 2011), future studies need to recruit a larger sample.

The assessment of the diagnostic accuracy (validity) of the COATS was not fully explored in this study due to the difficulty in ascertaining what a reference standard would entail for a nursing-specific oral assessment, and no resources to fund the time of an expert. Previous oral assessments that had assessed validity has used dental assessments as their reference standards and a dental examination using a dental expert. It could be argued that a nursing assessment aims to assess different oral health and cleanliness parameters so a true reference standard against which the assessment could be compared potentially does not exist. In this particular research the researcher decided to compare the two raters who were not nursing experts in oral care against a nursing expert in oral care (the researcher). Through doing this, assumptions were made that the COATS was a valid assessment and that the expert could make 100% correct diagnosis. With this in mind the results have to be viewed with caution. The lack of availability of an appropriate reference standard does pose problems for future studies. If a physical examination of the oral cavity is deemed to be necessary as part of the best available reference standard, then there still remains the issue of being able to position a stroke patient appropriately so that this can be undertaken. Furthermore as the COATS is a multi-dimension assessment and so it may be necessary to use multiple tests to explore the validity of the different aspects of the COATS

In the pilot study only two nurse were used to assess the reliability of the COATS and they were not necessarily a reflection of the nurses on an acute stroke unit. By only using two raters it is easier to control for rater bias and reduce collusion but it does not allow the researcher the opportunity to explore reliability in the clinical setting. Assessing reliability of multiple raters can be difficult and in some studies reliability has been reduced when more raters are used (Quinn et al. 2009). The advantages of using raters from the clinical area is that it will provide a more realistic measure of reliability in the clinical environment, however, additional raters will require a larger the sample size (Deeks et al. 2009).

Many of the previous oral assessments have used education to increase agreement and reduce bias and subjectively. The practicalities of providing education to a large team, that is transient, are immense. Nurses would need to be able to leave the ward for a few hours for training, regular updates and new staff would need training on arrival to the ward. With an already heavy workload and pressures of staffing in the current clinical climate providing education can be difficult. Having an oral assessment that can be used with minimal education is important because this will help with teams accepting and adopting the new clinical measure because the impact on workload is minimal (Rycroft-Malone 2004). However, by not providing education there is the risk that agreement between raters could be affected. This was potentially shown when the reference standard showed better agreement with the registered nurse compared to the unregistered nurse. One possible reason for this is that the registered nurse had a similar knowledge to the reference standard due to their professional training. If the COATS was to be used by unregistered nurses some consideration needs to be given to the issues of education and the quality and quantity of education provided. The next phase for this research would be to consider gaining funding to fully test the COATS for validity and reliability taking all the current limitations into consideration.

7.9 Summary

This chapter has presented the results of the pilot studying of a newly developed oral assessment, the COATS. The aim of the study was to assess the validity, reliability and feasibility of the COATS in a stroke population using registered and unregistered nurses. With further testing the COATS has the potential to be used as part of an oral care pathway in the clinical setting.

The next chapter will review the findings in this and the previous chapters. Chapter eight will provide a critical appraisal of the programme of studies presented in the thesis. Suggestions as to how the research may have been performed differently and provide recommendations for future research. Consideration will also be given to how the future research along with the initial findings presented in the thesis can inform patient care.

Chapter Eight

Conclusions and recommendations for future research

8.1 Introduction

This thesis has presented a series of studies aiming to develop a valid and reliable oral assessment for use in stroke patients. It is hoped it will allow nurses to identify oral problems, standardise the documentation of oral assessment, aid communication between health professionals, and inform planning of effective oral care. The series of studies consisted of: an integrative literature review; a qualitative study exploring the views and experiences of experts', health professionals', patients' and carers; and the development and pilot testing of the Comprehensive Oral Assessment Tool for Stroke (COATS). The result of these studies will be summarised and discussed in relation to previous research. The wider implications of the findings, especially in relation to assessment content and implementation, will be discussed along with recommendations for future research. Finally, the limitations of the thesis will be highlighted, along with how these studies have contributed to knowledge in the field of oral care.

8.2 Key findings

The integrative review of oral assessments that could be used in stroke patients highlighted that oral assessments, used in the medically ill or dependent populations, either measured oral cleanliness and or the risk of oral problems occurring. The quality of the assessments development and quality of the studies in which they were tested was poor. All the previous oral assessments identified were developed from the literature and/or clinical expert opinion rather than experts in oral health and experts in the population in which the assessments is to be used, health professionals and patients and carers. Areas in the oral cavity that were thought to represent oral cleanliness were lips, teeth, dentures, mucous membrane, gingivae, tongue, palate, and saliva. When assessing areas of the oral cavity, whether for research or clinical practice having good agreement between raters is essential if the assessment is to be used by multiple raters. However, agreement between raters was only measured in 9 of the 21 assessments. The agreement for each item varied across the studies which is potentially due to the variability in the study design and the psychometric testing of the assessment. Only one assessment showed the

potential to be used in a stroke population, the OHAT (Chalmers et al. 2005). However, the OHAT was developed to screen for the absence of dental disease in a medically-well but dependent population. As it did not meet the needs of acutely ill stroke patients in a hospital setting it was deemed not appropriate. In the absence of a suitable assessment the findings from the literature review were used to help inform the development of the new oral assessment specific to the needs of stroke patients.

In order to develop an oral assessment that was specific to stroke patients' needs, qualitative interviews were used to explore the views and experiences of oral care in stakeholders in stroke care: experts' in oral health and stroke; health professionals'; patients'; and carers'. Five themes emerged these were: the patient's ability to clean their oral cavity; assessing oral cleanliness and health; oral comfort; the need to assess or consider other medical and organisational factors that contribute to oral health; and the layout and format of the oral assessment. From the qualitative studies it became clear that different groups placed a different emphasis on each of the five themes depending on their role and identity in the social world of oral care. That is, whether they were experts in the knowledge and evidence relating to oral care and oral health, or performed or received oral care.

The findings from the literature review and the qualitative study were synthesised to inform the development of the COATS. It became apparent that the social world of the expert panel also influenced the items they selected for inclusion in the COATS regardless of the findings presented to them from the literature and the qualitative data. The expert panel decided that the assessment should cover three domains, ability, oral health and cleanliness, and comfort and wellbeing. Ability would assess the patient's physical and cognitive ability as well as their motivation to attend to oral care. Oral health and cleanliness would assess areas within the oral cavity such as: lips; teeth; gums; cheeks; tongue; roof of the mouth; and saliva. Although items such as gums and cheeks showed variable agreement in the literature review the dental expert wanted these items included even when the nurses in the group had concerns about their capability in assessing these areas. The last domain, comfort would assess pain and how the oral cavity felt, these were particularly important to patients and carers

The final study tested the COATS for content and face validity, intra and inter-rater agreement, diagnostic accuracy, and feasibility in a stroke population. Agreement within and between raters was measured; within agreement was compared on all those patients who the reference standard

had agreement with themselves. This was to account for any oral cavities that may have changed over the 24 hour period. Inter-rater agreement compared the reference standard with registered and unregistered nursing staff and the registered and unregistered nursing staff were also compared to each other. Intra-rater agreement was fair to very good for both the registered and unregistered nurse. The registered nurse had moderate to very good agreement and high sensitivity for all areas of the COATS, apart from gums and cheeks, when compared with the reference standard. The unregistered nurse only had fair to very good agreement for all areas of the COATS, apart from gums and cheeks, when compared with the reference standard. In summary the COATS currently has the potential to be used by registered nurses in a stroke population but not yet by unregistered nurses. More work is required to explore the reasons for inter-changing agreement found in the unregistered nurse and whether this can be addressed to increase agreement.

In exploring issues pertinent to the development of the assessment in this thesis two areas were highlighted, factors that contribute to assessment content and factors relating to the implementation of a new assessment.

8.3 Oral assessment content

Nursing is a holistic profession that considers the physical, psychological, environmental and spiritual factors that promote healing (Dossey and Keegan 2012). Developing an oral assessment that encompasses all these factors is important. Historically oral assessments have been developed following review of the literature and expert opinion with no consideration of what is important to the different stakeholders involved in providing and receiving the care. The 21 oral assessments identified in the literature review were either developed from the empirical literature or from dental expert opinion. The assessments all had a similar format and content and seemed to have drawn extensively from one of the first oral assessments, the PB developed, which measured the effects of care interventions in cleaning the oral cavity (Passos and Brand 1966). The focus was very much about assessing structures within and around the oral cavity to detect for alterations in the health of the tissue. This had a medical focus leaning towards the professional needs of dental medicine and oral health, rather than nursing and oral health.

Throughout the series of studies in this thesis it was apparent that different stakeholders held differently constructed social realities that influenced their decisions about what aspects of oral

assessment and oral care were important. This appeared to be influenced by their professional role and identity. Several different perspectives were identified: dental, nursing, allied health professional, patient, and carer. Within each of these perspectives different aspects were identified as being important when considering the content of an oral assessment.

In terms of professional role and identity, the dental experts followed a medical model. They focused on issues relating to dental health such as the presence of plaque, redness of ulceration in the oral cavity and the potential consequences this could have on dental and general health. Within dentistry the focus is primarily to prevent dental disease (Walsh et al. 2010; DH 2005), which in turn will potentially prevent complications such as chest infection (Li et al. 2000; Scannapieco 1999), and diabetes (Li et al. 2000). When selecting items for the COATS the dental experts insisted on the inclusion of certain items such as mucous membrane and gums being included despite the literature indicating that the agreement between raters in non-dental personnel was variable. This decision may have been influenced by their own professional knowledge and skills where they focus on assessing the gums and mucous membrane to inform them about oral health, with an aim to prevent atherosclerosis, heart disease (Bahekar et al. 2007; Meurman et al. 2004; Genco et al. 2002) and stroke (Meurman et al. 2004).

Nurses have a more holistic role, they are socialised to provide clinical judgement to the provision of care, to ensure health needs are met and supporting all the patients' spiritual, psychological and social needs (Henderson 2006). The nurse's role is complex, they work as co-ordinators collating and disseminating information, identifying problems, and liaising with other members of the team (Long et al. 2002). Nurses use assessment to inform their care and so they focused on many issues that prevented them from providing oral care which will be discussed in more detail in the next section. These issues however, also informed the layout and structure of the assessment. The nurses in the qualitative interviews highlighted that assumptions were made about the patient's ability to attend to oral care as well as the patient's physical and cognitive ability, these may have affected the oral assessment and oral care taking place. Areas within the oral cavity that were conventionally the remit of nurse and could be easily viewed on assessment were the areas the nurses wanted to be included in the oral assessment, such as teeth, tongue, palate and lips. Other items for inclusion was food becoming lodged in the cheek as this was a common problem in stroke patients with dysphagia and again is traditionally associated with feeding, a nursing role.

Allied health professionals saw their role in oral care as the expert coming to advise regarding certain care options. Their role involved them visiting the patient for short periods and so any changes in the oral cavity may be not be noticeable. They highlighted issues around functional ability, as well as comfort and wellbeing as being important for inclusion in the assessment.

Each patients perception of oral health and care is individual and their own health beliefs and routine appeared to influence what they thought should be included in an oral assessment (Chen and Tatsuoka 1984). The patients occasionally reported oral care was important from a medical perspective in controlling bacteria, this appeared to come from their own knowledge and beliefs of oral care. However, the majority of patients focused on oral comfort and well-being. An important factor was having a clean and fresh oral cavity as this contributed to how they felt and their quality of life, this concurs with previous studies that have shown the relationship between oral health and quality of life (Locker et al. 2000). In medically ill patients and those who have had a stroke it has been identified that changes in the oral cavity that occur due to their medical illness affects their psychological wellbeing and quality of life (McMillan et al. 2005; Locker et al. 2002). For many communication with others was affected, fear of halitosis and ill-fitting dentures and an inability to control saliva all contributed to how their viewed they oral health. Assessment of oral comfort was therefore a large factor for patients

Carer's perception was that patients should have a clean oral cavity all the time. For some carers it was difficult to ascertain why this was not the case. They were influenced by their own beliefs, behaviours and emotions relating to oral care. Carers therefore highlighted issues relating to comfort, as well as those areas in the oral cavity that they could see such as: teeth; dentures; food becoming lodged; lips; tongue; pallet; saliva; and cheeks.

Each of the different perspectives highlighted different aspects that were important, and these were influenced by their socialised role in the oral care process. Through examining the different perspectives the COATS was developed to ensure a comprehensive oral assessment that would meet the needs of all those concerned.

8.4 Oral assessment implementation

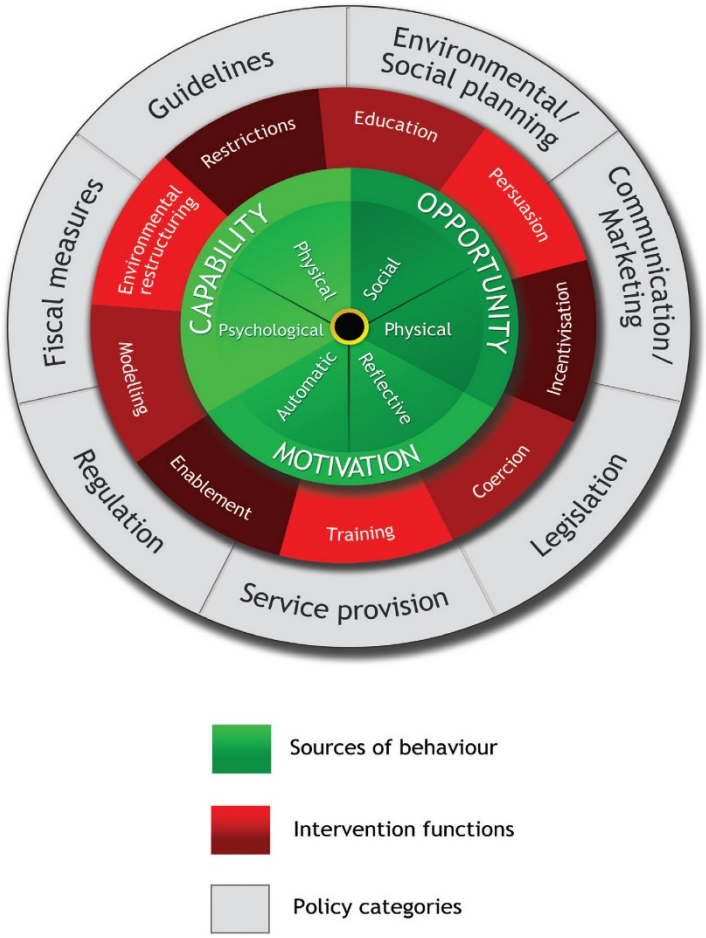
This series of studies have contributed to the existing knowledge of oral care in medically ill patients, and more specifically in stroke patients. In particular, all the studies have raised important issues for the implementation of oral care into clinical practice. These issues will now

be discussed in context of an implementation framework to understand what might aid knowledge translation and drive change in clinical practice.

Several frameworks exist that discuss the process of transferring new knowledge into clinical practice (Cane et al. 2012; Damschroder et al. 2009; Michie et al. 2005; Rycroft-Malone 2004). These frameworks have many similarities, considering the evidence, context in which the implementation is to take place, clinical and patient factors, the intervention itself and evaluation (Murray et al. 2010; Damschroder et al. 2009; Rycroft-Malone 2004). However, discussing the similarities and differences of the frameworks is beyond the scope of this thesis.

In the past implementation of new interventions into practice has on occasion failed due a lack of refinement of the intervention (Damschroder et al. 2009). One possible reason for the failure is limited change in the behaviour and environment of those who are implementing the intervention. Focussing on behaviour change is only one possible intervention that has been highlighted as a potential way forward in bringing about the change (Michie et al. 2011). For the purpose of this discussion the use of the Behaviour Change Wheel as a model for implementing the COATS will be discussed.

The behaviour change wheel (Figure 8-1) was developed where the hub (centre) contains the COM-B system, which consists of three components that can be used to identify potential behaviours that may need changing if the intervention is to be successfully implemented into clinical practice (Michie et al. 2011). The COM-B system was developed from the theoretical models that underpin behaviour change (Michie et al. 2005). Surrounding the hub is an inner layer of nine intervention functions which can be used to alter the behaviour and help bring about change. Finally the outer circle contains seven types of policy that can be used to help bring about the interventions to influence behaviour change.



(Michie et al. 2015)

Figure 8-1 Behaviour Change Wheel

Capability

Within this domain there are two areas: psychological capability; and physical capability. Psychological capability is their ability to engage in the processes, to comprehend, and provide rationale. This involves having the knowledge to influence physical capacity and having the skill to bring about a change in behaviour.

Psychological capability

The interviews with the dental experts showed that they had the knowledge and were able to provide rationale for why oral care was important. On the other hand the nurses and health professionals highlighted a gap in their own knowledge regarding the importance of oral care and the underpinning evidence. Throughout the interviews they did not refer to the current clinical guidelines (ICSWP 2012) relating to oral care in stroke patients. This is not a new phenonomen, a

lack of education and training specific to oral care has been documented for many years both in registered nurses, student nurses and unregistered nurses (McAuliffe 2007; Wardh et al. 1997; Adams 1996) and this does not appear to have changed over time. This lack of knowledge therefore affects the decisions the nurses make and reduces their skill in performing oral assessment and oral care.

The interventions that could potentially be used to allow the nurses to have the psychological capability to perform an oral assessment are education, training and enablement (Michie et al. 2011). Through enhancing knowledge and training there is the potential for skills and awareness of the importance of oral care to be influenced, increasing the nurse's rationale for performing oral care. One significant policy is the national clinical guidelines for stroke (ICSWP 2012) that support the need for education and training. Although these guidelines are available the nurses did not refer to the oral care guidelines during the interviews and if these impacted on the care they provided. Enablement may also another intervention that can impact on the nurses reasoning for providing oral care. This could be through the organisation prioritizing oral care and identifying the need to provide the correct resources so that nurses have ability to provide oral care. Guidelines can also impact on enablement, however, other policies would need to be used alongside the guidelines, such as regulation to audit the care provided. The organisation can also highlight and prioritise oral care as part of their service provision.

Physical capability

The dental experts, who had the skills to perform oral assessment felt that nurses did not have the skills to perform an in-depth examination and identify oral problems. The skill of the nurse should be to identify problems within the oral cavity but this was beyond their capabilities. The nurses reported a lack of skill in performing an oral assessment and oral care because they were afraid of causing harm. The health professionals felt they were not skilled at all to perform oral care because they had had no formal training. This lack of skill impacted on the quality of care they provided as well as whether they engaged in providing oral care. Having the necessary skill is an important factor that can impact on behaviour change and needs to be considered (Cane et al. 2012).

Training and enablement are the intervention functions that may be considered to impact on the nurse's skill in performing oral care. Consideration may need to be given to assessing what skill the nurses have and what skills they need to obtain and also the mode of delivery. Due to the

current political and clinical environment there is not the capacity for nursing staff to leave the ward for training. Other methods of providing education need to be considered; on line training, DVD training, oral care as mandatory training, enhance education of oral care at pre-registration nursing level are some possible methods that could be explored. If education and training could be provided this may impact on the skills of the nursing staff and result in a change in their behaviour (Michie et al. 2015; Cane et al. 2012). Policies that may help support the intervention functions are recognition of the regulation of oral care in trusts, such as nurses attending mandatory training on oral care every couple of years and oral care being made part of the service provision and basic nursing care. Trust may also look at novel ways to regulate this.

Opportunity

Opportunity incorporates all the factors that are external to the individual and that prompt the behaviour to take place, this can either be physical or social. In the case of oral assessment, social opportunity is the culture of the ward, the leadership, and other competing care pressures taking priority over oral care. Physical opportunity relates to the environment, having the resources and time available to perform the task (Michie et al. 2015).

Social Opportunity

The dental experts described oral care assessment as a care intervention that should be provided in order to prevent dental and potential medical complications. Their social norm is to prevent disease and ensure oral health through assessment of the oral cavity. This was not viewed as a difficult task. However, for nurses working in a ward environment the social norm was not to assess the oral cavity daily. In fact they reported a very ad hoc hap hazard approach to oral care. With no formal assessment of the oral cavity taking place. There was recognition that nurses are potentially performing oral assessments everyday but currently the culture is not to formally document this. The unregistered nurse was reported as performing the majority of oral care in both focus groups, but would not routinely perform an oral assessment as this was seen as the remit of the registered nurse.

The health professionals saw their role as specialist who would engage in oral assessment and oral care if it was part of their therapy session with the patient. For the occupational therapist this may be to educate the patient in using different techniques or different equipment to clean their teeth. The speech and language therapist felt they did assess the oral cavity with regards to

dysphagia and communication and any issues they would report back to the nurse. This assessment would be documented, however, they did not take responsibility for the oral assessment on a day to day basis, and this was very much seen as the nurse's role. Changing these cultures and professional boundaries would be difficult but has the potential to change oral assessment behaviour.

In an acute hospital setting, nurses constantly have to prioritise their workload minute by minute (Potter et al. 2005) and oral care was perceived to be prioritised differently in different clinical areas. Those nurses and health professionals in the rehabilitation setting felt that oral care was very much part of their normal day to day care. They thought that oral care was not performed to quite the same level or had the same priority in other ward areas. The patients actually highlighted a difference in ward culture between acute and rehabilitation wards. This was supported by the patients who perceived other pressing care needs prevented oral care from taking place.

The patient's physical and cognitive ability also hindered oral care. The dentist, nurses and health professionals all identified that stroke patients often had cognitive difficulties which prevented the nurses from gaining access to the oral cavity to perform oral care. Often the nurses reported they were unable to attend to oral care and appeared to be put off providing oral care if the patient was not compliant. Having a greater understanding of this barrier could potentially influence a behaviour change.

Interventions that have the potential to impact on social opportunity are restriction, environmental restructuring and enablement. Restriction allows the opportunity to increase the target behaviour, for instance through introducing the COATS as a daily oral assessment this could encourage daily oral assessment which then prompts the nurses physically attending to oral care. The COATS also then has an impact on restructuring normal ward routine and enabling oral care to be performed.

Physical opportunity

For oral assessment to take place there needs to be the correct environment and resources available. Having a supportive clinical environment that promotes oral assessment would encourage behaviour. If oral care is not high on the organisation agenda then this may discourage the nurses from performing an oral assessment because there is no impetus to do so (RCN 2012).

All the stakeholder groups reported time and workload had a large impact on whether oral care took place and this has been reported as a major issue in the literature (RCN 2012; Wardh et al. 2000). The registered nurses felt they had too many competing care needs and they often devolved this task to the unregistered nurses because oral care was not seen as high priority by the nurse or the organisation (RCN 2012). When considering implementation it is important to reflect on how the new intervention will impact on an already busy demanding role. The nurses wanted the intervention to be meaningful, not add to workload and easy to use. These were real concerns that needed to be considered in the development and implementation of the COATS if it is to be successfully integrated into clinical practice.

Having the correct resources is important. For oral assessment this would be an appropriate assessment that meets the needs of the population in which it is to be used in and appropriate for the clinician who has to use it (Wade 2004). Neither, the nurses or the health professionals reported using any form of oral assessment and were unclear if any existed. Throughout the focus groups the nurses felt that a lack of resources did impact on their behaviour and engagement in oral care.

Changing the ward environment may be one intervention that can prompt oral care. Through raising the priority of oral care within the ward culture and intervention. Guidelines are available to support the need for oral care to take place and the use of correct equipment (ICSWP 2012). However, these guidelines are not always enforced. The profile and importance of oral care may be increased if it was added to the Sentinel Stroke National Audit Programme (SSNAP) (Royal College of Physicians, Clinical Effectiveness and Evaluation Unit on behalf of the Inter collegiate Stroke Working Party 2015).

Motivation

Motivation to engage in the task is either reflective or automatic. In the case of oral assessment reflective motivation is influenced by their beliefs about capabilities, belief about consequences, intentions and goals. Automatic motivation is a person's own emotions or impulses that occur due to associated learning or innate character.

Reflective

The nurses own beliefs in their capabilities regarding oral care impacted on how they engaged in providing oral care. It appeared that knowledge and skills were closely linked to capability and self-efficacy. Previous research has highlighted that a lack of knowledge affects the nurse's confidence in performing oral care and when education is provided oral care provision and confidence improved (Binkley et al. 2004; Frenkel et al. 2002). The nurses reported oral care as important but their own evaluation of this importance affects whether oral care takes place. Some nurses reported reflecting on their own personal beliefs and that these motivated them to perform oral care. One registered nurse reported in the interviews that external pressures from the political arena and organisational audits meant that certain care processes would be performed over and above oral care because they were deemed more important. Currently within stroke care there is guidance to promote oral care (ICSWP 2012) however there is no measure as to whether these are met. The Sentinel Stroke National Audit Programme (SSNAP) (Intercollegiate Stroke Working Party 2015) audits care practices in stroke, however, oral care is not measured in this audit. Lack of goals set by distal organisations could affect how nurses engage in oral assessment. Nurses may be motivated to achieve the goals set by the organisation and government led bodies.

One method of increasing the nurse's motivation to perform oral assessment might be to increase the importance of oral care and their confidence in performing oral care. Both important in behaviour change, through education and training (Michie et al. 2011). Within the current clinical guidelines for stroke (ICSWP 2012) there is reference to education and training. The UK stroke forum has developed a resource to enhance the stroke specific knowledge and skills of health professionals, the Stroke Specific Education Framework (SSEF) (UK Stroke Forum 2015). This resource provides information on the minimum knowledge and skills health professionals are expected to have within their role. This resource could potentially increase the health professional's awareness of knowledge deficit and provide intrinsic motivation to engage in oral assessment.

Automatic motivation

Automatic motivation is the emotional response to behaviour. Nurses reported oral care as important but then would not perform an oral assessment or oral care. In some cases the nurse did not want to cause harm, or other care needs took precedence. The theory of cognitive

dissonance may give one explanation as to the disconnection between, attitude, beliefs and behaviour (Festinger 1962). Cognitive dissonance is an emotional state that occurs when two beliefs held are in conflict with one another. This disconnection causes an emotional response which is uncomfortable. Nurses assign oral care as a low priority, not because they believe it to be unimportant, but they don't have the time to do it. The belief that oral care is important conflicts with not performing oral care. In order to reduce the emotional feeling of discomfort this creates, the nurse justifies reasons why oral care does not occur. In this case it can be other competing care needs that are more important. Cognitive dissonance is a motivator in itself, in that it motivates the nurse not to engage in oral care. In order to create behaviour change the nurse needs to see the benefit of providing the oral assessment and oral care and have the knowledge to know to give oral care without causing harm.

The qualitative interviews and focus groups provided lots of barriers to why oral care, may not occur, this information was used to aid the development of the COATS. Many of the barriers highlighted also align themselves to the behaviour change system and need to be considered when implementing the COATS in practice.

8.5 Strengths and Limitations

This study has several strengths and limitations. Firstly, a strength is that it appears to be the first study that had developed an oral assessment for stroke patients using the current literature and the views of those involved in oral care, specifically oral assessment. Staff and patient interviews have provided invaluable data to underpin the development of the assessment. Furthermore, they have provided rich data to understand potential issues in the implementation of the assessment as part of an implementation package.

The research was undertaken with limited resources and time, which resulted in limitations to the methodology and its execution. A recent Cochrane review of "Staff-led interventions for improving oral hygiene in patient following stroke" (Brady et al. 2010) did not identify any stroke-specific assessments. However, a Cochrane review only considers studies that have used specific methodological design. This limits the types of studies that are included and potentially prevents the researcher from grasping what has already been found. An integrative review, on the other hand allows studies from all methodologies and therefore enables the researcher to include a larger breadth of study design (Thorne et al. 1997). An integrative review was therefore chosen

using a systematic approach to maintain rigor. However, comparing results from different methodologies can be challenging due to the different methodological designs. Ideally, when performing a review two reviewers are recommended to select the studies for inclusion to ensure validity (Deeks et al. 2009). Due to limited resources this was not achievable in this thesis and so to ensure bias was kept to a minimum a proportion of the potential papers were reviewed by a second reviewer. In an attempt to reduce the risk of selection bias the researcher would discuss any titles or abstracts, where it was not clear if they should be included, with the second reviewer. Other potential selection biases was the exclusion of non-English papers or studies that have not been published yet and so were unknown to the researcher. Through doing this integrative review it has highlighted a lack of oral assessments developed for use in strokes and a dependent population that have diagnostic accuracy and show good agreement between multiple raters.

Using an interpretive approach to gathering the data allowed the researcher to gain an insight into peoples lived experiences of oral care at the same time as guiding this exploration in order to answer the research question (Sandelowski 2009; Lopez and Willis 2004). The qualitative interviews gathered an expanse of data using one-to-one interviews and focus groups. Focus groups were used as the method of gathering health professionals' thoughts and experiences of oral care. The researcher wanted to explore all the health professionals views as a team, allowing all the participants to state their position, listen to others' views and re-evaluate their position (King and Horrocks 2010). Although the researcher was aware of the difficulties of managing the focus group (Happell 2007) it became apparent that those of a higher grade, who had experience of voicing their views, were more confident in taking part. Unregistered staff were less confident and therefore did not contribute as much, so their views and experiences may not be as evident in the results. Using one-to-one interviews may be a better method of capturing the richness of data from all grades of staff in the future. Future research in this area may consider using the Theoretical Domains Framework or another implementation framework to aid the development of the interview spine for the semi-structured interviews with a view to informing implementation of the intervention into clinical practice (Michie et al. 2015).

This was a piece of research being undertaken by one researcher with limited resources. This lead to the researcher using themselves to facilitate the focus groups and interviews. The researcher has the potential to introduce bias because of their own beliefs, professional role and interests may influence the direction of the interview content. On the other hand the researcher was able to guide the interview to ensure the research questions were discussed (Thorne et al. 1997). In an

attempt to address these potential biases the researcher stated their intentions and attempted to keep a neutral stance throughout, visiting their own subjectivity throughout (Peshkin 1988).

Once the COATs had been developed it was tested for validity, reliability and feasibility. Potentially using a pragmatic design would provide a more realistic view of introducing the COATS and testing agreement between nursing staff in a busy clinical setting (Roland and Torgerson 1998). However, due to limited time and a lack of resources a pilot study was performed to assess the agreement between nurse raters not embedded in the clinical environment. Using this approach has provided the researcher with some information regarding the potential reliability and validity of the COATS between different grades of nursing staff. However, it does not provide information on the performance of the COATS in a real life clinical environment.

Several issues were raised during the pilot study that may have affected the agreement found. Not all raters reached the optimum of 82 assessments so the results may not be representative of true agreement. Several reasons prevented the sample size from being met. Staff being off sick, staff not being available, and holidays. The sample size for intra-rater was low, partially due to only selecting those patients who the reference standard had intra-rater agreement in. This would need to be considered when developing a larger trial. Normal care would involve the rater examining the oral cavity independently. Although this was an option, all the researchers assessed the oral cavity at the same time. This was to reduce patient burden which had been identified in another study (Dickinson et al. 2001) and to ensure stability in the condition of the oral cavity between ratings. However, by all raters assessing the oral cavity at the same time there was a risk of un-blinding of their ratings. All raters were asked not to discuss their results when data was being collected but the researcher could not control for the raters discussing the study outside of data collection. Using the researcher as the reference standard did help to control for raters discussing their results but there were limitations to using the researcher.

When assessing agreement and validity of the COATS the researcher was the reference standard. Ideally an independent reference standard not involved in the research design would be used to reduce bias (Whiting et al. 2011). Identifying a best test available to assess this new measure was difficult and the resources were not available to support using a reference standard from oral health (dental expert) which has been used in previous study (Chalmers et al. 2005). The researcher was therefore chosen as the nurse expert in oral care. As identified in the literature a best test of assessing the oral cavity in dependent or stroke patients does not exist so for this pilot

study it was decided to compare the nurse expert raters of the COATS against the other raters. In doing this an assumption was made that the reference standard was an expert nurse in oral health and the COATS was valid. Although the researcher was aware that the COATS had not been shown to be valid, the results from the diagnostic testing provided the researcher with extra information about how accurate the nurse raters were at diagnosing problems against the nurse expert and what areas potentially required further development.

8.6 Future research

The thesis has provided the foundation on which to develop future research. There were limitations to the research undertaken but this thesis has highlighted that evidence is lacking to inform oral care in stroke patients. The COATS, through its preliminary testing of reliability, has shown that with further development it has the potential to be a valid and reliable oral assessment for use in stroke patients. The next phase is to consider the possible reasons for low agreement between the raters, specifically exploring the reasons for the unregistered nurse's agreement being poor. One possible explanation for this is the registered nurse uses other tacit knowledge to inform their assessment that they have gained in their professional role. However, this study did only have a small number of raters, so it was not possible to explore this factor, future studies may want to investigate this further.

Education and training is one method that is recommended to improve rater agreement (de Vet et al. 2011) and several studies did use education, however, this did not always appear to increase reliability . For pragmatic reasons previously outlined detailed education and training was not utilised in the research reported in this thesis. However, education and training could be the precursor to improve agreement as well as capability and motivation to perform an oral assessment. In order to overcome the barriers highlighted within this research novel methods of delivering education and training needs to be explored.

Once these issues have been addressed, the second phase would examine the implementation of the new COATS into clinical practice. Although the evidence advocates that oral care is important and the clinicians report they are aware of the evidence, there appears to be a gap between what is known and what is performed. The challenge of the second phase is therefore to develop a research study that will assess the effectiveness of the COATS in clinical care as well as re-evaluating rater agreement. To meet these challenges a pragmatic design using an

implementation framework such as the COM-B system (Michie et al. 2015) and the Theoretical Domains Framework (TDF) (Michie et al. 2005) may be beneficial, to capture data that is relevant to changing behaviour in the clinical environment.

Using the COM-B framework the research will need to identify what it is they want to change (oral assessment) and the behaviours that would need to be addressed (performing oral assessment) (Michie et al. 2015). Once the behaviour has been identified the next stage is identifying intervention functions that need addressing that will impact on capability, opportunity and motivation. It is likely these functions will include education, training, restructuring the environment, modelling good practice, enabling capability and opportunity by reducing barriers, and restriction using policies or rules. This would involve developing behaviour change techniques with key stakeholders, followed by a mode of delivery (Michie et al. 2015).

Education and training is one intervention that could have an impact on an oral assessment being performed. Currently within the culture of the NHS, nurses acknowledge oral care is an important aspect of nursing care. However, it is often disregarded or not performed due to lack of knowledge, and is seen as low priority in the hierarchy of care (RCN 2012; Wardh et al. 2000). This lack of knowledge to support care was also described in the focus groups. As reported in other studies, oral care knowledge is passed from colleague to colleague and in an ad hoc nature (Adams 1996). Nurses also make assumptions as to who requires oral care due to the lack of co-ordination of the oral care process (Boyce et al. 2006). If this is changed there is the potential that nurses will feel capable and motivated to assess the oral cavity, using the COATS, to inform care. Several studies have demonstrated that an education programme does improve the provision of oral care and patient outcomes (Brady et al. 2011; Bingham et al. 2010; Frenkel et al. 2002; Charteris and Kinsella 2001). Although these studies showed an improvement in patient outcome they did not assess if the knowledge received for the study was maintained and that this impact was sustained long-term. Incorporating education and training at organisational, expert, health professional, patient and carer level may impact on oral assessment, oral care and patient outcomes.

Patients also perceived that the nurses have too much work and that their oral care needs were not important. When planning interventions to initiate change it would be important to ensure patients are also involved. Patients should be encouraged to ask the nurses to assist them in assessing their oral cavity and cleaning their teeth twice a day. Increasing the organisation's awareness of the importance of oral care and the potential health benefits, would be important to

alter the organisational culture. By changing the culture on the ward and increasing the priority of oral care through leadership, leading by example, may increase the priority given to oral care.

Within the larger study it would be important to reassess rater agreement using the nurses in the clinical environment. This will provide a more realistic view of the clinical utility of the COATS in practice. This section of the research should ensure it addresses all the domains set out in QUDAS-2 to ensure robust measurement of diagnostic accuracy (Whiting et al. 2011). The appropriate statistical calculations would need to be undertaken to ensure the study was powered sufficiently to reduce the effect of random error. The sample should ideally be consecutive admissions where all potential participants are approached for inclusion reducing sample bias (Whiting et al. 2011).

The criterion validity of the COATS was not assessed within these series of studies. To test the criterion validity of the COATS a reference standard (best assessment available) for each item needs to be identified. A further review of the literature will need to be undertaken to identify what the reference standards could be, because there is not one single assessment that could test all the items in the COATS. Potential reference standards that have been used in a previous study (Chalmers et al. (2005) are, The World Health Organisation (WHO) lesions; Plaque index; Gingival index; Clinical examination for dry mouth plus self-reporting for pain and comfort. An independent expert performing these assessments would need to be recruited for the study. In oral care this would probably be an expert from oral health. To ensure good flow and timing and continued stability of the study the reference standard assessments should ideally be completed at the same time as the COATS (Whiting et al. 2011; Bossuyt et al. 2003).

8.7 Contribution to knowledge

Currently there is no oral assessment for stroke, which has been developed from the existing literature and the experiences of those who are involved providing or receiving oral care. It had been recognised that there was a need to develop clinical assessments and interventions to guide oral care in stroke patients (Brady et al. 2010). Although several studies have explored the introduction of complex oral interventions to guide oral care in stroke patients (Lam et al. 2012; Brady et al. 2011), there was still a need to develop an assessment that is able to identify oral problems and potentially evaluate the care provided by the nursing team and other health professionals.

The thesis has contributed to knowledge through examining the current literature for oral assessments developed for use in dependent populations. This appraisal of the literature identified that the quality of the assessment development was poor as well as the quality of the studies. There was no oral assessment identified that was specific to stroke and only 43% of the oral assessments, developed for use in a dependent population, had been tested for validity and reliability. In many cases the oral assessments were introduced into clinical care without knowing their validity, reliability and diagnostic accuracy.

Although previous studies had explored the impact of oral health on quality of life (Schimmel et al. 2009; McMillan et al. 2005; Locker et al. 2002). None of the studies that had developed oral assessments had explored the views and experiences of the experts in oral health and stroke, health professionals, patients and carers. When developing a complex intervention this is an important phase (Medical Research Council 2008). The qualitative interviews not only provided information for use in the development of a new assessment but also highlighted issues that would be important when implemented into practice. Many issues relating to capability, opportunity and motivation to perform oral assessment and oral care were highlighted. This is potentially the first piece of work that has explored all stakeholder group's views and experience and has revealed many issues that prevent oral assessment and care from taking place. It has provided an insight into the potential areas that need to be explored when developing new oral care interventions.

The new oral assessment, the COATS, has subsequently been developed using the literature and the views of the experts in oral health and stroke, those providing oral care and those receiving oral care. This has allowed the COATS to meet both the patient and the clinician's needs. The pilot test of the COATS suggests that it has the potential to be reliable between and within raters. After further testing it is hoped the COATS will provide a standardised assessment that will guide the oral care needs of hospitalised stroke patients and ultimately improve oral health.

Oral care is complex and oral assessment is only one component of this process. This series of studies have provided some novel findings that will contribute to the existing knowledge of oral care in a stroke and dependent population. The new knowledge will potentially inform further development of oral care interventions. It is hoped the knowledge will contribute to highlighting the importance of oral care in nursing, to the patient's well-being and health and in raising the oral care profile at an organisational, ward and individual level.

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Appendix 1 Search Strategy OVID

Search Strategy Dependent Patients Ovid Medline

	Search terms	Number of papers
1	"National Institute of Neurological Disorders and Stroke" / or exp Stroke/	84772
2	Cerebrovascular disorders/ or basal ganglia cerebrovascular disease/ or brain ischemia/ or dementia, vascular/ or intracranial arterial diseases/ or "intracranial embolism and thrombosis"/ or intracranial haemorrhages/ or exp stroke/	158835
3	Exp oral hygiene/ or dentist care/ or dental care for aged/ or dental care for chronically ill/ or dental care for disabled/ or pathology, oral/ or exp preventative dentistry/	49861
4	Evidence-based practice/ or exp evidence-based nursing/ or exp nursing/ or exp nursing research/ or clinical nursing research/ or nursing evaluation research/ or nursing methodology research/ or nursing, practical/	225087
5	Exp patient care/ or intensive care/	573486
6	Patient care/ or aftercare/ or "bloodless medical and surgical procedures"/ or exp critical care/ or hospitalization/ or exp institutionalisation/ or life support care/ or long-term care/ or exp nursing care/ or subacute care/	272748
7	1 or 2	158835
8	4 or 5 or 6	767691
9	3 and 7	105
10	3 and 8	1782
11	9 and "adult" (subjects)	450

Appendix 2 Search Strategy CINAHL

Search Strategy-Dependent Patients. Cinahl

	Search terms	Number of papers
1	Nursing	479995
2	Stroke	45260
3	Cerebrovascular Accident	150
4	2 and 3	45304
5	Oral assessment	501
6	Oral care	1968
7	Oral care and nursing	529
8	Oral hygiene and nursing	384
9	7 and 8	529
10	1 and 5	116
11	Oral health	6431
12	6 and 11	7280
13	Oral hygiene	3367
14	12 and 13	9472
15	4 and 14	91

Appendix 3 Oral assessment screening criteria

Oral Assessment SCREENING CRITERIA:

INCLUSION CRITERIA	GUIDANCE/DETAILS
Includes use of **Oral hygiene**	Oral hygiene is defined as oral care that delivers an intervention that aims to treat or maintain oral hygiene Include studies that examine oral hygiene, promote oral care Include studies that describe an intervention or plan of care for oral hygiene in dependent patients **Exclude** studies that treat an oral hygiene problem which is a result of a treatment or specific disease e.g. mucositis (as a result of cancer treatment), dry mouth **Exclude** studies examining dental issues
Primary purpose relates to **stroke** or **Dependent patient**	Studies that include stroke or patients who are dependent (hospitalised or institutionalised care) on others to carry out their oral hygiene. (Patients who have cognitive, physical problems, lack motivation and need prompting) **Exclude** studies that involve patients who can do oral care themselves (hospitalised and institutionalised **Exclude** studies whose sample is community dwellers, children, pregnancy, and healthy adults
Primary purpose relates to **Oral hygiene Interventions**	**Exclude** studies that examine nursing education and views **Exclude** studies that refer to dental health surveys or describe the oral health of the population being studied
Relating to **adults in hospital/long term care**	18+
Type of information: Research or evaluation i.e. studies collecting original data, systematic reviews of research, or national guidelines	Exclude descriptive studies that do not include an oral care programme Exclude literature reviews of oral hygiene if not in dependent patients Exclude non English papers; however keep the abstract if in English Exclude unpublished materials
Date: 1970-present	40 years should provide information regarding current oral hygiene practices

Appendix 4 Example of Cosmin Framework

COSMIN Criteria	Papers			
	Andersson 1999	Andersson 2002	Chalmers 2005	DeWalt 1975
A. Internal consistency	Poor	N/A	N/A	N/A
1. Does the scale consist of effect indicators, i.e. based on a reflective model?	N/A	N/A	N/A	N/A
2. Was the percentage of missing items given?	Good	N/A	N/A	N/A
3. Was there a description of how the missing items were handled?	Fair, not reported	N/A	N/A	N/A
4. Was the sample size included in the internal consistency analysis adequate?	Good	N/A	N/A	N/A
5. Was the unidimensionality of the scale checked? I.e. was factor analysis or IRT model applied?	Poor	N/A	N/A	N/A
6. Was the sample size included in the unidimensionality analysis adequate?	Poor	N/A	N/A	N/A
7. Was an internal consistency statistic calculated for each (unidimensional) (sub) scale separately?	Poor	N/A	N/A	N/A
8. Were there any important flaws in the design or methods of the study?	Fair, not reported	N/A	N/A	N/A
9. Was Cronbachs alpha applied (CTT)?	Fair	N/A	N/A	N/A
10. For TT, dichotomous scores: Was Cronbach's alpha or KR-20 calculated?	Poor	N/A	N/A	N/A
11. For IRT: Was a goodness of fit statistic at a global level calculated? X2 reliability coefficient of estimated latent trait value.	Poor	N/A	N/A	N/A

Appendix 4 Example of Cosmin Framework continued

COSMIN Criteria	Papers			
	Andersson 1999	Andersson 2002	Chalmers 2005	DeWalt 1975
Reliability	Fair	Fair	Poor	Poor
1. Was the percentage of missing items given?	Fair	Excellent	Good	Good
2. Was there a description of how the missing items were handles?	Good	Fair	Fair	Fair
3. Was the sample size included in the analysis adequate?	Good	Excellent	Excellent	Fair
4. Were at least two measurements available?	Excellent	Excellent	Excellent	Good
5. Were the administrations independent?	Excellent	Excellent	Excellent	Good
6. Was the time interval stated?	Excellent	Excellent	Excellent	Fair
7. Were patients stable in the interim period on the construct to be measured?	Good	Fair	Fair	Fair
8. Was the time interval appropriate?	Fair	Excellent	Fair	Fair
9. Were the test conditions similar for both measurements? E.g. type of administration	Good	Excellent	Good	Good
10. Were there any important flaws in the design or methods of the study?	Fair	Fair	Fair	Poor
11. For continuous scores: Was an interclass correlation coefficient (ICC) calculated?	N/A	N/A	N/A	N/A
12. For nominal, ordinal scores: was the kappa calculated?	Excellent	Excellent	Excellent	Poor
13. For ordinal scores: Was a weighted kappa calculated?	Good	Excellent	Poor	Poor
14. For ordinal scores: Was the weighting scheme described? E.g. linear, quadratic?	Fair	Excellent	Poor	Poor

Appendix 4 Example of Cosmin Framework continued

COSMIN Criteria	**Papers**			
Measurement error	Andersson 1999	Andersson 2002	Chalmers 2005	DeWalt 1975
1. Was the percentage of missing items given?	N/A	N/A	N/A	N/A
2. Was there a description of how the missing items were handles?	N/A	N/A	N/A	N/A
3. Was the sample size included in the analysis adequate?	N/A	N/A	N/A	N/A
4. Were at least two measurements available?	N/A	N/A	N/A	N/A
5. Were the administrations independent?	N/A	N/A	N/A	N/A
6. Was the time interval stated?	N/A	N/A	N/A	N/A
7. Were patients stable in the interim period on the construct to be measured?	N/A	N/A	N/A	N/A
8. Was the time interval appropriate?	N/A	N/A	N/A	N/A
9. Were the test conditions similar for both measurements? e.g. type of administration	N/A	N/A	N/A	N/A
10. Were there any important flaws in the design or methods of the study?	N/A	N/A	N/A	N/A
11. For CTT: Was standard error of measurement (SEM), smallest detectable change (SDC) or limits of agreement (LoA) calculated?	N/A	N/A	N/A	N/A

Appendix 4 Example of Cosmin Framework continued

COSMIN Criteria	Papers			
	Andersson 1999	Andersson 2002	Chalmers 2005	DeWalt 1975
Content Validity	N/A	N/A	Excellent	Poor
1. Was there an assessment of whether all items refer to relevant aspects of the construct to be measured?	N/A	N/A	Excellent	Poor
2. Was there an assessment of whether all items are relevant for the study population? (age, gender, disease, characteristics)	N/A	N/A	Excellent	Poor
3. Was there an assessment of whether all the items are relevant for the purpose of the measurement instrument?	N/A	N/A	Excellent	Fair
4. Was there an assessment of whether all items together comprehensively reflect the construct to be measured?	N/A	N/A	Excellent	Poor
5. Were there any important flaws in the design or methods of the study?	N/A	N/A	Excellent	Poor
Structural validity	N/A	N/A	N/A	N/A
1. Does the scale consist of effect indications, i.e. is it based on a reflective model?	N/A	N/A	N/A	N/A
2. Was the percentage of missing items given?	N/A	N/A	N/A	N/A
3. Was there a description of how the missing items were handles?	N/A	N/A	N/A	N/A
4. Was the sample size included in the analysis adequate?	N/A	N/A	N/A	N/A
5. Were there any important flaws in the design or methods of the study?	N/A	N/A	N/A	N/A
6. For CTT: Was exploratory or confirmatory factor analysis performed?	N/A	N/A	N/A	N/A
7. For IRT: Were IRT tests for determining the (uni-) dimensionality of the items performed?	N/A	N/A	N/A	N/A

Appendix 4 Example of Cosmin Framework continued

COSMIN Criteria	Papers			
	Andersson 1999	Andersson 2002	Chalmers 2005	DeWalt 1975
Hypothesis testing	N/A	N/A	N/A	N/A
1. Was the percentage of missing items given?	N/A	N/A	N/A	N/A
2. Was there a description of how the missing items were handles?	N/A	N/A	N/A	N/A
3. Was the sample size included in the analysis adequate?	N/A	N/A	N/A	N/A
4. Were hypotheses regarding correlations or means differences formulated a priori 9 (i.e. before data collection)?	N/A	N/A	N/A	N/A
5. Was the expected direction of correlations or mean differences included in the hypothesis?	N/A	N/A	N/A	N/A
6. Was the expected absolute or relative magnitude of correlations or mean differences included in the hypothesis?	N/A	N/A	N/A	N/A
7. for convergent validity: Was an adequate description provided of the comparator instrument (s)?	N/A	N/A	N/A	N/A
8. for convergent validity: Were the measurement properties of the comparator instrument(s) adequately described?	N/A	N/A	N/A	N/A
9. Were there any important flaws in the design or methods of the study?	N/A	N/A	N/A	N/A
10. Were design and statistical methods adequate for the hypothesis to be tested?	N/A	N/A	N/A	N/A

Appendix 4 Example of Cosmin Framework continued

COSMIN Criteria	Papers			
	Andersson 1999	Andersson 2002	Chalmers 2005	DeWalt 1975
Cross culture Validity	N/A	N/A	N/A	N/A
1. Was the percentage of missing items given?	N/A	N/A	N/A	N/A
2. Was there a description of how the missing items were handles?	N/A	N/A	N/A	N/A
3. Was the sample size included in the analysis adequate?	N/A	N/A	N/A	N/A
4. Were both the original language in which the instrument was developed, and the language in which the instrument was translated described?	N/A	N/A	N/A	N/A
5. Was the expertise of the people involved in the translation process adequately described?	N/A	N/A	N/A	N/A
6. Did the translators work independently from each other?	N/A	N/A	N/A	N/A
7. Were items translated forwards and backwards?	N/A	N/A	N/A	N/A
8. Was there an adequate description of how differences between the original and translated versions were resolved?	N/A	N/A	N/A	N/A
9. Was the translation reviewed by a committee (e.g. original developers)?	N/A	N/A	N/A	N/A
10. Was the instrument pre-tested to check interpretation, cultural relevance of the translation, and ease of comprehension?	N/A	N/A	N/A	N/A
11. Was the sample used in the pre-test adequately described?	N/A	N/A	N/A	N/A
12. Were the samples similar for all characteristics except language and/or cultural background?	N/A	N/A	N/A	N/A
13. Were there any important flaws in the design or methods of the study?	N/A	N/A	N/A	N/A
14. For CTT: was confirmatory factor analysis performed?	N/A	N/A	N/A	N/A
15. for IRT: Was differential item function (DIG) between languages groups assessed?	N/A	N/A	N/A	N/A

Appendix 4 Example of Cosmin Framework continued

COSMIN Criteria	Papers			
	Andersson 1999	Andersson 2002	Chalmers 2005	DeWalt 1975
Criterion Validity	N/A	N/A	Fair	N/A
1. Was the percentage of missing items given?	N/A	N/A	Excellent	N/A
2. Was there a description of how the missing items were handles?	N/A	N/A	Fair	N/A
3. Was the sample size included in the analysis adequate?	N/A	N/A	Excellent	N/A
4. Can the criterion used or employed be considered as a reasonable “gold standard"?	N/A	N/A	Excellent	N/A
5. Were there any important flaws in the design or methods of the study?	N/A	N/A	Fair	N/A
6. For continuous scores: Were correlations, or the area under the receiver operating curve calculated?	N/A	N/A	Excellent	N/A
7. For dichotomous scores: Were sensitivity and specificity determined?	N/A	N/A	N/A	N/A

Appendix 4 Example of Cosmin Framework continued

COSMIN Criteria	Papers			
	Andersson 1999	Andersson 2002	Chalmers 2005	DeWalt 1975
Responsiveness	N/A			Poor
1. Was the percentage of missing items given?	N/A	N/A	Excellent	Good
2. Was there descriptions of how missing items were handled?	N/A	N/A	Fair	Fair
3. Was the sample size included in the analysis adequate?	N/A	N/A	Excellent	Fair
4. Was a longitudinal design with at least two measurement used?	N/A	N/A	Excellent	Poor
5. Was the time interval stated?	N/A	N/A	Excellent	Poor
6. If anything occurred in the interim period was it adequately described?	N/A	N/A		Fair
7. Was a proportion of the patients changed?	N/A	N/A	Excellent	Poor
11. Was an adequate description provided of the comparator instrument(s)?	N/A	N/A	Good	Poor
12. Were the measurement properties of the comparator instrument(s) adequately described?	N/A	N/A	Poor	Poor
13. Were there any important flaws in the design or methods of the study?	N/A	N/A	Fair	Poor
14. Were design and statistical Methods adequate for the hypothesis to be tested?	N/A	N/A	Good	Fair
15. Can the criterion for change be considered as a reasonable gold standard?	N/A	N/A	Excellent	
16. Were there any important flaws in the design or methods of the study?	N/A	N/A		
17. for continuous scores: Were correlations between change scores, or the area under the receiver operator curve (ROC) calculated?	N/A	N/A		
18. for dichotomous scales: were sensitivity and specificity determined?	N/A	N/A	Poor	Poor

Appendix 4 Example of Cosmin Framework continued

COSMIN Criteria	Papers			
	Andersson 1999	Andersson 2002	Chalmers 2005	DeWalt 1975
Interpretability				
percentage of missing items	not reported	N	N	N
description of how missing items handled	not reported	Y	N	N
distribution of the total scores	reported	N	Y	N
percentage of the respondents who had the lowest possible score (total)	N	N	Y	N
percentage of the respondents who had the highest possible score (total)	N	N	Y	N
Scores and change scores (means, SD) for relevant groups	N	Y	Y	N
Minimal important change (MIC) or minimal important difference (MID)	N			N
Generalizability				
Median, or mean age (With SD and range)	61	N	Y	N
Distribution of sex	13 male/3 female	N	N	N
Important disease characteristics (e.g. severity, status, duration) and description of treatment	ICD 9 coding	N	Y	N
Setting (s) in which the study was conducted	Haematological ward	Rehab elderly	RH	N
Countries in which the study was conducted	Sweden	Sweden	Australia	USA
Language in which the scale was evaluated	English	English	English	English
Method used to select patients (random, convenience)	Convenience	Consecutive admissions	Convenience	Unknown
Percentage of missing responses.	unknown	yes	Unknown	Unknown

Appendix 5 Assessment of quality: QUADAS-2

Author **Year of publication**	
QUADAS-2 Assessment of bias	**Score (Yes, No, Unclear)**
Patient selection	
Was a consecutive or random sample of patients enrolled?	
Was a case-control design avoided?	
Did the study avoid inappropriate exclusions?	
Risk of bias (Low risk, High risk)	
Applicability: Are there concerns the included patients and setting do not match the review question?	
Index Test	
Were the index test results interpreted without knowledge of the results of the reference standard?	
If a threshold was used, was it pre-specified?	
Risk of bias (Low risk, High risk)	
Applicability: Are there concerns the index test, its conduct or its interpretation differ from the review question?	
Reference standard	
Is the reference standard likely to correctly classify the target condition?	
Were the reference standard results interpreted without knowledge of the results of the index test?	
Risk of bias (Low risk, High risk)	
Applicability, are there concerns the target condition as defined by the reference standard does not match the question?	
Flow and timing	
Was there an appropriate interval between the index test and reference standard?	
Did all patients receive the same reference standard?	
Were all patients included in the analysis?	
Risk of bias (Low risk, High risk)	
Overall quality	
Risk of bias (Low risk of bias, at risk of bias)	
Applicability (Low concern regarding applicability, concerns regarding applicability)	

Appendix 6 NHS Research Ethics Committee

NHS
Health Research Authority

NRES Committee North West - Lancaster
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7818
Fax: 0161 625 7299

19 December 2011

Mrs H Dickinson
Clinical Practice Research Unit
University of Central Lancashire
School of Health
Room 417, Brook Building
Preston
PR1 2HE

Dear Mrs Dickinson

Study title:	**Improving the evidence base for oral assessment in stroke patients.**
REC reference:	**11/NW/0692**
Amendment number:	**1**
Amendment date:	**13 December 2011**

The above amendment was reviewed by the Sub-Committee in correspondence.

This consists of changes to the Protocol, Information Sheets and Consent Forms. The changes relate to participants being able to request a copy of the transcript for verification. The option to have the transcript sent by post or email is available and participants have been given a time frame in which to return any comments.
The information includes specific details as to how contact details for the verification of transcripts will be collected and stored and also includes details of the procedure that will be adopted if the interviews/focus groups are not digitally recorded.

The Information Sheets now provide participants with a time point up to when it will be possible to withdraw and along with the Protocol have been amended to state what demographic data will be recorded and how.

Information in the Protocol now reflects the fact that the expert group will only have access to anonymised data.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Appendix 6 continued

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Participant Information Sheet: Family Member	4	18 November 2011
Participant Information Sheet: Health Professional	4	18 November 2011
Participant Information Sheet: Patient	4	18 November 2011
Protocol	3	18 November 2011
Notice of Substantial Amendment (non-CTIMPs)	1	13 December 2011
Interview Schedule: Carer	2	18 November 2011
Interview Schedule: Experts	2	18 November 2011
Focus Group Indicative Questions: Health Professionals	2	18 November 2011
Interview Schedule: Patient	2	18 November 2011
Participant Information Sheet: Expert	3	18 November 2011
Participant Consent Form: Family Members	4	18 November 2011
Participant Consent Form: Witness Consent Form for Patients	4	18 November 2011
Participant Consent Form: Patient	4	18 November 2011
Participant Consent Form: Health Professionals	4	18 November 2011
Participant Consent Form: Experts	4	18 November 2011

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

11/NW/0692: Please quote this number on all correspondence

Yours sincerely

P.P. L. Brown

Dr Lisa Booth
Chair

E-mail: [redacted]

Appendix 7 University ethical approval

6th December 2011

Michael Leathley & Hazel Dickinson
School of Health
University of Central Lancashire

Dear Michael & Hazel

Re: BuSH Ethics Committee Application
Unique reference Number: BuSH 022

The BuSH ethics committee has granted approval of your proposal application 'Improving the evidence base for oral assessment in stroke patients'

Please note that approval is granted up to the end of project date or for 5 years, whichever is the longer. This is on the assumption that the project does not significantly change in which case, you should check whether further ethical clearance is required.

We shall e-mail you a copy of the end-of-project report form to complete within a month of the anticipated date of project completion you specified on your application form. This should be completed, within 3 months, to complete the ethics governance procedures or, alternatively, an amended end-of-project date forwarded to roffice@uclan.ac.uk together with reason for the extension.

Please also note that it is the responsibility of the applicant to ensure that the ethics committee that has already approved this application is either run under the auspices of the National Research Ethics Service or is a fully constituted ethics committee, including at least one member independent of the organisation or professional group.

Yours sincerely

Gill Thomson
Deputy Vice Chair
BuSH Ethics Committee

Appendix 8 Research Governance

East Lancashire Hospitals NHS
NHS Trust

Ref No. 2011/061
Our Ref:

Tel: 01254 733008
Fax: 01254 733683
E-Mail: shirley.bibby@elht.nhs.uk

Research and Development
Level 3
Royal Blackburn Hospital
Haslingden Road
Blackburn
BB2 3HH

30 January 2012

Mrs Hazel Dickinson
Post Graduate Student
School of Health
Brook 417
University of Central Lancashire
Preston
PR1 2HE

Dear Mrs Dickinson

Study Title: **IMPROVING THE EVIDENCE BASE FOR ORAL ASSESSMENT IN STROKE PATIENTS**
REC ref: **11/NW/0692**

Letter of access for research

This letter confirms your right of access to conduct research through East Lancashire Hospitals NHS Trust for the purpose and on the terms and conditions set out below. This right of access commences on 30 January 2012 and ends on 31 January 2014 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at East Lancashire Hospitals NHS Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to East Lancashire Hospitals NHS Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through East Lancashire Hospitals NHS Trust, you will remain accountable to your employer The University of Manchester but you are required to follow the reasonable instructions of Dr N Roberts Stroke Consultant in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Appendix 8 continued

Aintree University Hospital NHS
NHS Foundation Trust

Where quality matters

R&D Director: Prof Robert Moots
R&D Deputy Director: Michelle Mossa
Tel: 0151 529 5870/1
Fax: 0151 529 5875
E-mail: michelle.mossa@aintree.nhs.uk

Research & Development Directorate
University Hospital Aintree
Room 2.06, Clinical Sciences Centre
Liverpool
L9 7AL

Mrs Hazel Dickinson
Clinical Practice Research Unit
University of Central Lancashire
School of Health
Room 417, Brook Building
Preston
PR1 2HE

Dear Mrs Dickinson

Re: Improving the evidence base for oral assessment in stroke patients

R&D ref: 437/11 **REC Ref:** 11/NW/0692

Thank you for submitting registration documents for the above study which have been reviewed in line with the Research Governance Framework. I am pleased to confirm that NHS Permission for the above study, sponsored by University of Central Lancashire, has been issued. Permission is based on the following REC approved documents:

	Version	Dated
Rec Approval Date:		21 October 2011
Protocol:	V3	18 November 2011
PIS/Consent:	V4	18 November 2011

R&D Trust Approval is conditional upon compliance with the terms set out in the Research Investigator Agreement.

In addition we ask that you:

- Ensure all staff coming into the Trust to work on this project have an Honorary Contract or Letter of Access issued by R&D before they commence work on the study at this site.
- Ensure that Annual Progress Reports, Safety Reports and End of Study Reports are sent to R&D as soon as they become available.

Please note that this approval is only valid until the project end date that has been provided and would ask that approval is obtained from R&D for this study to be extended.

Please also arrange to send details of all publications arising from this research to the R&D Department.

May I take the opportunity to wish you every success with your research project.

Yours sincerely,

Michelle Mossa
Deputy Director, Research & Development

Date: 16.01.2012

cc. Dr Michael Leathley
Professor Caroline Watkins
Professor John Crean

Appendix 9 Expert Interview Spine

Semi-structured Interview Schedule: Clinical and academic experts in oral health and stroke

Demographic data

Role (e.g. academic, clinical) and background (e.g. stroke, dental);

Prior knowledge

What do you understand by the term oral hygiene?

What do you understand by the term mouth care?

What is your prior knowledge/experience of oral hygiene/mouth care?

What do you understand by oral hygiene/mouth care in hospitalised patients?

Importance:

How would you rate the importance of oral hygiene/mouth care?

How important is oral hygiene/mouth care for hospitalised patients? Can you expand on this?

What aspects of oral hygiene/mouth care do you feel are important?

What aspects do you feel are not important?

What do you think oral hygiene/mouth care should involve? Can you expand on this further?

Process:

Who do you think carries out oral hygiene/mouth care?

What do you think the process of oral hygiene/mouth care should be?

What barriers do you think there are that prevent oral hygiene/mouth care from being carried out?

Can you list them?

What do you think would facilitate oral hygiene/mouth care in a ward setting?

Can you list them?

Can you describe the oral care processes you feel should happen?

What do you think happens in clinical practice?

Evaluation of care process:

What do you feel should be included in an assessment?

Can you explain why you think this?

Appendix 10 Example of a sampling frame

A	B	C	D	E
Surname	First Name	Role	Band	Randomisation
		Healthcare Assistant	3	0.04
-		Healthcare Assistant	3	0.07
		Healthcare Assistant	2	0.18
		Healthcare Assistant	2	0.33
		Healthcare Assistant	2	0.40
		Staff Nurse	5	0.09
		Staff Nurse	5	0.14
		Staff Nurse	5	0.15
		Staff Nurse	5	0.20
		Staff Nurse	5	0.25
		Staff Nurse	5	0.25
		Staff Nurse	5	0.27
		Staff Nurse	5	0.32
		Ward Manager	7	0.35
		Sister	6	0.48
		Stroke Nurse	6	0.49
		Stroke Nurse	6	0.50
		Stroke Nurse	6	0.60
		Stroke Nurse	6	0.82
		Physiotherapist	7	0.02
		Physiotherapist Assistant	3	0.17
		Physiotherapist	7	0.21
		Physiotherapist	5	0.52
		Physiotherapist	6	0.93
		Physiotherapist	5	0.97
		OT	6	0.42
		OT	3	0.44
		OT	7	0.51
		OT	5	0.56
		OT	3	0.57
		OT	5	0.74
		OT	4	0.94
		SALT	6	0.84

Appendix 11 Focus group indicative questions

Semi-Structured Interview Spine: Health Professional

Demographic data:
Role (e.g. nurse, therapist);
Years of service;
Prior knowledge:
What do you understand by the term oral hygiene?
What do you understand by the term mouth Care?
What is your prior knowledge/experience of oral hygiene/mouth care?
What do you understand by oral hygiene/mouth care in hospitalised patients?
Importance:
How would you rate the importance of oral hygiene/mouth care?
How important is oral hygiene/mouth care for hospitalised patients? Can you expand on this?
What aspects of oral hygiene/mouth care do you feel are important?
What aspects do you feel are less important?
What do you think oral hygiene/mouth care should involve? Can you expand on this further?
Process:
Who do you think caries out oral hygiene?
What do you think the process of oral hygiene/mouth care should be?
What barriers do you think there are that prevent oral hygiene/mouth care from being carried out?
Can you list them?
What do you think would facilitate oral hygiene/mouth care in a ward setting?
Can you list them?
Can you go through the oral care processes?
What do you think happens in clinical practice?
Why do you think things are/are not done well?
Evaluation of care process:
What do you feel should be included in an assessment?
Can you explain why you think this?

Appendix 12 Patient Interview Spine

Semi-structured Interview Schedule: Patient

Demographic information:
Age and sex;
Prior knowledge;
What do you understand by the term mouth care?
What do you expect mouth care in hospital would involve?
What is your normal routine at home?
Importance:
How would you rate the importance of oral hygiene in terms of your health?
How would you rate the importance of your oral hygiene in terms of your well-being?
Could you tell me how important mouth care is for you? Describe this?
What aspects of mouth care do you feel are important?
What aspects do you feel are less important?
What do you think mouth care should involve?
Telling the story (Process):
Can you tell me about your experience of receiving mouth care while in hospital?
Can you list for me some aspects of mouth care that you received?
What aspects of mouth care did you find satisfactory?
What aspects of mouth care did you not find satisfactory?
Would you change any aspects of the mouth care you received? If yes which aspects, if no why not?
Could you describe how your mouth felt after the care you received?
Process:
Was there anything in particular you were not prepared for/ had not had explained to you?
How do you feel about having an assessment of your mouth?
Can you recall anyone checking/ assessing your mouth?
If someone check your mouth can you describe what they did?
Can you describe the mouth care you received?
Can you describe the equipment used to clean your mouth?
How do you think nurses should clean your mouth?
What sort of equipment cleaning products do you think would be best?
How often would you like your mouth cleaned.
Evaluation of care process: In hindsight:
Could you rate your experience of mouth care?
If I was to tell you that nurses needed to assess the mouth what parts of the mouth do you think would be important to assess?
Is there anything else you want to add?

Appendix 13 Carer Interview Spine

Semi-structured Interview Schedule: Carer

Demographic Data:
How related to patient, age and sex;
Prior knowledge:
What do you understand by the term mouth care?
What do you expect mouth care in hospital would involve?
What is the normal routine for you relative at home?
Importance:
Could you tell me how important mouth care is for you? Describe this?
How would you rate the importance of oral hygiene in terms of health?
How would you rate the importance of oral hygiene in terms of well-being?
What aspects of mouth care do you feel are important?
What aspects do you feel are less important?
What do you think mouth care should involve?
Telling the story (Process):
Can you tell me about the mouth care your relative received?
Can you list for me some aspects of mouth care your relative received?
What aspects of mouth care that your relative received did you find satisfactory?
What aspects of mouth care that your relative received did you not find satisfactory?
Would you change any aspects of the mouth care that your relative received? If yes which aspects, if no why not?
Do you think your relative felt better after receiving their mouth care?
Process:
Was there anything in particular you were not prepared for/ had not had explained to you?
How do you feel about having an assessment of your mouth?
Can you recall anyone checking/assessing your relative's mouth?
If someone checks your mouth can you describe what they did?
Can you describe the mouth care your relative received?
Can you describe the equipment used to clean your relative's mouth?
How do you think nurses should clean your mouth?
What sort of equipment cleaning products do you think would be best?
How often would you like your relative's mouth cleaned?
Evaluation of care process: In hindsight:
Could you rate the mouth care your relative received?
If I was to tell you that nurses needed to assess the mouth what parts of the mouth do you think would be important to assess? Is there anything else you would like to add?

Appendix 14: Clinical and academic experts in oral health and stroke: Attitude to oral health

Chart 1 Attitude to oral health					
	1.1 Medical importance	**1.2 Importance of oral care**	**1.3 Own beliefs**	**1.4 Nursing importance**	**1.5 Importance for patients**
Wendy	Oral care is important due to the risk of dental disease (E1:40)	Important for the health of the mouth (E1:58)	Clean teeth regularly, remove dentures to clean them and use fluoride toothpaste.(E1:52)		
Pam	Important because can prevent other medical complications (E2:423)		Not cleaning teeth is a foreign concept (E2:203) Important aesthetically (E2:438-441)		
Claire	Some patients are at greater risk of medical complications due to treatments such as oxygen (E3:117)	Oral care should occur across the whole pathway (E3:112)	Obsessive about own oral health (E3:113)	Should be part of everyday nursing care (E3:119)	
Ruth	Preventing complications (E4:115)			Nurses knowledge of oral care and techniques (E4:115) Part of the nurse's role (E4:430)	
Robina	Important to care for the gums and teeth to enable effective communication and allow adequate nutrition (E5:45)	An important everyday function (E5:165)			

Appendix 14 continued

Chart 1 Attitude to oral health					
	1.1 Medical importance	**1.2 Importance of oral care**	**1.3 Own beliefs**	**1.4 Nursing importance**	**1.5 Importance for patients**
Robert	Doctors have a responsibility to maintain hydration (E6:97)	Important to relatives that good oral care occurs (E6:40)			
Emma	Impacts on nutrition, systemic issues (E7:12)	Within hospital there are a sub group who require help and support (E7:10)			Impacts on quality of life, comfort, pain and social interaction (E7:12)
June		Absence of pain, having adequate function (E8:46)	Regular oral care is brushing teeth twice daily (E8:46)	Simple measures could improve oral care (E8:365)	

Appendix 15: Clinical and academic experts in oral health and stroke: Oral care received while in hospital

Chart 2 Oral care received while in hospital				
	2.1 Provider of oral care	**2.2 Oral assessment**	**2.3 Frequency of care**	**2.4 Oral care provision**
Wendy				
Pam				
Claire	Oral care is mainly provided by untrained staff because they provide the personal care (E3:237) Trained nurses tend to do blood pressures and medications (E3:205)	We use an oral assessment that shows low, moderate or high risk (E3:337)	Those who are high risk have 3 hourly care, moderate risk twice a day care and low risk are self-caring (E3:337)	
Ruth				Oral care on stroke units is good compared to other wards (E4:88)
Robina		As part of the Occupational therapists role they work with the patient and develop strategies to promote independence (E5:60) Ask the patient how their mouth feels, look inside the mouth (E5:81)		Use appropriate aids and adaptations to promote independence (E5:96-98)
Robert	Very much seen as a nurse's role, in general it is presumed someone is doing the care (E6:168)			
Emma				Nurses often assess and provide care without formally documenting it or realising they are following a set format (E7:217)
June	Nurses on the ward provide oral care (E8:92)			

Appendix 16 Clinical and academic experts in oral health and stroke: Factors affecting the oral cavity and oral care while in hospital

Chart 3 Factors affecting the oral cavity and oral care while in hospital									
	3.1 Patients own beliefs and motivation	**3.2 Ability**	**3.3 Difficulty accessing the oral cavity**	**3.4 Staff's attitude/knowledge**	**3.5 Priority of care**	**3.6 Oral care process**	**3.7 Multi-disciplinary**	**3.8 External factors**	**3.9 Resources**
Wendy	For some people oral care is not high priority (E1:130) Some people never brush their teeth (E1: 131)	People with physical disability such as arthritis have difficulty cleaning teeth (E1:131) Mouth rinsing or spitting can be difficult in stroke patients affecting the use of mouth washes and toothpaste (E1:79)	Some patients have behavioural problems affecting the nurse's access to the oral cavity (E1:79) Difficult cleaning patient's oral cavity if they are in a supine position (E1:121)	Some staff don't see oral care as important (E1:121)	Tooth brushing is low priority in the list of care needs (E1:127) Certain medical and nursing issues are perceived to be of a higher priority (E1:127)				
Pam	Some patients don't see oral care as important (E2:206) A person's self-esteem and self-awareness impacts on whether they clean their teeth (E2:221)			Some nurses are not keen to clean other people's teeth (E2:369,378)			Communication between medics and dentists is poor (E2:260)	Peer pressure may influence people's decision to clean teeth due to fear of halitosis (E2:221)	Patients no not have a tooth brush and toothpaste when they come into hospital (E2:200)

Appendix 16 continued

Chart 3 Factors affecting the oral cavity and oral care while in hospital									
	3.1 Patient's own beliefs and motivation	**3.2 Physical ability**	**3.3 Difficulty accessing the oral cavity**	**3.4 Staff's attitude/knowledge**	**3.5 Priority of care**	**3.6 Oral care process**	**3.7 Multi-disciplinary**	**3.8 Organisational factors**	**3.9 Resources**
Claire					Oral care is no longer part of normal routine, it is seen as an extra job (E3:221)	Dentures are removed and not put back (E3:93) Dentures not cleaned (E3:93)			Pink sponges used to clean teeth and tongues where they should be used to add moisture (E3:161)
Ruth		Patients unable to attend to oral care due reduced ability to control the movement of the toothbrush to clean the mouth (E4:451)		Staff's knowledge and education (E4:289) Nurse don't see it as part of their role; they don't value the knowledge they have (E4:466-469) Some nurses don't enjoy cleaning teeth and dentures (E4:397)	Not seen as high priority (E4: 67, 94) The organisation see oral care as low priority due to other national drivers and local agendas (E4:409)	Oral care delegated to the health care assistants (E4:141)		Time is a big factor (E4:289)	Finances do not stretch to buying the appropriate equipment (E4:289)

Appendix 16 continued

Chart 3 Factors affecting the oral cavity and oral care while in hospital									
	3.1 Patient's own beliefs and motivation	**3.2 Physical ability**	**3.3 Difficulty accessing the oral cavity**	**3.4 Staff's attitude/knowledge**	**3.5 Priority of care**	**3.6 Oral care process**	**3.7 Multi-disciplinary**	**3.8 Organisational factors**	**3.9 Resources**
Robina		The patient's own ability to attend to their oral care (E5:198) Some patients are assessed as being independent but actually have cognitive difficulties or don't have the resources so need some help (E5:183)		No formal training during professional training regarding oral care (E5:249) All knowledge gained on the job (E5:252) Some staff dislike cleaning teeth and dentures, they find it unpleasant (E5:126)		Quality of care affected by the amount of knowledge and training people have received (E5:252)		Time is a large factor and skill mix (E5:168) Stroke patients have high level needs that need to be met within a time frame (E5:168)	
Robert		Older patients are at risk due to reduced saliva, ill-fitting dentures and tooth disease (E6:28) Stroke patients have swallowing problems which affects secretions (E6:64) Poor oral care affects general health (E6:64)		Tasks such as oral care that are not seen as highly skilled get delegated to the lowest denominator (E6:70)	Oral care often given low priority, not given the importance it deserves (E6:192) Organisational priorities affect ward priorities (E6:192)	Nurses have limited time so it is one care issue that gets missed (E6:153)	Drs don't take an active part in oral care, they don't look for oral lesions or other problems (E6:88)		

Appendix 16 continued

Chart 3 Factors affecting the oral cavity and oral care while in hospital									
	3.1 Patients own beliefs and motivation	**3.2 Physical ability**	**3.3 Difficulty accessing the oral cavity**	**3.4 Staff's attitude/knowledge**	**3.5 Priority of care**	**3.6 External factors**	**3.7 Multi-disciplinary**	**3.8 Oral care process**	**3.9 Resources**
Emma	Some patients may lack in knowledge impacting on their motivation (E7:32)	Patient's physical and cognitive ability to attend to oral care (E7: 32)		Lack of support for nurses to access training. Staff knowledge and understanding varies between each member of staff. (E7: 32) Some individuals have a poor attitude to oral health, others think that if someone is old they do not need oral care (E7:32)				A lack of consistency about "what is good oral health care", the guidance available is vague (E7:36)	
June				Nurses have some knowledge but it is limited (E8:191)	Oral care is seen as low priority. The nurses have a large workload and so need to prioritise their care. Other care needs take higher priority (E8: 161-167)		Medication and other external factors cause xerostomia and therefore increase the risk of oral disease (E8:221)	Dentures are often misplaced affecting communication and nutritional intake, also dentures often not cared for properly (E8: 113)	

Appendix 17 Clinical and academic experts in oral health and stroke: Impact on the patient

Chart 4 Impact on the patient			
	4.1 Patient well-being	**4.2 Physical**	**4.3 Assessing impact**
Wendy	Having a fresh clean mouth makes you felt better (E1:271)		
Pam			
Claire	Having a dirty mouth must feel unpleasant for the patients (E3:117)		
Ruth	For denture wearers not wearing their dentures impacts on their body image, affects how they feel (E4:391-394)		
Robina	Patients report problems such as a dry mouth which may prompt the staff to think their mouth maybe uncomfortable (E5:156)	Having excess saliva can also be distressing (E5:270) Some patients have sensation changes and feel they are drooling saliva (E5:270)	
Robert	Can only imagine how it feels due to own personal experience of a dry mouth (E6:46)		Difficult to know how some patients are feeling due their inability to communicate (E6:52)
Emma	Impacts on the patient's quality of life, nutrition, systemic issues, comfort, pain and social interaction (E7:12)		
June	Affects the person's self-esteem (E8:317)	The stroke can affect the person's own natural ability to defend against gingival disease (E8:140) Patients do not seek review of dentition until a long time after their stroke (E8:140)	

Appendix 18 Clinical and academic experts in oral health and stroke: Facilitators to oral care

	5.1 Correct resources	5.2 Frequency	5.3 Oral process	5.4 Assessing need	5.5 Multi-disciplinary	5.6 Knowledge
Wendy	Need correct fluoride toothpaste (E1:109) The patient having the correct equipment (E1:178)	Twice daily cleaning with toothbrush and toothpaste (E1:109)	Cleaning dentures with toothbrush and toothpaste (E1:52) Interdental cleaning (E1:64-67) Oral care should be part of a larger oral care routine (E1:127			
Pam				Asking the patients what they need, how their mouth's feel, what aspects of oral care they require the nurse to do (E2:321)	Better communication between nurses, medics, and dental practitioners (E2:297)	
Claire	Go back to using toothbrushes and toothpaste (E3:505)	Cleaning with a toothbrush twice daily (E3:85)	Only use sponges to apply moisture (E3:505) Keeping the tongue moist in-between cleaning (E3:149)	Understand about pocketing food and checking patient's mouths after every meal for food debris (E3:189)	Families can be educated to apply moisture when visiting (E3:281)	Nurses require increased knowledge regarding oral care, complications and contributing factors (E3:181)
Ruth	Having the correct treatments for each individual patient (E4:313-319)	Twice daily brushing with toothbrush and toothpaste plus 1-2 hourly mouth care (E4:241)	Linking oral care with dysphagia management due to the higher risk of oral complications (E4:103) Specific treatment options for those who are NBM (E4:238)			Enhancing the trained nurse's knowledge (E4:118)

Appendix 18 continued

Chart 5 Facilitators to oral care						
	5.1 Correct resources	**5.2 Frequency**	**5.3 Cleansing**	**5.5 Assessing individual needs**	**5.6 Multi-disciplinary**	**5.7 Knowledge**
Robina			Cleaning the mouth so that it feels comfortable and the patients will wear their dentures (E5:81) Different strategies to help with cleaning such as aids (E5:96)	Checking the oral cavity for problems such as ulcers, dirty tongue (E5:81) Are they wearing their dentures, does this impact on their communication? (E5:81)		
Robert			Need structure to the whole oral care process (E6:297)		Medical staff can do more with regards to taking an active role in the management of oral care (E6:162)	Training health care assistants to an acceptable level (E6:73)
Emma	Having the correct resources (E7:18)			Assessing ability to attend to oral care, both physically and cognitively (E7:16)		
June	Having the correct resources, suction toothbrushes (E8:101) Using high fluoride toothpaste and even antibacterial mouth wash (E8:209)	The patients should have access to facilities to clean their teeth twice a day (E8:197)	If the patient cannot do it for themselves then some else should provide the care (E8:86) Having oral care as part of a package, a care pathway would be ideal (E8:173	Assessing access to oral care facilities/equipment (E8:101)		Education about how to approach patients who may have behavioural problems and how to clean their mouths (E8:247)

Appendix 19 Clinical and academic experts in oral health and stroke: Assessment content

Chart 6 Assessment content				
	6.1 Ability	**6.2 Assessment of need**	**6.3 Areas within the oral cavity**	**6.4 Scoring**
Wendy	Patient's ability to perform their own oral care (E1:247)	Asking the patients if they have brushed their teeth today (E1:220)	Is there any plaque? Any food debris seen on the teeth? (E1:217-220)	Assessing the amount of food debris (E1:220)
Pam		Ask the patients if they have any specific problems in their oral cavity? (E2:351) Are they in pain? (E2:351)	Debris on the teeth (E2:351) Abnormalities in the oral cavity (E2:351)	
Claire				
Ruth	Are they able to participate in their own care? Do they need help from the nurse and if so how much? (E4:217)	Assessing the patient's normal routine, dentate or not, any existing dental problems (E4:217) Frequency of oral care for prevention and frequency for a specific problem (E4:370)	Teeth, gums, mucosa, tongue, palate, the whole mouth (E4:379)	
Robina		How well do their dentures fit? (E5:204) Medical complication that may affect the oral cavity, increase their risk of oral complications (E5:204)	Initial assessment of teeth tongue, lips, palate. The colour of lips; cracked lips or not, cut lips; colour of gums; is the tongue coated? (E5:198)	
Robert			Lips, mucosa, tongue, coating on the tongue, teeth (E6:139)	Descriptions that could be used are cracked lips, pain, and coating on the tongue, cleaned between teeth (E6:139)
Emma	Assess the whole person, comfort, need, ability, pain (E7:24)	Nursing specific and meaningful (E7:24)	Teeth/dentures, tongue, hard and soft palate, gums, lips, mucous membrane (E7:24)	Having a score of indicating severity might not change nursing care (E7:24)
June	Assessing dependence (E8:275)	Have they got false teeth? (E8:275) Are they in any discomfort, have they pain, do their teeth fit, any problems with their teeth? (E8:371)	Lips, the whole of the oral cavity, teeth (E8:332-338) Asking the patient how their mouth feels because this may be different from what the examination may show (E8:398)	Lips, are they crusty? Look in the mouth is it dry? Problems eating and drinking, chewing? (E8:371, 332)

Appendix 20 Clinical and academic experts in oral health and stroke: Assessment format

Chart 7 Assessment format				
	7.1 Layout	**7.2 Length**	**7.3 Implementation**	**7.4 Evaluation**
Wendy	Simple easy to use (E1:256)			
Pam	Assess the hard tissues separate from soft tissues (E2:345)	Short not too long (E2:345) Has relevant information (E2:345)		
Claire			Making sure it is part of the daily routine (E3:357)	
Ruth				Regular inspection and evaluation of the care plan (E4:439)
Robina				
Robert		The assessment needs to be timely and not onerous to complete (E6:228) Will add to patient care and not just another piece of paper (E6:228)		
Emma				Assess on admission and then daily (E7:28)
June				

Appendix 21 Health professionals: Attitude to oral health

Chart 1 Attitude to oral health					
	1.1 Medical importance	**1.2 Importance of oral care**	**1.3 Own beliefs**	**1.4 Nursing importance**	**1.5 Importance for patients**
Focus group one	Stroke patients are more at risk of infections (FG1:6)		Part of everyday living, you get up you clean your teeth ((FG1:30)	It is one of the most important things nurses can do. Especially for those who have lost the ability to swallow (FG1:32)	Neglecting oral hygiene could impact on nutritional intake and fluid intake which affects rehabilitation and recovery (FG1:32)
Focus group two	Important in patients with swallowing problems, they potentially could be aspirating saliva containing bacteria (FG2:7) Important to minimise risk (FG2:7)	The whole of oral care is important (FG2:81-84)	Important for items such as preventing halitosis (FG2:81-84) Important to everyone (FG2:164)		

Appendix 22 Health professionals: Oral care received while in hospital

Chart 2 Oral care received while in hospital					
	2.1 Provider of oral care	**2.3 Frequency of care**	**2.4 Oral care process**	**2.5 Location of oral care**	**2.6 Priority**
Focus group One	Oral care is provided as part of a therapy session if it is deemed necessary (FG1:81, 92) Oral care is part of washing and dressing (FG1:81)	Every time the nurses attend to pressure area care they do mouth care (FG1:62, 80) Three hourly care, mouth care should be given of a night but this does not routinely happen (FG1:64) Dependent on the patient's individual needs and the recommendations made by other professionals (FG1:32)	Normal practice is to use toothbrushes and mouth wash due to concern of aspiration using toothpaste (FG1:97) For teeth tend to use gauze swab on a finger (FG1:107) The senior nurse assumed care was being provided as requested, teeth cleaned twice daily, mouths checked after every meal for food, and then mouth care as required (FG1:37) Normal routine is to send false teeth home to prevent them getting lost (FG1:102)	Oral cavities in acute patients seems to be worse, not sure if this changes in rehabilitation (FG1:106)	
Focus group two	Occupational therapist provide oral care and speech and language therapist examine the oral cavity, physiotherapists don't really do hands on care (FG2:359-366)	Normal routine was 1-2 hourly care for those who required it (FG2:72) Twice daily cleaning (FG2:190)	Day staff clean teeth in the morning and night staff repeat at night unless the patient refuses (FG2:190) Just part of routine oral care (FG2:218-221)		If a problem is identified it is seen as high priority (FG2:65) If they are NBM or on PEG feeds then they are high priority (FG2:66)

Appendix 23 Health professionals: Factors affecting the oral cavity and oral care while in hospital

Chart 3 Factors affecting the oral cavity and oral care while in hospital								
	3.2 Ability	**3.3 Difficulty accessing the oral cavity**	**3.4 Staff's attitude/knowledge**	**3.5 Priority of care**	**3.6 Oral care process**	**3.7 Multi-disciplinary**	**3.8 External factors**	**3.10 Medical factors**
Focus group one	Swallowing affects the patient's ability to eat and drink which affects the oral cavity (FG1:7)	Patients will not always let us clean their mouths. Thy clamp down their teeth, turn their head away or resist (FG1:120-122)	Some nurses are more proactive in providing oral care (FG1:24) Some nurses dislike giving oral care or are frightened to give oral care (FG1:109) Nurses makes assumptions about who requires nursing care and this is related to their ability (FG1:48) Lack of training, mainly learning on the job (FG1:38-41) Learning off each other (FG1:40-41)	Some nurses see it as high priority (FG1:24-26) Forms for quality outcomes are taking priority over care (FG1:113)	Dentures being lost or sent home to prevent them getting lost (FG1:103-105)	No clarification between different staff about correct methods (FG1:50)	Time pressures, nurses see it as a list of jobs rather than patients who need care (FG1:36)	Patients not being able to drink due to swallowing difficulties so unable to flush the mouth out (FG1:7)
Focus group two	Physical factors such as whether they can eat and drink influence if care is given (FG1:29) Facial weakness as well as food getting lodged, loss of sensation within the oral cavity (FG2:29) If the false teeth don't fit then they rub and cause problems (FG2:327)	Patients won't open their mouths (FG2:152)	False teeth are always "manky" (FG2:324) Don't like cleaning false teeth (FG2:326) Training is an issue, not knowing what to use to clean the teeth (FG2:455) Scared of hurting the patient, not knowing how to clean the teeth (FG2:407)	Time is a large issue, having the opportunity as well as the time to do the care (FG2:107)			Having enough staff to allow time to carry out the care (FG2:107)	Mouth ulcers can effect chewing and moving food around the mouth (FG2:127)

Appendix 24 Health professionals: Impact on the patient

Chart 4 Impact on the patient		
	4.1 A person's well-being	**4.2 Physical**
Focus group one	Makes a person feel better (FG1:52) Comfort, it is perceived that having food left in the oral cavity would be uncomfortable (FG1:08) How the oral cavity feels may impact on other parts of the person, may affect mental state, engagement with others (FG1:08) The nurses could only imagine the impact of a patient not being able to control their saliva (FG1:63)	Unclean oral cavity can affect a patient's taste and how well they eat (FG1:52) Unable to control saliva (FG1:63)
Focus group two	Having a lot of mucous, coating and a dry mouth must feel really uncomfortable (FG2:424) Important because it can impact on a person's quality of life. Having a fresh oral cavity, well hydrated is important especially in those patients who are NBM (FG2:7,35) Can affect a person's confidence especially if they have halitosis (FG2:274) People feel paranoid and self-conscious and don't want a halitosis (FG2:282)	Can help with taste (FG2:35)

Appendix 25 Health professionals: Facilitators to oral care

Chart 5 Facilitators to oral care					
	5.1 Correct resources	**5.2 Frequency**	**5.4 Assessment of need**	**5.5 Multi-disciplinary**	**5.6 Knowledge**
Focus group one	Using small child toothbrush with hot water as this softens the gums (FG1:133)	Cleaning the mouth twice a day (FG1:61)		Educate the relatives from an early stage to be involved in providing oral care when they visit (FG1:142)	Increasing nurse's awareness and knowledge of oral care would be a large step (FG1:48, 137-139)
Focus group two		Ensuring oral care is performed regular and just a one off (FG2:80)	Having an assessment and documented plan of care that could be viewed by all of the team (FG2:175,549)		Training regarding what, how and when oral care should take place (FG2:549)

Appendix 26 Health professionals: Assessment content

Chart 6 Assessment content				
	6.1 Ability	**6.2 Assessment of need**	**6.3 Areas within the oral cavity**	**6.4 Scoring**
Focus group one		Signs of infection, how moist, any secretions, halitosis, pain (FG1:155) The assessment should be a team approach and part of the multidisciplinary team meeting (FG1:150)	Teeth, tongue, palate, back of the throat, gums, lips (FG1:146) Dentures and inside of the cheeks (FG1:150)	
Focus group two	Assessing the patients cognitive ability, do they need prompting, can they do the care themselves (FG2:306-312)	Assess patients on an individual basis (FG2:93)	Gums, tongue, cheeks, teeth, and dentures (FG2:315-322) Checking for food debris in the mouth, asking the patient (FG2:158)	Gums red and inflamed, coated tongue, ulcers (FG2:315-322)

Appendix 27 Health professionals: Assessment format

Chart 7 Assessment format			
	7.1 Layout	**7.2 Length**	**7.4 Evaluation**
Focus group one	Standardised format (FG1:173)	One piece of paper (FG1:173)	Frequency of assessment should be every time the nurse goes to the patient or twice daily (FG1:61)
Focus group two	Tick box to show the patient has had their oral care performed, oral care should be evidence based (FG2:499)	Quick and easy to use (FG2:494)	

Appendix 28 Patients: Attitude to oral health

Chart 1 Attitude to oral health			
	1.1 Medical importance	**1.3 Own beliefs**	**1.5 Importance for patients**
Rose	Important because if you do not care for your mouth then bacteria will be able to enter the body and spread (P1:76)	Not sure what oral hygiene or mouth care entails (P1:60) Never go the dentist (P1:138) Soak teeth every night. Once a week soak in a drop of bleach (P1:189)	
Madge		Clean dentures with toothpaste and a toothbrush every morning and night. Never takes teeth out of a night (P2:30-35) Moisturises lips every night (P2:35)	Wearing dentures while in hospital. Unable to wear them because of the stroke (P2:21-38) Feel better after you have cleaned your teeth (P2:41)
Grace		Oral care matters if someone is unwell (P3:61) Clean teeth three times a day (P3:11)	
Jane	Bacteria starts in the mouth (P4:43)	The dentists is very important in ensuring dentures fit well (P4:23) Older people are more at risk because they may not look after their teeth (P4:43)	Regular cleaning of the teeth and tongue is essential in maintaining oral health (P4:3-5)
Elsie		Clean teeth with toothbrush and toothpaste every morning. Plus use a mouthwash four times a day. Steradent to soak denture of a night (P5:12-16)	Important to prevent bad breath (P5:32) Makes the person feel better and look better (P5:36)
Cathy	Important because a lot of bacteria can collect in the oral cavity causing problems (P6:203)	Clean teeth twice daily or when going out (P6:91-99) Also use chewing gum to freshen breath (P6:143-145)	Cleaning teeth is like washing. You can't drink anything without cleaning your teeth (P6:109-115)

Appendix 28 Continued

Chat 1 Attitude to oral health			
	1.1 Medical importance	**1.3 Own beliefs**	**1.5 Importance for patients**
Con		Important to look after teeth and gums (P7:18-21) Clean teeth every day, sometimes twice a day using a tooth brush and toothpaste (P7:45-53) Partial dentures are soaked overnight in steradent and rinse in the morning (P7:45-53)	
Ada	Need to look after your teeth to stop ulcers, problems in the mouth and this is especially important when people are in hospital (P8:9-11) Having a dry mouth can affect your swallow (P8:49-51)	Visits the dentist every six months (P8:31) Cleans teeth three times a day when at home (P8:25-29)	Important because you will get halitosis and this is embarrassing when talking to people (P8:63) Clean fresh feeling when you have cleaned your teeth (P8:63) Having a dry mouth did not feel fresh, uncomfortable, felt as though there was something stuck on the roof of the mouth (P8:49-51)
Mary		Cleans teeth twice daily (P9:42)	Oral health affects how you feel (P9:89, 232)
Carol		Brushing teeth two or three times a day with toothpaste and then rinsing with a mouthwash (P10:33)	Important because she was a smoker and very conscious of having a smokers breath (P10:38-43)

Appendix 29 Patients: Oral care received while in hospital

Chart 2 Oral care received while in hospital				
	2.1 Provider of oral care	**2.2 Oral assessment**	**2.3 Frequency of care**	**2.4 Oral care process**
Rose	Nurses provided good care (P1:198-200)			Attended to own oral care using what was available (P1:62-6
Madge				
Grace				Nurses too busy to provide oral care (P3:50)
Jane	Nurses were asked to provide oral care by the patient (P4:109) Patients should perform their own oral care (P4:105)			The patient asked the nurse to give oral care (P4:105)
Elsie		The nurses examined the mouth (P5:96)	Two hourly (P5:83)	Cleaned own oral cavity everyday with wet wipes because there was nothing else available and oral cavity very dry (P5:48) A toothbrush was used with toothpaste to try to remove the coating on the tongue and the roof of the mouth (P5:96-98)
Cathy		Nurses assumed patients with mild symptoms could attend to their own oral care (P6:66-67)		Nurses appeared to clean the mouths of those patients who were immobile and did not assess others (P6:177)
Con	Patient tried to do own mouth care, nurses only offered a few times (P7:59-63)			Nurses too busy with more important jobs so patients should do it themselves (P7:167)
Ada	Nurses in rehabilitation prompted oral care from the first day (P8:37-43)	Nurse in acute care possibly thought could attend to oral care (P8:77-79)	Don't want to bother the nurses so I could clean my teeth more frequently like at home (P8:103)	Care varied between the acute stroke unit and the rehabilitation ward (P8:37-43) More oral care on the rehabilitation ward (P8:37-43) Teeth never cleaned on acute unit (P8:77-79) Offered a toothbrush and toothpaste every morning with a daily wash in rehabilitation (P8:139)

Appendix 29 continued

Chart 2..Oral care received while in hospital				
	2.1 Who provides oral care	**2.2 Oral assessment**	**2.3 Frequency of care**	**2.4 Oral care process**
Mary	On occasions my daughter would provide oral care in the evening and the nurses would provide the care in the morning (P9:109)			Not enough nurses to help with oral care in the acute setting. Patient felt they had no control over this (P9:128-129) Once in rehabilitation oral care provision improved (P9:109)
Carol				Unable to remember acute care (P10:63) In rehabilitation the nurses provided oral care intermittently (P10:81)

Appendix 30 Patients: Factors affecting the oral cavity and oral care while in hospital

Chart 3 Factors affecting the oral cavity and oral care while in hospital					
	3.2 Ability	**3.6 Oral care process**	**3.8 External factors**	**3.9 Resources**	**3.10 Medical factors**
Rose		Worried dentures would no longer fit because they had been sent home (P1:51-54)		No toothbrush to freshen up the oral cavity because sent home with the dentures (P1:74)	Inability to control saliva (P1:124) Being NBM and not able to freshen oral cavity with a drink. 150-152)
Madge					Not being able to wear dentures was affecting communication with others (P2:98) Dentures not fitting (P2:72)
Grace	Not being able to attend to oral care herself. Oral cavity felt unclean (P3:31-33)		Nurses too busy (P3:50)		
Jane			Nurses too busy, they have other priorities and patients should clean their own teeth (P4:105)		Having swallowing difficulties (P4:77) Not being able to chew could affect nutrition and general health (P4:77) Dry tongue may cause swallowing problems (P4:127)
Elsie					
Cathy	Nurses thought she could clean her own oral cavity (P6: 66)		Nurses have too many patients to look after (P6:73)	Not having the right equipment to clean the oral cavity (P6:85)	Facial weakness made swallowing difficult, food would pouch in the side of the mouth (P6:37)

Appendix 30 continued

Chart 3..Factors affecting the oral cavity and oral care while in hospital					
	3.2 Ability	**3.6 Oral care process**	**3.8 External factors**	**3.9 Resources**	**3.10 Medical factors**
Con	Found it difficult to attend to oral care due to old and new stroke causing bilateral arm weakness (P7:115-117)				Difficulty with wearing dentures following the stroke due to changes in the muscles (P7:115-117) Difficulty controlling food and removing food from the side of the mouth (P7:37-41, 129) Changes in the mouth also caused problems with controlling saliva (P7:36-37)
Ada	Staff make assumptions about how much oral care a person needs by how much they could do for themselves and this was not always correct (P8:83,217)				Having a dry mouth was uncomfortable and may affect a person's swallow (P8:49-51)
Mary	Inability to attend to own oral care needs (P9:232-239)		Not enough nurses to attend to everyone's oral care (P9:128)	Lack of dental services available for when a person may lose a tooth while in hospital (P9:63)	Having to drink thickened fluids made the mouth feel unpleasant and uncomfortable (P9:34,99)
Carol				Not having normal equipment to clean teeth (P10:95)	Tongue felt larger and uncomfortable difficult to manoeuvre around the mouth the remove food (P10:119)

Appendix 31 Patients: Impact on the patient

Chart 4 Impact on the patient			
	4.1 Patient well-being	**4.2 Physical impact**	**4.3 Assessing impact**
Rose		Feels rough, unclean and uncomfortable (P1:82-86)	
Madge	Not being able to wear dentures makes the person feel “not whole.” (P2:92)		
Grace	Having clean teeth makes you feel happy (P3:59)		
Jane	You do not feel yourself without your dentures in (P4:90-94) Having an uncomfortable or unclean mouth affects a person’s mood (P4:47) Cleaning teeth makes you feel better in yourself (P4:59)		
Elsie	Having a dry mouth was uncomfortable and patients did not like that feeling (P5:51-59) Hoping they did not have halitosis (P5:61)		
Cathy	Having a clean mouth impacts on how you feel yourself (P6:147) An unclean mouth makes a person feel worse (P6:148)		
Con	Not being able to control saliva creates anxiety (P7:165)	Makes the mouth feel fresh (P7:69)	
Ada	Concerned about halitosis and the impact this would have on others (P8:103) Unclean mouth makes you feel weary (P8:103)		Asked husband to check tongue for a coating because mouth felt really uncomfortable and concerned about halitosis (P8:103)
Mary	Having a drink has a positive impact on the patient (P9:320)		
Carol	Having oral care makes you feel brighter, sharper (P10:48)	Uncomfortable and scary having another person do your oral care (P10:66-67, 70-77)	

Appendix 32 Patients: Facilitators to oral care

Chart 5 Facilitators to oral care				
	5.1 Correct resources	**5.2 Frequency**	**5.3 Oral process**	**5.7 Interventions**
Rose				Being able to eat and drink had a great impact on how oral cavity feels (P1:202)
Madge				Mint sweets help add freshness (P2:154)
Grace		Oral care daily but up to three times a day would be preferable (P3:116-118)		Having a drink (P3:63)
Jane	Toothbrush, denture pot, toothpaste (P4:119-123)		All dentures should be removed, soaked in a denture pot with the correct name on. Dry the lips and moisturise them (P4:119-123)	
Elsie				
Cathy			All patients should be given the opportunity to have their mouth's cleaned and rinsed (P6:201)	
Con			For nurses to clean teeth rather than the patient (P7:105)	
Ada		For the patient to ask the nurses if they feel they require more frequent oral care (P8:105-109)		
Mary				Being able to have a drink (P9:320)
Carol	Having the use of perching stools to aid independence (P10:89-91)		Having the opportunity to clean their teeth in the bathroom (P10:89-91)	

Appendix 33 Patients: Assessment content

Chart 6 Assessment content		
	6.2 Assessment of need	**6.3 Areas within the oral cavity**
Rose		
Madge		Tongue (P2:138)
Grace	Nurses should assess well-being (P3:96-98)	Breath and tongue (P3:85,102)
Jane		Teeth, tongue and lips (P4:105,127)
Elsie		
Cathy		The whole of the oral cavity, tongue, teeth, gums, food in cheeks (P6:209-211)
Con	Patients could assess need through rubbing their tongue over their teeth and cheeks (P7:77-84)	The whole of the oral cavity (P7:141-143)
Ada		Teeth, tongue, gums, bleeding or infection (P8:175,197,271)
Mary		Inside the oral cavity for food in cheeks (P9:334)
Carol		Tongue, gums, lips. Cheeks, where food can become lodged (P10:105-113)

Appendix 34 Carers: Attitude to oral health

Chart 1 Attitude to oral health			
	1.1 Medical importance	**1.3 Own beliefs**	**1.5 Importance for patients**
Dot		Oral care is a simple care need that does not take a lot of time and resources, surprised at how easily the mouth deteriorates through a lack of care (C1:13,83) Important in health so should be just as important in ill health (C1:13) Visiting the dentist is part of the oral care routine (C1:71-73) Agnes cleaned her teeth every morning with a toothbrush and toothpaste (C1:37-41)	Very important (C1:71) Agnes always wore her dentures and would not be seen without them (C1:41)
John and Elaine		James regularly visited the dentist every six months (C2:42) James would clean his teeth twice a day (C2:30-38)	When people get older oral care may not be high priority for them (C2:47)
Jenny	Important in preventing heart conditions (C3:43)	Jenny valued oral care and felt it was very important. She wanted to have all her own teeth into old age (C3:27) Not sure what Bert's routine was as he was independent before the stroke (C3:21) Bert does visit the dentist regularly (C3:21)	Cleaning teeth has an impact on the person psychological well-being (C3:35-43)
Jean	Important to help maintain moisture and lubrication of the mouth (C4:17)	Ann has a regular routine of cleaning her teeth twice a day (C4:39-45)	Cleaning teeth and keeping the mouth healthy is important to the whole family (C4:37)
Sue		Important to keep the mouth and teeth clean (C4:35) Sue feels so strongly about oral care that she takes Barry to the bathroom after every meal to allow him to clean his oral cavity of excess food (C5:73) Barry cleans his teeth twice a day (C5:29)	

Appendix 35 Carers: Oral care received while in hospital

Chart 2 Oral care received while in hospital			
	2.1 Provider of oral care	**2.1 Frequency of care**	**2.3 Oral care process**
Dot	Dot and her sister were providing oral care for Agnes when she visits (C1:23)		Using the swabs dipped in the solution which are then squeezed out. Agnes would open her mouth and on request put her tongue out so it could be cleaned (C1:31,139)
John and Elaine	The nurses (C2:66)		The nurse must be doing something because after the first week the tongue was no longer coated (C2:181) The nurses swab his mouth and it is recorded on the chart (C2:24,121)
Jenny			The care in the acute stages could have been improved with better resources (C3:85) The care in the latter stages was good. Effervescent tablets were used or pineapple juice to swab around the mouth (C3:59,85) The new suction toothbrush is fantastic. His oral cavity is as good as it was before he had his stroke (C3:93)
Jean	The daughter and the nurses (C4:121-125)	Speech and language therapist requested oral care 2 hourly (C4:139)	There was a delay of three days before oral care took place (C4:99) Could clean Ann's teeth in the acute phase using a toothbrush without toothpaste due to the risk of aspiration (C4:101) Provided with glycerine swabs and sterile water buds (C4:121-125)
Sue	I provided oral care (C5: 73, 159, 190)		In the acute unit the relative thought the nurses were cleaning the patient's teeth but this was not the case (C5:271) After his meals he is wheeled to the bathroom to the sink. He then swills his mouth numerous times (C5:73,159,190)

Appendix 36 Carers: Factors affecting the oral cavity and oral care while in hospital

Chart 3 Factors affecting the oral cavity and oral care while in hospital						
	3.2 Ability	**3.5 Priority of care**	**3.8 Oral care process**	**3.8 External factors**	**3.10 medical factors**	**3.11 Patient factors**
Dot	Agnes could not physically attend to her oral care (C1:85)		Dot discussed the oral care provision with the staff. She felt that oral care was not occurring in between her visits because the oral cavity always deteriorated between visits (C1:105)		Medical complications such as dehydration may have contributed to Agnes unhealthy mouth (C1:155)	
John and Elaine	Being old and not capable of attending to his own oral care (C2:181)			The nurses are always busy so don't have the time (C2:183-185)	Being Nil by Mouth means that there was no flushing of the oral cavity increasing the risk of it becoming dry (C2:157-159)	
Jenny	Bert was unable to communicate to let the nurses know his wishes and how his oral cavity felt (C3:77)			Time management and people being allowed the time to provide oral care (C3:87)	Mouth breathing and oxygen therapy both dry out the mouth (C3:51,123) Bert had an infection following his stroke and the antibiotics caused thrush (C3:51,77) The swallowing problems Bert had following his stroke may have prevented the nurses from providing oral care due to their anxiety of aspiration (C3:91)	

Appendix 36 continued

Chart 3 Factors affecting the oral cavity and oral care while in hospital						
	3.2 Physical ability	**3.5 Priority of care**	**3.6 Oral care process**	**3.8 External factors**	**3.10 Medical factors**	**3.11 Patient factors**
Jean			Jean was anxious about trying to do something to make Ann's oral cavity look and feel better (C4:25)		Ann was NBM and so Jean kept asking the nurses about freshening the mouth as she could see it was getting dryer and dryer (C4:25) Although Ann was on a NG feed Jean felt her oral cavity was better when she also had intravenous fluids going. She was very concerned when these were discontinued and felt Ann's oral cavity deteriorated (C4:135) Swallowing problems appeared to prevent oral care from occurring due to fear of aspiration (C4:109)	
Sue	Inability to feel food lodged in the cheeks (C5:21) Ability to see where to put the toothbrush due to hemianopia (C5:293)	Oral care not seen as the most important care need (C5:200)			Food debris would become lodged in the cheek area due to altered sensation (C5:246)	Patient would not ask the nurses for help (C5:165-169)

Appendix 37 Carers: Impact on the patient and carer

Chart 4 Impact on the patient and carer			
	4.1 Patient well-being	**4.2 Physical impact**	**4.3 Assessing impact**
Dot	Agnes is a proud woman and has never been seen without her teeth (C1:59) Agnes appreciates having oral care (C1:164)	Agnes has sticky white saliva which hinders her communication (C1:95) Putting moisture in her mouth is like giving her a drink (C1:164)	Her mother's reaction tells her that she enjoys the oral care (C1:164)
John and Elaine	Some days they felt their dad was low in mood because he wanted a drink (C2:81) .	Liked having oral care (C2:105) Their dad complains he is very thirsty (C2:22) Recovery will be quicker once he starts eating and drinking again (C2: 97)	
Jenny	Feeling terrible because the condition of the oral cavity prevented her from giving her father a reassuring kiss and this made her feel guilty (C3:53) Oral care is about maintaining basic dignity, feeling clean and looked after (C3:53) The patient appeared to enjoy having oral care (C3:61) Providing oral care is a method of providing psychological care through patient contact (C3:87)	Yellow film on the tongue that was dried, hard and cracked like a snake's skin (C3:53, 107)	The patient relished having oral care (C3:61)
Jean	Oral care contributes to feeling better not worse (C4:29-31) People who are in hospital are already unwell and so having discomfort in the mouth can only contribute to these feelings (C4:67) Jean describes her mum's oral cavity as being something out of a horror movie (C4:139)		
Sue	It must be uncomfortable having an unclean oral cavity (C5:159)		

Appendix 38 Carer: Facilitators to oral care

Chart 5 Facilitators to oral care						
	5.1 Correct resources	**5.2 Frequency**	**5.3 Oral care process**	**5.4 Assessing need**	**5.5 Multi-disciplinary**	**5.7 Intervention**
Dot		Should be regular, preferably every three hours (C1:111)	Oral care should be recorded (C1:111)			
John and Elaine		Every couple of hours (C2:127 -130)				Freshening the mouth up (C2:127)
Jenny		Every few hours or as often as it can be provided (C3:117-119)			Carers being educated about oral care, family helping to provide oral care when visiting (C3:143-145)	
Jean		Oral care should be routine the same as doing blood pressures (C4:33, 264)	Oral care should start as soon as patients are admitted into hospital (C4:169)		Lots of other health workers could be involved in providing oral care (C4:252)	
Sue	Everyone should be given the means to clean their teeth (C5:315)	Every one to two hours (C5: 157, 253)	Everybody should be given the opportunity to clean their teeth (C5:317)	The nurses should check that patients have cleaned their teeth when they leave the bathroom (C5:315)	Relatives should be given a “to do list” when they visit which should include oral care (C5:287-291)	

Appendix 39 Carers: Assessment content

Chart 6 Assessment content	
	6.3 Areas within the oral cavity
Dot	Tongue as it is always coated, top lips, inside the cheeks, every part of the mouth, palate and gums (C1: 131-133, 153)
John and Elaine	Swallowing (C2:135)
Jenny	Tongue and teeth (C3: 107)
Jean	Tongue, throat, teeth, gums, lips (C4:153,208,220)
Sue	Check for ulcers, or spots (C5:244)

Appendix 40 Carers: Assessment format

Chart 7 Assessment format			
	7.1 Layout	**7.2 Length**	**7.4 Evaluation**
Sue			Frequency of assessment should be daily (C5:255)

Appendix 41 NHS Research Ethics Committee -reliability testing

NHS
Health Research Authority
National Research Ethics Service

NRES Committee North West - Haydock
HRA NRES Centre - Manchester
3rd Floor - Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7827
Facsimile: 0161 625 7299

22 November 2012

Mrs Hazel Dickinson
Brook 417
Clinical Practice Research Unit
School of Health
University of Central Lancashire
Preston
PR1 2HE

Dear Mrs Dickinson,

Study title:	**Oral assessment: testing reliability and utility of a Comprehensive Oral Assessment Tool for Stroke patients (COATS).**
REC reference:	**12/NW/0860**

Thank you for your application for ethical review, which was received on 21 November 2012. I can confirm that the application is valid and will be reviewed by the Committee at the meeting on 11 December 2012.

Meeting arrangements

The meeting will be held in the Haydock Park Racecourse, Tommy Whittle Stand, Newton-Le-Willows, Haydock, WA12 OHQ on 11 December 2012. The Committee would find it helpful if you could attend the meeting to respond to any questions from members. Other key investigators and a representative of the sponsor are also welcome to attend. This may avoid the need to request further information after the meeting and enable the Committee to make a decision on the application more quickly.

If you have a disability and need any practical support when attending the REC meeting you may wish to contact the REC office so appropriate arrangements can be made if necessary.

If you are unable to attend the meeting the Committee will review the application in your absence.

The review of the application has been scheduled for 2:40. Please note that it is difficult to be precise about the timing as it will depend on the progress of the meeting. We would kindly ask you to be prepared to wait beyond the allocated time if necessary.

Committee meetings are occasionally attended by observers, who will have no vested interest in the applications under review or take any part in discussion. All observers are required to sign a confidentiality agreement.

Appendix 41 continued

Documents received

The documents to be reviewed are as follows:

Document	Version	Date
Covering Letter: from Hazel Dickinson		19 November 2012
REC application: 89124/385225/1/115		19 November 2012
Protocol	1	24 October 2012
Investigator CV: Mrs Hazel Dickinson		14 November 2012
Investigator CV: Dr Michael J Leathley		20 May 2011
Investigator CV: Professor StJohn Crean		
Investigator CV: Professor Caroline Watkins		21 March 2012
Participant Information Sheet	1	24 October 2012
Written Consent Form for Patients	1	24 October 2012
Consultee Information Sheet	1	24 October 2012
Consultee Declaration Form	1	24 December 2012
Aphasia Friendly Information Sheet	1	24 October 2012
Written Aphasia Friendly Consent Form	1	24 October 2012
Witness Consent Form For Patients	1	24 October 2012
Oral Assessment: Data Collection Form	1	15 November 2012
Comprehensive Oral Assessment Tool (COATS)	1	15 November 2012
Utility Questionnaire	1	15 November 2012
Evidence of insurance or indemnity: AON- signed Dennis Poundford		02 August 2012

No changes may be made to the application before the meeting. If you envisage that changes might be required, we would advise you to withdraw the application and re-submit it.

Notification of the Committee's decision

You will receive written notification of the outcome of the review within 10 working days of the meeting. The Committee will issue a final ethical opinion on the application within a maximum of 60 days from the date of receipt, excluding any time taken by you to respond fully to one request for further information or clarification after the meeting.

R&D approval

All researchers and local research collaborators who intend to participate in this study at sites in the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland should apply to the R&D office for the relevant care organisation. A copy of the Site-Specific Information (SSI) Form should be included with the application for R&D approval. You should advise researchers and local collaborators accordingly.

The R&D approval process may take place at the same time as the ethical review. Final R&D approval will not be confirmed until after a favourable ethical opinion has been given by this Committee.

For guidance on applying for R&D approval, please contact the NHS R&D office at the lead site in the first instance. Further guidance resources for planning, setting up and conducting research in the NHS are listed at http://www.rdforum.nhs.uk

There is no requirement for separate Site-Specific Assessment as part of the ethical review of this research. The SSI Form should not be submitted to local RECs.

Appendix 41 continued

Communication with other bodies

All correspondence from the REC about the application will be copied to the research sponsor and to the R&D office for Lancashire Teaching Hospital NHS Trust. It will be your responsibility to ensure that other investigators, research collaborators and NHS care organisation(s) involved in the study are kept informed of the progress of the review, as necessary.

12/NW/0860	**Please quote this number on all correspondence**

Yours sincerely

Ms Josephine Foxall Dant
Assistant Co-ordinator

Email: nrescommittee.northwest-haydock@nhs.net

Enclosure: Further information about REC membership arrangements

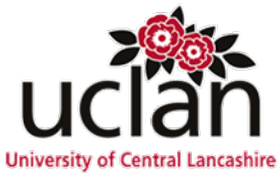
Copy to:

Dr Robert Walsh
University Director of Research
Adelphi Building
Preston
PR1 2HE

Ms Gemma Whiteley
Lancashire Teaching Hospitals NHS Foundation Trust
R&D Department
Preston
PR2 9HT

Appendix 42 University ethical approval

15th January 2013



Michael Leathley & Hazel Dickinson
School of Health
University of Central Lancashire

Dear Michael & Hazel

Re: BuSH Ethics Committee Application
Unique reference Number: BuSH 138

The BuSH ethics committee has granted approval of your proposal application 'Oral assessment: testing reliability and feasibility of the Comprehensive Oral Assessment for Stroke patients (COATS)'.

Please note that approval is granted up to the end of project date or for 5 years, whichever is the longer. This is on the assumption that the project does not significantly change in which case, you should check whether further ethical clearance is required.

We shall e-mail you a copy of the end-of-project report form to complete within a month of the anticipated date of project completion you specified on your application form. This should be completed, within 3 months, to complete the ethics governance procedures or, alternatively, an amended end-of-project date forwarded to roffice@uclan.ac.uk together with reason for the extension.

Please also note that it is the responsibility of the applicant to ensure that the ethics committee that has already approved this application is either run under the auspices of the National Research Ethics Service or is a fully constituted ethics committee, including at least one member independent of the organisation or professional group.

Yours sincerely

Gill Thomson
Vice Chair
BuSH Ethics Committee

Appendix 43 Governance approval reliability study

Lancashire Teaching Hospitals NHS
NHS Foundation Trust

Centre for Health Research and Innovation
Royal Preston Hospital
Sharoe Green Lane, Fulwood
Preston, PR2 9HT

Tel: 01772 528268
Fax: 01772 523184
Email: heather.adams@lthtr.nhs.uk
(RM&G Coordinator)

CENTRE FOR HEALTH RESEARCH AND INNOVATION
RESEARCH AND DEVELOPMENT DIRECTORATE

Our Ref: GW/HAA

NHS Permission for Research

12 February 2013

Mrs Hazel Dickinson
Graduate Research Student
University of Central Lancashire
417 Clinical Practice Research Unit
School of Health
University of Central Lancashire
Preston
PR1 2HE

Dear Hazel

R&D Ref:	1685	**IRAS Ref:**	89124
Study Title:	Oral assessment: testing reliability and utility of a comprehensive oral assessment tool for Stroke patients (COATS)		
REC Ref:	12/NW/0860		

This trial was reviewed on behalf of the Lancashire Teaching Hospitals NHS Foundation Trust by the Research Directorate Executive. Trust permission has accordingly been given and the Trust is happy for this study to go ahead, subject to the conditions listed in the attached document.

This letter acts as proof of NHS Permission to conduct the research project described in the Protocol submitted for review. Any variations to the protocol must be re-submitted to this Committee and new approval sought. The research project must not start until:

- Ethical approval, from the National Research Ethics Service
- The declaration attached to this letter has been signed, dated and returned to the Research Directorate.

Any failure to comply with these requirements will result in action being taken under the Lancashire Teaching Hospitals NHS Foundation Trust Policy for Fraud and Misconduct in Research.

List of documents reviewed and approved:

Document	Version	Date
Protocol	1	24 October 2012
Investigator CV: Mrs Hazel Dickinson		14 November 2012
Participant Information Sheet	2	07 January 2013
Consultee Information Sheet	2	07 January 2013

Appendix 43 continued

General Terms & Conditions of Research Governance Approval for Research undertaken within Lancashire Teaching Hospitals NHS Foundation Trust

Please read, sign your acceptance & return a completed, signed & dated copy of this document to the Research Directorate, Royal Preston Hospital within one month of the date of the attached letter. Please also be sure to keep a copy of these terms and conditions in your research file for your reference.

Title of Project:

Oral assessment: testing reliability and utility of a comprehensive oral assessment tool for Stroke patients (COATS)

Reference No: 1685

Ethics Approval **YES** [x] **Awaiting** [ ]

The project must be approved by an NHS Research Ethics Committee before it commences. Copy of all ethics approval letters must be supplied to the Research Directorate, Royal Preston Hospital

Human Tissue Act

The Human Tissue Authority (HTA) regulates the removal, storage, use and disposal of human bodies, organs and tissue from living and deceased persons. This includes 'residual' tissue following clinical and diagnostic procedures. The Human Tissue Act is enforceable by law and any individual or Trust found to be in breech of the Act will face severe penalties.
Samples for a single research Project:
If you undertake research on tissue samples, blood samples, sputum or other body fluids from living patients and/or deceased patients and tissue is removed and stored for the primary purpose of research and for a specific research project, their use is covered under the terms of the ethical approval given for that specific study. Any such tissues must be immediately disposed of, at the end of the project, in accordance with standard procedures.
Samples for multiple projects or long-term use:
If you are collecting or obtaining tissue samples, blood samples, sputum or other body fluids from living patients and/or deceased patients for general research or storage (tissue bank) purposes then you must notify the Research Directorate, Royal Preston Hospital **before** collection begins.

Further information on researchers' obligations under this Act can be obtained from Dr Tim Dawson, Consultant Neuropathologist or the following website www.hta.gov.org

1. This project involves the taking and/or storage and or use of human tissue samples (including blood, urine, CSF etc, ie anything that could contain human cells).
Yes [ ] **No** [ ]

2. If the answer to question 1, above, is yes, I feel, as the lead researcher on this project, that either

a) any human material collected in this project **falls** within the provision of the Human Tissue Act (for example, samples collected and stored for

Appendix 44 Comprehensive Oral Assessment for Stroke

COATS

Comprehensive Oral Assessment Tool for Stroke

Date:			-			-	2	0	1	3	Clinician no:		Patient Study no:			

Visit 1 2 (Please circle)

Pre Screening: Please circle each statement to assess need. If any of the responses are red please complete the COATS.

Can the patient go to the bathroom (to do their oral care)?	**Yes**	**No**
Can the patient attend to their own oral care?	**Yes**	**No**
Does the patient attend to their oral hygiene?	**Yes**	**No**

Area: Score 0, 1 or U (unable to assess) for each one

Action: Tick either or both for each area

Area	0	1	Score	Action	Comments
Lips	Smooth, pink	Dry cracked, red at the corners, broken, ulcerated		Oral care ☐ Medical Assessment ☐	
Teeth/ Dentures	No plaque	Visible plaque on teeth, food debris		Oral care ☐ Medical Assessment ☐	
Gums	Pink, moist	Swollen red edges		Oral care ☐ Medical Assessment ☐	
Cheeks	No food	Bolus of food in cheeks		Oral care ☐ Medical Assessment ☐	
Tongue	Pink, moist	Coating on the tongue, abrasions on the tongue, swollen tongue		Oral care ☐ Medical Assessment ☐	
Roof of mouth	Pink, moist	Red areas, thick mucus covering, broken, ulcerated areas		Oral care ☐ Medical Assessment ☐	
Saliva	Normal saliva, free flowing	Dry sticky saliva, no saliva, oral cavity dry		Oral care ☐ Medical Assessment ☐	
Pain	No pain	Pain		Oral care ☐ Medical Assessment ☐	
Ask the patient how the oral cavity feels.	Clean, fresh	Not clean, dirty		Oral care ☐ Medical Assessment ☐	
Do you wish to report on any aspects of the mouth (globally and specific) which is not reflected in the COATS? If yes please expand.					

Appendix 45 Feasibility Questionnaire

	Question	Answer
1.	Is the COATS easy to read? If no please state why.	
2.	Can you follow the instructions for the COATS? If not please state why.	
3.	Are the descriptors for each item clear? If no please state why?	
4.	Are the actions clear?	
5.	Could you use the COATS with every patient? If no please state what stopped you using it in every patient.	
6.	Is the lay out clear? If no please state why.	
7.	How often do you feel the COATS should be used? Please circle one.	Once a day/twice a day/after every meal/ Four times a day
8.	What aspects would you change if any and why?	