A SYMPTOM-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE FOR DYSPHAGIA

By

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Supervisors' Declaration

As the candidate's supervisor I have approved this thesis for submission.

Signed: _Sandie R Thomson_   Name: Prof S R Thomson Date: 16 May, 2014

As the candidate's co-supervisor I have approved this thesis for submission.

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Declaration

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Summary

Background

Dysphagia is a common clinical problem. It is a distressing symptom which impacts negatively on the quality of life (QOL) of patients. There is increasing recognition that assessing QOL gives a broader perspective when deciding on and assessing the effect of treatment of our patients. An abstract concept, QOL is perceived by many clinicians in South Africa as difficult to measure and hence they are reluctant use it to help with therapeutic decision making. There is a dearth of QOL information from third-world countries and there is no locally developed or validated tool to measure it. If we are to provide more holistic health care to our patients this situation needs to be rectified and an appropriate tool developed.

Aim

To develop a quality of life questionnaire specific for dysphagia relevant to our local population and validated it against established international questionnaires. The newly developed questionnaire needs to be comprehensive enough to measure general QOL as well as specific enough to be able to detect differences in QOL before and after treatment. Furthermore it needs to be brief and simple so as to be clearly understood and completed by our patient population with varied literacy competencies.

Methods

We formulated a questionnaire related to dysphagia and other symptoms commonly associated with it and named it the Greys Dysphagia Quality of Life (GREYS DQOL) questionnaire. The questionnaire contained questions pertaining to generic QOL issues as well as to dysphagia-related QOL issues. We administered the questionnaire to a sample of patients together with two other internationally used questionnaires. One of the international questionnaires, the Short Form 36 (SF-36) quality of life questionnaire is a fully validated generic quality of life questionnaire which is extensively used world-wide and in South Africa. The other, the Dysphagia Score (DS), is a dysphagia-specific questionnaire used internationally to assess patients with conditions presenting with dysphagia. We compared the results of the three questionnaires as well as the compliance of patients in answering the three questionnaires. Demographic data collected included age, gender and level of education.

Results

One hundred patients were entered into the study. The majority were males in their sixth and seventh decade of life. Most patients had no established diagnosis at the time of the study, but of those who did have a diagnosis, the most common cause of the dysphagia was malignant obstruction of the oesophagus. The literacy level amongst our patients was found to be low. Twenty three patients received no formal schooling and only 11 patients completed school to matriculation level. The quality of life of our sample population was poor according to all three questionnaires. The mean score for patients on the SADQOL questionnaire was 61 where a score of 0 indicates the best quality of life possible and a score of 100 indicates the worst quality of life possible. The mean score for patients on the SF-36 was 30, where 0 indicates the worst possible quality of life and 100 the best possible quality of life. The mean score for patients on the dysphagia score was 7, where 0 is the best score and 10 the worst.

The results of the new questionnaire correlated well with that of the international questionnaires, confirming test-validity. The compliance of patients in answering questions in the GREYS DQOL questionnaire was superior to that of the internationally used questionnaires. The level of education influenced the scores of the SF-36 but not those of the GREYS DQOL and DS. This makes the GREYS DQOL more appropriate for use in our patient population.

Conclusion

The GREYS DQOL questionnaire is simpler to comply with and correlates well with established international tools. We therefore consider it to be a good tool for assessing quality of life of patients presenting with dysphagia in South Africa. It can be used to assess QOL in our patients at initial presentation and after treatment is administered and is understood well by our patient population.

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Chapter 1: Introduction and Study Rationale

Dysphagia means difficulty in swallowing and is a term used to describe the symptom associated with any abnormality of the swallowing process other than pain[1]. Normal swallowing is a complex and well-coordinated process, which requires neural control regulated by interactions between cortical centres in both hemispheres of the brain, the swallowing centre in the brainstem, cranial nerves and pharyngeal receptors[2]. It comprises four phases; oral preparation, oral, pharyngeal, and oesophageal. Dysphagia may occur due to malfunction or anatomical defect of any of these four phases[3].

1.1 Dysphagia and the patient

The ability to swallow and eat is a basic human function which is not only life-sustaining but also life enhancing. It can provide pleasure and comfort and is central to most social interaction. Dysphagia interferes with this ability and in so doing has an immediate impact on daily life. This distressing symptom has been linked to depression, social withdrawal and decreased self-esteem and has a significant negative impact on quality of life QOL[4-7]. Consequences of dysphagia are numerous and include malnutrition and lower respiratory tract infection secondary to aspiration. Malnutrition itself has numerous complications which negatively affect QOL[2, 8, 9]. Symptoms commonly accompanying dysphagia include regurgitation, chest pain and choking. These symptoms themselves will affect the QOL of patients and lead to social embarrassment rendering patients unwilling to eat in public or at social gatherings[5]. The causes of dysphagia are numerous and many of these conditions are incurable[10, 11]. Treatment is therefore palliative and aimed at improving quality of life (QOL) in these patients. This would include palliation of the dysphagia as well as palliation of associated symptoms.

Algorithms for the objective assessment of dysphagia are well established[1] but the same cannot be said of subjective data gained from patients' perspective even though difficulty in swallowing has an immediate impact on daily life[6]. Patients are faced with a daily struggle to eat and drink for survival and mealtimes are often long and exhausting[12].

The effect of any symptom on QOL is dynamic and may change over time. For example, depression and anxiety may lessen as adjustments are made in coping with the illness. In addition the same symptom and condition may have different effects on different patients. Patients' expectations of treatment outcomes differ, making objective information less useful in managing certain illnesses[13].

General health measures of quality of life are not sufficiently sensitive to swallowing-related issues and there is a need for symptom-specific domains to capture meaningful data[6, 14]. While dysphagia-specific QOL have been developed and validated in the first world[6], this has not been done in the third world setting.

1.2 Palliative care and quality of life in South Africa

The World Health Organization defines palliative care as '*An approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual*'[15]. Palliative care is most commonly associated with cancer patients, but it can be applied to all patients with incurable diseases. QOL measurement is an important aspect of palliative care, given that maximizing the QOL of terminally ill patients is the main aim of this type of care[16].

Palliative care is an essential component of public health services in South Africa and is accompanied by significant challenges, including lack of resources, poor socio-economic conditions and a lack of trained palliative care personnel[17]. While South Africa has made sustained gains in palliative care provision, these are mainly through community based hospices and home based palliative care programmes and not necessarily in State hospital facilities, which experience huge pressure on bed numbers on a daily basis[15, 17]. Progress has been made in certain key areas of palliative care in South Africa, such as the development of national standards for cancer pain management [18].

A major barrier to the further development of palliative care in South Africa and Africa as a whole is the lack of data to inform service provision. There is a dearth of palliative care outcome measures developed and validated in South Africa[19]. Palliative care research in Africa has predominantly focussed on opioid availability and physical aspects of care, such as the assessment of pain and other symptoms, while

neglecting holistic outcomes such as QOL. In the developed world there has been rapid growth in QOL research that aims to understand patient experience, identify patient needs and evaluate the effectiveness of interventions and services. However, to date there has been very little research in this area in Africa, despite recognition of the importance of outcome measurement and the need to identify domains in which patients may need specific support[15, 19].

The functional status of patients declines as the latter stages of terminal disease approaches and is a good prognostic indicator[20]. Hospice patients have been shown to score lower in psychophysiological and functional well-being than healthy subjects but not necessarily lower in social and spiritual domains. The reasons for this are not clear but changes in priority and adaptation to life situations may play a role[21]. Measurement of QOL may clarify some of these findings and is therefore central to assessment of palliative care.

1.3 Measurement of quality of life

As physicians we often under appreciate the effects of a disease or symptoms on quality of life. We gauge treatment success by assessing so-called 'hard data' like survival, results of radiological investigations and laboratory results. If we are satisfied with these results then we are more likely to repeat the same course of treatment with other patients. We forget to assess whether our treatment has actually helped the patient. We forget to assess the effects of our treatment on the QOL of our patients. Little, if any, insight is gained from the patient regarding the success of the treatment. One of the reasons for this is the lack of tools which adequately assess QOL, and particularly disease or symptom specific QOL. Another reason is a lack of awareness of the importance of QOL when treating patients[22-24].

Quality of life is a term which applies to various aspects of life including politics, economics and spirituality. In the medical context, it is health-related QOL (HRQOL) which we are more concerned with. HRQOL measures the effects of symptoms, diseases and its treatment on the patient's overall well-being[25]. Patients often present to clinicians with symptoms or disabilities and treatment should be aimed at relieving these complaints and thereby improve QOL. Measuring outcomes in this context is challenging. The World Health Organization (WHO) framework of disease consequence is useful in assisting clinicians in choosing an outcome measure. The framework divides disease consequences into impairments, disabilities and handicaps. Each of these outcomes provides complementary information and has relative advantages

and disadvantages in assessing QOL. Impairments are restrictions of physiological or anatomical structure or function, disabilities are restrictions to perform activities within what is considered normal range and handicaps are restrictions that limit fulfilment of a usual role, like doing housework[26]. Measures of QOL are useful in assessing outcomes of treatment as they take input from the patient into consideration. These measures are usually classified as generic or specific.

Generic measures provide a broad general picture of the patient's health and include physical, mental, social and psychological aspects. Generic measures have the advantage of providing a comprehensive assessment of health and it allows for comparison across different population groups. The major disadvantage of generic measures is that they are not responsive to change in individual patients' conditions or to change after treatment has been administered.

Specific measures may be disease, symptom or population specific and focus on aspects of health care that are specific to an area of interest. They have the advantage of being more responsive to changes in QOL after intervention and of relating closely to areas routinely analysed by clinicians. The major drawback of specific instruments is that they have a relatively narrow focus compared to generic tools and therefore give limited information regarding overall health and QOL. To provide a complete assessment it may therefore be necessary to combine aspects of generic and specific questionnaires[23-27].

1.4 Study rationale

While there are a number of tools available to assess QOL in patients, the majority of these tools are developed in first world countries and many of the questions have little relevance to our local population[28]. Therefore their use in our local setting is questionable. This is understandable since health HRQOL is influenced by culture and perception[29]. Culture may be defined as '*the integrated patterns of human knowledge, beliefs and behaviour*'. It is known to impact on health attitudes, belief and behaviour[30, 31]. Many of the questions are related to social and economic factors which differ vastly between first and third world countries.

Another problem with these instruments is that they have been tested in population groups that differ in many aspects from our patient population. Many of the questions focus on issues that are important to these population groups and these issues may not be as important to our patients. Issues that are

important to our patients are not addressed. For example, questions asked in the short-form 36 health survey make reference to health limiting activities like playing golf or pushing a vacuum cleaner. While these issues may be important to individuals from first-world countries, many of our patients may not even know what golf or a vacuum cleaner is. Loss of weight may carry more significance with some of our patients compared to patients elsewhere. In addition concepts such as pain and anxiety can lack both intra- and intercultural equivalence among the divergent ethnic groups across South Africa. The impact of culture, in general, would affect results of QOL research in South Africa.

Objective assessment of swallowing dysfunction is well established, widely practised and include contrast and motility studies[5, 32, 33] while good quality validated tools for the more subjective QOL effects of dysphagia are lacking in comparison[8]. Dysphagia specific quality of life tools have been developed and validated in the first world[34, 35] but not in South Africa. Furthermore, there is discrepancy in the literature with respect to the correlation between objective and subjective swallowing evaluation[5]. There is therefore a need to develop QOL questionnaires that contain questions regarding dysphagia that are relevant to our local population. These should include both generic and disease or symptom specific questionnaires. The questions asked should address issues that are important to our patients. These questionnaires should be validated and used to assess the impact of disease or symptoms on our patient as well as the effectiveness of different treatment regimens, particularly those that are aimed at improving QOL rather than cure. Health care givers should be made aware of the importance of quality of life when caring for patients.

1.5 Outline of the thesis

The factors outlined above are detailed in the literature review which provides the relevant background to look at the impact of dysphagia on health in general, the progress made thus far with development of quality of life questionnaires and the results of similar studies. The methodology describes the development of our own Dysphagia QOL questionnaire and it comparison with existing validated questionnaires. The results and analysis are presented and their implications discussed.

Chapter 2: Literature Review

Developing an assessment tool for studying the impact of dysphagia on quality of life (QOL) in a South African context requires an understanding of the literature addressing these topics. This chapter reviews the key concepts necessary to understand the complexity of the task. It then presents analyses and discusses the pertinence of largely internationally developed questionnaires used in studies addressing the symptom of dysphagia. The literature provides a framework for the rationale of the study and the development of a composite dysphagia QOL tool for assessment and validation.

2.1 Definitions

2.1.1 Dysphagia

Dysphagia is a term which means difficulty in swallowing. The term itself is subjective, broad and non-specific. Swallowing is a highly complex process involving both voluntary and non-voluntary components and the intricate coordination of muscles and nerves. The ability to swallow safely and efficiently is a basic human need and an essential daily experience associated with the pleasure of eating [3, 36]. Dysphagia should not be confused with odynophagia which is 'painful swallowing'[1].

Any disruption or abnormality in the swallowing process may be defined as dysphagia. Persons with anatomical or physiologic deficits in the mouth, pharynx, larynx, and oesophagus may present with dysphagia. There are two types of dysphagia: oropharyngeal or 'high' dysphagia and oesophageal or 'low' dysphagia. The majority of patients we are exposed to as surgeons present with oesophageal dysphagia[1, 3].

2.1.2 Quality of life

'Quality of life' (QOL) as a concept is not easy to define. It is a broad concept encompassing a number of aspects ranging from standards of living to psychological, physical and social aspects of life. In other words, it is a comprehensive concept that includes objective and subjective aspects[37].

There are a number of attempts to define QOL however. The Group Quality of life at the Division of Mental Health from the World Health Organization defined QOL as '*the individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.*'[37]. In another definition it is defined as '*a broad range of human experiences related to one's overall well-being*'. It implies value based on subjective functioning in comparison with personal expectations and is defined by subjective experiences, states and perceptions[38]. Quality of life, by its very nature, is unique to the individual, while being easily understood by most people[38].

QOL is a multidimensional concept and includes a number of domains or dimensions. Some of these domains are[39]:

- Physical

- Psychological

- Social

- Level of independence

- Environment

- Spirituality

The physical, psychological and social domains are considered to be the three main dimensions of QOL. The physical domain refers to the ability to carry out daily activities and tasks that require energy expenditure, as perceived by the patient. The psychological domain incorporates aspects of emotional and mental well-being like depression, anxiety, fear and happiness and the social aspect refers to the patient's ability to relate to and interact with members of family, friends and acquaintances[40].

The subjective nature of QOL affects our ability to measure it. QOL depends on an individual's perceptions and therefore self-appraisal is a key factor in studies assessing QOL. In addition to being subjective, it is dynamic and changes over time. This change may be influenced by a number of patient and environmental factors. It may therefore be necessary to carry out repeated assessments[41, 42].

QOL includes both positive and negative dimensions[39]. Positive dimensions include aspects like role functioning and contentment while negative dimensions include aspects like pain and feelings of

depression. How much someone enjoys life and how much pain affects someone are both important aspects of QOL assessment[43].

As clinicians we are largely interested in health-related quality of life (HRQOL) because widely valued aspects of life exist that are not generally considered as 'health,' including income and freedom[25]. It has to be kept in mind though that almost all aspects of life can become health related. HRQOL is therefore often used interchangeably with overall QOL. Because illness and treatment affect the physical, psychological and social well-being of an individual, any definition of HRQOL should be all encompassing while allowing individual components to be assessed individually[44].

HRQOL can be defined as '*self-perceived aspects of well-being that are related to or affected by the presence of a disease or treatment*'. It includes the negative aspects of symptoms caused by a disease and/or its treatment[29]. It is important to measure HRQOL because physiological measures often correlate poorly with functional capacity and well-being and two patients with similar clinical criteria often have dramatically different responses[25].

This multidimensional concept should be defined from the perspective of the patient and clinicians should avoid using functional status as a surrogate marker to assess QOL[45].

2.2 Dysphagia

2.2.1 Incidence

The exact incidence of dysphagia is difficult to ascertain and depends on a number of factors, including the population group being studied and the level of health care provided in a particular setting. The reported incidence and prevalence of various forms of dysphagia vary depending on a number of factors and epidemiological data cannot be provided on a global basis since the prevalence of most diseases that may present with dysphagia tends to differ between different parts of the world. Also, prevalence will vary depending on the age of the patient, and it should be remembered that the spectrum of disorders in childhood dysphagia is different from that of adult-onset dysphagia. Therefore, only approximations are possible on a global scale. Generally, dysphagia occurs in all age groups but its prevalence increases with age. First-world statistics reports the prevalence of dysphagia in a primary care setting to be between 20%

and 25%. The prevalence increases to 30% in general medical wards and is as high as 60% in nursing homes[7, 36, 46, 47]. It is therefore a common problem encountered in clinical practice.

2.2.2 Causes

The causes of dysphagia are vast and depend on the type. Oropharyngeal dysphagia is most commonly caused by neuromuscular diseases like Parkinson's disease or stroke while oesophageal dysphagia is most commonly caused by mechanical obstruction of the oesophagus or motility disorders of the oesophagus[1]. Dysphagia complicates up to two thirds of cases of stroke while healthy ageing alone may affect the swallowing process[14]. However, the majority of patients presenting to a surgical department have a mechanical obstruction of the oesophagus, pharynx or mouth and in a large proportion of these patients, the source of the mechanical obstruction will be a malignancy. The common causes of dysphagia are listed below[1, 13, 14]:

- Cancer of the oesophagus
- Gastroesophageal reflux disease
- Motility disorders of the oesophagus
- Head and neck cancer
- Oesophageal diverticulae
- Stroke
- Neurodegenerative disorders e.g. Parkinsons
- Oesophageal webs
- Extrinsic compression e.g. thyroid goitre

2.2.3 The effects of dysphagia

Dysphagia as a symptom can have devastating effects on patients. It is associated with increased morbidity and mortality. Cowen and colleagues found that mortality was high in patients with severely abnormal swallowing and that advanced age, reduced serum albumin concentration, disorientation to person and higher morbidity scores were independent predictors of mortality[48]. This increased risk of death was independent of the actual cause of dysphagia[48].

The physical consequences of dysphagia are vast and include malnutrition, dehydration and respiratory infections. Untreated, any of these conditions may lead to death[7, 49]. Dysphagia may even be seen as a handicap, where handicap is defined as '*a reduction in functional capacity that limits the individual's ability to attain his or her physical goals*'[7].However, the treatment of dysphagia can result in improvement of these conditions[50].

Dysphagia contributes to a variety of mental disorders; most notably, anxiety and depression as well as negative effects on social aspects of health[2, 7, 36, 47, 51]. It is considered a disabling condition for an individual in terms of both the functional, as well as the emotional aspects[51]. Dysphagic patients perceive their ability to eat out or engage in social activity as being reduced[2]. Studies assessing the psychosocial aspects of dysphagia found that 41% of dysphagic individuals experienced anxiety or panic during meals and 36% avoided eating with others leading to increased feelings of social isolation and loss of self-esteem[7]. Reductions in self-confidence, social relations, and increased isolation were commonly experienced by these patients. Progressive dysphagia was found to be independently associated with depression and impairment of general health. Addressing the symptom of dysphagia itself with counselling and speech therapy can lead to an improvement in QOL[7,47, 51].

2.2.4 Evaluation of dysphagia

Table 1 (see p 12) summarises the studies looking at the measurement of dysphagia as a primary symptom among patients. In an analytical review of dysphagia scales, Sallum and colleagues compared dysphagia scales used in the literature in order to find the most objective tool for evaluation and follow up of dysphagia and came up with some interesting findings[52]. They found that most scales do not meet the requirements to be classified as a complete tool in the evaluation of any dysphagia. Many were specific to a certain disease and the few which had global evaluation had no statistical consistency to strengthen their assessments. The heterogeneity of the population groups in these studies makes comparisons between them difficult but each tool has its pros and cons and their usefulness depends on a number of factors including the aim of use.

The Dysphagia Handicap Index differentiates between patients with dysphagia and individuals without dysphagia with high reliability and validity. It was found to be sensitive to differences in scores based on severity of dysphagia and to be suitable for use in individuals with lower literacy levels[53]. When dysphagia and associated symptoms are compared to manometric findings using a weighted priority symptom score,

they are not always predictive of diagnosis. This emphasises the importance of subjective symptom evaluation over manometry in patients with dysphagia[54]. When symptom severity and frequency is added for dysphagia and associated symptoms, the resultant scores are useful in monitoring symptoms before and after surgery[55].

The Dysphagia Outcome and severity scale rates the functional severity of dysphagia based on objective assessment. While the scale showed good inter-rater agreement it was found to be limited due to the possibility of interpretation bias, making it a poor tool for follow up assessment[56]. The clinical dysphagia scale which is a dysphagia rating scale that can be used at the bedside to quantify the severity of dysphagia and predict the risk of aspiration in patients suffering from dysphagia relies on information from the clinician rather than the patient but shows excellent inter-rater agreement and proved to be a useful tool for the reliable detection of dysphagia[57]. Finally, using the frequency and severity of dysphagia alone as an assessment tool has been shown to correlate well with more generic QOL tools like the SF-36[58].

Table 1: Studies assessing the measurement of dysphagia

Year	Name of dysphagia scale	Author	Condition	Strengths	Weaknesses
2012	DHI	Silbergleit[53]	Variety	Covers both high and low dysphagia. Applicable to patients with lower literacy level	Only patients with mild to moderate dysphagia
2012	WPSS	Tsuboi[54]	Oesophageal motility disorders	Demonstrated association between symptoms and manometric findings. Brevity	Affected by limitations of manometry. Biased to patients reporting 3 or more symptoms
2011	CDS	Chun[57]	Variety	Good statistical concordance	Only applicable in high dysphagia
1999	DOSS	O' Neil[56]	Variety	Good statistical concordance	Interpretation bias because of subjectivity
2001	MDADI	Chen[34]	Head and neck cancer	Validated. Proven reliability	Limited to head and neck cancer
2002	SWAL-QOL	McHorney[88]	High dysphagia	Validated. Proven reliability	Results obtained as multiple scales. Long questionnaire
2007	DS	Youssef[58]	achalasia	Good practical application	Lacks comprehensiveness

DHI – Dysphagia Handicap Index   WPSS – Weighted Priority Symptom Score   CDS – Clinical Dysphagia scale

DOSS – Dysphagia Outcome and Severity Scale   FOIS – Functional Oral Intake Scale   ASDS – Acute Stroke Dysphagia Screen

SWAL-QOL – Swallow QOL   DS – Dysphagia Score

These studies highlight the lack of tools to evaluate dysphagia in a holistic manner. There are several assessment tools to analyse the symptom, but most of them are specific to a single disease[53]. There is still a need for more validated dysphagia-specific QOL tools.

2.3 Quality of life

The concept of QOL is not new and dates back in its origins to classical Greece. The subject was addressed by Aristotle in lectures given at the Lyceum in Athens and subsequently edited by his son as 'Nicomachean Ethics', in which is introduced the concept of 'eudaimonia' or well-being/happiness[59].

2.3.1 QOL measurement

QOL is usually measured by administering structured questionnaires which consist of a number of items that tap into different dimensions of QOL. The answers are given a score which makes it possible to obtain quantitative data from qualitative information. There are a number of modes of administration including self-administration, interviewer-administered and surrogate responder. Each of these modes has strengths and weaknesses. For example, self-administered questionnaires allow the respondent to divulge personal sensitive information more readily and use minimal resources but come with a greater likelihood of poor response rates and missing data. Interviewer-administered questionnaires on the other hand maximises response rates but may reduce willingness by the patient to divulge sensitive information. The mode of administration chosen should take into account the information required in a clinical setting and the aims of the study in a research setting[25, 40].

2.3.2 Properties of a good QOL instrument

Key properties of a good QOL instrument are validity, reliability and responsiveness. Validity examines whether an instrument measures what it intends to measure. Reliability implies that the instrument will produce consistent results after repeated administration and responsiveness is the ability to detect any changes in QOL resulting from disease or treatment[25, 60, 61]. The structure of the questionnaire is an important consideration. The question 'How is your quality of life' would yield limited information. A number of questions need to be asked in order to create a number of

domains. A domain refers to the area of behaviour or experience that we are trying to measure. The importance of each item in relation to the others also needs to be taken into account[25].

2.3.3 The importance of QOL measurement

The analysis of the influence of a chronic disease on different dimensions of QOL might help to identify effective treatments to improve the physical and psychological state of a patient[62]. Combining generic and disease or symptom specific questionnaires may avoid missing unexpected outcomes and ensure recognition of all clinically important changes[63]. Generic HRQOL instruments are designed to be applicable across all diseases or conditions, across different medical interventions and across a wide range of populations. In contrast, specific or targeted HRQOL measures are designed to be relevant to a particular condition or state[28].

There are many ways in which measurement of QOL can help improve patient care and outcomes, namely:[64]

- Improving efficacy assessment of different treatment modalities

- Indicating a need for supportive interventions

- As a prognostic indicator

- Aiding decision-making

- Informing resource allocation and healthcare policy

Improving the efficacy assessment of different treatment modalities is of particular importance in situations where the only treatment available to the patient is palliative, as in cases of advanced malignancy. Supportive interventions are important considerations when taking side-effects of different treatment regimens into account and this information can often only be obtained from the patient. QOL is well known as a prognostic indicator and input from patients about effects of different treatment options can aide in decision making. Resource allocation and health-care policies are largely dependent on QOL assessments in many countries. The prognostic significance of QOL is well established[44, 65]. For example, patient-reported outcomes (PRO's) have been shown to be better predictors of survival than computer tomography scans in patients with metastatic colorectal cancer. QOL can therefore possibly be used as a surrogate marker for improved survival in clinical trials. Patient-reported outcome assessment is gaining increasing importance in both clinical and trial settings.

2.4 Patient-reported outcomes

Patient-reported outcomes (PRO's) are assessment tools which in essence reflect how medical or surgical treatment, irrespective of the approach, can alter appreciably the quality of life of patients who seek treatment for relief of symptoms caused by specific disorders. Patients' satisfaction with the treatment depends largely on relief or significant improvement in their symptoms, but it is also influenced by their experience and the quality of the entire process of treatment. PRO's include a cluster of variables: HRQOL, symptoms, physical functioning, psychological well-being, treatment satisfaction, and treatment preferences[59]. The inclusion of these variables in the assessment of patients results in a more comprehensive and global assessment of patient care. Scientific evidence for the reliability of PROs was first reported in the 1970s with pain reporting and continued with studies that showed that patient-reported versions of performance status and symptom distress were prognostic for survival. The importance of assessing PRO's is reported in a number of publications[66-69]. Several authors illustrated the different points of view of clinicians and patients in rating the relative importance of different outcome measures. Suggestions from symptom research indicate that clinicians report fewer symptoms of lower severity than patients and that patient self-reporting could improve management of symptoms by notifying the clinician about objective symptoms, and alerting clinicians to patients' perceptions of the severity of more subjective symptoms (which might differ from their own perceptions)[67,68].

2.4.1 The importance of PRO's

Today measures of symptoms, health-related quality of life (HRQOL) and patient satisfaction are considered to be important and appropriate endpoints of outcome. Both physiological and patient-reported outcomes are important; the physiological measures reflect the system used by the professionals to obtain information that helps establish the efficacy of the intervention, thus confirming their clinical impression. The patient-reported measures reflect the subjective evaluation and reporting of the illness experiences and its treatment. The three most important aspects of PRO to consider are symptoms, HRQOL and patient satisfaction[70].

Patients usually consult their doctors because they experience one or more symptoms that signify an unpleasant and unwelcome change in their body. If after treatment the symptoms are

abolished or become less severe, the treatment was successful from the patients' perspective. Symptoms can be specific, like heartburn in GERD or rectal bleeding in patients with rectal cancer. Some symptoms, for example pain, are not specific and occur in almost every disease. Symptoms can be assessed separately or as part of a QOL questionnaire[70].

Doctors often assess results of treatment by objective measures like morbidity, survival and results of laboratory and radiological tests. Yet there may be a discrepancy between these objective measures and the functioning and feelings of the patients. These subjective measures can be documented by quality of life scales[70]. Many postsurgical patients, despite normal investigations and laboratory results, experience an extremely impaired quality of life[71]. This highlights the importance of PRO's relative to objective clinical variables.

Patient satisfaction is the patient's own perception of both the quality of treatment provided and its effectiveness, embodied in the ''patient experiences''. A measure of satisfaction documents patients' assessments or affective responses to different dimensions of the treatment experience. Such a measure gives information about the relationship between patient expectations and the treatment experience, and it can incorporate different aspects such as: (a) description of health care from the patient's viewpoint; (b) measurement of the process of care; and (c) evaluation of its outcome[66-70].

2.4.2 Conceptual framework

Different conceptual frameworks for understanding patient satisfaction have been proposed, and used as the basis for the development of measures. The patients' life experiences, education, and personal characteristics influence their expectations before treatment as well as satisfaction during and after the treatment. Individual expectations and satisfaction with the components of treatment are also independent predictors of overall satisfaction[70]. As an example, Holzer *et al.* evaluated the relationship between the preoperative expectations in patients with colorectal cancer and their age, gender, and socioeconomic status. These authors learned that while, as expected, complete cure of the disease was the prime expectation of the vast majority of patients; age, gender, and education had a significant influence on patient expectations[72]. Pettersen *et al.* developed and validated the patient experiences questionnaire**,** a self-report instrument that has ten rating scales including information on complaints, nursing services, communication, information examinations, contact with next-of-kin, doctor services, hospital and equipment,

information on medication, organization, and general satisfaction. They tested it on patients discharged from surgical and medical wards. The authors concluded that because there is no standard method or ultimate instrument for measuring patient experiences, there is a need to develop new questionnaires and scrutinise existing ones. The choice of instrument chosen would depend on not only on psychometric properties, but also on the health care system, the purpose of the study and in what setting it is carried out[73].

2.4.3 When obtaining PRO is not possible

There are situations in which it might not be possible to obtain the desired information from PRO's. Problems with self-report may arise when patients have insufficient cognitive or communication abilities, when they experience severe symptom distress, or when they find an interview to be physically or emotionally too taxing. Under these circumstances it may be feasible to obtain QOL information from their significant others or health care providers. These surrogate providers, or proxies, should be able to provide reliable and useful data on a range of HRQL domains, including patients' physical and psychosocial functioning, and a variety of physical and mental symptoms[74]. There is usually moderate agreement between individual patients and their proxies, although lower levels of agreement may be reported for psychosocial functioning. While a number of factors affect the degree of agreement between patients and proxies, significantly important determinants of agreement between ratings of a proxy and a patient have yet to be identified[68-70]. The ideal tool to obtain information about a patient's QOL from a surrogate provider does not exist and still needs to be developed. Whether this will be at all possible remains to be seen and further research is needed on the topic.

The increasing importance of PRO's, both in research and clinical application, cannot be denied. It has been shown that patients can understand and report the severity of their symptoms and those patient-reported versions of performance status and symptom distress are prognostic for survival[45, 75]. Physicians tend to underestimate the importance of subtle symptom-related problems[75]. Patient reporting is reliable in documenting the severity of specific disease-related patient symptoms, typically by the use of a linear analogue scale. Issues that still need to be addressed include thorough calibration of PROs for symptom monitoring and verification of the psychometric properties of these assessments. Information provided by patients on their condition and satisfaction with treatment is a key component of clinical care. The challenge is to

find efficient, sensitive, specific, practical, and understandable assessments to calibrate and interpret this information[66].

2.5 QOL instruments and dysphagia

There are a large number of QOL instruments available in the literature. While many are used in clinical trials, there use in clinical practice has not been established. This is despite the recognition that clinical and physiological assessments do not always provide a complete picture of the impact of disease on the well-being of the patient and that QOL assessments need to be integrated into overall patient assessment[76]. Not all instruments are fully validated and there may be circumstances in which specific tools are inappropriate for use in different population groups, despite these population groups sharing the same or similar disease processes. Choosing the correct instrument can therefore be a complicated process.

2.5.1 Classification

The different types of QOL instruments are listed below[25]. Both generic and disease-specific measures can be used to evaluate health-related quality of life. Generic instruments have the advantage of allowing comparisons among different diagnostic groups or to healthy populations. However, generic instruments may not tap particular domains relevant to the disease of interest and thus may not be sensitive enough to monitor health-related quality of life for a specific patient population76.

Generic instruments

- Health profiles
- Preference based measurements

Specific instruments

- Disease-specific (e.g. Achalasia)
- Population-specific (e.g. Africans, Elderly)
- Function-specific (e.g. sexual functioning)
- Symptom-specific (e.g. pain, dysphagia)

2.5.2 Medical Outcomes Study 36-item Short form health survey (SF-36)

The SF-36 is a widely used health status questionnaire comprised of 36 items selected from a larger pool of items in the medical outcomes study (MOS)[28]. The SF-36 health survey items were selected to maximise their associations with the long-form MOS scales from which they were derived. It is a shortened version of 149 validated health-related questions originally reported as part of a medical outcomes study. In order to maintain comprehensiveness the Sf-36 was shortened by representing health concepts most frequently included in widely used health surveys[77].

The SF-36 health survey looks into eight health concepts encompassing physical and mental aspects of QOL. Factor analyses of the SF-36 health survey provide strong support for a 2-factor model of health, with physical health reflected primarily by measures of physical functioning, pain and role limitations due to physical health problems, and mental health reflected primarily by measures of emotional well-being and role limitations caused by emotional problems[78].

The SF-36 is useful for assessing health in a global manner; for example, the SF-36 has been used around the world to assess QOL in patients with a variety of different chronic disease[79]. However, the SF-36 is often not sensitive enough to detect small differences in specific treatment groups with unique health care disabilities. Specific health-care instruments are tailored to detect these small differences in QOL when treatment groups are more homogeneous. These questionnaires are specific to a type of disease, population, domain, or symptom[27].

The experience to date with the SF-36 has been documented in more than 1000 publications. It has been validated in the literature and has been widely adopted because of its brevity and its comprehensiveness. The content validity of the SF-36 has been compared with that of other widely used generic health surveys and comparisons indicate that the SF-36 includes eight of the most frequently measured health concepts[80].

The SF-36 has been utilised for four distinct goals, namely

- To assess the effect of a condition on QOL
- To assess treatment outcome
- To compare the effect of treatment options for a given condition
- To compare the effect of a procedure against other unrelated procedures

Because of its widespread use, many other questionnaires are validated by examining its concordance with the SF-36[34, 76, 82-85].

The SF-36 and dysphagia

A number of studies used the SF-36 to assess QOL in patients suffering from conditions causing dysphagia. Some of these are listed below in Table 2:

Table 2: Studies using SF-36 to assess QOL in dysphagic patients

Year	Author	Condition	Additional questionnaires	Other information
2001	Dallal[86]	Oesophageal cancer	EORTC QLQ30, EORTC OES24	Thermal ablation vs. SEMS
2001	Chen[34]	Head and neck cancer	MDADI	Dysphagia in H&N cancer
2004	Mineo[87]	Achalasia		Long term outcome of Heller myotomy
2007	Youssef[58]	Achalasia	Dysphagia score	QOL after Heller myotomy

These studies showed that the SF-36 is an appropriate tool in the measurement of QOL in dysphagic patients. It may be used to validate newly developed instruments and has shown good responsiveness when assessing QOL in these patients. There is good correlation between SF-36 scores and severity of dysphagia in patients[34, 58, 86, 87].

The SF-36 questionnaire is therefore an appropriate tool to assess QOL in patients suffering from dysphagia.

2.5.3 Dysphagia score

There are a number of dysphagia scores available in the literature[2, 34, 88]. Some assess severity and/or frequency of dysphagia while others assess the degree of dysphagia in relation to food types.

Richards and colleagues used the Dysphagia score which adds severity and frequency of the symptom as part of an assessment comparing Heller myotomy with and without fundoplication for Achalasia[89]. It was subsequently used by other authors to assess success of surgery for

Achalasia[58, 90]. Achalasia is a motility disorder of the oesophagus. The pathophysiology is not fully understood but involves the selective loss of inhibitory neurons in the myenteric plexus, leading to the production of vasoactive intestinal polypeptide, nitric oxide, and inflammatory infiltrate responsible for lower oesophageal sphincter (LES) dysfunction. An unopposed excitation of the sphincter causes its dysfunction or failure to relax in response to swallowing[91]. Since dysphagia is the cardinal symptom of achalasia, the improvement of dysphagia will result in improvement of QOL. The score itself can then also be used to assess QOL in patients with dysphagia secondary to other conditions. While it is short and simple it is inadequate in assessing QOL as it only asks questions regarding the severity and frequency of dysphagia.

2.6 Studies assessing QOL

A number of factors can affect QOL, particularly HRQOL. Chronic disease and its treatment, whether pharmacological or surgical, influence the physical and psychological health of a patient[62]. Similarly, specific symptoms can impact on QOL. The impact of dysphagia on QOL has been assessed using generic, disease-specific and symptom specific QOL measures. The effects of different treatment strategies have been assessed in specific conditions as well as in a variety of conditions causing dysphagia[34, 52, 58, 88].

2.6.1 Assessment of dysphagia and its treatment in patients with cancer of the oesophagus

Dysphagia is the predominant symptom in the vast majority of patients with cancer of the oesophagus. Most patients diagnosed with oesophageal cancer are either not fit for curative surgery or are diagnosed at an advanced stage of disease, making palliative management the only option. The palliation of dysphagia has been practised for more than a century. Early attempts at palliative treatment of malignant dysphagia were met with constant failure. In 1959, Celestin described the palliation of malignant dysphagia using a plastic endoprosthesis introduced at laparotomy[92]. This form of treatment worked well and became popular over the next few decades. Endoscopic introduction of plastic stents was introduced in the 1970's eliminating the morbidity associated with laparotomy, but it was the introduction of self-expanding metal stents in the 1980's that revolutionised the palliation of malignant dysphagia. There are a number of options available for palliation of malignant dysphagia, e.g. Intraluminal brachytherapy, laser therapy and photodynamic therapy. While systemic reviews have shown no difference in the efficacy of the different options, oesophageal stenting with self-expanding metal stents remain

the most commonly used intervention. The single biggest advantage over other means of palliative treatment of malignant dysphagia is that stenting provides immediate relief of symptoms that lasts longer than that obtained after dilation alone[93-95].

A number of studies assessed quality of life in patients undergoing palliative treatment for oesophageal cancer. The instruments used in these studies ranged from generic to specific. The specific instruments are further divided into those that are cancer specific and those that are specific to oesophageal cancer[96].

2.6.2 Disease-specific QOL assessments

When it comes to disease-specific QOL instruments related to dysphagia, Achalasia and Gastro-oesophageal reflux disease (GORD) received the most attention. Achalasia is a motility disorder of the oesophagus due to loss of ganglion cells resulting in incomplete relaxation of the lower oesophageal sphincter on swallowing and lack of peristalsis. Dysphagia is the cardinal symptom. There are a number of treatment options available. None are curative and therefore QOL assessment is an integral part of the management of these patients. GORD is a disease caused by reflux of gastric content into the oesophagus resulting in a variety of symptoms including heartburn and dysphagia.

Several authors set out to develop and validate Achalasia-specific or GORD-specific QOL questionnaires and achieved variable success. Some of these involved translation of existing questionnaires but this only applied to European languages. Most of these questionnaires were tested for correlation with generic health measures like the SF-36[63, 84, 85, 97].

2.6.3 Symptom-specific QOL assessments

Chen and colleagues were the first group to develop a self-administered questionnaire designed specifically for evaluating the impact of dysphagia on QOL of patients with head and neck cancer. They started by forming focus groups consisting of Doctors and a speech pathologist. Patients with head and neck cancer were later added to the focus group and a questionnaire was developed. The questionnaire, which was called the M. D. Anderson Dysphagia inventory, was administered to one hundred patients together with the SF-36. The questionnaire was evaluated for reliability and validity. They also concluded that disease-specific instruments assessing QOL are more responsive to changes in patient status over time than their generic counterparts[34].

The SWAL-QOL quality of life and quality of care outcomes tools were developed and validated by McHorney and colleagues. The original questionnaire contained 93 items and was too long for practical use, so they reduced it into 2 patient-centred outcomes tools: (1) the SWAL-QOL, a 44-item tool that assesses ten quality of life concepts, and (2) the SWAL-CARE, a 15-item tool that assesses quality of care and patient satisfaction. They found that 33% of their dysphagia patients met clinical criteria for major depression[88]. This implies that it is an under detected problem in patients with dysphagia and underscores the importance of assessing mental health and QOL in patients with dysphagia.

Silberglite and colleagues set out to develop a develop a clinically efficient patient-reported outcomes tool that measures the handicapping effect of dysphagia on emotional, functional, and physical aspects of individual's lives. They compiled a series of dysphagia complaints made by patients during a one month period. The result was a 25-item test consisting of three scales; physical, emotional and functional. While most of the patients who participated reported mild or moderate dysphagia and few reported severe symptoms, they found that dysphagia had a significant impact on QOL[53].

2.7 Adaptation and translation of QOL questionnaires

Assessing QOL of patients in South Africa is a challenging concept. South Africa is a country with diverse cultures and languages. Often there is a distinct difference between the patient population and health care givers in terms of economics and cultural issues. Language barrier is a common problem in clinical practice[98]. Comparing self-reported quality of life issues across different population groups is a practice fraught with problems since HRQOL is a complex function of socioeconomic variables including education, household income and cultural conceptions of health[99].

Mullin *et al.* investigated the feasibility of translating a QOL instrument into three South African languages (Pedi, Tswana and Zulu). They translated the Functional Assessment of Cancer Therapy (FACT) questionnaire into the three languages and then administered them to patients. They found the challenges of considering social and cultural contexts in translations to be significant. They found their results to be encouraging and suggested further research in translating international questionnaires into African languages[98].

Jelsma *et al.* examined the reliability and validity of a Xhosa version of the EQ-5D which is a generic HRQOL measure that has been used as an outcome measure for a wide-variety of conditions, including cancer. They faced the same challenges as we did, including the lack of a gold standard but nevertheless reported reasonable validity and reliability of the instrument. Like the GREYS DQOL, the EQ-5D also used the VAS and this was a useful feature, especially for patients with lower literacy levels[100]. They used the same questionnaire to examine the determinants of self-reported HRQOL in a culturally and socially diverse South African community in the Western Cape. They concluded that the VAS is a valid measure of HRQOL across population groups but that individuals with lower socioeconomic status reported a worse HRQOL than their health state alone warranted[99]

Nyirenda *et al.* translated three instruments, namely the W.H.O. Disability Assessment Schedule (WHODAS), W.H.O. QOL score (WHOQOL) and Health State Score (HSS) adapted from the World Health Organization Study on global ageing and adult health from English to Zulu in an attempt to examine health and well-being of HIV infected patients. They back-translated the questionnaires before administering them and found that useful information on QOL could be obtained from these adapted questionnaires. They also found gender, education level and socioeconomic status to be strongly associated with HRQOL[101].

The table below summarises studies which recently translated international questionnaire to South African languages.

Table 3: International questionnaires translated in South Africa

Year	Author	Instruments	Pathology	Languages	Other findings
2000	Mullin[98]	FACT –G FACT –B	Cancers	Pedi Tswana Zulu	Difficulty with translating emotional problems and social well-being
2004	Jelsma[100]	EQ-5D	Variety	Xhosa	Need for more rigorous translation and validity testing of outcome measures in South Africa
2012	Nyirenda[101]	WHODAS WHOQOL HSS	HIV	Zulu	Female gender and increasing age associated with poorer QOL

FACT –G – Functional Assessment of Cancer Therapy – General   FACT –B – Functional Assessment of Cancer Therapy – Breast

EQ-5D – European Quality of life 5 Dimensions questionnaire   WHODAS – World Health Organization Disability Assessment Schedule

WHOQOL – World Health Organization Quality of Life instrument   HSS – Health State Score

These studies demonstrated the successful adaptation of tools developed in the first world to third world countries. They highlight the differences in perception of HRQOL among different socioeconomic and cultural communities. It should be kept in mind that the cross-cultural validation process is a complex one and that the need for this process could be considered an inherent weakness in QOL research in South Africa. The comparison and interpretation of QOL instruments across different countries is inconsistent making careful selection of the appropriate instrument a key aspect of QOL research[102, 103]. Finally, there is a need for more QOL instruments to be translated and tested for validity and reliability in South Africa.

2.8 Conclusion

Clinicians are recognizing the importance of measuring HRQOL in the holistic management of patients. Evidence supporting the importance of QOL as an assessment tool and treatment outcome is mounting. There is a dearth of literature regarding HRQOL from South Africa and Africa and no tool exists to measure HRQOL related to dysphagia in the South African context. There is therefore a need for such a tool to be developed.

Chapter 3: Study Aims

The aim of this study was to develop a symptom-specific quality of life questionnaire for dysphagia that is relevant to our local population. The questionnaire should have the following properties:

- It should be easy and simple to complete.
- It should adequately assess the quality of life of our patients.
- It should be possible to assess the impact of different treatment options on the quality of life of patients.
- The questions should highlight issues that are important to our patients.
- The questions should be easily understood and not contain terms which are foreign to our patient population.
- It should be possible to use the questionnaire with patients without formal education.

The first hypothesis to be tested is that the results of the newly developed questionnaire, which will be known as the Greys Dysphagia Quality Of Life (GREYS DQOL) questionnaire, correlate well with existing tools.

The specific objective is to determine the cut off points in the South African questionnaire scores that optimise sensitivity and specificity of predicting poor quality of life according to the gold standard. The gold standard in this case will be two other questionnaires, namely;

- The Short-Form 36 (SF-36) survey which is a validated generic QOL questionnaire.
- The dysphagia score which is an internationally used dysphagia scale.

The second hypothesis is that patients are more likely to complete the South African questionnaire than the international ones because they understand the questions better.

The result of achieving these goals would be a symptom-specific QOL tool for dysphagia that addresses the short-comings of similar tools available today. These shortcomings include:

- Questions that lack relevance to our local population.
- Lack of ability to assess overall QOL in patients with dysphagia comprehensively.
- Questions that are difficult to understand by patients with low education levels.

Once validated, the newly developed Greys questionnaire can then be used to assess the impact of dysphagia as well as the impact of different treatment options on the quality of life of our patients.

The final product would be a comprehensive QOL tool for dysphagia relevant to our local population that could be used to assess QOL at initial presentation as well as changes in QOL after treatment.

Chapter 4: Methods

Quality of life measures have become an important part of health outcomes appraisal, particularly in population groups suffering from incurable conditions. The majority of QOL instruments constructed to date have been developed and validated in a first-world setting, make cross-cultural comparisons difficult.

In order to develop a symptom-specific questionnaire that assessed quality of life (QOL) in our patients we had to overcome a number of difficulties. The first difficulty was defining what we were trying to measure. Health-related QOL (HRQOL) is a qualitative variable which is broad with multiple facets and giving it a quantitative value is challenging in itself. There are a number of definitions of QOL in the literature encompassing a wide variety of aspects of life other than health, including politics, economics and religion. The World Health Organization (W.H.O) definition of QOL states that it is '*the individuals' perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards and concerns*'[37]. This definition emphasises the subjective nature of this entity. It is a multidimensional concept necessitating the assessment of a number of domains to derive a comprehensive view of a person's QOL. Positive as well as negative aspects of life need to be included QOL assessments. The broad appeal of the definition of QOL results in richness of interpretation, but simultaneously makes it difficult to use in a scientific setting [43, 104, 105]. In this study we measured health-related QOL (HRQOL) which pertains to the effect of illness and treatment on QOL.

Another difficulty we faced when formulating this study was the issue of validation. Validation is considered a key psychometric property of any QOL instrument. It examines whether a questionnaire is measuring what it intends to measure. Validation is the process by which any data collection instrument, including questionnaires, is assessed for its dependability. Validating questionnaires is somewhat challenging as they usually evaluate subjective measures, which means they can be influenced by a range of factors that are hard to control. It is an indication of the degree to which a questionnaire reflects reality[27]. In this study we are faced with the challenge of validating a questionnaire where no gold standard exists. This is because the questions are

relevant to our local population and regards QOL aspects related to dysphagia. No such questionnaire exists.

We chose two existing questionnaire to be administered in concordance with our questionnaire, namely the short-form 36 (SF-36) and the Dysphagia Score. The SF-36 was chosen because it is a generic QOL questionnaire which is well validated and widely used. Translated versions were validated before for use in South Africa[106]

The dysphagia score is symptom-specific to dysphagia, like the proposed questionnaire. It explores two aspects of dysphagia namely the frequency and severity. An overall score is then given to the patient. The biggest advantage of the Dysphagia Score is its brevity. It fails, however, to give a comprehensive assessment of QOL.

The questions formulated would then incorporate similar questions to those used in the existing ones in order to compare the responses of the patients to the different questionnaires.

4.1 Formulating the questions for the new questionnaire

The formulation of questions for use in a questionnaire is a complex process which is largely a matter of subjective judgement. The description of a given life domain becomes so much more rigid when expressed through a specific question that the result is a loss of richness of interpretation[104]. Methods used to generate items for complex measurement scales like QOL questionnaires are heterogeneous and there is a lack of guidelines in the literature on how it should be done[107].

A questionnaire was compiled consisting of 25 questions which the patients would answer using a visual analogue scale. The questions were compiled by the main author and supervisor who together had substantial experience in assessing and managing patients in the same population group with dysphagia and therefore were aware of the main problems these patients had. The questions assessed the following;

    a) The symptom of dysphagia,
    b) Other symptoms related to conditions that commonly causes dysphagia, e.g. odynophagia, heartburn, regurgitation, and
    c) The general quality of life of the patient.

The first eight questions are as follows:

1) How often do you experience difficulty with swallowing liquids?

2) How often do you experience difficulty with swallowing soft foods?

3) How often do you experience difficulty with swallowing raw hard fruits?

4) How often do you experience difficulty with swallowing meat?

5) How bad is your difficulty in swallowing when swallowing liquids?

6) How bad is your difficulty in swallowing when swallowing soft foods?

7) How bad is your difficulty in swallowing when swallowing raw hard fruit?

8) How bad is your difficulty in swallowing when swallowing meat?

These questions assess the symptom of dysphagia in detail. Like the dysphagia score to which it is being compared it explores the frequency and severity of dysphagia. Unlike the dysphagia score, it discriminates between the different food groups starting with frequency and severity to swallowing liquids, then moving on to soft foods and hard foods and finally asking about meat. There are a number of reasons for this discrimination. Firstly, it gives an indication of the degree of dysphagia the patient suffers. A patient who has trouble with swallowing liquids as well as solids is much worse off than someone who can swallow liquids but struggles with solid food. This in turn will translate into a poorer quality of life. Some patients are able to adjust their diet according to their ability to swallow. They may therefore not experience any deficiency in QOL, whereas they still have a problem with swallowing certain foods. Many patients are heavily reliant on soft foods which form a large part of their staple diet. They will then show a poorer score when specifically asked about their ability to swallow soft foods, giving us a better idea of the impact on quality of life. For other patients the inability or difficulty in swallowing meat severely affects their QOL. These differences will be ascertained when administering these questions to the diverse cultural groups we serve.

These eight questions were compiled using the dysphagia score as a guide and answers to them may be compared directly to answers to the dysphagia score

The following eight questions are:

9) How often do you experience pain when swallowing liquids?

10) How often do you experience pain when swallowing soft foods?

11) How often do you experience pain when swallowing raw hard fruits?

12) How often do you experience pain when swallowing meat?

13) How bad is your pain on swallowing when swallowing liquids?

14) How bad is your pain on swallowing when swallowing soft foods?

15) How bad is your pain on swallowing when swallowing raw hard fruit?

16) How bad is your pain on swallowing when swallowing meat?

They explore the symptom of odynophagia in as much detail as dysphagia is being explored. The reason for this is two-fold. Firstly, odynophagia which means painful swallowing is related to many conditions which commonly cause dysphagia and will have an obvious impact on QOL. Secondly, many patients are unable to discriminate between dysphagia and odynophagia. They may be experiencing dysphagia but perceive it as odynophagia. This will not be picked up if these questions are not asked. These questions were not guided by either of the existing questionnaires.

The next six questions are:

17) How often do you get chest pain after eating?

18) How severe is your chest pain after eating?

19) How often do you experience heartburn?

20) How severe is your heartburn?

21) How often do you experience regurgitation (food returning to your mouth after swallowing)?

22) How much weight have you lost since being ill?

These questions ask about other symptoms that may occur in patients with conditions that cause dysphagia, viz. heartburn, regurgitation, chest pain and weight loss. They are explored because these symptoms will also affect QOL and sometimes the impact may be worse than that of

dysphagia. Omitting them may result in missing important factors affecting the QOL of these patients. Weight loss is a factor that affects general QOL since it is a distressing symptom to many of our patients. Like the previous eight questions, these were not guided by either of the existing questions.

The next two questions are:

23) How much has your illness affected your social life?
24) How much has your illness limited your work?

They explore the limitation to social activity and work. These questions are commonly asked in HRQOL questionnaires world-wide[63, 77, 80, 82, 88, 108]. These aspects of patients' lives are often ignored by physicians during clinical assessments and their inclusion in the questionnaires will provide better understanding of the impact of the symptom or disease process on QOL.

The last question is:

25) How satisfied are you with your current state of health?

This is a general question regarding the patient's perspective on his or her satisfaction with their current state of health. This is important to ask since the information obtained may yield surprising results. For example, a patient presenting with dysphagia secondary to cancer of the oesophagus may undergo extensive oncological treatment including chemotherapy and radiotherapy. This treatment may be palliative rather than curative and the patient may report a lower satisfaction with their current health following treatment than they did before treatment. This may occur despite a significant oncological response of the tumour to the treatment. This could help us review the treatment in other patients with the same condition.

The last three questions were guided by the SF-36 and answers to them can therefore be compared directly to answers to the SF-36. Definitions of all terms used in the questionnaire are given at the end of the questionnaire.

4.2 Use of the Visual Analogue Scale

The Visual Analogue Scale (VAS) uses horizontal lines, 10 cm long, representing a spectrum from very good to very poor. The respondents mark their response on the scale. As this type of scale does not contain a limited number of possible responses, the respondents are given greater freedom of expression than with other scales[104]. It is simple to use and easy to understand. It is commonly used in studies assessing pain and has been shown to have measurable value function[109].

It therefore seemed to be the best choice of scale to use with our patients since many may not have formal education and diversity in culture may result misunderstanding of possible answers if another scale such as the Lickert scale was used.

An example of the use of the VAS in the questionnaire is shown below;

25) How satisfied are you with your current state of health?

0 (completely satisfied)   10 (completely dissatisfied)

_____

The terms 'completely satisfied' and 'completely dissatisfied' are used as a guide on the VAS to assist the patient in answering the questions. This will ensure better uniformity when gathering data.

4.3 Questionnaire design

The length of the questionnaire was chosen to incorporate both comprehensiveness and brevity. We wanted to create a questionnaire that was as comprehensive as possible so as to get an understanding of the QOL of the respondent as best as we could. At the same time we wanted to avoid a long questionnaire which would prove taxing on patients who may already be frail from their disease process. Many of the questions are closely related e.g. the eight questions on dysphagia. This fact and the use of the V.A.S make it possible to complete the questionnaire in a few minutes.

The questionnaire was designed to be self-administered. However it is possible to complete the questionnaire with the help of a health care worker in the event that the patient needs help in understanding the questions. This situation would be rare since the questions were specifically designed to be simple and straightforward.

Patients were asked to mark a point on the V.A.S which was 10cm long. A mark out of ten could then be given for each question. The lower scores indicated a less severe symptom or better QOL while a higher score indicated increased severity of symptoms or poorer QOL. The score of all the questions can then be added up and the total out of a maximum of 250 can then be converted to a percentage. Thus, a higher Greys Dysphagia QOL score represented a poorer QOL.

4.4 Choice of international questionnaires

Two international questionnaires were chosen to test validate the GREYS DQOL questionnaire and compare the compliance of patients in answering questions from the different questionnaires.

4.4.1 Medical Outcomes Study 36-item Short form health survey (SF-36) (Appendix 5)

The Short Form 36 (SF-36) which is a well validated generic QOL questionnaire used commonly world-wide. The health concepts explored by the SF-36 are shown below [28].

- Physical functioning
- Role limitation due to physical problems
- Bodily pain
- General health perceptions
- Vitality
- Social functioning
- Role limitation due to emotional problems
- Mental health

The SF-36 was constructed to satisfy minimum psychometric standards necessary for group comparisons. The eight health concepts were selected from 40 concepts included in the Medical

Outcomes Study (MOS). Those chosen represent the most frequently measured concepts in widely used health surveys and those most affected by disease and treatment[77, 80]. The eight health concepts are summarised into two summary scales, viz. the physical component summary and the mental component summary scales. An overall score can then be given of which the minimum is 0 and the maximum is 100. The higher the SF-36 score, the better the QOL of the patient.

The biggest advantage of the SF-36 is that is strikes a good balance between comprehensiveness and brevity. Despite this advantage and the fact that it has been fully validated, there are a number of problems with using it as a tool to assess QOL in South Africa. It was developed in the first-world and many of the questions have either have no relevance to our patients or are poorly understood by them. An example is question 9 (see appendix 5) which states:

9. How much of the time during the past 4 weeks.

    a. Did you feel full of pep?

    b. Have you been a nervous person?

    c. Have you felt so down in the dumps nothing could cheer you up?

    d. Have you felt calm and peaceful?

    e. Did you have a lot of energy?

    f. Have you felt downhearted and blue?

    g. Did you feel worn out?

    h. Have you been a happy person?

    i. Did you feel tired?

Each of these questions has six possible answers as follows;

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

The respondent is required to tick a box next to the answer which they feel describes their feeling most accurately. Many of our patients would have difficulty in responding to these questions as they may not think about their mental state in these terms. They would not necessarily answer

these questions using terms like 'A good bit of the time'. This underscores the fact that HRQOL is influenced by culture and perception.

The SF-36 is designed to be self-administered by the patient. This is how it was administered to all literate respondents. For those who could not read, it was administered by an interviewer in the presence of the main investigator. The items and scales were constructed for scoring using the Likert method of summated ratings. The Likert scale is a psychometric response scale which attempts to assess a respondent's degree of agreement with a statement. It is a popular option for questionnaire because of ease of use. The major drawback of its use is the fact that the ideal number of response options is not well established and range from two options, usually 'yes' or ' no' to as many as nine. In the SF-36 there is inconsistency in the number of options available with some questions offering two and others six options. Furthermore, some questions require yes-no answers, while others assess degree of agreement with a statement and others still have a number of different answers. This may lead to confusion on the part of the respondents which is a weakness of the SF-36 in our setting. Analysis and interpretation of the resulting linear scales assumes that item scores are linearly related to the underlying health concept being measured[77, 80, 81].

4.4.2 The Dysphagia Score (Appendix 4)

The second international questionnaire used in this study is the Dysphagia Score which has not been validated but is used internationally specifically for patients with dysphagia[58, 89, 90]. The dysphagia score was used on patients suffering from dysphagia due to achalasia which is a motility disorder of the oesophagus which results in incomplete relaxation of the lower oesophageal sphincter during swallowing and aperistalsis of the oesophagus. It was shown to have good practical application[52, 58]. The first question asks about frequency of dysphagia and gives five options each with a score as seen below;

    0=never   1=<1d/week   2=1d/week   3=2-3d/week 4=4-6d/week 5=daily

The second question asks about the severity of dysphagia and also has five possible options as seen below;

    0=none   1=very mild   2=mild 3=moderate   4=mod. severe   5=severe

The respondent is required to tick whichever box closely reflects the frequency and severity of their symptom. A higher dysphagia score indicated increased severity of symptoms. This questionnaire fails to assess overall HRQOL as it only explores one symptom.

The GREYS DQOL score aims to be a HRQOL questionnaire which is symptom specific to dysphagia. It is for this reason the two international questionnaires were chosen as comparisons.

4.5 Demographic data

Demographic data, including age, sex and highest level of education obtained was collected.

4.6 Translation

Once the questions were compiled, the questionnaire, together with the SF-36 and the Dysphagia score questionnaire was sent to the language department at the University of Kwazulu Natal to be translated into Zulu. This is because Zulu and English are the 2 most common home languages in the province. Patients were given a choice to fill in either the original or the translated version.

4.7 Setting

The study was performed at Greys Hospital which is a tertiary hospital in KwaZulu-Natal. The hospital manages patients from the Pietermaritzburg metropolitan area as well as patients referred from surrounding district and regional hospitals and distant hospitals falling within the drainage area. These include hospitals serving largely rural based populations.

4.8 Sample

A minimum sample size for statistical significance was not possible to calculate at the beginning of the study since the expected differences were not known. Thus the sample size to be used was determined from logistical rather than statistical constraints. As this is a Masters degree study, a single year of data collection of approximately 100 patients would be sufficient to calculate initial statistical significance and power.

Patients presenting to our surgical department with dysphagia as their main complaint between May 2010 and April 2011 were entered into the study. The questionnaires were completed prior to treatment. The majority of patients presenting with dysphagia to our surgical department suffer from oesophageal cancer. Informed consent was obtained and an information document describing the details of the study was given to the patients. All patients were adults aged 18 years and older. The patients were asked to complete all three questionnaires. The V.A.S was explained to the patient and examples were given when needed. Similarly the method of answering the two international questionnaires was also explained to each patient. This was done by the main investigator with the help of an interpreter when needed. Patients were asked to answer all questions that they understood as truthfully as possible. The questionnaires were self-administered in English and Zulu. Patients who could not read had the questions read out to them by a nurse fluent in Zulu in the presence of the main investigator. This was only needed with Zulu-speaking patients. They were asked to indicate their answer on the VAS and asked to give their answers to the other questionnaires verbally to the person helping them. The option indicated by the patient was then ticked. This was also done by the main investigator with the help of an interpreter. Patients were allowed to ask clarification on any questions which they did not fully understand. If they still did not understand the explanation then they were told to skip the questions. Any questions that that were not understood or that the patient thought to have no relevance to their lives could be skipped. Different interpreters were used for different patients and none were trained in administering the questionnaire. The main investigator was therefore present at each administration. After completion, questionnaires were collected and filed.

4.9 Data collection

Once 100 questionnaires were completed the questionnaires were scored. The GREYS DQOL questionnaire was scored by measuring the point indicated on the VAS by the patient. The scores were added up and the final score given as a percentage. The SF-36 was scored using software obtained from the internet (www.nephrology.rei.edu/qol.htm). The same program was used to score SF-36 QOL in haemodialysis patients[110]. A physical component summary, mental component summary and overall final score out of 100 was obtained. The two components of the dysphagia score were added up to give a final score out of 10. The compliance of each patient in answering

the different questions was also measured. The level of education was divided into 3 groups and defined as follows:

1 - No formal education received

2 - Some formal education received but did not finish school to matriculation level

3 - Completed school to matriculation level

The final scores of each questionnaire were entered onto an Excel spread sheet and the data was analysed.

4.10 Data analysis

The scores of the patients, which indicated their symptom severity as well as their QOL were analysed. The scores of the three questionnaires were compared using Spearman correlation analysis. We used univariate and multivariate regression analysis to assess the relationship between age, gender, level of education and each of the three questionnaires.

We performed a chi squared to compare compliance of patients in answering the questions in the three questionnaires. We defined compliance by the number of questionnaires filled out completely. Thus, all questionnaires which were completed without the omission of a single question were counted against those which were incomplete. Compliance was looked at in order to assess whether patients were more likely to answer questions from the newly compiled questionnaire compared to the established questionnaires.

Box and whisker plots were used for descriptive statistical representation.

Chapter 5: Results

The aim of this research was to design and assess a new questionnaire which could be used in the South African context to assess the quality of life (QOL) experienced by patients experiencing dysphagia. The new questionnaire was based on questions from two others, one generic and one specific to dysphagia, which are used internationally. We added questions which were contextualised to give us more information about the patients in our setting. We exposed our sample to these two internationally recognised quality of life questionnaires as well as to the newly developed questionnaire which we developed. Patients had an option to complete the questionnaire in one of two languages, English or Zulu, which is the language most commonly spoken in KwaZulu-Natal.

In this chapter we provide basic demographic data of our sample, look at the compliance rates of questionnaire completion for the new and two internationally recognised questionnaires, and compare the results of the three tests in terms of the QOL score given by each patient. Each of these aspects of the data is dealt with separately below.

5.1 Questionnaire development

The newly developed questionnaire is named the Greys Dysphagia Quality Of life (GREYS DQOL) questionnaire. It consists of 25 questions exploring the symptom of dysphagia and its effects on QOL and includes questions which are both specific and general.

5.2 Demographics

5.2.1 Gender distribution

A total of 100 patients were entered into the study. There were 62 males and 38 females.

5.2.2 Age distribution

Two patients did not provide their age; the average age was worked out for n = 98 giving the mean age as 59 years (range 18-101, interquartile range 52-71). The box whisker plot below shows the age range to be wide with almost half the patients being in their 6th and 7th decade of life. Raw data is available in Appendix.
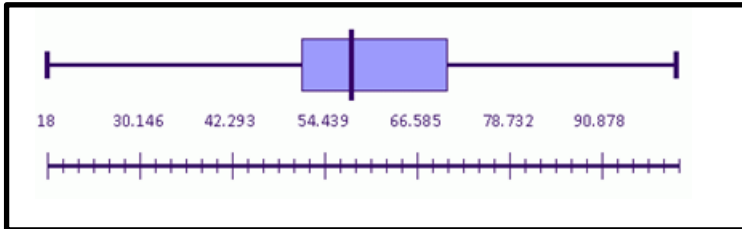
Figure 1: Box whisker plot for age of study population (n= 98)

5.2.3 Diagnosis

While the final diagnosis was not available for the majority of patients, it was known in 26 patients and of these 17 had malignant obstruction of the oesophagus.

5.2.4 Language preference

Half the respondents chose to answer the questionnaire in English while the other half opted to answer the questionnaire in Zulu.

5.3 Level of education

The level of education was obtained from 88 patients. Of the average grade completed at school was Grade 5 (five years of primary school education). Only three respondents received some form of tertiary education. Eleven patients completed school to matriculation level. Twenty three respondents received no formal schooling at all. Table 4 illustrates the level of education obtained by our patients as defined by the three levels described in Chapter 4.

Table 4: Level of education of sample population

Level of Education	Frequency	Percentage	Cumulative percentage
1 - no formal education	23	26	26
2 – Some formal education, did not complete school	54	61	87
3 – completed school to matriculation level	11	13	100
Total	88	100	

5.4 The QOL of our patients

Appendix 1 compares the results of the three questionnaires. The GREYS DQOL and the SF-36 are both scored out of 100 while the dysphagia score is scored out of 10. The mean score for patients on the GREYS DQOL questionnaire was 61 where a score of 0 indicates the best quality of life possible and a score of 100 indicates the worst quality of life possible. The mean score for patients on the SF 36 was 30, where 0 indicates the worst possible quality of life and 100 the best possible quality of life. The mean score for patients on the dysphagia score was 7, where 0 is the best score and 10 the worst. The results show a poor QOL for all three questionnaires with scores closer to the worst QOL than the best QOL.

5.5 Comparison of scores

The scores of the three questionnaires were compared. In order to compare the three instruments in the same direction, the SF-36 scores were inverted so that the highest score was worse than the lowest score. This was achieved by subtracting the score from 100 and using the difference. The DS score was multiplied by 10 so that all three scores could be compared as a total of 100. The box whisker plot below shows the three instruments.
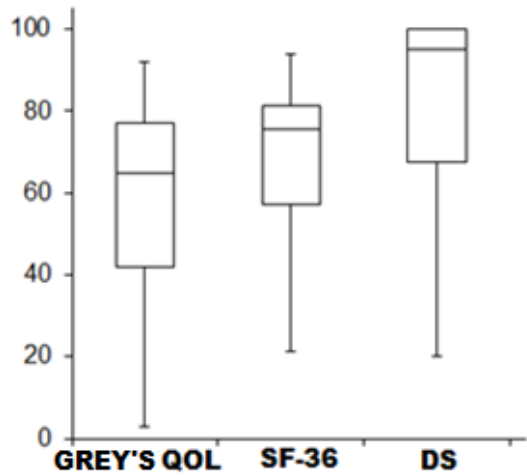
Figure 2: Comparison of scores from the three questionnaires

Table 5: Descriptive statistics for each questionnaire

Labels	GREYS DQOL	SF-36	DS
Min	3	1	0
Q_1	42	57.25	67.5
Median	65	75.5	95
Q_3	77	81.25	100
Max	100	86	100
IQR	35	24	32.5

While the quality of life scores for the patients were all closer to poorer quality of life than to the best possible quality of life for all three questionnaires, the GREYS DQOL questionnaire showed a wider variation in the scores.

5.6 Correlations

The newly compiled Greys Dysphagia Quality Of life (GREYS DQOL) questionnaire score correlated moderately with both the SF-36 and the Dysphagia Score. The results of the Spearman correlation are shown in the scatter plots below.
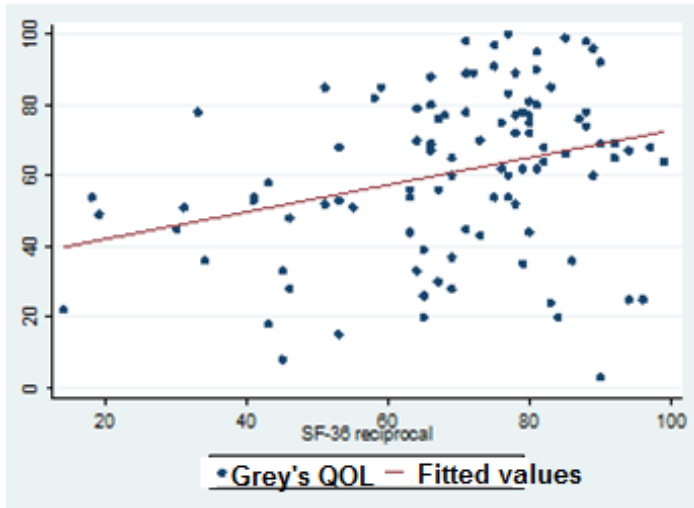
R = 0.29

Figure 3 : Scatter plot showing correlation between GREYS DQOL and SF-36 questionnaires
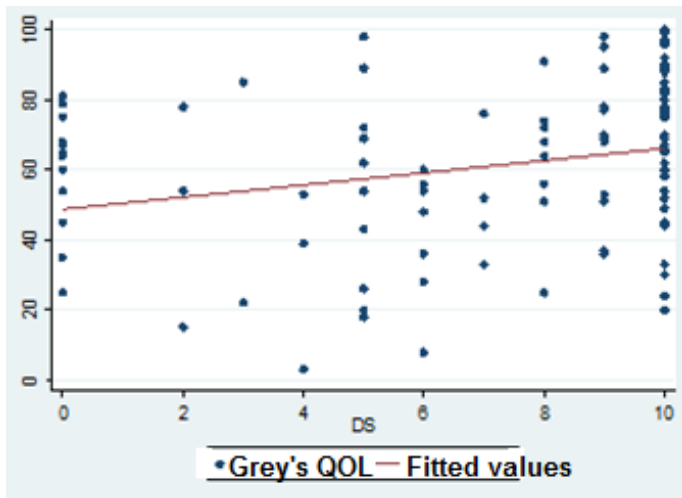
R = 0.30

Figure 4 : Scatter plot showing correlation between GREYS DQOL and Dysphagia score questionnaires

5.7 Compliance

Questions 1-8 of the GREYS DQOL questionnaire were designed to get the same information from the patient as that from the Dysphagia Score's two questions. Whilst there was no statistically significant difference between the completion rates of the two questionnaires (chi-square =1.008, p = 0.315) there are some differences in the way each questionnaire was answered. All patients attempted at least some of the GREYS DQOL questions while 13 patients did not answer either of the Dysphagia Score questions. Two patients answered under half of the GREYS DQOL questions in this section. Four patients left out one of the Dysphagia Score questions.

Questions 22 – 25 of the GREYS DQOL questionnaire were designed to get the same information as the SF-36 questionnaire. The GREYS DQOL had a better compliance for these questions than the SF-36 with 92% of the patients answering all the questions in the GREYS DQOL and only 57% of them answering the entire SF-36 questionnaire (Chi-square 32.4, p<0.01).

Both the GREYS DQOL and the SF-36 questionnaires are long questionnaires. Their relative length could affect the compliance. Comparing the compliance of the entire GREYS DQOL questionnaire with that of the entire SF-36 it is found that patients were more compliant with the GREYS DQOL questionnaire than the SF-36 (chi-square 4.253 p=0.039). When looking at the overall percentage of questions answered per questionnaire, however, the results were similar between the three questionnaires (see Appendix 2).

5.8 Relationship between the questionnaires and age, gender and level of education

(see Appendices 10 to 18)

Univariate analysis showed that age and gender had no influence on QOL score for each of the three questionnaires. Level of education had no influence on QOL scores for the GREYS DQOL and DS questionnaires. The score of the SF-36 was, however, influenced by level of education.

Multivariate regression analysis showed that the GREYS DQOL questionnaire score was not influenced age, gender or level of education (Table 6). The SF-36 score was influenced by age and more importantly, level of education making it a less appropriate tool for population groups with lower levels of education (Table 7).

Table 6: Multivariate regression analysis of GREYS DQOL vs. SF-36 reciprocal, DS, age, gender and level of education (significant results are highlighted in bold).

GREYS DQOL	Coeff	Std err	t	p>[t]	95% CI
SF-36 reciprocal	0.53	0.12	4.23	0.000	0.28-0.78
DS	2.27	0.63	3.59	0.001	1.01-3.53
Age	-0.12	0.16	-0.73	0.46	-0.45-0.21
Gender	3.54	4.44	0.80	0.42	-5.3-12.39
Level of education	3.08	3.82	0.81	0.42	-4.52-10.69
Cons	5.36	17.52	0.31	0.76	-29.49-40.23

Table 7: Multivariate regression analysis of SF-36 reciprocal vs. GREYS DQOL, DS, age, gender and level of education (significant results are highlighted in bold).

SF-36 reciprocal	Coeff	Std err	t	p>[t]	95% CI
GREYS DQOL	0.33	0.07	4.23	0.000	0.17-0.49
DS	-1.08	0.52	-2.05	0.04	-2.13- -0.03
Age	0.38	0.12	3.06	0.003	0.13-0.63
Gender	1.99	3.54	0.56	0.57	-5.06-9.05
Level of education	-7.17	2.95	-2.43	0.01	-13.05- -1.30
Cons	43.90	13.09	3.35	0.001	17.85-69.96

5.9 Summary of results

In summary, the overall QOL of our patients was found to be poor. The GREYS DQOL correlated well with the international questionnaires while demonstrating superior compliance. The level of education of our patients is low and while this did not influence the score of the GREYS DQOL questionnaire, it did influence the SF-36 score.

Chapter 6: Discussion and Conclusions

The impact of dysphagia on QOL is largely reflected by clinician-based assumption rather than input from patients and the most dysphagia literature focus on physiological assessment of swallowing function[3, 34, 88]. There is a need to gain knowledge about the patients' perspective regarding the impact of dysphagia on their QOL. As clinicians we are too reliant on anatomical and functional assessments and often forget about the patient and what they wanted when they decided to seek help in the first place. While clinical, laboratory and radiological assessments provide valuable information about the disease, it is impossible to separate the disease from an individual's personal, psychological and social context.

QOL assessments are often accepted as outcome measures in clinical research but are rarely used in routine clinical practice. The reasons for this hesitancy to use QOL instruments in the clinical setting are multifactorial and include the conceptual vagueness of QOL, the lack of awareness about the importance of QOL, time and resources required to implement these instruments and the paucity of fully validated, relevant and contextualised questionnaires[111, 112]. QOL measures have a number of potential uses in clinical practice. They can be used to prioritise problems, facilitate communication, identify preferences and monitor response to treatment[113]. Patients' satisfaction with treatment depends largely on relief of symptoms as well as the experience and quality of treatment given[59]. QOL assessment should therefore be part of routine clinical practice. While there are a number of generic and specific QOL assessment tools available in the literature, they were all developed in the first world setting and lack relevance when it comes to our local population[28].

We therefore set out to develop a questionnaire specifically assessing dysphagia related QOL and compared it to questionnaires that have been used in the literature. The questionnaire was designed to contain questions that have relevance to and are more easily understood by our local population. To our knowledge, no such questionnaire exists and we therefore have no tools with which to examine the true impact of dysphagia on the QOL of our patients. The newly developed

questionnaire could also be used to assess patient reported outcomes after treatment is administered for dysphagia thereby assisting in adapting existing protocols designed in the first world to the third-world setting.

6.1 Developing the questionnaire

We aimed to develop a new questionnaire with the following characteristics:

- It had to be symptom-specific to dysphagia.
- It had to include aspects of general QOL issues.
- The questions needed to have relevance to our patient population.
- The questions needed to be easily understood by our population.
- The questionnaire needed to be easy and simple enough to be completed by individuals without any formal education.
- The questionnaire needed to strike the right balance between assessing the full effect of dysphagia on QOL and being brief enough so as to avoid being tedious and time-consuming.

These aims were challenging since no gold standard exists for what we are trying to achieve. The newly designed questionnaire contains a combination of questions related to the symptom of dysphagia as well as QOL issues. There are a number of questions relating to dysphagia itself. The reason for this is that the QOL of patients will be affected differently depending on the degree and frequency of dysphagia and we chose to explore this in great detail in the questionnaire. Dysphagia to different types of foods, e.g. liquids, soft foods, meat, etc. is measured separately since some patients may not have access to all types of food due to social circumstances. A patient who only eats soft foods and has no access to meat or nutritional liquid feeds will, for example feel the impact of dysphagia to soft food to a much greater extent than someone who has access to all types of food. Conversely, the relief of dysphagia of a specific food type may have significant effects on QOL of some patients. Odynophagia is explored in similar detail since many of our patients are unable to differentiate odynophagia from dysphagia.

Symptoms associated with dysphagia like regurgitation, heartburn and chest pain occur commonly in conditions that cause dysphagia and for this reason questions regarding these symptoms are asked in the questionnaire. If ignored, the potentially important impact on QOL of these associated symptoms will be missed. Treatment aimed at relieving these symptoms could significantly impact on QOL since many patients use symptom relief to describe treatment

satisfaction. There is a strong relationship between symptom relief, health-related QOL and treatment satisfaction[84]. Many conditions presenting with dysphagia causes significant weight loss. The symptom of weight loss has many implications which may differ from patient to patient. For many, it is a distressing symptom indicating a poor prognosis. This will lead to feelings of anxiety and depression[114]. For other patients, the weight loss may not even be noticed until a significant amount of weight is lost and the symptom itself may have little impact on QOL. Significant weight loss is directly linked to malnutrition and malnutrition significantly affects patients' QOL and prognosis[115].

The last three questions in the questionnaire pertain to general QOL issues. The first explores limitation in social functioning. This question was chosen to cover the mental component of QOL since social functioning has been shown to be significantly affected by dysphagia and is considered part of the mental component of QOL in literature[7, 47]. The impact on social activity may be related to feelings of anxiety and depression which are associated with dysphagia. The question on limitation of work in turn covers the physical component of QOL as dysphagia has been shown to have a significant impact on physical functioning[47]. The final question is a general one enquiring about satisfaction general state of health. This gives us information from the patient's perspective which is an important aspect of measuring Health-related QOL. It will help to differentiate between patients who respond differently to a physical or mental limitation as well as effects of different treatment modalities[25].

6.2 Demographics

The results of the demographics in this study reflect the typical population that would suffer from dysphagia. The majority were male with an advanced mean age of 59. This is the typical patient profile of oesophageal malignancy which is a common diagnosis among our patients presenting with dysphagia. Cancer of the Oesophagus is a common malignancy in South Africa ranking in the top ten non-skin cancers among men and women (www.cansa.org.za). This disease is more common in males and in older patients, a fact which coincides with our patient demographics. These findings were supported by Mannell and Murray who reviewed 1926 cases of oesophageal cancer in South Africa and found that 1438 of these patients were male resulting in a male to female ratio of 3:1 and that the average age was 56 years. They stated that the typical South African patient with oesophageal cancer is a man 56 years of age and that the most common form

of treatment was palliative[116]. The diagnosis was unknown in the majority of patients because the questionnaires were administered to the patients on first presentation before any special investigations were performed to confirm the diagnosis.

The gender distribution of our sample population may have had an impact on the results of our study. The majority of our patients were male and in certain cultures men are less likely to complain about anything as there is an impression that complaining is a sign of weakness. This may be a reason why, in the general population, self-rated QOL scores tend to be lower in females than males[117, 118]. These factors may potentially skew results of QOL studies. This was not found in our study as gender had no influence on QOL life scores. The World Health Organisation QOL group's definition of QOL as "an individual's perceptions of their position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns" underscores the importance of cultural differences in QOL assessments[39]. Indeed, studies have found significant differences in perceived health status among patients of different socio-demographic backgrounds. Factors affecting patients' perceived health status include gender, age, education level, social relationships, presence of medical problems, race or ethnic group, socio-economic and employment status[117]. Manuti *et al.* assessed HRQOL of patients in one of the poorest areas of Italy using the SF-36 and found that the patients from this area had a poor HRQOL and that this perception was even poorer in subgroups of the population, according to several socio-demographic, clinical characteristics, and behavioural risk factors[119].

Exactly 50% of the patients opted to respond to the questionnaires in Zulu. Translation of QOL questionnaires has been an important methodological step in the expansion of cross-cultural research. Many instruments, including the SF-36 have undergone translation from the source questionnaire in English to a number of other languages. These translation efforts have mainly focused on European and Asian languages and have neglected African languages. Mullin *et al.* showed acceptable internal consistency when translating the English Functional assessment of cancer therapy questionnaire to three African languages and concluded that further research in this area is warranted[98]. The SF-36 has been used and translated in the South African setting before with good success[106].

6.3 Level of education

The level of education of our patients is an important consideration in the interpretation of the results of our study. The overall level of education was low with up to a quarter of our patients being without any formal education at all and only 12.5% of patients completing school. Education and income has been shown to affect SF-36 scores[118]. Measurement scoring is particularly problematic when using outcome instruments developed in the first world due to literacy deficiency in our country. The focus of these instruments is usually on self-completion questionnaires[19].

A low level of education is associated with limited health literacy. Health literacy is the ability to obtain, process, and understand health information to make appropriate health decisions. Patients with limited health literacy may have difficulty understanding written medical information, communicating with healthcare providers, and navigating complex healthcare systems. Studies in various patient populations demonstrate an association of limited health literacy with poorer health-related knowledge and poorer health status[109].

While QOL may be considered a universal concept, differences in age and gender as well as cultural differences will play a role in its measurement. Cultural background, socioeconomic status, educational level, and gender interact in the development of symptom or disease-related beliefs that affect patient concerns, anxieties and expectations from the health care process[120]. Of these factors, level of education played a significant role in this study.

6.4 The quality of life of our patients

The impact of dysphagia on QOL has been studied and found to be significant[2, 8, 34, 52-58]. It is one of the most distressing symptoms in patients with cancer-related oesophageal obstruction[93]. The ability to measure this impact is important; especially since the majority of patients presenting to our surgical department with conditions causing dysphagia will be subjected to palliative treatment. Quality of life is an important factor in the assessment of effectiveness of different treatment options in these circumstances. The score of the patients in each questionnaire indicate an overall poor QOL. In the study by Munati *et al.*[119] the overall QOL was also found to be poor among their patients. Yet the mean SF-36 score was 45. In our study it was 30, reflecting the

severity of the impact of dysphagia on QOL of our patients. The results of the GREYS DQOL questionnaire concur with those of the SF-36 and the results of the dysphagia score indicate high severity of the symptom. There is no doubt that treatment should be aimed at improving this and that it should not impact negatively on QOL. Assessing the QOL before and after treatment would therefore be invaluable.

There is evidence that overall QOL significantly predicts survival in patients with advanced malignancy, making it a useful prognostic indicator. Changes in QOL scores after treatment for cancer have also been found to be prognostically important, where improvements in physical well-being, mood, and pain scores significantly predicted longer survival[121]. Mortality is also high in patients with swallowing difficulty, with advance age being one of the independent predictors of mortality in this group of patients[121]. The results in this study therefore portend a poor prognosis for our patients.

6.5 Comparisons of scores

The GREYS DQOL showed a wider variation in scores compared to the other two questionnaires. It is not expected that the DS would show a wide variation because it consists of only 2 questions. It only explores the symptom of dysphagia. The impact of additional symptoms on QOL is not explored. Neither are other aspects of QOL.

6.6 Correlation

In order to test for validity, correlation between the GREYS DQOL questionnaire and the other two questionnaires was assessed. Validation is a process by which a data collection instrument is tested for dependability. It is often defined as the extent to which an instrument measures what it intends to measure[61]. Validating our questionnaire would be a difficult process since there is no gold standard to compare it to. While there are a number of QOL questionnaires available in the literature, the majority of them contain questions that have little relevance to our patients. The newly compiled questionnaire score correlated moderately with both the SF 36 as well as the dysphagia score on the Spearman correlation. This therefore confirms the validity of the GREYS

DQOL questionnaire through test validity. The SF-36 questionnaire was chosen because of its widespread use in the literature as well as the fact that it is validated internationally and in South Africa[77, 78, 80, 81, 106]. The relationship between the SF-36 and the dysphagia score is consistent with that of Youssef *et al.* who performed a similar study, but only included patients who had undergone laparoscopic Heller myotomy for achalasia in their study. They assessed QOL using the SF-36 and dysphagia by using the same dysphagia score used in our study. They found that the dysphagia score was inversely correlated with total the SF-36 score[58].

The new questionnaire addresses the shortcomings of the other two questionnaires used. The questions are more relevant to our patients than those in the Sf-36 and it explores QOL in more detail than the dysphagia score questionnaire.

6.7 Compliance

We defined compliance as the number of questionnaires filled out completely. The GREYS DQOL showed higher compliance when compared to the SF-36 and the dysphagia score. In order to obtain an accurate assessment of the impact of dysphagia on the QOL, patients would have to answer all the questions in each questionnaire. Any questions that are omitted will contribute to weakening the accuracy of the assessment. One of the problems of using internationally recognized questionnaires to assess the QOL of our patients is that many of the questions have no relevance to the patients. For example, asking about a round of golf, which is a question in the SF-36 questionnaire, has no relevance to someone who has not been exposed to golf as a sport. Many of our patients fall into that category. While designing the GREYS DQOL questionnaire, the patient profile of the area that we serve was taken into account. Taking into account the low level of education of our patient population it would therefore be a reasonable assumption that the majority of our patients are more concerned about basic human needs such as being able to work than they are about playing golf for example.

The reason for the higher compliance rate is possibly because of cultural differences between our population group and those tested in the internationally recognised questionnaires. We tried to overcome this difficulty with the development of a local questionnaire. The questions attempt to view the problem from the patients' perspective by taking into account the culture of the patients. Culture is defined as the '*integrated patterns of human knowledge beliefs and behaviour*'[122]. It

includes a number of aspects including art, tastes, ceremonies, rituals and institutions such as marriage in a given community. Health attitudes, beliefs and behaviour are products of culture. While there are several projects which translate standardised QOL measures for use in different cultural setting, these projects have tended to be concerned mostly with the languages of Europe and North America[39]. Cross-cultural validation of these instruments would therefore be needed in order to use them locally. This translation and adaptation process is important because the way the constructs such as participation, disability and health-related quality of life are understood in different cultures may vary and it cannot be assumed that instruments to assess QOL are cross-culturally valid[39, 43, 123]. Stevelink and van Brackel reviewed the extent to which insights in cultural equivalence testing have been applied to different HRQOL instruments the majority of the instruments received minimal rating for the categories of cultural equivalence. They defined cultural equivalence as '*the extent to which an instrument is equally suitable for use in two or more cultures*'[124]. The internationally validated questionnaires do not have cross-cultural validity and this is the main reason for the inferior compliance in completing them.

6.8 Relationship between the questionnaires and age, gender and level of education

The scores of the GREYS DQOL and DS was not influenced by age, gender or level of education on univariate and multivariate analysis while the SF-36 was influenced by level of education on both univariate and multivariate analysis. This is a significant finding since the overall level of education of our study population was low. It means that the GREYS DQOL questionnaire is a more suitable tool for QOL assessment in our population than the SF-36. A possible reason for this finding is the fact that the GREYS DQOL was developed locally by investigators with extensive experience in working with the local population. Respondents may find it easier to relate to the questions. Another possible reason is the use of the visual analogue scale as opposed to the Lickert scale. It has been shown that locally developed questionnaires as well as questionnaires with more visual options are more accurate than internationally developed and validated questionnaires in assessing QOL in individuals with lower literacy levels[117, 125]

6.9 Relevance

This study is based on the assumption that the South African questionnaire is more relevant to our local population. This assumption is valid since it was designed in KwaZulu Natal in South Africa

which is the same area that the patients live as opposed to the other two questionnaires that were designed in the first world. Furthermore, the questions were formulated by the main investigator and supervisor who together have extensive experience with patients presenting with dysphagia as their main complaint. Studies looking at QOL that are undertaken in different countries are expected to show divergences since health QOL is also modulated by cultural and care patterns[29]. Using a locally designed questionnaire would therefore give clinicians a more accurate assessment of the impact of dysphagia on the QOL of patients from the same area. The effectiveness of different treatment options could also be assessed more accurately.

6.10 Limitations of this study

The main limitation of this study is the difficulty in validating a newly designed questionnaire where no gold standard exists. This is an unavoidable limitation since it is the first study looking specifically at the impact of dysphagia on the QOL of patients in a South African setting. It was a necessary study since dysphagia is a common presenting complaint in our population and QOL studies are not often done on our patients. Previous authors faced with similar problems used face validity and content validity in order to validate their instruments. Face validity examines whether an instrument appears to be measuring what is intended to measure, and content validity examines the extent to which the domain of interest is comprehensively sampled by the questions in the instrument. One of the criteria to achieve content validity is to involve the target population in the question selection[16] and this was not fulfilled. Quantitative testing of face and content validity are rarely attempted[25]. Validity and reliability is difficult to test without a gold standard. This problem has been encountered before in the South African context[127]. Our questionnaire did, however, show sufficient correlation with the international ones confirming test validity.

Another limitation of the study is that test-retest reliability was not evaluated for the questionnaire. In order for this to be done, the same questionnaires would have to be administered to the same patients at different times and this was not done as all patients were given all three questionnaires at one setting only. The reason for this is that follow up is very difficult in our setting. Many patients are either unwilling or unable to return to hospital for a variety of reasons including economic, social and physical limitations. In addition, many patients

lack insight into their disease process and fail to return for follow up once they are feeling better. Some patients return to health care facilities in closer proximity to their homes for follow up[128]. The level of education of patients and the lack of understanding of the importance of follow up also play a role[129]. Indeed loss to follow up is one of the most common reasons for inadequate treatment of patients in South Africa[130].

The translation process also contributes to the limitations in this study. All three questionnaires were directly translated. While experience with translation is still limited, it is suggested in the literature that without rigorous back-translation and pretesting, questionnaires may be interpreted differently in a new language[131]. In addition, cultural differences may adversely affect an instrument's measurement properties. Future research should aim to back-translate and pretest all three questionnaires and repeat the validation process.

6.11 Future research

Future research should assess the factors affecting compliance of patients in completing the questionnaire in more detail and the change in quality of life of patients after receiving treatment for dysphagia. The responsiveness of the GREYS DQOL would be tested. The reasons for poor compliance in answering questionnaires should be sought. Social and cultural aspects of patient care should be taken into account. The results of the completed questionnaires should reflect a change in symptoms as well as quality of life associated with different treatment strategies.

6.12 Conclusions

In conclusion, this study shows that dysphagia does result in a poor quality of life of the affected individual and that the Greys Dysphagia QOL questionnaire can be used to assess the impact of dysphagia on as well as the impact of different treatment options on the quality of life of patients. It is a comprehensive symptom-specific tool which combines generic and dysphagia-specific QOL aspects. It is easy to complete with questions that are relevant to our local population and suitable for patients with low literacy levels. The treatment options currently used in our setting are known to improve dysphagia symptoms but their effect on QOL in our setting is not known

and needs to be evaluated. This study provides a simple, effective and locally appropriate tool to assess different modalities of therapy for conditions presenting with dysphagia in a developing world context.

This is the first time this is attempted, highlighting the inadequacy of holistic care in our setting. Further refinement will make it a tool to assess outcome and predict prognosis and it can then be used as a clinical as well as research tool.

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Appendices

Appendix 1: Results of scores for each patient

N	GREYS DQOL	SF-36	DS
1	80	19	10
2	77	32	9
3	33	36	10
4	8	55	6
5	3	10	4
6	30	33	10
7	20	16	5
8	66	15	10
9	81	20	0
10	89	22	5
11	45	70	0
12	67	6	0
13	24	17	10
14	68	47	9
15	36	66	6
16	28	54	6
17	53	59	9
18	76	33	7
19	49	81	10
20	83	23	10
21	35	21	0
22	74	12	8
23	54	59	6
24	45	29	10
25	33	55	7
26	44	20	10
27	65	31	0
28	82	42	10
29	62	24	10
30	85	41	10
31	92	10	10
32	51	45	8
33	77	22	10
34	62	21	10
35	54	25	0

36	22	86	3
37	70	36	9
38	89	29	10
39	69	10	10
40	77	20	10
41	65	8	10
42	76	13	10
43	90	19	10
44	15	47	2
45	89	28	9
46	78	12	2
47	75	24	0
48	64	18	0
49	54	23	2
50	60	23	0
51	98	12	5
52	70	27	10
53	78	21	9
54	88	34	10
55	79	36	0
56	97	25	10
57	95	19	9
58	98	29	9
59	100	23	10
60	58	57	10
61	20	35	10
62	85	49	10
63	64	1	8
64	54	37	5
65	85	17	3
66	18	57	5
67	62	19	5
68	43	27	5
69	52	22	10
70	72	20	5
71	53	47	4
72	26	35	5
73	75	20	10
74	52	49	7
75	68	3	0
76	69	8	5
77	80	34	10
78	60	31	6

79	28	31	6
80	48	54	6
81	37	31	9
82	25	4	0
83	25	6	8
84	69	34	9
85	60	11	10
86	78	29	10
87	96	11	10
88	56	33	6
89	68	18	8
90	54	82	10
91	72	22	8
92	91	25	8
93	78	67	10
94	51	69	9
95	44	37	7
96	99	15	10
97	36	14	9
98	67	34	10
99	39	35	4
100	56	37	8

GREYS DQOL – Greys Dysphagia Quality of Life

SF-36 – Short Form 36

DS – Dysphagia Score

Appendix 2: Compliance of patients in completing questionnaires

N	% of GREYS DQOL	% of SF-36	% of DS
1	100	100	100
2	100	94.5	100
3	100	100	100
4	100	100	100
5	76	72.2	100
6	100	100	100
7	100	97.2	100
8	76	100	100
9	84	100	0
10	100	100	50
11	100	100	0
12	100	100	0
13	84	97.2	100
14	100	100	100
15	100	100	100
16	100	100	100
17	100	100	100
18	100	100	100
19	100	100	100
20	100	100	100
21	100	91.7	0
22	100	86.1	100
23	100	100	100
24	100	100	100
25	100	97.2	100
26	100	100	100
27	100	97.2	0
28	100	97.2	100
29	100	97.2	100
30	100	100	100
31	96	97.2	100
32	100	100	100
33	100	86.1	100
34	100	100	100
35	100	97.2	0
36	100	100	100
37	100	100	100
38	100	97.2	100
39	100	100	100
40	100	97.2	100
41	100	100	100
42	96	83.3	100
43	96	100	100
44	68	100	100
45	100	88.9	100
46	100	100	50
47	100	97.2	0
48	100	86.1	0
49	100	97.2	50
50	100	100	0
51	100	97.2	100
52	100	100	100

53	100	100	100
54	100	100	100
55	100	100	0
56	100	100	100
57	100	100	100
58	100	100	100
59	100	100	100
60	96	100	100
61	96	100	100
62	100	100	100
63	92	77.8	100
64	100	100	100
65	96	100	100
66	100	97.2	100
67	100	94.4	50
68	96	100	100
69	100	83.3	100
70	100	97.2	100
71	100	100	100
72	100	100	100
73	80	97.2	100
74	100	88.9	100
75	100	100	100
76	100	100	100
77	100	97.2	100
78	100	100	100
79	100	97.2	100
80	100	97.2	100
81	84	100	100
82	100	69.4	0
83	100	100	100
84	100	100	100
85	100	100	100
86	100	100	100
87	96	100	100
88	96	100	100
89	100	100	100
90	100	100	100
91	100	100	100
92	100	100	100
93	100	77.8	100
94	100	97.2	100
95	100	97.2	100
96	100	100	100
97	100	91.7	100
98	100	100	100
99	100	94.4	100
100	100	97.2	100
Average	98.08	97.05	87

Appendix 3: The Study Protocol

The sections of the BREC Application relevant to the study protocol are included below:

SECTION 3: THE PROTOCOL

Type of Study: Clinical

3.1 THE PROJECT:
1. Aims (objectives of study) – please list.
   To develop a symptom-specific quality of life questionnaire for dysphagia relevant to our local population.

2. Hypothesis to be tested.
   The new quality of life questionnaire scores correlate well with the scores of the existing tools.
   There is a significant change (improvement) in QOL scores from pre to post treatment in Dysphagia patients.

3. Summary of the proposed research (restrict to 100 words)
   Specific objectives:
   1. To determine cut points in the new QOL scores that optimize sensitivity and specificity of predicting poor quality of life according to the gold standard.
   2. To attempt to determine whether Dysphagia scores which are currently available adequately assess quality of life of patients affected and are relevant to our local population. A locally relevant dysphagia QOL questionnaire may give us a better understanding of the impact dysphagia has on the QOL of our local population.

Methods
Cross –sectional validation study

The proposed questionnaire will assess the frequency and severity of dysphagia, odynophagia, heartburn and chest pain, the frequency of regurgitation and extent of weight loss. Limitations to work and social activity and overall satisfaction with health will also be assessed. The visual analogue scale will be used to assess responses. Questions will be asked in the patients' first language. Patients will be asked to complete the questionnaire on admission and after treatment has been administered. The Dysphagia score and short form – 36 (S-F 36) questionnaire will then be applied to the same patients and the results of the 3 questionnaires will be compared using Pearson's correlation. Demographic and clinical data will also be collected. ROC analysis will be used to determine cut points in the new QOL score which optimally predict poor quality of life according to the previously validated gold standard questionnaires.

Prospective cohort study

The minimum sample size for statistical significance was not possible to calculate since the expected difference of clinical relevance from pre to post treatment was not known. Thus the sample size to be used will be determined from logistical rather than statistical constraints. 1year of data collection will result in approximately 100 patients. This number will increased to account for dropout or death in the follow up period. The sample size can be increased if needed

Patients will be assessed at baseline (pre treatment) and again post treatment (one week to one month) with the new QOL questionnaire. Statistical significance of the change will be assessed using paired t-tests (for quantitative data) or McNemar's chi square tests (for categorical data)

4.   Keywords (for database):
Dysphagia, quality of life, oesophagus

5.   Background and Literature:
Dysphagia is a common symptom. Malignant obstruction is the commonest cause with Benign strictures and motility disorders accounting for the remainder The degree of dysphagia and its effect on quality of life (QOL) are poorly documented. QOL is adversely affected by dysphagia and this is under appreciated by physicians attending to these patients. A locally relevant and composite dysphagia and quality of life questionnaire would give physicians a better understanding of the impact of dysphagia on our patients, and would allow an objective reproducible assessment of the success of different treatment modalities.

Locally the most common cause is obstruction due to squamous carcinoma of the oesophagus with 600 new cases annually in the region. A variety of treatment options are available but comparative data on their effectiveness is lacking.
Dysphagia has a direct negative impact on QOL. In addition, conditions which commonly present with dysphagia give rise to other symptoms which affect QOL. Common conditions presenting with dysphagia as well as symptoms associated with dysphagia are listed below.

Causes of Dysphagia
Malignancy
Benign strictures (e.g. peptic stricture)
Motility disorders (e.g. achalasia)
Diverticulae (e.g. Zenkers diverticulum)
Extrinsic compression

Symptoms associated with dysphagia
Odynophagia
Chest pain
Heartburn
Regurgitation
Weight loss

A variety of medical, surgical and behavioral treatments to improve swallowing physiology are available. The effectiveness of these treatments is incompletely understood because comparative outcome assessments have been few.[1]

For the majority of conditions mentioned above, management is palliative rather than curative. For this reason it is important to understand how these conditions and there treatments affect QOL of patients. While there are a large number of tools to assess dysphagia and its effects on quality of life. not all are disease or symptom specific. Examples include the dysphagia score and GI QOL score. In addition the questions asked may not be relevant to our local population. The visual analogue scale (VAS) will be used in this study. This is a validated scale used to assess QOL which is easy to use and interpret. The visual analogue scale is an instrument that measures a characteristic or attitude that ranges across a continuum of values and cannot easily be directly measured.[2]

Until now, a limited number of studies have been carried out on the social importance of dysphagia and its consequences on the quality of life.[3] This fact underscores the need for a locally relevant quality of life assessment.

6. Key References: (Give approximately 5 key references).
   1. McHorney C, et al. The SWAL-QOL outcomes tool for oropharyngeal dysphagia in adults. Dysphagia 2000; 15:115-121
   2. Gould D, et al. Journal of clinical nursing. 2001; 10: 697-706
   3. Farri A, et al. Social importance of dysphagia: its impact on diagnosis and therapy. Acta Otorhinolaryngol Ital. 2007; 27: 83-6
   4. Torquati, et al. Laparoscopic myotomy for achalasia. Predictors of successful outcome after 200 cases. Ann Surg. 2006;243:587-593
   5. Eypasch E, et al. Gastrointestinal quality of life index: developement, validationand application of a new instrument. BJS 1995;82:216-222

3.2 PLAN OF INVESTIGATION:

(a) Design and/or experimental procedures :
In the case of Higher Degrees, please state name and department of person consulted regarding the design.
   a. **A cross-sectional validation study**
   b. **A prospective pre and post treatment cohort study**
      Person consulted – Mrs T Esterhuizen. Department of statistics

(b) Statistical Planning:

Has this project been discussed with:

a professional statistician?   Yes
a person with a statistical background?   Yes:.............No:............

If yes, *(a)* *Name of statistician:* **Mrs T Esterhuizen**
        (b) *Give details - outline statistical considerations such as randomisation, size of groups, exclusions etc.*

Patients will be asked to complete the questionnaire on admission and after treatment has been administered. The Dysphagia score and short form – 36 (S-F 36) questionnaire will then be applied to the same patients and the results of the 3 questionnaires will be compared using Pearson's correlation. Demographic and clinical data will also be collected. ROC analysis will be used to determine cut points in the new QOL score which optimally predict poor quality of life according to the previously validated gold standard questionnaires.

The sample size will be a minimum of 100 patients. This number will be increased to account for dropout or death in the follow up period.

Patients will be assessed at baseline (pre treatment) and again post treatment (one week to one month) with the new QOL questionnaire. Statistical significance of the change will be assessed using paired t-tests (for quantitative data) or McNemar's chi square tests (for categorical data)

If no, specify why statistical consultation was not obtained and motivate the design adopted.

(c) Participants:
Clinical data: Please indicate the numbers, source and age of the participants to be used:

Source:
Inpatients:..........Outpatients

Age (humans):
Adults:.........

Numbers : Indicate the number of participants in each of the above study-groups.

Approximately 100patients
Inpatients: ....Outpatients

Will you have control groups?

Detail inclusion and exclusion criteria:
All patients presenting with dysphagia as a primary symptom will be selected.
All patients in whom dysphagia is not the primary symptom will be excluded
All Patients lost to follow up will be excluded

Describe recruitment process for all groups:

(d) The Environment:
1.   Is this a multi-national study?   **No.** *If yes, state collaborating countries.*

2.   List all sites in South Africa in which the project will be carried out.

Greys Hospital
Edendale Hospital
Inkosi Albert Luthuli Central Hospital

3. Can the project have any negative consequences on participants, members of the public, researchers, field staff or the physical environment (incl. the laboratory)?

    No:……… *If yes, please give details.*

4. How many hours/week will the PI devote to this project?
    Timetable the project in terms of the resources and time available.
5 – 10 hours per week

3.3 ETHICAL ASPECTS:

(a) Responsibility: *In respect of any litigation which may result from this research*:
1. Are the pharmaceutical manufacturers prepared to take responsibility?

    Not applicable:………
    If yes, please supply details.

2. Have you ensured that reimbursement for participants and investigators is in accordance with 1) *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* – Department of Health (2006) – *and 2) Ethics in Health Research: Principles, Structures and Processes* – (2004)?

    Yes:………   *If no, please explain.*

3. If this project is to be conducted at another institution, is additional ethical clearance approval required?

    Not Applicable:…………..*If no, please explain.*

(b) Incentives / Reimbursement
1. List any incentives, explicit and implicit, that have or will be offered to study participants, either to recruit or to retain within the study.
None
2. List reimbursement / compensation for participation in the study (e.g. travel costs, out of pocket expenses, etc.).
N/A

(c) Potential risks or discomfort:
Compared to persons or patients with similar conditions indicate, for each study group, the potential additional

        Risk - None
        Discomfort - None

(d) Health Service Utilisation:
Compared with persons or participants with similar conditions indicate, for each study group, the likely <u>additional</u>:

Duration of hospital stay (days): 0

Outpatient attendances (number):   0

Laboratory services used: None

Samples to be drawn: none

Extent of nursing involvement: Assist with explaining questionnaire to patient

Have the nursing team who will be involved in the study been informed of the study and the nursing involvement which will be required?

Yes:………   *If no, please explain.*

Other (specify):

(e) Management:
In the case of participants drawn from patient populations, indicate, in respect of each sub-group, how management differs from that usually offered to patients with similar conditions.

No difference in management
(f) Community Consultation: N/A
In the case of community based studies, explain what consultation is planned within the community at the following stages:

1.   Preparation

2.   Implementation of the study and

3.   Dissemination of the results thereafter

(g) State the expected benefits arising from this study under the following headings:

1.   Possible direct benefits to study participants

2.   Clinical care
Ability to assess the effect of certain conditions on quality of life of patients
Ability to assess the effect of treatment of dysphagia on quality of life
Ability to assess adequacy of treatment of dysphagia

2.   Public health

3.   Financial

4.   Prospects of tested intervention being available to the study population if proven effective.

5.   Other (Specify)

Appendix 4: The Dysphagia Score Questionnaire

Frequency	**0**=never	**1**=<1d/week	**2**=1d/week	**3**=2-3d/week	**4**=4-6d/week	**5**=daily
Severity	**0**=none	**1**=very mild	**2**=mild	**3**=moderate	**4**=mod. severe	**5**=severe

Appendix 5: The SF-36 Questionnaire

Instructions for completing the questionnaire:

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

1. In general, would you say your health is?

☐ Excellent

☐ Very good

☐ Good

☐ Fair

☐ Poor

2. Compared to one year ago, how would you rate your health in general now?

☐ Much better now than a year ago

☐ Somewhat better now than a year ago

☐ About the same as one year ago

☐ Somewhat worse now than one year ago

☐ Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, by how much?

a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

☐ Yes, limited a lot

☐ Yes, limited a little

☐ No, not limited at all

b. Moderate activities, such as moving a table, pushing a vacuum cleaner,   bowling or playing golf?

    ☐ Yes, limited a lot

    ☐ Yes, limited a little

    ☐ No, not limited at all

c. Lifting or carrying groceries.

    ☐ Yes, limited a lot

    ☐ Yes, limited a little

    ☐ No, not limited at all

d. Climbing several flights of stairs.

    ☐ Yes, limited a lot

    ☐ Yes, limited a little

    ☐ No, not limited at all

e. Climbing one flight of stairs

    ☐ Yes, limited a lot

    ☐ Yes, limited a little

    ☐ No, not limited at all

f. Bending, kneeling or stooping

    ☐ Yes, limited a lot

    ☐ Yes, limited a little

    ☐ No, not limited at all

g. Walking more than one mile

   ☐ Yes, limited a lot

   ☐ Yes, limited a little

   ☐ No, not limited at all

h. Walking several blocks

   ☐ Yes, limited a lot

   ☐ Yes, limited a little

   ☐ No, not limited at all

i. Walking one block

   ☐ Yes, limited a lot

   ☐ Yes, limited a little

   ☐ No, not limited at all

j. Bathing or dressing yourself

   ☐ Yes, limited a lot

   ☐ Yes, limited a little

   ☐ No, not limited at all

4. During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of physical health?

a. Cut down the amount of time you spent on work or other activities?

   ☐ Yes

   ☐ No

b. Accomplished less than you would like?

   ☐ Yes

   ☐ No

c. Were limited in the kind of work or other activities

☐ Yes

☐ No

d. Had difficulty performing the work or other activities (for example, it took   (extra time)

☐ Yes

☐ No

5. During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of any emotional problems?

a. Cut down the amount of time you spent on work or other activities?

☐ Yes

☐ No

b. Accomplished less than you would like?

☐ Yes

☐ No

c. Didn't do work or other activities as carefully as usual

☐ Yes

☐ No

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with friends, family, neighbours or groups?

☐ Not at all

☐ Slightly

☐ Moderately

☐ Quite a bit

☐ Extremely

7. How much bodily pain have you had during the past 4 weeks?

☐ Not at all

☐ Slightly

☐ Moderately

☐ Quite a bit

☐ Extremely

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all

☐ Slightly

☐ Moderately

☐ Quite a bit

☐ Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

a. Did you feel full of pep?

☐ All of the time

☐ Most of the time

☐ A good bit of the time

☐ Some of the time

☐ A little of the time

☐ None of the time

b. Have you been a very nervous person?

☐ All of the time

☐ Most of the time

☐ A good bit of the time

☐ Some of the time

☐ A little of the time

☐ None of the time

c. Have you felt so down in the dumps nothing could cheer you up?

☐ All of the time

☐ Most of the time

☐ A good bit of the time

☐ Some of the time

☐ A little of the time

☐ None of the time

d. Have you felt calm and peaceful

☐ All of the time

☐ Most of the time

☐ A good bit of the time

☐ Some of the time

☐ A little of the time

☐ None of the time

e. Did you have a lot of energy?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

f. Have you felt downhearted and blue?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

g. Did you feel worn out?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

h. Have you been a happy person?

- ☐ All of the time
- ☐ Most of the time

- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

i. Did you feel tired?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interferes with your social activities (like visiting friends, relatives, etc.)?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people

- ☐ Definitely true
- ☐ Mostly true
- ☐ Don't know

XXX

☐ Mostly false

☐ Definitely false

b. I am as healthy as anybody I know

☐ Definitely true

☐ Mostly true

☐ Don't know

☐ Mostly false

☐ Definitely false

c. I expect my health to get worse

☐ Definitely true

☐ Mostly true

☐ Don't know

☐ Mostly false

☐ Definitely false

d. My health is excellent

☐ Definitely true

☐ Mostly true

☐ Don't know

☐ Mostly false

☐ Definitely false

Appendix 6: The GREYS DQOL Questionnaire

Demographic data

Name:_____ Age:___ Sex:___
Race:___

Address:_____

Type of dwelling:_____

Highest level of education:_____

Occupation:_____

Clinical data

Diagnosis:_____

Treatment received:_____

Date of above treatment:_____

Co-morbid disease:_____

Questionnaire

Dysphagia [a]

1) How often do you experience difficulty with swallowing liquids?

0(Never)   4(occasionally)   8(often)   10(always)

_____

2) How often do you experience difficulty with swallowing soft foods?

0(Never)   4(occasionally)   8(often)   10(always)

_____

3) How often do you experience difficulty with swallowing raw hard fruits?

0(Never)   4(occasionally)   8(often)   10(always)

_____

4) How often do you experience difficulty with swallowing meat?

0(Never)   4(occasionally)   8(often)   10(always) |

_____

5) How bad is your difficulty in swallowing when swallowing liquids?

0(none)   10(most severe)

_____

6) How bad is your difficulty in swallowing when swallowing soft foods?

0(none)   10(most severe)

_____

7) How bad is your difficulty in swallowing when swallowing raw hard fruit?

0(none)   10(most severe)

_____

8) How bad is your difficulty in swallowing when swallowing meat?

0(none)   10(most severe)

_____

__Odynophagia__ [b]

9) How often do you experience pain when swallowing liquids?

0(Never)   4(occasionally)   8(often)   10(always)

_____

10) How often do you experience pain when swallowing soft foods?

0(Never)   4(occasionally)   8(often)   10(always)

_____

11) How often do you experience pain when swallowing raw hard fruits?

0(Never)   4(occasionally)   8(often)   10(always)
_____

12) How often do you experience pain when swallowing meat?

0(Never)   4(occasionally)   8(often)   10(always)
_____

13) How bad is your pain on swallowing when swallowing liquids?

0(none)   10(most severe)
_____

14) How bad is your pain on swallowing when swallowing soft foods?

0(none)   10(most severe)
_____

15) How bad is your pain on swallowing when swallowing raw hard fruit?

0(none)   10(most severe)
_____

16) How bad is your pain on swallowing when swallowing meat?

0(none)   10(most severe)
_____

Chest pain [c]

17) How often do you get chest pain after eating?

0(Never)   4(occasionally)   8(often)   10(always)

_____

18) How severe is your chest pain after eating?

0(none)   10(most severe)

_____

Heartburn [d]

19) How often do you experience heartburn (a burning sensation in your chest extending from your stomach towards your throat)?

0(Never)   4(occasionally)   8(often)   10(always)

_____

20) How severe is your heartburn?

0(none)   10(most severe)

_____

Frequency of regurgitation [e]

21) How often do you experience regurgitation (food returning to your mouth after swallowing)?

0(Never)   4(occasionally)   8(often)   10(always)

_____

Amount of weight loss *f*

22) How much weight have you lost since being ill?

0(None)   10(>10kg)

_____

Limitation of social activity *g*

23) How much has your illness affected your social life?

0(None)   4(mild)   6(moderate)   10(no social life)

_____

Limitation of work *h*

24) How much has your illness limited your work?

0(None)   4(mild)   6(moderate)   10(unable to work)

_____

Satisfaction with current state of health *i*

25) How satisfied are you with your current state of health?

0(completely satisfied)   10(completely dissatisfied)

_____

a - Dysphagia can be defined as difficulty in swallowing or the sensation of food getting stuck while swallowing
b – Odynophagia can be defined as the experience of painful swallowing or feeling pain while swallowing
c – Chest pain should be felt behind the sternum, not while swallowing and not be due to other causes, like cardiac ischaemia
d – Heartburn if defined as a burning sensation in the chest usually progressing from the epigastric area upwards to the chest and throat
e – Regurgitation can be defined as the return of partially digested or undigested food to the mouth after swallowing
f – If the exact amount of weight loss is unknown an estimation can be given. The patient may report it as a change in size of clothes
g – Social activity will vary among different socioeconomic groups and examples may be given (like eating at a restaurant or eating with family or friends)
h – Limitation of work may include employement and/or housework
i – This should be an indication of overall feeling of well-being or illness

Appendix 7: Translated Dysphagia Score

<u>Ukubalwa Kwe- Dysphagia(Ukuba nobulukhuni bokugwinya)</u>

Kangakhi	0=akukaze	1=< usuku/ esontweni	2=usuku/ esontweni	3=2-3 izinsuku/ esontweni	4=4-6 izinsuku/ esontweni	5=zonke izinsuku
kangakana ni	0=akukho	1=kancane kakhulu	2= kancane	3=okuphakath i nendawo	4=kakhudlwana	5=kakhulu

Appendix 8: Translated S-F 36 questionnaire

0SF-36 Uphenyo Ngezempilo

Imithetho yokugcwalisa uhlu lwemibuzo: Sicela uphendule yonke imibuzo. Kunemibuzo ebonakala ifana neminye, kodwa uma ubhekisisa ayifani. Uyacelwa ukuthi ube nesineke ufundisise bese uphendula yilowo nalowo mbuzo ngokucophelela, ngokugcwalisa ukhethe lokho ocabanga ukuthi kuphendula lowombuzo ngokubona kwakho.

Igama
lesiguli:_____

Inombolo
yasesibhedlela:_____usuku_____

Umuntu osiza lowo ogcwalisa leli
fomu:_____

1. Ngokujwayekile ungathini ngempilo yakho?

    ☐ Inhle ngokubabazekayo

    ☐ Yinhle kakhulu

    ☐ Yinhle

    ☐ Iyemukeleka

    ☐ Yimbi

2. Uma uqhathanisa nesikhathi esingangonyaka esedlulile ungathi impilo yakho injani manje?

    ☐ Ingcono kakhulu kunesikhathi esingangonyaka esedlule

    ☐ Ingconywana kunesikhathi esingangonyaka esedlule

    ☐ Cishe kufane nje

    ☐ Ngingathi kuya ngokuba kubi kunesikhathi esingangonyaka esedlule

    ☐ Kubi kakhulu manje kunesikhathi esingangonyaka esedlule

3. Loku okulandelayo kukhuluma ngezinto ondgase uzenze ngosuku ulujwayelekile. Ngakube impilo yakho manje iyakuvimbela yini ukuthi wenze izinto ojwayele

    ukuzenza? Uma kunjalo, kangakanani?

a. Imisebenzi edinga amandla amakhilu njengokugijima, ukuqukula izinto ezisindayo nokudlala imidlalo edinga amandla.

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

b. Imisebenzi edinga amandl aphakathi nendawo, njengokududula itafula, ukusebenzisa ushini wokushanela ikhaphethi i-vaccum cleaner nokudlala igalofu?

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

c. Ukuphakamisa nokuthwala izimpahla zokudla okade uzithenga

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

d. Ukwenyuka izitebhisi eziyingcosana.

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

e. ukwenyuka izitebhisi ezimbalwa.

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

f. Ukugoba nokuguqa.

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

g. ukuhamba ngaphezu kwamakhilomitha amabili.

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

h Ukuhamba ibanga elingadlula izindlu eziyidlanzana edolobheni.

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

i Ukuhamba ibanga elingadlula isakhiwo esisodwa edolobheni.

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

j Ukuzigeza nokuzigqokisa.

☐ Yebo, kuyangivimbela kakhulu

☐ Yebo, kuyangivimbela nje kancane

☐ Cha, akungivimbeli nakancane

4. Emasontweni amane adlule uke waba nenye yalezi nkinga ezilandelayo emsebenzini nakwezinye izinto ozenzayo okube umphumelo wesimo sempilo yakho?

   a. Wehlise isikhathi osichitha emsebenzini wakho nakokunye okwenzayo

   ☐ Yebo

   ☐ Cha

   b. Wenze umsebenzi ongaphansi kwalokho ofisa ukukwenza

   ☐ Yebo

   ☐ Cha

   c. Ube nokuphazamiseka emsebenzini nokunye ojwayele ukukwenza

   ☐ Yebo

   ☐ Cha

d. Ube nobunzima ekwenzeni umsaebenzi nokunye ojwayele ukukwenza(uthathe

   isikhathi eside kunesijwayelekile)?

   ☐ Yebo

   ☐ Cha

5. Emasontweni amane adlule uke waba nenye yalezi nkinga ezilandelayo emsebenzini nakwezinye izinto ozenzayo okube umphumelo wesimo sempilo yakho?

   a. Wehlise isikhathi ovame ukusichitha emsebenzini wakho nokunye?

   ☐ Yebo

   ☐ Cha

   b. Wenze ngaphansi kwalokho obufisa ukukwenza?

   ☐ Yebo

   ☐ Cha

   c. Awuzange ukwazi ukwenza umsebenzi wakho nokunye ngendlela enokucophelela njengoba ujwayele ukwenza?

   ☐ Yebo

   ☐ Cha

6. Kulamasonto amane adlule ngabe impilo yakho yomzimba nomphefumulo ikuphazamise kangaknani ukuhlalisana kahle kwakho nabangani bakho, omakhelwane, umndeni wakho kanye nabanye osebenzisana nabo?

   ☐ Ayibathintanga nakancane

   ☐ Ibathintile kancane

   ☐ Ibathinte kakhudlwana

   ☐ Ibathinte impela

   ☐ Ibathinte kakhulu

7. Kungabe zingakanani izinhlungu emzimbeni wakho kulamasonto amane edlule?

   ☐ Ayibathintanga nakancane

   ☐ Ibathintile kancane

   ☐ Ibathinte kakhudlwana

   ☐ Ibathinte impela

   ☐ Ibathinte kakhulu

8. Kulamasonto amane adlule ngabe izinhlungu ziyiphazamise ngakanani indlela ohlala usebenza ngayo(umsebenzi wangaphandle kwasekhaya nowasendlini)?

   ☐ Ayibathintanga nakancane

   ☐ Ibathintile kancane

☐ Ibathinte kakhudlwana

☐ Ibathinte impela

☐ Ibathinte kakhulu

9. Lemibuzo iqndene nokuthi uzizwa unjani nokuthi izinto bezikuhambela kanjani kulamasonto amane adlule. Embuzweni ngamunye soicela usinike impendulo eyodwa ocabanga ukuthi iyona echaza ismo sakho. Singakanani isikhathi kulamasonto adlule:

a. Lapho wazizwa uphila kahle kakhulu?

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

b. Ngabe usuke waba umuntu ohlala unovalo?

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

c. Uke wazizwa unenhliziyo ebuhlungu nephansi wezwa sengathi akukholutho olungakujabulisa?

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

d. Uzizwe unokuthula noxolo ngaphakathi kuwena

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

e. Uke wazizwa unomfuthop namandla amaningi?

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

f. Uke wazizwa wehlile emoyeni kukubi konke?

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

g. Uke wazizwa ukhathele kakhulu?

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

h. Umthetho wakho ungumuntu ohlala eneme?

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

i. Uke wazizwa ukhathele?

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

10. Emasontweni amane adlule singakanani isikhathi lapho impilo yakho yomzimba

kanye nezinkingan zomphefumulo kuphazamise izinto ojwayele ukuzenza

(njengokuvakashela abangane, izihlobo nokunye)?

☐ Sonke isikhathi

☐ Isikhathi esiningi

☐ Isikhashana nje impela

☐ Ngesinye isikhathi

☐ Izikhashana eziyingcosana/ezimbalwa

☐ Akukaze kwenzeke nakancane

11. KiyiQINISO kangakanani kumbe kungaMANGA kangakanani lokhu okulandelayo

kuwena?

a. Ngivama ukugula kalula kunabanye abantu

☐ Kuyiqiniso kakhulu

☐ Kuvmise ukuba yiqiniso

☐ Angazi

☐ Kuvamiso ukungabi yiqiso

☐ Akusilona iqiniso nakancane

b. Ngiphila njengabo bonke engibaziyo

☐ Kuyiqiniso kakhulu

☐ Kuvmise ukuba yiqiniso

☐ Angazi

☐ Kuvamiso ukungabi yiqiso

☐ Akusilona iqiniso nakancane

c. Ngilindele ukuthi impilo yami iye ngokuba yimbi kunalokhu

☐ Kuyiqiniso kakhulu

☐ Kuvmise ukuba yiqiniso

☐ Angazi

☐ Kuvamiso ukungabi yiqiso

☐ Akusilona iqiniso nakancane

d. Impilo yami yinhle kakhulu

☐ Kuyiqiniso kakhulu

☐ Kuvmise ukuba yiqiniso

☐ Angazi

☐ Kuvamiso ukungabi yiqiso

☐ Akusilona iqiniso nakancane

Appendix 9: Translated GREYS DQOL questionnaire

IMIBUZO YOCWANINGO ENGABUZWA

Imininingwane eqondene nalowo ophendula lemibuzo

Igama:_____Iminyaka yobudala:_____Ubulili:_____Ubuzwe:_____

Ikheli:_____

Uhlobo lwendlu yakhe:_____

Izinga lemfundo afinyelela kulo:_____

Umsebenzi awenzayo: _____

Imininingwane emaqondana nokugula

Igama lesifo esimphethe:_____

Indlela aselashwe ngayo:_____

Usuku alashwa ngalo:_____

Ezinye izifo ezimphethe:_____

Imibuzo :_____

Ukugwinya kalukhuni [a]

1) Kuvame kangakanani ukuthi ube nobulukhuni bokugwinya izinto eziphuzwayo?

0(akwenzeki)   4(akuvamisile)   (kuvamisile)   10(njalo nje)

_____

2) Kuvame kangakanani ukuthi ube nobulukhuni bokugwinya ukudla okuqinile?

0(akwenzeki)   4(akuvamisile)   8(kuvamisile)   10(njalo nje)

_____

3) Kuvamise kangakanani ukuthi ube nobulukhuni bokugwinya izithelo ezingaphekwanga

0(akwenzeki)   4(akuvamile)   8(kuvamile)   10(njalo nje)

_____

4) Kuvamise kangakanani ukuthi ube nobulukhuni uma ugwinya inyama?

0(akwenzeki)   4(akuvamile)   8(kuvamile)   10(njalo nje)

_____

5) Kulukhuni kangakanani ukugwinya iziphuzo namanzi?

0(akulukhuni)   10(kulukhuni kakhulu)

_____

6) Kulukhuni kangakanani ukugwinya ukudla okuthambile?

0(akulukhuni)   10(kulukhuni kakhulu)

_____

7) Kulukhuni kangakanani ukugwinya izithelo ezingaphekwanga?

0(akulukhuni)   10(kulukhuni kakhulu)

_____

8) Kulukhuni kangakanani ukugwinya inyama?

0(akulukhuni)   10(Kulukhuni kakhulu)

_____

Ukuba nobuhlungu uma ugwinya [b]

9) Kuvamise kangakanani ukuthi ube nobuhlungu uma ugwinya okuphuzwayo njengamanzi?

0(akwenzeki)   4(kuqabuka nje)   8(kuvamisile)   10(njalo nje)

_____

10) Kuvamise kangakanani ukuthi uzwe ubuhlungu uma ugwinya ukudla okuthambile?

0(akwenzeki)   4(kuqabuka nje)   8(kuvamile)   10(njalo nje)

_____

11) Kuvamise kangakanani ukuthi ube nobuhlungu uma ugwinya iaithelo ezingaphekwanga?

0(akwenzeki)   4(kuqabuka nje)   8(kuvamile)   10(njalo nje)

_____

12) Kuvamise kangakanani ukuthi uzwe ubuhlungu uma ugwinya inyama?

0(akwenzeki)   4(kuqabuka nje)   8(kuvamile)   10(njalo nje)

_____

13) Kubuhlungu kangakanani ukugwinya uma ugwinya amanzi nezinye iziphuzo?

0(akubuhlungu)   10(kubuhlungu kakhulu)

_____

14) Kubuhlungu kangakanani uma ugwinya ukudla okuthambile?

0(akubuhlungu)   10(kubuhlungu kakhulu)

_____

15) Kubuhlungu kangakanani uma ugwinya izithelo ezingaphekwanga?

0(akubuhlungu)   10(kubuhlungu kakhulu)

_____

16) Kubuhlungu kangakanani uma ugwinya inyama?

0(akubuhlungu)   10(kubuhlungu kakhulu)

_____

Ubuhlungu besifuba [c]

17) Kuvamise kangakanani ukuthi uzwe izinhlungu esifubeni emva kokudla?

0(akwenzeki)   4(kuqabuka nje)   8(kuvamile)   10(njalo nje)

_____

18) Kubuhlungu kangakanani esifubeni emva kokudla?

0(akubuhlungu)   10(kubuhlungu kakhulu)

_____

Isilungulela [d]

19) Kuvamise kangakanani ukuthi ube nesilungulela (ukushisa okusesifubeni kusuka esiswini kudlulele emphinjeni)

0(angibi nasilungulela) 4(kuqabuka nje)   8(kuvamile)   10(njalo nje)

_____

20) Sikuphatha kangakanani isilungulela?

0(asingiphathi)   10(singiphatha kakhulu)

_____

Ukuvama ukubuyisa [e]

21) Uvamise kangakanani ukubuyisa(ukubuya kokudla osukugwinyile)

0(akwenzeki)   4(kuke kwenzeke) 8(Kuvanile ukwenzeka)   10(njalo nje)

_____

Izinga lokwehla kwesisindo somzimba [f]

22) Sehle kangakanani isisindo somzimba wakho kusukela ngesikhathi uqala ukugula?

0(asehlanga)   10(ngaphezu kuka 10 kg)

_____

Ukungasakwazi ukubamba iqhaza emphakathini njengakuqala [g]

23) Ngabe ukugula kwakho kuyiphazamise kangakanani indlela ojwayele ukuphila ngayo emphakathini?

0(akuzange)   4(kancane)   6(kakhudlwana)   10(akusavumi ngenze lutho)

_____

Ukungasakwazi ukusebenza [h]

24) Ukugula kwakho kukuphazamise kangakanani emsebenzini?

0(akuzange)   4(kancane)   6(kakhudlwana)   10(akusebenzeki)

_____

Ukweneliseka ngempilo yakho njengamanje [i]

25) Weneliseke kangakanani ngesimo sempilo yakho njengamanje.

0(ngeneliseke kakhulu)   10(angenelisekanga nakancane)

_____

a –Dysphagia-leligama lisho ukuba lukhuni kokugwinya, okwenza umuntu ezwe sengathi ukudla kubambeke emphinjeni.

b- Odynophagia- leligama lisho ukuzwa ubuhlungu ngesikhathi ugwinya

c-ubuhlungu besifuba kufanele ubuzwe emva kwethambo elihlanganisa izimbambo ngaphambili esifubeni. Lobuhlungu akubona obenzeka uma ugwinya kumbe okwenziwa isifo esenziwaa ukuncipha kwegazi enhliziyweni

d-Heartburn-Isilungulela usizwa ngokushisa okuzwa esifubeni; kusuka esiswini kunyuke kuze esifubeni nasemphinjeni.

e-Ukubuyisa kusho ukubuya kokudla osekusesiswini sekugayekile noma kungakagayeki kahle kubuyele emlonyeni kade sewukugwinyile.

f-Uma umuntu engazi ukuthi uselahlekelwe yisisindo esingakanani kunganikezwa isilinganiso njengokuthi nje bengigqoka ingubo engaka sengigqoka engaka.

g-Ukubamba iqhaza emphakathini kuyehlukana, kuye ngokuthi lowo muntu uphila impilo enjani; imifanekiso inganikezwa (enjengokudla ezindaweni ezidayisa ukudla noma ukudla nomndeni kumbe nabangani)

h-Ukungasakwazi ukusebenza ngendlela ejwayelekile kungasho ukuqashwa emsebenzini kanye /noma umsebenzi wasendlini.

i-Lokhu kufanele kukhombise sonke isimo sempilo ekahle, noma ukugula.

L

Appendix 10 : Results of unvariate regression analysis

GREYS DQOL vs. Gender

GREYS DQOL	Coeff	Std err	t	p>[t]	95% CI
Gender	8.31	4.74	1.75	0.08	-1.08-17.72
Cons	49.51	6.93	7.14	0.00	35.75-63.28

GREYS DQOL vs. Age

GREYS DQOL	Coeff	Std err	t	p>[t]	95% CI
Age	0.22	0.15	1.43	0.15	-0.08-0.54
Cons	47.77	9.68	4.94	0.00	28.55-66.99

GREYS DQOL vs. Level of education

GREYS DQOL	Coeff	Std err	t	p>[t]	95% CI
Level of education	-2.88	4.009	-0.72	0.47	-10.85-5.08
Cons	67.009	7.85	8.53	0.00	51.38-82.62

SF-36 vs. Level of education

SF-36 reciprocal	Coeff	Std err	t	p>[t]	95% CI
Level of education	-10.48	3.18	-3.29	**0.001**	-16.82- -4.14
Cons	88.51	6.24	14.17	0.00	76.09-100.93

DS vs. Level of education

DS	Coeff	Std err	t	p>[t]	95% CI
Level of education	-0.49	0.59	-0.82	0.41	-1.68-0.69
Cons	8.007	1.17	6.82	0.00	5.67-10.33

DS vs. Age

DS	Coeff	Std err	t	p>[t]	95% CI
Age	0.007	0.02	0.33	0.74	-0.03-0.05
Cons	6.60	1.42	4.64	0.00	3.78-9.43

DS vs. Gender

DS	Coeff	Std err	t	p>[t]	95% CI
Gender	-0.41	0.71	-0.58	0.56	-1.82-0.99
Cons	7.59	1.03	7.31	0.00	5.53-9.65

Appendix 11: Postgraduate approval

05 August 2009

UNIVERSITY OF
KWAZULU-NATAL

Professor S.R. Thomson
Department of Surgery
Nelson R. Mandela School of Medicine

Dear Professor Thomson,

PROTOCOL : A symptom – specific quality of life questionnaire for dysphagia.
MMedSci, Ferndale LC, Surgery

The Postgraduate Education Committee ratified the approval of the abovementioned
study on 02 June 2009

Please note:

- The Postgraduate Education Committee must review any changes made to this
  study.

- The study may not begin without the approval of the Biomedical Research
  Ethics Committee.

May I take this opportunity to wish the student every success with the study.

Many thanks
Yours sincerely,

Professor P. Moodley
Dean's Assistant : MMedSc & PhD
Postgraduate Education Committee
HD/FerndaleL

cc   Dr L.C. Ferndale
      P.O. Box 78151
      Avondale Road
      Morningside
      Durban
      4001

Appendix 12: Ethical approval

UNIVERSITY OF
KWAZULU-NATAL

RESEARCH OFFICE
Biomedical Research Ethics Administration
Westville Campus, Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za
Website: http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx

20 May 2010

Dr. Lucien Ferndale
Department Surgery
Nelson R. Mandela School of Medicine
University of KwaZulu

Dear Dr Ferndale

PROTOCOL: A quality of life questionnaire for dysphagia.REF: BE019/010

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application dated 22 January 2010.

The study was approved pending appropriate responses to queries raised. Your responses dated 13 May 2010 to queries raised on 18 February 2010 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 20 May 2010 for Grey's Hospital.

This approval is valid for one year from **20 May 2010**. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/ResearchEthics11415.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** at a full sitting of the Biomedical Research Ethics Committee meeting to be held on **08 June 2010.**

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor D.R Wassenaar
Chair: Biomedical Research Ethics Committee

LV