Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Department of Health and Rehabilitation Sciences
Divisions of Communication Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa.

A Masters study by dissertation in Speech Language Pathology
April 2015

Researcher: Nicoll Kenny
Supervisor: Associate Professor Shajila Singh
The copyright of this thesis vests in the author. No quotation from it or information derived from it is to be published without full acknowledgement of the source. The thesis is to be used for private study or non-commercial research purposes only.

Published by the University of Cape Town (UCT) in terms of the non-exclusive license granted to UCT by the author.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Acknowledgements

I would like to acknowledge the research site for allowing me the opportunity to gather data there in order to fulfil the aims of my study. The staff who work within the archive department at Chris Hani Baragwanath Academic Hospital were always friendly and most helpful in gathering files for me to review.

To my friends, and colleagues, in The Speech Therapy Department at Chris Hani Baragwanath Academic Hospital, particularly Dr. Sadna Balton, I am most grateful for your continued support throughout the process of my study.

I would like to acknowledge the constant guidance that I received from my supervisor, Associate Professor Shajila Singh. Without your continued support and guidance, both emotionally and academically, this research project would not have been possible. I appreciate the hours of work that you put into my project to ensure that it was of the best possible standard. Thank you for sharing with me the incredible knowledge that you have in the fields of adult dysphagia and research.

To my Dad, for always allowing me the opportunity to follow my passion and fulfil my dreams.

My family and friends who have been a constant support through the difficult times, praising me and encouraging me to keep going – I cannot put into words how much your support meant to me. You all played a part in pushing me to the end of this research project.

To my Aunt and Uncle, Shell and Miles, who edited my document. Thank you for the hours of work you put in and for your excellent eye for perfection and punctuation.

To my husband, Nicholas, thank you for your continued support and love over the entire process. For the constant reminders that I will succeed, that I am doing a great job and for the hours of chatting through various hurdles to help me to reach a solution. For the cups of tea delivered to my desk, for the dinners that you cooked whilst I worked and for the love you gave me throughout – Thank you.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Author’s Declaration

PLAGIARISM DECLARATION

I, Nicoll Kenny, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and have used the APA system of referencing.

I declare that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever

SIGNATURE:  

DATE: 1 April 2015
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Abstract

Objective: Patients with dysphagia, who are unable to meet their daily hydration and nutritional needs orally, may require enteral nutrition, either via a nasogastric tube (NGT) as a short term provision, or via a gastrostomy tube for longer term provision. The presence of dysphagia, specific medical conditions and the presence of comorbidities place patients, who require enteral nutrition, at risk for mortality. High rates of mortality are reported in international literature, in patients following the placement of long term enteral nutrition via percutaneous endoscopic gastrostomy (PEG). High mortality rates following the placement of enteral nutrition in patients treated by Speech Language Therapists (SLTs) at Chris Hani Baragwanath Academic Hospital (CHBAH) were noted anecdotally. No study has previously been done to analyse the outcomes and risks of the placement of enteral nutrition in the adult population with dysphagia in the South African context. This study aimed to compare survival times in patients with dysphagia, who had a single morbidity and multiple morbidities, who were recommended for enteral nutrition to those who were recommended for oral palliative nutrition, and the risks associated with a higher risk of mortality post placement of enteral nutrition. Design: The study employed an observational cohort design, using both retrospective and prospective methods. Three cohorts were included in the study. 1) Participants with multiple morbidities who were recommended for enteral nutrition (n=212), 2) Participants with a single morbidity who were recommended for enteral nutrition (n=35) and, 3) Participants who were placed on oral palliative nutrition (n=10). Results: A high rate or mortality was noted in all participants who were placed on enteral nutrition (regardless of it being NGT or PEG). Survival time was longer in participants with a single morbidity (54 days) compared to those with multiple morbidities (24 days) who received a PEG. Survival of participants with multiple morbidities who were on oral palliative nutrition, was only five days less (19 days) than participants with multiple morbidities who had a PEG placed. Mortality rates were high following the placement of enteral nutrition which could be attributed to the participants underlying medical condition and level of morbidities present. Conclusion: Findings of this study highlight the need for greater consideration of the risk factors that may place a patient at risk of mortality following the placement of enteral nutrition. It brings into question the futility of some PEG procedures in a cohort of participants that show such poor survival, and encourages clinicians to explore the option of oral palliative nutrition as a recommendation for patients who are expected to have a high risk of mortality if recommended for and placed with enteral nutrition.

Key words: dysphagia, enteral nutrition, mortality, multiple morbidities, single morbidity, oral palliative nutrition, South Africa
### Table of contents

<table>
<thead>
<tr>
<th>Sections</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>1</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>2</td>
</tr>
<tr>
<td>Author’s declaration</td>
<td>3</td>
</tr>
<tr>
<td>Abstract</td>
<td>4</td>
</tr>
<tr>
<td>Table of contents</td>
<td>5</td>
</tr>
<tr>
<td>List of tables</td>
<td>6-7</td>
</tr>
<tr>
<td>List of figures</td>
<td>8</td>
</tr>
<tr>
<td>List of appendices</td>
<td>9</td>
</tr>
<tr>
<td>Glossary</td>
<td>10-11</td>
</tr>
<tr>
<td>Introduction and Rationale</td>
<td>12-15</td>
</tr>
<tr>
<td>Research context</td>
<td>15-18</td>
</tr>
<tr>
<td>Literature review</td>
<td>18-31</td>
</tr>
<tr>
<td>Methodology</td>
<td>32-56</td>
</tr>
<tr>
<td>Results</td>
<td>57-71</td>
</tr>
<tr>
<td>Discussion</td>
<td>72-84</td>
</tr>
<tr>
<td>Limitations of the study</td>
<td>85-86</td>
</tr>
<tr>
<td>Implications for future research</td>
<td>86</td>
</tr>
<tr>
<td>Conclusion</td>
<td>86-87</td>
</tr>
<tr>
<td>References</td>
<td>88-110</td>
</tr>
<tr>
<td>Appendices</td>
<td>111-123</td>
</tr>
</tbody>
</table>
# List of Tables

<table>
<thead>
<tr>
<th>Tables</th>
<th>Title</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1</td>
<td>Early mortality rates post PEG placement in participants with various medical conditions in different countries globally</td>
<td>24</td>
</tr>
<tr>
<td>Table 2</td>
<td>Biographical information of participants</td>
<td>41</td>
</tr>
<tr>
<td>Table 3</td>
<td>Primary medical diagnosis of participants</td>
<td>42</td>
</tr>
<tr>
<td>Table 4</td>
<td>Data collection tool checklist</td>
<td>44</td>
</tr>
<tr>
<td>Table 5</td>
<td>Mode of intake recommended by a Speech Language Therapist and a medical Doctor</td>
<td>57</td>
</tr>
<tr>
<td>Table 6</td>
<td>Number of PEG tubes not placed after recommendation in participants with multiple morbidities versus a single morbidity</td>
<td>58</td>
</tr>
<tr>
<td>Table 7</td>
<td>The time lapse from assessment of a patient to the recommendations for enteral nutrition to the placement of it</td>
<td>59</td>
</tr>
<tr>
<td>Table 8</td>
<td>Primary medical condition of participants who were recommended for short and long term enteral nutrition</td>
<td>61</td>
</tr>
<tr>
<td>Table 9</td>
<td>Mortality rates of participants with multiple morbidities and a single morbidity who were recommended for short and long term enteral nutrition at different time points</td>
<td>62</td>
</tr>
<tr>
<td>Table 10</td>
<td>Mortality rate post PEG placement of participants with single and multiple morbidities</td>
<td>64</td>
</tr>
<tr>
<td>Table 11</td>
<td>Comparison of survival times between participants with multiple morbidities and a single morbidity who were received a PEG and participants who were placed on oral palliative nutrition</td>
<td>65</td>
</tr>
<tr>
<td>Table 12</td>
<td>Factors that place a patient at risk for mortality after NGT versus PEG placement</td>
<td>68</td>
</tr>
<tr>
<td>Table 13</td>
<td>Factors that place a patient with single and multiple morbidities at risk of mortality post PEG insertion</td>
<td>69</td>
</tr>
</tbody>
</table>
Table 14  The risk of mortality in patients with specific comorbidities after PEG placement
## List of Figures

<table>
<thead>
<tr>
<th>Figures</th>
<th>Title</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1</td>
<td>Indications for the recommendation of enteral nutrition in single and multiple morbidities</td>
<td>60</td>
</tr>
<tr>
<td>Figure 2</td>
<td>Kaplan Meier graph showing survival of patients who were fitted with an NGT post recommendation (green) and those not fitted post recommendation (blue)</td>
<td>63</td>
</tr>
<tr>
<td>Figure 3</td>
<td>Kaplan Meier graph comparing survival of patients fitted with an NGT (blue) or a PEG (green)</td>
<td>64</td>
</tr>
<tr>
<td>Figure 4</td>
<td>Kaplan Meier graph comparing survival of patients with multiple morbidities who were fitted with a PEG (blue) and those with a single morbidity who were fitted with a PEG (green)</td>
<td>66</td>
</tr>
</tbody>
</table>
### List of Appendices

<table>
<thead>
<tr>
<th>Appendices</th>
<th>Appendix Title</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Charlson Comorbidity Index</td>
<td>111</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Data collection tool</td>
<td>112</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Ethics approval letter from The Faculty of Health Sciences Human Research Ethics Committee at The University of Cape Town</td>
<td>113</td>
</tr>
<tr>
<td>Appendix D</td>
<td>Permission to amend the name of the study</td>
<td>114-115</td>
</tr>
<tr>
<td>Appendix E</td>
<td>Ethics approval letter from the internal ethics committee at Chris Hani Baragwanath Academic Hospital</td>
<td>116</td>
</tr>
<tr>
<td>Appendix F</td>
<td>Approval letter from the head of the Speech Therapy and Audiology Department to conduct research within the department</td>
<td>117-120</td>
</tr>
<tr>
<td>Appendix G</td>
<td>Approval letter from the head of the GIT department to conduct research within the department</td>
<td>121</td>
</tr>
<tr>
<td>Appendix H</td>
<td>Informed consent letter for participants to sign</td>
<td>122-123</td>
</tr>
<tr>
<td>Appendix I</td>
<td>Consent letter for participant’s family member or guardian to sign in the event that the participant cannot sign consent to participate in the study</td>
<td>124-125</td>
</tr>
</tbody>
</table>
Glossary

**Comorbidity:** A comorbidity refers to the presence of one or more disorders or diseases that co-occur with the primary medical diagnosis. In this research study an adjusted version of The Charlson Comorbidity Index was used to rate the level of comorbidity present within participants (Charlson, Pompei, Ales & MacKenzie, 1987).

**Enteral nutrition:** Throughout the document the term ‘enteral nutrition’ will refer to enteral tube feeding. The term ‘enteral nutrition’ is defined as “…the provision of nutrition into the stomach or small intestine and including both oral nutritional supplements and tube feeding” (Lochs et al., 2006), but it is acknowledged that in many research studies (Lochs et al., 2006) it refers to “tube feeding”.

**Long term enteral nutrition:** The provision of feeds via a tube placed in the stomach using the method of percutaneous endoscopic gastrostomy (PEG), which is the preferred method used at Chris Hani Baragwanath Academic Hospital (CHBAH). The method of long term tube placement via open gastrostomy was not used in this study population.

**Multiple morbidities:** A participant with multiple morbidities had a primary medical diagnosis along with two or more comorbidities, such as hypertension, diabetes, respiratory disease, renal disease, liver disease, paralysis or cardiac conditions. These participants had a high comorbidity score (>4) when calculated using The Charlson Comorbidity Index. The level was set at >4 (and not >5, which is noted as “high” in the Index) in accordance to a study that used the same method to assess morbidity in participants following PEG placement (Kobayashi, Cooper, Chak, Sivak & Wong, 2002).

**Oral palliative nutrition:** This refers to the approach that was used if a participant was noted to have a large number of risk factors that would place them at risk for mortality following the placement of enteral nutrition. Instead of being recommended for enteral nutrition, these participants were counselled about maintenance of hydration and nutrition in the safest way and were left on oral intake as a form of palliation.

**Short term enteral nutrition:** The provision of feeds via a nasogastric tube (NGT).

**Single morbidity:** A participant with a single morbidity had a single medical condition with no co-occurring morbidities. Examples of a single morbidity within the study population...
were: 1) head and neck cancer, 2) a traumatic brain injury, and 3) a hypoxic injury as a result of cardiac arrest whilst on the operating table for a caesarean section.
Introduction and Rationale

Whilst working in the adult wards at Chris Hani Baragwanath Academic Hospital (CHBAH) for two years, a high mortality rate was noted by a Speech Language Therapist (SLT) in the patient population receiving long term enteral nutrition. These patients had various medical conditions and had been assessed by an SLT and were diagnosed with dysphagia which prevented them from being able to take nutrition or hydration orally. The SLT began a search of current literature to determine if high mortality in populations fitted with long term enteral nutrition was specific to the population at CHBAH, or if it was a global trend. A large amount of literature documenting high mortality rates in patients fitted with long term enteral nutrition, and the risk factors associated with mortality, was found from a number of studies across the world (Abuksis, Mor, Plaut, Fraser & Niv, 2004; Blomberg, Lagergren, Martin, Mattsson & Lagergren, 2011; Gumaste, Bhamidimarri, Bansal, Sidhu, Baum & Walfish, 2014; Gundogan, et al, 2014; Grant, Rudberg & Brody, 1998; Ha & Hauge, 2003; Johnston, Tham & Mason, 2008; Kobayashi et al., 2002; Kurien, McAlindon, Westaby & Sanders, 2010; Laskaratos et al., 2013; Lee et al., 2013; Malmgren, Hede, Karlstrom, Cederholm, Lundquist, Wiren & Faxen-Irving, 2011; Nair, Hertan & Pitchumoni, 2000; Poulose, Kaiser, Beck, Jackson, Nealon, Sharp & Holzman, 2013; Prosser-Loose & Paterson, 2006; Richards, Tanikella, Arora, Guha & Dekovich, 2013; Richter-Schrag, Richter, Ruthmann, Olchewski, Hopt & Fischer, 2011; Smith, Perring, Engoren & Sferra, 2008; Smoliner, Volkert, Wittrich, Sieber & Wirth, 2012; Zopf, Maiss, Konturek, Rabe, Hahn & Schwab, 2011). The risk factors included the presence of certain medical conditions, a high rate of comorbidities, age over 60 years, a blood albumin level of lower than or equal to 35 g/L and a body mass index (BMI) of lower than or equal to 18.5 kg/m² (Abuksis et al., 2004; Grant et al., 1998; Ha & Hauge, 2003; Johnston et al., 2008; Kirchgatterer et al., 2007; Malmgren et al., 2011; Poulsen, 2009; Richter-Schrag et al., 2011; Smith et al., 2008; Smoliner et al., 2012; Zopf et al., 2011).

Late in 2012 the Speech Therapy team working with the adult population at CHBAH, reviewed and modified the SLT criteria for the recommendation of long term enteral nutrition based on current literature. The reviewed criteria was implemented in January 2013.
Criteria for recommendation of PEG before research into risk factors for mortality post placement (pre 2013)

Any patient with dysphagia who was assessed by an SLT and was found to be unable to take nutrition and hydration orally were recommended for enteral nutrition. In some cases long term enteral nutrition, via percutaneous endoscopic gastrostomy (PEG), was recommended after the first assessment. The indications for the recommendation of enteral nutrition included patients who had dysphagia affecting ability of oral intake, patients who were unresponsive on assessment, due to decreased levels of arousal, and patients who refused oral intake, often due to the presence of dementia or reduced cognitive ability.

The decision to recommend either short or long term enteral nutrition was made by the SLT who assessed the patient. Short term enteral nutrition was recommended if a patient had recently been admitted to hospital, was in the acute stages of illness and the SLT determined that the patient would benefit from therapy to remediate the dysphagia, and would not require tube feeds for a long period. Long term enteral nutrition was recommended if a patient had already been on short term enteral nutrition for a period longer than 4 weeks at the time of assessment by an SLT, if a patient had decreased arousal for several days or weeks, making an assessment by an SLT impossible or if a patient had shown limited or no progress in therapy that aimed to remediate dysphagia.

When referring patients for long term enteral nutrition, an SLT considered only the patients inability to take nutrition and hydration orally for an extended period. Aspects like patient age, current nutritional status, medical condition and prognosis, and how these may affect patient survival after the placement of long term enteral nutrition, were not considered in the decision making process.

Criteria for the recommendation of PEG when risk factors leading to mortality post placement were considered before a recommendation was made (2013- present)

In line with current literature (Abuksis et al., 2004; Blomberg, Lagergren, Martin, Mattsson, & Lagergren, 2012; Ha & Hauge, 2003; Johnston et al., 2008; Kobayashi et al., 2002; Malmgren et al., 2011; Nair et al., 2000; Prosser-Loose & Paterson, 2006; Richards et al., 2013; Richter-Schrag et al., 2011; Smith et al., 2008; Smoliner et al., 2012; Zopf et al., 2011) the decision to refer a patient for the placement of long term enteral nutrition changed to take into consideration many aspects that were not previously considered. A patient would only be
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

considered and recommended for PEG placement if they were expected to have a good prognosis for survival post placement (Abuksis et al., 2004). Risk factors that may increase the chance of mortality post placement of PEG were considered and if a patient fell into a high risk category then they were not referred for the procedure (Johnston et al., 2008; Zopf et al., 2011). Risk factors included an age over 60 years, a BMI lower than 18.5 kg/m², decreased nutritional intake during the period of hospitalisation, medical diagnosis and the presence of comorbidities, such as diabetes, cardiovascular disease and respiratory difficulties.

Patients who were considered high risk and therefore not appropriate candidates for long term enteral nutrition were counselled by an SLT, with their family members, on the option of oral nutrition, with the possible risk of aspiration and/or inadequate intake, as an alternative to PEG placement which carried significant risk of mortality post placement due to the patients existing risk factors. These patients were discharged from the hospital or from Speech Therapy services on what was termed “oral palliative nutrition”. This term refers to the intake of patients who had oral pharyngeal phase dysphagia and/or inadequate intake on oral feeds but who had a poor prognosis and for whom PEG would have been a futile procedure. Instead of aggressive intervention with the placement of a long term feeding tube, these patients were recommended for a palliative approach to feeding intervention, with supported education on maintenance of hydration and nutrition and safety via oral intake.

The aim of this research was to compare two different approaches, used by SLTs working at a tertiary level hospital in South Africa, around the recommendation of method of intake in patients with dysphagia who had multiple morbidities. Survival times were analysed to determine which approach yielded the best result for the patient, so that an SLT could be better informed of aspects to consider when recommending a method of intake within this population, to ensure highest survival time. It was an intention of the researcher, that the results of this study be considered in the creation of a protocol that can be used by SLTs, in a hospital setting, when recommending enteral nutrition for patients with oral pharyngeal dysphagia, to ensure best outcomes for patients.

An SLT is not the only professional who can recommend enteral nutrition for a patient with dysphagia. In many cases a medical Doctor will do this, without referral to an SLT for assessment and management. This study included a group of patients with a single morbidity, with dysphagia, who were referred for enteral nutrition by a medical Doctor, but were never
assessed or managed by an SLT. The reason for the inclusion of this group of patients was to compare the survival times of patients with dysphagia, with a single morbidity versus multiple morbidities, who were recommended for different types of intake (NGT, PEG and oral palliative intake), in order to inform decisions for the recommendation of method of intake for patients with dysphagia.

Research Context

In order for the reader to understand the context of the study it is necessary for the researcher to provide information about the setting in which the study was conducted as well as the processes within the hospital with regards to referral criteria and treatment methods for patients with dysphagia.

CHBAH is a tertiary level hospital situated in Soweto in the Province of Gauteng and is financed by the Gauteng Provincial Government. It is the largest hospital in Africa with 2800 beds and over 4690 staff members. A tertiary level hospital by nature is expected to receive referrals from provincial hospitals and provide services based on speciality and not geographical location (Mohapi & Basu, 2012). CHBAH serves the population of Soweto but also offers services to patients from many different districts and provinces, due to its availability of specialised services.

South Africa is unique to other countries in that it has a quadruple burden of disease with its death and disability attributable to four areas; 1) Communicable/maternal/perinatal/nutritional diseases, 2) Non-communicable diseases, 3) Injuries and 4) Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) (Bradshaw et al., 2002). Communicable, nutritional diseases, non-communicable, injuries and HIV/AIDS all play a large role in the presentation of adult patients with dysphagia who are admitted to tertiary level hospitals in South Africa and require assessment and treatment by an SLT.

A SLT working within the South African context will play a role in the rehabilitation of people who fall into the various categories of burden of disease. Dysphagia can result from many different disease categories and is commonly assessed and managed by the SLT, with recommendation for enteral nutrition commonly made.
A patient who is suspected of having dysphagia will be referred to an SLT by another health care provider, for example, the medical doctor, nurse, or a member of the allied medical team. The SLT will assess and manage the patient and recommend either oral or non-oral intake. If a patient requires short term enteral nutrition then the SLT will discuss the option with the patient and note it in the. A medical doctor or a nurse is responsible for placement of a nasogastric tube (NGT). A referral will then be made to a dietician for further enteral nutrition follow up.

A recommendation of an NGT or a PEG did not necessarily result in the placement of one. Reasons for non-placement are discussed as part of the study results. The primary method of enteral nutrition which is being recommended is documented in the hospital file by the professional who makes the recommendation. A patient who is referred for PEG will have an NGT placed as an interim measure to provide hydration and nutrition whilst awaiting PEG placement. Such a patient could then be noted as having been recommended for both NGT and PEG.

If long term enteral nutrition is recommended by the SLT, it will be documented in the hospital file and discussed with the patient and medical doctor. If the patient consents to the placement of long term enteral nutrition, the medical doctor will organise with the gastroenterologist for the patient to be booked onto the procedure list. The most common method of placement of long term enteral nutrition at CHBAH is via a PEG. If a patient has anatomical abnormalities that make a PEG impossible then there is referral for a gastrostomy.

Patients who were assessed and managed by Speech Therapy at CHBAH had multiple morbidities, which refers to the co-occurrence of two of more medical conditions (Whitson & Boyd, 2014). These can include hypertension (HPT) and diabetes, cardiovascular disease, respiratory disease, malnutrition, hemiplegia, HIV/AIDS, tumours, lymphoma, liver disease, renal failure and psychiatric disorders (Quan et al., 2005).

The Charlson Comorbidity Index (Appendix A) is a measure of comorbidity and the effects thereof on a patient’s survival rate after a medical procedure. It is used in many institutions as a method to determine if a particular form of aggressive intervention, such as a surgery, is
indicated and justified in a patient according to their comorbidities. Patient comorbidity is scored according to the effect the comorbidity will have on survival. The cumulative score is classified into mild, moderate or high risk with a score of equal to or over five being considered high risk (Charlson et al., 1987). The age adjusted Charlson comorbidity scale takes a patient’s age into consideration when it calculates a risk score, as age is noted to have a direct effect on survival. Kobayashi et al. (2002) used an adapted Charlson comorbidity scale to determine the appropriateness of referral for PEG placement and set their level of high risk to a score equal to or above four. Patients with a score equal to or higher than four had an increased risk of mortality post-surgical procedure. The scale is not used at CHBAH as a standard measure when assessing the appropriateness of a recommendation for a PEG, but it was used as a tool within this study as it was noted to be valuable in categorising high risk patients in the study by Kobayashi et al. (2002).

Important to note are the different applications of The Charlson Comorbidity Index that this study used. In this study the primary medical diagnosis of the participant was not included in the scoring of morbidity on the Charlson Comorbidity Index. Only concomitant disorders were noted as comorbidities. For example: on the index, a score of “6” is given to a patient with a cancer, but in this study a participant who had head and neck cancer and no other comorbidities was not given a score of “6” but was rather classified as having a single morbidity. Another point to note is the inclusion of HIV/AIDS as a morbidity on the index. The original Charlson Comorbidity Index which was developed in the 1980s and attributed a high score to persons with HIV/AIDS. The reason for the high score was due to the high rate of mortality in persons with HIV/AIDS at that time. There has been a greater survival rate in this population due to the introduction of antiretroviral medications, so it is argued that the scoring on the Charlson Comorbidity Index, for these patients, should be adjusted as they now have an improved prognosis (Zavascki & Fuchs, 2006). The researcher agrees with this suggestion, but as it is not suggested what score should now be attributed to patients with HIV/AIDS, the researcher decided to omit the inclusion of HIV/AIDS as a comorbidity in this study.

The change in criteria for which patients were referred for long term enteral nutrition, made by the Speech Therapy Department at CHBAH and implemented in January 2013, introduced the option of “oral palliative nutrition”. A patient with dysphagia who was considered to have a poor chance of survival post PEG insertion, because of the presence of risk factors which
increased their chance of mortality, could now be offered an option other than enteral nutrition as a method of intake. Literature refers to patients who deferred PEG placement until they were well enough to undergo the procedure when a positive outcome was expected (Abuksis et al., 2004). Under the revised criteria that was implemented by the Speech Therapy Department at CHBAH, a patient did not defer PEG placement, as they never came back in the future for placement, but rather were recommended for “oral palliative nutrition” and managed with supportive education on maintaining hydration and nutrition in the safest way considering their diagnosis of dysphagia.

Patients who were referred for enteral nutrition by a medical Doctor typically had a single morbidity. The main medical diagnosis in this cohort was head and neck cancer, with the remaining conditions including trauma as a result of traumatic brain injury (TBI), a single case of a degenerative neurological disorder and three cases where patients had a hypoxic episode in theatre as a result of cardiac arrest and were unconscious for a period afterwards and were subsequently recommended for and received a PEG. None of these patients had co-occurring medical conditions and were hence classified as having a single morbidity.

**Literature Review**

Enteral feeding is defined as the provision of nutrition into the stomach or small intestine and includes both oral nutritional supplements and tube feeding (Lochs et al., 2006). It is acknowledged that many research studies refer to enteral nutrition only as tube feeding (Lochs et al., 2006), which is the definition that will be used in this study. Provision of enteral nutrition can be is indicated for a number of reasons. Patients who need optimal hydration and nutrition in order to meet daily nutritional requirements, but are unable to gain this orally due to the presence of oral or pharyngeal phase dysphagia as a result of their medical condition, will require enteral nutrition (Bankhead et al., 2009; Blomberg et al., 2012; DiBaise & Scolapio, 2007; Erdil, Saka & Ates, 2005; Gundogan et al., 2014; Holmes, 2011; Sharp & Shega, 2009; Vivanti, Campbell, Suter, Hannan-Jones & Hulcombe, 2009). This would include patients who are unable to swallow due to neurological damage or degeneration (DiBaise & Scolapio, 2007; Kobayashi et al., 2002; Nicholson, Korman, & Richardson, 2000; Paramsothy, Papadopoulos, Mollison & Leong, 2009; Prosser-Loose & Paterson, 2006; Rio et al., 2010; Stroud, Duncan & Nightingale, 2003), or those who have structural abnormalities that make oral nutrition impossible, as in the case of patients with
advanced stage head and neck cancer or oesophageal cancer (Baldwin et al., 2011; Nguyen et al., 2006; Wermker, Jung, Huppmeier & Kleinheinz, 2012). Patients with head and neck cancer may also be at risk for developing dysphagia after treatment as a result of tissue damage to the swallow mechanisms from radiation (Wermker et al., 2012) and may be recommended for prophylactic PEG placement (Nguyen et al., 2006). Patients with head and neck cancer may be able to receive oral nutrition, but may also require enteral nutrition as a supplement to oral intake to ensure sufficient intake of daily nutritional requirements when receiving radiotherapy (Wermker et al., 2012). In the cases of trauma to the body, or after surgery, enteral nutrition is also recommended to aid with sufficient caloric intake to minimise loss of body fat and aid recovery (de Aguilar-Nascimento, Bicudo-Salomao, & Portari-Filho, 2012; Darbar, 2001; Hartl, Gerber, Quanhong & Ghajar, 2008; Stroud et al., 2003; Vassilyadi, Panteliadou, & Panteliadis, 2013; Vizzini & Aranda-Michel, 2011).

Patients with certain medical conditions are more likely to require enteral nutrition because of concomitant dysphagia or increased nutritional needs. The most common indicator for long term enteral nutrition is cerebral vascular accident (CVA), as noted in many studies with sample sizes varying between 42 and 1041 (Blomberg et al., 2012; Erdil et al., 2005; Janes, Price & Khan, 2005; Kirchgatterer et al., 2007; Kobayashi et al., 2002; Lee et al., 2013; Malmgren et al., 2011; Nicholson et al., 2000; Paramsothy et al., 2009; Richter-Schrag et al., 2011; Smith et al., 2008; Smoliner et al., 2012; Thomson, Carver, & Sloan, 2002). Dysphagia with resulting malnutrition and/or dehydration is common in patients who have had a CVA, explaining the high need for enteral nutrition within this population (Crary Humphrey, Carnaby-Mann, Sambandam, Miller & Silliman, 2012; Kobayashi et al., 2002; Prosser-Loose & Paterson, 2006; Sura, Madhavan, Carnaby & Crary, 2012). Patients with other neurological deficits, such as those with traumatic head injury or neuro-degenerative diseases, may also require short or long term enteral nutrition as a safe method to gain hydration and nutrition (Darbar, 2001; Denes, 2004; Hartl et al., 2008; Holmes, 2011; Vizzini & Aranda-Michel, 2011; Zhang, Sanders & Fraser, 2012).

There are different methods of enteral nutrition, each with specific indicators, benefits and challenges. The route of enteral nutrition chosen is determined according to the length of time for which enteral support is required and the type of enteral support needed for a specific patient. The different types of enteral nutrition available are nasogastric tubes (NGTs), nasojejunal tubes (NJT), gastrostomy tubes (GTs) and jejenostomy tubes (JT), percutaneous endoscopic gastrostomy (PEG) or percutaneous endoscopic jejenostomy (PEJ).
Before the development of percutaneous endoscopic placement of feeding tubes by Gauderer & Ponsky in the early 1980s, the procedure to place a tube had to be done under general anaesthetic. PEG has now become the most popular form of placement of tubes for the provision of long term enteral nutrition because of the ease of insertion which is minimally invasive and does not require general anaesthetic (Laskaratos et al., 2013; Swaminath, Longstreth, Runnman & Yang, 2010; Wilhelm, Ortega & Stellato, 2010). A surgical gastrostomy may still be performed in cases where PEG is not possible due to obstruction which makes the passing of the scope down the gastrointestinal tract impossible (McClave & Chang, 2003). Higher complication rates after the placement of a feeding tube via open gastrostomy were noted (Dwyer, Watts, Thurber, Benoit & Fakhry, 2002; Moller, Lindberg & Zilling, 1999) when compared to the complications post placement of a PEG. These complications included, internal leakage, peritonitis, fistula, dislodgement, external leakage and skin infection. Higher mortality rates were noted in patients who had a surgical gastrostomy performed (29%, n=35) versus those who had a PEG (17%, n=12), although differences in mortality between the groups were not significant (Moller et al., 1999).

The provision of nutrition into the stomach via NGT or gastrostomy/PEG is common (Erdil et al., 2005; Lee et al., 2013), but gastrointestinal intolerance of tube feedings, which are identified by the presence of large gastric residual volumes, nausea and vomiting, ileus, abdominal distension, and diarrhoea (MacDougall, 2010) is a major factor limiting adequate enteral intake in patients. In cases such as these the stomach may be bypassed and nutrition delivered to a lower part of the gastrointestinal tract (Codner, 2012; DiBaise & Scolapio, 2007; McClave & Chang, 2003). Benefits of NJT/PEJ feeding include an improvement in energy intake due to improved absorption in the small bowel and a decreased risk of reflux related aspiration due to feeds being delivered into an area further away from the pharynx (Hsu et al., 2009). This benefit however is not noted in all literature with no difference in energy intake and risk of aspiration between NGT and NJT fed patients noted by Davies et al. (2012).

The benefits within various groups of patients of early enteral nutritional have been documented (Davies et al., 2012; Doig, Heighes, Simpson & Sweetman, 2011; Lu, Huang, Yu, Zhu, Cai, Gu & Su, 2011; Silva et al., 2013). It is recommended that for the delivery of early enteral nutrition, the placement of NGTs be utilised in the acute stages of disease (Bankhead et al., 2009; Dziewas et al., 2002; Kobayashi et al., 2002; Maitines, Ugenti, Memeo, Clemente & Lambrenghi, 2009; Prosser-Loose & Paterson, 2006). NGTs are
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

NGTs have benefits in that they are easy to insert and require no surgical procedure or administration of anaesthetics for placement (Gomes, Lustosa, Matos, Andriolo & Waisberg & Waisberg, 2012; Kobayashi et al., 2002; Rio et al., 2010) however they have many known associated risks. They are poorly tolerated by patients and are often pulled out after insertion, which reduces the nutritional advantage which was the aim of placement (Beavan et al., 2010; Kim, Stotts, Froelicher, Engler, Porter & Kwak 2012; Roy, Person, Souday, Kerkeni, Dib & Asfar, 2005). NGTs are often placed incorrectly by the professional inserting them, with incidence reported to be 0.3-27%, as cited in Hegde & Rao (2010). A misplaced NGT can result in aspiration pneumonia which can be fatal (Hegde & Rao, 2010). Patient positioning during NGT feeding can also result in aspiration pneumonia with most hospitalized patients being in a sedated state or lying flat when feeds are given via the NGT (Dziewas et al., 2004; Mizock, 2007). An increase in reflux with NGT placement is noted (Gomes et al., 2012; McClave & Chang, 2003) particularly if patients had pre-existing gastro-oesophageal reflux (GOR) (Jung et al., 2011). Similar negative effects are noted with the use of PEGs with no difference in complications from NGT versus PEG (Gomes et al., 2012).

If a patient requires enteral nutrition for a period longer than 4-6 weeks, and their prognosis justifies the intervention, placement of a long term tube for the provision of enteral nutrition should be recommended (Abuksis et al., 2004 Janes et al., 2005; Johnston et al., 2008; Rio et al., 2010) in the form of a gastrostomy or PEG tube. There are some contrasting views, however, with one study suggesting waiting for a period of at least 6-8 weeks with an NGT in situ, before considering insertion of a PEG to ensure a better prognostic outcome (Maitines et al., 2009). Others do not consider time as a factor, in the decision to recommend long term enteral nutrition, but rather the prognosis of the patient and argue that a patient in the end stages of disease should not be considered for PEG but should rather receive nutrition via NGT (Rio et al., 2010).

The placement of a PEG for the provision of enteral nutrition is considered a life-saving procedure in some cases (Anis et al., 2006; Jordan, Philpin, Warring, Cheung & Williams, 2006) and many patients who have a PEG attest to this fact and the benefit that PEG feeding
provides them (Anis et al., 2006; Osborne, Collin, Posluns, Stokes & Vandenbussche, 2012). One study noted particularly positive patient reports on their experiences living with a PEG tube, with 84% (N=51) noting a positive or neutral effect of the tube on their lives, 90% (N=51) expressing a view that the tube was worthwhile and 96% (N=51) noting that they would recommend it to another patient (Osborne et al., 2012).

Negative experiences of patients who have a PEG tube and the negative impact that a PEG has on a patient's quality of life, are extensively reported on in the literature. Common difficulties associated with having a PEG tube, which affect quality of life, include a high level of complication, like tube blockage, leakage and discomfort (Rogers, Thomson, O’Toole & Lowe, 2007), interference with family life, social activities and hobbies (Brotherton, Abbott & Aggett, 2006; Jordan et al., 2006; Martin, Blomberg & Lagergren, 2012; Rogers et al., 2007), interference with intimacy (Rogers et al., 2007), negative reactions from others (Brotherton et al., 2006), a burden placed on family or caregivers (Brotherton et al., 2006) and a feeling of missing out on meal times and food (Brotherton et al., 2006). Similar negative effects on quality of life are reported in patients who receive NGT feeds (Brotherton & Judd, 2007), but the majority of literature focuses on assessment of the quality of life of patients who receive enteral nutrition via a PEG because PEG is used for long-term delivery of enteral nutrition. A study in Taiwan noted that the majority of patients in Taiwan are discharged home on NGT feeds because of a refusal to have a PEG placed (Lin, Li & Watson, 2011). The reasons given for a refusal of PEG by the patient or their caregivers are concern over leakage and infection following a PEG, a worry that the patient is too old and frail to undergo an operation and a cultural belief that the patient will not die “whole” if they have a PEG in situ (Lin et al., 2011).

Despite the benefits that a PEG tube can provide a patient, such as improved nutrition and a longer survival time, quality of life is affected (Jordan et al., 2006). There is a need for health care professionals to counsel patients on the effects that a PEG tube will have on their quality of life (Rogers et al., 2007), by shifting the focus of management post PEG insertion to include social aspects and not only clinical needs (Brotherton et al., 2006).

PEGs, GTs and NGTs all have advantages and possible complications. The outcomes discussed in literature relate to mortality and improved nutrition. Adequate nutrition is closely linked to better results in medical outcomes and survival (Codner, 2012; Vassilyadi et al., 2013). PEG is noted to be superior to NGT with regard to improvement in general
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

medical outcomes (Gomes et al., 2012) with NGT candidates being statistically more prone to intervention failure, such as tube blockage or leakage, feed interruption and recurrent displacement, than patients who were fitted with PEG, regardless of the patient’s underlying medical condition (Gomes et al., 2012). With better provision of feeds when a PEG is used, better medical outcomes can be expected as a patient is more likely to receive adequate hydration and nutrition.

No difference was found in the rate of complications between NGT and PEG cohorts, with 42% (n=105) of patients with PEG and 42.68% (n=108) of patients with NGT experiencing complications post placement (Gomes et al., 2012). The rate of mortality that each group of patients faced post placement was not significantly different, with rates of 37.24% (n=105) and 35.71% (n=105) respectively in patients with PEG and NGT (Gomes et al., 2012). There was no difference in mortality rate (Azzopardi & Ellul, 2013; Gomes et al., 2012) or the occurrence of pneumonia post placement (Gomes et al., 2012). When patients who had a CVA were considered as a separate group from other medical conditions, neither NGT nor PEG were superior in the delivery of nutrition. The presence of dysphagia was the key indicator for mortality rather than the type of enteral nutrition used (Laskaratos et al., 2013).

There exists debate around which method of enteral intake is best suited for patients with head and neck cancer specifically. A large majority of patients with cancer are malnourished throughout the disease process and will require enteral nutrition (Sobani, Ghaffar & Ahmed, 2011). When considering which method of enteral nutrition to recommend in this patient population one needs to consider the benefits and drawbacks of both methods. In one study, PEG is noted to be superior to NGT as it resulted in greater weight gain and lower mortality (Sobani et al. 2011) but others note a lower clinical risk of complications, and a greater chance of returning to full oral feeds after a six month period, with patients left on NGT feeds rather than fitted with PEG (Sheth, Sharp & Walters, 2013). It is argued that a patient with an NGT will be more eager to feed orally in order to progress towards removal of the tube because of the visibility of an NGT, which can be unsightly to some. Beginning partial oral intake makes muscle atrophy less likely and speeds up the return to full oral intake, compared to those receiving nutrition exclusively via a PEG (Sheth et al., 2013).

Poor nutrition is linked directly to poor outcomes, specifically an increased rate of morbidity and mortality (Codner, 2012; Vassilyadi et al., 2013). It has been established through a review of various studies that a patient who is fed via a PEG has a lower chance of
intervention failure (Gomes et al., 2012), which is the failure to start tube feeds after a recommendation has been made. Intervention failures include non-adherence to tube usage, interrupted feeds, a blocked or leaking tube and misplacement of tubes (Gomes et al., 2012). All of these factors are commonly noted with the use of NGT (Kim et al., 2012; MacDougall, 2010). It then follows that a patient who is fed via a PEG will have less intervention failure, which will facilitate improved nutrition, which in turn improves clinical outcomes.

Factors other than improved nutrition need to be considered when comparing the outcomes associated with enteral nutrition via PEG and NGT. Gomes et al. (2012) noted no difference in mortality rates post insertion between patients with dysphagia, with varying medical conditions including neurological fallout and head and neck cancer, who received enteral nutrition via a PEG versus an NGT. When considering mortality as an outcome after PEG placement, its rate as a direct result of a PEG procedure is low (Blomberg et al., 2011; Nicholson et al., 2000). Mortality rate in the first few weeks post PEG is noted to be ‘high’ (Malmgren et al., 2011) with varying reports of percentages ranging between 10% and 36% depending on sample size and medical conditions included (Abuksis et al., 2004; Erdil et al., 2005; Ha et al., 2003; Johnston et al., 2008; Keung, Liu, Nuzhad, Rabinowits & Patel, 2012; Malmgren et al., 2011; Sanders, Carter, D’Silva, James, Bolton & Bardhan, 2000). In one study, patients with dementia were separated from the other medical conditions, and the 30 day mortality rate was high at 54% (Sanders et al., 2000). These 30 day mortality figures come from both developed and developing countries where a variety of medical conditions were included in the sample. When considering the time frames in which patients died post PEG placement, the largest majority died within the 30 day period, which is the reason that only this period is depicted in table one.
### Table 1: Early mortality rates post PEG placement in participants with various medical conditions in different countries globally

<table>
<thead>
<tr>
<th>30 day mortality rate (%)</th>
<th>Sample size (N)</th>
<th>Medical condition of participants</th>
<th>Country where the study was conducted</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.8%</td>
<td>359</td>
<td>Head and neck cancer (n=97) CVA (n=73) Malignancy (n=61) Head injury (n=59) Cerebral palsy (n=38) Congenital anomaly (n=19) Motor neuron disease (n=7) Dementia (n=5)</td>
<td>Bosnia Herzegovina</td>
<td>Vanis, Saray, Gornjakovic &amp; Mesihovic, 2012</td>
</tr>
<tr>
<td>22%</td>
<td>201</td>
<td>CVA (n=97) Malignant oesophageal obstruction (n=33) Dementia (n=16) Other neurologic disorders (n=13) Parkinsons (n=12) Other (n=23) Other malignancies (n=5)</td>
<td>Sweden</td>
<td>Malmgren et al., 2011</td>
</tr>
<tr>
<td>10%</td>
<td>77</td>
<td>Neurologic disorders (n=71) Head and neck cancer (n=6)</td>
<td>Turkey</td>
<td>Ermis et al., 2012</td>
</tr>
<tr>
<td>20%</td>
<td>128</td>
<td>CVA (n=34) Non neurologic cerebral hypoxia (n=30) Cranial tumour (n=23) Head and neck cancer (n=19) Motor neuron disease (n=13) Other (n=9)</td>
<td>Turkey</td>
<td>Gundogan et al., 2014</td>
</tr>
<tr>
<td>19%</td>
<td>83</td>
<td>CVA (n=83)</td>
<td>Norway</td>
<td>Ha &amp; Hauge, 2003</td>
</tr>
<tr>
<td>22%</td>
<td>112</td>
<td>CVA (n=33) Head and neck cancer (n=27) Chronic neurological disorders (n=22) Other (n=30)</td>
<td>Britain</td>
<td>Janes et al., 2005</td>
</tr>
<tr>
<td>18.5%</td>
<td>187</td>
<td>Malignancy (n=187)</td>
<td>America</td>
<td>Keung et al., 2012</td>
</tr>
<tr>
<td>36%</td>
<td>61</td>
<td>CVA (n=50) Dementia (n=21) Malignancy (n=9)</td>
<td>Israel</td>
<td>Abuksis et al., 2004</td>
</tr>
</tbody>
</table>
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Number (n)</th>
<th>28%</th>
<th>Country</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head and neck trauma (n=3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVA (n=120)</td>
<td>361</td>
<td></td>
<td>America</td>
<td>Sanders et al., 2000</td>
</tr>
<tr>
<td>Dementia (n=103)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oropharyngeal malignancy (n=65)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (n=73)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The reasons for high mortality rates need to be understood so that the rate can be lowered; literature notes one of the reasons to be poor patient selection. Patients with risk factors that place them at risk of mortality are being recommended for PEG, resulting in poor outcomes that are being linked to the PEG procedure, when in fact these patients were at risk of death regardless of PEG placement (Kurien et al., 2011; Richards et al., 2013). There is strong evidence linking certain underlying medical conditions to higher mortality post insertion (Abuskis et al., 2004; Erdil et al., 2005; Grant, Bradley, Pothier, Bailey, Caldera, Baldwin & Birchall, 2008; Johnston et al., 2008; Kurien et al., 2011; Laskaratos et al., 2013; Prouse et al., 2013; Schettler, Momma, Markowski, Schaper, Klamt, Vaezpour & Schneider, 2013; Stroud et al., 2003) with the highest mortality rate being in patients who had CVA and malignancies (Malmgren et al., 2011; Prouse et al., 2013).

The timing of PEG placement (Abuksis et al., 2000; Smith et al., 2008) is noted also to affect outcome. Many authors suggest a delay in the placement of long term enteral nutrition, for 30 days, to ensure a better chance of survival, leaving patients on short term enteral nutrition for a longer period (Abuksis et al., 2000; Smith et al., 2008). Mortality in patients with CVA usually occurs in the acute stage when a patient is still in hospital (Cowey, 2012). A patient who receives a PEG at this stage is at high risk of dying due to an underlying medical condition (Cowey, 2012), and will then reflect high mortality in the statistics of CVA patients fitted with PEG. Dysphagia is common with CVA (Cowey, 2012) but many CVA patients will regain their ability to swallow within two weeks post infarct (Westaby, Young, O’Toole, Smith & Sanders, 2010). The timing for placement of PEG in a patient with CVA is critical, and should only be considered if a patient has not regained their ability to swallow within four weeks and is no longer in the acute stages post onset (Kumar et al., 2012; Prosser-Loose & Paterson, 2006). During the acute stages post CVA, an NGT is recommended for the provision of hydration and nutrition (Prosser-Loose & Paterson, 2006).

Other risk factors that have been found to negatively influence post PEG insertion survival rates are noted in the literature, these include increased age, low BMI, low blood albumin.
levels, and a high number of comorbidities. Along with primary medical condition and timing of placement, these factors also need to be considered when recommending a patient for the procedure to decrease the chance of poor outcomes. One such risk factor is increased age; patients over the age of 60 were found, unanimously, to have the highest mortality rate at 30-days post insertion (Abuksis et al., 2004; Grant et al., 1998; Ha & Hauge, 2003; Johnston et al., 2008; Kirchgatterer et al., 2007; Malmgren et al., 2011; Poulsen, 2009; Richter-Schrag et al., 2011; Smith et al., 2008; Smoliner et al., 2012; Zopf et al., 2011). Age together with diminished mental capacity, as with patients who have dementia, tripled the short term mortality post placement (Malmgren et al., 2011), and cautions against PEG placement specifically in older patients with dementia.

Strong evidence links poor nutrition upon hospitalization with poor medical outcomes, such as greater incidence of morbidity and mortality (Codner, 2012; Koretz, Avenell, Lipman, Braunschweig, & Milne, 2007; Vassilyadi et al., 2013). Malnourishment is measured in the literature using the body mass index (BMI), with a BMI of <18.5 indicating malnutrition (WHO, 1995). Malnourishment can be as a result of the disease process or due to socioeconomic factors (Norman, Pitchard, Lochs & Pirlich, 2008) and can be further exacerbated by hospitalization (Codner, 2012; Johnston et al., 2008; Kim et al., 2012; Prosser-Loose et al., 2006; Shroud, Duncan, & Nightingale, 2003; Silva et al., 2013; Vassilyadi et al., 2013), because of interruptions in the provision of enteral nutrition for various reasons, inadequate nutrition prescribed and an inability of a patient, who may be on oral intake, to physically eat independently (Norman et al., 2008). Malnourishment at the time of PEG placement was a crucial factor noted to place a patient at risk for mortality following the placement of a tube for the provision of long term enteral nutrition (Abuksis et al., 2004; Azzopardi & Ellul, 2013; Blomberg et al., 2011; Janes et al., 2005; Johnston et al., 2008; Zopf et al., 2011).

Upon admission to hospital an NGT may be placed to improve nutrition before placement of a PEG (Blomberg et al., 2011). But NGT feeds can result in minimal improvement in nutritional status because of interrupted feeds when a patient goes for a procedure, late placement and commencement of feeds or accidental removal of tubes (Beavan et al., 2010; Kim et al., 2012; MacDougall, 2010). A nutritionally compromised patient would then benefit from placement of a PEG with the aim of improving nutrition, based on evidence that PEG placement facilitates better improvement in nutrition (Erdil et al., 2005; Sobani et al.,
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

2011). PEG placement, however, comes with a high risk of mortality due to the patient’s initial poor nutritional status.

Based on the high mortality rate of malnourished patients, research (Abuksis et al., 2004; Azzopardi & Ellul, 2013; Blomberg et al., 2011; Janes et al., 2005; Johnston et al., 2008; Zopf et al., 2011) suggests that it is important to consider the nutritional status of individuals prior to PEG insertion. A review of the literature on markers of a patient’s nutritional status suggests that albumin levels may be used as a marker of malnutrition (Pear, 2007). Albumin is a protein made by the liver, and is a measure of protein in the body. Albumin balances the amount of blood flowing through the body’s arteries and veins and helps to transport calcium, progesterone, bilirubin and medications through the blood. A serum albumin test will measure the amount of protein in the blood and can be used as an indicator of the presence of liver or kidney disease (Pratt, 2010) which can affect patient survival. Normal levels of albumin are considered to be in the range of 3.4-5.4 g/dL or 35-50 g/L, depending on how specific laboratories measure it. Literature has noted the link between low albumin levels pre-insertion of PEG and a high mortality rate post insertion (Blomberg et al., 2011). This link confirms that hypo-albuminaemia is a risk factor that should be considered in all patients being medically worked up for PEG placement (Azzopardi & Ellul, 2013; Blomberg et al., 2011; Johnston et al., 2008; Kurien et al., 2011; Nair et al., 2000).

Various co-morbidities like diabetes and cardiac disease were also noted to be significant risk factors for high mortality in patients post PEG insertion (Janes et al., 2005; Johnston et al., 2008; Kurien et al., 2011; Pear, 2007; Zopf et al., 2011).

Considering the multitude of risk factors that exist for poor outcome post PEG insertion, it follows that a patient should be individually assessed for the presence of any risk factors before being recommended for the procedure (O’Mahony, 2012; Playford, 2010; Tanswell, Barrett, Emm, Lycett, Charles, Evans & Hearing, 2007). A comprehensive assessment process by a multi-disciplinary team needs to consider factors such as: 1) the potential benefits to the individual should they receive a PEG, 2) biochemical parameters, like blood albumin level 3) multiple comorbidities, 4) patient prognosis, 5) and other existing risk factors that may place this patient at risk of mortality post procedure, like age over 60 years and a low BMI (Azzopardi & Ellul, 2013; Buscaglia, 2006; DeLegge, McClave, Disario & Baskin, Brown, Fang & Ginsberg, 2005; Ha & Hauge, 2003; Janes et al., 2005; Johnston et
al., 2008; Kobayashi et al., 2002; Longcroft-Wheaton, Marden, Colleypriest, Gavin, Taylor & Forrant, 2009; Richter-Schrag et al., 2011; Smoliner et al., 2012; Tanswell et al., 2007).

If a patient is considered a high risk candidate after the assessment process, then PEG should be avoided (Lee et al., 2013). In cases such as these a patient should be counselled appropriately on the available options and associated risks of each option of intake, including oral, NGT and PEG. A health care professional, either a medical Doctor, an SLT or a Dietician, can make a recommendation for enteral nutrition based on their knowledge but a cognitively intact patient must make the final decision after being fully informed about the benefits and risks involved in all the recommended management plans (DeLegge et al., 2005).

There are many ethical considerations that exist around patient care of any kind, like autonomy, beneficence, and non-maleficence. It is important to consider these when making a recommendation for enteral nutrition. Particularly important, when reflecting on the high mortality rate post PEG procedures, is the concept of futility (DeLegge et al., 2005). Futility refers to a medical intervention that would have no effect, or if there was an effect, it would not be one that the patient benefitted from (DeLegge et al., 2005). Many patients are fitted with tubes for the provision of long term enteral nutrition where no effect or benefit is proven in terms of nutritional improvement or survival (Johnston et al., 2008).

This is most particularly noted in the case of patients with advanced dementia being fitted with a tube for the provision of long term enteral nutrition (Goldberg & Altman, 2014; Sampson, Candy & Janes, 2009). In this population, literature notes that the placement of a PEG has no benefit to the patient and can actually lead to decreased survival due to the complications, such as aspiration, that result from the placement (DeLegge et al., 2005; Sampson et al., 2009). The use of long term enteral nutrition in patients with malignancy, with the aim of nutritional gain, needs to be questioned as literature notes no real nutritional gain in these patients post placement (Baldwin et al., 2011; Keung et al., 2012; Poulose et al., 2013).

Azzopardi & Ellul (2013) raise the point that, in certain patient populations, the insertion of a PEG will only prolong a life which is of poor quality and it needs to be determined through discussion whether this is ethical. Another consideration in South Africa particularly, is whether it is appropriate to perform futile procedures in resource stretched public hospitals (Naidoo, 2012). If a PEG is placed in cases where a patient has poor prognosis and is
considered high risk for mortality post PEG placement, the argument could be made that the resources should be spared and be used to provided procedures that will benefit other patients who are expected to have a lower mortality rate.

The use of protocols in patient care ensures that best practice, which is determined from literature, is adhered to. They are important documents to which health care professionals should refer to guide practice that will result in the provision of the best possible care (Heyland, Cahill, Dhaliwal, Sun, Day & McClave, 2010). Protocols for the assessment and management of patients with dysphagia who require enteral nutrition do exist (Bankhead et al., 2009; Loser et al., 2005; Westaby et al., 2010; Wilhelm et al., 2010) but do not include considerations like assessment of risk factors to justify the PEG procedure.

Although protocols exist (Bankhead et al., 2009; Loser et al., 2005; Westaby et al., 2010; Wilhelm et al., 2010), and knowledge around risk factors post PEG are known, adherence to protocols cannot be assumed. The presence of risk factors in patients does not always deter a health professional in making a recommendation for PEG placement, as is evident in the literature, which continues to reveal high mortality rates, despite the knowledge of risk factors and their effect on mortality (Johnston et al., 2008).

The decision to refer a patient for a PEG procedure includes many factors that need to be considered together to help clinicians make a recommendation that is in the best interests of the patient. The concept of palliative care needs to be introduced as a real alternative for patients who are not considered candidates for PEG placement due to the presence of risk factors that will put them at high risk for mortality post placement. Palliative care is defined as “…an all-encompassing approach to care that begins months or years before death” (World Health Organisation 2002). The provision of hydration and nutrition in end of life care is an area of debate and can become a highly emotional topic. It is suggested that the decision to place a feeding tube revolve around the basic principles of medical ethics (Delegge et al., 2005). Informed consent from an adult who is cognitively intact is imperative, and the benefits from the placement of enteral nutrition must outweigh the risk of the procedure, which should cause the patient no harm (Delegge et al., 2005).

In the case of many studies cited throughout this literature review, PEG placement does not always benefit the patient, and although the actual PEG procedure does not harm the patient, the risk of mortality post placement is high, which in turn is harmful to the patient. The choice of refusing a PEG and remaining on oral intake as a form of palliative care should be
made available to all patients and their family members, with provision of education and support for the decision they may make. The inclusion of a palliative care option for patients who do not wish to have a PEG placed as it would provide them with an alternative option, and it would also ensure that futile procedures are avoided which would uphold medical ethics.

Important to note are positive outcomes as a result of long term enteral nutrition, which should also guide decisions for recommendation. One such outcome post PEG placement, which is discussed in the literature, is the ability to return to oral feeding post placement. Return to oral feeding post PEG placement can occur in patient populations with a mixture of medical conditions depending on factors such as the presence of dysphagia, age, and the underlying medical condition that necessitated PEG placement (Ha & Hauge, 2003; Nguyen et al., 2006; Paramsothy et al., 2009). Factors identified in literature that determined a return to oral intake, were the ability to take some amount of nutrition orally at 3 and 6 months post PEG placement (Paramsothy et al., 2009), regression of the tumour that had originally caused dysphagia post chemo/radiotherapy (Nguyen et al. 2006; Paramsothy et al., 2009) and regaining of the swallow post CVA (Ha & Hauge, 2003; Paramsothy et al., 2009). In a population consisting of 70% (n=302) of patients who had CVA, Yokohama et al. (2009) identify a younger age, the absence of dysphagia and intervention by a speech therapist to regain the swallow pre PEG placement, as factors that contribute to a return to oral intake.

Based on a review of current and available literature, it can be noted that there are various risk factors that exist which place patients at high risk for mortality post placement of a PEG tube for the provision of long term enteral nutrition. South African specific literature, relating to the risk factors contributing to a high mortality rate post PEG placement, is lacking.

This study aims to comment on patient mortality post placement of different types of enteral nutrition (NGT and PEG) as well as patients who were on oral intake as an alternative to PEG placement. The outcomes of this South African specific population will be compared to international outcomes to comment on the practices around enteral nutrition and its recommendation. This study also hopes to contribute to the area of appropriate patient selection for PEG placement, using a South African specific population, in order to guide clinicians who work with patients requiring enteral nutrition within a South African context.
Methodology

Aims and Objectives

Three groups of adult participants with dysphagia were included in this study:

a. Participants with multiple morbidities on enteral nutrition (NGT or PEG) placement
b. Participants with multiple morbidities on oral palliative nutrition, instead of enteral nutrition
c. Participants with a single morbidity on enteral nutrition

The aim and objectives were:

1. In patients with dysphagia managed by a Speech Language Therapist and by a medical Doctor, to
   a. Describe the number of cases of the different modes of nutritional intake (i.e. oral, enteral (NGT or PEG tube) or a combination of tube and oral) that were recommended
   b. Determine whether there were any significant differences in the mode of intake recommendations between the three groups
   c. Determine whether there were any significant differences in the timing of placement of enteral nutrition (i.e. NGT and PEG tube) after it had been recommended
      - NGT - from time of SLT recommendation to placement
      - PEG – from time of SLT assessment to recommendation
      - PEG- from time of medical Doctor recommendation to placement

2. To compare the indications for a recommendation for short or long term enteral nutrition

3. To compare mortality outcomes for long and short term enteral nutrition
   i) Pre placement
   ii) One day
iii) One week  
iv) One month  
v) Three months  
vi) Six months post placement

4. To compare survival times  
i) Across different modes of nutritional intake  
a. Short term enteral nutrition (NGT)  
b. Long term enteral nutrition (PEG)  
c. Oral palliative intake  
i) Between single morbidity and multiple morbidities on long term enteral nutrition (PEG)

5. Determine which of the following were risk factors for mortality post placement of short and long term enteral nutrition  
i) Increased age  
ii) Low blood albumin levels  
iii) Decreased quantity or absent intake of hydration and nutrition prior to placement of long term enteral nutrition (including interrupted feeds if NGT was the primary route of intake pre PEG placement)  
v) Presence of two or more comorbidities  
v) Low body mass index at time of long term enteral nutrition placement

Research Design

Observational cohort study.

An observational cohort design was used for this study (Mann, 2003). Use of this type of study design allows the researcher to comment on outcomes post exposure to a variable (Mann, 2003). The outcome being studied is mortality, and the variable which participants are exposed to is short and long term enteral nutrition. The main aim of a cohort study is to compare the risk of a certain outcome to exposure to a variable (Thadhani & Tonelli, 2006), such as the risk of mortality following exposure to the variable of enteral nutrition. The aims
of this study include commenting on the outcome (mortality) of participants recommended for short and long term enteral nutrition, as well as determining the risk factors linked to mortality from exposure to short and long term enteral nutrition, which include increased age, decreased BMI, low albumin levels and comorbidities present. By using an observational cohort design the aims of the study are able to be fulfilled.

This type of design is observational in nature as the researcher observes outcomes as they happen and is not involved in directly manipulating a variable, as would be the case in an experimental design (Mann, 2003). A cohort study is best suited to a situation where it is believed that there is an association between an outcome and exposure to a particular variable (Carlson & Morrison, 2009) but where ethics do not allow for direct exposure of a participant to that variable (Mann, 2003). This design is best suited to this study as it would be unethical to either expose or deliberately not expose a patient to different types of enteral nutrition, or to deprive a patient of enteral nutrition, in order to study the differing outcomes.

There are two different types of cohort studies; retrospective and prospective. Retrospective cohort studies use data that has been collected previously for other reasons (Mann, 2003) and track a sample of people who have already been exposed to the variable. The aim is to document the experience of the participant from the time of exposure to a variable and follow them to note the outcomes that occur after exposure (Thadhani & Tonelli 2006). Retrospective data was included in this study because the researcher noted, anecdotally, that there were high mortality figures for patients recommended for, and fitted specifically with, long term enteral nutrition tubes.

It was necessary to review folders from the past, when risk factors for mortality post placement were not considered by the SLT who was making recommendations for long term enteral nutrition. This was done in order to be able to compare patient care in these patients to that of patients who were managed after a change in approach of recommendation for PEG. At the time that the researcher began the study the new approach to management of PEG recommendations, where risk factors were considered, had already been implemented. For this reason, data for the participants with multiple morbidities, who were assessed and managed by an SLT, was collected retrospectively as their management had already taken place.
Using a retrospective approach the data available to the researcher was recorded in the past, leaving the researcher with no control over the available data, which may have missing parts (Song & Chung, 2010). Data may be incomplete or missing parts relating specifically to the study question because it was not originally collected with the aims of the study in mind (Mann, 2003; Thadhani & Tonelli 2006. Missing data was a difficulty experienced by the researcher in respect of missing data on patient weight and height. BMI data was absent, which affected the ability to comment on decreased BMI as a risk factor in participants with multiple morbidities who received PEG placement.

Prospective cohort studies begin before the sample have been exposed to the variable and follow the sample for a period into the future, which allows for the researcher to make inferences about possible risk factors that may have affected outcome (Mann, 2003). It is possible to make similar comments with a retrospective cohort.

The reason that a prospective aspect was included in this study was because the researcher wanted to include, into the analysis of outcomes post recommendation for enteral nutrition, a comparison of participants with a single morbidity who were receiving PEG on recommendation of a professional other than an SLT. These participants had not yet been exposed to a variable and had no outcome recorded in a hospital file, making a retrospective data collection approach impossible. For the prospective part of this study, an aim of the research was to compare the outcomes of a group of participants who were managed under one approach to the recommendation of enteral nutrition to another group of participants who were managed under a different approach. Both of these approaches were implemented by the Speech Therapy Department at CHBAH for use when recommending patients for enteral nutrition. The two different approaches had already been, and were being used, at the time the research project was realised, so a retrospective approach was best suited to collect data for outcomes under these approaches. For the prospective part of this study, a further aim of the study was to compare these two participant groups who received care under two different approaches to a third group of participants who were not managed by an SLT using their approach for the recommendation of enteral nutrition, but were recommended for enteral nutrition by a medical Doctor with no consultation from an SLT.

When using a prospective approach for data collection, the researcher waits for outcomes to occur, and for the disease processes to run their course, in order to make inferences (Song & Chung, 2010). This can result in a lengthy and costly period of data collection as it is
necessary to allow for an appropriate amount of time for outcomes to occur (Thadhani & Tonelli, 2006). There were no monetary implications as a result of waiting for follow up periods to occur, but the follow up period did delay the process of statistical analysis and write up of results.

**Validity and Reliability**

**Internal Validity**

A study with high internal validity can state that changes seen in the results are as a result of exposure to a variable and not random or due to error (Carlson & Morrison, 2009). Components of internal validity that could be threatened in an observational study are selection bias, which includes loss to follow up, and confounding variables (Grimes & Schulz, 2002).

Selection bias can occur if the participants chosen are not inherently similar; in this case outcomes noted could then be attributed to differences in the participant and not the variable being observed (Grimes & Schulz, 2002; Gurwitz et al., 2005). To exclude selection bias the researcher must include participants who all possess similar characteristics and who are most representative of the population being studied (Gurwitz et al., 2005). Yu and Tse (2012) note that selection bias from the researcher’s point of view is not a difficulty as long as inclusion and exclusion criteria are clearly noted and all eligible participants are included. This study included participants with similar attributes; they all had various medical conditions that required the placement of enteral nutrition. Differences were present between participants, but were necessary as these differences were variables whose effects were being observed as an outcome. These included variables such as age, medical condition, BMI and comorbidities, and type of enteral nutrition received.

Loss to follow up can skew the results of a study if there are unequal drop outs between the groups within a study (Carlson & Morrison, 2009). Although retrospective data has already been documented, it is possible that a patient was not followed up in the medical file to the point at which the study aims require, because information was not originally documented with the study aims in mind and could therefore all relevant information for the study may not have been collected (Mann, 2003). The medical files accessed for this study documented all patient information and outcomes up until the point that the patient was discharged from hospital. After this point the patient was considered lost to follow up, and if mortality had not
occurred at the point up until discharge from hospital then mortality as an outcome could not be analysed in these participants. This was the case for 8 participants with multiple morbidities who had a PEG placed. After their PEG placement they were discharged from hospital and it is unknown whether they survived or not. In a prospective study there is risk of loss to follow up and it is an important factor to consider how to successfully follow up on participants (Yu and Tse, 2012). This study followed up participants at regular intervals for up to six months. By making regular contact with participants in a study, the potential for loss to follow up is minimised (Hunt & White, 1998).

Within a study, loss to follow up should not exceed 20% of the sample size or else it could affect results (Song & Chung, 2010). In this study 10% (2 participants, n=19) of the participants who had a single morbidity and were fitted with a PEG, were lost to follow up due to a disconnected phone when the researcher called at the three month follow up time. This is under the suggested percentage, so should not impact on results. In the cohort of participants with multiple morbidities who were fitted with a PEG, 66% (8 participants, n=12) were lost to follow up because they were discharged from hospital before an outcome was achieved. This is a large percentage of loss to follow up, and could affect results which is why it must be acknowledged as a major limitation of the study. The large loss to follow up in this cohort of participants occurred because the method of retrospective data collection was used. It was necessary to collect these participant’s data retrospectively in order to fulfil the aim of the study that looked at analysing the outcome of participants who were fitted with a PEG under one of the approaches for the recommendation of enteral nutrition, used by the Speech Therapy Department at CHBAH, which was an event that had already occurred at the time the study was realised.

Many participants passed away during the data collection period, but death was an outcome being measured in this study. It was not considered as a loss to follow up but rather a result that was documented and analysed as part of the study aims.

A study adheres to internal validity if there are no confounding variables, other than the independent variable, that could explain the outcomes observed (Polit & Beck, 2013; Singh, 2007). A confounding variable is one that can be linked to both the outcome and the exposure (Thadhani & Tonelli, 2006).
It is difficult to eliminate all confounding variables unless the study consists of a control group, in which case the researcher must comment on these variables in the write up of the results. Within this study, the patient’s underlying medical condition is a variable that is independent of the variable being measured (i.e., enteral nutrition), but it could affect outcome. Patients who receive the placement of long term enteral nutrition often die because of their underlying medical condition and not as a result of the PEG procedure (Poulose et al., 2013). An aim of the study is to comment on whether placement of long term enteral nutrition affects mortality, but a patient’s medical condition could affect mortality as well, making it a confounding variable. This confounding variable has been noted by the researcher and will be considered appropriately when interpreting the results.

**External Validity**

External validity refers to whether the results of a study can be inferred onto a general population (Carlson & Morrison, 2009). A study with a sample that is not representative will lack external validity (Carlson & Morrison, 2009). The sample for this study comprised of participants who had dysphagia due to an underlying medical condition and as a result may have received short or long term enteral nutrition. This population could exist anywhere in the world which make the results of this study largely transferable to a greater population.

Carlson and Morrison (2009) note that a common error leading to weak external validity is the inclusion of participants from only one institution or geographical area. This study collected data from only one hospital in Gauteng, South Africa. The hospital used, however, is a state hospital, and in South Africa 84% of the population access healthcare in state hospitals (Statistics South Africa, 2011). It is still uncertain though, whether the population accessing healthcare at CHBAH would be representative of the greater South African population, which could be noted as a limitation to the study. But the results of the study could still be applicable to patients in similar settings and who share similar characteristics to those included in the study.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

**Reliability**

Intra-rater reliability was established by the researcher collecting data from the same patient hospital file at two different times and ensuring a 95% level of accuracy (Dixon & Pearce, 2012). The patient hospital files were coded, by the researcher, by giving each patient a number, so that the researcher was blinded to the file and reviewed it one week later without access to the original data set. This process was repeated throughout the data collection period on every tenth file to ensure that the process of data collection remained the same throughout. After every ten files that the researcher reviewed, a break in collection would take place so that the researcher could go back and re-analyse the first of those ten files. It is noted that in most studies a random number of files for review are selected for reliability checks (Kimberlin & Winterstein, 2008; Yawn and Wollan, 2005). Every tenth file was reviewed and a 95.8% rate of reliability was achieved. Literature notes that 95% is an acceptable level of agreement for intra-rater reliability (Dixon & Pearce, 2012). The rate of agreement was calculated by doing a basic percentage calculation.

Other forms of reliability were not applicable to this study, and have therefore not been discussed.

**Participants**

There were three groups of participants included in the study:

- Participants with multiple morbidities on enteral nutrition (NGT or PEG) placement
- Participants with multiple morbidities on oral palliative nutrition, instead of enteral nutrition
- Participants with a single morbidity on enteral nutrition

**Inclusion Criteria**

Any adult patient (over 18 years of age) with dysphagia who was assessed and managed as an in-patient at Chris Hani Baragwanath Academic Hospital (CHBAH) and recommended for enteral nutrition by an SLT or a medical Doctor or for oral palliative nutrition by an SLT.

**Exclusion Criteria**

There are no exclusion criteria for this study
Sampling Method

Convenience sampling, which was used in the study, is a non-random method of sampling where participants all possess certain qualities that the researcher wishes to look at to fulfil the purpose of the study (Babbie, 2012). When using this type of sampling method, the researcher cannot ensure that every member of a population has the chance of getting selected, which could affect external validity (Johnson & Christensen, 2010). In this study, convenience sampling was the best possible method to use for both the retrospective and prospective part of the study. Specific criteria had to be fulfilled in order for participants to be able to take part in the study, in which case random assignment would not have been feasible because the researcher had to select participants with dysphagia, who had multiple morbidities and who had been referred for enteral nutrition under both approaches used by the Speech Therapy Department as well as participants who had a single morbidity and were referred for enteral nutrition by a medical Doctor.

Recruitment Strategy

Recruitment does not apply to participants whose data was collected retrospectively. The researcher accessed the names of patients who fulfilled the study criteria from Speech Therapy records where after their hospital records were obtained from hospital archives for review. The names of patients who were referred for PEG placement by a medical Doctor were obtained from the gastrointestinal (GIT) department booking diary prior to the date of PEG insertion.

Sample size

It is important in the planning of a study to determine the required sample size to ensure that the study will be worthwhile and reveal significant results, but also for it to be feasible and financially viable (Lenth, 2001). A data collection period of six months was indicated by the researcher, as it was deemed a sufficient amount of time to obtain an adequate sample of participants. All patients who were assessed and managed for dysphagia by Speech Therapy within a six month period were included into the study. This was a total of 313 patients. Of those only 257 were recommended for short and long term enteral nutrition, and were therefore included in the final sample for the study in accordance to the inclusion criteria.
A power analysis was done using G*Power 3.1.9.2 to determine a sample size that would ensure a well powered study. It was determined that a sample size of 252 would be sufficient.

The total sample size of the study was slightly bigger than the suggested sample size needed to ensure a sufficiently powered study. This ideal sample size identified includes the entire sample and not the individual cohorts of participants which were compared to each other. The small sample sizes in the individual cohorts could have affected the possibility of getting statistically significant results upon analysis.

There were 212 participants with multiple morbidities who were referred for short of long term enteral nutrition by an SLT or a medical Doctor and 10 participants with a multiple morbidity who were referred for oral palliative nutrition by an SLT and 35 participants with a single morbidity who were recommended for a PEG by a medical Doctor.

**Participant description**

<table>
<thead>
<tr>
<th>Participant group</th>
<th>Age (%)</th>
<th>Sex (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Under 60 years</td>
<td>Over 60 years</td>
</tr>
<tr>
<td>Participants with multiple morbidities on enteral nutrition</td>
<td>212</td>
<td>46.7</td>
</tr>
<tr>
<td></td>
<td>47.2</td>
<td>52.8</td>
</tr>
<tr>
<td>Participants with multiple morbidities on oral palliative nutrition</td>
<td>10</td>
<td>30</td>
</tr>
</tbody>
</table>
Participants with a single morbidity on enteral nutrition 35

For participants with multiple morbidities on enteral nutrition the mean age was 59.2 years with a range of 18-94. For participants with multiple morbidities on oral palliative nutrition the mean age was 55.7 years with a range of 25-78. For participants with a single morbidity on enteral nutrition the mean age was 49.4 years with a range of 18-71.

Table 3: Primary medical diagnosis of participants

<table>
<thead>
<tr>
<th>Primary medical diagnosis (%)</th>
<th>Neurological</th>
<th>Trauma</th>
<th>Non communicable diseases</th>
<th>Infectious diseases</th>
<th>Delirium and dehydration</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Group (n)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants with multiple morbidities on enteral nutrition</td>
<td>212</td>
<td>58.3</td>
<td>12.9</td>
<td>11.6</td>
<td>7.3</td>
<td>6</td>
</tr>
<tr>
<td>Participants with multiple morbidities on oral palliative nutrition</td>
<td>10</td>
<td>40</td>
<td>0</td>
<td>50</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Participants with a single morbidity on enteral nutrition</td>
<td>19</td>
<td>21.1</td>
<td>15.8</td>
<td>63.1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Note: For participants with a single morbidity on enteral nutrition n=19 and not 35 because the remaining 16 participants who died before PEG placement were not included in the participant description because these participant files were never reviewed by the
The mean Charlson Index score for participants with multiple morbidities on enteral nutrition was 6.32 (range: 2-13) and the score for participants with multiple morbidities on oral palliative nutrition was 5.9 (range: 5-10).

A breakdown of the medical conditions that appeared in each category is as follows:

Neurological: CVA, neurosurgical, TBI, degenerative diseases (including dementia and motor neuron disorders)

Trauma: Ingestion, external trauma to the head or body (gunshot wound or stab wound).

Non communicable diseases: Head and neck cancer, malignancy.

Infectious diseases: RVD encephalopathy, Tuberculosis meningitis (TBM), meningitis.

Delirium and dehydration: No clear medical diagnosis given except for “delirium and dehydration”.

Other: gastrointestinal disease, cardiac condition, sepsis, renal failure, hypoglycaemia, pancreatitis, anaemia, metabolic disorder.

The categories were made with consideration of the South African Burden of Disease profile. There is some overlap where specific medical conditions could have fitted into two different categories, like RVD encephalopathy could be considered ‘neurological’ as well as an ‘infectious disease’. The researcher wished to categorise the medical conditions as closely as possible to the South African Burden of Disease profile as this research was conducted in South Africa.

**Data Collection Tool**

An instrument was constructed by the researcher for the collection of data. The data collection tool was created on Epidata 3.1. (Appendix B) which allowed for all the relevant
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

data for each participant to be recorded in a systematic manner. The tool comprised of 27 fields to be completed for each participant. These fields included (1) basic patient information (hospital number, code to ensure anonymity, sex, age, weight and height), (2) medical information (primary and secondary medical condition, comorbidities, method of respiration), (3) dysphagia information (details of assessment, management and type of enteral nutrition recommended and medical professional who recommended it), (4) risks present pre placement (Decreased BMI, age over 60 years, presence of comorbidities, lack of nutrition and hydration pre placement) and (5) outcomes (mortality) after placement at different time frames (one day, one week, 30 days, three months and six months). The same tool was used to collect data for all three cohorts within the study. Each category contained a list of all possible options which were coded with numbers. The researcher would enter a single number into the cell next to the corresponding statement. For example under the category ‘sex’ a number (1) would denote ‘male’ and a number (2) would denote ‘female’; if the participant was ‘male’ then the researcher would type a number (1) into the cell next to the category of ‘sex’. The coding of words with corresponding numbering made data entry easier as only a number needed to be entered each time as a pose to a whole word.

Reliability and Validity of the Tool

Reliability of a tool refers to the tool’s ability to consistently give the same result when used countless times (Goddard & Melville, 2004). The data for all three cohorts was entered using the same tool, by the same researcher.

Content validity is determined by how well items on a test represent the construct that they are aiming to describe (Kimberlin & Winterstein, 2008). There is no statistical measure available to test content validity so it is often addressed by consulting professionals in the field of study (Kimberlin & Winterstein, 2008) or by a review of relevant literature. Construct validity refers to how accurately the tool measures the construct that it is meant to measure (Kimberlin & Winterstein, 2008). All evidence of content validity adds to proof of construct validity (Kimberlin & Winterstein, 2008).

In this study content and construct validity were addressed by reviewing current literature in the field to ensure that all aspects included in the tool were based on current literature on PEG and adult dysphagia (see Table 4).
## Table 4: Data collection tool checklist

<table>
<thead>
<tr>
<th>Information</th>
<th>Rationale</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Biographical information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1 Group</td>
<td>Three cohorts were used in the study, a 1, 3 or 3 were entered to identify which cohort that participant belonged to</td>
<td></td>
</tr>
<tr>
<td>1.2 Reference code</td>
<td>Each participant had a reference code allocated to them in order to maintain confidentiality and anonymity</td>
<td>Helsinki, 2013</td>
</tr>
<tr>
<td>1.3 Sex</td>
<td>This information was required in order to be able to describe the participants</td>
<td></td>
</tr>
<tr>
<td>1.4 Date of Birth</td>
<td>This was recorded in order to determine age, which was analysed as a risk factor for mortality as a study aim</td>
<td>Abuksis et al., 2004; Blomberg et al., 2012; Grant et al., 1998; Ha &amp; Hauge, 2003; Kobayashi et al., 2002; Malmgren et al., 2011; Nair et al., 2000; Richter-Schrag et al., 2011; Smith et al., 2008</td>
</tr>
<tr>
<td>1.5 Height and weight</td>
<td>This was recorded in order to calculate body mass index (BMI), which was analysed as a risk for mortality as a study aim</td>
<td>Blomberg et al., 2012; Richter-Schrag et al., 2011</td>
</tr>
<tr>
<td><strong>2. Primary medical conditions</strong></td>
<td>These medical conditions were included in the data collection tool as they are commonly associated with adult patients who have dysphagia and may require enteral nutrition</td>
<td></td>
</tr>
<tr>
<td>2.1 Neurological</td>
<td>Adults with neurological deficits commonly present with dysphagia and require enteral nutrition</td>
<td>Bankhead et al., 2009; Blomberg et al., 2012; Donovan, Daniels, Edmiaston, Weinhardt, Summers &amp; Mitchell, 2012; Gundogan et al., 2014; Holmes, 2011; Malmgren et al., 2011; Rio et al., 2010; Sharp &amp; Shega, 2009; Vivanti et al., 2009</td>
</tr>
<tr>
<td>2.2 Trauma</td>
<td>Adults who have experienced trauma to the head, neck and/or body may present with dysphagia and may require enteral nutrition. South Africa has a high level of interpersonal violence which makes this category important in a study using a South African population</td>
<td>Harrison, 2009; Mokhosi &amp; Grieve, 2004; Norman et al., 2007</td>
</tr>
<tr>
<td>2.3 Non-communicable Disease</td>
<td>The prevalence of non-communicable disease is high in South Africa and contributes to</td>
<td>Gundogan et al., 2014; Mayosi et al., 2009; Nguyen et al., 2006; Rimon, Kagansky &amp; Levy, 2005;</td>
</tr>
</tbody>
</table>
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

high rates of morbidity and mortality. Adults with these diseases will commonly present with dysphagia and will require enteral nutrition

Wermker et al., 2012; Zhang et al., 2012

2.4 Infectious Disease

Infectious diseases are common in the South Africa context and can result in serious neurological fallout, which can cause dysphagia which will require a patient to receive enteral nutrition

Levine et al., 2012; Rosenbloom, Sullivan & Pfefferbaum, 2010; Portegies & Rosenberg, 1998; Schneider, Bradshaw, Styen, Norman & Laubscher, 2009

2.5 Delirium and Dehydration

This was included in the list as it was noted by the researcher, when reviewing files in the pilot study, that it was a diagnosis commonly noted in hospital files as the primary diagnosis

2.6 Other

These included: Gastrointestinal disease, cardiac conditions, sepsis, renal failure, hypoglycaemia, pancreatitis, anaemia and metabolic disorders

These were included in the list as “other” as they were noted upon review of the files to be the present as medical conditions, but did not fit into the pre-defined medical condition categories for the study

3. General Medical Information

3.1 RVD and TB status

These diagnosis were noted under the infectious disease category if they are noted as the primary medical condition. But were also captured separately as important medical information within the South African context because of the high rate of infection in South Africa and the effect these comorbid diseases can have on a patients general health

Bradshaw et al., 2002; Brew, Crowe, Landay, Cysique & Guillemin, 2009

3.2 Comorbidities

These included commonly noted comorbidities in hospital files such as: diabetes, respiratory disease, hypertension, renal failure and hemiparesis

Kobayashi et al., 2002; Smith et al., 2008; Quan, et al., 2005; Zopf, 2011

3.3 Patient State at Assessment

This was important to include as it provided information on why enteral nutrition may have been indicated prior to an assessment by an SLT. Ie. In the case a patient was unconscious at the time of

Lloyd & Powell-Tuck, 2004; Stroud et al., 2003
### 3.4 Albumin level

This was recorded as it was information which was analysed as a risk for mortality as a study aim

Blomberg et al., 2011; Janes et al., 2005; Nair et al., 2000; Lang et al., 2004

### 4. Dysphagia and Enteral Nutrition Information

<table>
<thead>
<tr>
<th>4.1 The type of dysphagia</th>
<th>Adult patients can present with difficulties in any phase of the swallow which will determine the extent of nutritional intake they are capable of and the safety of this intake. The type of dysphagia (oral phase, pharyngeal phase or oesophageal phase) is important to note as it can inform decisions about the method of intake (oral, short or long term enteral nutrition). The type of dysphagia that a participant had was determined by the SLT after a clinical (bedside) evaluation and documented in the hospital file. A diagnosis of oesophageal phase dysphagia was documented if there was a confirmed diagnosis in the hospital file based on an objective study.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blackwell &amp; Littlejohns, 2010; Erdil et al., 2005; Holmes, 2011; Seidl, Nusser-Muller-Busch, Westhofen &amp; Ernst, 2008; Via &amp; Mechanick, 2013</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.2 Methods of intake (current, post assessment and/or treatment by an SLT)</th>
<th>These categories were included to identify the method of intake participants were recommended for before an SLT assessment and after assessment and/or treatment. The information can provide details about the use of enteral nutrition upon admission before an SLT has assessed, and the amount and type of enteral nutrition recommended by an SLT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blackwell &amp; Littlejohns, 2010; Erdil et al., 2005; Holmes, 2011; Seidl, Nusser-Muller-Busch, Westhofen &amp; Ernst, 2008; Via &amp; Mechanick, 2013</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.3 Timing of recommendation for enteral nutrition (by an SLT and a medical Doctor)</th>
<th>The timing of the recommendation and placement of enteral nutrition was included as it was required to analyse as a risk factor for mortality as a study aim</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Abuksis et al., 2004; Prosser-Loose &amp; Paterson, 2006; Westaby et al., 2010</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.4 Recommendation made by another professional</th>
<th>This information was recorded as one of the study aims was to compare the differences in recommendation for enteral nutrition between SLTs and medical Doctors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stroud et al., 2003; Tanswell et al., 2007</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.5 Delay in or failure of placement of enteral nutrition post recommendation</th>
<th>Delays in the placement of enteral nutrition when needed can exacerbate malnutrition and increase morbidity and mortality.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Kim et al., 2012; MacDougall, 2010</td>
</tr>
</tbody>
</table>
4.6 Interrupted feeds on short term enteral nutrition

The delays or interruptions in feeding are important to note as they can affect survival. Beavan et al., 2010; Kim et al., 2012; MacDougall, 2010

5. Outcomes

It was important to capture outcomes for patients who demised on oral intake, short term enteral nutrition and long term enteral nutrition or before the placement of enteral nutrition in different places as these patients’ survival rates were compared in analysis.

5.1 Final outcome if on oral feeds

Patients whose outcome was recorded here included those who had dysphagia and who would have been on enteral nutrition at some point, but whom were discharged from hospital or who demised on oral intake.

5.2 Demised before assessment

This was recorded in order to fulfil the study aims.

5.3 Demised before placement of short term enteral nutrition

This was recorded in order to fulfil the study aims.

5.4 Demised before placement of long term enteral nutrition

This was recorded in order to fulfil the study aims.

5.5 Demised after placement (Different time points given as 1 day, 1 week, 1 month, 3 months and 6 months)

This was recorded in order to fulfil the study aims. Codner, 2012; Gomes et al., 2012; Vassilyadi et al., 2013

After construction, the tool was reviewed by an SLT who had been working in the field of adult dysphagia within the Speech Therapy Department at CHBAH for four years. The SLT agreed with the elements that had been included in the tool based on her knowledge in the area, which ensured face validity of the tool.

Procedure

Following approval of the study by The University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (HREC REF: 503/2013) (Appendix C), approval was requested and obtained from the Internal Ethics Review Board at CHBAH (Appendix E) and from the Heads of Departments that were to be involved in the study (Speech Therapy and Gastroenterology) (Appendices F and G). A pilot study was then conducted, after which
changes were made to the data collection tool before data collection for the main study commenced.

**Pilot Study**

A pilot study is done before the main study is started in order to test the feasibility of the study, the instruments that are going to be used to collect data in the main study and the basic procedures that have been planned for the main study (Thabane et al., 2010; Van Teijlingen & Hundley, 2004). Conducting a pilot study is important as it allows the researcher to replicate the main study on a smaller scale so that any difficulties in recruitment of participants, data collection, and data analysis can be identified and changed accordingly (Van Teijlingen & Hundley, 2004) which will ensure that processes in the main study run without difficulty.

The pilot study was done after the completion of the data collection tool in order to test its feasibility. Johanson and Brooks (2009) suggest a basic number of 12 participants per group where the study is expected to have three groups of participants. In line with recommendations from the literature, 36 files were reviewed by the researcher.

Minor changes were made to the data collection tool after the completion of the pilot study, which included:

1. Addition of medical conditions which had previously been left off the existing list. The additions to the list reduced the frequency of the non-specific “other” being selected in the drop down list during data collection
2. Addition of a joint comorbidity of “hypertension and diabetes” to the list of comorbidities as these were noted to co-occur frequently in the review of files in the pilot study.

After the data for the pilot study had been collected, it was noted that there were areas that had a lot of missing or incomplete data, such as the weight and height of participants. It was decided that although there were many blanks in this area the section would not be omitted from the tool that would be used for the main research project. The reason for this was that the same tool would be used to collect data for participants with a single morbidity who were
referred for PEG by a medical Doctor, where there would be no missing data for weight and height due to the prospective nature of data collection for this cohort.

The data from the pilot study was not analysed by a statistician as the statistician indicated that a complete set of data was preferable to start analysis. The researcher discussed the pilot data with the same statistician who would analyse the data at the end of the study and deliberated the data collection tool. The researcher and the statistician both agreed that the tool contained the relevant questions to allow for the researcher to capture data that could be analysed to fulfil the aims of the study.

Data Collection

Data collection for the study took place over a period of time which included data collection of both retrospective and prospective data. Collection of data for participants with multiple morbidities who were assessed and managed by Speech Therapy involved retrospective review of medical folders. During this period, the researcher worked within the archive department at CHBAH as hospital policy does not allow for hospital files to be removed from the property. The researcher reviewed each file and entered data onto the electronic Epidata spreadsheet for each participant prior to reviewing the folder for the next participant. Each participant’s name and hospital number was written into a code book and assigned a number prior to reviewing the folder. The process of replacing a patient name and hospital number with a number ensured anonymity of information once it was collected and entered into the electronic spreadsheet. The data had to be made anonymous to uphold patient confidentiality because it was going to be seen by the statistician in the data analysis phase. The codebook was kept by the researcher in a locked cupboard and was never left in the same place as the laptop containing the patient data to ensure confidentiality (Babbie, 2012).

A diary was kept by the researcher, with notes about medical conditions and how each one was classified, so that data collection was uniform throughout as it was done over a period of two months. For example, a patient who had sustained a traumatic brain injury (TBI) and had undergone neurosurgery as a result, would have their primary medical condition noted as “TBI” and their secondary medical condition noted as “neurosurgical”. Vassar and Holzmann (2013) noted that failure to create and utilise a standard procedure as set out in a manual or
diary to ensure consistent method of data abstraction is one of the main methodological threats in retrospective folder reviews.

In the period of prospective data collection, for participants with a single morbidity who were referred for PEG placement by a medical Doctor, the researcher obtained informed consent from participants prior to review of their medical folder. The researcher used the information, as set out on the informed consent form (Appendix H), to introduce herself to the patient, to introduce the study, and to give the patient information on the study and their role should they choose to consent to take part. The patient was given the opportunity to ask any questions and was then asked to sign the consent form. Thereafter the researcher reviewed the participant file to obtain the relevant information needed in accordance with the data collection tool.

If the participant was unable to sign consent themselves, a different form (Appendix I) was used. It was addressed to the participant’s legal proxy to sign on their behalf. This form had the same information about the study as the form for participants who were able to sign for themselves. It also gave the legal proxy the opportunity to ask questions and decide whether they would consent for their family member to take part in the study. The legal proxy was approached by the researcher during visiting hours at the hospital to discuss the study and ask for consent on behalf of the participant.

The consent form was written by the researcher in English. Considering that there are a multitude of languages spoken by people in South Africa, with no specific language dominating the Gauteng province (Statistics South Africa; 2011), the consent form was not physically translated but rather was to be translated into the chosen language when verbally administered, if necessary. Due to the lack of access to translators within the government setting, therapists often rely on trained Speech Therapy assistants to help translate during assessment and therapy sessions. This is not ideal, and according to The Committee for Human Research at the University of California (2003), a qualified translator should be used. Trained SLT assistants, who spoke a variety of languages, were available to translate the consent form if it were required. During the course of this study, all participants or their proxies were able to understand and communicate in English.”
Participants who were referred for enteral nutrition by a medical Doctor were in-patients at CHBAH at the time of data collection. The researcher located the patient within the ward before the scheduled date of PEG insertion, received informed consent and then reviewed the medical folder. After PEG insertion the researcher followed up on the participant at the specified periods (one day, one week, 30 days, three months and six months). Follow up was within the ward if the participant was still an in-patient or telephonically if the participant had been discharged from CHBAH. Follow up data collection for this group of participants was recorded by the researcher on a hardcopy of the electronic spreadsheet as this was more feasible than carrying a laptop around to the hospital wards. Once data was complete for one participant (if the specified follow up time frame was over, or if the participant had demised before the end of the follow up period) the researcher entered the information onto the electronic spreadsheet in the same manner as data of other participants.

All data was entered into the electronic spreadsheet by one researcher. Every care was taken to ensure accurate data capturing that was free from human error. The Epidata programme used by the researcher to collect the data enables checks to be put into place to ensure that it is mostly free of human error when it is entered. These checks consisted of double inputting of data which the program automatically checked for differences in input, ensuring accurate input of data by the researcher. Human error is possible when inputting data from a file onto a computer, but with this method of data input human error would be checked by the computer program. The researcher reviewed each file twice within the same period of time and input the data into the programme immediately. If data inserted the second time differed from the data inserted the first time then the programme would alert the researcher to the discrepancy. This would then be reviewed and corrected by the researcher. These checks resulted in accurate input of data throughout the collection period.

Data inserted into the tool was done using numbers, with each number reflecting a word or phrase. A key code was made to document the numbers and their corresponding words or phrases. For example a list of possible medical conditions was coded by the researcher with traumatic brain injury (TBI) as number 1. When the researcher input data into the tool the number 1 was used to reflect a participant with a TBI. This coding made input quicker as
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

whole words or phrases did not need to be typed in each time. The tool aimed to record data systematically from pre-existing records in order to fulfil the aims of the study.

**Data Management**

Although all data was entered onto one spreadsheet concurrently, each data set was coded as either group one, two or three to make individual analysis of groups and comparisons between groups easy. Group one referred to participants with multiple morbidities who were referred for enteral nutrition. Group two referred to the participants with multiple morbidities who were placed on oral palliative nutrition. Group three referred to participants with a single morbidity who were referred for enteral nutrition.

When reviewing the file and noting the method of intake that was recommended, a nasogastric tube (NGT) could have been recommended either by an SLT, a medical Doctor or both. The professional who recommended the method of intake (NGT/percutaneous endoscopic gastrostomy (PEG)/oral) first in the patient file was the professional who was recorded as having made the recommendation.

**Data Analysis**

Difficulties arose during the period of data collection for participants whose information was collected retrospectively, with regard to missing data. Missing or incomplete data was omitted from the analysis of that section and the sample size was adjusted accordingly for analysis. This method was in accordance with Howell (2008) who suggests that in an observational study, missing data can be dealt with by using ‘casewise deletion’ where all cases that have missing data are dropped from the final analysis.

Missing data included patient albumin levels which are not always routinely done for every patient admitted to CHBAH. Within hospital records at CHBAH weight is primarily recorded by the dietician at their first patient consult, but not all patients are seen by a dietician. When a consult by the dietician was recorded in the hospital file, weight was recorded as an estimated weight with no height recorded.
In acute settings where a patient is immobile or unconscious it can be impossible to measure weight and height accurately (Ferro-Luzzi & James, 1996). It is suggested in literature that other methods for commenting on nutritional status, such as a measurement of upper arm circumference which can be used in cases where weighing is not possible (Ferro-Luzzi & James, 1996). No such data was recorded in the hospital files reviewed by the researcher. The information on nutritional status that was recorded by the dietician in the hospital file made it impossible to calculate body mass index in order to comment on nutritional status. The researcher consulted with a registered dietician from The University of Cape Town (F. Herrmann, personal communication, June 9, 2013) and it was noted that “estimated weight” held no relevance and could not be used to comment on as a reliable measure. BMI as a possible risk factor for poor outcome could not, therefore, be included in the groups where data was collected retrospectively. Weight and height detail was collected for every patient whose data was collected prospectively as the researcher had direct contact with these participants and BMI could be calculated in this group.

Data collection for participants who were assessed and managed by Speech Therapy ended at the point that their hospital stay ended or at the point of demise. Of these participants, those who had placement of a PEG were not followed up on past the point of discharge as they fell into the group of retrospective data collection.

Participants whose data was collected prospectively were followed up to the point of 6 months or until demise if it occurred within the 6 month period. Every effort was made to contact participants for follow up telephonically. In one case a patient could not be contacted as, when the researcher called to follow up, the number taken down at the start of data collection was no longer in service. This participants’ data was analysed up until the point of loss to follow up and data after which it was left out of the analysis and noted to be a loss to follow up.

Statistical Analysis

Descriptive statistics were used for categorical variables (sex and primary medical condition) and were represented as frequencies and percentages. For continuous variables (age, comorbidities present, dysphagia present, respiratory status, albumin levels, weight and
height) descriptive statistics were presented using mean ± standard deviation or as a median value with inclusion of the range.

To determine whether the relationships between two categorical variables were statistically significant, the chi-square test of independence was carried out. Alpha was set at 0.05 significance level for all analyses.

Where there are continuous variables, chi-square cannot be used so a *t*-test is used to determine significance (Lind, Marchal & Wathen, 2005). A *t*-test is sufficient where there is an inclusion of only two groups for analysis. This included analysis of comparisons between NGT and PEG as well as a comparison of survival between participants fitted with an NGT 1 day after recommendation versus anytime over 1 day.

Kaplan Meier (KM) graphs measure the number of participants that survive for a certain amount of time after a specific type of intervention (Goel, Khanna, & Kishore, 2010) and in this study were used to explore participant survival after placement of enteral nutrition, between the 3 cohorts included in the study. A non-parametric statistical test called a logrank test was done for each Kaplan Meier graph to compare the graphs and determine if survival rates were different, as this cannot be determined correctly just by looking at the plots on the graph (Bewick, Cheek, & Ball, 2004; Walters, 2009). A logrank test can determine if there is a difference in survival between two groups but it cannot identify any variables that may have caused the difference (Bewick et al., 2004).

Cox regression hazard analysis assessed the magnitude of risk of death (Bewick et al., 2009) according to the key exposure variables, such as: age, time of placement, nutritional status at time of placement and comorbidities present, first exploring one factor at a time and then doing a multivariate/adjusted analysis. The analysis produced an estimated hazard ratio or ‘risk of death’ according to a participant’s exposure to a certain variable. A positive regression coefficient highlights a positive link between that variable and the hazard (risk of death) (Bewick et al., 2009). All hazard coefficients should be tested for significance, as a significant result will alert the researcher to the fact that in the study, the hazard had a direct effect on death, and was not just a risk. A non-significant *p* value will reveal that the variable placed a participant at risk of death (if accompanied by a positive regression coefficient), but that the variable was not an independent variable resulting in mortality.
Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 19.0 for Windows.

**Ethical Considerations**

This study will be conducted in accordance with Helsinki 2013.

Ethics approval was obtained from the University of Cape Town’s Faculty of Health Sciences Human Research Ethics Committee before commencement of the study (Appendix C).

Autonomy: In research ethics, autonomy refers to a participant’s right to make an informed decision about whether they want to consent to take part in a study and their right to withdraw from the study at any point (World Medical Association Declaration of Helsinki, 2013). In this study, information about the study was provided to each participant and they were given a choice of whether or not they wanted to sign consent to take part. Implied consent was obtained from all participants whose information was collected prospectively (Appendices H and I). Participants whose data was collected retrospectively were not directly involved in the study at the time of data collection, so implied consent was not obtained. Rather consent from the hospital ethics board to review medical files of patients who had previously been treated at CHBAH was obtained (Appendix E).

Confidentiality: All data was stored on a laptop that was password protected and kept in a safe, locked room when not in use. Patient names were not recorded but rather coded at the time of data collection to ensure confidentiality. Coding also aided in the blinding process to assess reliability. Coding was done by assigning each patient with a number that was used throughout the study process. At the end of the data collection period all identifying information was destroyed so that no link could be made between codes and patient names.

Beneficence: Participants were not directly involved in this study and were not expected to take part in any kind of testing. Participants who were involved in the study did not benefit from this study but the results could be used to benefit others who receive enteral nutrition in the future.
Non-maleficence: This refers to the need to do no harm (World Medical Association Declaration of Helsinki, 2013). Participants whose data was collected prospectively were not required to do anything extraordinary in order to be included in the study, and therefore were not at any risk of harm. The retrospective aspect of the study meant that data was collected via a folder review and therefore posed no harm to participants.

Justice: All participants who met the inclusion criteria had an equal chance of being included in the study. Those who did not meet the criteria were not at a disadvantage for not having been included as no direct benefits were experienced by study participants anyway. The benefits of the study will be equally applicable to a similar population from which the participants were drawn.
Results

Results of the study are reported according to the study aims.

1. Mode of intake

Different modes of intake that were recommended for participants in the study by both an SLT and a medical Doctor are noted in Table 5.

Table 5: Mode of intake recommended by a Speech Language Therapist and a medical Doctor

<table>
<thead>
<tr>
<th></th>
<th>NGT n (%)</th>
<th>PEG n (%)</th>
<th>Oral palliative nutrition n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SLT</td>
<td>102 (65.4)</td>
<td>56 (61.5)</td>
<td>10 (100)</td>
</tr>
<tr>
<td>Medical Doctor</td>
<td>54 (34.6)</td>
<td>35 (38.5)</td>
<td>--</td>
</tr>
<tr>
<td>Total (N=257)</td>
<td>156</td>
<td>91</td>
<td>10</td>
</tr>
</tbody>
</table>

Short Term Enteral Nutrition

In the population of patients with multiple morbidities (n=212) an NGT was recommended most frequently by an SLT. The difference between the number of NGTs recommended by an SLT and a medical Doctor is significant (Chi-square; \( p = .003 \)), with an SLT recommending more NGTs than a medical Doctor.

Placement of NGT Post Recommendation

Out of those patients recommended for NGT placement (n=156), 71.1% (n=110) of patients had an NGT placed after recommendation. There was a significant difference (Chi-square; \( p < .001 \)) between those who had an NGT placed after recommendation by a Speech Therapist (61.1% n=62) versus a medical Doctor (9.2% n=5) with more placements occurring after recommendation by a Speech Therapist.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

**Long Term Enteral Nutrition**

In the population of participants with multiple morbidities (n=212), a PEG was recommended 100% of the time by an SLT. In the population of patients with a single morbidity (n=35), a PEG was recommended 100% of the time by a medical Doctor. In the total study sample (N=257) the percentage of patients recommended for PEG by a Speech Therapist was 61.5% (n=56) and by a medical Doctor it was 14.1% (n=35). There is a significant difference in the professional who recommended PEG placement (Chi-square; \( p = .050 \)).

**Placement of PEG Post Recommendation**

A significantly greater number of PEGs were placed in participants with a single morbidity than were placed for participants who had multiple morbidities (Chi-square; \( p = .001 \)).

Table 6 depicts the reasons why a PEG was not fitted after it was recommended in participants with multiple morbidities and a single morbidity.

<table>
<thead>
<tr>
<th>Reason PEG was not placed</th>
<th>Patients with single morbidity who were recommended for PEG by a medical Doctor n=35</th>
<th>Patients with multiple morbidities who were recommended for PEG by a Speech Therapist n=56</th>
</tr>
</thead>
<tbody>
<tr>
<td>Died before placement</td>
<td>6</td>
<td>28</td>
</tr>
<tr>
<td>No longer needed PEG at time of insertion</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Unknown reason</td>
<td>2</td>
<td>14</td>
</tr>
<tr>
<td>Discharged from hospital before placement</td>
<td>2</td>
<td>--</td>
</tr>
<tr>
<td>Refused procedure</td>
<td>4</td>
<td>--</td>
</tr>
</tbody>
</table>

In the group of patients with multiple comorbidities a significantly greater (Chi-square; \( p = .001 \)) number of patients (50%; n=56) died before the placement of PEG than those with a single morbidity (17.1%; n=35). This result highlights the importance of considering the
number of morbidities that a patient presents with before making a recommendation for PEG, as multiple morbidities place a patient at great risk of mortality.

**Timing of placement of enteral nutrition post recommendation**

The time lapse between enteral nutrition recommendation and placement in single and multiple morbidities and how it related to mortality post placement of enteral nutrition is depicted in Table 7.

**Table 7:** The time lapse from assessment of a patient to the recommendations for enteral nutrition to the placement of it

<table>
<thead>
<tr>
<th>Time to placement (in days)</th>
<th>Significance (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NGT in participants with multiple morbidities: from time of SLT recommendation to placement</strong></td>
<td>Mean ± STD 2.74 ± 2.13 (median: 2; range: 0-8; mode: 2).</td>
</tr>
<tr>
<td><strong>NGT in participants with multiple morbidities: from time of Dr recommendation to placement</strong></td>
<td>Data not available from patient files. *A Dr will not record recommendation of an NGT but rather just place it</td>
</tr>
<tr>
<td><strong>PEG in participants with multiple morbidities: from time of assessment of patient by Speech Therapist to recommendation for PEG</strong></td>
<td>Mean ± STD 4.78 ± 3.373 (median: 4; range: 0-9; mode: 1)</td>
</tr>
<tr>
<td><strong>PEG in participants with a single morbidity: from time of Dr recommendation for PEG to placement</strong></td>
<td>Mean ± STD 13.8 ± 9.579 (median: 10; range: 0-39; mode: 9)</td>
</tr>
</tbody>
</table>

The average time it took for an NGT to be placed after recommendation was made was great, with the largest majority of participants waiting 2 days for placement. There was no statistical
significance linking mortality to the time lapse in placement of an NGT ($p=.189$). An SLT would recommend a PEG an average of 4.78 days after first assessing a patient with multiple morbidities, with the largest majority of participants with multiple morbidities being recommended for a PEG 1 day post assessment. In participants with a single morbidity there was a relatively short time lapse from when a PEG was recommended to when it was placed, with no statistical significance linking the time lapse to mortality post placement.

2. Indications for Enteral Nutrition

The presence of dysphagia

Inability to achieve adequate nutrition and hydration orally due to dysphagia, or refusal of hydration and nutrition orally, resulted in the recommendation for enteral nutrition.

![Figure 1: Indications for the recommendation of enteral nutrition in single and multiple morbidities](image-url)

*Pharyngeal phase dysphagia was not diagnosed on a videofluoroscopy, but on a clinical assessment by a Speech Therapist

Medical conditions requiring enteral nutrition
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Enteral nutrition could have been recommended as a result of a medical condition that resulted in the need for it. Table 8 notes the presence of various medical conditions that required either short or long term enteral nutrition.

Table 8: Primary medical condition of participants who were recommended for short and long term enteral nutrition

<table>
<thead>
<tr>
<th>Medical condition</th>
<th>NGT (n=156)</th>
<th>PEG (n=91)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Neurological</td>
<td>114 (73.1)</td>
<td>23 (25.3)</td>
</tr>
<tr>
<td>Trauma</td>
<td>4 (2.6)</td>
<td>19 (20.9)</td>
</tr>
<tr>
<td>Non communicable diseases</td>
<td>13 (8.3)</td>
<td>28 (30.8)</td>
</tr>
<tr>
<td>Infectious diseases</td>
<td>13 (8.3)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Delirium and dehydration</td>
<td>3 (1.9)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>9 (5.8)</td>
<td>2 (3)</td>
</tr>
</tbody>
</table>

NGTs were recommended most frequently for participants who had a neurological deficit. There was an equal number of recommendations made for an NGT in participants with infectious and non-communicable diseases. The most common medical condition requiring a PEG was non communicable diseases, followed by neurological deficits and trauma.

3. Mortality rate of participants recommended for NGT and PEG

Mortality rates of participants recommended for short and long term enteral nutrition were compared at different points in time after recommendation or placement was made and are noted in Table 9.
The greatest rate of mortality occurred at the point pre placement of enteral nutrition, the highest rate being pre PEG placement compared to pre NGT placement. The greatest overall percentage of mortality was noted in participants who were recommended for and/or fitted with an NGT versus PEG.

### 4.1 Survival times across modalities

#### a) Short term enteral nutrition (NGT)

Of the patients who were recommended for an NGT, 80.8% (n=156) died at some point during the study period. The greatest majority of these participants died within 1 month of insertion. Survival time differed between participants who had an NGT placed after it was recommended and those who did not. The median survival (range: 0-75) for participants who had an NGT placed was significantly longer (23 days) compared with 8 days for participants.
who did not have an NGT placed. A log-rank test confirmed that difference in survival between participants who were fitted with an NGT post recommendation had significantly greater survival than those who were not fitted with an NGT post recommendation ($p=.013$; Figure 2).

![Kaplan Meier graph showing survival of patients who were fitted with an NGT post recommendation (green) and those not fitted post recommendation (blue).](image)

<table>
<thead>
<tr>
<th>Time (days to death)</th>
<th>Probability of survival (%)</th>
<th>Log rank $p=.013$</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th>NGT placed after recommendation</th>
<th>NGT not placed after recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of subjects</td>
<td>65</td>
<td>28</td>
</tr>
<tr>
<td>Event</td>
<td>44.6% (29)</td>
<td>46.4% (42)</td>
</tr>
<tr>
<td>Censored</td>
<td>55.4% (36)</td>
<td>53.6% (15)</td>
</tr>
<tr>
<td>Median survival time (95%; CL)</td>
<td>23 (10.729 35.271)</td>
<td>8 (1.865 14.135)</td>
</tr>
</tbody>
</table>

Figure 2: Kaplan Meier graph showing survival of patients who were fitted with an NGT post recommendation (green) and those not fitted post recommendation (blue).

Note: The number of subjects refers to the total number of subjects included in the analysis (event + censored). Event refers to the number of participants for whom there was complete data of all variables needed to conduct the analysis. Censored (indicated by small vertical dashes across the curves) refers to the number of participants for whom there was incomplete data at one of the points in time and could therefore not be analysed in full.

**b) Long term enteral nutrition (PEG)**

Of the 91 participants who were referred for PEG placement, 31 PEGs were placed. Of these 31 participants, 1 participant survived throughout the study period of six months and 12 were lost to follow up making it impossible to comment on outcome. The mortality rate of
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

participants with both multiple morbidities and a single morbidity, who had a PEG placed in noted in Table 10.

**Table 10:** Mortality rate post PEG placement of participants with single and multiple morbidities

<table>
<thead>
<tr>
<th></th>
<th>Patients with PEG in situ</th>
<th>Patients with NGT in situ</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 day</td>
<td>0</td>
<td>40.7% (35)</td>
</tr>
<tr>
<td>1 week</td>
<td>2 (11.1)</td>
<td>59.3% (51)</td>
</tr>
<tr>
<td>1 month</td>
<td>7 (13.2)</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>5 (27.8)</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>4 (22.2)</td>
<td></td>
</tr>
</tbody>
</table>

**Comparison of survival time between NGT and PEG (both multiple morbidities and single morbidity)**

![Graph showing comparison of survival time between NGT and PEG](image)

<table>
<thead>
<tr>
<th></th>
<th>No. of subjects</th>
<th>Event</th>
<th>Censored</th>
<th>Median survival time (95%; CL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with PEG in situ</td>
<td>18</td>
<td>100% (18)</td>
<td>0% (0)</td>
<td>30 (0.000 69.499)</td>
</tr>
<tr>
<td>Patients with NGT in situ</td>
<td>86</td>
<td>40.7% (35)</td>
<td>59.3% (51)</td>
<td>20 (9.640 30.360)</td>
</tr>
</tbody>
</table>
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Figure 3: Kaplan Meier graph comparing survival of patients fitted with an NGT (blue) or a PEG (green).

Note: The number of subjects refers to the total number of subjects included in the analysis (event + censored). Event refers to the number of participants for whom there was complete data of all variables needed to conduct the analysis. Censored (indicated by small vertical dashes across the curves) refers to the number of participants for whom there was incomplete data at one of the points in time and could therefore not be analysed in full survival.

Survival time differed between patients who had a PEG placed and those who had an NGT placed. The median survival for patients who had a PEG placed was significantly greater at 30 days compared with 20 days for patients who had an NGT placed (log rank test; $p = .043$; Figure 3).

c) Oral palliative nutrition

The median survival (range: 2-19) for patients who were placed on oral palliative nutrition, instead of being recommended for enteral nutrition, was 19 days. When compared to the survival times of participants who were on enteral nutrition the log rank statistic showed no significant difference ($p = .737$; Table 11).

Table 11: Comparison of survival times between participants with multiple morbidities and a single morbidity who were received a PEG and participants who were placed on oral palliative nutrition

<table>
<thead>
<tr>
<th>No. of subjects</th>
<th>Event</th>
<th>Censored</th>
<th>Median survival time (95%; CL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants with a single morbidity fitted with PEG</td>
<td>15</td>
<td>100% (15)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Participants with multiple morbidities fitted with PEG</td>
<td>3</td>
<td>100% (3)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Participants on oral palliative nutrition</td>
<td>10</td>
<td>40% (4)</td>
<td>60% (6)</td>
</tr>
</tbody>
</table>

Note: The number of subjects refers to the total number of subjects included in the analysis (event + censored). Event refers to the number of participants for whom there was complete data of all variables needed to conduct
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

the analysis. Censored (indicated by small vertical dashes across the curves) refers to the number of participants for whom there was incomplete data at one of the points in time and could therefore not be analysed in full.

When ‘NA’ is reported for the confidence level it means that horizontal line did not intersect with the confidence interval for that data set.

All participants who were placed on oral palliative nutrition were followed up to the point that they were discharged form hospital. At the point of discharge from hospital, 6 participants were still alive. In this same time period, 4 participants had died (allowing for their data to be used in a survival analysis). Participants who demised on oral palliative nutrition survived for a median of 19 days, compared to a survival rate of 24 days for patients with multiple morbidities who were fitted with a PEG and 54 days for patients with a single morbidity who were fitted with a PEG.

4.2) Multiple morbidities with PEG versus single morbidity with PEG

<table>
<thead>
<tr>
<th></th>
<th>No. of subjects</th>
<th>Event</th>
<th>Censored</th>
<th>Median survival time (95%; CL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with a single morbidity fitted with PEG</td>
<td>15</td>
<td>100% (15)</td>
<td>0% (0)</td>
<td>54 (17.392, 90.608)</td>
</tr>
<tr>
<td>Patients with multiple morbidities fitted with PEG</td>
<td>3</td>
<td>100% (3)</td>
<td>0% (0)</td>
<td>24 (NA)</td>
</tr>
</tbody>
</table>

Log rank \( p = .038 \)
Figure 4: Kaplan Meier graph comparing survival of patients with multiple morbidities who were fitted with a PEG (blue) and those with a single morbidity who were fitted with a PEG (green).

Note: The number of subjects refers to the total number of subjects included in the analysis (event + censored). Event refers to the number of participants for whom there was complete data of all variables needed to conduct the analysis. Censored (indicated by small vertical dashes across the curves) refers to the number of participants for whom there was incomplete data at one of the points in time and could therefore not be analysed in full.

The median survival post PEG placement for patients with a single morbidity was significantly longer (54 days) compared to the survival of patients with multiple morbidities which was 24 days (log rank test; \( p = .038 \); Figure 4). Due to the retrospective nature of data collection for participants with multiple morbidities who had a PEG placed, complete follow up data was only available for 3 participants. One should interpret this Figure 4 with caution because of the small cohort used, which could cause an unreliable representation of survival.

5. Risk factors for mortality post placement of short and long term enteral nutrition

A risk factor analysis was conducted using Cox regression hazard analysis. The risk factor analysis included all patients who were recommended for short and/or long term enteral nutrition.

When interpreting the results of a Cox regression hazard analysis, it is important to analyse the hazard ratio and the \( p \)-value which will indicate the significance level of this figure. A hazard ratio can be a negative or a positive number. If it is a negative number it means that the variable had no effect on the outcome, and if it is a positive number it means that the variable did have some kind of effect on the outcome. In the study, all hazard ratio figures had a positive value, which means that many variables (increased age, decreased BMI, decreased albumin level and a high Charlson score) placed a participant at a greater risk of mortality.

A \( p \)-value that is significant, alongside a positive hazard ratio, means that the variable independently influences the outcome. In this case none of the \( p \)-values that accompanied the hazard ratios were significant (\( p > 0.05 \)). This indicates that no single variable (increased age, decreased BMI, decreased albumin level and a high Charlson score) could be attributed to having independently affected survival rate. There may have been other factors that confounded the outcome.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

The researcher can interpret the results by noting that all variables placed the participant at a certain risk of mortality, but none were an independent contributor to mortality.

**Risks for mortality post placement of NGT versus PEG in participants with multiple and single morbidity**

Table 12 depicts the variables that were positively linked to a greater risk of mortality for participants, based on the method of enteral nutrition that was in situ (NGT versus PEG).

**Table 12: Factors that place a patient at risk for mortality after NGT versus PEG placement**

<table>
<thead>
<tr>
<th></th>
<th>Type of enteral nutrition</th>
<th>HR</th>
<th>95% CI of OR</th>
<th>p value (Cox regression)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased age (&gt; 60 years)</td>
<td>NGT</td>
<td>0.635</td>
<td>.285-1.417</td>
<td>.268</td>
</tr>
<tr>
<td></td>
<td>PEG</td>
<td>1.462</td>
<td>.403-5.313</td>
<td>.564</td>
</tr>
<tr>
<td>High Charlson score (greater than or equal to 4)</td>
<td>NGT</td>
<td>0.267</td>
<td>.049-1.444</td>
<td>.125</td>
</tr>
<tr>
<td></td>
<td>PEG</td>
<td>1.296</td>
<td>.431-3.899</td>
<td>.645</td>
</tr>
<tr>
<td>Interrupted NGT feeds</td>
<td>NGT</td>
<td>2.102</td>
<td>.708-6.236</td>
<td>.181</td>
</tr>
<tr>
<td></td>
<td>PEG</td>
<td>0.856</td>
<td>.286-2.560</td>
<td>.781</td>
</tr>
<tr>
<td>Low albumin (lower than or equal to 35 g/L)</td>
<td>NGT</td>
<td>0.958</td>
<td>.189-4.867</td>
<td>.959</td>
</tr>
<tr>
<td></td>
<td>PEG</td>
<td>0.856</td>
<td>.286-2.560</td>
<td>.781</td>
</tr>
</tbody>
</table>
Note: HR: Hazard ratio; CI: Confidence intervals

Although not independently contributing to mortality, increased age of patients who were recommended for a PEG was a factor which increased the risk of mortality by 1.5 times in these patients than in those who were younger than 60 years old. There was no greater risk for mortality in patients with an increased age who were recommended for an NGT.

Patients with a high Charlson score who were recommended for a PEG had a 1.3 times greater risk of mortality than those who had a low Charlson score. There was no greater risk for mortality in patients with a high Charlson score who were recommend for an NGT. Low albumin did not greatly increase the risk of mortality in patients with either an NGT or a PEG. Patients who had interrupted feeds whilst on NGT feeds had a 2.1 times higher risk of mortality than those who did not have interrupted feeds. No single hazard ratio was found to be significant, which means that although a variable can be linked to the possibility of a higher mortality rate, in this study there was no single variable that independently had an effect on survival time.

**Risk factors for morality post placement of PEG in participants with a single morbidity versus multiple morbidities**

Table 13 depicts the variables that were positively linked to a greater risk of mortality for participants with multiple morbidities who had a PEG versus those with a single morbidity who had a PEG.

**Table 13:** Factors that place a patient with single and multiple morbidities at risk of mortality post PEG insertion

<table>
<thead>
<tr>
<th>Group</th>
<th>HR</th>
<th>95% CI of OR</th>
<th>p value (Cox regression)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased age (&gt; 60 years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple morbidity</td>
<td>0.837</td>
<td>.555-1.262</td>
<td>.396</td>
</tr>
<tr>
<td>Single morbidity</td>
<td>1.462</td>
<td>.403-5.313</td>
<td>.564</td>
</tr>
</tbody>
</table>
A high Charlson score (>4), which indicates high level of comorbidities, and a low albumin level were risk factors for mortality post PEG placement in patients with multiple morbidities. A patient with a high Charlson score had a 2.9 times greater risk of mortality than a patient with a low Charlson score. A patient with multiple morbidities and a low albumin level had 1.3 times higher risk of mortality than those with an albumin count within normal levels.

Increased age and a decreased BMI placed a patient with a single morbidity at greater risk for mortality post PEG placement. A patient aged over 60 years, with a single morbidity at the time of PEG placement, had a 1.5 times greater risk of death than one who was under the age of 60. A patient with a single morbidity and a low BMI who was fitted with a PEG, had a 1.4 times greater risk of mortality than a participant whose BMI fell within the normal range.

Again, no single hazard ratio was found to be significant, which means that although a variable can be linked to the possibility of a higher mortality rate, in this study there was no
single variable that independently had an effect on survival time for participants with varying morbidities who had a PEG placed.

**Risk factors for mortality post placement of PEG in participants with both single and multiple morbidities**

Table 14 depicts the risk of mortality in participants with specific comorbidities, frequently seen in the South African population, such as hypertension, diabetes and respiratory disease.

**Table 14: The risk of mortality in patients with specific comorbidities after PEG placement**

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>HR</th>
<th>95% CI of OR</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(Cox regression)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>2.3</td>
<td>.434-.12.527</td>
<td>.323</td>
</tr>
<tr>
<td>Hypertension and diabetes</td>
<td>2.3</td>
<td>.251-.21.360</td>
<td>.459</td>
</tr>
<tr>
<td>Respiratory disease</td>
<td>1.4</td>
<td>.398-.4.816</td>
<td>.610</td>
</tr>
</tbody>
</table>

Note: HR: Hazard ratio; CI: Confidence intervals

For participants with morbidities who had a PEG placed, a risk factor analysis was done on specific comorbidities to determine which may pose the greatest risk of mortality post placement of enteral nutrition. Hypertension, diabetes and respiratory disease, which were the most common morbidities within the study sample, were included in the analysis. A participant with hypertension has a 2.3 times higher risk of mortality post PEG placement. A participant with hypertension and diabetes has a 2.3 times greater risk of mortality post placement. Respiratory disease posed a lesser risk of mortality post PEG placement, with a 1.4 times greater chance of mortality if present than if not.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

No single comorbidity was noted to have independently affected survival rates in this study population, but all three were noted to have a positive link to the risk of mortality.

Discussion

The rate of mortality in patients, in this study, who were recommended for and received, both short and long term enteral nutrition, was high both pre and post placement of tubes for the provision of enteral nutrition.

The high mortality rate in participants who were awaiting enteral nutrition could be attributed to multiple factors. Participants who were recommended for NGT placement did not always have one placed. These participants would, contrary to the recommendation by a medical Doctor or an SLT, be receiving oral intake or, in the case of unconscious patients, be receiving only intravenous fluids. In the case of unconscious patients, enteral nutrition should be automatically placed (Lloyd & Powell-Tuck, 2004; Stroud et al., 2003), but as noted during a review of the study participants’ hospital folders, this was not always the case. A
recommendation for NGT placement would be written in the hospital file, by the referring health professional, but the file would only note when the NGT was in situ, and not the reason for the delay in placement.

It is concerning to note the high number of participants who did not have an NGT placed after it had been recommended by a health professional. A high percentage of patients in the study died whilst awaiting the placement of an NGT. The probable impact of a lack of nutrition via an NGT is similar to, and can be compared with, the reported impact of interrupted enteral nutrition which resulted in higher mortality (Beavan et al., 2010; Kim et al., 2012). This study noted a positive link between the risk of mortality (a 2.1 times greater risk) and interrupted NGT feeds. This result was not significant, so cannot be said to have had an independent effect on mortality in the study population, but can be noted as a risk factor linked to mortality.

Survival time differed between participants who, following recommendation, had an NGT placed and those who did not. The median survival time was significantly longer ($p=0.013$) for patients who had an NGT placed (23 days) than patients who did not have an NGT placed (8 days). It is impossible to note whether the failure to place an NGT directly influenced mortality, as there are many confounding variables. When considering these variables, many of them could have affected survival time. The two groups were similar with regard to underlying medical condition, with participants presenting with an equal mix of medical conditions. The majority of these including neurological followed by non-communicable diseases, communicable diseases, trauma and delirium. All participants had dysphagia, but the type of dysphagia present in participants who had an NGT placed versus those who did not could be important for survival. Oral phase dysphagia may affect a person’s ability to achieve adequate hydration and nutrition due to limited intake. Pharyngeal phase dysphagia could place a person at fatal risk if aspiration is a symptom of the disorder. In the sample of participants who had an NGT recommended, one third who did not have an NGT placed had a diagnosis of pharyngeal phase dysphagia. This could account for the poorer survival rate in patients who did not have an NGT placed following recommendation. These patients had a risk of aspiration which increased the likelihood of morbidity and mortality. The type of dysphagia could have been an influencing factor on mortality, as could the failure to initiate enteral nutrition intake after it is recommended.
Also of concern is the high mean number of days (M: 2.74; range: 0-8) it took for an NGT to be placed post recommendation. Enteral nutrition is recommended in patients who are unable to maintain their hydration and nutritional requirements orally (Erdil et al., 2005; Holmes, 2011). If enteral nutrition is not placed, after a recommendation is made, a patient will be at risk of inadequate or unsafe intake, which can have a detrimental effect on their outcome by increasing morbidity and mortality. This study noted no significant ($p=.188$) link between the timing of placement of an NGT and mortality. But important to note is that whilst the non-immediate placement of an NGT had no effect on mortality, ultimate placement of an NGT post recommendation did have a significant effect on mortality, albeit only increasing median survival time by 15 days.

In this study, the failure to place all the recommended NGTs highlights a lack of adherence to established guidelines on enteral nutrition recommendations and placement (Bankhead et al., 2009; Kreymann et al., 2006; Loser et al., 2005; Westaby et al., 2010; Wilhelm et al., 2010). Guidelines for best practice are intended to ensure the best outcome for the patient, and should be adhered to. It would be beneficial to consider the reasons for the lack of placement in a future study so that better adherence to recommendations regarding enteral nutrition placement can be achieved, which would in turn benefit patients and could ensure more favourable outcomes in terms of survival rate.

Mortality rates of participants who had an NGT placed were high. In this study, the majority of participants who had an NGT in situ died within 1 month of placement. The high mortality rates noted in participants who had an NGT in situ could be indicative of the underlying medical condition and/or the presence of dysphagia. The primary medical condition in participants with an NGT in situ was a neurological deficit. Mortality rates in patients who have suffered neurological fallout is high, particularly in the acute stages (Laskaratos et al., 2013). The medical diagnosis of participants who had an NGT in situ could have therefore been a factor in the high mortality rates noted in this cohort. Participants who had an NGT in situ formed part of the cohort with multiple morbidities. The presence of multiple morbidities can place a patient at a greater risk of mortality, which too could explain the high mortality rates noted in this cohort. Many participants who had an NGT in situ experienced interrupted feeds, which was found to have a positive link to an increased risk of mortality, although it was not identified as an independent factor causing mortality.
The benefits of early enteral nutrition have been proven to affect outcomes of hospitalised patients. They have been linked specifically to shorter hospitalisation (Lloyd & Powell-Tuck, 2004; Malmgren et al., 2011; Prosser-Loose & Paterson, 2006), improved nutrition, a lower rate of treatment failure (Kim et al., 2012) and lower morbidity and mortality (Hartl et al., 2008). In this study over 80% of the participants who had an NGT placed died, although survival time was longer for patients who had an NGT versus those who did not. The positive outcomes that are mentioned within the literature, particularly that of lower mortality, were not noted in this study within the cohort of participants fitted with an NGT. The reasons for this could be attributed to underlying medical condition and the presence of a high level of comorbidity.

Mortality rates were high in participants who were awaiting the placement of long term enteral nutrition. The rate was higher in participants who had multiple morbidities than those who had a single morbidity. In this study, a total of 37.3% (n=91) of patients died before PEG placement. In the cohort of participants with multiple morbidities, who died before placement had, as their underlying medical condition, a neurological deficit, had pharyngeal phase dysphagia and a high level of comorbidities as indicated by a high score on the Charlson Comorbidity Index. A patient’s underlying medical condition, as well as the presence of comorbidities, can place them at a higher risk of death (Blomberg et al., 2012; Erdil et al., 2005; Kirchgatterer et al., 2007). The presence of dysphagia, particularly pharyngeal phase dysphagia which can include aspiration, is also a risk factor for mortality (Carrion et al., 2014; Koidou, Kollias & Sdravou, 2014). This high level of morbidity and the presence of an underlying neurological condition in participants who were referred for PEG placement, contribute to the vulnerability of this cohort and could explain the high mortality rates.

This cohort of participants were referred for PEG placement by an SLT. In this study it is not possible to comment on the period of time that a patient had been in hospital before a referral was made to an SLT for a dysphagia assessment. It is not possible then, to comment on the effect that a possible delay in referral to an SLT may have had on a participant’s outcome. If there was a delayed referral to an SLT, there may have been a delay in the recommendation for enteral nutrition, which could have affected outcomes. Data was available in this study
for comment to be made on the time lapse between the first dysphagia assessment by an SLT and the recommendation for a PEG.

All patients who were recommend for a PEG by an SLT were receiving hydration and nutrition via an NGT at the time of PEG recommendation, but were considered PEG candidates due to the severity of dysphagia, or the lack of progress in therapy to remediate the swallow. If one considers the high mortality rate within one week of NGT placement, in this study, together with the fact that the majority of recommendations for PEG by an SLT took place within the first week after initial dysphagia assessment (Mean ± STD 4.78 ± 3.373), one could conclude that the timing of PEG recommendations was too hasty. Patients who died either before NGT placement, or within one week of placement, are inappropriate candidates for PEG due to their high risk of mortality before PEG placement. In this study, participants who were referred too hastily for PEG placement, add to the mortality figures ‘pre PEG placement’, when in fact they should never have been considered as candidates.

Literature suggests the need to carefully assess a patient and identify all risk factors for mortality before a decision is made for the recommendation of a PEG. (O’Mahony, 2012; Playford, 2010; Richards et al., 2013; Tanswell et al., 2007). A patient who is considered a high risk for mortality should not be considered a candidate for the procedure as it would be a futile intervention. Better patient selection would improve the outcome of patients who are recommended for and fitted with a PEG (Kurien et al., 2010). The high mortality rate of participant’s pre PEG placement in this study highlights the lack of a holistic consideration of all factors that could influence outcome, before recommendation for is made PEG.

Mortality figures post PEG placement in this study were higher than those noted in other studies. Mortality rate at 1 week post placement was 6.5%, which was higher than that reported in literature (Azzopardi & Ellul, 2013; Janes et al., 2005; Smith et al., 2008). At 30 days post placement, the mortality rate was 22.6%, which was higher than that reported in some studies (Azzopardi & Ellul, 2013; Gumaste et al., 2014; Gundogan et al., 2014; Kirchgatterer et al., 2007; Lee et al., 2013; Paramsothy et al., 2009; Richter-Schrag et al., 2011; Zopf et al., 2011) but equal to the rate in others (Malmgren et al., 2011; Smith et al., 2008). The 90 and 180 day mortality rate in this study were 16.1% and 13% respectively. The 90 day mortality rate was higher than some literature (Zopf et al., 2011) and lower than others.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

(Janes et al., 2005; Malmgren et al., 2011). The 180 day mortality rate was also lower than that noted by Janes et al. (2005). In participants for whom there was complete data for follow up until 6 months post PEG placement (n=21), only 1 participant was still alive at the end of the study period.

It is noted that high mortality rates post PEG placement are not a result of the procedure (Erdil et al., 2005) and reasons for high mortality rates have been suggested. These include 1) poor timing in the placement of PEG (Abuksis et al., 2000), and 2) inappropriate patient selection (Blomberg et al., 2012; Erdil et al., 2005; Kirchgatterer et al., 2007; Kurien et al., 2010; Laskaratos et al., 2013; Richards et al., 2013).

The notion of poor timing in the placement of PEG is linked to poor patient selection. If a patient has an underlying medical condition that places them at risk for mortality, it can be argued that they would have died regardless, and early PEG insertion, at a time when they are at risk of death due to an underlying medical condition, means that they die with a PEG in situ which makes their death a statistic of mortality post PEG placement. To counteract early PEG placement, it is suggested that if a patient still requires a PEG after their condition has stabilised, and they are still alive to receive it, only then should it be considered. Abuksis et al. (2000) noted a lower mortality rate in patients who were deferred for PEG placement until they were discharged from hospital and if it was still required at 30 days post discharge.

In this study there was no significant effect (p=0.221) on the timing between a PEG recommendation to PEG placement and mortality post placement. Participants who had a PEG placed one week versus one month after it was recommended did not survive significantly longer. Correspondingly, those who waited over a month after recommendation for PEG placement did not have a significantly longer survival than those who were fitted almost immediately. The large majority of patients in this study who had a PEG placed ended up dying, regardless of the timing of placement from recommendation.

When analysing the results of this study, it would appear that the high mortality rates can be attributed to underlying participants underlying medical conditions, and level of morbidity. The mortality levels post PEG placement in this study could indicate poor patient selection, rather than the effect of timing on placement.

A patients underlying medical condition, as well as the presence of morbidities can place them at risk for mortality, regardless of whether a PEG is placed or not. There are also a
series of risk factors that have been identified as placing a patient at greater risk of mortality post PEG insertion. These include increased age, decreased body mass index, increased number of morbidities, and decreased blood albumin levels.

These risk factors were analysed in this study, and were noted to have a positive link to the risk of mortality. None of the risk factors were found to be significant, which means that no single factor can be directly attributed to an increased mortality rate. These results caution a clinician to consider aspects such as increased age, decreased body mass index, increased number of morbidities and decreased blood albumin levels when making a recommendation for PEG placement.

The primary medical condition in this study for participants who were recommended for long term enteral nutrition was non communicable diseases, more specifically head and neck cancer. This result is in contrast to, but still in line with, the majority of literature which cites neurological deficits to be the main indicator for the recommendation of a PEG and head and neck cancer as the second most common indicator (Barker et al., 2012; Blomberg et al., 2012; Erdil et al., 2005; Gumaste et al., 2014; Kirchgatterer et al., 2007; Kobayashi et al., 2002; Malmgren et al., 2011; Paramsothy et al., 2009; Richter-Schrag et al., 2011; Smoliner et al., 2012). The second most common indicator for the placement of PEG was a neurological deficit. The population of patients who had a neurological deficit were at risk for death due to their underlying medical condition (Sabin, 2008). Patients with head and neck cancer have a 5-year survival rate of 35-50%, but if in advanced stages at the time of treatment, this rate drops and can range from 0-50% (Semple, Sullivan, Dunwoody & Kernohan, 2004). Patients often wait too long before seeking medical attention, resulting in a late stage of cancer at the time of diagnosis (Sing & Subramaniam, 2006). The staging of cancer that a patient presented with was not collected within this study. It would be an interesting factor to consider when recommending intervention for nutrition in patients with head and neck cancer, as it would affect outcome and survival. If participants with head and neck cancer in this study were in the advanced stages of cancer, this may have reduced their survival time post PEG placement, and would have negatively affected the survival times of participants with a single morbidity who were fitted with PEG.

The majority of participants who had a medical diagnosis of head and neck cancer, who were referred for PEG placement, fell into the cohort of participants who had a single morbidity. The majority of those with neurological fallout, who were referred for PEG placement, fell
into the cohort of participants who had multiple morbidities. This study considered survival rates of patients with a single morbidity and those with multiple morbidities who had a PEG placed. Patients with a single morbidity survived for 54 days compared to patients with multiple morbidities who survived for 24 days. The survival times reflect the sentiment that a patient with multiple morbidities is at greater risk of early mortality post PEG insertion due to their fragile state (Kobayashi et al., 2002; Lang et al., 2004; Poulsen, 2009). Barker et al. (2012) considered the mortality rate in their study and concluded that, despite careful patient selection, the high mortality rate warns against PEG placement in patients with multiple morbidities.

This study also compared the outcomes of participants fitted with PEG (with multiple morbidities and a single morbidity) to those who were identified as having multiple risk factors that would place them at risk for mortality post PEG insertion and as a result were not referred for PEG placement, but rather for oral palliative nutrition. Participants who received oral palliative nutrition survived for 19 days; only five days less than those who had multiple morbidities and underwent PEG placement and survived for 24 days. It could be argued that, the resources used to place a PEG in patients who will only survive an extra five days, should rather be reserved for those who will receive maximum benefit. Patients who did not receive a PEG, but who were on oral palliative nutrition, survived for only five days less than patients with multiple morbidities who had a PEG placed. With survival time not much different between these two groups consideration should be given to the recommendation of an oral palliative approach rather than a PEG. This could spare valuable resources and avoid a futile procedure.

If a patient is considered to be a high risk for mortality, certain procedures may be deemed futile, such as a procedure that will cause further suffering and no benefit (Holmes, 2011). The decision to place a PEG should be based on the perceived benefit it will bring to the patient (DeLegge et al., 2005) and if no benefit is presumed, then the procedure should not be done. A patient who is identified as a high risk for mortality post PEG placement should not receive a PEG but rather they and their families should be counselled on the risks that exist and the reasons for deferred placement. It can be argued that a survival time of an additional five days for patients with multiple morbidities who received PEG compared to those with multiple morbidities who were put onto oral palliative nutrition, is not sufficient to warrant the use of resources on a PEG which appears to be futile.
A patient is often recommended for a PEG if they are showing no signs of recovering their swallow and have been on NGT feeds for an extended period of time. Conflicting evidence exists around the time frame of NGT intake and when a patient should be recommend for a PEG. Most literature recommends NGT feeding in the acute stages of disease (Prosser-Loose & Paterson, 2006) for a time period of four to six weeks (Stroud et al., 2003). The majority of the patients in this study had, as per recommendations in literature, an NGT in situ for under six weeks. At the point that NGT feeds had gone over the recommended time frame, a medical professional would have recommended a PEG for patients.

The amount of time an NGT has been in situ is not the only consideration when deciding if a patient would benefit from a PEG. Literature notes that a PEG should be considered if a patient has been on NGT feeds for this period, is showing no signs of being able to feed orally and is at high risk for malnutrition (Stroud et al., 2003). Given the high mortality rates post PEG insertion, it cannot stand that this is the only consideration in the decision to recommend a PEG or not. A major factor should be the determination of whether the patient’s prognosis justifies the intervention (Abuksis et al., 2004; Rio et al., 2010).

The median survival time of participants with multiple morbidities, in this study, who demised with an NGT in situ, was 20 days. When one compares this to participants with multiple morbidities who were fitted with a PEG, the difference in survival time is only four days, with PEG participants surviving for 24 days. The result suggests that in patients with multiple morbidities, the placement of a PEG versus a patient remaining on NGT feeds, may lead to four additional days survival. This comparison in survival rates, again raises the question of whether participants with multiple morbidities should receive PEG placement, if median survival time in these participants versus those on NGT feeds was only four days longer.

Ultimately, in this study the outcome for both, patients who were receiving intake via NGT and those receiving intake via a PEG was death, which is not favourable. This leaves no clear decision of which method of enteral nutrition is best to recommend within a cohort of participants with multiple morbidities. Important to consider though is that a patient with multiple morbidities who had a PEG inserted survived for a median of only four more days than a patient with multiple morbidities who had an NGT in situ at the time of death. These four days leads one to question whether a PEG procedure yielding these results is beneficial or futile.
When comparing participants with multiple morbidities to those with a single morbidity, and deciding which method of enteral nutrition is best, there are considerations to make. A patient with a single morbidity who had a PEG placed had the longest median survival time of 54 days. A patient with multiple morbidities who had a PEG placed had a median survival time of 24 days and a 1.3 times greater risk of death if PEG was placed instead of NGT. Although a participant with a single morbidity with a PEG in situ survived for a longer median time than a participant with multiple morbidities with a PEG in situ, the ultimate outcome was mortality. There was not much difference in survival time of participants who received different forms on enteral nutrition (NGT versus PEG), with mortality as the outcome for a large majority of these participants.

The results of this study highlight the need for other forms of intake to be considered before a PEG is recommended. A patient may wish to refuse a PEG procedure and remain on NGT or go home on an oral intake, even if it means that they will survive for fewer days than patients who may decide to have a PEG placed. This is a decision that needs to be honoured and respected by health care professionals (Daniel, Rhodes, Vitale & Shega, 2014).

In participants with multiple morbidities, there was a minimal difference in the survival times of participants who were on oral palliative nutrition and those who received NGT feeds and PEG feeds. This leads one to conclude that in a cohort of patients with multiple morbidities it may be best to spare resources used in the placement of both NGT and PEG for the provision of nutrition and to consider discharging a patient on oral palliative nutrition, with education on maintaining hydration and nutrition orally in the safest way.

Ultimately, based on the clear risk factors and definite poor outcome expected, a patient with multiple morbidities should not be considered for a PEG. This study noted a positive link between the risk of mortality in participants with multiple morbidities and PEG placement. A participant with a single morbidity was noted to have the highest median survival time in this study, but still needs to be considered on an individual basis with the risk factors weighted up. This study noted a positive link between the risk of mortality and a low body mass index and increased age in participants with a single morbidity. Although participants with a single morbidity survived for a longer period, risk factors for mortality post PEG placement still exist in this cohort. Although not noted in this study, good outcome in patients with head and neck cancer who undergo PEG placement and not only survive, but benefit from the
nutritional value the PEG provides and move back onto a full oral diet when appropriate (Richter-Schrag et al., 2011; Wermker et al., 2012; Zuercher, Grosjean & Monnier, 2011).

Based on the findings, of survival rates, in this study, a decision on the type of enteral nutrition to recommend in different cohorts of patients, cannot be definitively stated. The results aim to guide health professionals in decision making. In a cohort of patients who have multiple morbidities and have a poor prognosis, based on the factors that are identified as placing a patient at a higher risk for mortality after PEG (a high Charlson score, increased age, decreased BMI and decreased albumin levels), health care professionals need to strongly consider avoidance of any aggressive intervention with regards to enteral nutrition. In cases where a patient is considered a high risk for mortality should they have a PEG placed, a strong recommendation for a palliative approach, where enteral nutrition is avoided, should be discussed with the patient and their family. By considering the small difference in the survival times in this study of participants with multiple morbidities who had different forms of nutrition (oral palliative, NGT and PEG), health care professionals need to seriously consider whether a recommendation of enteral nutrition for these patients is appropriate.

The decisions around the recommendation of enteral nutrition, particularly in very ill patients who have a poor prognosis, are not easy for health care professionals to make. Clear guidelines that are based on evidence based outcomes of patients who have had enteral nutrition placed are crucial in order to provide help to health care professionals to navigate the difficult decisions that are often clouded with human emotion. The results of this study reveal important findings on survival rates for different cohorts of participants and factors affecting survival. It is the hope of the researcher that these findings can be used as a starting point for health professionals when deciding on the recommendation for enteral nutrition in the adult population in the South African context. It is also the hope that there is careful assessment of the individual patient by a multi-disciplinary team, which must include counselling of the patient on possible outcomes of the procedure with a strong emphasis on patient autonomy as key in the decision making process.

A role not often considered by Speech Therapists is that of palliative care. The results of this study highlight the need to consider this approach rather than an aggressive intervention in patients who cannot maintain hydration and nutrition orally, and who are at risk of mortality if fitted with a tube for the provision of enteral nutrition.
The provision of artificial nutrition and hydration (ANH) to patients who are in the end stages of disease is debated within literature, and can evoke emotional responses (Dev, Dalal & Bruera, 2012). Many feel that to deprive a patient of hydration and nutrition is unethical and the situation can make health professionals uncomfortable (Bryon, de Casterle & Gastmans, 2012; Delegge et al., 2005). It is common for patients in the end stages of disease to have little or no oral intake (Stiles, 2013). In a study on nurses’ perceptions on ANH in palliative care, it was found that there were more clinical reasons given for the withholding of ANH than for giving it (Stiles, 2013). Reasons for why ANH should be given were emotive and not based on clinical fact (Stiles, 2013). Decisions to provide ANH which are based on emotion, and not clinical evidence, are not in the best interests of the patient, with each case being discussed individually (Dev et al., 2012).

In practice, there comes a time, when a decision needs to be made about the hydration and nutrition of a patient in the end stages of disease. The Speech Therapist, involved in the assessment and treatment of dysphagia, is often the professional who, based on assessment findings that will best fit the patient’s current needs, is in a position to recommend a form of intake. It is crucial, therefore, that any medical professional who is managing a patient in the end stages of disease, including a Speech Therapist, have adequate training in the field of palliative care and ANH (Bryon et al., 2012; Stiles, 2013) or has the referral routes available to trained palliative care Doctors who can help with the decision around a patient’s hydration and nutrition needs. This may reduce the number of inappropriate referrals for tubes to provide both short and long term enteral nutrition. A more conservative approach, based on the principles of palliative care, can be used.

Referral sources for enteral nutrition were considered in this study. The results indicate that short term enteral nutrition via an NGT was recommended for dysphagia more often by an SLT than by a medical Doctor. This finding suggests that when assessing a patient both medical Doctors and SLTs are aware of the possibility of dysphagia and the need for enteral nutrition in patients with dysphagia as a method to help with delivery of hydration and nutrition. An SLT may be more aware than a medical Doctor of dysphagia and the need for enteral nutrition because it is within the SLTs scope of practice to assess and manage dysphagia specifically (Seidl et al., 2008). The fact that a greater number of patients were referred for enteral nutrition by an SLT may indicate that an SLT, conducting a full assessment as opposed to a screener that a medical doctor may conduct, is more aware of small degrees of difficulty caused by dysphagia. None of the participants in the study had an
objective assessment, such as a videofluoroscopy (VFSS), to diagnose pharyngeal phase 
dysphagia. The SLT conducted a bedside evaluation to assess the swallow and on the basis of 
the findings would infer the patient as having pharyngeal phase dysphagia. The reliability of 
the SLTs clinical assessment and interpretation of the signs of dysphagia noted could be 
challenged. A definitive diagnosis of pharyngeal phase dysphagia would require an objective 
assessment such as VFSS or fiberoptic endoscopic evaluation of the swallow (FEES).

Of the participants in the study, all of whom had a diagnosis of dysphagia, only a third were 
recommended for short term enteral nutrition by a medical Doctor. It is concerning that the 
remaining two thirds of these participants, who had been treated by a medical Doctor at the 
time of referral to an SLT, were only referred for NGT placement when assessed by an SLT. 
A medical doctor will have first contact with a patient upon admission. If a patient is 
admitted over a weekend when an SLT may not be on duty, and not referred for NGT 
placement by a medical Doctor, the patient could be left at risk of dysphagia until an 
assessment by an SLT is done the following week.

Literature notes that all patients who are admitted to hospital should be screened for 
dysphagia and malnutrition on admission, and placed on enteral nutrition immediately if 
needed (Bankhead et al., 2009; Scottish Intercollegiate Guidelines Network; Malmgren et al., 
2011). This study did not collect data on screening procedures post admission and cannot 
comment on whether dysphagia screening by medical Doctors occurs as a routine procedure 
when a patient is admitted with neurological damage. The discrepancy between the number 
of NGTs recommended by a medical Doctor and by an SLT could indicate the need for a 
dysphagia screening upon admission to ensure that all dysphagia patients are correctly 
identified in a timely manner in order to minimise risk in this population. Screening for 
dysphagia may not be the best use of a medical Doctors time due to the fact that they in short 
supply and have scarce skills that are best used for other procedures. A solution to this could 
be the introduction of a dysphagia screening protocol for other health care professionals, such 
as Nurses, to administer (Donovan et al., 2012; Freeland, Garrett, Pathak, Anderson & 
Daniels, 2012)

This study also looked at the recommendation practices of long term enteral nutrition. Long 
term enteral nutrition was also recommended most often by an SLT but, in comparison to 
short term enteral nutrition, was placed more frequently after a recommendation was made by 
a medical Doctor rather than by an SLT. This may be because a Doctor who is referring for
the placement of a PEG has a more direct line of contact with the gastrointestinal (GIT) Doctors who will perform the procedure and so are able to ensure better follow through for the procedure after it has been recommended. An SLT, however, who recommends a PEG needs to work through the medical Doctor in the ward who will contact GIT to consult on the patient. This finding may reveal the need for a greater focus on multi-disciplinary team (MDT) work where an SLT is able to consult directly with a GIT Doctor to discuss patient referrals for PEG placement.

None of the participants with a single morbidity, who were recommended for PEG placement by a medical Doctor, were ever referred to an SLT for a dysphagia assessment. They were diagnosed with oral pharyngeal phase dysphagia by a medical Doctor and referred for a PEG. This finding, again, highlights the need for greater MDT work in the assessment and management of patients with dysphagia. The large majority of these participants had head and neck cancer. The awareness that a medical Doctor may have about the disease process in head and neck cancer may prompt a greater number of referrals for PEG placement than from another medical professional, and the belief that a dysphagia assessment by an SLT is not warranted as the patient will require enteral nutrition regardless. Some studies suggest that PEG placement in head and neck cancer patients can exacerbate dysphagia and reduce a patient’s ability to return to oral intake (Langmore, Krisciunas, Miloro, Evans & Cheng, 2011) as patients become too reliant on PEG feeding. This alone would be a sufficient reason to refer these patients to an SLT for assessment to establish if oral feeding, alongside PEG feeds, is possible. Oral intake throughout a period of PEG feeding would help patients move back onto oral feeds in the future, if this was a possibility.

Further evidence exists to support the involvement of an SLT in the assessment and treatment of patients with head and neck cancer. Langmore et al. (2011) highlight a need in head and neck cancer patients for the use of swallow manoeuvres via training from an SLT as opposed to compensatory strategies which can be suggested by a medical Doctor. It is important for an SLT to assess a patient with head and neck cancer and to determine the most optimal approach for each patient to be able to recover swallowing or to compensate for losses due to surgical or chemo-radiation intervention.

Strong emphasis is placed upon a multi-disciplinary approach when assessing patients who may be recommended for long term enteral nutrition (O’Mahony, 2012; Playford, 2010; Tanswell et al., 2007). In this study the lack of referral of head and neck cancer patients and
those with neurological fallout as a result of cardiac arrest, as well as the referral for PEG based solely on a Doctor’s recommendation, shows a lack of a multi-disciplinary approach. When plans for treatment were made, and before referral for a PEG, all patients should have been discussed at a team level, as well as with the patient and their family or caregiver.

A more rigorous assessment procedure, by a multi-disciplinary team, for all patients who are considered for a recommendation for PEG needs to be put into place. This will ensure that all aspects that could affect outcome are considered and an informed decision based on the best interests of the patient can be made, which upholds the medical ethics of autonomy, beneficence and non-maleficence.

**Limitations to the Study**

While the main aims of the study were met, there were some unavoidable limitations that must be noted. The retrospective nature of the study resulted in many limitations. A major limitation of retrospective data collection is the possibility of missing data. This was experienced in the study, with regards to missing data for BMI in the cohort of participants with multiple morbidities. This resulted in the risk factor of low BMI being impossible to calculate in this cohort of participants.

There were time constraints for the data collection period, due to the study being a Masters dissertation with a time limit for submission, from the point of registration. These constraints meant that only the number of patients who were referred for enteral nutrition in a specified time frame could be included in the study. This impacted on sample sizes for each of the cohorts and could have resulted in a lack of statistical significance of results. Many studies that analyse survival do so for a period of one year or more into. This study had to place a limit of six months on the follow up of participants, so as to meet the deadline of submission within the specified limit set by the University for postgraduate dissertation. A longer follow up period, along with a larger sample size, could have resulted in different results.

There was a large number of participants who were lost to follow up, particularly in the cohort of participants with multiple morbidities who were fitted with a PEG. The retrospective nature of data collection for this cohort meant that follow up post the point of the last medical note in the patient file was not possible. It would have been impossible to collect prospective data on this cohort, because at the time that the study commenced, the
change in approach to the recommendations for PEG by an SLT working at CHBAH had already changed. The only way to collect data on participants who were referred for PEG placement under the old approach to the recommendation for PEG, was by using a retrospective approach.

The loss to follow did impact on the sample size of participants whose survival times could be analysed. The effect of this can be noted in the high number of participants who fell under “censored” and not “event” in the statistical output tables found under the Kaplan Meier graphs. ‘Censoring’ means that the survival time could not be accurately determined, because there was missing data from some sets due to drop out or loss to follow up (Rich, Neely, Paniello, Voekler, Nussenbaum & Wang, 2010). Despite a high level of censoring on some of the Kaplan Meier graphs, significant differences in survival times were noted, which means that the results shown are useful and reliable.

**Implications for Future Research**

Future research in this area should focus on prospective data collection to limit the occurrence of missing data. It should also look to increase the sample sizes of each cohort, and include a longer follow up time of patients who are referred for enteral nutrition. Research should consider follow up of patients who are now managed under the new approach and placed on oral palliative nutrition instead of receiving a PEG. A structured follow up of these patients should be considered, with regards to checking on optimization of hydration and nutrition and safety under this management strategy. These participants could be followed up and reassessed for long term enteral nutrition, if appropriate, after which outcomes could be assessed on patients who have a PEG placed immediately versus those who return as an out-patient and have a PEG placed if prognosis is improved. Future research could look at including ‘improved nutritional status’ and ‘return to oral feeds’ as outcome measures, to be analysed, in different cohorts of adult patients fitted with long term enteral nutrition.

**Conclusion**

The aims of this study were met. There is a high mortality rate in patients who are recommended for, and fitted with, tubes for the provision of both short and long term enteral
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

nutrition. The reasons for high mortality appear to be linked to the patient’s level of morbidity and their underlying medical condition. The high levels of mortality in the study population were not limited to a particular type of enteral nutrition but was high across cohorts regardless of the type of enteral nutrition placed. This leads one to conclude that a greater focus should be placed on a palliative approach to nutrition and hydration, with education on meeting hydration and nutritional needs in the safest way. This approach should be considered in patients who present with similar medical profiles to those in this study, as an aggressive approach that employs the use of enteral nutrition does not appear to reduce mortality or prolong survival greatly.

This study highlights the need for any patient with dysphagia, with a single morbidity or multiple morbidities, who may require enteral nutrition, to be assessed and managed by a multi-disciplinary team in a holistic manner. An SLT should be involved in the assessment and management of all patients with dysphagia who may require enteral nutrition, and health care professionals need to be made more aware of the need for SLT dysphagia services to ensure appropriate referrals, in order to achieve optimal patient outcomes. All aspects linked to possible mortality must be considered, and risks and benefits weighted up, before a recommendation for enteral nutrition is made. In the decision making process for patients who are considered for the placement of enteral nutrition, the ethical considerations of beneficence and non-maleficence are key to deciding if a procedure is necessary or futile.

References


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa


Appendix A: Charlson Comorbidity Index
(Charlson, Pompei, Ales & MacKenzie, 1987)

1. Indication
Assess whether a patient will live long enough to benefit from a specific screening measure or medical intervention

2. Scoring:
Comorbidity Component (Apply 1 point to each unless otherwise noted)
1. Myocardial Infarction
2. Congestive Heart Failure
3. Peripheral Vascular Disease
4. Cerebrovascular Disease
5. Dementia
6. COPD
7. Connective Tissue Disease
8. Peptic Ulcer Disease
9. Diabetes Mellitus (1 point uncomplicated, 2 points if end-organ damage)
10. Moderate to Severe Chronic Kidney Disease (2 points)
11. Hemiplegia (2 points)
12. Leukemia (2 points)
13. Malignant Lymphoma (2 points)
14. Solid Tumor (2 points, 6 points if metastatic)
15. Liver Disease (1 point mild, 3 points if moderate to severe)
16. AIDS (6 points)

Age
1. Age <40 years: 0 points
2. Age 41-50 years: 1 points
3. Age 51-60 years: 2 points
4. Age 61-70 years: 3 points
5. Age 71-80 years: 4 points

**Appendix B:** Data collection tool

Group #
Patient code ####
Sex #
Date of birth ########
Height ###
Weight ###

Primary medical condition ##
Secondary medical condition ##
RVD status #
TB status #
Comorbidities ##
Respiratory #

Patient state at assessment #
Type of dysphagia #
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Current method of intake #
Method of intake recommended post assessment #
Time frame of EN need #
Enteral nutrition recommended #
Enteral nutrition placed/in place #

Albumin level ####
Interrupted feeds documented #

Demised before placement #

Demised 1 day after placement #
Demised within 7 days after placement #
Demised within 30 days after placement #
Demised within 6 months after placement #
Demised within 1 year after placement #

Appendix C: Ethics approval letter from The Faculty of Health Sciences Human Research Ethics Committee at The University of Cape Town
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Human Research Ethics Committee
Room E62-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone (021) 403 6339 • Facsimile (021) 403 6411
e-mail: shustakethomas@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

23 August 2013

HREC REF: 503/2013

A/Prof S Singh
Health & Rehab
F45, OMB

Dear A/Prof Singh

PROJECT TITLE: RISKS AND OUTCOMES FOR ENTERAL NUTRITION AMONG ADULTS WITH AND WITHOUT DYSPHAGIA AT A TERTIARY LEVEL HOSPITAL IN SOUTH AFRICA

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has formally approved the above-mentioned study.

Approval is granted for one year till the 30th August 2014

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period. (Forms can be found on our website: www.health.uct.ac.za/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC. REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001238
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

shustakethomas
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

### Appendix D: Permission to amend the name of the study

**University of Cape Town**

*Faculty of Health Sciences*

*Form D9: Approval for Change of Title*

Please complete and return to Jackie Cogill (Jackie.cogill@uct.ac.za) in the Postgraduate Office

**Name and student no**

Nicoll Kenny KNNNIC005

**Degree name (e.g. MSc(Med) in Physiology)**

MSc in Speech Therapy and Audiology

**Email address for correspondence**

noodlekenny@gmail.com

**Student signature:**

![Signature](signature-image)

**Date:**

30 March 2015

**Qualifications**

Speech Therapy Honours

**Old Title**

Risk and outcomes for enteral nutrition among adults with and without dysphagia at a tertiary level hospital in South Africa

**Proposed new title**

Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa.

**Proposed title change supported by Departmental Research Committee (DRC)**

**Name of Chair, Departmental Research Committee:**

Michele Paige

**Signature:**

![Signature](signature-image)

**Please give reason for the need for to change your thesis/dissertation title:**

Initially I thought I would include participants without dysphagia who had enteral nutrition but then it was decided that it would be too difficult to recruit every patient in the hospital who had enteral nutrition, unless they had dysphagia in which case they would have been assessed and managed by Speech Therapy. This part was then omitted and the project included only participants who had dysphagia.

*(if you require more space than this then please attach a separate page)*

**I support / do not support the thesis/dissertation title change as requested by this student**

**Supervisor name and signature:**

Name: Shajile A Singh

Signature: [Signature]

Date: 30 March 2015

**I recommend / do not recommend the thesis/dissertation title change as requested by this student**

**HOD name and signature**

Name: Helen Buchanan

Signature: [Signature]

Date: 30 March 2015

**I approve / do not approve the thesis/dissertation title change as requested by the above student**

**Deputy Dean: Postgraduate Affairs**

Name: [Name]

Signature: [Signature]

Date: [Date]
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Approval to amend the name of the study was sought by the researcher. The D9 documentation has been signed and approved by the Chair of The Departmental Research Committee, Shajila Singh (supervisor of the study) and by the HOD for Communication Sciences at The University of Cape Town. It has been sent to the post graduate office and is awaiting approval there. The name amendment will be updated on peoplesoft system as soon as it has been processed by the post graduate office. Please do not hesitate to contact the researcher should you require any further communication on this matter.

Email: noodlekenny@gmail.com

Phone: 082 902 1054
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Appendix E: Ethics approval letter from the internal ethics committee at Chris Hani

GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 27 March 2015

TITLE OF PROJECT: Risks and outcomes for enteral nutrition among adults with and without dysphagia at a tertiary level hospital in South Africa

UNIVERSITY: Cape Town

Principal Investigator: N Kenny

Department: Speech and Hearing Therapy

Supervisor (If relevant): S Singh

Permission Head Department (where research conducted): Yes

Date of start of proposed study: 2014
Date of completion of data collection: 2015

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- The Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- The MAC will be informed of any serious adverse events as soon as they occur
- Permission is granted for the duration of the Ethics Committee approval.

Recommended
(On behalf of the MAC)
Date: 27 March 2015

Approved/Not Approved
Hospital Management
Date: 30/03/15
Appendix F: Approval letter from the head of the Speech Therapy and Audiology Department to conduct research within the department
Aims and Objectives

Three groups of adult patients with dysphagia were included in this study:

Patients with multiple comorbidities who were assessed by Speech Therapy and referred for enteral nutrition (NGT and/or PEG) placement

Patients who were assessed and recommended by Speech Therapy for oral palliation instead of enteral nutrition because they were considered high risk for mortality post enteral nutrition placement

Patients with a single morbidity who were referred for enteral nutrition (NGT and/or PEG) placement by a medical Doctor

The aim and objectives were to:

1. In patients with dysphagia managed by speech therapists and by doctors, to
   a. Describe the mode of nutritional intake (i.e. oral, enteral (NGT and PEG tube) or a combination) recommended
   b. Determine whether there were any significant differences in the mode of intake recommendations
   c. Determine whether there were any significant differences in the rate of enteral nutrition (i.e. NGT and PEG tube) placed after it had been recommended

2. Compare the indications for a recommendation for short or long term enteral nutrition

3. To determine the time period taken to effect enteral nutrition recommendations
   a. NGT - from time of Speech Therapy recommendation to placement
   b. PEG - from time of Speech Therapy assessment to recommendation
   c. PEG - from time of medical Doctor recommendation to placement

4. For those who were recommended for short term enteral or long term enteral nutrition compare the outcome of mortality
   a. Pre placement
   b. One day post placement
   c. One week post placement
   d. One month post placement
   e. Three months post placement
   f. Six months post placement

5. A comparison of the survival time of patients who received different modes of intake
   a. Patients fitted with NGT versus patients fitted with PEG
   b. Patients with single morbidity fitted with PEG versus patients with multiple morbidities with PEG
   c. Patients who were deferred for PEG and received oral intake versus patients who received a PEG

6. Determine which of the following were risk factors for mortality post placement of enteral nutrition
   Increased age (older than 60 years)
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Low albumin levels (lower than or equal to 35 g/L)
Decreased quantity or absent intake of hydration and nutrition prior to placement of long term enteral nutrition (including interrupted feeds if NGT was the primary route of intake pre PEG placement)
Presence of comorbidities (A score greater than or equal to four as rated using The Charlson Comorbidity Index)
A short length of time (in days) between recommendation for and placement of enteral nutrition (NGT and PEG)
Low body mass index at time of long term enteral nutrition placement (Lower than or equal to 18.5 kg/m²) (applicable only to patients whose BMI was available in hospital file)

Data collection will take place outside of work hours and will not impact on the work of any of the staff a CHBAH. For the retrospective data needed the researcher will need access to names of patients who were assessed and managed by Speech Therapy. The researcher will then access the hospital files from the archive department at CHBAH.

For patients who will form part of the prospective data set, the researcher will need access to the booking diary for PEG procedures in order to get the names of patients who have been referred for PEG by a medical Doctor. The GIT who performs the PEG procedures will not be required to take part in the study and so will not be inconvenienced in any way. Once the researcher has the patient name she will locate the patient in the wards and obtain informed consent from the patient and then review their medical file as per the procedure for date recording.

All ethical considerations have been met in accordance with Helsinki 2008.

Autonomy: Implied consent will be obtained from patients whose information is being collected prospectively so that autonomy will be upheld. Autonomy does not apply to the data collected from folders as no direct participation is required from volunteers.

Confidentiality: This will be upheld by storing data on a lap top that is password protected and is kept in a safe, locked room when not in use. Patient names will not be recorded, but rather coded at the time of data collection to ensure confidentiality and aid in the blinding process to assess reliability. Coding will be done by assigning each patient with a number that will be used throughout the study process. At the end of the study period all identifying information will be destroyed so that no link can be made between codes and patients.

Beneficence: Participants are not directly involved in this study, and will not be expected to take part in any kind of testing. Participants who are involved in the study will not benefit from this study but the results could be used to benefit others who receive enteral nutrition in the future.

Non-maleficence: No harm will be caused from conducting this study as it involves no direct participation from patients. Basic information that forms part of a medical work up pre surgery will be included, but no extraordinary involvement is required from participants so no harm is expected from the study.

Justice: All participants who meet the inclusion will have an equal chance of being included in the study. The benefits of the study will be applicable to a similar population from which the participants were drawn.

I will be supervised by a member of faculty at The University of Cape Town (Prof. Shajila Singh) who will help to guide the research process and ensure all aspects are considered. At any point in the research process the student and supervisor will be available to discuss problems that may arise.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

There are no financial benefits for the researcher taking part. All results and write up from the study will be shared with your department.

I therefore request permission to conduct my research at your site, using medical folders of adult patients who were assessed and managed by Speech Therapy and GIT within the wards during the set study period.

This study has met the ethics approval from The Faculty of Health Sciences at The University of Cape Town

HEREC#: 503/2013

Regards,

Nicoll Kenny

Tel: 082 902 1054

Email: noodlekenny@gmail.com

Prof Shajila Singh (research supervisor): shajila.singh@uct.ac.za

If you have any questions about the ethics of this study please contact the chairperson of Faculty of Health Sciences Human Research Ethics Committee: Prof Mark Blockman.

Marc.Blockman@uct.ac.za, Tel: 021 406-649

<table>
<thead>
<tr>
<th>Name of person providing permission</th>
<th>Department</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Sadna Balton</td>
<td>Speech Therapy &amp; Audiology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chris Hani Baragwanath</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Academic Hospital</td>
<td></td>
</tr>
</tbody>
</table>

123
Appendix G: Approval letter from the head of the GIT department to conduct research within the department

There are no financial benefits for the researcher taking part. All results and write up from the study will be shared with your department.

I therefore request permission to conduct my research at your site, using medical folders of adult patients who were assessed and managed by Speech Therapy and GIT within the wards during the set study period.

This study has met the ethics approval from The Faculty of Health Sciences at The University of Cape Town

HEREC#: 503/2013

Regards,

Nicoll Kenny

Tel: 082 902 1054

Email: noodle.kenny@gmail.com

Prof Shejila Singh (research supervisor): shejila.singh@uct.ac.za

If you have any questions about the ethics of this study please contact the chairperson of Faculty of Health Sciences Human Research Ethics Committee: Prof Mark Blockman.

Marc.Blockman@uct.ac.za, Tel: 021 406-649

<table>
<thead>
<tr>
<th>Name of person providing permission</th>
<th>Department</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reidwaan Ally</td>
<td>Head GIT</td>
<td></td>
</tr>
</tbody>
</table>

CHBAH 3/13
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Appendix H: Informed consent letter for participants to sign

UNIVERSITY OF CAPE TOWN
DIVISION OF COMMUNICATION SCIENCES AND DISORDERS

PERMISSION TO TAKE PART IN A RESEARCH STUDY

Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Who is conducting this study: This research study is being done by Nicoll Kenny, who works in Speech Therapy at CHBAH, as part of her Master’s degree study at the University of Cape Town.

Purpose of the study: The purpose of the study is to see what happens to participants after they have had a tube put into their stomach to help them to eat and drink.

Why have you been selected to be a part of this study: You are being asked to take part in this study because you will have/ have had a tube placed into your stomach to help you with getting the necessary food and liquids for your well-being.

What will be expected from you in this study: You will have to give the researcher permission to look at your hospital file and collect information like: your age; sex; weight and nutritional status; reasons why you are in the hospital; reasons why you needed the feeding tube; How you are eating now; Do you have any problems with swallowing.

This information will be collected at 4 different times 5 different times: (i) at the beginning when they have the tube put in, (ii) 1 week later, (iii) 1 month later, (iv) 3 months later and (v) 6 months after the surgery. If you go home the researcher will phone you to ask you some questions about your feeding tube on the phone.

This study is not harmful to you because the researcher will not be doing anything to you – but will review your hospital file and phone you after you leave hospital to ask you about your feeding tube and how it is working. You will not be paid for taking part in this study but the information that we get from all the patients may be helpful to other patients in the future who need feeding tubes.

All the information that we get from your file will be kept private and will not be given to anybody else to look at. It will be locked away in a cabinet to keep it safe and your name will not be used so nobody will know that you took part in this study. At the end of the study all the information with your name will be destroyed.

Research studies include people who have made a choice to take part. You can choose if you want to take part and you can change your mind at any point and say that you do not want to take part anymore. You will still get the best medical care and nobody will treat you differently if you do not want to take part.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

If you have any questions about the study and concerns: You may contact the researcher Nicoll Kenny at noodlekenny@gmail.com or 082 902 1054; or her supervisor, Prof Shajila Singh at Shajila.singh@uct.ac.za

For serious concern about your rights or welfare within the study please contact: The Chair of the University of Cape Town’s Faculty of Health Sciences, Human Research Ethics Committee – Prof Marc Blockman at marc.blockman@uct.ac.za

If you wish to participate in this study, you should sign below.

Noted: I have been given a chance to ask any questions that I have about the research I am agreeing to take part in.

______________  ____________________________________________
Date                  Participant’s Signature for Consent

______________  ____________________________________________
Date                  Person Obtaining Consent
Appendix I: Consent letter for participant’s family member or guardian to sign in the event that the participant cannot sign consent to participate in the study

UNIVERSITY OF CAPE TOWN
DIVISION OF COMMUNICATION SCIENCES AND DISORDERS

PERMISSION TO TAKE PART IN A RESEARCH STUDY

Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Who is conducting this study: This research study is being done by Nicoll Kenny, who works in Speech Therapy at CHBAH, as part of her Master’s degree study at the University of Cape Town.

Purpose of the study: The purpose of the study is to see what happens to participants after they have had a tube put into their stomach to help to them to eat and drink.

Why has your family member been selected to be a part of this study: They are being asked to take part in this study because they will have/ have had a tube placed into their stomach to help them with getting the necessary food and liquids for their well-being.

What will be expected from them in this study: You will have to give the researcher permission to look at their hospital file and collect information like: their age; sex; weight and nutritional status; reasons why they are in the hospital; reasons why they needed the feeding tube; how they are eating now; if they have any problems with swallowing.

This information will be collected at 5 different times: (i) at the beginning when they have the tube put in, (ii) 1 week later, (iii) 1 month later, (iv) 3 months later and (v) 6 months after the surgery. If they go home the researcher will phone you to answer some questions about their feeding tube on the phone.

This study is not harmful to them because the researcher will not be doing anything to them – but will review their hospital file and phone you after you leave hospital to ask you about their feeding tube and how it is working. They will not be paid for taking part in this study but the information that we get from all the patients may be helpful to other patients in the future who need feeding tubes.

All the information that we get from their file will be kept private and will not be given to anybody else to look at. It will be locked away in a cabinet to keep it safe and their name will not be used so nobody will know that they took part in this study. At the end of the study all the information with their name will be destroyed.

Research studies include people who have made a choice to take part. You can choose if you want your family member to take part and you can change your mind at any point and say that you do not want them to take part anymore. They will still get the best medical care and nobody will treat them differently if you do not want them to take part.
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

Should your family member be able to give their consent in the future when they are recovered, they will be approached by the researcher to sign consent for themselves to continue taking part in the study.

**If you have any questions about the study and concerns:** You may contact the researcher Nicoll Kenny at noodlekenny@gmail.com or 082 902 1054; or her supervisor, Prof Shajila Singh at Shajila.singh@uct.ac.za

For serious concerns about your family members rights or welfare within the study please contact: The Chair of the University of Cape Town’s Faculty of Health Sciences, Human Research Ethics Committee – Prof Marc Blockman at marc.blockman@uct.ac.za

If you wish to participate in this study, you should sign below.

Noted: I have been given a chance to ask any questions that I have about the research I am agreeing to allow my family member to take part in.

________________________
Date

Guardian / family member’s signature for consent on behalf of patient

________________________
Date

Person Obtaining Consent
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa

31/03/2015


< 1% match (Internet from 02-Jul-2013)

< 1% match (publications)

< 1% match (student papers from 09-Aug-2014)
Submitted to National University of Ireland, Galway on 2014-08-09

< 1% match (Internet from 14-Apr-2014)

< 1% match (Internet from 12-Nov-2014)
http://turningpointnutrition.ca/images/NutritionandsTBI_DoD.pdf

< 1% match (Internet from 23-Jan-2015)

< 1% match (publications)

< 1% match (publications)

< 1% match (publications)
Everett E. Vokes. "Head and Neck Cancer". New England Journal of Medicine, 01/21/1993

< 1% match (Internet from 27-Nov-2014)

< 1% match (Internet from 24-Mar-2013)

< 1% match (Internet from 12-Oct-2014)
http://67.207.206.99/~msav/20823

< 1% match (publications)
<table>
<thead>
<tr>
<th>Date</th>
<th>Author/Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>31/03/2015</td>
<td>&lt; 1% match (Internet from 14-Apr-2014)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.asxweb.org/clinical/cpg/P18510443111008565.pdf">http://www.asxweb.org/clinical/cpg/P18510443111008565.pdf</a></td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (Internet from 20-Jan-2015)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (Internet from 26-Sep-2018)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (Internet from 28-Feb-2013)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.esdey.rhs.uk/EasySiteWeb/getresource.axd?AssetID=1357288&amp;hps=full&amp;servicemtype=Attachment">http://www.esdey.rhs.uk/EasySiteWeb/getresource.axd?AssetID=1357288&amp;hps=full&amp;servicemtype=Attachment</a></td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (Internet from 24-Sep-2010)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.andreamiversity.info/eng/ssb/MCA%20os-b0708.doc">http://www.andreamiversity.info/eng/ssb/MCA%20os-b0708.doc</a></td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (Internet from 19-Feb-2015)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (publications)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (publications)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (Internet from 11-May-2010)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (publications)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (publications)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (publications)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (publications)</td>
</tr>
<tr>
<td></td>
<td>&lt; 1% match (publications)</td>
</tr>
</tbody>
</table>

Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa
Risks and outcomes for enteral nutrition among adults with dysphagia at a tertiary level hospital in South Africa