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IMMEDIATE PALLIATIVE CARE INVOLVEMENT
IN METASTATIC LUNG CANCER

A MASTER'S THESIS SUBMITTED TO THE GRADUATE FACULTY
GRADUATE SCHOOL BETHEL UNIVERSITY

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IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF
MASTER OF SCIENCE IN PHYSICIAN ASSISTANT

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ABSTRACT

This was a quality improvement project that will allow improvements to be made in healthcare services offered and the overall health status of Stage IV metastatic lung cancer patients receiving palliative care referrals. Data was collected retrospectively from electronic medical records of Stage IV metastatic lung cancer patients with palliative care referrals between January 2019 and March 2020. The palliative care referrals between January 2019 and August 2019 were given per oncologist discretion in timing compared to August 2019-March 2020 when new patients received nurse navigator driven palliative care referrals immediately upon diagnosis. Data analysis looked at correlations for each group as presented regarding treatment dates, ethnicity, and gender. An attempt to determine quality of life measures through the PROMs survey was made; however, there was not enough data to make a determination due to the limited number of completed surveys.

The study found that nurse navigator driven palliative care referrals did not increase palliative care received by patients diagnosed with Stage IV metastatic lung cancer. There was no significant difference between palliative care patients receiving a referral based on oncologist discretion versus receiving immediate referrals through a nurse navigator; therefore, the effect of palliative care referrals upon initial diagnosis on the severity of anxiety, sadness, and pain in patients with Stage IV metastatic lung cancer, as well as narcotic need, and treatments received is indeterminate.

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Chapter 1: Introduction

Introduction

Metastatic non-small cell lung cancer is a devastating disease that causes multiple symptoms resulting in poor quality of life (Temel et al., 2010, p.733). It is the most common cancer-related cause of death throughout the world and has a prognosis of less than one year upon diagnosis. (Temel et al., 2010, p.733). Metastatic stage IV lung cancer is a type of cancer that has spread from the lungs throughout the body, which can be difficult to treat. People with metastatic lung cancer have a poor prognosis and need palliative care involvement (Leonard, 2019, para. 2; Rowland, 2010).

However, involvement of palliative care should occur at the time of diagnosis to improve patient symptoms and quality of life, as well as extend the patients' life expectancy (Rowland, 2010). This chapter will cover information about the importance of palliative care in metastatic lung cancer, as well as the purpose and questions of the study. This study will identify what effect, if any, does immediate, nurse navigator driven palliative care referrals at time of diagnosis have on patients with metastatic non-small cell lung cancer.

Background to Problem

Palliative care is defined as an interdisciplinary medical specialty that aims to optimize quality of life for patients with serious, life-limiting illnesses and their families (Rhee, Mchugh, Tun, Gerhart, & O'Mahony, 2014; Kelley & Morrison, 2015; Kelley & Meier, 2010). Palliative care is provided in conjunction with curative therapies and life-prolonging medical treatments (Kelley & Meier, 2010). Improving the quality of life for

patients with Stage IV metastatic lung cancer is a significant challenge due to the progressive nature of the disease (Temel et al., 2010).

The study conducted by Temel et al. (2010) showed statistically significant improvements in early implementation of palliative care combined with traditional oncologic treatment in patients with metastatic non-small cell lung cancer. The patients in the study were evaluated and a prolonged survival rate of approximately 2 months and improved quality of life with the early palliative care implementation was noted (Temel et al., 2010). “Physicians tend to perceive palliative care as the alternative to life-prolonging or curative care rather than as a simultaneously delivered adjunct to disease-focused treatment” (Kelley & Meier, 2010, p.781).

The study by Temel et al. confirms the beneficial outcomes of a simultaneous care plan in patients who receive palliative care and disease-specific treatments at the initial time of diagnosis (Kelley & Meier, 2010). By identifying a link between early palliative care referral and patient outcomes, healthcare providers will be able to implement early palliative care into their routine practice in order to improve outcomes in patients with metastatic lung cancer.

Little research has been performed on specific elements of palliative care that are provided and received by patients (Kelley & Meier, 2010). By studying the actual components of palliative care that are deemed beneficial, evidence will be established for best medical practice. Palliative care is indicated in various patient populations and should be evaluated in other disease populations and medical facilities in order to assess the benefit of new approaches (Kelley & Meier, 2010).

Problem Statement

Studies have shown that immediate palliative care involvement upon the initial diagnosis of Stage IV metastatic lung cancer patients led to healthcare improvements. Improving quality of life for patients with Stage IV metastatic lung cancer is a significant challenge due to the progressive nature of the disease (Temel et al., 2019). Patients who received early palliative care implementation had improved quality of life, longer life expectancy, and the quality of care in comparison to patients who received later standardized palliative care consults (Temel et al., 2010; Ma et al., 2019).

Purpose

The purpose of the study is to assess the impact and implications of early initiated palliative care consultation on the outcomes of metastatic lung cancer patients at Regions Hospital. The study will determine what effect, if any, does immediate palliative care consults issued by nurse navigators upon the initial diagnosis of Stage IV metastatic lung cancer have on patients. Additional factors among patients in the study will be analyzed statistically to further look at other variables conducive to improved patient outcomes.

Significance of Problem

The study has significance for both current healthcare providers and patients diagnosed with Stage IV metastatic lung cancer. The quality improvement design of the study will allow improvements to be made in healthcare services offered and the overall health status of patients in the studied groups (U.S. Department of Health and Human Resources and Services Administration Editorial Team, 2011). “Physicians tend to perceive palliative care as the alternative to life-prolonging or curative care rather than as a simultaneously delivered adjunct to disease-focused treatment” (Kelley & Meier, 2010, p. 781). The study may encourage Stage IV metastatic lung cancer patients to discuss the

benefits of early palliative care consults with their oncologists. The findings from the study may prompt further research into expanded implementation of immediate palliative care consults in patients with other forms of cancer and chronic terminal illnesses.

Research Question

The following research question will be explored in this study: does an immediate palliative care referral increase palliative care?

Limitations of Study

Delimitations to the study include studying patients with Stage IV metastatic lung cancer at Regions Hospital in St Paul, Minnesota. The study will include patients who received immediate nurse navigator driven palliative care consults upon initial diagnosis and patients who received palliative care consults later in the disease progression under physician discretion in the years 2018 to 2019. These delimitations were set to adequately assess the implications of the new palliative care guidelines set at Regions Hospital in this patient population.

Limitations to the study include the limited time period in which research is obtained, the patient population studied in a very specific location versus a nationwide study including other healthcare facilities implementing the new palliative care guidelines. Researcher bias limitation needs to be evaluated due to the promising literature indicating improved quality of life for patients who do receive the immediate palliative care consults upon initial diagnosis.

Definition of Terms

The following definitions will be used frequently throughout the research paper.

Cancer: “cells growing out of control in the body” (“The American Cancer Society Medical and Editorial Team,” 2019).

Epidemiology: “the branch of medicine dealing with the incidence and prevalence of disease in large populations and with detection of the source and cause in epidemics of infectious disease” (“Epidemiology,” 2019).

Hospice: “A) a health-care facility for the terminally ill that emphasizes pain control and emotional support for the patient and family, typically refraining from taking extraordinary measures to prolong life. B) Similar program of care and support for the terminally ill at home” (“Hospice,” 2019).

Lung cancer: “a type of cancer that originates in the lungs” (“The American Cancer Society Medical and Editorial Team,” 2019).

Metastasis: “the transference of disease-producing organisms or of malignant cancerous cells to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces” (“Metastasis,” 2019).

Non-Small Cell Lung Cancer: “a type of lung cancer that includes adenocarcinoma and squamous cell carcinoma” (“The American Cancer Society Medical and Editorial Team,” 2019).

Palliative Care: “medical care focused on improving the quality of life of patients with serious illness, as by treating symptoms and providing emotional support” (“Palliative care,” 2019).

Conclusion

This chapter covered information about the importance of palliative care in metastatic lung cancer, as well as the purpose and questions of the study. This study will

identify what effect, if any, immediate nurse navigator driven palliative care referrals at the time of diagnosis has on patient outcomes in metastatic lung cancer. The next chapter will review lung cancer sites of metastases, treatment options, palliative care approaches, and research studies correlating with improved patient outcomes.

Chapter 2: Literature Review

Introduction

The following literature review will discuss the impact and implications of early initiated palliative care consultations on the outcomes of metastatic lung cancer patients. The literature review will provide a background into lung cancer itself, discussing the epidemiology, various types, lung cancer metastasis sites, and survival rates of patients. It will also provide a background into what palliative care is, and how immediate palliative care referrals have impacted the healthcare system today.

Lung Cancer

Epidemiology. According to the American Cancer Society (2019a), “lung cancer (both small cell and non-small cell) is the second most common cancer in both men and women” (para. 2). “Lung cancer accounts for about 13% of new cancer cases,” and there is estimated to be “228,150 new cases of lung cancer (116,440 in men and 111,710 in women),” as well as “142,670 deaths from lung cancer (76,650 in men and 66,020 in women)” in 2019 (“The American Cancer Society Medical and Editorial Content Team,” 2019a, para. 3).

The largest cause of cancer related death is lung cancer, which is associated with more deaths than cancers from etiologies of breast, colon, and prostate combined (“The American Cancer Society Medical and Editorial Content Team,” 2019a, para. 4).

Generally, lung cancer occurs in people ages 45 to 70 years old with the vast majority of people being diagnosed ages 65 or greater. Patients diagnosed with lung cancer are, on average, 70 years old (“The American Cancer Society Medical and Editorial Content

Team,” 2019a, para. 5). According to the American Cancer Society (2019a), 1 out of 15 men and 1 out of 17 women will develop lung cancer during their lives (para. 6).

Main Types.

Non-small cell lung cancer. The most common type of lung cancer is non-small cell lung cancer (NSCLC), which presents as 80 to 85% of lung cancer cases (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 9). The three primary subtypes of NSCLC include adenocarcinoma, squamous cell carcinoma, and large cell carcinoma, which have comparable treatment strategies and prognoses (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 9).

Adenocarcinoma. Adenocarcinoma affects lung cells that produce and secrete mucus within the lungs, and it is generally located in the outer lungs (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 10 & 12). This is the most common lung cancer in non-smokers, but it is predominantly found in previous and present smokers (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 11).

Adenocarcinoma “is more common in women than in men, and it is more likely to occur in younger people than other types of lung cancer.... and is more likely to be found before it as spread” according to the American Cancer Society (2019d, para. 11 & 12). Patients diagnosed with adenocarcinoma usually have a better prognosis than patients with other lung cancers (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 13).

Squamous cell carcinoma. Squamous cell carcinoma (SCC) affects the central, inner lining of squamous cells within the airway of the lungs (“The American Cancer

Society Medical and Editorial Content Team,” 2019d, para. 14). In most scenarios, SCC occurs from toxins acquired through smoking (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 14).

Large cell carcinoma. Large cell carcinoma (LCC) is a very fast-growing, undifferentiated cancer that may present anywhere within the lungs (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 15). LCC has the capability to spread rapidly making treatment difficult. For this reason, LCC – although a NSCLC – is comparable to small cell lung cancer (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 15).

Small cell lung cancer. Small cell lung cancer (SCLC) occurs in 10 to 15% of lung cancer cases (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 17). With quick growth and spread – being much faster than NSCLC – SCLC has already spread upon diagnosis in 70% of patients (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 17). Treatment of SCLC through chemotherapy and radiation is generally successful; however, most patients with successful initial treatment of SCLC will recur (“The American Cancer Society Medical and Editorial Content Team,” 2019d, para. 17).

Risk Factors. The most common risk factor for lung cancer resulting in approximately 90% of lung cancer cases and 80% of lung cancer related deaths is tobacco smoking (“The American Cancer Society Medical and Editorial Content Team,” 2019b, para. 4; de Groot, Wu, Carter, & Munden, 2018). People that smoke have a much greater chance of developing lung cancer than non-smokers, and the risk increases to a greater extent the longer and more packs that are smoked. Additionally, cigar and pipe smokers

have a similar likelihood of developing lung cancer compared to cigarette smokers (“The American Cancer Society Medical and Editorial Content Team,” 2019b, para. 5&6).

Secondhand smoke or environmental smoke is another risk factor that increases chances of lung cancer development and causes 7,000+ deaths from lung cancer annually (“The American Cancer Society Medical and Editorial Content Team,” 2019b, para. 7).

Secondhand smoke (SHS) is defined by the involuntary exposure of nonsmokers to tobacco smoke from other individuals smoking (Samet & Sockrider, 2018). SHS contains over 7,000 chemical compounds, 70 of which are known carcinogens. Due to the link of secondhand smoke to lung cancer in nonsmokers, it has been classified as a group A carcinogen (Samet & Sockrider, 2018). Cotinine is the product formed after the chemical nicotine enters the body (Hukkanen, Jacob, & Benowitz, 2005).

Thirdhand smoke (THS) is defined as residual particles of tobacco smoke that settle on surfaces indoors (Jacob et al., 2017). THS clings to clothes, furniture, curtains, walls, bedding, carpet, and vehicles long after the smoking has ceased. THS bound to an object’s surface can persistently affect indoor air quality for days, weeks, and/or months, and provides adequate time for chemical reactions to occur between the THS and normal pollutants in indoor air (Jacob et al., 2017). Thirdhand smoke has become a recent interest in research due to some tobacco specific nitrosamines (TSNAs) with high carcinogenic potential (Jacob et al., 2017).

Other risk factors that may lead to lung cancers include exposures to radon, asbestos, radioactive materials, radiation therapy, arsenic, and air pollution (“The American Cancer Society Medical and Editorial Content Team,” 2019b). Additionally, patients with family histories of lung cancer or with personal previous history of lung

cancer are at a greater risk (“The American Cancer Society Medical and Editorial Content Team,” 2019b, para. 22&23).

Metastases. Metastatic lung cancer is a condition that occurs when cancer cells from an original tumor within the lung spread to other locations in the body. Lung cancer is transmitted throughout the body by vascular and/or lymphatic systems, and generally spreads to the adrenal glands, brain, bones, liver, or contralateral lung. It is possible for other organs to become involved in later disease stages (Popper, 2016).

Due to the asymptomatic and aggressive nature of lung cancer, many of these cancers do not present until metastasizing to stage IV. This makes lung cancer the leading cause of cancer mortality worldwide (Poler, 2003). In 2019, it is projected that nearly 142,670 deaths will occur from lung cancer according to physician researchers Kathryn Arbour and Gregory Riely (2019). Of the presenting lung cancer cases, approximately 85% will be non-small cell lung cancers (NSCLC) (Govindan et al., 2006).

The most recent staging system for lung cancer seen in Table 1 is the eighth edition TNM staging system. The TNM staging system utilizes three descriptive categories which includes tumor characteristics, local lymph node involvement, and distant metastases (Thomas & Gould, 2019). The eighth edition has three further subcategories for those with distant metastases: M1a, M1b and M1c. M1a is assigned to those with metastases confined solely to the thoracic region (Thomas & Gould, 2019). M1b is assigned to those with a single metastasis outside of the thoracic region (Thomas & Gould, 2019). M1c comprises those with multiple extra-thoracic metastases (Thomas & Gould, 2019).

The TNM with M1a, M1b, and M1c criteria are utilized to stage both small cell lung cancer (SCLC) and NSCLC diagnoses (Thomas & Gould, 2019). Metastatic lung

cancer is now classified as either IVA, in which no or a single extra-thoracic metastasis exists, or IVB which involves multiple extra-thoracic metastases (Thomas & Gould, 2019). The IVA/IVB staging system is intended to better reflect disease prognosis and to further guide treatment planning (Thomas & Gould, 2019). Based on eighth edition staging, IVA two-year prognosis is 23% and five-year prognosis is 10% while IVB two-year prognosis is 10% and five-year prognosis is 0% (Thomas & Gould, 2019). The TNM staging system can be found in Appendix A.

Survival Rates. According to the American Lung Association (2019), “the five-year survival rate (18.6 percent) is lower than many other leading cancer sites, such as colorectal (64.5 percent), breast (89.6 percent) and prostate (98.2 percent)” (“American Lung Association Scientific and Medical Editorial Review Panel,” 2019, para. 6). Lung cancer patients with localized disease have a 56% five-year survival rate, but very few cases are diagnosed while the disease is still localized (“American Lung Association Scientific and Medical Editorial Review Panel,” 2019, para. 6). In contrast, patients with metastatic cancer spreading systemically have a 5% five-year survival rate (“American Lung Association Scientific and Medical Editorial Review Panel,” 2019, para. 6). Of the people diagnosed with lung cancer, greater than 50% die within 12 months (“American Lung Association Scientific and Medical Editorial Review Panel,” 2019, para. 6).

Non-Small Cell Lung Cancer Metastases

At the time of diagnosis, “40% of new NSCLC cases have distant metastases” (Yang et al., 2019). In a retrospective study of 1,542 NSCLC patients, distant metastasis was present in 729 patients (Tamura et al., 2015). The most commonly affected sites of metastases in order of prevalence include “bone, lung, brain, adrenal gland, liver and extra-

thoracic lymph node” (Tamura et al., 2015). Metastatic spread in NSCLC often first involves the lymph nodes and in TNM staging is "a powerful prognostic predictor” (Yang et al., 2019).

Nodal involvement is highly associated with multi-organ metastases. NSCLC patients with low nodal involvement (low N scores in the TNM staging system), typically have metastases confined to the thorax (associated with M1a classification) (Yang et al., 2019). With multiple nodes involved, as in N3 classification, patients often have spread of metastases outside of the thoracic region (associated with M1b classification) (Yang et al., 2019).

“Bone metastasis is the most common in patients with lung adenocarcinoma” (Liao, Fan, & Wang, 2019). Bone involvement is believed to adversely affect survival due to the weakening of the skeletal system and associated pathologies including “pathological fractures, spinal cord compression and hypercalcemia of malignancy” (Tamura et al., 2015). Treatment for bone metastases includes systemic chemotherapy, radiation therapy for localized bone lesions, or surgery to prevent and treat pathological fractures (Lilenbaum, 2019). Average overall survival of those with bone metastases was five months (Liao et al., 2019).

Over the course of the disease, “brain metastases will develop in approximately 25% to 50% of patients with NSCLC with 10% to 20% of them having [brain metastases] when the disease is first diagnosed” (Khalifa, Amini, Popat, Gaspar, & Faivre-Finn, 2016). Patients who develop brain metastases after diagnosis will do so within two years of diagnosis (Dempke et al., 2015). Traditional treatment options for brain metastases include surgery, whole-brain radiation therapy in combination with steroid therapy, and

systemic chemotherapy (Dempke et al., 2015). However, many of these options are limited due to the nature of brain involvement (Dempke et al., 2015).

Brain metastases have been correlated with poor performance status, which disqualifies many individuals from surgical treatment (Dempke et al., 2015). Whole brain radiotherapy when added to surgical treatment exhibits effective local control, however no improvements were noted in overall survival for NSCLC (Khalifa et al., 2016). Systemic chemotherapy also has limitations in efficacy for brain metastases (Dempke et al., 2015). Systemic chemotherapy agents have general poor blood brain barrier penetration, with only a 15% to 30% brain metastasis response rate depending on agent used (Dempke et al., 2015).

Newer targeted therapies are promising with higher intracranial activity, but further study is necessary to determine improved outcomes in overall survival (Dempke et al., 2015). Brain metastases resulting from NSCLC overall adversely affect quality of life and survival, with the median overall survival being three to 15 months (Khalifa et al., 2016). Metastases to the liver are an unfavorable factor in NSCLC prognosis (Tamura et al., 2015). Chemotherapy agents used in the treatment of NSCLC are not properly metabolized or activated by a liver containing cancerous metastases (Tamura et al., 2015).

Therefore, liver metastases typically do not respond well to systemic chemotherapy (Tamura et al., 2015). Liver dysfunction resulting from metastases may disqualify NSCLC from continued chemotherapy use (Tamura et al., 2015). When comparing isolated organ metastasis for most commonly afflicted metastatic sites, stage IV NSCLC patients with “liver metastasis alone had the worst prognosis, with a median overall survival of four months” (Liao et al., 2019).

Small Cell Lung Cancer Metastases

Most patients with SCLC have extensive-stage disease at the time of presentation, characterized by distant metastasis with possible pleural effusions or lymph node involvement on the contralateral side (Kelly, 2018). The most common sites for metastasis in SCLC include the liver, adrenal glands, bone and bone marrow, and brain (Glisson & Byers, 2019). Metastatic involvement of the bone marrow can be detected in up to 30% of asymptomatic patients (Glisson & Byers, 2019). Bone marrow involvement is also present in 15% to 30% of patients at presentation (Glisson & Byers, 2019); however, only 2% to 6% of patients have bone marrow as a solitary site of metastasis (Glisson & Byers, 2019).

Brain metastases are found in 15% of patients at diagnosis, including those without symptoms (Glisson & Byers, 2019). Brain involvement in SCLC is often associated with a poorer prognosis; metastases to the brain tend to be numerous and distributed throughout all areas of the brain (Loeffler, 2018). Prognosis for specific metastatic sites is challenging to determine due to confounding variables of multiple metastatic sites (Glisson & Byers, 2019). However, increasing number of organs involved is correlated with worse prognosis and involvement of brain, bone marrow and the liver are considered unfavorable prognostic factors (Glisson & Byers, 2019).

The main therapy for all patients with extensive-stage SCLC is systemic chemotherapy with or without added radiation therapy (Kelly, 2018), regardless of metastatic sites. The clinical decision to add radiation therapy is for palliative rather than curative therapy (Glisson & Byers, 2019). Despite a high response to both therapy options, SCLC relapse is common within months (Kelly, 2018). The average survival for extensive-

stage SCLC is eight to 13 months from time of diagnosis, with less than 5% of patients surviving past two years (Kelly, 2018).

Background of Palliative Care

Approaches. When caring for chronically ill patients and discussing end of life care, it is imperative to understand the difference between palliative care and hospice. Palliative care is defined as an interdisciplinary medical specialty that aims to optimize quality of life for patients with serious, life-limiting illnesses and their families (Rhee, Mchugh, Tun, Gerhart, & O’Mahony, 2014; Kelley & Morrison, 2015; Kelley & Meier, 2010). Palliative care is provided as an adjunct with curative therapies and life-prolonging medical treatments (Kelley & Meier, 2010). In order to meet the needs of seriously ill patients, the palliative care team includes medical professionals from physicians, nursing, social work, nutrition, rehabilitation, pharmacy, and chaplains (Kelley & Morrison, 2015).

“Hospice care becomes appropriate when curative treatments are no longer beneficial, when burdens of treatments exceed the benefits, or when patients are entering the last weeks to months of life” (Kelley & Meier, 2010, p.781). In 1967, Dame Cicely Saunders developed hospice in hopes of creating a care plan for patients dying from advanced cancer (Kelley & Morrison, 2015). Patients qualify for hospice when they have been given a diagnosis of six months or less to live and elect to discontinue restorative treatments (Kelley & Morrison, 2015). Table 2, from “Palliative Care for the Seriously Ill,” compares palliative care and hospice by looking at the model of care, patients who are eligible for each program, the location in which each program is implemented, and reimbursement factors (Kelley & Morrison, 2015).

Table 2***Palliative care versus hospice (Kelley & Morrison, 2015, p. 748)***

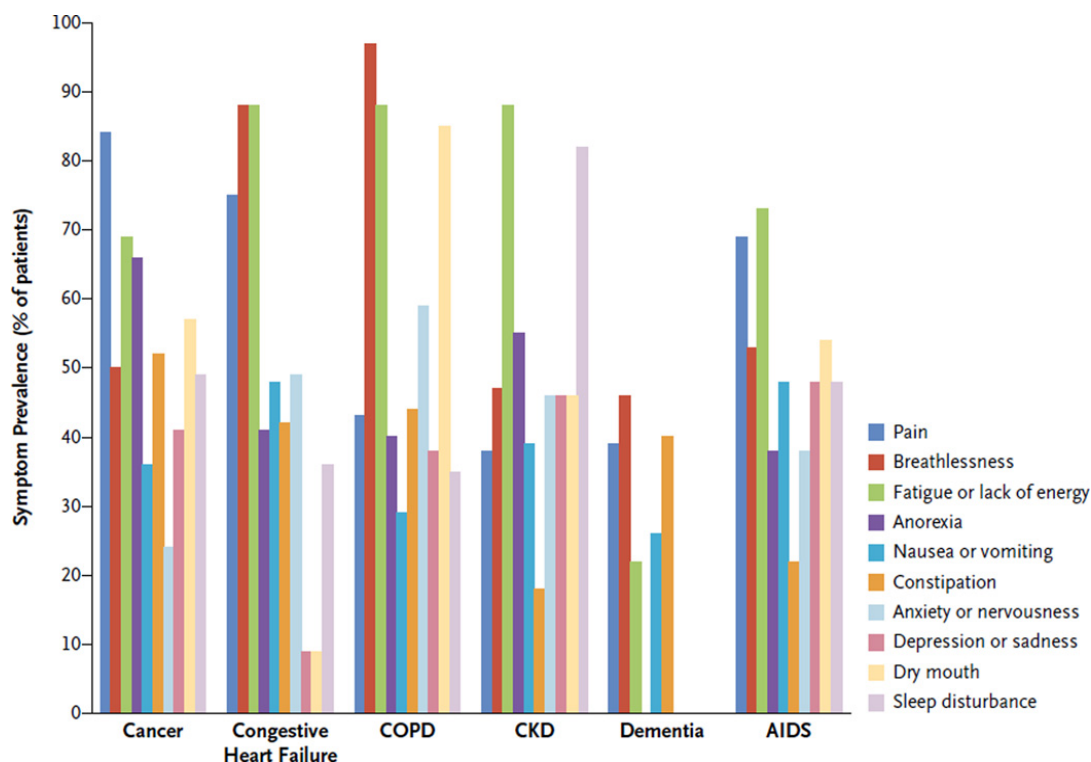
Characteristic	Palliative Care	Hospice
Model of care	Interdisciplinary team, including physicians, nurses, social workers, chaplains, and staff from other disciplines as needed; primary goal is improved quality of life	Interdisciplinary team, including physicians, nurses, social workers, chaplains, and volunteers, as dictated by statute; primary goals are improved quality of life and relief of suffering (physical, emotional, and spiritual)
Eligibility	Patients of all ages and with any diagnosis or stage of illness; patients may continue all life-prolonging and disease-directed treatments	Patients of all ages who have a prognosis of survival of ≤ 6 mo, if the disease follows its usual course; patients must forgo Medicare coverage for curative and other treatments related to terminal illness
Place	Hospitals (most common), hospital clinics, group practices, cancer centers, home care programs, or nursing homes	Home (most common), assisted-living facilities, nursing homes, residential hospice facilities, inpatient hospice units, or hospice-contracted inpatient beds
Payment	Physician and nurse practitioner fees covered by Medicare Part B for inpatient or outpatient care; hospital teams are included within Medicare Part A or commercial insurance payments to hospitals for care episodes; flexible bundled payments under Medicare Advantage, Managed Medicaid, ACOs, and other commercial payers	Medicare hospice benefit; standard hospice benefit from commercial payers is usually modeled after Medicare; Medicaid, although coverage varies by state; medication costs are included for illnesses related to the terminal illness

Components. Several core components that all palliative care plans encompass, include treatment of physical and psychological symptoms, spiritual support, and communication skills to provide goals of healthcare (Kelley & Morrison, 2015). Primary care physicians are trained to address all of the core components, allowing for the complicated cases to be addressed by palliative care specialists (Kelley & Morrison, 2015). Most primary clinicians, however, have not had formal training in palliative care topics.

Physical symptoms commonly associated with palliative care patients include pain, dyspnea, cough, anorexia, and fatigue (Chandrasekar, Tribett, & Ramchandran, 2016). Routine clinical histories, review of systems, and primary assessment used to identify such symptoms lead to enhanced patient comfort (Blinderman & Billings, 2015). Figure 1 shows the wide variety of symptoms present in chronic illnesses and the prevalence of each symptom based on the diagnosis of the patient (Kelley & Morrison, 2015).

Figure 1

Symptoms comparison in advanced illnesses (Kelley & Morrison, 2015, p. 749)



Evidence suggests that most patients suffering from chronic illnesses wish to express their spirituality concerns with their physicians (Kelley & Morrison, 2015). Several studies have shown a correlation between improved quality of life in cancer patients whose spiritual needs were recognized (Kelley & Morrison, 2015; Nawawi et al., 2012). A study based on survey results asked advanced lung cancer patients to classify the importance of seven factors that contributed to their decisions regarding medical treatment (Nawawi, Balboni, & Balboni, 2012). “Patients’ faith in God was considered by patients and their caregivers to be a key factor in medical decision-making- ranked only second behind the ability of the treatment to cure disease” (Nawawi et al., 2012, p. 270). When asked about roles in addressing spiritual concerns of patients, less than 50% of physicians considered it an important part of healthcare (Kelley & Morrison, 2015).

Communication among providers and patients has been studied extensively in the past decade. Palliative care requires communication of serious news, prognosis uncertainty, discussing treatment options, and establishing overall goals of care. “Clinical studies have shown the use of NURSE (naming, understanding, respecting, supporting, and exploring) have improved effective communication regarding empathy of care” (Kelley & Morrison, 2015, p. 750). Prospective cohort studies assessing patients with stage IV cancer who actively discussed care plan goals with their physician show evidence of a decreased incidence of mortality in an ICU (Kelley & Morrison, 2015).

Delivery Modes. Palliative care in the United States is traditionally utilized in acute care hospitals (Kelley & Morrison, 2015). Within a decade, palliative care programs have amplified by approximately 150% (Kelley & Morrison, 2015). Ninety percent of larger hospitals containing 300+ beds, in addition to 67% of hospitals with 50 beds currently have palliative care programs (Kelley & Morrison, 2015). In acute care hospitals, interdisciplinary teams address palliative care needs. Current changes in delivery models include automatic palliative care referrals for patients requiring both a palliative care team and another specialty team, such as oncology (Kelley & Morrison, 2015). Community based palliative care is traditionally thought of as hospice programs. Hospice programs are available to patients choosing to discontinue therapeutic treatment after prognosis of six months or less to live (Kelley & Morrison, 2015).

Community based palliative care programs are now being utilized to benefit chronically ill patients who do not qualify for hospice (Kelley & Morrison, 2015). After the Affordable Care Act (ACA) was passed, many private payers and Medicare patients have taken advantage of community-based palliative care programs to help reduce

healthcare costs and improve quality of life (Kelley & Morrison, 2015). The community palliative care team continue to use an interdisciplinary team and focus on symptom management and caregiver support at home (Kelley & Morrison, 2015). Even though the community-based palliative care idea is fairly new, randomized clinical trials have shown patients with chronic illnesses gain increased symptom management, greater satisfaction scores, and reduced hospitalization rates (Kelley & Morrison, 2015).

Lastly, long-term care encompasses a vast need for palliative care teams. Nearly 1.8 million United States citizens reside in nursing homes (Kelley & Morrison, 2015). “More than 25% of elderly persons die in nursing homes, 67% of persons with advanced dementia live their final days in this setting” (Kelley & Morrison, 2015, p.751). Three models of palliative care utilized in nursing home settings, including hospice care, palliative care consultation from an external source, and internal palliative care teams that work specifically in the nursing home (Kelley & Morrison, 2015).

Nursing homes and hospice agencies can form agreements to provide services to residents when appropriate (Kelley & Morrison, 2015). “Hospice utilization in nursing homes is associated with higher family satisfaction, decreased rates of invasive therapies, and better symptom management” (Kelley & Morrison, 2015, p. 752). The palliative care consultation model is one which a palliative care physician consults nursing home physicians; which is billed under Medicare Part B (Kelley & Morrison, 2015). Internal palliative care teams in nursing homes are specifically utilized with residents diagnosed with advanced stage dementia (Kelley & Morrison, 2015).

Challenges. “Physicians tend to perceive palliative care as the alternative to life-prolonging or curative care rather than as a simultaneously delivered adjunct to disease-

focused treatment” (Kelley & Meier, 2010, p.781). The scope of palliative care teams ranges from institution to institution and some lack integral elements, like social work and chaplains (Rhee et al., 2014). This challenge is further exaggerated by the specific palliative care team and practice approach, that can be drastically different depending on the healthcare facility (Ma et al., 2019; Rhee et al., 2014). Furthermore, palliative care teams are often nonexistent in rural community hospitals (Rhee et al., 2014). Currently, it is estimated that for every 1,300 patients diagnosed with a chronic illness, there is one palliative care physician available (Rhee et al., 2010).

Each year, nearly 300 hospital and palliative care fellows graduate; yet the number of palliative care physicians is not enough to meet the demands necessary within the healthcare system (Rhee et al., 2014). Medical programs are actively trying to address this shortage by integrating primary palliative care into curriculums. The curriculum would include pain management, care goal discussions, the delivery of unfortunate news to patients and families, which would allow primary physicians to address basic palliative care needs (Rhee et al., 2010).

Early Palliative Care Implementation

Metastatic Non-Small Cell Lung Cancer. Former research has indicated the benefit of early palliative care. In one such study, the effect of early palliative care on quality of life and end of life care was examined in patients newly diagnosed with metastatic, non-small cell lung cancer (Temel et al., 2010). A group of 151 participants diagnosed within the past eight weeks with metastatic NSLC were selected from Massachusetts General Hospital in Boston and randomly placed into two different groups (Temel et al., 2010).

The control group received only standard oncologic care, while the intervention group received early palliative care in addition to standard oncologic care (Temel et al., 2010). Standard oncologic care was not determined by the study. The intervention group received at least one palliative care visit per month with additional visits scheduled if requested by the patient, oncologist or palliative care team (Temel et al., 2010). Palliative care guidelines were adapted from the National Consensus Project for Quality Palliative Care and the specific care provided was documented in electronic medical records (Temel et al., 2010). Of the care provided, physical and psychosocial symptom assessments, assistance with treatment decisions, determining care goals, and coordinating care based on the needs of each patient were evaluated (Temel et al., 2010).

To determine the effect of early palliative care on quality of life, researchers utilized the Functional Assessment of Cancer Therapy-Lung (FACT-L) scale to assess physical, emotional, social and functional wellness (Temel et al., 2010). The Hospital Anxiety and Depression scale was used to assess for changes in mood (Temel et al., 2010). Both the control and intervention group completed the FACT-L and Hospital Anxiety and Depression assessments at the start of the study and again at 12 weeks into the study (Temel et al., 2010). To analyze end of life care, researchers obtained data from medical records (Temel et al., 2010).

The results of the study at the 12-week assessment showed when patients received additional early palliative care versus standard oncologic care alone, depression scores were lower (16% versus 38%) and quality of life was improved (FACT-L score of 98 versus 91.5) (Temel et al., 2010). Higher median survival rates were also seen in the

intervention group with median survival being 11.6 months as compared to 8.9 months for the control group (Temel et al., 2010).

Medical Intensive Care Unit. The study conducted by Ma et al. (2019) in two medical intensive care units (ICUs) at Barnes Jewish Hospital in St. Louis, Missouri was groundbreaking in evaluating early palliative care consultations in high-risk ICU patients. The purpose of this study was to determine the impact of early triggered palliative care consultation on the outcomes of high-risk ICU patients (Ma et al., 2019). “Patients 18 years and older consecutively admitted on weekdays to the MICUs were screened for study enrollment using a tool comprised of nine predetermined palliative care criteria to identify patients at high risk for morbidity and mortality based on severe or chronic organ dysfunction” (Ma et al., 2019, p. 2).

There were 242 patients that met the study’s baseline criteria, including 117 patients in the intervention group and 116 patients in the control group (Ma et al., 2019). The control group consisted of patients receiving palliative care consultations at the discretion of the MICU physicians (Ma et al., 2019). The intervention group consisted of patients that received palliative care consults within 48 hours of admission to the ICU (Ma et al., 2019). The interprofessional palliative care team at Barnes Jewish Hospital was made up of a palliative care physician, nurse practitioners, a fellow specializing in palliative care, social workers, and a chaplain (Ma et al., 2019).

The patients in the intervention group were followed by this palliative care team until they were discharged (Ma et al., 2019). The consultations provided by the palliative care team addressed various issues regarding the patients’ care. This included a “chart review of the patient’s hospitalization, meeting with the patient and available healthcare

proxies, identification of physical and emotional needs of the patient and family, discussion with the primary team on how best to meet those needs, and communication between all parties with respect to goals, values, and treatment decisions” (Ma et al., 2019, p. 3).

The primary outcome evaluated from the Ma et al. (2019) study was the number of patients in the ICU who changed their code status to do not resuscitate (DNR)/ do not intubate (DNI). The patients in the intervention group (50.5%) that changed code statuses to DNR/DNI was significantly higher than that of the control group (23.4%) (Ma et al., 2019). Secondary outcomes were also evaluated among the patients, assessing “ICU length of stay, discharge to hospice care, days on the ventilator, tracheostomy placement, CPR, mortality, post discharge ER visits, and hospital readmission rates” (Ma et al., 2019, p. 4-6).

There was no significant difference between the intervention and control group in hospital mortality, ICU length of stay, or 30-day mortality (Ma et al., 2019). Statistically significant variations between the intervention and control group included transfer to hospice care (18.6%-intervention vs 4.9%-control), tracheostomy placement (1.0%-intervention vs 7.8%- control), and overall MICU operating costs (\$9,860-intervention vs \$15,660- control) (Ma et al., 2019). While this study was conducted in a single healthcare facility, it serves as an integral approach with early palliative care intervention in ICU high-risk patient populations (Ma et al., 2019).

Conclusion

The current literature reveals that early implementation of palliative care consults in Stage IV metastatic lung cancer patients can improve quality of life, overall life

expectancy, and the quality of care in comparison to patients who received later standardized palliative care consults (Temel et al., 2010; Ma et al., 2019). While the studies conducted by Temel et al. (2010) and Ma et al. (2019) show statistically significant variables in the intervention groups who received early palliative care consults, there is little research done on specific elements of palliative care that are provided and received by patients.

By studying the actual components of palliative care that are deemed beneficial, evidence will be established for best medical practice. With modification of the study design, additional factors among patients will be analyzed statistically to further look at other variables conducive to improved patient outcomes. This study may encourage Stage IV metastatic lung cancer patients to discuss the benefits of early palliative care consults with their oncologists. The findings from the study may prompt further research into expanded implementation of immediate palliative care consults in patients with other forms of cancer and chronic terminal illnesses.

Chapter 3: Methods

Introduction

The purpose of the study is to assess the impact and implications of early initiated palliative care consultation on the outcomes of metastatic lung cancer patients at Regions Hospital. Additional factors among patients in the study will be analyzed statistically to further look at other variables conducive to improved patient outcomes. The research question that will be addressed in this study include the following: to what effect, if any, does immediate palliative care consults issued upon the initial diagnosis of Stage IV metastatic lung cancer have on patient anxiety, sadness, pain, narcotic need, and cancer treatments at one and six months?

Study Design

The study design is a quality improvement project that will allow improvements to be made in healthcare services offered and the overall health status of patients in the studied groups. A group of participants will be identified based on pre-existing criteria, in this case, patients diagnosed with Stage IV metastatic lung cancer. Data will be collected retrospectively from electronic medical records regarding Regions Hospital Stage IV metastatic lung cancer patients with palliative care referrals in the past two years.

The population will be studied retrospectively from January 2019-August 2019 when patients were referred to palliative care per oncologist preference in timing compared to August 2019-March 2020 when new patients received nurse navigator driven palliative care referrals immediately upon diagnosis. Approval to access deidentified data from Regions Hospital was obtained and can be found in Appendix B.

Data analysis will include sorting data into an Excel spreadsheet based on patients' age, ethnicity, interpreter need, claim of a religion, type of lung cancer (small cell or non-small cell), brain metastasis, number of comorbidities (chronic obstructive pulmonary disease, congestive heart failure, dialysis, depression, anxiety, vascular disease, cardiovascular disease), baseline ECOG performance status, baseline pain severity, and baseline narcotic need, as well as baseline and six month patient reported outcome measures (PROMs) (Appendix C) responses regarding the severity of anxiety, sadness, pain, narcotic need and dyspnea. The researchers will be looking for correlations in patterns within both groups of patients and their outcomes based on the palliative care referral. The Excel spreadsheet with outcomes analyzed can be found in Appendix D.

Study Site

The participants were selected from Regions Hospital oncology clinic in St. Paul, Minnesota. This location was chosen as they had recently implemented a program of nurse navigator driven immediate palliative care referrals for patients with Stage IV metastatic lung cancer. Participants were selected based on their diagnosis of Stage IV metastatic lung cancer. A letter of intent for research affiliation with Regions Hospital and Dr. Peter Hurley can be found in Appendix E.

Population

Participants were required to be age eighteen or greater and could be any gender and any ethnicity. Inclusion criteria includes patients who were diagnosed with Stage IV metastatic lung cancer prior to the early palliative care initiation period, and patients who were diagnosed with Stage IV metastatic lung cancer after the early palliative care initiation was implemented at Regions Hospital. The appropriate Internal Review Board

(IRB) measures were taken to gain permission from Region's and Bethel to perform the quality improvement project. The Region's IRB approval is in Appendix F and Bethel IRB approval in Appendix G.

Criteria for exclusion were those patients who did not receive a diagnosis of Stage IV metastatic lung cancer, patients not treated at Regions Hospital after diagnosis of Stage IV metastatic lung cancer, and those with other forms of Stage IV cancer, not including specifically lung cancer. In order to detect a significant difference with a standard deviation of two, at least 50 subjects are needed for each group analyzed. The subjects will be studied retrospectively from January 2019-August 2019 when patients were referred to palliative care per oncologist preference in timing compared to August 2019-March 2020 when new patients received palliative care referrals placed by nurse navigators immediately upon diagnosis. The total study subject goal is 100 chart reviews consisting of 50 from each group in which data was analyzed using the excel spreadsheet tool.

Instrument and Procedure

The study's researchers developed the Excel spreadsheet used to collect experimental data. The spreadsheet tool will be reviewed to determine whether it is all encompassing to complete the goals of evaluating the target population. The panel of reviewers will include one physician who works regularly with the target population, and one quality improvement physician. After review, the spreadsheet will be edited to meet all suggestions to achieve appropriate readability.

Data Analysis

The data collected from Regions Hospital will be analyzed using either MANOVA, individualized t tests, or a MANCOVA test. Analysis will include correlational studies

and trend analysis comparing the time of palliative care referral with patient outcomes measured through the severity of patient anxiety, sadness, and pain, as well as narcotic need and treatment received at one, three, and six months. The quantitative data will be organized into tables and charts to determine other significant trends in patient demographics within each group.

Reliability and Validity

Since all subject charts will be analyzed using the same spreadsheet, every measurement will be consistent and could be reproduced; it will therefore be reliable. A panel of reviewers will evaluate the spreadsheet for validity, further enhancing the reliability of the research instrument. Demographic data about the patients will be collected, allowing for population-related external validity.

Dispensation of Data

The collected data will be transferred to a hard drive and placed in the possession of the Bethel University Physician Assistant Program research coordinator. The data will be stored in a secure, locked space. Data will be destroyed in accordance with the policies of the Physician Assistant Program.

Limitations and Delimitations

Delimitations to the study include studying patients with Stage IV metastatic lung cancer at Regions Hospital in St. Paul, Minnesota. The study will include patients who received nurse navigator driven immediate palliative care consults upon initial diagnosis in August 2019 through March 2020 and patients who received palliative care consults later in the disease progression under physician discretion between January 2019 and August

2019. These delimitations were set to adequately assess the implications of the new palliative care guidelines set at Regions Hospital in this patient population.

Limitations to the study include the limited time period in which research is obtained, the patient population studied in a very specific location versus a nationwide study including other healthcare facilities implementing the new palliative care guidelines. Researcher bias limitation needs to be evaluated due to the promising literature indicating improved quality of life for patients who do receive the immediate palliative care consults upon initial diagnosis.

Conclusion

In conclusion, this study was performed to examine the effects of immediate palliative care referrals upon diagnosis on the severity of anxiety, sadness, and pain in patients with Stage IV metastatic lung cancer, as well as narcotic need and treatments received. This was done by comparing measured outcomes in patients referred to palliative care by oncologist preference with those referred immediately by nurse navigators upon diagnosis. The intent of the study was to collect, analyze, and compare measured outcomes between the two groups. The collected data and analysis will be reviewed in the following chapters.

Chapter 4: Results

Introduction

Chapter four contains the results of data analysis. Data is organized according to two main participant groups: Group 1 (patient population studied retrospectively from January 2019-August 2019 with palliative care referrals per oncologist discretion of timing) compared to group 2 (patient population studied retrospectively from September 2019-March 2020 with palliative care referrals driven by a nurse navigator immediately upon diagnosis). Correlations for each group are presented regarding treatment dates, ethnicity, and gender.

Statistical Analysis

Statistical analyses were performed using JASP, a statistical software to determine correlations between the groups and variables collected. The quantitative data was organized into tables and charts to determine other significant trends in patient demographics – which included treatment dates, ethnicity, and gender – within each group. Each statistical analysis performed revealed high p-values when comparing variables which is shown in the tables below.

As seen in **Table 3**, there was no significant difference between treatment dates and palliative care referrals. This indicates that palliative care referrals placed under physician discretion versus driven by a nurse navigator did not improve the number of immediate palliative care referrals for patients with Stage IV metastatic lung cancer. The correlation between palliative care referrals placed for patients of white and non-white ethnicities was statistically analyzed in **Table 4**, which reveals that there is no significant difference in palliative care referrals placed for patients with different ethnicities.

Legend:

- 1: patient population studied January 2019-August 2019 (palliative care referrals per oncologist discretion)
- 2: patient population studied September 2019-March 2020 (palliative care referrals per nurse navigator immediately upon diagnosis)
- 3: male gender
- 4: female gender

Table 3*Comparison between treatment dates and palliative care referral***Contingency Tables**

Treatment Dates		Palliative Care Referral (Y=1, N=2)		
		No	Yes	Total
1	Count	28.000	31.000	59.000
	Expected count	28.320	30.680	59.000
	% within row	47.458 %	52.542 %	100.000 %
2	Count	20.000	21.000	41.000
	Expected count	19.680	21.320	41.000
	% within row	48.780 %	51.220 %	100.000 %
Total	Count	48.000	52.000	100.000
	Expected count	48.000	52.000	100.000
	% within row	48.000 %	52.000 %	100.000 %

Chi-Squared Tests

	Value	df	p
X ²	0.017	1	0.896
N	100		

There is no significant difference between treatment dates and palliative care referral, χ^2 (df=1, N = 100) = 0.017, $p = 0.896$. 1 correlates with patients from January 2019 through August 2019. 2 correlates with September 2019 to March 2020.

Table 4*Comparison between ethnicity and palliative care referral***Contingency Tables**

Ethnicity		Palliative Care Referral (Y=1, N=2)		
		No	Yes	Total
Non-White	Count	10.000	13.000	23.000
	Expected count	11.152	11.848	23.000
	% within row	43.478 %	56.522 %	100.000 %
White	Count	38.000	38.000	76.000
	Expected count	36.848	39.152	76.000
	% within row	50.000 %	50.000 %	100.000 %

Contingency Tables

Ethnicity		Palliative Care Referral (Y=1, N=2)		
		No	Yes	Total
Total	Count	48.000	51.000	99.000
	Expected count	48.000	51.000	99.000
	% within row	48.485 %	51.515 %	100.000 %

Chi-Squared Tests		
	Value df	p
X ²	0.301 1	0.583
N	99	

There is no significant difference between ethnicity and palliative care referral, χ^2 (df=1, N = 99) = 0.301, $p = 0.583$.

Table 5 and **Table 6** demonstrate that there was no significant difference between treatment date and length of palliative care referral from diagnosis. Early palliative care referral within 30 days of diagnosis occurred in 35.593 percent of patients in group 1 under physician discretion compared to 39.024 percent of patients in group 2 under nurse navigator driven referral. Data analysis for this study determined that palliative care referrals did not significantly occur more immediately through a nurse navigator in group 2 versus by physician discretion in group 1. However, as seen in **Table 6** the length of palliative care referral trended toward a shorter mean through a nurse navigator compared to by physician discretion, 49.810 days compared to 81.000 days, respectively.

Table 5
Comparison between treatment dates and length of palliative care referral from diagnosis

Contingency Tables

Treatment Date		Length of Palliative Care Referral from Diagnosis (Categories)			Total
		None	Early (<30 days)	Late (>30 days)	
1	Count	28.000	21.000	10.000	59.000
	Expected count	28.320	21.830	8.850	59.000

Contingency Tables

Treatment Date		Length of Palliative Care Referral from Diagnosis (Categories)			Total
		None	Early (<30 days)	Late (>30 days)	
2	% within row	47.458 %	35.593 %	16.949 %	100.000 %
	Count	20.000	16.000	5.000	41.000
	Expected count	19.680	15.170	6.150	41.000
Total	% within row	48.780 %	39.024 %	12.195 %	100.000 %
	Count	48.000	37.000	15.000	100.000
	Expected count	48.000	37.000	15.000	100.000
	% within row	48.000 %	37.000 %	15.000 %	100.000 %

Chi-Squared Tests

	Value	df	p
X ²	0.450	2	0.798
N	100		

There is no significant difference between treatment date and length of palliative care referral from diagnosis, χ^2 (df=1, N = 100) = 0.450, $p = 0.798$.

Table 6

Independent samples t-test, test of equality variances, and group descriptives for length of palliative care referral from diagnosis between groups 1 and 2

Independent Samples T-Test

	t	df	p	Cohen's d
Length of Palliative Care Referral from Diagnosis (Days)	1.024	50.000	0.311	0.289

Assumption Checks

Test of Equality of Variances (Levene's)

	F	df	p
Length of Palliative Care Referral from Diagnosis (Days)	2.877	1	0.096

Group Descriptives

	Group N	Mean	SD	SE	
Length of Palliative Care Referral from Diagnosis (Days)	1	31	81.000	128.665	23.109

Group Descriptives

	Group	N	Mean	SD	SE
	2	21	49.810	65.027	14.190

There was no significant difference between the length of palliative care referral from diagnosis for group 1 ($M = 81.0$) and group 2 ($M = 49.81$), $t(50) = 1.024$, $p = 0.311$, $d = 0.289$.

Table 7 includes data analyzing gender and palliative care referral. This data was collected to determine if either male or female gender impacted patient likelihood of palliative care referral independent from treatment date group. Of the 54 males and 46 females included in this study, 51.852 percent of males and 52.174 percent of females received palliative care referrals. Statistical analysis demonstrates that there was no significant difference between gender and palliative care referrals, indicating gender did not impact receipt of palliative care referral.

Table 7***Comparison between gender and palliative care referral*****Contingency Tables**

		Palliative Care Referral (Y=1, N=2)		
		No	Yes	Total
3	Gender (F=4, M=3)			
	Count	26.000	28.000	54.000
	Expected count	25.920	28.080	54.000
	% within row	48.148 %	51.852 %	100.000 %
4	Count	22.000	24.000	46.000
	Expected count	22.080	23.920	46.000
	% within row	47.826 %	52.174 %	100.000 %
Total	Count	48.000	52.000	100.000
	Expected count	48.000	52.000	100.000
	% within row	48.000 %	52.000 %	100.000 %

Chi-Squared Tests

Contingency Tables

Gender (F=4, M=3)	Palliative Care Referral (Y=1, N=2)			Total
	No	Yes		
	Value	df	p	
X ²	0.001	1	0.974	
N	100			

There is no significant difference between gender and palliative care referral, χ^2 (df = 1, N = 100) = 0.001, $p = 0.974$.

Additional data was collected and analyzed to determine if there was a significant difference in length of palliative care referral from diagnosis between male and female gender. This data is summarized in **Table 8** and **Table 9**. Of the 100 patients included in this study, 33.333 percent of males and 41.304 percent of females received early palliative care referrals within 30 days of diagnosis. Statistical analysis demonstrates that there was no significant difference between male or female gender and length of palliative care referral from diagnosis. This indicates that gender did not impact likelihood of receiving early palliative care referral within 30 days of diagnosis.

Table 8

Comparison between gender and length of palliative care referral from diagnosis

Contingency Tables

Gender (F=4, M=3)		Length of Palliative Care Referral from Diagnosis (Categories)			Total
		None	Early (<30 days)	Late (>30 days)	
3	Count	26.000	18.000	10.000	54.000
	Expected count	25.920	19.980	8.100	54.000
	% within row	48.148 %	33.333 %	18.519 %	100.000 %
4	Count	22.000	19.000	5.000	46.000

Contingency Tables

Gender (F=4, M=3)		Length of Palliative Care Referral from Diagnosis (Categories)			Total
		None	Early (<30 days)	Late (>30 days)	
Total	Expected count	22.080	17.020	6.900	46.000
	% within row	47.826 %	41.304 %	10.870 %	100.000 %
	Count	48.000	37.000	15.000	100.000
	Expected count	48.000	37.000	15.000	100.000
	% within row	48.000 %	37.000 %	15.000 %	100.000 %

Chi-Squared Tests

	Value	df	p
X ²	1.396	2	0.498
N	100		

There is no significant difference between gender and length of palliative care referral from diagnosis, χ^2 (df = 2, N = 100) = 1.396, $p = 0.498$.

Table 9

Independent samples t-test, test of equality variances, and group descriptives for length of palliative care referral from diagnosis between groups 3 and 4

Independent Samples T-Test

	t	df	p	Cohen's d
Length of Palliative Care Referral from Diagnosis (Days)	0.514	50.000	0.610	0.143

Assumption Checks

Test of Equality of Variances (Levene's)

	F	df	p
Length of Palliative Care Referral from Diagnosis (Days)	0.121	1	0.729

Group Descriptives

	Group	N	Mean	SD	SE
Length of Palliative Care Referral from Diagnosis (Days)	3	28	75.571	118.390	22.374
	4	24	60.042	95.970	19.590

There was no significant difference between the length of palliative care referral from diagnosis for group 3 ($M = 75.571$) and group 4 ($M = 60.042$), $t(50) = 0.514$, $p = 0.610$, $d = 0.143$.

Conclusion

Statistical results from the data analysis were included in this chapter. The small sample size of our groups, in addition to limited patient reported outcome responses, made analysis of the variables difficult for the demographics of treatment dates, ethnicity, and gender between palliative care referrals and length of palliative care referrals. Chapter 5 will include an interpretation and conclusion of the study results from Chapter 4.

Chapter 5: Conclusion

Introduction

With the growing amount of evidence indicating the promise in early palliative care implementation, not only in metastatic lung cancer patients, but in all patients with chronic disease states, this research project served to analyze what effect, if any, does immediate palliative care consults issued by nurse navigators upon the initial diagnosis of Stage IV metastatic lung cancer have on patients? Based on studies that linked early palliative care implementation to improved outcomes regarding survival rate, quality of life, and code status transition (Temel et al., 2010; Ma et al., 2019), this study anticipated that the PROMs surveys completed by patients would reveal a significant difference between the two groups in regard to patient reported outcomes of pain, anxiety, and narcotic need. Additional factors among patients in the study, including gender and ethnicity, were analyzed statistically to further look at other variables conducive to improved patient outcomes. The following research question is addressed in this section; does a nurse navigator driven palliative care referral increase palliative care?

Summary of Results

Based on the collected data, it was found that nurse navigator driven palliative care referral did not increase palliative care received by patients diagnosed with Stage IV metastatic lung cancer. There was no statistically significant difference in the number of patients who received palliative care between those who received referral based on oncologist discretion and those who received a nurse navigator driven referral at the time of diagnosis. Additionally, there was no statistically significant difference found between the two groups for the length of time it took to receive palliative care referral from the time

of diagnosis. Demographic variables were analyzed to determine if any differences in palliative care referral existed among patients of different gender or ethnicity. For each of these variables, no significant difference was found for receiving palliative care referral.

The results demonstrating no difference in the number of patients who received palliative care between the two groups receiving palliative care referrals immediately from nurse navigators versus physician timed referrals were not as expected, which was disappointing due to promising literature that was previously reviewed. The Temel et al study assessed the quality of life and mood of patients diagnosed with metastatic non-small cell lung cancer at baseline and again at 12 weeks. They utilized the Functional Assessment of Cancer Therapy-Lung (FACT-L) scale and the Hospital Anxiety and Depression Scale to evaluate these factors. Participants assigned to the early initiated palliative care group had higher FACT-L scores, indicating higher quality of life ($P=0.03$) and fewer depressive symptoms ($P=0.01$) than those receiving standardized palliative care at the discretion of physicians (Temel et al., 2010). Overall, early initiation of palliative care in metastatic non-small cell lung cancer patients resulted in prolongation of life by about 2 months, improved quality of life, and less depressive mood symptoms (Temel et al., 2010).

Interpretation of our study findings suggest oncologist determined palliative care referral was optimized prior to the implementation of nurse navigator driven referral. Additional interpretation of results indicates the nurse navigator driven referral system was not a truly automatic referral system as there was no statistically significant difference found between the two groups for the length of time it took to receive palliative care referral from the time of diagnosis. Furthermore, the results indicated that delivery of

palliative care for each group was independent of demographic variables. However, it is important to note that this study involved both a limited sample size and limited time frame of study in addition to a limited number of PROMs surveys to evaluate and statistically analyze the data. Further research involving a larger sample size is therefore necessary to determine the validity of these results, as well as implementing a more automatic system for both palliative care referrals and PROMs survey completion.

Due to the limited number of PROMs surveys completed by patients diagnosed with Stage IV metastatic lung cancer, there is not a correlation with the literature review regarding patient outcomes as it remains unclear what effect nurse navigator driven palliative care referrals had on patient outcomes measured through anxiety, pain, narcotic need, and treatment. An attempt to determine quality of life measures through the PROMs survey was made; however, there was not enough data to make a determination due to the limited number of completed surveys. Further research requiring completion of the PROMs surveys is needed to determine any significant differences that may exist between the two groups for these outcome measures.

Literature review did reveal previous studies that have shown that immediate palliative care involvement upon the initial diagnosis of Stage IV metastatic lung cancer patients led to healthcare improvements. Patients who received early palliative care implementation had improved quality of life, longer life expectancy, and the quality of care in comparison to patients who received later standardized palliative care consults (Temel et al., 2010; Ma et al., 2019). Little research has been performed on specific elements of palliative care that are provided and received by patients (Kelley & Meier, 2010). By studying the actual components of palliative care that are deemed beneficial, evidence will

be established for best medical practice. Palliative care is indicated in various patient populations and should be evaluated in other disease populations and medical facilities in order to assess the benefit of new approaches (Kelley & Meier, 2010).

Limitations

Limitations to the study include utilizing a nurse navigator driven palliative care referral instead of a completely automatic palliative care referral. Despite efforts by nurse navigators, palliative care referrals were not 100% automatic for patients diagnosed with Stage IV metastatic lung cancer. Furthermore, a limited number of patient reported outcome measures (PROMs) surveys were completed by patients diagnosed with and being treated for Stage IV metastatic lung cancer requiring palliative care referrals. The unavailability of all the patients' PROMs surveys from lack of completion by patients resulted in an incomplete study with little data for statistical analysis.

Other limitations to note include the limited time period in which research was obtained, the patient population studied in a very specific location versus a nationwide study including other healthcare facilities implementing the new palliative care guidelines. The study was performed in a single hospital with a specific group of oncologists and palliative care providers, which limits comparison to other locations and different types of chronic illnesses that would benefit from palliative care. Additionally, researcher bias needs to be evaluated due to the promising literature indicating improved quality of life for patients who do receive the immediate palliative care consults upon initial diagnosis.

Recommendations for Further Research

If this study were repeated, the researchers recommend a larger sample size consisting of more varied demographic groups. Ideally, each demographic group would

have approximately the same number of participants to avoid results that are weighted toward one specific chronic illness. This may prompt further research into expanded implementation of immediate palliative care consults in patients with other forms of cancer and chronic terminal illnesses.

Additionally, results could be improved if patients were required to fill out the PROMs surveys at monthly appointments to indicate if nurse navigator driven palliative care referrals increase palliative care at Region's Hospital. This could be improved if PROMs surveys were administered for patients to fill out during their initial intake with nursing staff at appointments similar to administering a Patient Health Questionnaire-9 (PHQ-9) survey prior to an annual physical appointment. The PROMs surveys could be uploaded immediately into the electronic medical record (EMR) by nursing staff allowing for greater patient completion of the survey. This would allow for baseline outcomes to be compared with outcomes once initiating the automatic palliative care referral system.

Another consideration for future research includes the implementation of automatic palliative care referrals through EMR systems at the time of diagnosis rather than utilizing nurse navigator driven referrals. Automatic palliative care referrals would allow a truly immediate palliative care referral that could only be missed with malfunctioning of the EMR software system utilized by the hospital. If working properly through the EMR, automatic palliative care referrals would ensure consistency in referral placement for all patients at the time of diagnosis.

Conclusions

This was a quality improvement project that will allow improvements to be made in healthcare services offered and the overall health status of Stage IV metastatic lung cancer

patients receiving palliative care referrals. Data was collected retrospectively from electronic medical records of Stage IV metastatic lung cancer patients with palliative care referrals between January 2019 and March 2020. The palliative care referrals between January 2019 and August 2019 were given per oncologist discretion in timing compared to August 2019-March 2020 when new patients received nurse navigator driven palliative care referrals immediately upon diagnosis. Data analysis looked at correlations for each group as presented regarding treatment dates, ethnicity, and gender. An attempt to determine quality of life measures through the PROMs survey was made; however, there was not enough data to make a determination due to the limited number of completed surveys.

This study found that nurse navigator driven palliative care referrals did not increase palliative care received by patients diagnosed with Stage IV metastatic lung cancer. There was no significant difference between palliative care patients receiving a referral based on oncologist discretion versus receiving referrals through a nurse navigator; therefore, the effect of immediate palliative care referrals upon initial diagnosis on the severity of anxiety, sadness, and pain in patients with Stage IV metastatic lung cancer, as well as narcotic need, and treatments received is indeterminate.

Literature review did reveal previous studies that have shown that immediate palliative care involvement upon the initial diagnosis of Stage IV metastatic lung cancer patients led to healthcare improvements. Patients who received early palliative care implementation had improved quality of life, longer life expectancy, and the quality of care in comparison to patients who received later standardized palliative care consults (Temel et al., 2010; Ma et al., 2019). Little research has been performed on specific elements of

palliative care that are provided and received by patients (Kelley & Meier, 2010). By studying the actual components of palliative care that are deemed beneficial, evidence will be established for best medical practice. Palliative care is indicated in various patient populations and should be evaluated in other disease populations and medical facilities in order to assess the benefit of new approaches (Kelley & Meier, 2010).

In conclusion, there was no difference in palliative care referrals placed by physician discretion versus those driven by nurse navigators. In order to improve this process, we would suggest a new system that would require patients willing to complete PROMs surveys to fill out the survey at monthly appointments to indicate if nurse navigator driven palliative care referrals increase palliative care. This could be improved if PROMs surveys were administered to patients during their initial intake with nursing staff at appointments. The PROMs surveys could be completed in the electronic medical record (EMR) directly or uploaded immediately by the nurses, allowing for greater completion of the survey. This would allow for baseline outcomes to be compared with outcomes once initiating the automatic palliative care referral system. Additionally, implementation of automatic palliative care referrals through EMR at the time of diagnosis could be utilized instead of nurse navigator driven referrals. Once these suggestions have been made, an additional quality improvement project could be initiated to analyze Stage IV metastatic lung cancer patients' quality of life with early implemented palliative care.

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Appendix A – Table 1: TNM staging (8th edition)**Table 1**

TNM staging system (“The American Cancer Society Medical and Editorial Content Team,” 2019c)

AJCC Stage	Stage grouping	Stage description*
Occult (hidden) cancer	TX	The main tumor can’t be assessed for some reason, or cancer cells are seen in a sample of sputum or other lung fluids, but the cancer isn’t found with other tests, so its location can’t be determined (TX). The cancer is not thought to have spread to nearby lymph nodes (N0) or to distant parts of the body (M0).
	N0	
	M0	
0	Tis	The tumor is found only in the top layers of cells lining the air passages, but it has not invaded deeper into other lung tissues (Tis). The cancer has not spread to nearby lymph nodes (N0) or to distant parts of the body (M0).
	N0	
	M0	
IA1	T1mi	The cancer is a minimally invasive adenocarcinoma . The tumor is no larger than 3 centimeters (cm) across, and the part that has invaded into deeper lung tissues is no more than ½ cm across. The cancer has not spread to nearby lymph nodes (N0) or to distant parts of the body (M0).
	N0	
	M0	OR
	T1a	The tumor is no larger than 1 cm across, it has not reached the membranes that surround the lungs, and it does not affect the
	N0	

	M0	main branches of the bronchi (T1a). The cancer has not spread to nearby lymph nodes (N0) or to distant parts of the body (M0).
IA2	T1b N0 M0	The tumor is larger than 1 cm but no larger than 2 cm across. It has not reached the membranes that surround the lungs, and it does not affect the main branches of the bronchi (T1b). The cancer has not spread to nearby lymph nodes (N0) or to distant parts of the body (M0).
IA3	T1c N0 M0	The tumor is larger than 2 cm but no larger than 3 cm across. It has not reached the membranes that surround the lungs, and it does not affect the main branches of the bronchi (T1c). The cancer has not spread to nearby lymph nodes (N0) or to distant parts of the body (M0).
IB	T2a N0 M0	The tumor has one or more of the following features (T2a): <ul style="list-style-type: none"> • It is larger than 3 cm but not larger than 4 cm across. • It has grown into a main bronchus but is not within 2 cm of the carina (the point where the windpipe splits into the left and right main bronchi) and it is not larger than 4 cm across. • It has grown into the visceral pleura (the membranes surrounding the lungs) and is not larger than 4 cm across.

		<ul style="list-style-type: none"> It is partially clogging the airways (and is not larger than 4 cm across). <p>The cancer has not spread to nearby lymph nodes (N0) or to distant parts of the body (M0).</p>
IIA	T2b N0 M0	<p>The tumor has one or more of the following features (T2b):</p> <ul style="list-style-type: none"> It is larger than 4 cm but not larger than 5 cm across. It has grown into a main bronchus but is not within 2 cm of the carina (the point where the windpipe splits into the left and right main bronchi) and it is larger than 4 cm but not larger than 5 cm across. The tumor has grown into the visceral pleura (the membranes surrounding the lungs) and is larger than 4 cm but not larger than 5 cm across. The tumor is partially clogging the airways (and is larger than 4 cm but not larger than 5 cm across). <p>The cancer has not spread to nearby lymph nodes (N0) or to distant parts of the body (M0).</p>
	T1a/T1b/T1c N1 M0	<p>The tumor is no larger than 3 cm across, has not grown into the membranes that surround the lungs, and does not affect the main branches of the bronchi (T1). It has spread to lymph nodes within the lung and/or around the area where the bronchus enters the lung (hilar lymph nodes). These lymph nodes are on</p>

IIB		the same side as the cancer (N1). The cancer has not spread to distant parts of the body (M0).
	OR	
	T2a/T2b N1 M0	<p>The tumor has one or more of the following features (T2):</p> <ul style="list-style-type: none"> • It is larger than 3 cm but not larger than 5 cm across. • It has grown into a main bronchus, but is not within 2 cm of the carina (the point where the windpipe splits into the left and right main bronchi) and it is not larger than 5 cm across. • It has grown into the visceral pleura (the membranes surrounding the lungs) and is not larger than 5 cm. • It is partially clogging the airways (and is not larger than 5 cm). <p>The cancer has also spread to lymph nodes within the lung and/or around the area where the bronchus enters the lung (hilar lymph nodes). These lymph nodes are on the same side as the cancer (N1). The cancer has not spread to distant parts of the body (M0).</p>
	OR	
T3 N0	<p>The tumor has one or more of the following features (T3):</p> <ul style="list-style-type: none"> • It is larger than 5 cm but not larger than 7 cm across. 	

	M0	<ul style="list-style-type: none"> • It has grown into the chest wall, the inner lining of the chest wall (parietal pleura), the phrenic nerve, or membranes of the sac surrounding the heart (parietal pericardium). • There are 2 or more separate tumor nodules in the same lobe of a lung. <p>The cancer has not spread to nearby lymph nodes (N0) or distant parts of the body (M0).</p>
IIIA	T1a/T1b/T1c N2 M0	<p>The cancer is no larger than 3 cm across, has not grown into the membranes that surround the lungs, and does not affect the main branches of the bronchi (T1). The cancer has spread to lymph nodes around the carina (the point where the windpipe splits into the left and right bronchi) or in the space between the lungs (mediastinum). These lymph nodes are on the same side as the main lung tumor (N2). The cancer has not spread to distant parts of the body (M0).</p>
	OR	
	T2a/T2b N2 M0	<p>The tumor has one or more of the following features (T2):</p> <ul style="list-style-type: none"> • It is larger than 3 cm but not larger than 5 cm across. • It has grown into a main bronchus, but is not within 2 cm of the carina (the point where the windpipe splits

		<p>into the left and right main bronchi) and it is not larger than 5 cm across.</p> <ul style="list-style-type: none"> • It has grown into the visceral pleura (the membranes surrounding the lungs) and is not larger than 5 cm. • It is partially clogging the airways (and is not larger than 5 cm). <p>The cancer has spread to lymph nodes around the carina (the point where the windpipe splits into the left and right bronchi) or in the space between the lungs (mediastinum). These lymph nodes are on the same side as the main lung tumor (N2). The cancer has not spread to distant parts of the body (M0).</p>
OR		
	<p>T3 N1 M0</p>	<p>The tumor has one or more of the following features (T3):</p> <ul style="list-style-type: none"> • It is larger than 5 cm but not larger than 7 cm across. • It has grown into the chest wall, the inner lining of the chest wall (parietal pleura), the phrenic nerve, or membranes of the sac surrounding the heart (parietal pericardium). • There are 2 or more separate tumor nodules in the same lobe of a lung. <p>The cancer has also spread to lymph nodes within the lung and/or around the area where the bronchus enters the lung (hilar</p>

		lymph nodes). These lymph nodes are on the same side as the cancer (N1). The cancer has not spread to distant parts of the body (M0).
	OR	
	<p style="text-align: center;">T4</p> <p style="text-align: center;">N0 or N1</p> <p style="text-align: center;">M0</p>	<p>The tumor has one or more of the following features (T4):</p> <ul style="list-style-type: none"> • It is larger than 7 cm across. • It has grown into the space between the lungs (mediastinum), the heart, the large blood vessels near the heart (such as the aorta), the windpipe (trachea), the tube connecting the throat to the stomach (esophagus), the thin muscle separating the chest from the abdomen (diaphragm), the backbone, or the carina. • There are 2 or more separate tumor nodules in different lobes of the same lung. <p>The cancer may or may not have spread to lymph nodes within the lung and/or around the area where the bronchus enters the lung (hilar lymph nodes). Any affected lymph nodes are on the same side as the cancer (N0 or N1). The cancer has not spread to distant parts of the body (M0).</p>
	<p>T1a/T1b/T1c</p> <p style="text-align: center;">N3</p> <p style="text-align: center;">M0</p>	<p>The cancer is no larger than 3 cm across, has not grown into the membranes that surround the lungs, and does not affect the main branches of the bronchi (T1). The cancer has spread to</p>

IIIB		lymph nodes near the collarbone on either side of the body, and/or has spread to hilar or mediastinal lymph nodes on the other side of the body from the main tumor (N3). The cancer has not spread to distant parts of the body (M0).
	OR	
	T2a/T2b N3 M0	<p>The tumor has one or more of the following features (T2):</p> <ul style="list-style-type: none"> • It is larger than 3 cm but not larger than 5 cm across. • It has grown into a main bronchus, but is not within 2 cm of the carina (the point where the windpipe splits into the left and right main bronchi) and it is not larger than 5 cm across. • It has grown into the visceral pleura (the membranes surrounding the lungs) and is not larger than 5 cm. • It is partially clogging the airways (and is not larger than 5 cm). <p>The cancer has spread to lymph nodes near the collarbone on either side of the body, and/or has spread to hilar or mediastinal lymph nodes on the other side of the body from the main tumor (N3). The cancer has not spread to distant parts of the body (M0).</p>
	OR	
	T3	The tumor has one or more of the following features (T3):

	<p>N2</p> <p>M0</p>	<ul style="list-style-type: none"> • It is larger than 5 cm but not larger than 7 cm across. • It has grown into the chest wall, the inner lining of the chest wall (parietal pleura), the phrenic nerve, or membranes of the sac surrounding the heart (parietal pericardium). • There are 2 or more separate tumor nodules in the same lobe of a lung. <p>The cancer has spread to lymph nodes around the carina (the point where the windpipe splits into the left and right bronchi) or in the space between the lungs (mediastinum). These lymph nodes are on the same side as the main lung tumor (N2). The cancer has not spread to distant parts of the body (M0).</p>
OR		
	<p>T4</p> <p>N2</p> <p>M0</p>	<p>The tumor has one or more of the following features (T4):</p> <ul style="list-style-type: none"> • It is larger than 7 cm across. • It has grown into the space between the lungs (mediastinum), the heart, the large blood vessels near the heart (such as the aorta), the windpipe (trachea), the tube connecting the throat to the stomach (esophagus), the thin muscle separating the chest from the abdomen (diaphragm), the backbone, or the carina (the point

		<p>where the windpipe splits into the left and right main bronchi).</p> <ul style="list-style-type: none"> • There are 2 or more separate tumor nodules in different lobes of the same lung. <p>The cancer has spread to lymph nodes around the carina (the point where the windpipe splits into the left and right bronchi) or in the space between the lungs (mediastinum). These lymph nodes are on the same side as the main lung tumor (N2). The cancer has not spread to distant parts of the body (M0).</p>
<p>IIIC</p>	<p>T3 N3 M0</p>	<p>The tumor has one or more of the following features (T3):</p> <ul style="list-style-type: none"> • It is larger than 5 cm but not larger than 7 cm across. • It has grown into the chest wall, the inner lining of the chest wall (parietal pleura), the phrenic nerve, or membranes of the sac surrounding the heart (parietal pericardium). • There are 2 or more separate tumor nodules in the same lobe of a lung. <p>The cancer has spread to lymph nodes near the collarbone on either side of the body, and/or has spread to hilar or mediastinal lymph nodes on the other side of the body from the main tumor (N3). The cancer has not spread to distant parts of the body (M0).</p>

OR	
T4 N3 M0	<p>The tumor has one or more of the following features (T4):</p> <ul style="list-style-type: none"> • It is larger than 7 cm across. • It has grown into the space between the lungs (mediastinum), the heart, the large blood vessels near the heart (such as the aorta), the windpipe (trachea), the tube connecting the throat to the stomach (esophagus), the thin muscle separating the chest from the abdomen (diaphragm), the backbone (spine), or the carina (the point where the windpipe splits into the left and right main bronchi). • There are 2 or more separate tumor nodules in different lobes of the same lung. <p>The cancer has spread to lymph nodes near the collarbone on either side of the body, and/or has spread to hilar or mediastinal lymph nodes on the other side of the body from the main tumor (N3). The cancer has not spread to distant parts of the body (M0).</p>
IVA	<p>The cancer can be any size and may or may not have grown into nearby structures (any T). It may or may not have reached nearby lymph nodes (any N). In addition, any of the following is true (M1a):</p>

		<ul style="list-style-type: none"> • The cancer has spread to the other lung. • Cancer cells are found in the fluid around the lung (called a malignant pleural effusion). • Cancer cells are found in the fluid around the heart (called a malignant pericardial effusion).
	OR	
	<p>Any T</p> <p>Any N</p> <p>M1b</p>	<p>The cancer can be any size and may or may not have grown into nearby structures (any T). It may or may not have reached nearby lymph nodes (any N). It has spread as a single tumor outside of the chest, such as to a distant lymph node or an organ such as the liver, bones, or brain (M1b).</p>
IVB	<p>Any T</p> <p>Any N</p> <p>M1c</p>	<p>The cancer can be any size and may or may not have grown into nearby structures (any T). It may or may not have reached nearby lymph nodes (any N). It has spread as more than one tumor outside the chest, such as to distant lymph nodes and/or to other organs such as the liver, bones, or brain (M1c).</p>

Note: *The following additional categories are not listed in the table above:

- **T0:** There is no evidence of a primary tumor.
- **NX:** Nearby lymph nodes cannot be assessed due to lack of information.

Appendix B – Regions Hospital permission to access data

From: Bellefy, Rebecca R
Sent: Wednesday, November 06, 2019 10:43 AM
To: 'erin-hamar@bethel.edu'; 'megan-biegler@bethel.edu'; 'stephanie-spinolo@bethel.edu'
Cc: Hurley, Peter J
Subject: Welcome to Your PA QI-Research Student Rotation

Welcome! We are excited to have you start your PA research project with Oncology rotation at Regions Hospital. Your orientation will be on **Wed. November 13th, 2019**.

The following information will guide you through your first day and provide important information for a successful rotation. Please note that you will also receive another email a few weeks before your rotation with additional details of your schedule.

Parking

On your first day, please park in the West parking ramp located on Jackson St. Enter the ramp on Jackson at 14th St. and park on Level F or G (top floor). Please bring your parking ticket with you to have it validated. After your first day, you will be assigned to the Robert Street Ramp, located on the corner of Robert St. and University Ave. Student parking is \$10.00 per calendar month. You must bring cash or a check to pay for a student parking pass. Make sure to have your car information with you (license plate number, make and model).

Your first day

Please come to the Internal Medicine Education office at **3:30 p.m. on November 13th**. Our office is located on the 7th floor of the Central Building, Room C7379. Follow the signs for the Central Building when you enter the hospital from the West parking ramp. We are the office immediately to your left as you step off the Central elevator. I'll go over the following:

- Help get your parking arranged.
- Help get your Regions Hospital badge.
- Take you on a tour to see the location of:
 - o Regions Hospital Auditorium (where you'll go for IM Grand Rounds), 3rd Floor East – every Weds., from 12-1
 - o Student/ Resident Training Room (where you'll go to attend Medical Student Lectures), Room S2221 – over the noon hour most days (I'll show you where the schedule is located)
 - o Cafeteria and coffee shop
 - o Check your Epic access to make sure you can access the system.
 - o Review Amion.com (logon: regions) to show you how to page someone.
- After we're done, I'll take you up to the Library for you to begin your QI – Research Project.

Important information for your rotation at Regions Hospital

- Dress code is business casual (no jeans). If you have a white coat, we ask that students wear their white coat.

EPIC Training

An Epic Training Packet is attached for your reference.

Actions for You

- Flu Shot: You are required to report your influenza vaccination status. Bring your completed form with you, so I can give you an orange clip for your badge to show you have been vaccinated.

- We have an online tool that we use for capturing information about your rotation at Regions Hospital, called New Innovations (NI). This tool helps to track students' information and clinical hours at HealthPartners/ Regions Hospital over time.

- To log into NI, go to the website: www.new-innov.com. Then click on the "Client Login" button in the upper right corner. From here you will see a log-in screen where you will enter the information above to get logged in. You will be directed to reset your password. Then, you will be directed to your home page where you will see a link to your Onboarding Checklist.

- As you know, Dr. Hurley will be your lead preceptor and is the person who should sign your Student Packet (explained and included in your Onboarding Checklist). His email address is: Peter.J.Hurley@HealthPartners.Com

If you should have any questions, please feel free to contact me.

Looking forward to meeting you in person!

Attachment: Epic Training Packet
Regions Map
Flu Vaccine Form & Schedule

Best Regards,

Rebecca R. Bellefy

Program Associate

[Office of Health Professional Education](#)

Regions Hospital, 640 Jackson Street | MS: 11107E | St. Paul, MN, 55101

Office: 651-254-3486 | Fax: 651-254-3662

Appendix C – Regions oncology department patient reported outcome measures (PROM)

MyCareOutcomesSurvey

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As individuals go through treatment for their cancer they sometimes experience different symptoms and side effects. For each question, please check or mark an X in the one box that best describes your experiences over the past 7 days...

Date of Data Entry _____

Name of person who entered survey data _____

1. In the last 7 days, how OFTEN did you have NAUSEA?

Never Rarely Occasionally Frequently Almost Constantly

In the last 7 days, what was the SEVERITY of your NAUSEA at its WORST?

None Mild Moderate Severe Very Severe

2. In the last 7 days, what was the SEVERITY of your CONSTIPATION at its WORST?

None Mild Moderate Severe Very Severe

3. In the last 7 days, how OFTEN did you have PAIN?

Never Rarely Occasionally Frequently Almost Constantly

In the last 7 days, what was the SEVERITY of your PAIN at its WORST?

None Mild Moderate Severe Very Severe

In the last 7 days, how much did PAIN INTERFERE with your usual or daily activities?

Not at all A little bit Somewhat Quite a bit Very Much

4. In the last 7 days, how OFTEN did you have TEMPERATURES 100.4 DEGREES or higher?

Never Rarely Occasionally Frequently Almost Constantly

5. In the past 7 days, what was the SEVERITY of your BLEEDING (nosebleeds, bruising, blood in stool) at its WORST?

None Mild Moderate Severe Very Severe

6. In the past 7 days, what was the SEVERITY of your FATIGUE, TIREDNESS, OR LACK OF ENERGY at its WORST?

None Mild Moderate Severe Very Severe

Confidential

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In the last 7 days, were you able to carry out your everyday physical activities (walking, climbing stairs, carrying groceries, or moving a chair)?

Not at all A little bit Somewhat Quite a bit Very Much

7. In the past 7 days, what was the SEVERITY of NUMBNESS OR TINGLING IN YOUR HANDS OR FEET at its worst?

None Mild Moderate Severe Very Severe

In the last 7 days, how much did NUMBNESS OR TINGLING IN YOUR HANDS OR FEET INTERFERE with your usual or daily activities?

Not at all A little bit Somewhat Quite a bit Very Much

8. In the past 7 days, what was the SEVERITY of your SHORTNESS of BREATH at its worst?

None Mild Moderate Severe Very Severe

In the last 7 days, how much did SHORTNESS OF BREATH INTERFERE with your usual or daily activities?

Not at all A little bit Somewhat Quite a bit Very Much

9. In the past 7 days, what was the SEVERITY of your COUGH at its worst?

None Mild Moderate Severe Very Severe

In the last 7 days, how much did COUGH INTERFERE with your usual or daily activities?

Not at all A little bit Somewhat Quite a bit Very Much

10. In the last 7 days, how OFTEN did you have ARM OR LEG SWELLING

Never Rarely Occasionally Frequently Almost Constantly

In the last 7 days, what was the SEVERITY of your ARM OR LEG SWELLING at its WORST?

None Mild Moderate Severe Very Severe

In the last 7 days, how much did ARM OR LEG SWELLING INTERFERE with your usual or daily activities?

Not at all A little bit Somewhat Quite a bit Very Much

11. In the past 7 days, how often did you experience a DECREASE in EATING AND DRINKING?

Never Rarely Occasionally Frequently Almost Constantly

In the last 7 days, how much did DECREASED EATING AND DRINKING INTERFERE with your usual or daily activities?

Not at all A little bit Somewhat Quite a bit Very Much

12. In the last 7 days, how often did you have LOOSE or WATERY STOOLS (Diarrhea)?

Confidential

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Never Rarely Occasionally Frequently Almost Constantly

13. In the last 7 days, what was the SEVERITY of your Mouth or Throat Sores at their worst?

None Mild Moderate Severe Very Severe

In the last 7 days, how much did your mouth sores interfere with your usual or daily activities?

Not at all A little bit Somewhat Quite a bit Very Much

14. In the last 7 days, how OFTEN did you have a HEADACHE?

Never Rarely Occasionally Frequently Almost Constantly

In the last 7 days, what was the SEVERITY of your HEADACHE at its WORST?

None Mild Moderate Severe Very Severe

In the last 7 days, how much did your HEADACHE INTERFERE with your usual or daily activities?

Not at all A little bit Somewhat Quite a bit Very Much

15. In the last 7 days, how OFTEN did you have FEEL ANXIETY?

Never Rarely Occasionally Frequently Almost Constantly

In the last 7 days, what was the SEVERITY of your ANXIETY at its WORST?

None Mild Moderate Severe Very Severe

Confidential

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Not at all A little bit Somewhat Quite a bit Very Much

18. In the past 7 days, what was the SEVERITY of your INSOMNIA (difficulty falling asleep, staying asleep, or waking up early) at its WORST?

None Mild Moderate Severe Very Severe

In the last 7 days, how much did INSOMNIA (difficulty falling asleep, staying asleep, or waking up early) INTERFERE with your usual or daily activities?

Not at all A little bit Somewhat Quite a bit Very Much

19. In the past 7 days, how often did you have concerns about your satisfaction with your sex life and intimacy with your partner?

Never Rarely Occasionally Frequently Almost Constantly

20. In the past 7 days, how often did you have concerns about your financial or legal wellbeing?

Never Rarely Occasionally Frequently Almost Constantly

21. How often do you have concerns about transportation to your appointments?

Never Rarely Occasionally Frequently Almost Constantly

22. How often do you have legal concerns or legal questions?

Never Rarely Occasionally Frequently Almost Constantly

Appendix E – Research advisory agreement

COMMITTEE REQUEST FORM
Bethel University Physician Assistant Program

Student Name(s): Megan Biegler Date: 11/1/2019
Stephanie Spinolo
Erin Hamar

Area of Interest for Graduate research:
Oncology

I agree that as a part of the research advisory committee I will act as a consultant to the students in the design, implementation and interpretation of students' research. As a committee member I acknowledge my responsibilities in reviewing the research proposal and attending both the proposal and final oral defense and approving the final research project.

Committee Member Name: Pete Hurley (Pete Hurley)

Appendix F – Regions Hospital IRB approval form

March 10, 2020

Regions Hospital Oncology

RE: Immediate Palliative Care Involvement in Metastatic Lung Cancer

This letter is to inform you that the HealthPartners Institute Research Subjects Protection Program (RSPP) Office has reviewed your request for a determination of human subjects research for the above referenced project.

The Office has determined that this project is a quality improvement initiative and does not meet the definition of Human Subjects Research (45 CFR 46.102(d)). Therefore, no additional IRB review or oversight is required at this time.

If the design of this project changes such that you or others at HealthPartners may be conducting research with human subjects, then please contact the RSPP Office to review these changes prior to implementation.

If you have any questions regarding this communication, please contact me at 952-967-5025 or Amy.A.Fehrer@HealthPartners.Com. Thank you.

Sincerely,

Amy Fehrer, MPH

Senior Manager, Research Subjects Protection Program

HealthPartners Institute

Appendix G – Bethel University IRB approval form

May 7, 2020

Erin, Megan, & Stephanie;

As granted by the Bethel University Human Subjects committee as the program director, I write this letter to you in approval of Level 3 Bethel IRB of your project entitled: "Immediate Palliative Care Involvement in Metastatic Lung Cancer." This approval is good for one year from today's date. You may proceed with data collection and analysis. Please let me know if you have any questions.

Sincerely;

Wallace Boeve, EdD, PA-C
Program Director
Physician Assistant Program
Bethel University
w-boeve@bethel.edu
[651 308-1398](tel:6513081398) cell
[651 635-1013](tel:6516351013) office
[651 635-8039](tel:6516358039) fax
<http://gs.bethel.edu/academics/masters/physician-assistant>

CC: Bethel IRB Chair, Craig Paulson
Faculty Chair Advisor, Wallace Boeve
PA Program Research Coordinator, Lisa Naser