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The Application of Self-Administered Nutrition Screening Tools and Evaluations of the Impact of Malnutrition on Quality of Life in Individuals with Head and Neck Cancer

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Health and Rehabilitation Sciences

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Abstract

Background: Individuals with head and neck cancer (HNCA) are at an increased risk of malnutrition. Therefore, self-administered nutrition screens which attempt to address their nutritional concerns may yield benefits for treatment outcomes and quality of life (QOL).

Methods: 34 participants (26 men, 8 women) completed one demographic and two QOL surveys, two nutrition self-screening tools, a nutrition assessment and an ease-of-use questionnaire. Results of the screens were compared to those of the assessment, and relationships between QOL, nutrition status, and demographics were examined.

Results: 32.3% of participants were identified as nutritionally compromised. The sensitivity and specificity for the PG-SGA SF and Pt-Global Application were found to be 81.8% and 100%, and 63.6% and 100%, respectively. Additionally, alterations in nutrition status were found to influence QOL.

Conclusions: Data suggest that self-administered nutrition screens may be a viable option which enable proactive identification of nutritional concerns associated with HNCA.

Keywords: head and neck cancer, nutrition screening, quality of life, PG-SGA, Pt-Global, PG-SGA SF

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CHAPTER 1: INTRODUCTION AND REVIEW OF LITERATURE

Overview

Current statistics regarding the prevalence of cancer indicate that it is one of the leading causes of morbidity and mortality in the world (Ferlay et al., 2015). In a review performed by Ferlay et al. (2015) it was estimated that approximately 14.1 million individuals were diagnosed with cancer in 2012 and 8.2 million deaths resulted from the disease. While these numbers are staggering, Ferlay et al. (2015) projects the cancer incidence rate to reach above 20 million annually by year 2025. However, one positive trend which has been observed in recent years is that cancer survivorship rates are also increasing due to improvements in diagnostic tools and treatment effectiveness (Arends et al., 2016; Maruvka, Tang & Michor, 2014). Though the cancer may not be completely cured, it is slowly being converted into a chronic condition. Thus, quality of life (QOL) issues are becoming increasingly relevant for those diagnosed with and treated for cancer as these higher incidence and survivorship rates mean more individuals are going to be facing these types of challenges (Payakachat, Ounpraseuth & Suen, 2013).

QOL is a multidimensional construct which has been defined by the World Health Organization (WHO) as a state of "...complete physical, mental and social well-being and not merely the absence of disease." How Individuals with cancer feel physically and mentally, their functionality, as well as the disease and treatment related side-effects all have the potential to influence QOL. It is well documented that individuals with cancer generally experience a relatively low QOL due to the many challenges they face during treatment and recovery (List et al., 1996; List et al., 1997; Payakachat et al., 2013). Of

the multitude of factors which must be considered while treating individuals with cancer, maintenance of their nutrition status is a particularly important concern. Though malnutrition-related issues in oncology have been reported in clinical medicine throughout the 19th century, it was not until Charles Butterworth Jr's report of malnutrition in hospitalized patients in 1974 and Seltzer's description of nutrition screening in 1979 that nutrition associated with cancer began to receive significant attention (Butterworth, 1974; Seltzer et al., 1979). However, malnutrition in hospitalized settings continues to exist today at alarming rates (Barker, Gout & Crowe, 2011; Giner, Laviano, Meguid & Gleason, 1996). This was a topic central to a recent systematic review of literature regarding the nutritional status of individuals with cancer performed by Lis, Gupta, Lammersfeld, Markman and Vashi (2012) which found that of the 26 articles which met their inclusion criteria, 24 of them concluded that better nutrition status was associated with better QOL. However, malnutrition remains an under-recognized clinical issue in many hospitalized and outpatient populations, including those with cancer. Considering the consequences malnourishment can have on treated individuals as well as the costs required to address nutrition related concerns once they have progressed to later stages, it too regularly goes undiagnosed and untreated (Barker et al., 2011; Tappenden et al., 2013).

Combining common definitions due to the lack of universal agreement, malnutrition has been outlined as a subacute or chronic state of nutritional imbalance (deficiency or excess), resulting from lack of nutrient intake or impaired nutrient metabolism and inflammatory activity, which causes adverse effects on the body,

functioning, and clinical outcome (Lochs, Allison, Meier, et al., 2006; Soeters et al., 2008; Teitelbaum et al., 2005). The European Society for Clinical Nutrition and Metabolism (ESPEN) has further outlined nutritional risk as being the situation where the outcome of a disease or treatment has the potential to be influenced by the nutritional and metabolic status of the afflicted individual (Kondrup et al., 2003). Individuals diagnosed with cancer are particularly susceptible to experiencing malnutrition and various diet-related problems as a result of the malignant disease, its treatment and the commonly experienced side-effects each of these produce (Gupta, Vashi, Lammersfeld, & Braun, 2011; Lee, Shin, Bae & Lim, 2016; Takenaka et al., 2014).

The approximate incidence of malnutrition in the cancer population varies between 40-80% (Baldwin & Weekes, 2011; Isenring, Bauer & Capra, 2003) and prevalence varies between 50-80% (Tong, Isenring & Yates, 2009) depending on factors such as cancer type, tumour stage, location, treatment modality and identification method (Baldwin & Weekes, 2011; Lis et al., 2012). These numbers take on increased importance when one notes that upwards of 20% of individuals with cancer succumb to the associated malnutrition itself, as opposed to the malignant disease (Ambrus, Ambrus, Mink & Picken, 1975; Ottery, 1996; Wu et al., 2009). These statistics partially explain why many individuals with cancer make changes to their eating habits in attempts to maintain their health (Maskarinec, Murphy, Shumay & Kakai, 2001). Minimum energy and protein intake levels for individuals diagnosed with cancer have been outlined by both ESPEN and The American Society on Parenteral and Enteral Nutrition (ASPEN) as being 30 to 35 cal/kg and 1.2 to 2.0 grams of protein/kg body

weight respectively; however, even when these requirements are met, weight loss and malnutrition can still occur (Arends et al., 2006). Possibly a better approach presented by Arends et al. (2016) is determining the total energy expenditure of the individual by calculating their resting and physical activity energy expenditure levels and then calculating intake requirements from these results. However, this would likely be time consuming and depend on accuracy of the data collected, calling the practicability and reliability into question. Thus, reliable, effective, and practical nutrition services are still being searched for in busy clinical settings. Further, Lee et al. (2016) reported in a study that 90% of breast and gynecologic cancer survivors called for these nutrition services in order to address their nutrition-related concerns, emphasizing their importance.

Nutritional management is, therefore, an essential component of cancer care. This may be particularly true for those diagnosed with a head and neck cancer (HNCa) due to the nutrition compromising tendencies of tumours in these locations and the common associated treatments.

HNCa and Compromised Nutrition Status

HNCa comprises malignancies occurring in the upper digestive track such as the oral cavity, oropharynx, hypopharynx and larynx (Langius et al., 2013b). Representing approximately 4-5% of newly diagnosed cancers every year (Symonds, Deehan, Meredith, & Mills, 2012), these types of cancers are the sixth most common worldwide with the eighth highest mortality rate (Ferlay et al., 2015; Ganzer, Rothpletz-Puglia, Byham-Gray, Murphy, & Touger-Decker, 2015; Jemal et al., 2011). The annual global incidence of HNCa is more than 550,000 and results in approximately 300,000 deaths

each year (Jemal et al., 2011). The majority of HNCa cases are squamous cell carcinomas, however, individuals may still suffer from locoregionally advanced states of the disease (Jemal et al., 2008) and traditional treatments often result in various and significant functional and psychosocial impairments (List et al., 1997). As such, individuals with HNCa face many challenges and their QOL has been shown to deteriorate due to factors such as age, socio-economics, tumor location, treatment modality, treatment-related toxicity, and other disease specific symptoms (Languis et al., 2013; Penner, 2009; Reeve et al., 2016; Terrell et al., 2004; Wells et al., 2016). This is very important as health related QOL has been widely associated with the survival and mortality rates of individuals with HNCa (Farnebo, Malila, Mäkitie & Laurell, 2016; Karvonen-Gutierrez et al., 2008; Osthus, Aarstad, Aarstad & Olofsson, 2011; van Nieuwenhuizen, Buffart, Brug, Leemans & Verdonck-de Leeuw, 2015). To address these threats to QOL, individuals with HNCa require a variety of supportive care services (Chen et al., 2009; Oskam et al., 2013). As poor nutrition status has been associated with worse QOL in those with HNCa (Barrios, Tsakos, García-Medina, Martínez-Lara & Bravo, 2014) it is crucial that their nutrition-related concerns are addressed.

As a general observation, individuals with HNCa are among the most frequently confronted with nutritional and diet-related issues of all cancer subgroups (Chasen & Bhargava, 2009; Lees, 1999; Maskarinec et al., 2001). This is because many anatomical structures associated with normal nutrient intake have the potential to be impacted by the tumour and its treatment (Maskarinec et al., 2001). Though incidence rates vary throughout the literature it has been reported that malnutrition may be present in up to

as much as 35-80% of the HNCa population again depending on tumour location, treatment modality and method of identification (Gupta et al., 2011; Lees, 1999; Takenaka et al., 2014). Additionally, eating problems such as dysphagia (difficulty swallowing), odynophagia (painful swallowing), xerostomia (salivary gland dysfunction causing mouth dryness and potentially reduced salivary flow) and mucositis (painful inflammation and ulceration of the mucous membranes lining the digestive tract) are common issues before, during and following cancer therapy (Larsson, Hedelin, Johansson & Athlin, 2005; Nourissat et al., 2012; Ottosson, Zackrisson, Kjellén, Nilsson & Laurell, 2013). Such side-effects of the tumour and its treatment can considerably diminish nutrient intake and make maintaining adequate nutrition and hydration difficult, subsequently increasing the risk of nutritional deficiency and dehydration (Grant & Kravits, 2000). This can result in weight losses which may exceed as much as 20% of the individual's pretreatment bodyweight due to metabolic abnormalities, increased energy expenditure and reduced dietary intake (Ehrsson, Langius-Eklöf & Laurell, 2011; Kubrak, Olson & Baracos, 2013). This significant nutritional decline and weight loss is clinically relevant as it has been shown to reduce the effectiveness of treatment, impair functionality, reduce QOL, and lower the survival rates of hospitalized individuals with HNCa (Farhangfar et al., 2014; Kubrak et al., 2013). Thus, when reflecting on the care and QOL of individuals with HNCa more attention must be dedicated to considering the impact of nutritional status. These concerns are likely also prominent among the outpatient population.

Currently, much of the literature related to nutrition in those with HNCa has focused on the hospitalized patient population. Thus, the experience of outpatients with HNCa has not been well explored. This is concerning as it is likely that they too may experience similar nutritional challenges to those of hospitalized individuals. However, how different treatment modalities influence the nutritional experience of these individuals, as well as examination into the challenges they commonly experience are questions which have not received significant attention. If the nutritional concerns of an outpatient population are found to be similar to that of their hospitalized counterparts, they could be suffering similar impacts to their QOL. Further attention dedicated into exploration of the unique challenges the outpatient population faces in regard to their nutritional status and how this influences their health and QOL must be pursued. Thus, the primary focus of this research was to attempt to identify the nutritional status of outpatients with HNCa through implementation of two self-administered nutrition screening tools. Specific questions we address in this study include an assessment of the reliability of self-administered nutrition screens, examination of the common nutrition impact symptoms in the outpatient HNCa population, and how these nutritional concerns may influence perceived QOL.

Lack of a Universal Definition of Malnutrition and Screening Method

Nutritional deficiencies can have a vast array of consequences for individuals with HNCa such as increased infections rates, treatment disruptions and increases in morbidity and mortality (Capuano et al., 2008). To overcome these concerns nutritional supports may be necessary to meet daily nutritional requirements (Dawson, Taylor &

Bragg, 2015). Various efforts have attempted to standardize these nutrition support guidelines. Current examples include a Wiki platform that allowed professionals worldwide to input their nutritional recommendations for individuals with HNCa (Brown et al., 2013), the 'ESPEN guidelines on nutrition in cancer patients' (Arends et al., 2016), and the American Dietetic Association medical nutrition therapy protocol ("Medical nutrition therapy protocols", 1999). However, despite these various efforts, their effects in clinical settings are often impeded due to frequent lack of interest in nutritional aspects of cancer care (Arends et al., 2016) as well as the variability in both the content and implementation of these guidelines. This lack of clarity makes it difficult to identify the most effective methods of nutrition support and intervention for the HNCa population (Nugent, Lewis, & O'Sullivan, 2011).

Despite the lack of guidelines, nutritional concerns can still be addressed through adoption of proactive interventions which seek to avert malnutrition-related consequences by preventing nutritional declines (Cushen, Power, & Ryan, 2015). Currently, screening and assessment tools are used to assess nutritional status in clinical settings, including oncology. However, these assessments are complicated by that fact that agreement has yet to be achieved on a universally accepted definition of malnutrition in the HNCa population (Meijers, van Bokhorst-de van der Schueren, Schols, Soeters & Halfens, 2010; Soeters et al., 2008).

Though experts tend to agree that energy and protein deficiency, as well as decreases in fat-free mass are important aspects of the definition, there is less consensus regarding the importance of other elements such as the role of functional

status and inflammation (Dechaphunkul et al., 2013; Meijers et al., 2010). Even the elements which are currently accepted as being important are debated among experts regarding the cut-off points at which these factors become significant indicators of malnutrition (Meijers et al., 2010). This has complicated the operationalization and identification of malnutrition beyond the simple symptoms of involuntary weight loss, reduced body mass index (BMI) and nutritional intake (Meijers et al., 2010). Due to this lack of agreement, current definitions of what health care professionals consider to constitute a diagnosis of malnutrition has varied. ESPEN believes that “malnutrition is a state of nutrition in which a deficiency, excess, or imbalance of energy, protein and other nutrients causes measurable adverse effects on tissue/body form (body shape, size, and composition) and function, and clinical outcome” (Lochs, Allison, Meier, et al., 2006, p. 182). ASPEN defined malnutrition as “any disorder of nutrition status including disorders resulting from a deficiency of nutrient intake, impaired nutrient metabolism, or overnutrition” (Teitelbaum et al., 2005, p. 282). In the literature, various other definitions have been used, the most common being unintentional weight loss of >10% in the last 6 months or >5% in the last 3 months (Gorenc, Kozjek, & Strojjan, 2015). In addition to these definitions, the National Cancer Institute’s Common Toxicity Criteria has outlined different degrees of weight loss; less than <5% as Grade 0; 5%-10% as Grade 1; 10-20% as Grade 2; and >20% as Grade 3 (National Cancer Institute, 2005). The inconsistencies and lack of agreement among the definitions of weight loss and malnutrition is concerning. Only once the pathophysiology of malnutrition is firmly

agreed upon can there be generation of an appropriate and accurate definition and measurement tool to assess and diagnose the condition (Soeters et al., 2008).

The current lack of a universal definition of malnutrition makes the formation and validation of tools which can accurately identify and assess the condition difficult. Until a universal classification of weight loss and malnutrition is identified, there will be no common ground from which nutrition screens, assessments and interventions can be structured. As this is presently the case, the criteria and methods used to screen for the risk of malnutrition in the HNCa population has varied (Thoresen et al., 2013). This has resulted in inconsistencies regarding the classification of individuals based on their nutritional status (Thoresen et al., 2013) giving rise to the concern of misclassification (Elia, Zellipour & Stratton, 2005; Platek, Hertroijs, Nicholson & Parekh, 2015). As a result, individuals who require nutritional interventions may be missed and those who receive them may be well-nourished. This has consequences for both the individual and the healthcare system, decreasing the efficiency and effectiveness of clinical nutrition services (Platek et al., 2015). When this lack of guidelines is considered along with other current barriers to the implementation of nutrition screens, it is not surprising that compliance has been low. Competing duties of healthcare professionals, the lack of resources, time restrictions, as well as many other challenges have restricted regular nutrition screening (Elia et al., 2005). A reliable nutrition screening tool for the HNCa population which could overcome such barriers would be extremely beneficial. Such a measure would reduce the potential of misclassification while also enabling early identification and intervention, improving treatment outcomes and resource allocation.

However, for a nutritional screening tool to be effective for individuals with HNCa, it first must accurately assess, either directly or indirectly the main causes of malnutrition within this population. This is by no means a simple task as the malnutrition experienced by individuals diagnosed with HNCa is often a complicated multifactorial problem.

Causes of Malnutrition in HNCa Populations

Unintentional weight loss leading to malnutrition in individuals diagnosed with HNCa is a serious and complicated issue. Often, the malnutrition experienced is due to a combination of the cancer and its treatment, the resulting side effects and metabolic alterations each of these produce, as well as other personal factors (Languis et al., 2013a; Langius et al., 2016). These factors combine to increase the difficulty of nutrient consumption for individuals with HNCa and may subsequently result in abnormal metabolic activity such as elevated energy expenditure leading to energy imbalances (Arends et al., 2006; Dechaphunkul et al., 2013). The metabolic alterations and dietary issues can have synergistic effects on nutrition, increasing nutritional decline. The multifactorial and complex nature of the condition makes addressing the nutritional deficiency of individuals with HNCa difficult. One factor impairing the nutrition status of individuals with HNCa is the tumour itself due both to its anatomical location and the potential symptoms it can produce.

Tumour Related Causes of Malnutrition in HNCa

Tumours of the head and neck can impair oral intake in many ways. Nutrient intake impairment often increases with later tumour stages and tumours located in

oropharynx/oral cavity leading to greater degrees of weight loss (Bozzetti, 2009; Ehrsson et al., 2011; Lønbro, Petersen, Andersen & Johansen, 2016; Ravasco, Monteiro-Grillo, Vidal & Camilo, 2003). The tumour's anatomical location can generate nutrition impact symptoms such as nausea and vomiting, increasing malnutrition risk by impairing nutrient retention and making achievement of adequate hydration and nutrition difficult (Capuano et al., 2010; Grant & Kravits, 2000; Santarpia, Contaldo & Pasanisi, 2011). The tumour may also mechanically impede oral intake through symptoms such as dysphagia and odynophagia which impair swallowing function (Alshadwi et al., 2013; Jager-Wittenaar et al., 2011; Santarpia et al., 2011;).

Dysphagia is often considered one of the most common and disabling nutrition-related complications resulting from HNCa and its therapy (Chasen & Bhargava, 2009; Kubrak et al., 2010). This is particularly true for those with tumours of the oral cavity or oropharynx (List et al., 1997; Rinkel et al., 2015). Often the severity of the dysphagia experienced is dependent on the size and anatomical location of the lesion, the surgical resection and reconstruction, and comorbidities (Chasen & Bhargava, 2009). Severe dysphagia can make consumption of various food types difficult, which may significantly impact nutrition. Furthermore, as swallowing function declines muscles associated with proper swallowing can lose mass which further decreases nutrient intake and increases weight loss (Lis et al., 2012). As such, swallowing problems are a particularly important nutritional concern for individuals with HNCa.

Continuous or occasional pain caused by tumours during oral consumption is also a common tumour-related problem which may alter or limit oral intake (Larsson et al.,

2005; Santarpia et al., 2011). Pain has been identified as an important variable during treatment as it has been associated with increased functional impairments, depression, decreased QOL, psychological distress and aggregate symptom burden (List et al., 1997).

These nutritional impacts which result from the tumour may result in the development of tumour-induced metabolic dysfunction (Fearon, Voss, Hustead & Cancer Cachexia Study Group, 2006; Santarpia et al., 2011), leading to symptoms such as elevated energy expenditure, skeletal muscle catabolism (the breakdown of muscle mass to produce energy) and tumour-induced anorexia (Fearon et al., 2006; Mueller, Compher & Ellen, 2011). All of these factors may collectively increase weight loss and the corresponding risk of malnutrition. Thus, the tumour itself can lead to significant weight loss for individuals with HNCa which is only exacerbated once treatment begins.

Treatment Related Causes of Malnutrition in HNCa

It is well documented that common treatment modalities for HNCa such as radiotherapy, chemotherapy, and surgery have the potential for side-effects which cause weight loss and malnutrition. Antineoplastic treatments, especially when combined, may increase nutritional demand or cause side-effects which reduce dietary intake (Ehrsson et al., 2011; Van Cutsem & Arends, 2005). Surgery can lead to anorexia, pain, disfigurement, asthenia (abnormal physical weakness or lack of energy), anxiety, depression, xerostomia, and impairments in mastication, swallowing, communication, and potentially breathing (Doyle & Keith, 2005; List et al., 1996; List et al., 1997; Miller & Bozeman, 2012; Oskam et al., 2013; Payakachat et al., 2013; Penner, 2009). The side-effects of surgical interventions can influence the ability and willingness of individuals

with HNCa to intake nutrition orally which then can result in nutritional declines (List et al., 1997; Macqueen & Frost, 1998; Ravasco et al., 2003).

Other treatment methods such as chemotherapy and radiotherapy commonly involve intensive treatment regimens which are associated with elevated metabolic rates and increased treatment-related toxicity and complications (Jager-Wittenaar et al., 2011; Payakachat et al., 2013). The side-effects of these regimens are often the primary factors limiting the nutrient intake of individuals with HNCa (Macqueen & Frost, 1998) and commonly result in unintentional weight loss (Dawson et al., 2015). This was exemplified in a study performed by Langius et al. (2016) which concluded that radiation to lymph nodes and higher radiation doses to the primary tumour were predictors of increased side-effects and critical weight loss in individuals with cancer. Additionally, the treatment field is also an important consideration during HNCa treatment due to its potential influences on nutrition. It can cause radiation induced mucositis (an inflammatory response of mucosal epithelial cells) which is associated with pain during chewing and swallowing, oral bleeding, odynophagia, dysphagia, and mucosal ulcerations (Hayward & Shea, 2009; Miller & Bozeman, 2012; Santarpia et al., 2011). This can be further exacerbated by the radio-sensitizing drugs administered during cancer treatments (Hayward & Shea, 2009). Overall, treatment fields for HNCa can include organs and structures important for chewing and swallowing which if altered as a side-effect of treatment can result in temporary or permanent chewing and swallowing dysfunction which may then influence nutrient intake (Alshadwi et al., 2013; Eisbruch et al., 2002). This is especially concerning for those individuals with HNCa receiving a

combination of radiation and chemotherapy, which increases treatment toxicity (Santarpia et al., 2011).

Increases in treatment toxicity during HNCa treatment has been associated with xerostomia, stomatitis (inflammation of oral tissue, mucosa, dentition, and periodontium), anorexia, dysgeusia (alterations in taste), anosmia (loss of smell), trismus (reduced mobility of the jaw muscles), nausea and vomiting, sore throat, constipation (Alshadwi et al., 2013; Chasen & Bhargava, 2009; Hayward & Shea, 2009), fibrosis of tissues (including muscle and connective tissue) and possible neurotrauma causing dysphagia (Chasen & Bhargava, 2009). These nutritional concerns can have long-lasting impacts on individuals treated for HNCa (Payakachat et al., 2013). Consequently, individuals with HNCa are not only at risk of malnutrition prior to and during treatment, but also throughout the survivorship period.

The importance of treatment-related nutritional concerns is emphasized by that fact that regardless of the individual nutrition impact symptoms present, increases in aggregate symptom burden has been shown to further reduce nutrient intake, survival rates, and QOL (Capuano et al., 2010; Farhangfar et al., 2014; List et al., 1997; Reeve et al., 2016). Hall, Groome, and Rothwell (2000) concluded that 18% of individuals with HNCa included in their study died of the increased comorbidity associated with treatment and that many of these nutritional concerns remained burdensome for up to 7.5 years following treatment. Treatment-related concerns may be particularly important for individuals with HNCa who are in advanced stages of the disease or experiencing limited performance status as both of these factors have been associated

with greater aggregate symptom burden (Farhangfar et al., 2014). Thus, it is critical that the nutrition-related impacts of treatment be addressed for those with HNCa. If tumour and treatment characteristics were the only factors which needed to be considered to implement a nutrition management strategy the solution would be straightforward. Unfortunately, tumour and treatment characteristics must be considered alongside other variables and personal factors specific to the individual being treated for HNCa.

Objective Personal Factors Causing Malnutrition in HNCa

For a complete description of what causes malnutrition in individuals with HNCa, consideration must be given not only to tumour and treatment-related factors, but also to personal factors. This latter category includes objective factors such as tobacco and alcohol consumption which suppresses appetite and therefore influence nutrition (Alshadwi et al., 2013; Hall et al., 2000; Reeve et al., 2016). The risk of malnutrition also tends to increase as one ages (Roller, Egelseer, Eisenberger & Wirnsberger, 2016; Stratton & Elia, 2005) due to various factors such as poor appetite and dentition, loss of taste and smell, gastrointestinal disorders, isolation, poverty, inability to prepare food, confusion, and dementia (Hickson, 2006). Conversely, it is also possible for younger individuals to experience increased weight loss based on their higher activity levels and energy expenditure (Langius et al., 2016) or greater reductions in muscle mass due to functional declines associated with treatment (Languis et al., 2016). Additionally, it should also be noted that the selected treatment modality can be influenced by age, resulting in differing impacts to nutritional status.

As older individuals are expected to fare worse during treatment there is greater focus placed on supportive aspects of care (Languis et al., 2016). This supportive focus can be less present with younger individuals who are expected to better tolerate more intense treatment regimens (Reeve et al., 2016; VanderWalde, Fleming, Weiss & Chera, 2013). The more intense treatments can have consequences for the QOL and nutrition status of younger individuals (Reeve et al., 2016; VanderWalde et al., 2013). Overall, it is imperative that all individuals with HNCa are informed regarding the likely impacts to their nutrition based on their age. This is especially important seeing as those with insufficient information tend to experience greater difficulties maintaining weight and experience more treatment-related side-effects (Gorenc et al., 2015).

Finally, economic factors are often forgotten influencers of nutrition status as they can also impact treatment progression, nutrient intake, and QOL (Wells et al., 2016). This is concerning as individuals treated for HNCa have among the highest risk of experiencing disability and ceasing employment, limiting financial income (Liu, 2008; Penner, 2009; Taylor et al., 2004). This is a problem as foods high in nutritional value tend to be more expensive, causing individuals with limited financial resources to opt for the cheaper and less nutritious options. Additionally, cancer treatments and nutritional supplements can be expensive (Russell, 2007), which may influence their use if individuals lack insurance coverage and are unable to pay out-of-pocket. This would have consequences for nutrition status, disease progression, treatment outcome, and QOL (Reeve et al., 2016).

Subjective Personal Factors Causing Malnutrition in HNCa

Individuals with HNCa are also affected by subjective factors which may impair nutrient intake. For example, nutritional status may be negatively affected as the individual's food enjoyment declines (Hayward & Shea, 2009; McQuestion, 2006; Redda & Allis, 2006). The symptoms and side-effects experienced during HNCa treatment such as xerostomia, suppressed appetite, swallowing difficulty and many others may result in increases in the time and effort required to consume food (Gorenc et al., 2015; McQuestion, 2006). These difficulties can decrease eating-related QOL as well as one's motivation to consume food orally as eating becomes less enjoyable and more simply about survival (Álvarez-Camacho et al., 2016a; Pateman, Ford, Batstone & Farah, 2015).

As nutrition impact symptoms are common among those treated for HNCa, it is not surprising that food aversion is also a common concern in up to 60% of these individuals (Chasen & Bhargava, 2009). Meals may become stressful and time-consuming events due to the extra time devoted to mastication and swallowing; individuals also may feel uncomfortable or embarrassed by not being able to eat in ways deemed socially acceptable; for example, they may struggle with keeping their mouths clean during eating or experience frequent coughing (McQuestion, 2006; Ottosson, Laurell & Olsson, 2013; Penner, 2009). These difficulties may impair nutritional intake as well as lead to social isolation, exclusion or disruption of relationships with social supports, and a hesitance to eat in the presence of others who do not understand their situation (Álvarez-Camacho et al., 2016b; Chasen & Bhargava, 2009; List et al., 1996; Ma, Poulin, Feldstain & Chasen, 2013; Penner, 2009). This potential impact on one's social

activities results in an increased risk of depression for individuals with HNCa (List et al., 1996; Van Liew et al., 2017). This emphasizes the impact the emotional burden may have on the individual as well as their nutritional status.

The emotional stress and existential crisis the individual may experience during a cancer diagnosis and treatment may reduce nutrient intake, causing nutritional decline (Capra, Ferguson & Ried, 2001; Larsson et al., 2005). Thus, the psychological, social, and emotional domains of food consumption are also afflicted (Ottosson et al., 2013a; Reeve et al., 2016). This subjective concern may be particularly important for younger individuals as aggressive treatments are more common, increasing the extent and severity of potential comorbidities, psychological impacts, and distress experienced (Dawson et al., 2015; Hoffman, McCarthy & Ng, 2008).

Cancer Cachexia as a Cause of Malnutrition in HNCa

Overall, tumour-, treatment- and personal factors all combine to produce the levels of malnutrition that individuals with HNCa experience. The anorexia resulting from these nutrition impact symptoms is a serious and multidimensional nutritional issue which when combined with the associated metabolic abnormalities can ultimately lead to cancer cachexia. Cancer cachexia is a metabolic syndrome which combines anorexia, reduced nutrient absorption, appetite and/or diet alterations, hormone-induced metabolic changes, weakness, anemia, and edema which is a distinct nutritional problem from either simple starvation or chronic malnutrition (Arends et al., 2016; Couch et al., 2015; Miller & Bozeman, 2012; Ravasco et al., 2003; Thomas, 2007;). During simple starvation and chronic malnutrition metabolic rates tend to adaptively decline

with reduced energy intake, whereas cachexia is associated with hypermetabolism (Baracos, 2006).

Cachexia is a complex systemic response to starvation, proinflammatory cytokines, and hypermetabolic states caused by the underlying malignant disease, negative energy balance, and skeletal muscle wasting which results from reductions in nutrient intake (Baracos, 2006; Chasen & Bhargava, 2009; Couch et al., 2015; Dechaphunkul et al., 2013; Miller & Bozeman, 2012; Thomas, 2007). The potential metabolic alterations associated with cachexia such as hypermetabolism, insulin resistance, lipolysis, proteolysis results due to failures in anabolic pathways and activation of catabolic ones (Baracos, 2006). This leads to decreases in protein synthesis and depletion of physiologic energy and protein reserves at a rate that is greater than would be expected based on the food intake rates (Baracos, 2006; Couch et al., 2015). These metabolic alterations along with symptoms such as decreased appetite, functional impairments, inflammation reducing body cell mass, and fatigue, can greatly impact the nutritional status and body composition of the individual and have detrimental effects on overall performance status and QOL (Barac-Nieto, Spurr, Lotero & Maksud, 1978; Chasen & Bhargava, 2009; Couch et al., 2015; Gorenc et al., 2015). Perhaps most importantly and understandably, cachexia has been identified as a condition that is associated with high mortality rates (Thoresen et al., 2013). Approximately 20% of individuals who succumb to HNCa do so as a result of functional cardiac impairment that occurs in response to the wasting of the cardiac muscle associated with cachexia (Couch

et al., 2015; Prakash et al., 2010; Der-Torossian, Gourin & Couch, 2012; Tisdale, 2002).

Thus, cachexia poses threats to nutrition status, QOL, and survival.

Concerns associated with cancer cachexia are further confounded by the fact that conventional nutritional support methods such as nutritional supplements and appetite stimulants are unable to fully reverse the weight loss experienced (Baracos, 2006; Chasen & Bhargava, 2009; Dechaphunkul et al., 2013; Thomas, 2007). This is likely why cachexia is associated with greater treatment toxicities and reduced treatment tolerance (Couch et al., 2015). Despite the consequences and morbidity generated by cancer cachexia, this complex condition is not completely understood.

Overall, the intertwining effects of the tumour, its treatment and personal factors create a multidimensional nutritional problem for which intervention is complicated. The fact that so many factors combine to produce the malnutrition experienced by individuals with HNCa warrants interprofessional collaboration. The implementation of an accurate and standardized screening tool to identify these causes of malnutrition could yield significant benefits to both treatment outcomes and QOL. If nutritional concerns are continually disregarded aspects of cancer care the consequences to the healthcare system and the individuals it cares for could be severe.

Consequences of Malnutrition in HNCa

The incidence of malnutrition among individuals with HNCa has been estimated to be between 35-80% and that nearly 20% of individuals with HNCa die as either a direct result of it or its associated consequences, as opposed to solely the cancer (Gupta

et al., 2011; Takenaka et al., 2014; Wu et al., 2009). Weight loss of just 5% over six months is associated with various side-effects and consequences (Ma et al., 2013). Increased mortality, morbidity, fatigue, impaired QOL, impaired immunity, more frequent and severe treatment induced toxicities and treatment interruptions, reduced treatment response rates, and greater hospital readmission rates are all consequences associated with malnutrition (Capuno et al., 2008; Correia & Waitzberg, 2003; Bozzetti, 2009; Gorenc et al., 2015; Nitenberg & Raynard, 2000). Malnutrition resulting from HNCa and its treatment has also been associated with higher rates of insomnia, anxiety, depression, psychological distress and reduced physical, role, social, cognitive and emotional functioning (Arends et al., 2016; Capuano et al., 2010; Ma et al., 2013; Oskam et al., 2013; Schmidt, Olson, Kubrak, Parliament & Ghosh, 2013). Approximately 35-40% of individuals with HNCa experience these types of distressing issues over the course of their illness and rates increase as nutrition status declines (Ma et al., 2013). Additionally, 5-year survival rates are inversely proportional to weight loss, illustrating how the effects of malnutrition extend into survivorship (Languis et al., 2013a). These symptoms and side-effects can contribute to further disease progression and a declining QOL and a subset may even result in further impairments to nutritional status. These consequences are concerning given that >50% of individuals in advanced stages of HNCa experience impaired nutrition and significant involuntary weight loss at diagnosis prior to commencing treatment (Chasen & Bhargava, 2009; Larsson et al., 2005; van Leeuwen, Sauerwein, Kuik, Snow, & Quak, 1997;). These numbers increase over the treatment

period in the absence of nutritional interventions (Chasen & Bhargava, 2009). This can result in consequences for the treated individual as well as the healthcare system.

Past studies have assessed the impact of malnutrition on the healthcare system and shown that the average cost of hospitalization is much greater for malnourished individuals (Nitenberg & Raynard, 2000). These increased costs of malnutrition are indirectly attributable to longer hospital stays, increased resource use (consultations, treatments, etc.), higher rates of re-admissions, higher infection rates and poor wound healing (Abizanda, Sinclair, Barcons, Lizán & Rodríguez-Mañas, 2016; Correia & Waitzberg, 2003; Lim et al., 2012). Groups such as ESPEN and the Alliance to Advance Patient Nutrition have expressed their belief that addressing clinical nutritional concerns could reduce costs and improve outcomes and QOL (Kondrup et al., 2003; Tappenden et al., 2013). Standardized nutrition screening and care could achieve this goal. Thus, the routine implementation of guidelines and tools to meet this need is warranted as it would result in benefits not only to the individual, but to the healthcare system as well.

Screening Nutrition Status in HNCa

By definition, screening in medicine is the process of identifying someone at risk from a given population of individuals who may not have any obvious signs or symptoms (Cayne & Bolander, 1991). Though the risk of malnutrition is expected to be high for individuals with HNCa, unless obvious signs are present, it should not be assumed that they are at risk until it is proven through nutritional screening. Thus, screening for nutritional risk and the making of appropriate referrals for nutrition assessment are considered to be fundamental first steps in the nutritional care pathway (Atkins,

Basualdo-Hammond, Hotson & Dietitians of Canada, 2010). For hospitalized individuals, nutrition screening should be undertaken immediately following admission and at regular intervals thereafter, ideally by a nurse in daily contact with them (Arends et al., 2016; Davies, 2005). Nutrition screens briefly examine characteristics commonly associated with nutrition problems through a short survey or questionnaire (typically requiring less than 5 minutes) (Lee, Choi, Son & Lyu, 2013, p. 118; Mueller et al., 2011, p. 16; Zekri et al., 2014). Through screening, those at nutritional risk can be identified to undergo further detailed nutrition assessments and, if necessary, interventions. The aim of this process is to prevent nutritional declines and long-term nutritional impacts, as well as to reduce morbidity and mortality during and following treatment (Arends et al., 2016; Miller & Bozeman, 2012). Thus, the content, practicability, intended purpose, reliability, and predictive and content validity are all important considerations when selecting a screening tool in order to ensure the appropriate individuals are being identified as nutritionally compromised (Cushen et al., 2015). An efficient screening tool which addresses these considerations would be beneficial to clinical care.

ASPEN has recommended that healthcare institutions generate and approve some type of standard nutrition screening process (Ukleja et al., 2010). Additionally, in the US, the Joint Commission mandates nutrition screening within 24 hours of admission to an acute care center as it is a “Medicare Condition of Participation” (Joint Commission International Accreditation Standards for Hospitals, 2013) and, therefore, a requirement for accreditation or certification of United States healthcare facilities (Centers for Medicare & Medicaid Services, 2003; Skipper, Ferguson, Thompson, Castellanos, &

Porcari, 2012). Nutrition screening for individuals with HNCa is in accordance with these goals and is a promising means through which nutritional concerns could be addressed.

Current Situation of Nutritional Screening Tools

Despite the potential benefits of standardized routine nutrition screening, compliance to these nutrition evaluations remains low likely due to the lack of interest in nutrition-related aspects of care (Arends et al., 2016). Despite nutrition screening practices being mandated, there is debate regarding which tool should be used and who should be responsible for performing nutrition screens. This lack of agreement has complicated the establishment of consistent practices. Various screening tools have been promoted, each of which assesses malnutrition slightly differently. Within oncology, many of the promoted screens are sophisticated, time-intensive, and require skilled personnel to complete (Zekri et al., 2014). As well, different subsets of nutrition screening tools have been recommended, including but not limited to, the Nutritional Risk Screening 2002 (NRS 2002), Malnutrition Universal Screening Tool (MUST), Mini Nutritional Assessment (MNA), Nutritional Risk Index (NRI) and Malnutrition Screening Tool (MST) (Gorenc et al., 2015; Jones, 2002; Kondrup et al., 2003; Lis et al., 2012). These screening tools have been created to best fit the needs of various healthcare settings and professionals, and each has its strengths and weaknesses. However, many of these tools were validated using biased processes or underwent insufficient evaluations of their effectiveness (Jones, 2002). For example, some tools were validated using the same rater to complete the nutrition screen and assessment, introducing potential biases (Ferguson, Capra, Bauer & Banks, 1999; Laporte et al., 2015). Other

research on nutrition screens has been conducted using trained researchers or healthcare professionals which potentially inflates results regarding the accuracy of the screening tool in question (Ferguson et al., 1999; Laporte et al., 2015). Resultantly, the validity and reliability of these tools is unclear in 'real-world' settings where nutrition screens are often completed by busy staff with limited training (Laporte et al., 2015).

As a result of this lack of standardization in nutrition screening, BMI and body weight loss are often the primary tools utilized for nutrition screening (DeCicco, Wunderlich, & Emmolo, 2011). Although effective indicators in some studies, BMI methods have limitations as alone they often fail to indicate important disease or therapy-related changes in the individual's caloric intake and metabolism (DeCicco et al., 2011; Isenring, Capra & Bauer, 2004). Additionally, the cut-off points for BMI are often arbitrary and based on young, healthy adults (Davies, 2005) which may not be appropriate for individuals with cancer. Furthermore, it is possible for individuals with BMIs of <18.5 to remain well-nourished while malnutrition may be overlooked in those classified as normal or overweight (Davies, 2005; Gupta et al., 2011; Isenring, Cross, Daniels, Kellett & Koczwara, 2006; Ottosson et al., 2013b; Soeters et al., 2008). Higher levels of body fat may mask the loss of lean body mass, leading to unidentified malnutrition (Bauer, Capra & Ferguson, 2002; Isenring et al., 2004). Additionally, studies have shown that a BMI of >25 is associated with increases in weight loss experienced by individuals treated for HNCa (Lønbro et al., 2016). Thus, using BMI as the sole indicator of nutrition status is not recommended and additional nutritional screening methods are

necessary. However, barriers present in both the healthcare system and current screening tools complicate their routine implementation in clinical settings.

Current Issues Regarding the Implementation of Routine Nutrition Screens

Routine screening for malnutrition has been made mandatory in the UK, US and parts of Europe. However, compliance has been low or, as previously indicated, simple measurements such as BMI have been used despite their limitations. Routine nutrition screening has not been possible due to various challenges such as limited human and financial resources and time restrictions (Abbott et al., 2014; Santarpia et al., 2011). It is estimated that these nutrition care practices would result in an additional 0.3-2.0 hours of professional labour per evaluation (Arends et al., 2016). As clinicians already experience heavy workloads, provision of these services often fall to other healthcare team members.

As physicians are unable to regularly provide nutrition services, tasks such as nutrition screening is generally carried out by nurses (Green & Watson, 2005). Nurses are arguably the most appropriate members of the healthcare team to screen for poor nutritional status as they are likely to have more frequent interaction with the individuals being screened (Molassiotis & Holmes, 2005). However, nurses themselves have outlined various challenges impeding their ability to implement regular nutrition screens, such as heavy workloads, their perception that professional judgement is just as useful as screening tools for identifying malnutrition, inadequate nutrition screening knowledge and training and a lack of awareness of evidence-based nutrition screening practices (Raja et al., 2008). This is supported by Martin, van der Schueren, Blauwhoff-

Buskermolen, Baracos and Gramlich (2014) who identified that the lack of clear guidelines for nutrition screens was the main barrier to their routine implementation. Without clear guidelines the difficulty of accurately detecting individuals at nutrition risk in a standardized manner increases.

Further barriers to the implementation of nutrition screens identified by Martin et al. (2014) included disagreement regarding which tools were most appropriate, whose responsibility it was to perform the screens, and what proper protocol was following screening. To date, these concerns have posed major challenges to the regular completion of nutrition screens in clinical oncology.

The Ideal Nutritional Screening Tool

The ideal nutrition screening tool would be able to proactively identify individuals at risk of malnutrition with 100% sensitivity and specificity. This is, however, unlikely an achievable goal. A good screening tool is characterized by both sensitivity and specificity of at least 80% (Azad, Murphy, Amos & Toppan, 1999; Platek et al., 2015). Sensitivity enables appropriate detection and referral of malnourished individuals, while specificity reduces interventions provided to those who are well-nourished and prevents unnecessary referrals (Shahar & Hussain, 2007). Though both sensitivity and specificity are important, the need to correctly classify all malnourished individuals (tool sensitivity) may take precedence (Skipper et al., 2012). ESPEN has further stated that an idealized screening tool should be simple, able to be standardized, rapid, non-invasive, and cost-effective for clinical practice (Kondrup et al., 2003). Additionally, Soeters et al. (2008) suggested that nutritional assessments which evaluate nutrient balance, body

composition, inflammatory activity, and functionality would provide an accurate description of an individual's nutritional state. Thus, screening tools which incorporate similar measurements may also prove effective. However, screening tools should avoid calculations and the need for laboratory data as these measures complicate nutrition screening (Green & Watson, 2005; Leuenberger, Kurmann & Stanga, 2010). Finally, an ideal screening tool should be linked to a protocol for action to direct the next steps of nutrition care to ensure efficient and effective allocation of resources (Leuenberger et al., 2010). Thus, a simple and efficient tool could enable proactive nutrition screening in clinical settings and even potentially be self-administered.

In the clinical literature, it does not appear as though any current tools meet all the criteria of an ideal nutrition screening tool, nor have self-administered nutrition screening tools been given significant attention. Only minimal work has been done assessing the application of self-administered nutritional screens in clinical settings. If proven accurate and effective, such screens could yield unique benefits. Self-administered nutrition screens can be rapid, simple, reliable, and feasible for clinical settings and could facilitate the regular completion of screens (McGurk, Jackson & Elia, 2013). Given that current nutrition screens have been unable to overcome such challenges the potential utility of self-administered nutrition screens deserves further exploration. Allowing individuals to facilitate their own routine nutrition screens would enable them to become advocates for the maintenance of their nutrition status, ensuring significant attention is given to identifying and addressing nutrition-related concerns. Additionally, lack of human resources and heavy workloads of healthcare

professionals would no longer be a barrier as self-administered nutrition screens would be completed by the individuals being treated. This proactive approach would enable early identification of nutritional concerns which could then be addressed, preventing various malnutrition-related consequences and saving both time and money. Therefore, it can be argued that an effective self-administered nutrition screening tool would significantly benefit the clinical identification, monitoring, and management of nutritional concerns associated with cancer. However, it must be noted that despite the potential benefits of self-screens, caution must be taken during their implementation as there would be concerns regarding their validity and reliability when completed by certain populations of individuals (Cawood, Elia, Sharp, & Stratton, 2012).

When considering concerns regarding the validity and reliability of self-screening instruments, attention must be directed to the potential for both over- and under-reporting. For example, after contemplating their health state, individuals with HNCa may become more attentive to factors which could be negatively influencing their health and nutrition. Therefore, the potential for over- or under-reporting of such variables may in part be dependent on their subjective interpretation of what is clinically relevant (McClement, 2005). Additionally, though it is likely a lesser concern for physical information, it remains a possibility that for a variety of individual reasons patients may conceal this physical information. Recall bias may also lead an individual to misreport screen information as various factors can influence an individual's ability to recall information (Coughlin, 1990). Thus, the added potential for bias and the occurrence of either over- or under-reporting means that unintentional misreporting is an ongoing

concern. Careful thought must be dedicated to assessing how these concerns may present in specific populations of patients and how they can be accounted for.

Finally, the ideal nutrition screening instrument will have considered how the prevalence rates of malnutrition may influence positive and negative predictive values. This is because different cancer types, even different HNCa subgroups, are associated with differing prevalence rates of nutritional concerns (Arends et al., 2016; Zekri et al., 2014). Thus, the same tool will have differing predictive values dependent on the prevalence rates of malnutrition in the particular patient population; positive predictive values tend to increase with increasing prevalence rates, while negative predictive values decrease. Conversely, with decreasing prevalence rates, positive predictive values tend to decline while negative predictive values increase. Predictive values and how they vary depending on the prevalence of nutritional concerns are important considerations for healthcare providers. These values inform healthcare providers of the likelihood of a patient with a positive result having the disease as well as one with a negative result not having the disease. Thus, the psychometric properties of any screening tool and how these can be influenced by prevalence rates must always be considered.

Assessment of Nutritional Status in HNCa

Any individual identified as at risk of malnutrition following a nutrition screen, should undergo a complete assessment by a qualified professional (Davies, 2005; Leuenberger et al., 2010; Meijers et al., 2010; Soeters et al., 2008). Nutritional assessments provide an accurate definition of an individual's nutritional status and a foundation for future nutritional monitoring and interventions (Arends et al., 2016;

Cushen et al., 2015; Ottosson et al., 2013a). Such measures aim to improve clinical outcomes by addressing malnutrition when it presents, improve QOL, and reduce adverse effects of anticancer treatments (Arends et al., 2016; Cushen et al., 2015).

Methods of Nutrition Assessment

Various nutrition assessments have been utilized within the cancer population, each with strengths and weaknesses. Often the circumstances will dictate which method of assessment is used, but inclusion of both objective and subjective parameters is common. Nutrition assessments are laborious and comprehensive examinations of nutritional concerns which combine nutrition information, past medical histories, physical examinations, anthropometric measurements, and laboratory data (Mueller et al., 2011). However, these assessment tools are not used at admission to hospital to assess nutrition due to their complexity and the lack of resources needed for their completion (Isenring et al., 2006; Smith, Smith, Ledgard, Doig, & Chesher, 2009). Thus, a preference for less laborious nutritional assessment tools has emerged. Current nutritional assessment methods commonly used for individuals with cancer include the Subjective Global Assessment (SGA) and the Patient Generated-SGA (PG-SGA). Though both are comprehensive nutrition assessments, the PG-SGA, developed by Ottery et al., was validated specifically for assessing the nutritional status of individuals with cancer.

SGA Nutrition Assessment

The SGA is a simple, cost-effective and easy-to-apply nutritional assessment tool with fair-to-good predictive validity recommended by the ASPEN board of directors for a

variety of patient groups (Gupta et al., 2011; Lis et al., 2012; Shirodkar & Mohandas, 2005; Platek, et al., 2015; van Bokhorst-de van der Schueren, Guaitoli, Jansma & de Vet, 2014). The SGA includes a comprehensive assessment completed by a healthcare professional of symptoms which can influence nutritional intake, functionality and physical capacity, dietary intake, and gastrointestinal symptoms (Lim et al., 2013). The SGA also includes a physical examination of any muscle wasting, fat depletion, and nutrition-related edema (Lim et al., 2013). Overall, the SGA is patient-centered, incorporates the clinical history of the individual, and does not require laboratory testing or medical imaging exams, easing its implementation (Gupta et al., 2011; Wakahara et al., 2007). However, for SGA assessments to be reliable, they are required to be performed by trained personnel and the grading depends on the accurate reporting of the histories and physical observations of the individual being assessed (Wakahara et al., 2007). This rigorous process has resulted in professional resistance to the regular performance of the SGA upon hospital admittance (Leuenberger et al., 2010). Moreover, the SGA is not sensitive enough to detect short-term changes in nutrition status (Bector, Vagianos, Suh & Duerksen, 2016). Thus, the SGA has more often been used as a reference standard against which other nutrition screening tools have been evaluated (Cushen et al., 2015; Platek et al., 2015). Despite the positives of the SGA, it has inherent limitations and also is not specific to individuals with cancer, leading to the consideration of other assessment tools such as the PG-SGA.

PG-SGA Nutrition Assessment

The Nutrition Dietetic Practice Group of the American Dietetic Association has promoted the PG-SGA as the gold standard for nutritional assessments in oncology (Gorenc et al., 2015). Many studies have also promoted the PG-SGA and it is commonly utilized as a standard which other nutritional assessments and screens have been evaluated against (Abe Vicente, Barão, Silva & Forones, 2013; Beck et al., 2015; Kim et al., 2011). The PG-SGA is a simple tool adapted from the SGA and developed for individuals with cancer. It has proven to be a sensitive, specific, and reliable tool for predicting nutrition status as defined by the SGA (Cushen et al., 2015; Gorenc et al., 2015; Gupta et al., 2011). The PG-SGA consists of a self-completed assessment of the individual's histories (weight, food intake, symptoms, and functioning) and a clinician assessment of the metabolic demands of the disease, its impact on nutritional requirements and a physical examination (Gorenc et al., 2015). Thus, the PG-SGA enables quick nutrition assessments and allows the clinician to spend more time addressing problems rather than gathering information (Gupta et al., 2011).

The PG-SGA utilizes two scoring methods. The continuous scoring method allows for prioritization of those individuals in need of more urgent care, effectively allocating limited resources, while the PG-SGA global rating scores (A, B, or C) give an overall depiction of the individual's nutrition status (Bauer et al., 2002; Gupta et al., 2011). These scores are then linked to triage recommendations to guide the next steps of the nutrition care process. Overall, the PG-SGA is less time intensive than the SGA, identifies a more extensive range of nutrition impact symptoms and incorporates a scoring system

which enables prioritization of individuals in most urgent need of care and effective resource allocation (Bauer et al., 2002). For these reasons the PG-SGA has been the most studied, validated, and commonly accepted nutrition assessment method for individuals with cancer (Boléo-Tomé, Monteiro-Grillo, Camilo, & Ravasco, 2012; Cushen et al., 2015). However, the PG-SGA still relies on the literacy of the individual performing the assessment, is considered to be time-consuming, and requires examiner training (Leuenberger et al., 2010). As such, the routine implementation of the PG-SGA in clinical settings remains limited as there is neither time nor resources to regularly apply this tool. It would, therefore, seem that the only way to ensure every individual who needs a nutritional assessment receives one is to have assessments preceded by screens. Though all individuals with HNCa would still undergo nutrition screens, only those identified as being at nutritional risk would undergo the laborious and comprehensive nutritional assessments, effectively utilizing and allocating limited human and financial resources.

Statement of Problem

Though various screening tools currently exist and have been used in oncology settings, there has been little consistency in their clinical application and the compliance to nutrition screening practices. The absence of a universal definition for malnutrition makes it difficult to determine which screening tool produces the most accurate classification of the problem (Isenring, & Elia, 2015; Meijers et al., 2010). This has meant that the number of individuals identified as being at nutrition risk has depended on the screening tool utilized, making comparisons between studies difficult. Without standard nutrition guidelines regarding the identification of individuals at nutritional risk, the

provision of nutritional interventions and how we monitor and follow-up will continue to vary. Additionally, without clear guidelines, compliance to nutritional care practices in oncology may remain low due to healthcare professionals lack of confidence in malnutrition identification protocols (Spiro, Baldwin, Patterson, Thomas & Andreyev, 2006). This may result in the nutritional concerns of some individuals going unrecognized in certain healthcare settings. Furthermore, healthcare resources are not likely to be allocated to this important issue as long as the prevalence of malnutrition varies based on the method used to identify it (Platek et al., 2011). This is especially true for the outpatient HNCa population, a group that is currently underrepresented in literature, as their nutritional concerns and challenges may be less apparent.

Without sensitive and specific screening tools, nutritional complications may worsen. Though validated and more accurate nutrition assessment methods are available such as the SGA and the PG-SGA, their routine implementation is impractical. It is, therefore, important that alternative nutrition evaluation methods be explored such as self-administered nutrition screens. Implementation of such screening tools could be a step towards ensuring that every individual in need of nutrition care services receives them. Consequently, the proposed study sought to improve the maintenance of the nutritional status of outpatient individuals with HNCa by increasing compliance to nutrition screening through validation of two self-administered nutrition screening tools for this population. The self-screening tools selected were the PG-SGA short form (PG-SGA SF) and the Pt-Global Application. These tools were compared to the PG-SGA to assess their sensitivity, specificity and predictive values. Other objectives included the

gathering of information on individual ability to perform self-screens as well as the presence and extent of malnutrition-related concerns in the HNCa population and their impacts on QOL.

Significance of Project

The literature promotes early and proactive nutritional interventions as these cost-effective strategies prevent malnourishment more successfully than approaches delayed until later stages of excessive weight loss (Baracos, 2006; Isenring, Bauer & Capra, 2007; Langius et al., 2016; Prevost, Joubert, Heutte, & Babin, 2014; Ravasco, Monteiro Grillo & Camilo, 2008; Uster et al., 2013). Additionally, studies have presented conflicting conclusions regarding how interventions such as nutrition supplementation (Baldwin & Weekes, 2012) and nutrition counselling (Arends et al., 2016; Platek, 2012;) influences mortality rates, weight changes and energy intake when delayed until later stages of treatment as the effectiveness of such methods depends on compliance to nutritional regimens. Tube feeding, on the other hand, only inconsistently yields benefits for individuals with cancer (Huhmann & August, 2009; Paleri & Patterson, 2010). It has been associated with decreases in their willingness to consume food orally which can result in muscle atrophy and late swallowing difficulties, leading to further nutritional declines and reduced QOL (Paleri & Patterson, 2010; Reeve et al., 2016; Terrell et al., 2004; Wells et al., 2016). Thus, nutritional interventions must be initiated early in order to be most effective (Bloch, 2000; Capra et al., 2001; Piquet et al., 2002; Prevost et al., 2014). The costs and risks associated with delaying nutrition interventions until later stages of treatment outweigh the inconsistent benefits they produce. Standardized

nutrition screening practices could enable proactive approaches for addressing nutritional concerns and reduce the need for costlier and less effective nutrition interventions later on.

Standardizing clinical nutrition screening has been outlined as a top priority of the Canadian Malnutrition Task Force (Laporte et al., 2015). Standardized screens able to overcome challenges associated with current screening tools would be beneficial in terms of efficiency, safety, healthcare and QOL (Abbott et al., 2014; Lim et al., 2012; Tappenden et al., 2013). A valid and efficient self-administered nutrition screening tool for the outpatient HNCa population with acceptable sensitivity and specificity would achieve this goal (Abbott et al., 2014; Larsson et al., 2005; Tappenden et al., 2013). Additionally, the cost savings of nutritional screening protocols have been estimated to be around \$217 million annually according to Barents Group of KPMG Peat Marwick LLP (1996), which has been supported by other studies (David, Bernstein & Coifman, 2013). Thus, improving nutrition care practices for those at nutritional risk has been identified as the fourth largest potential cost saving initiative by the National Institute for Health and Care Excellence (2013). Cost savings of up to \$1,500 per malnourished individual have been identified in recent studies (Somanchi, Tao & Mullin, 2011). Though screening practices may result in minor cost increases initially, these costs would be justified and counteracted by reduced clinical expenses incurred attempting to correct the malnutrition-related consequences individuals with HNCa experience later on (Abizanda et al., 2016; Correia & Waitzberg, 2003; Norman, Pichard, Lochs, & Pirlich, 2008).

Therefore, not only does screening benefit QOL and overall healthcare, but it can greatly reduce healthcare expenditures.

However, as long as compliance to nutritional evaluations remains low, whether due to the lack of efficient and validated screening tools or lack of standard nutrition guidelines, proactive management of nutritional concerns will be difficult. Nutrition evaluations in the oncology population will continually be overlooked or performed inappropriately or too late. To prevent malnutrition and its associated consequences, the development of new methods enabling routine nutrition screens are warranted (Isenring et al., 2004; Tappenden et al., 2013). This is especially important in situations where malnutrition is deemed to have high prevalence, such as in the HNCa population.

CHAPTER 2: METHOD

Participants

The population utilized in this study included both adult men and women diagnosed with and treated for HNCa. Participants were between the ages of 30 and 80 years. The mean age of all participants was 61.8 (SD= 10.02). Of those who participated, there were 26 males who had a mean age of 60.12 (SD=9.92, range 42 - 79 years) and 8 females who had a mean age of 67.375 (SD=9.47, range 50 - 80 years).

This study identified 37 individuals as potential participants of which 35 consented. The two participants who opted not to consent indicated that they were unable enroll in the study due to time restrictions. Of the individuals who initially consented to participate 32 completed the study on site while three selected to complete the study at home and return it by mail. Of the three individuals who took the package off-site, one male did not return it. Overall, complete study data were obtained for 34 individuals (26 males and 8 females) resulting in a participation rate of 91.9% (89.7% and 100% response rates for males and females, respectively). All participants had been diagnosed with HNCa with exclusion of those with skin cancers. Comprehensive demographic information of all participants is presented in Table 1.

Table 1. Participant Demographic Information				
Demographic Information, N=34			Treatment Information	
	Male, n= 26, (76.5%)	Female, n= 8, (23.5%)	Cancer Site	
Age - Mean (SD)	60.116 (9.92)	67.375 (9.47)	Oral Cavity	15 (44%)
Married/ Partnered	18 (69%)	5 (62.5%)	Larynx	11 (32.25%)
Current/Former Alcohol consumption	23 (88.5%)	7 (87.5%)	Thyroid	3 (8.75%)
Current/Former Tobacco consumption	21 (81%)	7 (87.5%)	Pharynx	5 (15%)
Occupational Status			Treatment Modality	
Working	10 (38.5%)	2 (25%)	Surgery alone	16 (47%)
Volunteer	0	0	Surgery and radiation	8 (23.5%)
Retired	11 (42%)	6 (75%)	Surgery, radiation and chemotherapy	4 (11.75%)
Other	5 (19%)	0	Other	6 (17.75%)
Highest Level of Education Completed			Average Number of Months Since Diagnosis	
Completed High School	7 (27%)	2 (25%)	<6 Months	6 (17.75%)
Some college/ post-secondary	5 (19%)	2 (25%)	6- <12 Months	4 (11.75%)
Completed college/ post-secondary	8 (31%)	1 (12.5%)	12- <18 Months	2 (5.75%)
Graduate Program	2 (7.5%)	1 (12.5%)	18- <24 Months	4 (11.75%)
Other	4 (15.5%)	2 (25%)	24- >24 Months	18 (53%)
Household Income (\$)			Average Number of Months Since Treatment Completion	
<25,000	3 (11.5%)	1 (12.5%)	Not yet completed	3 (8.75%)
25,000-50,000	6 (23%)	1 (12.5%)	<6 Months	7 (20.5%)
50,001-75,000	2 (7.5%)	2 (25%)	6- <12 Months	5 (15%)
>75,000	7 (27%)	3 (37.5%)	12-<18 Months	4 (11.75%)
Prefer not to say	8 (31%)	1 (12.5%)	18-24 Months	15 (44%)

Initial Identification of Potential Participants

Primary physicians identified potential participants during the patient's regular clinical appointment at the London Health Sciences Centre, Victoria Campus, located in London, Ontario. During this initial contact, the physician briefly outlined the purpose of the study to the potential participant and referred them to the primary researcher if they expressed interest in obtaining additional information and potentially participating. The primary investigator then provided a complete description of the study as well as full details regarding study involvement, including the risks, benefits, and potential outcomes. Once individuals had been fully informed, they were asked if they would like to consent to participating in the study. Upon written confirmation of consent patients were given a letter of information, a support services contact list, a demographic information sheet (Appendix C), two QOL surveys (the EORTC-QLQ-C30 and the EORTC-QLQ-H&N35), two self-administered nutrition screens (the PG-SGA SF and the patient completed portion of the Pt-Global App), and an ease-of-use questionnaire. Participants also were asked to complete a PG-SGA nutrition assessment, including a brief non-invasive physical exam administered independently by a physician. Prior to commencing the research and gathering of data from participants, ethical approval was obtained from Western University's Health Sciences Research Ethics Board (Appendix A).

Inclusion Criteria

As noted, all potential participants had to be between the ages of 30 and 80 years, were outpatients diagnosed and/or being treated for HNCa regardless of treatment modality, and were between 3 months post-diagnosis and 24 months post-

treatment. In order to be included in the study, participants were also required by self-report to be able to read, write, and understand English in order to understand instructions, provide informed consent, and complete study tasks.

Exclusion Criteria

Participants with any form of skin cancer (basal cell, squamous cell, or melanoma) were excluded as these cancers should not put a patient at an increased risk of nutritional decline (Britton et al., 2016; Brown et al., 2013). Participants outside the pre-determined age range or who were less than 3 months post-diagnosis or more than 24 months post-treatment also were excluded. Participants who were unable to read or speak English were excluded as they may have experienced difficulty completing the tasks necessary for the study. For similar reasons participants with severe physical disabilities, dementia or other obvious cognitive impairments, or those who indicated that their vision did not permit them to see the questionnaires were also excluded.

Measurement Instruments

Patient Generated – Subjective Global Assessment (PG-SGA) version 3.22.15

Prior to using this measure, written permission was obtained from its developer (Dr. Ottery and the Pt-Global team at info@pt-global.org). These researchers are the copyright holders of the PG-SGA, thus, approval was sought to utilize this nutritional measurement tool through completion of the online permission form. The main purpose for completion of this form is to maintain records regarding the usage of the PG-SGA.

The PG-SGA comprises an assessment of the patient's self-generated medical histories (weight, food intake, symptoms, and activities and function) and a professional assessment (including patient diagnosis, age, metabolic stress, and physical exam). The PG-SGA utilizes a continuous scoring system, enabling the triaging and prioritization of patients requiring more urgent treatment (Bauer, et al., 2002) as well as a Global Assessment (categorizing patients as A= well-nourished, B= moderately malnourished or suspected malnutrition, or C= severely malnourished). The PG-SGA yields a score from "0" (no need for nutrition intervention) to "50" (immediate nutrition intervention required). In the oncology setting a minimum score of one is assigned due to the presence of the malignant disease while scores greater than or equal to nine indicate critical need for symptom management and/or nutritional intervention. Prior research has indicated that scores of 9 or greater have been identified as appropriate cut-offs for the initiation of urgent nutrition intervention (Bauer et al., 2002).

The patient completed portion of the PG-SGA consists of 4 boxes regarding the individual's medical histories (Appendix F). In Box 1 (Weight) and Box 3 (Symptoms) scores are additive and the final score is recorded. In Box 2 (Food intake) and Box 4 (Activities and Function) only one option corresponding to a particular score is selected and recorded. The remaining portion of the PG-SGA is completed by a professional (Appendix F). Box 5 (Disease and its relation to nutritional requirements) and Box 6 (Metabolic Demand) scores are additive while Box 7 (Physical Exam) is not. Box 7 is a subjective rating of the total body deficit through a brief non-invasive physical exam. The physical exam assesses three components of body composition (muscle, fat, and

fluid status) for their degree of deficit. Subjective ratings given to each of these physical components include “0” (no abnormality), “1+” (mild), “2+” (moderate), and “3+” (severe). Based off of these subjective ratings an overall score for the entire physical exam is given ranging from “0” (no malnourishment) to “3+” (severe malnourishment).

The PG-SGA has been accepted by the Oncology Nutrition Dietetic Practice Group of the American Dietetic Association as the gold standard for nutrition assessment for those with cancer (Bauer et al., 2002). In a study conducted by Bauer et al. (2002) the PG-SGA was shown to have a sensitivity of 98%, specificity of 82%, and a positive and negative predictive value of 95% and 93%, respectively. Additionally, the concurrent validity between the PG-SGA and the original SGA was acceptable, with expected correlations existing between PG-SGA scores, BMI and percentage weight loss in the past six months (Bauer et al., 2002). Further, it was also shown that there was a low internal consistency between the seven items of the PG-SGA indicating they were all contributing fairly independently to the final scoring. Various studies have confirmed that the PG-SGA has acceptable psychometric properties (Ravasco et al., 2003). Thus the PG-SGA has demonstrated that it is a simple, efficient, valid and reliable nutrition assessment tool which meets psychometric requirements, permitting its use for the identification and triaging of malnourished oncology patients in clinical settings.

Patient Generated – Subjective Global Assessment Short Form (PG-SGA SF)

The PG-SGA SF, also referred to as the abridged PG-SGA, is entirely self-completed by the patient. The PG-SGA SF consists of four sections which are identical to

the previously described patient completed portion of the current PG-SGA. Thus, the PG-SGA SF includes four sections which cover the topics of weight history, food intake, symptoms, and activity/functionality respectively. The PG-SGA SF utilizes a similar continuous scoring system to output a triage score. However, as the professional portion of the PG-SGA is not included on the PG-SGA SF, scores are adjusted and can range from 0 (no nutrition problems) to 36 (severe nutrition problems).

In studies performed by Gabrielson et al. (2013) and Abbott et al. (2016) the validity of the PG-SGA SF has been assessed using heterogeneous groups of oncology outpatients. The Gabrielson et al. (2013) study indicated that the PG-SGA SF, using a cut-off score of equal to or greater than seven to indicate nutritional compromise, yielded a sensitivity of 94% and a specificity of 78%. Both studies concluded that the PG-SGA SF appears to be a practical and effective nutrition screening tool for identifying nutrition risk in oncology patients. However, these studies had heavy focuses on breast, colorectal and gastrointestinal cancers and included only very few participants with HNCa. Thus, the tools accuracy and sensitivity within the HNCa population when used as a self-screen has not been well investigated. Consequently, further investigation into the applicability of the PG-SGA SF in the HNCa population would appear to be warranted.

Pt-Global Application

The Pt-Global Application launched in 2014. It is a simplified and user friendly version of the PG-SGA in an automated format which aims to streamline and increase the ease of the nutrition screening process (Ottery et al., 2015). Like the PG-SGA, the Pt-

Global Application also utilizes a continuous scoring system (0-50) and provides and Global Assessment ranking (A, B, or C) which enables the triaging and prioritization of patients as well as a summary of their overall nutritional status (Appendix G).

The Pt-Global Application consists of seven different sections. The first five sections are self-completed by the patient. Section 1 (Patient) gathers information regarding patient characteristics such as name, age, height and gender. Following this, sections 2 through 5 are identical to the first 4 boxes of the PG-SGA and gather information regarding weight history, food intake, symptoms, and activity/functionality, respectively. The remainder of the Pt-Global App is to be completed by a healthcare professional and section 6 (Professional portion) of the Pt-Global Application contains three tabs which correspond to boxes 5, 6 and 7 of the PG-SGA. Thus, the remaining three tabs examine the diagnosis, metabolic stress, and provides a brief non-invasive physical examination. The final section of the Pt-Global Application is the Results section where all calculations are completed automatically to yield the PG-SGA triage score and overall Global Assessment category ranking. Additionally, colour coding indicates the level of concern for each section (i.e., green indicates no concern whereas red indicates high concern) and there is a BMI calculation based off of input height and weight.

Ottery et al. (2015) found that the Pt-Global Application had positive ratings on items such as layout, user-friendliness, relevance and appropriateness. It was also found that the majority of professionals, researchers, and laypersons who used the application over the course of the study considered it appropriate for use in both clinical and research settings (Ottery et al., 2015). Given that the Pt-Global App is simply an

automated format of the original PG-SGA with a few additional features it is likely that the sensitivity, specificity, and positive and negative predictive values will be very similar to those of the paper based version of the PG-SGA.

The European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)

The EORTC QLQ-C30 is a QOL questionnaire designed specifically for oncology populations which covers the physical, emotional and social domains (Appendix D). The website for the EORTC group is located at: <http://groups.eortc.be/qol>. The EORTC QLQ-C30 was designed to measure an individual's self-perception of their QOL through a 30-item questionnaire (Niezgoda & Pater, 1993). The first 28 questions assess symptoms commonly reported by the oncology population as well as how these are influencing their functioning and QOL. These questions utilize a scale which ranges from 1 to 4. A score of "1" means that the indicated symptom is "not at all" influencing the individual's QOL while a score of "4" indicates the symptom is "very much" influencing their QOL. Included are 3 symptomatic scales regarding fatigue (3 questions), nausea (2 questions), pain (2 questions), 6 single questions evaluating dyspnea, sleeplessness, lack of appetite, constipation, diarrhea and financial problems and an assessment of the five functional scales: physical (5 questions), role (2 questions), emotional (4 questions), cognitive (2 questions) and social (2 questions) (Żmijewska-Tomczak et al., 2014). The final two questions of the EORTC QLQ-C30 address global perceptions of the individual's health and QOL. These final two questions utilize a scale which ranges from "1" (a "very poor" perception) to "7" (an "excellent" perception) (Żmijewska-Tomczak et al., 2014). The

EORTC QLQ-C30 has been validated and displayed strong reliability and sensitivity to change when assessing the QOL of individuals with different types of cancers including head and neck (Bjordal & Kaasa, 1992; Osoba, Zee, Pater, Kaizer, & Latreille, 1994; Sherman et al., 2000).

The European Organization for the Research and Treatment of Cancer Head and Neck Cancer Module (EORTC QLQ- H&N35)

HNCa and common treatment modalities affect a variety of body functions and can cause significant physical, emotional and social problems, considerably reducing QOL. Therefore, the EORTC QLQ-H&N35 was developed by the EORTC Quality of Life Group as a site specific module for the HNCa population (Appendix E). The EORTC QLQ-H&N35 is a QOL survey which has demonstrated strong reliability, validity and sensitivity to change (Bjordal & Kaasa, 1992; Sherman et al., 2000;). It is a site-specific questionnaire which assesses concerns commonly reported by individuals with HNCa. The EORTC QLQ-H&N35 consists of 35 self-reported items which are divided into seven subscales assessing pain (4 questions), swallowing (5 questions), senses (2 questions), speaking (3 questions), social contact (4 questions), eating in the presence of others (4 questions), and sexuality (2 questions) (Żmijewska-Tomczak et al., 2014). Six single questions then address issues such as teeth problems, problems opening the mouth, dryness of the oral cavity, thick saliva, coughing, and feeling ill (Żmijewska-Tomczak et al., 2014). The first 30 questions utilize a scale ranging from 1-4 to assess the influence of the examined symptoms on the individual's QOL. A score of "1" indicates that the particular symptom or problem has "not at all" influenced their QOL while a score of "4"

indicates that it has “very much” influenced their QOL. The final five questions are scored in binary fashion as either “no” (1) or “yes” (2). These questions assess the patient’s requirement for pain-killers, nutritional supplements or a feeding tube, as well as whether the patient has lost or gained weight (Żmijewska-Tomczak et al., 2014). The EORTC QLQ-H&N35 can be used in addition to the EORTC QLQ-C30 when assessing symptoms and side effects of treatments influencing the QOL of individuals with HNCa (Aronson et al., 1993; Oskam et al., 2013; Żmijewska-Tomczak et al., 2014).

Ease-of-Use Questionnaire

The ease-of-use questionnaire used in this study is designed to assess the participant’s perspective regarding their experience with the two self-completed nutrition screening tools (PG-SGA SF & Pt-Global Application). The questionnaire consists of 12 questions (Appendix F). The first 10 questions utilize a scale ranging from 1 (strongly disagree) to 5 (strongly agree) and assesses the participant’s impressions regarding each of the tools organization, question difficulty, efficiency and simplicity. The final two questions are response questions asking participants if they experienced difficulties utilizing either tool or whether they had any suggestions for improvements.

Data Acquisition Procedure

The study population utilized within this project can be considered one of convenience. Individuals meeting all inclusion and exclusion criteria were identified and asked to participate in the study. Data collection occurred at the London Health Sciences Centre, Victoria Campus, London, Ontario between February and May 2017. Those

interested in participating in the study received an information letter briefly outlining the study and its purpose, ethical guidelines, as well as the potential risks and benefits of participation. After confirmation of consent, participants completed the demographic survey and the two QOL surveys. Following this the two nutrition self-screening tools were administered in a counter balanced manner to prevent the completion order of the two screens from inadvertently introducing bias. Then finally, the ease-of-use questionnaire was administered to gather patient perceptions regarding their user experience with the two nutrition screening tools.

Participants either completed all self-administered forms on site or, if they were unable to complete the forms at that time, took the package with them and returned the forms by mail using pre-addressed and pre-stamped envelopes. However, despite a portion of the package being able to be completed by study participants at home, the nutritional evaluations were required to be completed on site as was the brief and non-invasive physical exam. This was because the materials required to complete the self-screens and the physician required to administer the non-invasive physical exam could only be found at this location. Remaining information from the professionally completed sections of the PG-SGA were gathered by the researcher from charts. In order to maintain confidentiality and de-identify personal information, participants were each assigned a coded number assuring that they were not able to be personally identified over the course of the study; this information was only accessible to the research team. Participants were timed and observed as they completed the nutrition self-screens. Information obtained from these nutrition self-screens was not disclosed to the

professional who administered the PG-SGA nutrition assessment to prevent potential bias. The entire process required an average of 21.3 minutes to complete (range = 15 to 35 minutes). In the case of those who completed the questionnaires outside of clinic, the researcher asked the participant to provide the amount of time required for completion prior to returning the completed packet of materials to the researcher.

Data Analysis

Descriptive and Comparative Statistics

Overall, and as described in earlier sections of this chapter, the study included administration of the PG-SGA, the PG-SGA SF, the Pt-Global Application, the EORTC QLQ-C30, the EORTC QLQ-H&N35, an ease-of-use questionnaire and a demographic survey. All participant scores were calculated according to the recommended procedural guidelines for each measure. Global QOL, the five functioning scales and the nine symptom scales from the EORTC QLQ-C30 were assessed and documented. The 18 symptom scales from the QLQ-H&N35 were also assessed and recorded. Additionally, Global Assessment scores and triaging scores were obtained and recorded from each of the nutrition measurement tools, the PG-SGA, the PG-SGA SF and Pt-Global App. Descriptive statistics were used to outline and summarize participant characteristics such as demographic and tumour/treatment related data. Factors such as gender, age, treatment modality, cancer site, marital status, occupational status, educational achievement and QOL scores were compared to nutrition status scores through the use of comparative statistics. Additionally, comparative statistics were also utilized to determine if any correlations existed between the scores obtained from the nutrition

measurements and any of the domain scales of the EORTC QLQ-C30 or EORTC QOL-H&N35. Parametric statistics including t-tests and Pearson correlation coefficients along with nonparametric statistics such as Mann-Whitney U tests were performed in order to evaluate the differences between individuals classified as well-nourished versus nutritionally compromised by the PG-SGA nutrition assessment.

Assessment of Reliability

The sensitivity, specificity, accuracy, and the positive/negative predictive values (PPV/NPV) of the self-administered nutrition screening tools were calculated. Receiver operating characteristic (ROC) curves were used to plot and assess the rates of true and false positives of the nutrition screening tools compared to the PG-SGA nutrition assessment. Briefly, ROC analyses assesses the sensitivity and specificity of a given test. An area under the curve on the resulting plot of 1 represents a perfect test while an area of 0.5 represents a test which is a poor measure of the given construct. As sample sizes in the present investigation were assumed to be adequate, asymptotic significance tests were utilized to identify the significance level of results obtained from the ROC analyses.

CHAPTER 3: RESULTS

The following sections will present results obtained from the PG-SGA, the nutrition screens (PG-SGA SF & Pt-Global Application), the ease-of-use survey, and the QOL questionnaires (EORTC QLQ-C30 & EORTC QLQ-H&N35) gathered as part of this study. Initially, descriptive statistics including measures of central tendency are reported for items completed by participants. Following this, supplementary observational analyses were made assessing nutrition trends associated with demographic factors such as participant age, treatment modality, and smoking status.

Comments provided by participants on open-ended questions on both the demographic information survey and the ease-of-use survey have also been summarized to identify topics/issues which they felt were important. The intention behind this was to better our understanding of the experience of individual participants.

Patient Generated – Subjective Global Assessment (PG-SGA)

Of the 34 participants, 23 (18 males and 5 females) were identified by the PG-SGA as having good nutrition status (Category A), 9 (6 males and 3 females) had a moderately compromised nutrition status (Category B), while 2 males were identified as having severely compromised nutrition status (Category C). Thus, nutritional complications, classified as either Category B or C, were present in 32.3% of participants (30.7% of males and 37.5% of females). Although the majority of participants presented as being well-nourished, this does not imply that the remaining nutritional issues that emerged were any less concerning. Specifically, for those participants who presented

with a compromised nutrition status, many were found to be moderately malnourished (M = 11; range 7-17). Detailed participant responses are presented in Table 2.

Table 2 provides the mean scores calculated for each of the 4 boxes of the patient completed portion PG-SGA, as well as for the final professionally completed portion. Results have been segregated by nutrition status. It can be seen that the nutritionally compromised individuals had higher mean scores than did the well-nourished individuals on all assessment boxes (indicating a worse nutrition status). The greatest difference was observed for box 3 “symptoms influencing nutrient consumption”. The most commonly reported nutrition impact symptom identified was “dry mouth”, followed closely by “lack of appetite” and an “impaired sense of taste”. The least commonly reported nutrition impact symptoms were “vomiting” and an “impaired sense of smell”.

Score Summary				Nutrition Impact Symptoms		
	WN (n=23)	NC (n=11)	P-Value		WN (n=23)	NC (n=11)
Males	18	8		No Problems Eating	16 (69.5%)	1 (9%)
Females	5	3		No Appetite	0	8 (73%)
Mean Box 1	0.04	0.36	0.282	Nausea	0	1 (9%)
Mean Box 2	0.35	1.45	0.019*	Constipation	0	2 (18%)
Mean Box 3	0.52	6	1.78x10 ⁻⁴ *	Mouth Sores	0	1 (9%)
Mean Box 4	0.39	1.36	1.39x10 ⁻⁴ *	Funny/No Taste	2 (8.5%)	6 (54.5%)
Mean Professional Score	1.52	2.18	0.014*	Swallowing Problems	3 (13%)	3 (27.5%)
Mean PG-SGA Score	2.83	11.36	2.00x10 ⁻⁶ *	Pain	0	2 (18%)
Average Category	A	B		Vomiting	0	0
Weight Change in Past 2 Weeks				Diarrhea	0	1 (9%)
Increased	7 (30.5%)	4 (36.5%)		Dry Mouth	2 (8.5%)	7 (63.5%)
Unchanged	15 (65%)	5 (45.5%)		Funny/No Smell	0	0
Decreased	1 (4.5%)	2 (18%)		Feels Full Quickly	0	5 (45.5%)
Food Intake				Fatigue	1 (4.5%)	4 (36.5%)
More than usual	2 (8.5%)	3 (27.5%)		Other	0	1 (9%)
Unchanged	21 (91.5%)	5 (45.5%)		Activities and Function		
Less than usual	0	3 (27.5%)		Normal with no limitations	14 (61%)	1 (9%)
Normal food, but less than normal amount	4 (17.5%)	3 (27.5%)		Not normal self, but able to be up and about with fairly normal activities	9 (39%)	6 (54.5%)
Little solid food	2 (8.5%)	3 (27.5%)		Not feeling up to most things, but in bed or chair less than half the day	0	3 (27.5%)
Only nutritional Supplements	0	0		Able to do little activity and spend most of the day in bed or chair	0	1 (9%)
Only liquids	0	1 (9%)		Pretty much bed ridden, rarely out of bed	0	0
Very little of anything	0	1 (9%)				
Only tube feedings or nutrition by vein	2 (8.5%)	0				
None Selected	15 (65%)	3 (27.5%)				

*Well-Nourished (WN), Nutritionally Compromised (NC).

Patient Generated – Subjective Global Assessment Short Form (PG-SGA SF)

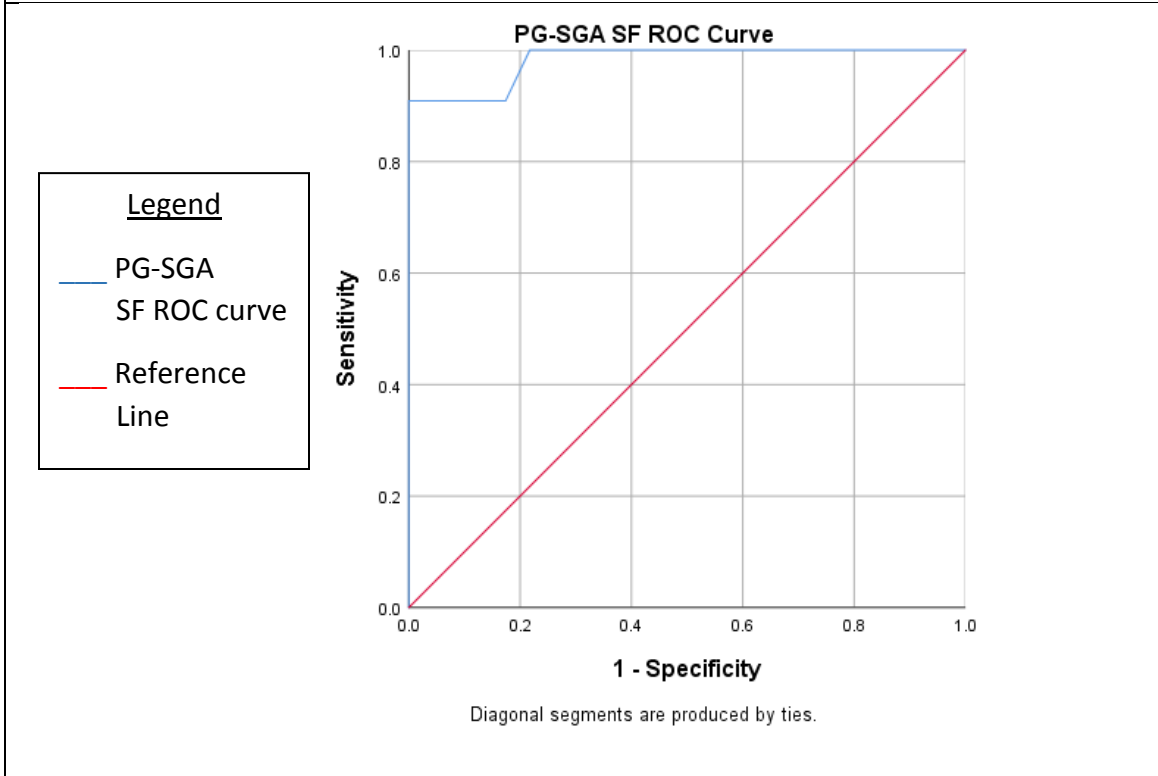
Mean scores for the PG-SGA SF were calculated and are presented in Table 3. Of the 34 participants, 25 individuals (20 males and 5 females) were identified by the PG-SGA SF as being well-nourished (Category A), while 9 (6 males and 3 females) were identified as being nutritionally compromised (Category B or C). Thus, nutritional concerns were present in 26.47% of participants (23.08% of males and 37.5% of females) and scores ranged from 0 - 15. For the nutritionally compromised group, the majority were moderately malnourished with a mean nutrition score of 10.22. In contrast, those identified as being well-nourished had a mean nutrition score of 1.56. The PG-SGA SF also agreed with the PG-SGA, identifying “dry mouth” as the most common nutrition impact symptom, followed by “lack of appetite” and an “impaired sense of taste” while the least common were “vomiting” and an “impaired sense of smell”. On average the PG-SGA SF took participants 1.82 minutes to complete.

Overall, the PG-SGA SF showed good agreement with the PG-SGA and demonstrated a sensitivity of 81.8% and a 100% specificity. Additionally, the positive predictive value of the PG-SGA SF was 100%, while the negative predictive value was 92%. A ROC analysis revealed an area under the curve of 0.982 (with lower and upper bound score 0.943 and 1.000, respectively). An asymptotic significance test then identified an a priori significance level of $p=7.0 \times 10^{-6}$. Further details regarding this ROC curve analysis can be found in Figure 1. Thus, the PG-SGA SF demonstrated acceptable levels of accuracy as well as a strong ability to predict PG-SGA nutrition scores and nutrition category ratings.

Score Summary				Nutrition Impact Symptoms		
	WN (n=25)	NC (n=9)	P-value		WN (n=25)	NC (n=9)
Males	20	6		No Problems Eating	17 (68%)	0
Females	5	3		No Appetite	0	8 (89%)
Mean Box 1	0.04	0.44	0.268	Nausea	0	1 (11%)
Mean Box 2	0.52	1.22	0.079*	Constipation	0	2 (22%)
Mean Box 3	0.56	7.11	1.20x10 ⁻⁵ *	Mouth Sores	0	1 (11%)
Mean Box 4	0.44	1.44	2.27x10 ⁻⁴ *	Funny/No Taste	2 (8%)	6 (66.5%)
Mean PG-SGA SF Score	1.56	10.22	3x10 ⁻⁶ *	Swallowing Problems	3 (12%)	3 (33.5%)
Average Category	A	B		Pain	0	2 (22%)
Weight Change in Past 2 Weeks				Vomiting	0	0
Increased	7 (28%)	4 (44.5%)		Diarrhea	0	1 (11%)
Unchanged	17 (68%)	3 (33.5%)		Dry Mouth	3 (12%)	6 (66.5%)
Decreased	1 (4%)	2 (22%)		Funny/No Smell	0	0
Food Intake				Feels Full Quickly	0	5 (55.5%)
More than usual	3 (12%)	2 (22%)		Fatigue	2 (8%)	3 (33.5%)
Unchanged	22 (88%)	4 (44.5%)		Other	1 (4%)	0
Less than usual	0	3 (33.5%)		Activities and Function		
Normal food, but less than normal amount	4 (16%)	3 (33.5%)		Normal with no limitations	15 (60%)	0
Little solid food	3 (12%)	2 (22%)		Not normal self, but able to be up and about with fairly normal activities	9 (36%)	6 (66.5%)
Only liquids	1 (4%)	0		Not feeling up to most things, but in bed or chair less than half the day	1 (4%)	2 (22%)
Only nutritional Supplements	0	0		Able to do little activity and spend most of the day in bed or chair	0	1 (11%)
Very little of anything	0	1 (11%)		Pretty much bed ridden, rarely out of bed	0	0
Only tube feedings or nutrition by vein	2 (8%)	0		Agreement with PG-SGA Assessment		
None selected	15 (60%)	3 (33.5%)		Sensitivity	81.8%	
				Specificity	100%	
				Positive Predictive Value	100%	
				Negative Predictive Value	92%	

* Well-Nourished (WN), Nutritionally Compromised (NC).

Figure 1. PG-SGA SF Receiver Operating Curve (ROC)



Pt-Global Application

Mean scores for the Pt-Global Application were calculated and are presented in Table 4. The Pt-Global application identified 7 of 34 study participants (4 males and 3 females) as being nutritionally compromised (Category B or C), while 27 (22 males and 5 females) were identified as well-nourished (Category A). Thus, the Pt-Global Application identified nutritional complications in 20.6% of participants (15.4% of males and 37.5% of females) with scores ranging from 0 - 13. For those who presented with a compromised nutrition status, the mean nutrition score was 9.71; those identified as well-nourished presented with a mean score of 1.7. The most commonly reported nutrition impact symptoms on the Pt-Global application were, “dry mouth” and “lack of

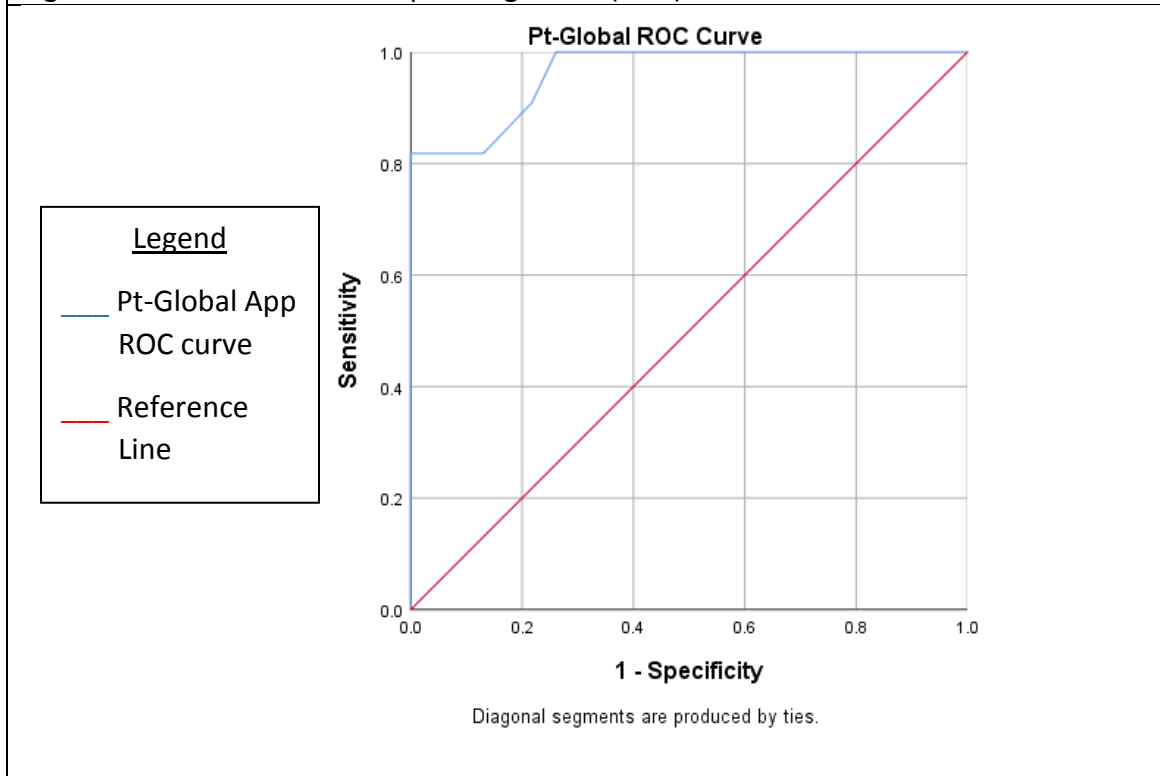
appetite”, while the least reported symptoms were “vomiting” and “diarrhea”. On average the Pt-Global Application took participants 3.71 minutes to complete.

Overall, the Pt-Global Application demonstrated fair agreement with the PG-SGA demonstrating a sensitivity of 63.6% and a specificity of 100%. Additionally, the positive and negative predictive values of the Pt-Global Application were identified to be 100% and 85.2%, respectively. Again, an ROC curve analysis was performed which identified an area under the curve of 0.962 (with lower and upper bound scores of 0.904 and 1.000, respectively). The following asymptotic significant test revealed a significance of $p=1.7 \times 10^{-5}$. Further details regarding this ROC curve analysis can be found in Figure 2. Thus, the Pt-Global Application demonstrated a moderate ability to predict PG-SGA nutrition and category ratings, and accuracy ratings all reached acceptable levels with the exception of sensitivity which fell below the 80% benchmark value.

Table 4. Pt-Global Application Screen Scores						
Score Summary				Nutrition Impact Symptoms		
	WN (n=27)	NC (n=7)	P-value		WN (n=27)	NC (n=7)
Males	22	4		No Problems Eating	20 (74%)	1 (14%)
Females	5	3		No Appetite	1 (3.5%)	6 (85.5%)
Mean Box 1 Score	0.04	0.57	6.090	Nausea	0	1 (14%)
Mean Box 2 Score	0.52	1.14	0.136	Constipation	0	1 (14%)
Mean Box 3 Score	0.63	6.43	0.002*	Mouth Sores	0	1 (14%)
Mean Box 4 Score	0.52	1.57	0.001*	Funny/No Taste	2 (7.5%)	3 (43%)
Mean Pt-Global Score	1.7	9.71	1.46x10 ⁻⁴ *	Swallowing Problems	3 (11%)	2 (28.5%)
Average Category	A	B		Pain	0	2 (28.5%)
Weight Change in Past 2 Weeks				Vomiting	0	0
Increased	9 (33%)	2 (28.5%)		Diarrhea	0	0
Unchanged	17 (63%)	3 (43%)		Dry Mouth	2 (7.5%)	5 (71.5%)
Decreased	1 (3.5%)	2 (28.5%)		Funny/No Smell	0	1 (14%)
Food Intake				Feels Full Quickly	1 (3.5%)	3 (43%)
More than usual	2 (7.5%)	1 (14%)		Fatigue	2 (7.5%)	1 (14%)
Unchanged	24 (89%)	2 (28.5%)		Other	1 (3.5%)	0
Less than usual	1 (3.5%)	4 (57%)		Activities and Function		
Normal food, but less than normal amount	5 (18.5%)	4 (57%)		Normal with no limitations	15 (55.5%)	0
Little solid food	3 (11%)	0		Not normal self, but able to be up and about with fairly normal activities	10 (37%)	4 (57%)
Only liquids	1 (3.5%)	0		Not feeling up to most things, but in bed or chair less than half the day	2 (7.5%)	2 (28.5%)
Only nutritional Supplements	0	0		Able to do little activity and spend most of the day in bed or chair	0	1 (14%)
Very little of anything	0	1 (14%)		Pretty much bed ridden, rarely out of bed	0	0
Only tube feedings or nutrition by vein	2 (7.5%)	0		Agreement with PG-SGA Assessment		
None selected	16 (59.5%)	2 (28.5%)		Sensitivity	63.6%	
				Specificity	100%	
				Positive Predictive Value	100%	
				Negative Predictive Value	85.2%	

* Well-Nourished (WN), Nutritionally Compromised (NC).

Figure 2. Pt-Global Receiver Operating Curve (ROC)



Ease-of-Use Survey

The mean, mode, median, range, and standard deviations for the 10 questions presented on the ease-of-use survey are summarized in Table 5. Recall that higher scores indicate a greater level agreement with the statement. What is clear based on these data is that the current participants preferred the PG-SGA SF over the Pt-Global Application. Mean scores for all questions asked on the ease-of-use survey were higher for those regarding the PG-SGA SF. This indicates that participants were commonly in stronger agreement with the statements for the PG-SGA SF than for the Pt-Global Application.

Table 5. Ease-of-Use Survey Scores						
	N	Range	Mean	Mode	Median	SD
PG-SGA SF						
Q1. Easy to use	34	1-5	4.11	4	4	0.84
Q2. Organized in understandable way	34	1-5	4.29	4	4	0.68
Q3. Easy to understand	34	1-5	4.29	4	4	0.678
Q4. Able to be completed quickly with ease without professional aid	34	1-5	3.97	4	4	1.11
Q5. Simple tool for assessing nutrition status	34	1-5	3.97	4	4	0.834
Pt-Global App						
Q6. Easy to use	34	1-5	3.76	4	4	1.13
Q7. Organized in understandable way	34	1-5	4.06	4	4	0.98
Q8. Easy to understand	34	1-5	4	4	4	0.95
Q9. Able to be completed quickly with ease without professional aid	34	1-5	3.76	4	4	1.3
Q10. Simple tool for assessing nutrition status	34	1-5	3.74	4	4	0.99

Results of the EORTC QLQ-C30

The mean, range, and standard deviation scores for each of the 30 questions included on the EORTC QLQ-C30 were calculated. These scores were then segregated by nutrition status to highlight differences between the QOL scores of the well-nourished and nutritionally compromised groups. Items were scaled from 1 (“not at all a problem”) to 4 (“very much a problem”). An arbitrary level of significant difference between well-nourished and nutritionally compromised means was set at 0.5. For both the well-nourished and nutritionally compromised groups, Question 18 “were you tired” received the highest mean score of 1.78 and 2.55, respectively. For the well-nourished group, Question 5 “did you need help eating, dressing, washing yourself or using the toilet”

received the lowest mean score of 1. This differed from the nutritionally compromised group who indicated that Question 15 “have you vomited” was their least concerning problem (M = 1). What is important to note is that for every item the score of the nutritionally compromised group was either similar to or greater in value when compared to the well-nourished group. These scores suggest that the nutritionally compromised individuals are having their perceived QOL influenced by these factors to a greater degree than the well-nourished group.

Detailed measures of central tendency for each of the EORTC QLQ-C30 domains (Global QOL, physical, role, emotional, cognitive and social functioning, fatigue, nausea, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulties) are presented in Table 6; again, these data have been segregated by nutrition status.

Domain scores could range from 0 (worst possible functioning) to 100 (best possible functioning). Well-nourished participants physical functioning revealed the highest mean domain score (92.17) while their emotional functioning had the lowest mean score (82.25). In contrast, the nutritionally compromised individuals reported that their role functioning was best (M = 72.12) while their social functioning was the worst (M = 56.06). Most importantly for the present study, significant differences were observed between the physical, cognitive and social functioning domains of the well-nourished and nutritionally compromised groups. In each instance, the perceived QOL of the nutritionally compromised group was worse.

This trend toward a worse perceived QOL for the nutritionally compromised group held true for all the symptoms scale scores as well, with the exception diarrhea which was insignificant. Symptom scales also had the possibility to range from 0 (not at all a problem) to 100 (very much a problem). Those individuals identified as nutritionally compromised also reported experiencing a greater degree of QOL impact on the C30, with “fatigue”, “appetite loss”, and “constipation” reaching significance. The symptom reported to have the greatest influence on QOL for the nutritionally compromised group was “appetite loss” (M = 42.42), while “nausea” was the least influential (M = 4.55).

Additionally, the mean Global QOL domain scores for the well-nourished and nutritionally compromised groups differed significantly. This revealed that when individual perceptions of personal Global QOL were compared, the nutritionally compromised group perceived their QOL to be significantly worse.

Table 6. EORTC QLQ-C30 Domain/Symptom Scores										
	N		Range	Mean		Median		SD		P-value
	WN	NC		WN	NC	WN	NC	WN	NC	
Global Health Status										
Global QOL	23	11	0-100	78.62	55.3	83.33	58.33	14.5	16.75	3.44x10 ⁻⁴ *
Functional Domain Scales										
Physical	23	11	0-100	92.17	72.12	93.33	73.33	11.57	17.19	0.001*
Role	23	11	0-100	86.23	72.73	100	83.33	20.01	32.32	0.155
Emotional	23	11	0-100	82.25	70.45	83.33	66.67	17.94	22.19	0.124
Cognitive	23	11	0-100	91.3	63.64	100	66.67	10.85	14.91	4.00x10 ⁻⁶ *
Social	23	11	0-100	86.23	56.06	100	66.67	21.23	32.53	0.003*
Symptoms/Items										
Fatigue	23	11	0-100	20.29	38.38	22.22	44.44	16.92	19.75	0.016*
Nausea	23	11	0-100	3.62	4.55	0	0	9.78	10.67	0.808
Pain	23	11	0-100	18.11	31.82	16.67	33.33	21.93	24.09	0.125
Dyspnoea	23	11	0-100	11.59	27.27	0	33.33	18.67	31.45	0.087
Insomnia	23	11	0-100	24.64	30.3	33.33	33.33	28.18	37.86	0.632
Appetite loss	23	11	0-100	4.35	42.42	0	33.33	11.23	37.11	0.010*
Constipation	23	11	0-100	4.35	30.3	0	33.33	11.23	36.51	0.048*
Diarrhea	23	11	0-100	7.25	6.06	0	0	13.75	13.33	0.817
Financial	23	11	0-100	13.04	33.33	0	0	19.01	43.33	0.175

* Well-Nourished (WN), Nutritionally Compromised (NC).

Results of the EORTC QLQ-H&N35

The means, ranges, and standard deviations for the 35 questions of the EORTC QLQ-H&N35 were calculated; again, scores were segregated by nutrition status for comparison. Scores ranged from 1 (“not at all a problem”) to 4 (“very much a problem”) for the first 30 items. An arbitrary level of significant difference between well-nourished and nutritionally compromised means was set at 0.5. For the nutritionally compromised group Question 7, “have you had problems swallowing solid food?” received the highest mean score of 2.91 while Question 4, “have you had a painful throat?”, received the lowest mean score of 1.09. Questions 31-35 were excluded from consideration as these

questions utilize a different rating scale. Of importance for this study is the finding that in every instance where a significant difference was observed between H&N35 items, the greater QOL impact was reported by the nutritionally compromised group.

Detailed measures for each of the symptom domains are summarized in Table 7. Symptom domains had the potential to range from 0 (“not at all afflicting”) to 100 (“completely afflicting”). For the nutritionally compromised group, “dry mouth” presented the highest mean score (M = 57.56) while “pain” had the lowest mean score (M = 9.8). What is again important to point out is that with exception of “pain”, “nutritional supplements” and “weight gain”, none of which achieved significance, all H&N35 symptom domain scores received higher ratings from the nutritionally compromised group, indicating a greater perceived influence. Significant differences were observed between the scores of the “senses” and “speech problems” domains as well as the “teeth” and “dry mouth” domains. Additional domains which approached significance which had face value for nutrition status were “swallowing”, “trouble with social eating” and “social contact” and “sticky saliva”.

	N		Range	Mean		Median		SD		P-Value
	WN	NC		WN	NC	WN	NC	WN	NC	
Symptoms scales/items										
Pain	23	11	0-100	14.49	9.85	16.7	0	14.79	14.13	0.405
Swallowing	23	11	0-100	15.22	31.06	8.33	25	22.74	20.13	0.065
Senses problems	23	11	0-100	10.14	42.42	0	50	14.53	28.75	0.005*
Speech problems	23	11	0-100	20.77	40.4	11.1	33.33	23	28.53	0.045*
Trouble with social eating	23	11	0-100	13.41	31.82	0	25	26.89	21.85	0.064
Trouble with social contact	23	11	0-100	8.99	28.48	0	20	15.18	27.43	0.055
Less sexuality	23	11	0-100	20.29	27.27	0	0	31.83	37.11	0.587
Teeth	23	11	0-100	14.49	42.42	0	33.33	25.68	32.07	0.012*
Opening mouth	23	11	0-100	11.59	30.3	0	33.33	18.67	33.2	0.120
Dry mouth	23	11	0-100	24.64	57.56	0	66.67	29.84	35.08	0.010*
Sticky saliva	23	11	0-100	14.49	33.33	0	33.33	23.73	28.42	0.058
Coughing	23	11	0-100	24.64	39.39	33.3	33.33	26.41	31.2	0.173
Felt ill	23	11	0-100	5.8	18.18	0	0	12.63	21.85	0.119
Pain killers	23	11	0-100	34.78	54.55	0	100	47.63	49.79	0.287
Nutritional supplements	23	11	0-100	30.43	27.27	0	0	46.01	44.54	0.855
Feeding tube	23	11	0-100	13.04	18.18	0	0	33.68	38.57	0.703
Weight loss	23	11	0-100	8.7	27.27	0	0	28.18	44.54	0.245
Weight gain	23	11	0-100	30.43	18.18	0	0	46.01	38.57	0.464

* Well-Nourished (WN), Nutritionally Compromised (NC).

Consistency of Responses

Participant's responses for both EORTC surveys and the nutrition evaluations demonstrated consistency. When individuals reported a better perceived global QOL and nutrition status, other domains tended to also be rated highly. Conversely, when

individuals indicated that they had a lower perceived Global QOL and nutrition status, they tended to report a worse perceived functioning and an increased symptom burden.

Correlation Assessment of Measures

The scores for global QOL, the five functional domains, and 12 of the 27 symptom scales from both EORTC measures, as well as PG-SGA scores were compared to identify potential relationships. This correlational assessment revealed moderate-to-strong relationships between various measures (Table 8).

A moderate inverse relationship was identified between the PG-SGA scores and the Global QOL scores, $r(32) = -0.5, p < 0.01$. Thus, with increasing nutritional concerns, QOL scores tended to decline. Moderate-to-strong relationships were also identified between the PG-SGA nutrition scores and many EORTC functional domains, the strongest of which was identified for the physical functioning domain, $r(32) = -0.63, p < 0.01$. As for the item/symptom scales, the strongest correlations with the PG-SGA nutrition scores were found for loss of appetite, $r(32) = 0.58, p < 0.01$, constipation, $r(32) = 0.56, p < 0.01$, and senses problems, $r(32) = 0.6, p < 0.01$. Remaining values identified by the correlational analysis can be found in Table 8.

Table 8. Correlation Matrix

	G-QOL	PG-SGA	PF	RF	EF	CF	SF	F	N&V	A	C	S	SP	TSE	T	OM	DM	SS	FI
Global Health	1	-.504**	.510**	.568**	.652**	.504**	.653**	-.582**	-0.092	-.426*	-.505**	-.439**	-.473**	-.480**	-.628**	-.394*	-.579**	-.341*	-.510**
PG-SGA Score		1	-.627**	-0.242	-0.241	-.532**	-.512**	.390*	0.111	.582**	.564**	.401*	.599**	.443**	.395*	.368*	.437**	0.301	.400*
Physical			1	.474**	.514**	0.335	.498**	-.606**	0.023	-.418*	-.673**	-0.315	-.493**	-.399*	-.373*	-0.066	-.419*	-0.275	-.284
Role				1	.700**	.485**	.571**	-.695**	-0.107	-.427*	-.550**	-.464**	-.374*	-.661**	-.395*	-0.309	-.400*	-0.292	-.416*
Emotional					1	.439**	.708**	-.789**	-0.326	-0.162	-.457**	-0.224	-0.215	-.492**	-.761**	-.376*	-.552**	-0.143	-.651**
Cognitive						1	.450**	-.488**	-0.334	-.510**	-0.284	-.364*	-.499**	-.374*	-.390*	-.476**	-0.323	-0.289	-.535**
Social							1	-.525**	-0.250	-0.291	-.505**	-0.338	-0.189	-.562**	-.669**	-.344*	-.620**	-0.305	-.593**
Fatigue								1	.375*	.483**	.564**	0.300	.429*	.413*	.488**	0.258	.603**	.345*	.596**
Nausea & Vomiting									1	0.223	-0.132	0.257	0.101	0.129	0.072	0.176	0.305	0.187	.730**
Appetite Loss										1	.412*	.426*	.703**	0.223	0.108	.343*	.347*	.476**	0.323
Constipation											1	.349*	0.251	.486**	0.283	0.154	.553**	.379*	0.236
Swallowing												1	.464**	.709**	0.073	0.328	0.292	.641**	0.320
Senses Problem													1	.407*	0.196	.469**	0.175	.411*	0.287
Trouble Social Eating														1	0.299	.450**	.376*	0.321	.492**
Teeth															1	.422*	.470**	0.007	.428*
Opening mouth																1	.393*	0.277	.566**
Dry mouth																	1	.442**	.562**
Sticky Saliva																		1	0.200
Felt ill																			1

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

Supplemental Observational Analysis of Data

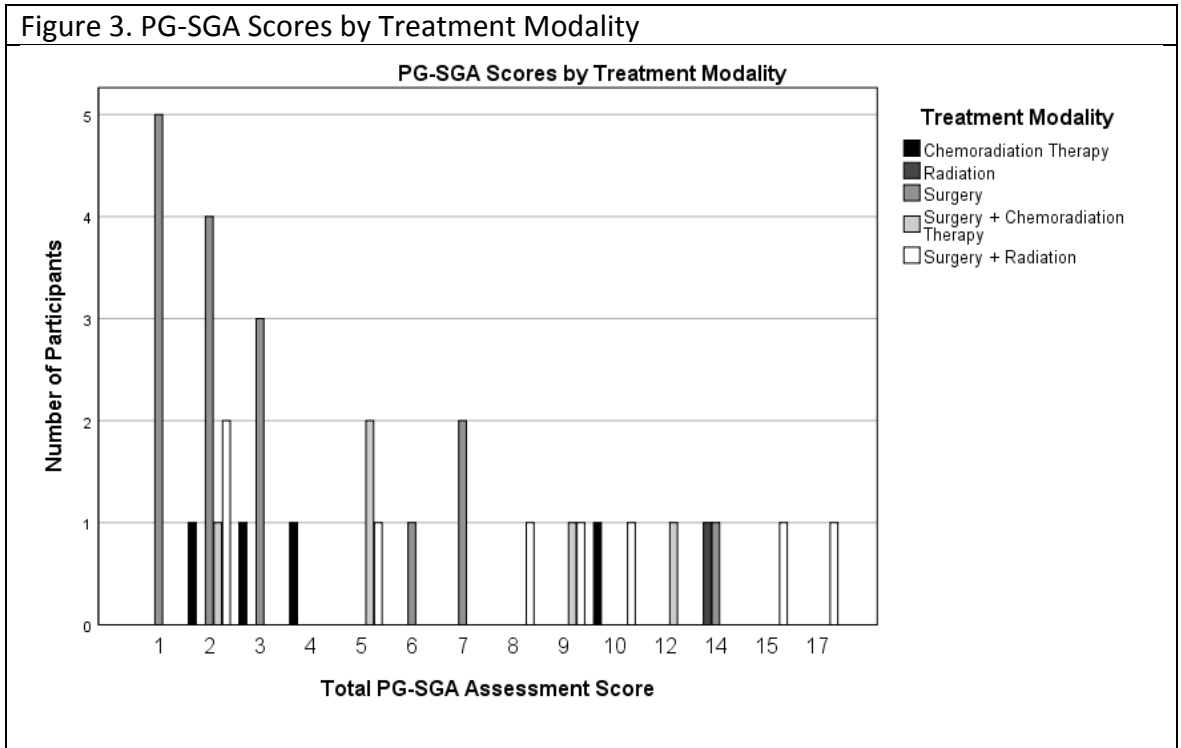
Gender Comparisons

Scores between male and female participants were compared for the Global QOL and PG-SGA measures. During these comparisons, statistically significant differences were not found between any of these measures based on gender.

Treatment modality

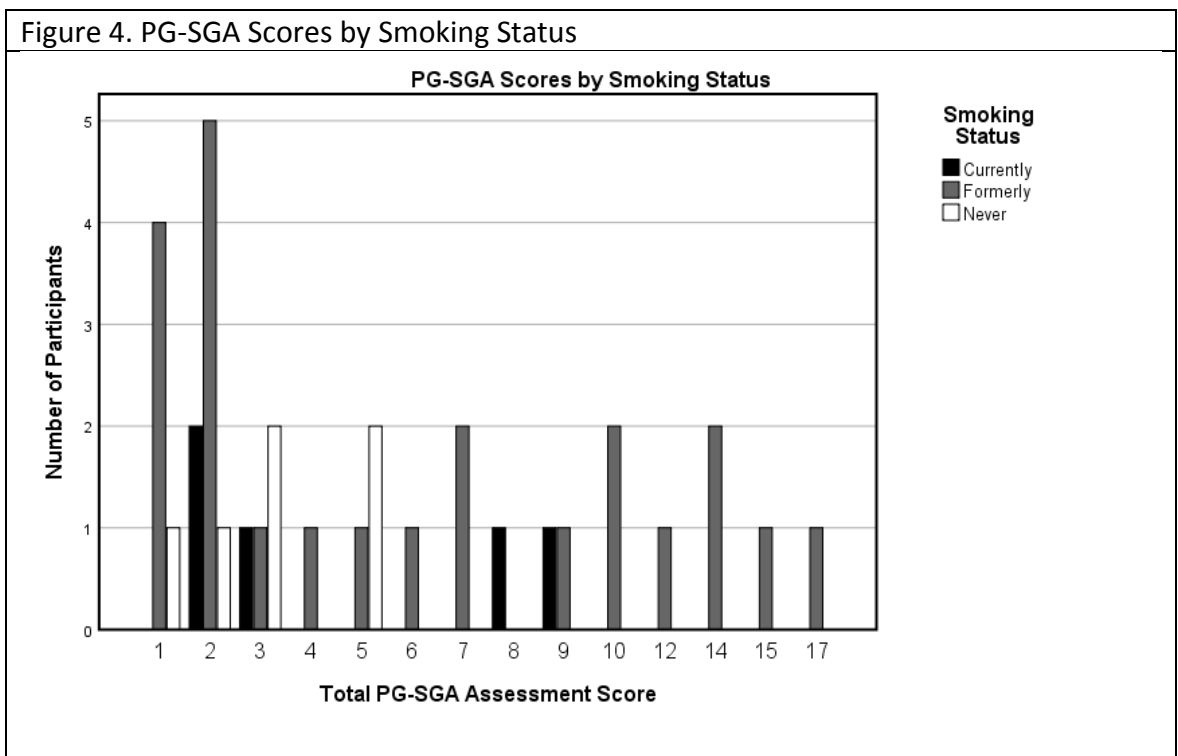
The types of HNCa treatments received varied and tended to have an influence on the participants' nutrition status. The first analysis assessed whether there was a difference between the nutrition scores of those participants who received surgery alone as a treatment (range= 1 – 14) vs. other types of treatment such as chemotherapy, radiation therapy or a combined modality (range= 2 - 17). A t-test indicated that there was a significant difference between groups ($t(33)=2.75$, $p<0.01$). An additional t-test also indicated a significant difference between the QOL of the two groups ($t(33)=3.95$, $p<0.001$). Those who received surgery alone had a mean PG-SGA score of 3.88, while those who received any other individual treatment type or a combination of treatments had a mean PG-SGA score of 7.29. Figure 3 presents a detailed list of PG-SGA nutrition scores by treatment modality. A Mann-Whitney U test revealed significant differences for the PG-SGA nutrition assessment scores, $U(33)=64$, $p<0.01$, across the different treatment modality categories. Further, an additional Mann-Whitney U test identified significant differences for Global QOL scores, $U(33)=48.5$, $p<0.01$, across treatment modality categories. No significant differences between the categories of treatment modality for the variable of time post treatment were observed.

Figure 3. PG-SGA Scores by Treatment Modality



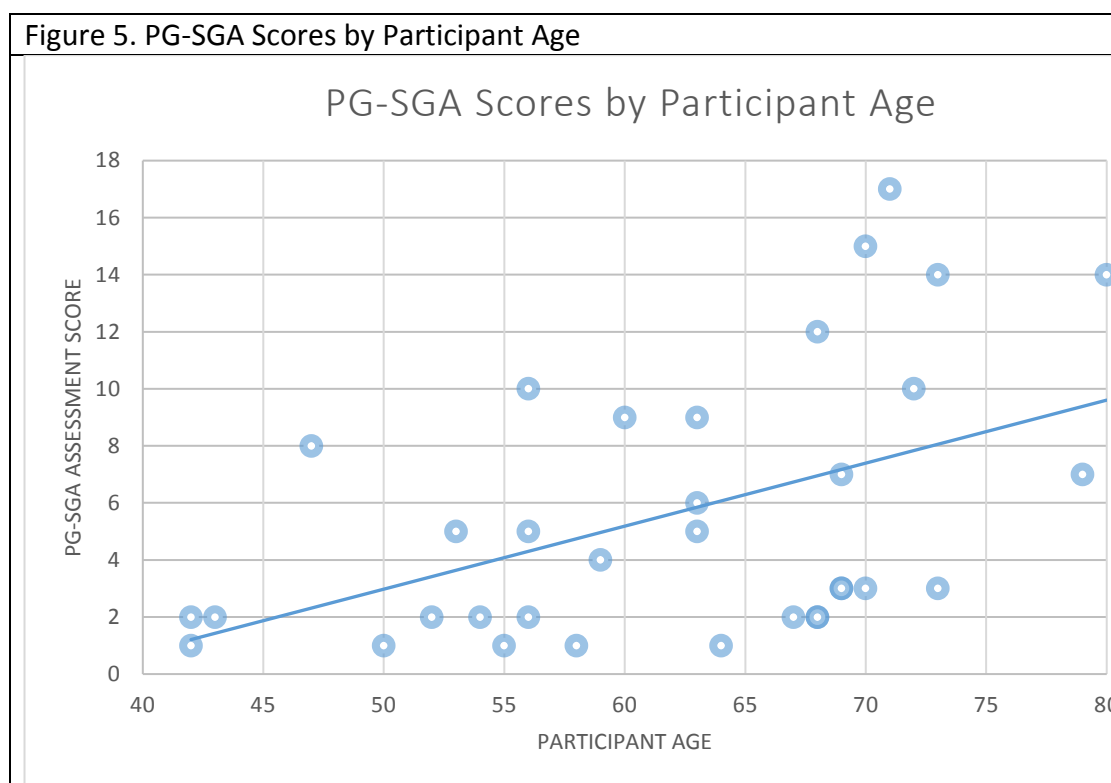
Smoking status

A t-test was used to identify if there was a significant difference between the mean PG-SGA nutrition scores of current and former smokers compared to non-smokers (6.11 and 3.17, respectively). This test did identify a level of significant difference between the two groups ($t(33)=2.58, p<0.05$). Next current and former smoking groups were differentiated (Figure 4). Participants who indicated that they had never smoked, tended to have lower PG-SGA scores (range = 1 – 5), while those who indicated they were former smokers tended to present with the highest PG-SGA scores (range = 1-17) and thus higher nutritional concerns.



Age

A correlational assessment between participant age and PG-SGA assessment scores revealed that nutrition scores increased with age (indicating a worse overall nutrition status) and this relationship is depicted in Figure 5. The Pearson correlation between age and PG-SGA nutrition score was $r(32)=0.48$, $p<0.01$. The correlation between age and the Global QOL domain scores however, was insignificant.



Summary

The present investigation assessed the ability of the PG-SGA SF and Pt-Global Application to predict PG-SGA nutrition assessment scores. All accuracy ratings for both screening tools achieved the 80% acceptability benchmark with the exception of Pt-Global sensitivity. Following this, EORTC scores of those identified as well-nourished were compared to those identified as nutritionally compromised. Various

items achieved significant levels of difference with worse QOL scores reported by the nutritionally compromised group. There did prove to be significant correlations between nutrition and QOL measures. As nutrition scores increased (greater nutritional concerns) QOL ratings decreased, functional domain scores declined, and symptom domain scores increased. Finally, significant differences were found to exist between the nutrition scores of individuals based on their treatment modality, smoking status, and age.

CHAPTER 4: DISCUSSION

The purpose of the present investigation was to assess the accuracy of two nutrition self-screening tools when compared to the PG-SGA. This allowed for the determination of whether either self-screening tool could be reliably used to efficiently and proactively identify individuals at nutritional risk. Additionally, the relationship between the nutrition status and QOL of individuals diagnosed and treated for HNCa on an outpatient basis was assessed. This study also aimed to identify the common nutritional concerns following HNCa treatment. Various nutrition impact symptoms, functional domains and the interrelations between the two were examined. Thus, the specific questions targeted in this study were:

- 1) Are nutritional self-screens able to be reliably completed by outpatients with HNCa and are the results comparable to those of nutritional assessments?
- 2) What are the commonly reported symptoms impacting the nutrition status of individuals with HNCa being treated on an outpatient basis?
- 3) What is the relationship between nutrition status and overall QOL among individuals diagnosed with HNCa being treated on an outpatient basis?

Throughout the following sections of this discussion these questions, as well as the specific issues that arose from the data obtained will be addressed. This will begin with a discussion of the findings gathered from the statistical analyses of the PG-SGA nutrition assessment and both nutrition screening tools. This will include how the nutrition screens related to the PG-SGA, identification of commonly reported nutrition impact symptoms, and how responses differed between the well-nourished and nutritionally compromised. Following this, results from the statistical

analysis of both QOL surveys (EORTC QLQ-C30 and EORTC QLQ-H&N35) will be outlined. The relationship between nutritional status and QOL and how the various domains differed between well-nourished and nutritionally compromised individuals will be discussed. The final sections of this chapter will outline the study limitations, the potential clinical implications, and the possible directions for future research into self-administered nutrition screening in those with HNCa.

Patient Generated – Subjective Global Assessment (PG-SGA)

Recall that the PG-SGA was specifically designed to assess the nutritional status of individuals with cancer. However, due to limitations such as time restrictions and heavy workloads of healthcare professionals, its routine implementation has been suggested to be impractical. However, for research and comparison purposes it remains a validated nutrition assessment for the cancer population (Abe Vicente et al., 2013).

Based on the PG-SGA nutrition assessment data obtained in the present study, the majority of participants identified themselves as having low to moderate nutritional concerns. In fact, two-thirds (67.7%) were considered to be well-nourished while the remaining participants (32.3%) were identified as experiencing some degree of nutritional compromise. Therefore, the prevalence of nutrition related issues found in the present study is slightly lower than numbers reported in past studies of individuals with HNCa (Baldwin & Weekes, 2011; Isenring, Bauer & Capra, 2003). This in part may be explained by considering the demographics of our study population. Specifically, the present study assessed individuals who were being treated on an outpatient basis, many of who were approximately a year post-

treatment. Further, many participants in the current cohort received surgery as their sole treatment modality. These factors all contribute to lower nutrition-related concerns. For example, outpatients would be expected to have lower nutritional compromise than those individuals who require hospital admittance as their cancer-related circumstances are likely less severe (Ravera, Bozzetti, Ammatuna, & Radaelli, 1987; Stratton et al., 2004). Additionally, nutrition impact symptoms are expected to decline with time post-treatment as recovery time increases (Isenring et al., 2007). Finally, surgical treatments tend to be associated with a lesser degree of nutritional compromise than other treatment modalities as its effects tend to be more short-term (Van Cutsem & Arends, 2005). These trends may offer a possible explanation for the lower rate of nutritional compromise reported in the present investigation.

However, despite lower rates than expected, nutritional concerns were still found to exist in 32.3% of our population. Knowing the broad impact that compromised nutrition status can have on an individual's treatment outcome and recovery, the finding that one-third of current participants were nutritionally challenged is concerning. This emphasizes the need to consider the nutritional concerns of outpatients both during and following HNCa treatment. It also should be noted that despite the observation of a relatively lower percentage of nutritionally compromised individuals when compared to past reports (Gupta et al., 2011; Shaw et al., 2014; Takenaka et al., 2014), certain individuals did still experience and reported significant nutritional problems. Scores gathered from the PG-SGA assessment ranged from 1 – 17 from a possible range of 0 - 50 (M = 5.6) which suggests that following diagnosis and treatment for HNCa, an individual's nutrition status can vary greatly; further, one's status can be influenced by a variety of factors, the most

common of which was identified by the present study as being “Dry Mouth”, this agrees with past literature (Larsson et al., 2005). Though not all individuals will experience nutritional concerns, it would be irresponsible from a healthcare perspective to disregard those who are experiencing such problems as they may be hindering recovery and functioning (van Leeuwen et al., 1997). Though nutrition assessments have inherent limitations which may prevent routine implementation, it is possible that self-administered nutrition screening tools may overcome these limitations (Cawood et al., 2012). The finding that one third of study participants presented with nutrition related concerns justifies exploration into the ability of nutrition screening tools to be self-administered in an accurate and reliable manner by individuals of the outpatient HNCa population.

Patient Generated – Subjective Global Assessment Short Form (PG-SGA SF)

Though literature exploring the application of the PG-SGA SF is relatively small, there has been a focus on the oncology population. From these studies, the PG-SGA SF has proven to be a reliable tool for assessing the nutrition status of oncology outpatients with fair-to-good sensitivity and specificity (Abbott et al., 2016; Gabrielson et al., 2013). As this tool has proven reliable for a broad cancer population, explorations into its applicability in oncology populations where nutritional concerns tend to be more severe is warranted, such as in the HNCa population. This was assessed through examination of the sensitivity, specificity, and positive and negative predictive values of the PG-SGA SF. Scores obtained on the PG-SGA SF ranged from 0 - 15 (M = 3.85) from a possible range of 0 - 36, results that are comparable to those of the PG-SGA. The most commonly reported symptom on the

PG-SGA SF was “dry mouth”, a finding that is in agreement with the PG-SGA. Overall, the PG-SGA SF identified almost 27% of participants as being nutritionally compromised, a similar rate to that of the PG-SGA. This rate is lower than other prevalence rates reported in literature of between 35-80% (Gupta et al., 2011; Lees, 1999; Takenaka et al., 2014) however, recent studies have reported similar rates using the PG-SGA SF (Jager-Wittenaar & Ottery, 2017). The resultant sensitivity and specificity were 81.8% and 100%, respectively, and the positive and negative predictive values were 100% and 92%, respectively, this again is in agreement with past literature (Jager-Wittenaar & Ottery, 2017). Thus, all values reached or exceeded cut-off points of above 80% for the PG-SGA SF (Azad, et al., 1999). Additionally, averaging 1.82 minutes to complete, the PG-SGA SF was able to be quickly self-completed by participants.

It must be noted, however, that sensitivity, specificity, and negative and positive predictive values were expected to be high as the PG-SGA SF is based on the original PG-SGA (the PG-SGA SF is identical to the first four boxes of the PG-SGA assessment). Ideally, we would hope that any nutritional screen would be able to accurately identify malnutrition when present, while at the same time not requiring additional evaluation for those not experiencing nutritional deficits. As seen throughout this study, however, there were occasions where additional scoring (i.e., the professionally completed portion of the PG-SGA) resulted in several individuals being identified as nutritionally compromised. Thus, the increased efficiency of the PG-SGA SF came at a small expense to its accuracy relative to the PG-SGA assessment. However, as previously stated, all values assessing accuracy and reliability of the PG-SGA SF reached acceptable levels in the present study (Isenring,

Banks, Ferguson, & Bauer, 2012). This warrants further investigation into the use of the PG-SGA SF as a self-administered nutrition screening tool. Doing so could provide the much needed first step in the nutrition care pathway for these outpatients with HNCa. Further, results obtained may provide an efficient and proactive means of identifying HNCa outpatients at nutritional risk. Once risk is identified, those individuals can then receive comprehensive nutritional assessments to further identify problems and potentially lead to intervention.

Pt-Global Application

The Pt-Global Application was designed by Dr. Faith Ottery and her team in an attempt to streamline and increase the efficiency of the nutrition screening process (Ottery et al., 2015). Like the PG-SGA SF, the Pt-Global Application is also based on the original PG-SGA. The Pt-Global Application is identical to the PG-SGA except that it is in an automated format. This enables the Pt-Global Application to be utilized as either a nutrition screening tool (if only patient reported sections are completed) or a nutrition assessment tool (both patient and professional reported sections are completed). Thus, if utilized for screening purposes, it has the potential to be entirely self-completed by patients. The Pt-Global application may increase the efficiency of the nutrition screening process by reducing the time required to complete an accurate nutrition screen as all calculations and output scores are completed by the automated tool. This increased level of efficiency could make the Pt-Global application a practical first step in the nutrition care pathway for outpatients with HNCa. However, at present there is no information on the utility of the Pt-Global Application as a screening tool within the HNCa population. Therefore, one of the

aims of the present investigation was to assess whether the Pt-Global Application could be used as a nutrition screening tool on an outpatient basis for those being treated for HNCa. This was completed by examining the sensitivity and specificity, as well as positive and negative predictive values of the Pt-Global Application.

Pt-Global Application scores obtained ranged from 0 - 13 (M = 3.35) from a possible range of 0 - 36, which are slightly lower than the PG-SGA assessment scores. The most commonly reported nutrition impact symptoms reported on the Pt-Global Application were, “dry mouth” and “lack of appetite”. The finding that “dry mouth” was the most commonly reported nutrition impact symptom agreed with results obtained by the PG-SGA as well as with past literature (Larsson et al., 2005). However, it was reported by fewer individuals on the Pt-Global Application than on either of the PG-SGA SF or PG-SGA. This inconsistency between the Pt-Global Application and both the PG-SGA SF and PG-SGA may illustrate the potential for misreporting when this automated tool is used. Overall, 20.6% of participants were identified using the Pt-Global Application as being nutritionally compromised. This is slightly lower than the rate reported for the PG-SGA SF, which only differs by mode of delivery, and lower than rates reported in the literature (Gupta et al., 2011; Jager-Wittenaar & Ottery, 2017; Lees, 1999; Takenaka et al., 2014). Additionally, the Pt-Global Application took slightly longer to complete, averaging 3.71 minutes. These findings might be partially explained by examining the results obtained from the ease-of-use survey. Our participants reported either no preference between the two screening tools, or preferred the paper-based PG-SGA SF nutrition screen. Those who preferred the paper-based PG-SGA SF may have been uncomfortable or inexperienced with using automated tools such as the Pt-Global Application. Despite

this, sensitivity and specificity values of 63.6% and 100%, respectively, were achieved by the Pt-Global Application as well as a positive and negative predictive values of 100% and 85.2%, respectively. Again, these ratings were expected to be high given that the Pt-Global Application is based on the original PG-SGA. However, like the PG-SGA SF, the Pt-Global Application was also not as precise as the PG-SGA assessment and was unable to replicate its results with 100% accuracy.

The lower scores and decreased accuracy of the Pt-Global Application can have consequences for the treatment of those individuals who were nutritionally borderline regarding their category rating of A, B, or C, or their triaging recommendations output by the tool. The results they received from the Pt-Global Application may not have been as serious/urgent as those provided by the more thorough PG-SGA assessment. That being noted, the Pt-Global Application still managed to achieve acceptable levels of specificity and negative and positive predictive values. These psychometric properties are similar to those reported for other nutrition screening tools (Jager-Wittenaar & Ottery, 2017; Skipper et al., 2012). It is, however, critical to seek a clinical screen that holds the greatest likelihood of identifying nutritional problems when they in fact are present, yet also reduces the likelihood of misidentification. These findings are believed to warrant its potential for use, or at the very least, further investigation into its applicability as a self-administered nutrition screening tool for individuals of the HNCa population being treated on an outpatient basis.

Ease-of-Use Survey

The concluding segments the ease-of-use survey included open-ended questions where participants could provide additional information. The two final questions of the ease-of-use survey addressed any comments/concerns participants had regarding each nutrition screening tool used within the present study. Of the 34 participants, seven provided additional comments which provided an opportunity to better our understanding of the participant's experience with each of the tools.

The majority of participant comments pertained to the difficulty of using the Pt-Global Application without professional assistance. Individuals who are unfamiliar using technology and mobile/computer applications may feel uncomfortable using the Pt-Global Application. This could potentially lead to misreporting of the information required by the Pt-Global nutrition screen, which then could result in errors in the final nutrition scores and triaging recommendations. This concern was consistent with the data collected within the present investigation. Mean scores for all ease-of-use survey questions were higher for the PG-SGA SF when compared to the corresponding questions for the Pt-Global Application. This indicates that participants were in higher agreement for the statements when they referred to the PG-SGA SF. This suggests that participants felt that the PG-SGA SF paper-based nutrition screening form was easier to use.

It is not surprising that a generation which is unfamiliar and less comfortable with these types of electronic applications might experience difficulties attempting to utilize them in clinical and research settings. As time progresses and the generations which grew up using these applications age and begin forming the HNCa population

it is possible that the Pt-Global Application may gain favour over a paper-based format. However, efforts that assess differences in screening tool preference between younger and older demographic groups is needed to determine whether this assumption is valid.

Results of the EORTC QLQ-C30

The responses provided by study participants to questions of the EORTC indicated that the experience of an individual being treated on an outpatient basis for HNCa can vary greatly. Though some individuals did not report experiencing any symptoms, the majority reported experiencing at least a few of the concerns addressed by the EORTC QLQ-C30. Some participants (n = 21) experienced no or minimal impact to their QOL (a sum score of 42 or less on the first 28 questions of the QLQ-C30), while six experienced a moderate-to-large impact on QOL (a sum score of 56 or greater). The most commonly reported items were Question 10 “Did you need rest?”, Question 18 “Were you tired?”, and Question 22 “Did you worry?” with 22, 25, and 22, participants, respectively, noting concerns. This also was a common concern of individuals with HNCa reported in a study by Capra et al. (2001). However, for symptoms reported to be experienced “Very much” within the present investigation, there was wide variation. Participants reported a symptom as “Very much” a concern 34 times, with 19 different items on the QLQ-C30 being selected at least once. The individualized nature of how nutritional status is influenced over the course of HNCa therapy has been outlined in various other studies utilizing hospitalized patients (Arends et al., 2016; Capra et al., 2001; Larsson et al., 2005). This variability also being present in outpatient makes it difficult to identify which

areas one should target to improve the QOL of this population. The best approach seems to be to individualize therapies to identify and address those factors having the greatest negative influence on QOL.

What became apparent once nutrition status was brought into consideration was that the majority of symptoms reported as “Very much” a concern had been reported by nutritionally compromised individuals (28 of the 34). Furthermore, whenever a significant difference was observed between the means of reported items it was the nutritionally compromised group which presented with the greater QOL concern. A similar trend was observed when participants rated their personal health and Global QOL status. The nutritionally compromised individuals continued to indicate lower mean scores for these domains. This suggests that a correlation existed between nutrition status and a worse perceived personal health and Global QOL status in the present investigation, a finding that agrees with past reports (Silander, Nyman & Hammerlid, 2013). However, as this is a correlational assessment it is difficult to determine if nutrition status is what is causing lower perceptions of health and Global QOL, or vice versa. Further research is needed in order to investigate the direction of this correlation.

Another interesting finding was that a similar pattern became apparent when the participant functional domain scores were observed. That is, for every functional domain assessed by the QLQ-C30, the mean scores of the nutritionally compromised group were lower, with the “Physical”, “Social”, and “Cognitive” domains all reaching significance. The finding that functionality is increasingly impaired with declining nutrition status agrees with past studies (Farhangfar et al., 2014; Kubrak et al., 2013).

Overall, when comparing perceived personal “functional status” in the present investigation, those comprising the nutritionally compromised group judged their functioning to be worse. This pattern held true for all the symptom domains as well, with one exception (diarrhea) which was not significant. The nutritionally compromised individuals indicated that they were experiencing these symptoms to a higher degree with “fatigue”, “appetite loss”, and “constipation” reaching significance. This finding that greater symptom burden was associated with greater nutritional concerns also agrees with past literature (Capuano et al., 2010; Farhangfar et al., 2014; List et al., 1997; Reeve et al., 2016). The cumulative effects of a greater symptom burden and lower perceived functional status may offer a partial explanation for the lower Global QOL domain scores reported by the nutritionally compromised individuals in the present study. Overall, the data suggest that nutrition status of HNCa outpatients is associated with their functionality, symptom burden, and perceived health and Global QOL. This illustrates the importance of nutrition care practices such as screening.

Results of the EORTC QLQ-H&N35

The EORTC QLQ-H&N35 module was designed specifically for individuals with HNCa. As was the case with the EORTC QLQ-C30, though the majority of participants reported experiencing a subset of the symptoms, individual experiences varied. Some participants (n = 19) experienced none or minimal impact to their QOL (determined by a sum score of 52 or less), while a few others (n = 7) experienced a moderate-to-large impact on QOL (a score of ≥ 70). The most commonly reported symptoms on the H&N35 were Question 15 “Have you coughed?” and Question 11 “Did you have a

dry mouth?" (n= 21 and 20, respectively). Additionally, the symptom which was most commonly reported as "Very much" a concern was Question 7 "Have you had trouble swallowing solid food?" (n=5). The high prevalence of dry mouth and swallowing problems reported in the present cohort agrees with past literature on others with HNCa (Chasen & Bhargava, 2009; Larsson et al., 2005). These observations highlight the need for the implementation of routine nutrition screening practices as it is clear that these nutrition symptoms are present in those treated for HNCa. Furthermore, various differences were once again observed between the mean scores of individual items reported by the nutritionally compromised and well-nourished groups. In every instance a significant difference was observed it was the nutritionally compromised who had reported the greater QOL concern. This suggests that those who were nutritionally compromised at the time of the study also reported greater QOL impacts based on the QLQ-H&N35, a finding supported by past literature (Silander et al., 2013). Thus, efforts which aim to address the nutrition related concerns of individuals with HNCa through nutrition screening could identify and address these issues which may result in appreciable benefits for health and QOL.

EORTC QLQ-H&N35 domain scores produced similar results to those of the QLQ-C30 in regards to the differences between the well-nourished and nutritionally compromised groups. The nutritionally compromised group reported greater QOL concerns for all symptom domains with exception of "Pain", "Nutritional supplementation" and "Weight gain" none of which reached significance. To explain these findings, it could be assumed that nutritional supplements would help individuals remain well-nourished and thus retain, or possibly even gain, weight. Despite debate, the benefit of nutritional supplementation, has positively influenced

weight retention in individuals with cancer (Baldwin & Weekes, 2012). Additionally, the experience of pain was possibly a greater concern for the well-nourished group because the use of pain-killers was much more common among the nutritionally compromised group. Domains reaching significance included “senses” and “speech problems”, “teeth”, and “dry mouth”. These significant findings for our outpatient cohort agree with past findings regarding the common concerns of hospitalized patients with HNCa (Alshadwi et al., 2013; Chasen & Bhargava, 2009; Hayward & Shea, 2009; Larsson et al., 2005). Overall, for the majority of these QOL symptoms, the nutritionally compromised group perceived that they were experiencing them to a greater extent. This again warrants efforts targeting the nutritional concerns of outpatients treated for HNCa as doing so could mitigate their effects and result in QOL improvements.

In summary, data obtained from the QLQ-C30 and H&N35 demonstrate that a significant variability exists among individuals with HNCa in regard to their perception of nutrition status, functionality and QOL. Possibly the most important finding for the present study was the differences identified between the well-nourished and nutritionally compromised groups. These results suggest that there is an association between the incidence of a poor nutrition status and the experience of a worse functionality and QOL for outpatients with HNCa.

Consistency of Responses

The present data illustrate a correlation between participant’s responses for the QOL, nutrition measures, and functional and symptom domain scores. When individuals reported a lower perceived QOL, they also tended to present with poorer

nutrition scores and worse functional and symptom domain scores. This suggests that those participants who were experiencing greater nutrition related concerns also tended to experience a greater symptom burden, worse functionality and a lower perceived health and Global QOL status.

Correlational Analysis

The domains selected for the correlational analysis were those which were thought to, or have proven in the past to, retain a potential to influence nutrition status (Farhangfar et al., 2014; Kubrak et al., 2010). This resulted in the inclusion of Global QOL scores, the five functional domain scores, and 12 of the 27 “symptom” domain scores from each of the EORTC QLQ-C30 and H&N35 in addition to the nutrition scores recorded by the PG-SGA nutrition assessment. This correlational analysis revealed a number of moderate positive and negative relationships which are remarkable. First, a moderate inverse relationship was found between the Global QOL domain and the nutrition scores obtained from the PG-SGA nutrition assessment. This suggests that with higher nutrition related concerns QOL decreases (Silander et al., 2013). This illustrates that, at least in part, QOL is influenced negatively by a declining nutritional status.

Next, moderate relationships were also discovered to exist among the PG-SGA nutrition scores, Global QOL and the physical, cognitive and social functioning domain scores. The presence of these relationships suggests that as nutritional status worsens, functional ability may decline (Farhangfar et al., 2014; Kubrak et al., 2013). This is a logical conclusion given that a declining nutrition status may decrease one’s social functioning as they no longer desire to eat with friends and family (Penner,

2009). Worse nutrition status also has the potential to result in increased tiredness which can negatively influence physical and cognitive functioning (Capuano et al., 2010; Ma et al., 2013). Conversely, the reverse could also be true and a reduced functional status could be resulting in a declining nutrition status. Despite the precipitating factor being difficult to identify, it is evident that many interrelated factors are influencing the nutrition status, functionality, and Global QOL of individuals with HNCa.

Next, when evaluating the correlations present between the PG-SGA assessment scores and the individual symptom scores of the EORTC QLQ-C30 and H&N35 various moderate associations were identified. The symptoms identified as being most strongly correlated with PG-SGA scores were “Senses problems”, $r(32) = 0.6, p < 0.01$, “Appetite loss”, $r(32) = 0.58, p < 0.01$, and “Constipation”, $r(32) = 0.56, p < 0.01$. These three symptom domains also had moderate-to-strong correlations with Global QOL and subsets of the functional domains. This suggest that as individuals experience these symptoms to a higher degree, it becomes more likely that their nutritional status will decline along with their perception of their Global QOL and functionality (). These findings are not unexpected, individuals with cancer commonly experience these types of symptoms which can influence QOL (Capuano et al., 2010; Farhangfar et al., 2014; Gorenc et al., 2015; List et al., 1997; McQuestion, 2006; Reeve et al., 2016). Efforts attempting to identify and address these types of short- and long-term nutritional concerns could result in improvements for nutrition status, functionality, and the perceived health and QOL of individuals with HNCa.

Supplemental Observational Analysis

Multiple relationships present within this investigation may offer useful insights into how the nutrition status of outpatient individuals with HNCa may be influenced. However, it must be noted that the experiences of individuals within the present study varied significantly. Thus, supplemental analyses of the data were completed in order to consider further influences on participant nutrition status.

First a visual examination of potential trends related to treatment modality were considered. As HNCa can occur at a variety of different sites and stages, the treatment options also vary. T-tests were performed to assess the data across the different treatment modality categories which suggested that individuals who had received surgery alone retained a better nutrition status ($t(33)=2.75, p<0.01$), as well as a better Global QOL ($t(33)=3.95, p<0.001$). An assessment of time-post treatment revealed no significant relationships with treatment type, nutrition, or QOL scores, a finding which diverges from past studies (Tong et al., 2009). Thus, time-post treatment did not provide an explanation for these observed trends in the present study, suggesting that treatment modality influenced both nutrition status and QOL. This is not an unexpected finding as it has been reported in past studies that surgery tends to have less severe impacts on nutrition than alternative treatment modalities (Arends et al., 2016; Van Cutsem & Arends, 2005).

Next, the influence of smoking status on nutrition status was explored as tobacco consumption is known to influence appetite (Alshadwi et al., 2013). Statistical analysis revealed the mean nutrition scores of non-smokers and the combined group of current and past smokers differed significantly ($t(33)=2.58$,

$p < 0.05$). Non-smokers presented with lower nutritional concerns, a finding which agrees with past literature (Haghjoo, 2015). It was interesting however, that former smokers presented with higher nutrition scores than current tobacco users. This finding is possibly related to the former smoker's tendency to have longer histories of tobacco use which may result in greater, long-lasting, nutritional compromise.

Finally, the influence of age on nutrition status was examined as nutrition-related concerns tend to become more common as one ages (Stratton & Elia, 2005). Data in the present investigation supported this, illustrating that nutritional concerns increased with age, $r(32) = 0.48$, $p < 0.01$. However, the correlation between age and QOL scores was insignificant. This suggests that despite increasing nutrition-related complications with age, individual participants were not necessarily perceiving corresponding declines in their QOL with age. Thus, perceived QOL may not be a strong indication of nutritional concerns. This justifies the implementation of routine nutrition screening in order to identify and proactively manage the nutritional concerns of individuals with HNCa, mitigating their negative effects.

Summary

The results of this preliminary study suggest that PG-SGA SF and Pt-Global Application can serve as self-administered nutrition screens. Both instruments could potentially be utilized as effective first steps in the nutrition care pathway for outpatients with HNCa. Thus, both tools deserve to be investigated further regarding their ability to be administered on a routine basis in healthcare settings. Currently, the PG-SGA SF is preferred over the Pt-Global Application by the outpatient HNCa population. This however, could change as comfort levels utilizing electronic

applications increase. The findings from the present investigation also illustrated that nutrition status is indeed influenced by HNCa and its treatment on an individualized basis. These impacts on nutrition status can have significant corresponding impacts on individual Global QOL. Further, a worse nutrition status was found to be associated with a lower perceived functional ability, as well as an increased symptom burden. Finally, the data also suggest that nutrition status may be influenced by factors such as treatment modality, smoking status, and age. These findings illustrate the importance of nutrition care practices from a QOL perspective and provide justification for the implementation of routine nutrition screening in the outpatient HNCa population.

Clinical implications

The frequent failure to recognize and treat malnutrition in populations where it is a common concern, such as for those with HNCa, has been stated as being unacceptable (Elia et al., 2005). Early identification of malnutrition in those treated for HNCa would enable early intervention and present a tremendous opportunity to reduce weight loss, healthcare costs, treatment complications, hospital readmissions, mortality and morbidity rates, improve performance status, clinical outcomes, overall care and QOL (Capuano et al., 2010; Isenring et al., 2004; Tappenden et al., 2013). However, for these benefits to become a reality, nutrition status must be regularly assessed and the appropriate interventions must be provided. Proactive approaches to nutrition management tend to be more successful than approaches delayed until later stages of excessive weight loss (Baldwin & Weekes, 2012; Isenring et al., 2007;

Langius et al., 2016; Ravasco et al., 2008;). Until nutritional evaluations become routine, proactive solutions addressing nutritional concerns will likely remain evasive.

In the present study the PG-SGA SF achieved acceptable levels of accuracy and reliability, supporting its potential to be used as a nutrition screening tool in the HNCa outpatient population. The Pt-Global Application did achieve acceptable levels of specificity, however, more work must be done to improve the sensitivity of the tool or comfort levels using electronic applications must increase if this nutrition screening tool is to be used effectively. If these changes occur, the Pt-Global Application could potentially streamline the nutrition screening process.

Thus, either of the current PG-SGA SF or an improved version of the Pt-Global Application, if proven reliable, could be implemented in clinical practice.

Implementation of these nutrition screens may enable the efficient and accurate identification of those at nutritional risk who may require further comprehensive nutrition assessments. Similarly, findings from such screening may also serve to reduce unnecessary referrals. This would yield many benefits such as increased efficiency, timely access to information, safety, improved healthcare as well as significantly reduce healthcare expenses (David et al., 2013). Additionally, as the PG-SGA SF and Pt-Global Application can be utilized as self-administered measurements, they overcome many challenges and limitations associated with current screening tools such as limited time and financial resources (Abbott et al., 2014; Santarpia et al., 2011).

Overall, the findings of the present study indicate that self-administered nutrition screens are viable options for addressing the nutrition related concerns of

HNCa outpatients. Thus, the use of screening to identify nutrition concerns appears justified and investigations into the implementation of efficient screening tools has been suggested (Cawood et al., 2012; Kondrup et al., 2003). As nutrition concerns are common and costly side-effects of HNCa treatment which take significant time to address, screening and addressing them proactively could reduce costs spent addressing them at later stages of treatment (Abizanda et al., 2016; Baracos, 2006; Prevost et al., 2014). Thus, nutrition screening may yield benefits for individual health and QOL as well as the healthcare system.

Limitations of Present Study

Certain limitations exist relative to the present study. The first is sample size. Given the relatively limited number of participants, casual conclusions cannot be made regarding the changes to nutrition status following a diagnosis and treatment for HNCa. Additionally, only a single recruitment site was utilized in the present study, a surgical clinic. Thus, results cannot be generalized to participants diagnosed and treated at different locations as the patient population, the type of treatment services and the quality of those provided services may differ at a separate location. Also, as participants in this study performed self-assessments on both the nutrition screens and the QOL instruments, it is possible that participant bias was present in how they perceived and reported their health, QOL and nutrition status. Recall bias is always a concern when participants are asked to report on past behaviours. Finally, data were only collected from participants who were between three months post-diagnosis to two years post-treatment. Thus, it is possible that the data does not

capture the full experience of individuals with HNCa given the variability of treatment side-effects and potential longer-term issues.

The demographic variability of the study population presents a further limitation. Participants varied across demographic variables and various subgroups of patients existed, each characterized by their own unique variability. Such variability prevents generalized claims from being made due to the mediating or moderating factors accompanying each of these unique circumstances. This limitation could be addressed by increasing the number of participants and identifying homogenous subgroups. The increased homogeneity would enable more accurate assessments of factors influencing the nutrition status of outpatient individuals with HNCa by minimizing the effects of mediating and moderating factors. Determining how these factors influence the nutrition of individuals with HNCa may provide insights for future investigations on self-administered nutrition screens.

Directions for Future Research

Though the absence of a universal definition for malnutrition in the HNCa population from which nutrition evaluations and interventions can be based remains an issue, this should not discourage future efforts that seek to address nutritional concerns (Cushen et al., 2015). This study provided a strong justification for the routine use of nutrition screening tools in the healthcare system. It has provided a starting point for research that seeks to assess how instruments such as the PG-SGA SF and Pt-Global Application might be used over the course of the diagnosis, treatment, and follow-up. Though, the topic of nutrition status in oncology is gaining increasing recognition, limited information exists on the use self-administered

nutrition screens in the area of HNCA and the majority of work currently completed focuses on hospitalized individuals. Continued research into how these types of instruments might be used in clinical settings is important (Cawood et al., 2012; Kondrup et al., 2003). The efficient implementation of such tools could help mitigate the consequences associated with the treatment of HNCA, decrease post-treatment complications, optimize rehabilitation efforts, and reduce the workloads of healthcare professionals (Cawood et al., 2012; David et al., 2013).

Future research might assess the impact of altering threshold scores of the self-administered nutrition screens used in this study in order to increase their accuracy ratings. Additional research might also be performed assessing the ability of the Pt-Global Application as a self-administered nutrition screen to be completed over the internet as this tool is application based. Examinations into the compliance of individuals to complete the Pt-Global Application online and the reliability of these screens could therefore be targeted in future studies.

Though it is unlikely that the nutritional concerns associated with HNCA treatment can be completely eliminated, understanding which factors have the greatest influence on nutrition status and how an impaired nutrition status influences functionality may provide valuable information moving forward. This information may guide targeted therapies for nutritional concerns, resulting in reductions in healthcare expenses as well as QOL and health status improvements.

Overall, the primary goal of continuing research into self-administered nutrition screening tools in the HNCA population is to find an instrument which achieves acceptable rates of sensitivity and specificity in order to justify its routine

implementation. Such a tool would enable proactive identification of nutritional concerns while also transferring the responsibility of completing these screens from busy healthcare professionals to the individual (Cawood et al., 2012; David et al., 2013).

Conclusions

Though treatments for individuals diagnosed with cancers continue to improve, these individuals still face an array of treatment-related consequences. Decreases in functional abilities and QOL are among some of the most common outcomes associated with cancer treatments (Ma et al., 2013; Sherman et al., 2000). Treatment for HNCa is no exception. Though treatment methods vary due to the heterogeneity of this cancer, they often retain the potential to have psychosocial and physical impacts on the individuals being treated (Penner, 2009). These impacts can result in a diminishing nutrition status for individuals diagnosed and treated for HNCa and this was supported by the findings of this initial study. The data collected suggest that compromised nutrition status remains a common concern for those treated for HNCa. Further, the findings of the present study agree with past literature that nutrition status can be influenced by many variables such as treatment modality (Van Cutsem & Arends, 2005), smoking status (Hall et al., 2000; Reeve et al., 2016), and age (Stratton & Elia, 2005).

The findings of the present investigation suggest that nutrition screening could help to proactively identify nutritional concerns of outpatients with HNCa. As healthcare professionals are already experiencing heavy workloads, measurements which can effectively and reliably be utilized for self-screening are desirable and have

been called for (Cawood et al., 2012). The findings from this study support this method of self-screening nutrition status as a viable option with paper-based screening tools currently being the preferred mode of delivery. Given that diminished nutrition status is associated with an array of negative implications for treatment outcomes and the rehabilitation process, the use of self-administered nutrition screening tools, such as the PG-SGA SF and the Pt-Global Application may provide a cost-effective solution. Such instruments would proactively identify nutrition-related concerns while also lessening the burden experienced by healthcare professionals. This could yield benefits for the health and QOL of HNCa outpatients (Capuano et al., 2010; Isenring et al., 2004; Tappenden et al., 2013). Thus, continued efforts exploring these crucial concepts are warranted due to the potential for both short- and long-term improvements in patient care, treatment outcomes, and QOL.

REFERENCES

- Aaronson, N. K., Ahmedzai, S., Bergman, B., Bullinger, M., Cull, A., Duez, N. J., . . . Takeda, F. (1993). The European Organisation for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. *Journal of the National Cancer Institute*, 85, 365-376.
- Abbott, J., Teleni, L., McKavanagh, D., Watson, J., McCarthy, A., & Isenring, E. (2014). A novel, automated nutrition screening system as a predictor of nutritional risk in an oncology day treatment unit (ODTU). *Supportive Care in Cancer*, 22(8), 2107-2112. doi:10.1007/s00520-014-2210-7
- Abbott, J., Teleni, L., McKavanagh, D., Watson, J., McCarthy, A. L., & Isenring, E. (2016). Patient-Generated Subjective Global Assessment Short Form (PG-SGASF) is a valid screening tool in chemotherapy outpatients. *Supportive Care in Cancer*, 1-5.
- Abe Vicente, M., Barão, K., Silva, T. D., & Forones, N. M. (2013). What are the most effective methods for assessment of nutritional status in outpatients with gastric and colorectal cancer? *Nutrición Hospitalaria*, 28(3), 585-591. doi: 10.3305/nh.2013.28.3.6413
- Abizanda, P., Sinclair, A., Barcons, N., Lizán, L., & Rodríguez-Mañas, L. (2016). Costs of malnutrition in institutionalized and community-dwelling older adults: A systematic review. *Journal of the American Medical Directors Association*, 17(1), 17-23. doi: 10.1016/j.jamda.2015.07.005
- Alshadwi, A., Nadershah, M., Carlson, E. R., Young, L. S., Burke, P. A., & Daley, B. J. (2013). Nutritional considerations for head and neck cancer patients: a review of the literature. *Journal of Oral and Maxillofacial Surgery*, 71(11), 1853-1860.
- Álvarez-Camacho, M., Gonella, S., Ghosh, S., Kubrak, C., Scrimger, R. A., Chu, K. P., & Wismer, W. V. (2016). The impact of taste and smell alterations on quality of life in head and neck cancer patients. *Quality of Life Research*, 25(6), 1495-1504. doi: 10.1007/s11136-015-1185-2
- Álvarez-Camacho, M., Martínez-Michel, L., Gonella, S., Scrimger, R. A., Chu, K. P., & Wismer, W. V. (2016). Physical symptom burden of post-treatment head and neck cancer patients influences their characterization of food: Findings of a repertory grid study. *European Journal of Oncology Nursing*, 22, 54-62. doi: 10.1016/j.ejon.2016.03.008
- Ambrus, J. L., Ambrus, C. M., Mink, I. B., Picken, J. W. (1975). Causes of death in cancer patients. *J Med Clin Exp Theoret*. 6:61.
- Arends, J., Bachmann, P., Baracos, V., Barthelemy, N., Bertz, H., Bozzetti, F., . . . Preiser, J. (2016). ESPEN guidelines on nutrition in cancer patients. *Clinical Nutrition*. doi: 10.1016/j.clnu.2016.07.015

- Arends, J., Bodoky, G., Bozzetti, F., Fearon, K., Muscaritoli, M., Selga, G., . . . ESPEN (European Society for Parenteral and Enteral Nutrition). (2006). ESPEN guidelines on enteral nutrition: Non-surgical oncology. *Clinical Nutrition, 25*(2), 245-259. doi: 10.1016/j.clnu.2006.01.020
- Atkins, M., Basualdo-Hammond, C., Hotson, B., & Dietitians of Canada. (2010). Canadian perspectives on the nutrition care process and international dietetics and nutrition terminology. *Canadian Journal of Dietetic Practice and Research: A Publication of Dietitians of Canada, 71*(2), e18.
- Azad, N., Murphy, J., Amos, S. S., & Toppan, J. (1999). Nutrition survey in an elderly population following admission to a tertiary care hospital. *Canadian Medical Association Journal, 161*(5), 511-515.
- Baldwin, C., & Weekes, C. E. (2011). Dietary advice for illness-related malnutrition in adults. *The Cochrane Database of Systematic Reviews, 1*(1), CD002011.
- Baldwin, C., & Weekes, C. E. (2012). Dietary counselling with or without oral nutritional supplements in the management of malnourished patients: A systematic review and meta-analysis of randomised controlled trials. *Journal of Human Nutrition and Dietetics, 25*(5), 411-426. doi: 10.1111/j.1365-277X.2012.01264.x
- Barac-Nieto, M., Spurr, G. B., Lotero, H., & Maksud, M. G. (1978). Body composition in chronic undernutrition. *The American Journal of Clinical Nutrition, 31*(1), 23.
- Baracos, V. E. (2006). Cancer-associated cachexia and underlying biological mechanisms. *Annu. Rev. Nutr., 26*, 435-461.
- Barents Group of KPMG Peat Marwick LLP. (1996). The clinical and cost- effectiveness of medical nutrition therapies: evidence and estimates of potential Medicare savings from the use of selected nutrition intervention. *Summary report prepared for the Nutrition Screening Initiative.*
- Barrios, R., Tsakos, G., García-Medina, B., Martínez-Lara, I., & Bravo, M. (2014). Oral health-related quality of life and malnutrition in patients treated for oral cancer. *Supportive Care in Cancer, 22*(11), 2927-2933.
- Barker, L. A., Gout, B. S., & Crowe, T. C. (2011). Hospital malnutrition: Prevalence, identification and impact on patients and the healthcare system. *International Journal of Environmental Research and Public Health, 8*(2), 514-527. doi: 10.3390/ijerph8020514
- Bauer, J., & Capra, S. (2003). Comparison of a malnutrition screening tool with subjective global assessment in hospitalised patients with cancer-sensitivity and specificity. *Asia Pacific journal of clinical nutrition, 12*(3), 257-260.
- Bauer, J., Capra, S., & Ferguson, M. (2002). Use of the scored patient-generated subjective global assessment (PG-SGA) as a nutrition assessment tool in

- patients with cancer. *European Journal of Clinical Nutrition*, 56(8), 779-785. doi: 10.1038/sj.ejcn.1601412
- Beck, A. K., Baker, A., Britton, B., Wratten, C., Bauer, J., Wolfenden, L., & Carter, G. (2015). Fidelity considerations in translational research: Eating as treatment - a stepped wedge, randomised controlled trial of a dietitian delivered behaviour change counselling intervention for head and neck cancer patients undergoing radiotherapy. *Trials*, 16(1), 465. doi: 10.1186/s13063-015-0978-5
- Bector, S., Vagianos, K., Suh, M., & Duerksen, D. R. (2016). Does the Subjective Global Assessment predict outcome in critically ill medical patients? *Journal of intensive care medicine*, 31(7), 485-489.
- Bjordal, K., & Kaasa, S. (1992). Psychometric validation of the EORTC core QOL questionnaire, 30-item version and a diagnosis-specific module for head and neck cancer patients. *Acta Oncologica*, 31, 311-321.
- Bloch, A. (2000). Nutrition support in cancer. *Seminars in Oncology Nursing*, 16(2), 122-127. doi: 10.1053/on.2000.5555
- Boléo-Tomé, C., Monteiro-Grillo, I., Camilo, M., & Ravasco, P. (2012). Validation of the malnutrition universal screening tool (MUST) in cancer. *British Journal of Nutrition*, 108(02), 343-348.
- Bozzetti, F. (2009). Screening the nutritional status in oncology: A preliminary report on 1,000 outpatients. *Supportive Care in Cancer*, 17(3), 279-284. doi: 10.1007/s00520-008-0476-3
- Britton, B., Baker, A., Clover, K., McElduff, P., Wratten, C., & Carter, G. (2016). Heads up: A pilot trial of a psychological intervention to improve nutrition in head and neck cancer patients undergoing radiotherapy. *European Journal of Cancer Care*, doi: 10.1111/ecc.12502
- Brown, T., Findlay, M., Dincklage, J., Davidson, W., Hill, J., Isenring, E., . . . Bauer, J. (2013). Using a wiki platform to promote guidelines internationally and maintain their currency: Evidence-based guidelines for the nutritional management of adult patients with head and neck cancer. *Journal of Human Nutrition and Dietetics*, 26(2), 182-190. doi: 10.1111/jhn.12036
- Butterworth, C. E. (1974). The skeleton in the hospital closet. *Nutrition Today*, 50(2), 98-102.
- Capra, S., Ferguson, M., & Ried, K. (2001). Cancer: Impact of nutrition intervention outcome—nutrition issues for patients. *Nutrition*, 17(9), 769-772. doi: 10.1016/S0899-9007(01)00632-3
- Capuano, G., Gentile, P. C., Bianciardi, F., Tosti, M., Palladino, A., & Di Palma, M. (2010). Prevalence and influence of malnutrition on quality of life and performance status in patients with locally advanced head and neck cancer before treatment. *Supportive care in cancer*, 18(4), 433-437.

- Capuano, G., Grosso, A., Gentile, P. C., Battista, M., Bianciardi, F., Di Palma, A., ... & Coiro, G. (2008). Influence of weight loss on outcomes in patients with head and neck cancer undergoing concomitant chemoradiotherapy. *Head & neck*, *30*(4), 503-508.
- Cawood, A. L., Elia, M., Sharp, S. K., & Stratton, R. J. (2012). Malnutrition self-screening by using MUST in hospital outpatients: validity, reliability, and ease of use. *The American journal of clinical nutrition*, *96*(5), 1000-1007.
- Cayne, B. S., & Bolander, D. O. (Eds.). (1991). *New Webster's dictionary and thesaurus of the English language*. Lexicon Publications.
- Centers for Medicare & Medicaid Services (CMS), HHS. (2003). Medicare and medicaid programs; hospital conditions of participation: Quality assessment and performance improvement. final rule. *Federal Register*, *68*(16), 3435.
- Chasen, M. R., & Bhargava, R. (2009). A descriptive review of the factors contributing to nutritional compromise in patients with head and neck cancer. *Supportive care in cancer*, *17*(11), 1345-1351.
- Chen, S., Tsai, M., Liu, C., Yu, W., Liao, C., & Chang, J. T. (2009). Support needs of patients with oral cancer and burden to their family caregivers. *Cancer Nursing*, *32*(6), 473-481. doi:10.1097/NCC.0b013e3181b14e94
- Correia, M. I. T., & Waitzberg, D. L. (2003). The impact of malnutrition on morbidity, mortality, length of hospital stay and costs evaluated through a multivariate model analysis. *Clinical nutrition*, *22*(3), 235-239.
- Couch, M. E., Dittus, K., Toth, M. J., Willis, M. S., Guttridge, D. C., George, J. R., . . . Eisele, D. W. (2015). Cancer cachexia update in head and neck cancer: Definitions and diagnostic features. *Head & Neck*, *37*(4), 594-604. doi:10.1002/hed.23599
- Coughlin, S. S. (1990). Recall bias in epidemiologic studies. *Journal of clinical epidemiology*, *43*(1), 87-91.
- Cushen, S. J., Power, D. G., & Ryan, A. M. (2015). Nutrition assessment in oncology. *Topics in Clinical Nutrition*, *30*(1), 103-119.
- David, G., Bernstein, L. H., & Coifman, R. R. (2013). The automated malnutrition assessment. *Nutrition (Burbank, Los Angeles County, Calif.)*, *29*(1), 113-121. doi: 10.1016/j.nut.2012.04.017
- Davies, M. (2005). Nutritional screening and assessment in cancer-associated malnutrition. *European Journal of Oncology Nursing*, *9*, S64-S73.
- Dawson, P., Taylor, A., & Bragg, C. (2015). Exploration of risk factors for weight loss in head and neck cancer patients. *Journal of Radiotherapy in Practice*, *14*(04), 343-352.

- DeCicco, P. V., Wunderlich, S. M., & Emmolo, J. S. (2011). Determination of malnourishment in the head and neck cancer patient: assessment tools and nutrition education of radiation oncologists. *Supportive Care in Cancer, 19*(1), 123-130.
- Dechaphunkul, T., Martin, L., Alberda, C., Olson, K., Baracos, V., & Gramlich, L. (2013). Malnutrition assessment in patients with cancers of the head and neck: a call to action and consensus. *Critical reviews in oncology/hematology, 88*(2), 459-476.
- Der-Torossian, H., Gourin, C. G., & Couch, M. E. (2012). Translational implications of novel findings in cancer cachexia: The use of metabolomics and the potential of cardiac malfunction. *Current Opinion in Supportive and Palliative Care, 6*(4), 446-450. doi: 10.1097/SPC.0b013e328359b695
- Doyle, P.C. and Keith, R.C. (Eds.) (2005). Contemporary Considerations in the Treatment and Rehabilitation of Head and Neck Cancer: Voice, Speech, and Swallowing. Austin, TX: Pro-Ed Publishers.
- Ehrsson, Y. T., Langius-Eklöf, A., & Laurell, G. (2011). Nutritional surveillance and weight loss in head and neck cancer patients. *Supportive Care in Cancer, 20*(4), 757-765. doi: 10.1007/s00520-011-1146-4
- Eisbruch, A., Lyden, T., Bradford, C. R., Dawson, L. A., Haxer, M. J., Miller, A. E., ... & Wolf, G. T. (2002). Objective assessment of swallowing dysfunction and aspiration after radiation concurrent with chemotherapy for head-and-neck cancer. *International Journal of Radiation Oncology* Biology* Physics, 53*(1), 23-28.
- Elia, M., Zellipour, L., & Stratton, R. J. (2005). To screen or not to screen for adult malnutrition? *Clinical Nutrition, 24*(6), 867-884. doi:10.1016/j.clnu.2005.03.004
- Farhangfar, A., Makarewicz, M., Ghosh, S., Jha, N., Scrimger, R., Gramlich, L., & Baracos, V. (2014). Nutrition impact symptoms in a population cohort of head and neck cancer patients: multivariate regression analysis of symptoms on oral intake, weight loss and survival. *Oral oncology, 50*(9), 877-883.
- Farnebo, L., Malila, N., Mäkitie, A., Laurell, G. (2016). Early death among head and neck cancer patients. *Current Opinion in Otolaryngology & Head and Neck Surgery, 24*(2), 115-120. doi: 10.1097/MOO.0000000000000236
- Fearon, K. C., Voss, A. C., Hustead, D. S., & Cancer Cachexia Study Group. (2006). Definition of cancer cachexia: Effect of weight loss, reduced food intake, and systemic inflammation on functional status and prognosis. *The American Journal of Clinical Nutrition, 83*(6), 1345.
- Ferguson, M., Capra, S., Bauer, J., & Banks, M. (1999). Development of a valid and reliable malnutrition screening tool for adult acute hospital patients. *Nutrition, 15*(6), 458-464. doi: 10.1016/S0899-9007(99)00084-2

- Ferlay, J., Soerjomataram, I., Dikshit, R., Eser, S., Mathers, C., Rebelo, M., . . . Bray, F. (2015). Cancer incidence and mortality worldwide: Sources, methods and major patterns in GLOBOCAN 2012. *International Journal of Cancer*, *136*(5), E359-E386. doi: 10.1002/ijc.29210
- Gabrielson, D. K., Scaffidi, D., Leung, E., Stoyanoff, L., Robinson, J., Nisenbaum, R., . . . Darling, P. B. (2013). Use of an abridged scored patient-generated subjective global assessment (abPG-SGA) as a nutritional screening tool for cancer patients in an outpatient setting. *Nutrition and Cancer*, *65*(2), 234.
- Ganzer, H., Rothpletz-Puglia, P., Byham-Gray, L., Murphy, B. A., & Touger-Decker, R. (2015). The eating experience in long-term survivors of head and neck cancer: a mixed-methods study. *Supportive Care in Cancer*, *23*(11), 3257-3268.
- Giner, M., Laviano, A., Meguid, M. M., & Gleason, J. R. (1996). In 1995 a correlation between malnutrition and poor outcome in critically ill patients still exists. *Nutrition*, *12*(1), 23-29. doi:10.1016/0899-9007(95)00015-1
- Gorenc, M., Kozjek, N. R., & Strojan, P. (2015). Malnutrition and cachexia in patients with head and neck cancer treated with (chemo) radiotherapy. *Reports of Practical Oncology & Radiotherapy*, *20*(4), 249-258.
- Grant, M., & Kravits, K. (2000). Symptoms and their impact on nutrition. *Seminars in Oncology Nursing*, *16*(2), 113-121.
- Green, S. M., & Watson, R. (2005). Nutritional screening and assessment tools for use by nurses: literature review. *Journal of advanced nursing*, *50*(1), 69-83.
- Gupta, D., Vashi, P. G., Lammersfeld, C. A., & Braun, D. P. (2011). Role of nutritional status in predicting the length of stay in cancer: a systematic review of the epidemiological literature. *Annals of Nutrition and Metabolism*, *59*(2-4), 96-106.
- Haghjoo, S. (2015). Malnutrition associated with head and neck cancers. *Reviews in Clinical Medicine*, *2*(2), 76-79.
- Hall, S. F., Groome, P. A., & Rothwell, D. (2000). The impact of comorbidity on the survival of patients with squamous cell carcinoma of the head and neck. *Head & neck*, *22*(4), 317-322.
- Hayward, M. C., & Shea, A. M. (2009). Nutritional needs of patients with malignancies of the head and neck. *Seminars in Oncology Nursing*, *25*(3), 203-211.
- Hickson, M. (2006). Malnutrition and ageing. *Postgraduate Medical Journal*, *82*(963), 2-8. doi: <http://doi.org/10.1136/pgmj.2005.037564>
- Hoffman, K. E., McCarthy, E. P., & Ng, A. K. (2008). Psychological distress in long-term survivors of adult-onset cancer: Results from a national survey. *International Journal of Radiation Oncology, Biology, Physics*, *72*(1), S101-S102. doi: 10.1016/j.ijrobp.2008.06.997

- Huhmann, M. B., & August, D. A. (2009). Nutrition support in surgical oncology. *Nutrition in Clinical Practice, 24*(4), 520-526.
- Isenring, E. A., Banks, M., Ferguson, M., & Bauer, J. D. (2012). Beyond malnutrition screening: Appropriate methods to guide nutrition care for aged care residents. *Journal of the Academy of Nutrition and Dietetics, 112*(3), 376. doi:10.1016/j.jada.2011.09.038
- Isenring E., Bauer J., Capra S. (2003). The scored Patient-generated Subjective Global Assessment (PG-SGA) and its association with quality of life in ambulatory patients receiving radiotherapy. *Eur J Clin Nutr, 57*, 305–309.
- Isenring, E. A., Bauer, J. D., & Capra, S. (2007). Nutrition support using the American Dietetic Association medical nutrition therapy protocol for radiation oncology patients improves dietary intake compared with standard practice. *Journal of the American Dietetic Association, 107*(3), 404-412.
- Isenring, E. A., Capra, S., & Bauer, J. D. (2004). Nutrition intervention is beneficial in oncology outpatients receiving radiotherapy to the gastrointestinal or head and neck area. *British Journal of Cancer, 91*(3), 447-452. doi: 10.1038/sj.bjc.6601962
- Isenring, E., Cross, G., Daniels, L., Kellett, E., & Koczwara, B. (2006). Validity of the malnutrition screening tool as an effective predictor of nutritional risk in oncology outpatients receiving chemotherapy. *Supportive Care in Cancer, 14*(11), 1152-1156. doi: 10.1007/s00520-006-0070-5
- Isenring, E., & Elia, M. (2015). Which screening method is appropriate for older cancer patients at risk for malnutrition. *Nutrition, 31*(4), 594-597.
- Jager-Wittenaar, H., Dijkstra, P. U., Vissink, A., Langendijk, J. A., van der Laan, Bernard F. A. M, Pruijm, J., & Roodenburg, J. L. N. (2011). Changes in nutritional status and dietary intake during and after head and neck cancer treatment. *Head and Neck-Journal for the Sciences and Specialties of the Head and Neck, 33*(6), 863-870. doi: 10.1002/hed.21546
- Jager-Wittenaar, H., & Ottery, F. D. (2017). Assessing nutritional status in cancer: role of the Patient-Generated Subjective Global Assessment. *Current Opinion in Clinical Nutrition & Metabolic Care, 20*(5), 322-329.
- Jemal, A., Siegel, R., Ward, E., Hao, Y., Xu, J., Murray, T., & Thun, M. J. (2008). Cancer statistics, 2008. *CA: a cancer journal for clinicians, 58*(2), 71-96.
- Jemal, A., Bray, F., Center, M. M., Ferlay, J., Ward, E., & Forman, D. (2011). Global cancer statistics. *CA: A Cancer Journal for Clinicians, 61*(2), 69-90. doi:10.3322/caac.20107

- Joint Commission International. Joint Commission International Accreditation Standards for Hospitals, 5th ed. Oak Brook, IL: Joint Commission Resources, 2013.
- Jones, J. M. (2002). The methodology of nutritional screening and assessment tools. *Journal of Human Nutrition and Dietetics*, 15(1), 59-71. doi: 10.1046/j.1365-277X.2002.00327.x
- Karvonen-Gutierrez, C. A., Ronis, D. L., Fowler, K. E., Terrell, J. E., Gruber, S. B., & Duffy, S. A. (2008). Quality of life scores predict survival among patients with head and neck cancer. *Journal of Clinical Oncology*, 26(16), 2754-2760. doi: 10.1200/JCO.2007.12.9510
- Kim, J., Wie, G., Cho, Y., Kim, S., Kim, S., Son, K., . . . Joung, H. (2011). Development and validation of a nutrition screening tool for hospitalized cancer patients. *Clinical Nutrition (Edinburgh, Scotland)*, 30(6), 724. doi: 10.1016/j.clnu.2011.06.001
- Kondrup, J., Allison, S. P., Elia, M., Vellas, B., Plauth, M., & Educational and Clinical Practice Committee, European Society of Parenteral and Enteral Nutrition (ESPEN). (2003). ESPEN guidelines for nutrition screening 2002. *Clinical Nutrition*, 22(4), 415-421. doi: 10.1016/S0261-5614(03)00098-0
- Kubrak, C., Olson, K., & Baracos, V. E. (2013). The head and neck symptom checklist©: An instrument to evaluate nutrition impact symptoms effect on energy intake and weight loss. *Supportive Care in Cancer*, 21(11), 3127-3136.
- Kubrak, C., Olson, K., Jha, N., Jensen, L., McCargar, L., Seikaly, H., . . . Baracos, V. E. (2010). Nutrition impact symptoms: Key determinants of reduced dietary intake, weight loss, and reduced functional capacity of patients with head and neck cancer before treatment. *Head & Neck*, 32(3), 290-300.
- Langius, J. A. E., Bakker, S., Rietveld, D. H. F., Kruizenga, H. M., Langendijk, J. A., Weijs, P. J. M., & Leemans, C. R. (2013). Critical weight loss is a major prognostic indicator for disease-specific survival in patients with head and neck cancer receiving radiotherapy. *British journal of cancer*, 109(5), 1093-1099.
- Langius, J. A. E., Twisk, J., Kampman, M., Doornaert, P., Kramer, M. H. H., Weijs, P. J. M., & Leemans, C. R. (2016). Prediction model to predict critical weight loss in patients with head and neck cancer during (chemo)radiotherapy. *Oral Oncology*, 52, 91-96. doi: 10.1016/j.oraloncology.2015.10.021
- Langius, J. A. E., van Dijk, A. M., Doornaert, P., Kruizenga, H. M., Langendijk, J. A., Leemans, C. R., . . . Verdonck-de Leeuw, I. M. (2013). More than 10% weight loss in head and neck cancer patients during radiotherapy is independently associated with deterioration in quality of life. *Nutrition and Cancer*, 65(1), 76-83.

- Laporte, M., Keller, H. H., Payette, H., Allard, J. P., Duerksen, D. R., Bernier, P., ... & Teterina, A. (2015). Validity and reliability of the new Canadian Nutrition Screening tool in the 'real-world' hospital setting. *European journal of clinical nutrition*, *69*(5), 558-564.
- Larsson, M., Hedelin, B., Johansson, I., Athlin, E. (2005). Eating problems and weight loss for patients with head and neck cancer: A chart review from diagnosis until one year after treatment. *Cancer Nursing*, *28*(6), 425-435. doi: 10.1097/00002820-200511000-00004
- Lee, H.-K., Choi, H.-S., Son, E.-J., & Lyu, E.-S. (2013). Analysis of the Prevalence and Risk Factors of Malnutrition among Hospitalized Patients in Busan. *Preventive Nutrition and Food Science*, *18*(2), 117–123.
- Lee, Y., Shin, H., Bae, E., & Lim, H. (2016). Aspects of health-related factors and nutritional care needs by survival stage among female cancer patients in south korea. *PLoS One*, *11*(10), e0163281. doi: 10.1371/journal.pone.0163281
- Lees. (1999). Incidence of weight loss in head and neck cancer patients on commencing radiotherapy treatment at a regional oncology centre. *European Journal of Cancer Care*, *8*(3), 133-136. doi: 10.1046/j.1365-2354.1999.00156.x
- Leuenberger, M., Kurmann, S., & Stanga, Z. (2010). Nutritional screening tools in daily clinical practice: The focus on cancer. *Supportive Care in Cancer*, *18*(S2), 17-27.
- Lim, S. L., Ang, E., Foo, Y. L., Ng, L. Y., Tong, C. Y., Ferguson, M., & Daniels, L. (2013). Validity and reliability of nutrition screening administered by nurses. *Nutrition in Clinical Practice*, *28*(6), 730-736. doi: 10.1177/0884533613502812
- Lim, S. L., Ong, K. C. B., Chan, Y. H., Loke, W. C., Ferguson, M., & Daniels, L. (2012). Malnutrition and its impact on cost of hospitalization, length of stay, readmission and 3-year mortality. *Clinical Nutrition*, *31*(3), 345-350.
- Lis, C. G., Gupta, D., Lammersfeld, C. A., Markman, M., & Vashi, P. G. (2012). Role of nutritional status in predicting quality of life outcomes in cancer--a systematic review of the epidemiological literature. *Nutrition Journal*, *11*(1), 27-27. doi: 10.1186/1475-2891-11-27
- List, M. A., Ritter-Sterr, C. A., Baker, T. M., Colangelo, L. A., Matz, G., Pauloski, B. R., & Logemann, J. A. (1996). Longitudinal assessment of quality of life in laryngeal cancer patients. *Head & Neck*, *18*(1), 1-10. doi: 10.1002/(SICI)1097-0347(199601/02)18:1<1::AID-HED1>3.0.CO;2-7
- List, M. A., Mumby, P., Haraf, D., Siston, A., Mick, R., MacCracken, E., & Vokes, E. (1997). Performance and quality of life outcome in patients completing concomitant chemoradiotherapy protocols for head and neck cancer. *Quality of Life Research*, *6*(3), 274-284. doi: 10.1023/A:1026419023481

- Liu, H. (2008). Changes of satisfaction with appearance and working status for head and neck tumour patients. *Journal of Clinical Nursing*, 17(14), 1930-1938. doi: 10.1111/j.1365-2702.2008.02291.x
- Lochs, H., Allison, S. P., Meier, R., Pirlich, M., Kondrup, J., van den Berghe, G., & Pichard, C. (2006). Introductory to the ESPEN Guidelines on Enteral Nutrition: Terminology, definitions and general topics. *Clinical nutrition*, 25(2), 180-186.
- Lønbro, S., Petersen, G. B., Andersen, J. R., & Johansen, J. (2016). Prediction of critical weight loss during radiation treatment in head and neck cancer patients is dependent on BMI. *Supportive Care in Cancer*, 24(5), 2101-2109.
- Ma, L., Poulin, P., Feldstain, A., & Chasen, M. R. (2013). The association between malnutrition and psychological distress in patients with advanced head-and-neck cancer. *Current Oncology*, 20(6), e554.
- Macqueen, C. E., & Frost, G. (1998). Visual analogue scales: a screening tool for assessing nutritional need in head and neck radiotherapy patients. *Journal of Human Nutrition and Dietetics*, 11(2), 115-124.
- Martin, L., de van der Schueren, Marian A E, Blauwhoff-Buskermolten, S., Baracos, V., & Gramlich, L. (2014). Identifying the barriers and enablers to nutrition care in head and neck and esophageal cancers: An international qualitative study. *JPEN. Journal of Parenteral and Enteral Nutrition*, 40(3), 355. doi: 10.1177/0148607114552847
- Maruvka, Y. E., Tang, M., & Michor, F. (2014). On the validity of using increases in 5-year survival rates to measure success in the fight against cancer: E83100. *PLoS One*, 9(7) doi: 10.1371/journal.pone.0083100
- Maskarinec, G., Murphy, S., Shumay, D. M., & Kakai, H. (2001). Dietary changes among cancer survivors. *European Journal of Cancer Care*, 10(1), 12-20. doi: 10.1046/j.1365-2354.2001.00245.x
- McClement, S. (2005). Cancer anorexia-cachexia syndrome: psychological effect on the patient and family. *Journal of Wound Ostomy & Continence Nursing*, 32(4), 264-268.
- McGurk, P., Jackson, J. M., & Elia, M. (2013). Rapid and reliable self-screening for nutritional risk in hospital outpatients using an electronic system. *Nutrition (Burbank, Los Angeles County, Calif.)*, 29(4), 693-696. doi: 10.1016/j.nut.2012.12.020
- McQuestion, M. A. (2006). A qualitative descriptive study of patients' experiences of receiving primary radiation therapy for head and neck cancer. *Unpublished master's thesis, University of Toronto, Toronto, Ontario.*

- Meijers, J. M. M., van Bokhorst-de van der Schueren, Marian A.E, Schols, J. M. G. A., Soeters, P. B., & Halfens, R. J. G. (2010). Defining malnutrition: Mission or mission impossible? *Nutrition*, 26(4), 432-440. doi: 10.1016/j.nut.2009.06.012
- Medical nutrition therapy protocols: An introduction. (1999). *Journal of the American Dietetic Association*, 99(3), 351. doi:10.1016/S0002-8223(99)00090-5
- Miller, K. R., & Bozeman, M. C. (2012). Nutrition therapy issues in esophageal cancer. *Current Gastroenterology Reports*, 14(4), 356-366. doi: 10.1007/s11894-012-0272-6
- Molassiotis, A., & Holmes, H. S. (2005). Management of cancer-associated malnutrition. *European Journal of Oncology Nursing*, 9, S33-S34. doi: 10.1016/j.ejon.2005.09.002
- Mueller, C., Compher, C., & Ellen, D. M. (2011). ASPEN clinical guidelines nutrition screening, assessment, and intervention in adults. *Journal of Parenteral and Enteral Nutrition*, 35(1), 16-24
- National Cancer Institute. 2005. Common toxicity criteria. Available from: <http://ctep.cancer.gov/forms/CTCAEv3.pdf>
- National Institute for Health and Care Excellence. 2013. Cost saving guidance. Available from: <http://www.nice.org.uk/usingguidance/benefitsofimplementation/costsavingsguidance.jsp>
- Niezgoda, H. E., & Pater, J. L. (1993). A validation study of the domains of the core EORTC Quality of Life Questionnaire. *Quality of Life Research*, 2(5), 319 - 325.
- Nitenberg, G., & Raynard, B. (2000). Nutritional support of the cancer patient: Issues and dilemmas. *Critical Reviews in Oncology and Hematology*, 34(3), 137-168. doi: 10.1016/S1040-8428(00)00048-2
- Norman, K., Pichard, C., Lochs, H., & Pirlich, M. (2008). Prognostic impact of disease-related malnutrition. *Clinical Nutrition*, 27(1), 5-15. doi: 10.1016/j.clnu.2007.10.007
- Nourissat, A., Bairati, I., Fortin, A., G elinas, M., Nabid, A., Brochet, F., . . . Meyer, F. (2012). Factors associated with weight loss during radiotherapy in patients with stage I or II head and neck cancer. *Supportive Care in Cancer*, 20(3), 591-599.
- Nugent, B., Lewis, S., & O'Sullivan, J. M. (2011). Enteral feeding methods for nutritional management in patients with head and neck cancers being treated with radiotherapy and/or chemotherapy (a cochrane systematic review): Abstracts. *Journal of Human Nutrition and Dietetics*, 24(3), 298-299. doi: 10.1111/j.1365-277X.2011.01175_28.x
- Oskam, I. M., Verdonck-de Leeuw, I. M., Aaronson, N. K., Witte, B. I., de Bree, R., Doornaert, P., . . . Leemans, C. R. (2013). Prospective evaluation of health-

- related quality of life in long-term oral and oropharyngeal cancer survivors and the perceived need for supportive care. *Oral Oncology*, 49(5), 443-448. doi: 10.1016/j.oraloncology.2012.12.005
- Osoba, D., Zee, B., Pater, J., Kaizer, L., & Latreille, J. (1994). Psychometric properties and responsiveness of the EORTC Quality of Life Questionnaire (QLQ-C30) in patients with breast, ovarian and lung cancer. *Quality of Life Research*, 3(5), 353- 364.
- Osthus, A. A., Aarstad, A. K. H., Aarstad, H. J., & Olofsson, J. (2011). Head and neck specific health related quality of life scores predict subsequent survival in successfully treated head and neck cancer patients: A prospective cohort study. *Oral Oncology*, 47(10), 974-979. doi: 10.1016/j.oraloncology.2011.07.010
- Ottery, F. D. (1996). Definition of standardized nutritional assessment and interventional pathways in oncology. *Nutrition*, 12(1), S15-S19. doi: 10.1016/0899-9007(95)00067-4
- Ottery, F. D., Isenring, E., Kasenic, S., DeBolt, S. P., Sealy, M. J., & Jager-Wittenaar, H. (2015). Patient-generated subjective global assessment: Innovation from paper to digital app.
- Ottosson, S., Laurell, G., Olsson, C. (2013). The experience of food, eating and meals following radiotherapy for head and neck cancer: A qualitative study. *Journal of Clinical Nursing*, 22(7-8), 1034-1043.
- Ottosson, S., Zackrisson, B., Kjellén, E., Nilsson, P., & Laurell, G. (2013). Weight loss in patients with head and neck cancer during and after conventional and accelerated radiotherapy. *Acta Oncologica*, 52(4), 711-718.
- Paleri, V., & Patterson, J. (2010). Use of gastrostomy in head and neck cancer: A systematic review to identify areas for future research. *Clinical Otolaryngology*, 35(3), 177-189. doi: 10.1111/j.1749-4486.2010.02128.x
- Pateman, K. A., Ford, P. J., Batstone, M. D., & Farah, C. S. (2015). Coping with an altered mouth and perceived supportive care needs following head and neck cancer treatment. *Supportive Care in Cancer*, 23(8), 2365-2373.
- Payakachat, N., Ounpraseuth, S., & Suen, J. Y. (2013). Late complications and long-term quality of life for survivors (>5 years) with history of head and neck cancer. *Head & Neck*, 35(6), 819-825. doi:10.1002/hed.23035
- Penner, J. L. (2009). Psychosocial care of patients with head and neck cancer. *Seminars in Oncology Nursing*, 25(3), 231-241. doi: 10.1016/j.soncn.2009.05.008
- Piquet M, Ozsahin M, Larpin I, et al. (2002). Early nutritional intervention in oropharyngeal cancer patients undergoing radiotherapy. *Supportive Care in Cancer*, 10: 502-504.

- Platek, M. E. (2012). The role of dietary counseling and nutrition support in head and neck cancer patients. *Current Opinion in Supportive and Palliative Care*, 6(4), 438-445. doi: 10.1097/SPC.0b013e32835999d5
- Platek, M. E., Hertroijs, D. F. L., Nicholson, J. M., & Parekh, N. (2015). Sensitivity and specificity of malnutrition screening tools used in the adult hospitalized patient setting: A systematic review. *Topics in Clinical Nutrition*, 30(4), 289-301.
- Platek, M. E., Popp, J. V., Possinger, C. S., DeNysschen, C. A., Horvath, P., & Brown, J. K. (2011). Comparison of the prevalence of malnutrition diagnosis in head and neck, gastrointestinal, and lung cancer patients by 3 classification methods. *Cancer Nursing*, 34(5), 410-416.
- Prakash, G., Bakhshi, S., Raina, V., et al. (2010). Characteristics and pattern of mortality in cancer patients at a tertiary care oncology center: report of 259 cases. *Asian Pac J Cancer Prev*. 11, 1755–1759.
- Prevost, V., Joubert, C., Heutte, N., & Babin, E. (2014). Assessment of nutritional status and quality of life in patients treated for head and neck cancer. *European annals of otorhinolaryngology, head and neck diseases*, 131(2), 113-120.
- Raja, R., Gibson, S., Turner, A., Winderlich, J., Porter, J., Cant, R., & Aroni, R. (2008). Nurses' views and practices regarding use of validated nutrition screening tools. *Australian Journal of Advanced Nursing, the*, 26(1), 26-33.
- Ravasco, RD., P., Monteiro Grillo, I., & Camilo, M. (2008). The long term follow-up of a prospective randomised controlled trial of nutritional therapy in head and neck cancer patients submitted to radiotherapy. *Journal of Clinical Oncology*, 26(15).
- Ravasco, P., Monteiro-Grillo, I., Vidal, P. M., & Camilo, M. E. (2003). Nutritional deterioration in cancer: The role of disease and diet. *Clinical Oncology*, 15(8), 443-450. doi: 10.1016/S0936-6555(03)00155-9
- Ravera, E., Bozzetti, F., Ammatuna, M., & Radaelli, G. (1987). Impact of hospitalization on the nutritional status of cancer patients. *Tumori*, 73(4), 375-380.
- Redda, M. G. R., & Allis, S. (2006). Radiotherapy-induced taste impairment. *Cancer Treatment Reviews*, 32(7), 541-547. doi: 10.1016/j.ctrv.2006.06.003
- Reeve, B. B., Cai, J., Zhang, H., Weissler, M. C., Wisniewski, K., Gross, H., & Olshan, A. F. (2016). Factors that impact health-related quality of life over time for individuals with head and neck cancer: Factors associated with quality of life. *The Laryngoscope*, 126(12), 2718-2725. doi: 10.1002/lary.26073
- Rinkel, R. N., Verdonck-de Leeuw, I. M., Doornaert, P., Buter, J., Bree, R., Langendijk, J. A., ... & Leemans, C. R. (2015). Prevalence of swallowing and speech problems in daily life after chemoradiation for head and neck cancer based on cut-off

scores of the patient-reported outcome measures SWAL-QOL and SHI.
European Archives of Oto-Rhino-Laryngology, 1-7.

- Roller, R. E., Egelseer, D., Eisenberger, A., & Wirnsberger, G. H. (2016). The graz malnutrition screening (GMS): A new hospital screening tool for malnutrition. *The British Journal of Nutrition*, 115(4), 650-657.
- Russell, C. A. (2007). The impact of malnutrition on healthcare costs and economic considerations for the use of oral nutritional supplements. *Clinical Nutrition Supplements*, 2(1), 25-32.
- Santarpia, L., Contaldo, F., & Pasanisi, F. (2011). Nutritional screening and early treatment of malnutrition in cancer patients. *Journal of cachexia, sarcopenia and muscle*, 2(1), 27-35.
- Schmidt, K. N., Olson, K., Kubrak, C., Parliament, M., & Ghosh, S. (2013). Validation of the head and neck patient symptom checklist as a nutrition impact symptom assessment tool for head and neck cancer patients. *Supportive Care in Cancer*, 21(1), 27-34.
- Seltzer, M. H., Bastidas, J. A., Cooper, D. M., Engler, P., Slocum, B., & Fletcher, H. S. (1979). Instant nutritional assessment. *Journal of Parenteral and Enteral Nutrition*, 3(3), 157-159.
- Shahar, S., & Hussain, S. S. (2007). Validation of nutritional screening tools against anthropometric and functional assessments among elderly people in Selangor. *Malaysian J. Nutr*, 13, 29-44.
- Shaw, C., Fleuret, C., Pickard, J. M., Mohammed, K., Black, G., & Wedlake, L. (2014). Comparison of a novel, simple nutrition screening tool for adult oncology inpatients and the Malnutrition Screening Tool (MST) against the Patient-Generated Subjective Global Assessment (PG-SGA). *Supportive Care in Cancer*, 23(1), 47-54.
- Sherman, A.C., Simonton, S., Adams, D.C., Vural, E., Owens, B., & Hanna, E. (2000). Assessing QOL in patients with head and neck cancer: Cross-validation of European Organization for Research and Treatment of Cancer (EORTC) QOL head and neck module (QLQ-H&N35). *Archives in Otolaryngology, Head and Neck Surgery*, 126, 459-467.
- Shirodkar, M., & Mohandas, K. M. (2005). Subjective global assessment: a simple and reliable screening tool for malnutrition among Indians. *Indian Journal of Gastroenterology*, 24(6), 246.
- Silander, E., Nyman, J. & Hammerlid, E. (2013). An exploration of factors predicting malnutrition in patients with advanced head and neck cancer. *The Laryngoscope*, 123(10), 2428-2434. doi:10.1002/lary.23877

- Skipper, A., Ferguson, M., Thompson, K., Castellanos, V. H., & Porcari, J. (2012). Nutrition screening tools: An analysis of the evidence. *Journal of Parenteral and Enteral Nutrition*, 36(3), 292-298.
- Smith, S. F., Smith, R. C., Ledgard, J. P., Doig, G., & Chesher, D. (2009). An effective automated nutrition screen for hospitalized patients. *Nutrition*, 25(3), 309-315.
- Soeters, P. B., Reijven, P. L. M., van Bokhorst-de van der Schueren, Marian A.E, Schols, J. M. G. A., Halfens, R. J. G., Meijers, J. M. M., & van Gemert, W. G. (2008). A rational approach to nutritional assessment. *Clinical Nutrition*, 27(5), 706-716. doi: 10.1016/j.clnu.2008.07.009
- Somanchi, M., Tao, X., & Mullin, G. E. (2011). The facilitated early enteral and dietary management effectiveness trial in hospitalized patients with malnutrition. *Journal of Parenteral and Enteral Nutrition*, 35(2), 209-216. doi:10.1177/0148607110392234
- Spiro, A., Baldwin, C., Patterson, A., Thomas, J., & Andreyev, H. J. N. (2006). The views and practice of oncologists towards nutritional support in patients receiving chemotherapy. *British journal of cancer*, 95(4), 431-434.
- Stratton, R. J., & Elia, M. (2005). Geographic inequalities in malnutrition prevalence in the elderly across England. *Proceedings of the Nutrition Society*, 64, 12-17.
- Stratton, R. J., Hackston, A., Longmore, D., Dixon, R., Price, S., Stroud, M., . . . Elia, M. (2004). Malnutrition in hospital outpatients and inpatients: Prevalence, concurrent validity and ease of use of the 'malnutrition universal screening tool' ('MUST') for adults. *British Journal of Nutrition*, 92(5), 799-808. doi:10.1079/BJN20041258
- Symonds, R. P., Deehan, C., Meredith, C., & Mills, J. A. (2012). *Walter and Miller's Textbook of Radiotherapy: Radiation Physics, Therapy and Oncology*. Elsevier Health Sciences.
- Takenaka, Y., Yamamoto, M., Nakahara, S., Yamamoto, Y., Yasui, T., Hanamoto, A., ... & Inohara, H. (2014). Factors associated with malnutrition in patients with head and neck cancer. *Acta otolaryngologica*, 134(10), 1079-1085.
- Tappenden, K. A., Quatrara, B., Parkhurst, M. L., Malone, A. M., Fanjiang, G., & Ziegler, T. R. (2013). Critical role of nutrition in improving quality of care: An interdisciplinary call to action to address adult hospital malnutrition. *Journal of Parenteral and Enteral Nutrition*, 37(4), 482-497.
- Taylor, J. C., Terrell, J. E., Ronis, D. L., Fowler, K. E., Bishop, C., Lambert, M. T., . . . University of Michigan Head and Neck Cancer Team. (2004). Disability in patients with head and neck cancer. *Archives of Otolaryngology–Head & Neck Surgery*, 130(6), 764-769. doi: 10.1001/archotol.130.6.764

- Teitelbaum, D., Guenter, P., Howell, W. H., Kochevar, M. E., Roth, J., & Seidner, D. L. (2005). Definition of terms, style, and conventions used in A.S.P.E.N. guidelines and standards. *Nutrition in Clinical Practice: Official Publication of the American Society for Parenteral and Enteral Nutrition*, 20(2), 281-285.
- Terrell, J. E., Ronis, D. L., Fowler, K. E., Bradford, C. R., Chepeha, D. B., Prince, M. E., . . . Duffy, S. A. (2004). Clinical predictors of quality of life in patients with head and neck cancer. *Archives of Otolaryngology–Head & Neck Surgery*, 130(4), 401-408. doi: 10.1001/archotol.130.4.401
- Thomas, D. R. (2007). Loss of skeletal muscle mass in aging: Examining the relationship of starvation, sarcopenia and cachexia. *Clinical Nutrition*, 26(4), 389-399. doi: 10.1016/j.clnu.2007.03.008
- Thoresen, L., Frykholm, G., Lydersen, S., Ulveland, H., Baracos, V., Prado, C. M. M., . . . Hälsouniversitetet. (2013). Nutritional status, cachexia and survival in patients with advanced colorectal carcinoma. different assessment criteria for nutritional status provide unequal results. *Clinical Nutrition (Edinburgh, Scotland)*, 32(1), 65. doi: 10.1016/j.clnu.2012.05.009
- Tisdale, M. J. (2002). Cachexia in cancer patients. *Nature Reviews Cancer*, 2(11), 862-871. doi: 10.1038/nrc927
- Tong H, Isenring E, Yates P. (2009). The prevalence of nutrition impact symptoms and their relationship to quality of life and clinical outcomes in medical oncology patients. *Support Care Cancer*, 17, 83–90.
- Ukleja, A., Freeman, K. L., Gilbert, K., Kochevar, M., Kraft, M. D., Russell, M. K., . . . Task Force on Standards for Nutrition Support: Adult Hospitalized Patients, and the American Society for Parenteral and Enteral Nutrition Board of Directors. (2010). Standards for nutrition support: Adult hospitalized patients. *Nutrition in Clinical Practice*, 25(4), 403-414. doi: 10.1177/0884533610374200
- Uster, A., Riefenacht, U., Ruelin, M., Pless, M., Siano, M., Haefner, M., . . . Ballmer, P. (2013). Influence of a nutritional intervention on dietary intake and quality of life in cancer patients: A randomized controlled trial. *Nutrition*, 29(11-12), 1342-1349. doi: 10.1016/j.nut.2013.05.004
- van Bokhorst-de van der Schueren, M., Guaitoli, P. R., Jansma, E. P., & de Vet, H. C. W. (2014). Nutrition screening tools: Does one size fit all? A systematic review of screening tools for the hospital setting. *Clinical Nutrition (Edinburgh, Scotland)*, 33(1), 39-58. doi: 10.1016/j.clnu.2013.04.008
- Van Cutsem, E., & Arends, J. (2005). The causes and consequences of cancer-associated malnutrition. *European Journal of Oncology Nursing*, 9, S51-S63. doi: 10.1016/j.ejon.2005.09.007

- van Leeuwen, P. A., Sauerwein, H. P., Kuik, D. J., Snow, G. B., & Quak, J. J. (1997). Assessment of malnutrition parameters in head and neck cancer and their relation to postoperative complications. *Head & neck*, *19*(5), 419-425.
- Van Liew, J. R., Brock, R. L., Christensen, A. J., Karnell, L. H., Pagedar, N. A., & Funk, G. F. (2017). Weight loss after head and neck cancer: A dynamic relationship with depressive symptoms: Depressive symptoms and weight loss in head and neck cancer. *Head & Neck*, *39*(2), 370-379. doi: 10.1002/hed.24601
- van Nieuwenhuizen, A. J., Buffart, L. M., Brug, J., Leemans, C. R., & Verdonck-de Leeuw, I. M. (2015). The association between health related quality of life and survival in patients with head and neck cancer: a systematic review. *Oral oncology*, *51*(1), 1-11.
- VanderWalde, N. A., Fleming, M., Weiss, J., & Chera, B. S. (2013). Treatment of older patients with head and neck cancer: A review. *The Oncologist*, *18*(5), 568-578. doi: 10.1634/theoncologist.2012-0427
- Wakahara, T., Shiraki, M., Murase, K., Fukushima, H., Matsuura, K., Fukao, A., ... & Iwasa, J. (2007). Nutritional screening with Subjective Global Assessment predicts hospital stay in patients with digestive diseases. *Nutrition*, *23*(9), 634-639.
- Wells, M., Swartzman, S., Lang, H., Cunningham, M., Taylor, L., Thomson, J., . . . & McCowan, C. (2016). Predictors of quality of life in head and neck cancer survivors up to 5 years after end of treatment: A cross-sectional survey. *Supportive Care in Cancer*, *24*(6), 2463-2472. doi: 10.1007/s00520-015-3045-6
- Wu B. W., Yin T., Cao W. X., Gu Z. D., Wang X. J., Yan M., Liu B.Y. (2009). Clinical application of subjective global assessment in Chinese patients with gastrointestinal cancer. *World J Gastroenterol* *15*, 3542–3549.
- Zekri, J., Morganti, J., Rizvi, A., Sadiq, B. B., Kerr, I., & Aslam, M. (2014). Novel simple and practical nutritional screening tool for cancer inpatients: A pilot study. *Supportive Care in Cancer*, *22*(5), 1401-1408.
- Żmijewska-Tomczak, M., Milecki, P., Olek-Hrab, K., Hojan, K., Golusiński, W., Rucińska, A., & Adamska, A. (2014). Factors influencing quality of life in patients during radiotherapy for head and neck cancer. *Archives of Medical Science: AMS*, *10*(6), 1153–1159. doi: <http://doi.org/10.5114/aoms.2013.34317>

APPENDICES

APPENDIX A



**Western
Research**

Research Ethics

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Dr. Philip Doyle
Department & Institution: Health Sciences/Communication Sciences & Disorders, Western University

Review Type: Delegated
HSREB File Number: 108539
Study Title: Use of a Self-Administered Malnutrition Screening Tool and Evaluation of Nutrition Status in Individuals with Head and Neck Cancer

HSREB Initial Approval Date: February 08, 2017
HSREB Expiry Date: February 08, 2018

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Revised Western University Protocol	Received January 31, 2017	
Revised Letter of Information & Consent	v1	2017/01/31
Data Collection Form/Case Report Form	Clean Demographic Survey	2016/10/27
Instruments	PG-SGA v3.22.15	
Instruments	EORTC QLQ-C30	
Instruments	EORTC QLQ-HN35	
Instruments	Ease of use form	
Other	Support services information for participants	

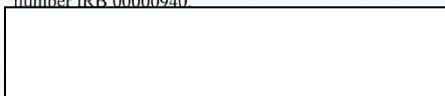
The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.



HSREB Vice Chair
Jarris __ Nicola Morphet __ Karen Gopaul

APPENDIX B



Laboratory for Well-Being and Quality of life in Oncology University of Western Ontario

Letter of Information

Principal Investigators: Philip C. Doyle, Ph.D., Mark J.P. Lynch, M.Sc., Julie A. Theurer, Ph.D.

Project Title: “The application of self-administered nutrition screening tools and evaluations of the impact of malnutrition on quality of life in individuals with head and neck cancer”

Purpose of the study

The purpose of this letter is to provide you with information required for you to make an informed decision regarding participation in this research. This study will examine the ability of up to 100 individuals with head and neck cancer to self-screen their nutrition status, as well as how nutrition status relates to quality of life in this population. This study will identify if individuals with head and neck cancer have an ability to reliably self-screen nutrition status; this may give this group a more direct and active role in their treatment and help professionals understand their nutrition status. Parts of this study represent a Master’s thesis project for one of the investigators (ML).

Activities of participants

If you agree to participate, you will complete a general demographic information survey (e.g., age, gender, etc.). You will then complete two nutrition status self-screens (PG-SGA SF & Pt-Global App) as well as an ease-of-use questionnaire. During this visit, you will also complete two quality of life questionnaires (EORTC-QLQ-C30 & EORTC-QLQ-HN35). Information gathered from each survey and questionnaire will be coded so that your identity remains confidential. Following this you will then undergo a brief non-invasive physician administered examination for the PG-SGA nutrition assessment. The remaining information for completion of the nutrition assessment shall be gathered by the researcher from patient charts. The entire procedure (questionnaire completion, nutrition screen and nutrition assessment) will take place in a quiet clinic room at the London Health Sciences Centre and should take less than 20 minutes.

Exclusion Criteria

You will be excluded from participating in the study if you are younger than 30 or older than 80 years of age. Individuals with skin cancers shall be excluded as these types of cancers should not increase the risk of nutritional decline. Participants unable to read or speak English will be excluded as these individuals would struggle to complete the tasks necessary for this study. For similar reasons participants with severe physical disabilities, dementia or other obvious cognitive impairments, or if their vision does not permit them to see the questionnaires shall also be excluded.

Possible risks involved

There are no known risks or discomforts associated with participation in this research study.

Participation is voluntary. You may refuse to participate, refuse to answer any questions or perform any part nutrition screens or nutrition assessment, or withdraw from the study at any time. You do not waive any legal rights by signing the consent form. Finally, withdrawal from the study will in no way influence your continuing medical care. There is no discomfort with either the nutrition screens or nutrition assessment.

Possible benefits involved

Due to the nature of this study, you will not directly benefit from the data obtained and you will not be compensated for your participation in this research. We would, however, be happy to share the results of our findings with you should you desire.

Voluntary Participation

Participation in this study is voluntary and you may refuse to participate, refuse to answer any questions or withdraw from the study at any time. Doing so will have no effect on your current or future medical care. By signing the consent form to participate within this study you do not waive any legal rights.

Confidentiality

All data collected will remain confidential to the best of our ability. Your data will be identified by a code known only to the investigators. If the results are published, your name will not be used. If you choose to withdraw from this study, your data will be removed and destroyed from our database. It is also a possibility that qualified representatives from Lawson Quality Assurance Education Program and University of Western Ontario Health Sciences Research Ethics Board may look at participants' records for quality assurance.

Contacts for further questions

If you require any further information regarding this research project or your participation in the study, please feel free to contact:

Philip Doyle, Ph.D. or Mark J.P. Lynch, M.Sc.
Laboratory for Well-Being and Quality of Life in Oncology, Rehabilitation Sciences Elborn College, University of Western Ontario, London, Ontario N6G 1H1

If you have any questions about your rights as a research participant or the conduct of this study, you may contact:

David Hill, FCAHS
Lawson Health Research Institute Director and Integrated Vice President, Research for London Health Sciences Centre and St. Joseph's Health Care London

Western University, The Office of Human Research Ethics
Room 5150 Support Services Building, 1393 Western Road, London, Ontario, Canada,

This letter is for you to keep.

APPENDIX C

Demographic Information Survey

Title: “The application of self-administered nutrition screening tools and evaluations of the impact of malnutrition on quality of life in individuals with head and neck cancer”

Study Investigators: Philip Doyle, Ph.D., Mark Lynch, B.H.Sc., M.Sc. (Candidate), Julie Theurer, Ph.D.

Please read the following questions carefully and provide answers as accurately as possible. For multiple choice options, please circle all choices that apply to you. If no suitable options exist, please use the space provided to explain. Also, if there is any additional information that you feel is important to report regarding your body image or perceived QOL, please use the back of these pages to include it.

Sex: M / F / Other

Age: _____ Year of Birth: _____

Month of Birth: _____ Number of months since your diagnosis: _____

What is your current treatment status?

- a) Currently waiting for treatment
- b) Currently undergoing treatment
- c) Completed treatment

Site of Cancer:

- a) Oral cavity (e.g., lip, tongue, cheek, tonsil, etc.)
- b) Larynx (voice box)
- c) Throat (e.g., pharynx, hypopharynx, oropharynx)
- d) Thyroid
- e) Sinuses/Paranasal sinuses
- f) Other

If “other”, please specify:

Method of Treatment:

- a) Surgery
- b) Radiation therapy
- c) Chemotherapy
- d) Chemoradiation therapy
- e) Other

If “other”, please specify:

Marital Status (circle one):

- a) Married
- b) Separated
- c) Divorced
- d) Widowed
- e) Common-law
- f) Engaged
- g) Single
- h) Other

If "other", please specify:

Occupational Status:

- a) Currently working – full-time
- b) Currently working – part-time
- c) Volunteer
- d) Retired
- e) Other

If "other", please specify:

Highest Level of Education Achieved:

- a) Less than high school
- b) Some high school
- c) Completed High school
- d) Some college/post secondary
- e) Completed college/post-secondary
- f) Apprenticeship
- g) Trade school
- c) Undergraduate University degree (i.e., Bachelor's degree)
- d) Post-graduate University degree (i.e., Master's degree, Doctorate)
- e) Other

If "other", please specify:

Tobaccos use status:

- a) Currently use tobacco products
- b) Formerly used tobacco products
- c) Never used tobacco products

If you currently use, or used tobacco products, approximately what quantity of what product (e.g., cigarettes, chewing tobacco, cigars, etc.) do/did you consume in an average week?

Alcohol use status:

- a) Currently consume alcohol
- b) Formerly consumed alcohol
- c) Never consumed alcohol

If you currently consume, or used to consume alcohol, approximately how many beverages do/did you consume in an average week? _____

Household income (optional):

- a) Less than \$25,000
- b) \$25,000 - \$50,000
- c) \$50,001 - \$ 75,000
- d) Greater than \$75,000
- e) Would prefer not to say

Please feel free to include any additional information that you feel is important specific to this project in the space provided below or on the opposite side of this document. Thank you.

APPENDIX D



EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: ? ? ? ?
 Your birthdate (Day, Month, Year): ? ? ? ? ? ? ? ? ? ?
 Today's date (Day, Month, Year): ? ? ? ? ? ? ? ? ? ?

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1 2 3 4 5 6 7

Very poor

Excellent

30. How would you rate your overall quality of life during the past week?

1 2 3 4 5 6 7

Very poor

Excellent

APPENDIX E



EORTC QLQ - H&N35

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:	Not at all	A	Quite a	Very
		little	bit	much
31. Have you had pain in your mouth?	1	2	3	4
32. Have you had pain in your jaw?	1	2	3	4
33. Have you had soreness in your mouth?	1	2	3	4
34. Have you had a painful throat?	1	2	3	4
35. Have you had problems swallowing liquids?	1	2	3	4
36. Have you had problems swallowing pureed food?	1	2	3	4
37. Have you had problems swallowing solid food?	1	2	3	4
38. Have you choked when swallowing?	1	2	3	4
39. Have you had problems with your teeth?	1	2	3	4
40. Have you had problems opening your mouth	1	2	3	4
41. Have you had a dry mouth?	1	2	3	4
42. Have you had sticky saliva?	1	2	3	4
43. Have you had problems with your sense of smell?	1	2	3	4
44. Have you had problems with your sense of taste?	1	2	3	4
45. Have you coughed?	1	2	3	4
46. Have you been hoarse?	1	2	3	4
47. Have you felt ill?	1	2	3	4
48. Has your appearance bothered you?	1	2	3	4

Please go on to the next page

During the past week:	Not at all	A little	Quite a bit	Very much
49. Have you had trouble eating?	1	2	3	4
50. Have you had trouble eating in front of your family?	1	2	3	4
51. Have you had trouble eating in front of other people?	1	2	3	4
52. Have you had trouble enjoying your meals?	1	2	3	4
53. Have you had trouble talking to other people?	1	2	3	4
54. Have you had trouble talking on the telephone?	1	2	3	4
55. Have you had trouble having social contact with your relatives?	1	2	3	4
56. Have you had trouble having social contact with friends?	1	2	3	4
57. Have you had trouble going out in public?	1	2	3	4
58. Have you had trouble having physical contact with family or friends?	1	2	3	4
59. Have you felt less interest in sex?	1	2	3	4
60. Have you felt less sexual enjoyment?	1	2	3	4

During the past week:	No	Yes
61. Have you used pain-killers?	1	2
62. Have you taken any nutritional supplements (excluding vitamins)?	1	2
63. Have you used a feeding tube?	1	2
64. Have you lost weight?	1	2
65. Have you gained weight?	1	2

Scored Patient-Generated Subjective Global Assessment (PG-SGA)



History: Boxes 1 - 4 are designed to be completed by the patient.
[Boxes 1-4 are referred to as the PG-SGA Short Form (SF)]

1. Weight (See Worksheet 1)

In summary of my current and recent weight:

I currently weigh about _____ kg
I am about _____ cm tall

One month ago I weighed about _____ kg
Six months ago I weighed about _____ kg

During the past two weeks my weight has:
 decreased (1) not changed (0) increased (0)

Box 1

Patient Identification Information

2. Food intake: As compared to my normal intake, I would rate my food intake during the past month as

- unchanged (0)
- more than usual (0)
- less than usual (1)

I am now taking

- normal food but less than normal amount (1)
- little solid food (2)
- only liquids (3)
- only nutritional supplements (3)
- very little of anything (4)
- only tube feedings or only nutrition by vein (0) **Box 2**

3. Symptoms: I have had the following problems that have kept me from eating enough during the past two weeks (check all that apply)

- no problems eating (0)
- no appetite, just did not feel like eating (3) vomiting (3)
- nausea (1) diarrhea (3)
- constipation (1) dry mouth (1)
- mouth sores (2) smells bother me (1)
- things taste funny or have no taste (1) feel full quickly (1)
- problems swallowing (2) fatigue (1)
- pain; where? (3) _____
- other (1)** _____
- **Examples: depression, money, or dental problems **Box 3**

4. Activities and Function:

Over the past month, I would generally rate my activity as:

- normal with no limitations (0)
- not my normal self, but able to be up and about with fairly normal activities (1)
- not feeling up to most things, but in bed or chair less than half the day (2)
- able to do little activity and spend most of the day in bed or chair (3)
- pretty much bed ridden, rarely out of bed (3)

Box 4

The remainder of this form is to be completed by your doctor, nurse, dietitian, or therapist. Thank you.

Additive Score of Boxes 1-4 **A**

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Scored Patient-Generated Subjective Global Assessment (PG-SGA)

Additive Score of Boxes 1-4 (See Side 1) A

Worksheet 1 – Scoring Weight Loss

To determine score, use 1-month weight data if available. Use 6-month data only if there is no 1-month weight data. Use points below to score weight change and add one extra point if patient has lost weight during the past 2 weeks. Enter total point score in Box 1 of PG-SGA.

Weight loss in 1 month	Points	Weight loss in 6 months
10% or greater	4	20% or greater
5-9.9%	3	10-19.9%
3-4.9%	2	6-9.9%
2-2.9%	1	2-5.9%
0-1.9%	0	0-1.9%

Numerical score from Worksheet 1

5. Worksheet 2 – Disease and its relation to nutritional requirements:

Score is derived by adding 1 point for each of the following conditions:

- Cancer
- AIDS
- Pulmonary or cardiac cachexia
- Chronic renal insufficiency
- Presence of decubitus, open wound or fistula
- Presence of trauma
- Age greater than 65

Other relevant diagnoses (specify) _____

Primary disease staging (circle if known or appropriate) I II III IV Other B

Numerical score from Worksheet 2

6. Worksheet 3 – Metabolic Demand

Score for metabolic stress is determined by a number of variables known to increase protein & caloric needs. Note: Score fever intensity or duration, whichever is greater. The score is additive so that a patient who has a fever of 38.8 °C (3 points) for < 72 hrs (1 point) and who is on 10 mg of prednisone chronically (2 points) would have an additive score for this section of 5 points.

Stress	none (0)	low (1)	moderate (2)	high (3)
Fever	no fever	> 37.2 and < 38.3	≥ 38.5 and < 38.8	≥ 38.8 °C
Fever duration	no fever	> 72 hours	72 hours	> 72 hours
Corticosteroids	no corticosteroids	low dose (< 10 mg prednisone equivalents/day)	moderate dose (≥ 10 and < 30 mg prednisone equivalents/day)	high dose (≥ 30 mg prednisone equivalents/day)

Numerical score from Worksheet 3 C

7. Worksheet 4 – Physical Exam

Exam includes a subjective evaluation of 3 aspects of body composition: fat, muscle, & fluid. Since this is subjective, each aspect of the exam is rated for degree. Muscle deficit/loss impacts point score more than fat deficit/loss. Definition of categories: 0 = no abnormality, 1+ = mild, 2+ = moderate, 3+ = severe. Rating in these categories is *not* additive but are used to clinically assess the degree of deficit (or presence of excess fluid).

Muscle Status	0	1+	2+	3+
temples (temporalis muscle)	0	1+	2+	3+
clavicles (pectoralis & deltoids)	0	1+	2+	3+
shoulders (deltoids)	0	1+	2+	3+
interosseous muscles	0	1+	2+	3+
scapula (latissimus dorsi, trapezius, deltoids)	0	1+	2+	3+
thigh (quadriceps)	0	1+	2+	3+
calf (gastrocnemius)	0	1+	2+	3+
Global muscle status rating	0	1+	2+	3+

Fat Status	0	1+	2+	3+
orbital fat pads	0	1+	2+	3+
triceps skin fold	0	1+	2+	3+
fat overlying lower ribs	0	1+	2+	3+
Global fat deficit rating	0	1+	2+	3+

Fluid Status	0	1+	2+	3+
ankle edema	0	1+	2+	3+
sacral edema	0	1+	2+	3+
ascites	0	1+	2+	3+
Global fluid status rating	0	1+	2+	3+

Point score for the physical exam is determined by the overall subjective rating of the total body deficit.
 No deficit score = 0 points
 Mild deficit score = 1 point
 Moderate deficit score = 2 points
 Severe deficit score = 3 points

Numerical Score for Worksheet 4 D

Total PG-SGA Score (Total numerical score of A+B+C+D)

Global PG-SGA Category Rating (Stage A, Stage B or Stage C)

Clinician Signature _____ Date _____

Worksheet 5 – PG-SGA Global Assessment Categories

Category	Stage A	Stage B	Stage C
Weight	Well-nourished No weight loss No deficit OR Significant recent improvement	Moderate/suspected malnutrition < 5% loss in 1 month (< 10% in 6 months) Definite decrease in intake	Severely malnourished > 5% loss in 1 month (> 10% in 6 months) Severe deficit in intake
Nutrition Impact	None	Presence of NIS (Box 3 of PG-SGA)	Presence of NIS (Box 3 of PG-SGA)
Functioning	adequate intake	Moderate functional deficit	Severe functional deficit
Physical Exam	recent improvement No deficit OR Significant deficit but with recent clinical improvement	OR Recent deterioration of muscle mass, OR muscle tone on palpation &/or loss of SQ fat	OR Recent significant deterioration (e.g., severe loss muscle, fat, possible edema)

Nutritional Triage Recommendations: Additive score is used to define specific nutritional interventions including patient & family education, symptom management including pharmacologic intervention, and appropriate nutrient intervention (food, nutritional supplements, enteral, or parenteral triage).

First line nutritional intervention includes optimal symptom management.

Triage based on PG-SGA point score

- 0-1 Re-assessment required at this time. Re-assessment on routine and regular basis during treatment.
- 2-3 Patient & family education, patient education with pharmacologic intervention as indicated by symptoms survey (Box 3) and lab values as appropriate.
- 4-5 Requires intervention by dietitian, in conjunction with nurse or physician as indicated by symptoms (Box 3).
- ≥ 9 Indicates a critical need for improved symptom management and/or nutrient intervention options.

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APPENDIX G



APPENDIX H

Ease of use form

Initials:
Age:
Gender:

For each item identified below, circle the number to the right of each question that best describes your level of agreement with the statement.

Survey Item	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1. The PG-SGA SF is easy to use.	1	2	3	4	5
2. The PG-SGA SF is organized in a way that is easy to understand.	1	2	3	4	5
3. The items and questions asked on the PG-SGA SF were simple and easy to understand.	1	2	3	4	5
4. The PG-SGA SF can be completed quickly and easily without the aid of a professional.	1	2	3	4	5
5. The PG-SGA SF was a simple tool for assessing my own nutrition status.	1	2	3	4	5
6. The Pt-Global App is easy to use.	1	2	3	4	5
7. The Pt-Global App is organized in a way that is easy to understand.	1	2	3	4	5
8. The items and questions asked on the Pt-Global App were simple and easy to understand.	1	2	3	4	5
9. The Pt-Global App can be completed quickly and easily without the aid of a professional.	1	2	3	4	5
10. The Pt-Global App was a simple tool for assessing my own nutrition status.	1	2	3	4	5
11. If you experienced any difficulties using the PG-SGA SF please list them to the right along with any suggestions for improvement.					
12. If you experienced any difficulties using the Pt-Global App please list them to the right along with any suggestions for improvement.					

CURRICULUM VITAE

MARK LYNCH

M.Sc. Candidate

EDUCATION

Western University

Masters of Science in Health and Rehabilitation Sciences

2015-present

Western University

Honours of Health Science, Specialization in Biology

2011-2015

EMPLOYMENT

Research Assistant

The Laboratory for Well-Being and Quality of Life in Oncology

2015 – Present

Teaching Assistant

HS 2700A – Health Issues in Childhood and Adolescence,
Western University

2016

AWARDS AND ACHIEVEMENTS

Western Graduate Research Scholarship (\$10,000)

2016-2017

Western Graduate Research Scholarship (\$10,000)

2015-2016

Faculty of Health Sciences Dean's List

2014-2015

Faculty of Health Sciences Dean's List

2013-2014

Faculty of Health Sciences Dean's List

2012-2013

SCHOLARLY AND PROFESSIONAL ACTIVITIES

Student Member, Rehabilitation Sciences Journal Club

2015 – Present

Medical Observer, Otolaryngology Head & Neck Surgery

– London Health Sciences Centre

2015 – Present

EXTRA-CURRICULAR ACTIVITIES

Canadian Cancer Society Volunteer	2015 – Present
Technical Director of U8 division St. Thomas Soccer Club	2015 – Present
Men's Premier Division St. Thomas Soccer Club	2010 – Present
Men's Second Division St. Thomas Soccer Club	2010 – Present

MEMBERSHIP OF LEARNED SOCIETIES

Society of Graduate Students, Western University	2015 – Present
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RESEARCH PROJECTS

Lynch, M. & Doyle, P.C. (2017). The application of self-administered nutrition screening tools and evaluations of the impact of malnutrition on quality of life in individuals with head and neck cancer.

Davis, E., Doyle, P.C., **Lynch, M.**, MacDonald, C. & Jovanovic, N. (2017). Relationship of Postlaryngectomy Voice Disability with Age and Time Post-Treatment. (Currently under review).

Lynch, M. & Doyle, P.C. (2017). Impact of fatigue on quality of life in individuals with head and neck cancer. (Currently in progress).