PILOTING A SELF-REPORTED SYMPTOM ASSESSMENT TOOL IN THREE
OUTPATIENT ONCOLOGY PALLIATIVE CARE CLINICS AT NC CANCER HOSPITAL

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A project submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice in the Doctor of Nursing Practice Program in the School of Nursing.

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ABSTRACT

Mallikaben Patel: Piloting a Self-Reported Symptom Assessment Tool in Three Outpatient Oncology Palliative Care Clinics at NC Cancer Hospital
(Under the direction of Ashley Bryant)

Objective: Describe the process of implementing Edmonton Symptom Assessment System -Revised (ESAS-r) with single-item quality of life (ESAS-r + 1 QoL) form into the three Oncology Clinics for all Outpatient Oncology Palliative Care (OOPC) patients.

Background: Literature supports the high symptom burden experienced by oncology palliative care patients due to disease process and treatment side effects. Despite this, symptoms are often not screened sufficiently or consistently in the outpatient oncology palliative care setting.

Aim Statement: The pilot project will help recognize barriers and facilitators to incorporating ESAS-r + 1 QoL form before implementing into the routine practice.

Methods: To assess effective implementation of ESAS-r + 1 QoL form at each OOPC visit, four consecutive Plan-Do-Study-Act (PDSA) three-week cycles were performed. At the end of each PDSA cycle, barrier and facilitators were recognized by the DNP student and changes were made. The pilot project structure was based on the RE-AIM framework.

Results: Effectiveness of the implementation was determined by percentage of adherence using following formula [(number of Esas-r +1 QoL forms completed per clinic / Number of OOPC completed patient appointments per clinic) X100]. A total of 372 patient appointments were completed during the pilot period, with overall 59% compliance to completing the ESAS-r

+1 QoL form. The first PDSA cycle compliance was 69%, 58% in second PDSA cycle, 52% in third PDSA cycle, and 65% in fourth PDSA cycle.

Conclusion: We were able to implement ESAS-r + 1 QoL form in the complex clinical setting. Because of turnover in staff, we identified some barriers for sustainability. This will include robust instructions that provide a brief overview of the clinic workflow and education for all staff members involved in the implementation process. For future directions, we recommend integrating this form into the electronic medical record for monitoring of patient outcomes.

To the patient whose overwhelming symptoms related to their cancer diagnosis or its treatment has changed how I view symptom management forever, this work is dedicated to you.

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LIST OF ABBREVIATIONS

ASCO	American Society of Clinical Oncology
CMA	Certified Medical Assistant
CMS	Center for Medicare and Medicaid Services
EORTC-QLQ	European Organization for Research of the Treatment of Cancer – quality of life questionnaires with C30 and C15-PAL (Palliative Care)
eRAPID	Electronic Patient Self-Reported of Adverse-events: Patient information and advice
ESAS-r	The Edmonton Symptom Assessment System-revised
FACIT-Pal	The Functional Assessment of Chronic Illness Therapy – Palliative Care
FACT-G	The Functional Assessment of Cancer Therapy – General
HRQoL	Health related quality of life
iPEHOC	The Improving Patient Experience and Health Outcome Collaborative
IRB	Institutional Review Board
IT	Information technology
MQOL & MQOL-R	McGill Quality of Life Questionnaire and Revised
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute
NRC	Nursing Research Council
NSCLC	Non-small-cell lung cancer
OPCQoL	The Oncology Palliative Care Quality of Life Questionnaire
PC	Palliative Care
POS	The Palliative Care Outcome Scale
QODD	Quality of Death and Dying
QoL	Quality of Life

QUAL-E	The Quality of Life at the End of Life
RE-AIM	The Reach, Effectiveness, Adoption, Implementation, and Maintenance
UNC-OOPC	UNC Outpatient Oncology Palliative Care

CHAPTER 1: INTRODUCTION

Problem Introduction

The American Cancer Society (ACS) has estimated that 1.8 million new cancer cases occurred in 2020 and 606,520 cancer-related deaths in the United States (US) (American Cancer Society, n.d.). Although advancements in cancer treatments has allowed for patients to live longer, the burden of symptoms such as nausea, pain, depression, and nutritional imbalance remains for these patients. To address these burdens, clinicians increasingly turn to palliative care (PC), which the World Health Organization (WHO) palliative care as an approach to improve the quality of life (QoL) of patients and their caregivers through the prevention and treatment of suffering by means of early identification, assessment, and treatment of physical, psychological, and spiritual problems (WHO, n.d.). To help aid this early identification of symptoms, patient-reported outcomes (PROs) are essential. The Food and Drug Administration (FDA) define PROs as “any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else” (U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research, 2006) patient. Patient reported outcomes (PROs) help to identify decrements in health-related quality of life (HRQoL) domains, which the Centers for Disease and control (CDC) defines as “an individual’s or group’s perceived physical and mental health over time” (Moriarty, Zack, & Kobau, 2003). The goal of introducing PC early in the advanced cancer disease trajectory is to manage refractory physical symptoms, complex psychological issues, and improve patient QoL (Dans et al., 2017; Glare, 2013; LeBlanc & El-Jawahri, 2015; Meier, 2011). PC involves

empathetic communication about prognosis, symptom assessment and management, reduction of unnecessary health utilization, and promotion of advance care planning (Haun et al., 2017; LeBlanc & El-Jawahri, 2015). Palliative care is often administered to patients with advanced cancers, significant side effects, and functional status losses (Goldberg et al., 2019).

The top three symptoms reported by patients with an advanced cancer diagnosis in the longitudinal study by Tai et al. (2016) are pain, anorexia, and constipation. Approximately 50% (Nipps et al., 2017) of the patients with advanced cancer experienced moderate to severe physical and psychological symptom burden during hospitalization. In the outpatient setting, it is essential that the assessment of these symptoms should be performed during the transition of care. With an increased focus on patient centered care, patients are more actively participating in their treatment plans. The consistent method of collecting PROs in the outpatient PC clinic can enable clinicians to enhance person-centered care, facilitate patient/caregiver-clinician communication, and promote shared decision-making (Antunes et al., 2013). QoL assessment instruments are promoted as a resource for providers to efficiently assess and respond to needs that are relevant to QoL from patients' and caregivers' point of view (Aktas, Walsh, & Kirkova, 2015; Sawatzky et al., 2017).

PC providers frequently address symptom management and coping with illness during PC visits, but the content of PC visits varies across disease trajectory to respond to patient needs and health status changes (Hoerger et al., 2018). Increased provider time spent addressing coping during PC visit was associated with improved PRO in QoL and depressive symptoms (Hoerger et al., 2018). Symptom management was examined by providers more often with patients experiencing worsening QoL, depression, and anxiety, likely due to higher symptom burden (Hoerger et al., 2018).

Guidelines. American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) acknowledge that PC improves health-related quality of life (HRQoL), reduces symptom burden, reduces health care resource use, improves provider-patient relationship, and may lengthen survival (Dans et al., 2017; Kamal, Gradison, Maguire, Taylor, & Abernethy, 2014). The NCCN guideline was developed to ensure that each patient with cancer experience the best QoL throughout their disease trajectory (Dans et al., 2017). The guideline includes recommendations for screening, assessment, and management of PC needs. This DNP project has focused specifically on the screening process in outpatient clinics (Dans et al., 2017). A gap exists in PC interventions during the screening process in outpatient clinics. The recommendation for intensifying PC intervention is based on patient outcomes such as reduced distress, optimized QoL, relief of caregiver burden, strengthened relationships, acceptable sense of control, personal growth, and enhanced meaning (Dans et al., 2017). Ongoing reassessment of these outcomes is recommended by NCCN (Dans et al., 2017). Specific time intervals for assessments are not included in the guideline.

In order to create and sustain collaboration between oncologists and the palliative medicine team in a demonstrably valuable manner, the nature of the PC intervention and its process should be promoted and its impact measured (Kamal et al., 2014). The ASCO's Quality Oncology Practice Initiative (QOPIs) are widely used cancer quality metrics in the United States including end-of-life (EOL) care (Kamal et al., 2014). ASCO recommends that comprehensive cancer care should include incorporation of palliative care earlier in the metastatic cancer diagnosis because the adverse effects of chemotherapy can often impact the patient's QoL.

Summary Statement

Previous study has assessed higher symptom burden and lower quality of life during hospitalization (Nipp et al., 2017); however, these patients have not been adequately researched

in the outpatient setting. Therefore, it is imperative to continue to assess symptoms in the outpatient setting. A consistent method for symptoms and QoL assessment is needed in the outpatient PC setting to better understand patients' needs, help create an individualized treatment plan, and improve patient outcomes. This study addresses this need by deploying PROs, which provide clinicians with the opportunity to discuss coping and symptom management in order to improve patients' QOL. In this study, PROs will be used to provide clinicians the opportunity to discuss coping and symptom management with the aim to improve patient's QoL (Hoerger et al., 2018).

Problem Statement

The literature supports the use of QoL assessment tool, but the question remains which PRO and QOL tool is most appropriate for the PC oncology patient population. Often, long questionnaires or lengthy interviews are difficult to complete by severely ill patients who are frail, tired, and unable to concentrate for a long period of time. There is great need for a validated QoL tool that is short, easy to use, multidimensional, and contains global QoL questions regarding overall health (van Dongen-Leunis, Redekop, & Uyl-de Groot, 2016).

One strategy to address this need is use of the ESAS-r which is designed to assess nine symptoms common in patients with a cancer diagnosis: pain, tiredness, drowsiness, nausea, appetite, shortness of breath, depression, anxiety, wellbeing, and blank space to fill in symptoms not listed above (Watanabe et al., 2011). The ESAS was originally developed for a PC setting with validation in PC and hospice patients and to measure symptoms severity in cancer patients being seen by a PC service (Paice, 2004). The ESAS-r measures physical and psychological domains by asking patients to rate the nine common symptoms in PC patients and one fill in the blank (McGee et al., 2018). The tool uses a 0 to 10 numeric rating scale to rate the severity of the symptom, 0 being absent of symptom and 10 being worst possible severity. The ESAS has been

revised to make it easier to complete, with added description for symptoms (Watanabe et al., 2011). The scale does not require recall, as it assesses the timeframe of “now.” The ESAS-r also includes a body diagram to identify the pain site (Watanabe et al., 2011). The single global QoL question from the European Organization for the Research and Treatment of Cancer (EORTC) – Quality of Life in Palliative Care Patients (EORTC-QLQ-C15-PAL) was added to ESAS-r. The single QoL question has been validated comparability with multi-item questionnaires in the sub-domains of a comprehensive tool (Stiel et al., 2011).

Based on the literature support and my communication with the palliative care team, it was decided to move forward with the ESAS-r with the global QoL question. Going forward, this combination tool will be referred to as the ESAS-r + 1 QoL item tool. It has been used extensively in the palliative care population with cancer (Aktas et al., 2015; Chang, Hwang, & Feuerman, 2000; Gilbert et al., 2012; Koesel, Tocchi, Burke, Yap, & Harrison, 2019; Rauenzahn et al., 2017; Riechelmann, Krzyzanowska, O’Carroll, & Zimmermann, 2007; Shamieh et al., 2017; Watanabe et al., 2011). The original ESAS has been rigorously tested. It can be generalized, therefore, that it also had a higher global psychometric quality score (Aktas et al., 2015) in comparison to MSAS and MDASI. It is a practical tool with robust psychometric properties for clinical use that has been tested in various populations (Aktas et al., 2015). The ESAS-r has been used extensively in cancer palliative care, inpatient, and outpatient studies. It is easily administered and less time-consuming in comparison to other tools included in the literature review. It is reliable and validated with good internal consistency.

The site of this project, University of North Carolina Healthcare (UNC-HC) in Chapel Hill, North Carolina, is a level 5 trauma center with over 900 inpatient beds. The UNC Outpatient Oncology Palliative Care (UNC-OOPC) strives to provide medical care to help

improve QoL for patient and families (“UNC Outpatient Oncology Palliative Care - UNC Lineberger,” n.d.). Prior to this project, the clinic did not utilize any standard tool to assess HRQoL or general QoL to align with NCCN and the content areas identified by an ASCO expert panel.

Purpose of the Project

The purpose of this DNP project was to pilot the Edmonton Symptom Assessment System- Revised (ESAS-r) with an added single global QoL question from the European Organization for the Research and Treatment of Cancer (EORTC) – Quality of Life in Palliative Care Patients (EORTC-QLQ-C15-PAL) using the palliative care guideline in the UNC-OOPC.

CHAPTER 2: REVIEW OF LITERATURE

Exploring facilitators and barriers to implementation of PROs in palliative care setting can help guide the process of implementation and its effect of routine use of PROs on patient outcomes in the outpatient clinics. Despite the palliative care guidelines, the adoption of PROs in PC clinical practice has been slow due to lack of appropriate instruments, time and financial/professional incentives; lack of consensus regarding what outcome domains to include and what assessment measures to use; and providers remaining unconvinced of the benefits of routinely monitoring outcomes (Antunes, Harding, Higginson, & EUROIMPACT, 2014; Greenhalgh, Long, & Flynn, 2005; Howell et al., 2015).

Search Strategy

The goal of this literature review was to identify evidence about the relationship between use of ESAS or ESAS-r in a palliative care setting and how it can improve patient outcome or QOL. After describing the search method, the review will discuss the study and sample characteristics, interventions, results, and provide an assessment of the evidence. The databases searched were PubMed, CINAHL, and Google Scholar. The articles published in English language and published during the years 2014-2020 were considered for the review to ensure most recent and relevant research. The following search terms were used “("Palliative Care" OR "Hospice Care" OR "Hospice and Palliative Care Nursing" OR palliative OR Palliation OR hospice), ESAS or ESAS-r, outcome, satisfaction, quality of life, quality improvement, symptom assessment” in all three databases. The additional search term “patient reported outcome” was added in Google Scholar to create more relevant search result. Figure 1 shows the flow diagram

of the article selection process. The DNP student independently screened titles and abstracts and identified potentially relevant articles.

Figure 1: Literature Review Flow Diagram of Relevant Article Selection.

Study and Sample Characteristics

A variety of study designs were used in this literature review. A brief relevant description of aim/purpose, study characteristics, sample characteristics, and key findings can be found in Appendix E, Table 3. One study was a prospective observational study (Ghoshal, Salins, Deodhar, Damani, & Muckaden, 2017), five cohort studies (Barbera et al., 2015; Diplock et al., 2019; Doris Howell et al., 2020; Koesel, Tocchi, Burke, Yap, & Harrison, 2019; Merchant et al.,

2019), one systematic review in which nine out of thirty-four studies evaluated effects of patient reported outcome (PROs) tool use on symptom severity over time (Van Egdom et al., 2019), one literature review with thirty articles (D Howell et al., 2015), one expert opinion with a pilot study (Basch, Barbera, Kerrigan, & Velikova, 2018), and one mix-method design (Brooks, Poague, Formagini, Sinclair, & Nelson-Brantley, 2020).

Included studies focused on patients with all cancers, seen in the outpatient setting, and had US and international settings. The studies location ranged from the United States, Europe, Canada, and India. The sample ranged from 30 to 70,854 adults with cancer focused on all adult populations. Population included in all studies in the review had existing or new diagnosis of cancer and age 18 or older (Barbera et al., 2015; Basch et al., 2018; Brooks et al., 2020; Diplock et al., 2019; Ghoshal et al., 2017; D Howell et al., 2015; Doris Howell et al., 2020; Koesel et al., 2019; Merchant et al., 2019; Van Egdom et al., 2019). In this review, six out of ten studies used ESAS or ESAS-r (Barbera et al., 2015; Brooks et al., 2020; Diplock et al., 2019; Ghoshal et al., 2017; Koesel et al., 2019; Merchant et al., 2019), two used variety of PROMs (D Howell et al., 2015; Van Egdom et al., 2019), and two used unique tool that was implemented electronically and was available outside the clinic setting (Basch et al., 2018; Doris Howell et al., 2020).

Interventions

The observational study used ESAS to assess (n=500) symptom burden with standard PC care with completed 15 and 30 day follow up (n=402) (Ghoshal et al., 2017). The aim of the study was to examine if better overall symptom control can improve fatigue score using ESAS (Ghoshal et al., 2017). A cohort study compared two similar groups at baseline and 2 weeks later one group using ESAS to assess the impact on HRQoL (n=108) and control group received usual care (=160) (Diplock et al., 2019). A cohort study Koesel et al. (2019) evaluated patients with advanced cancer at two PC clinics using ESAS at baseline and two subsequent follow up using a

cohort study. ESAS score for pain, fatigue, and anxiety were recorded (n=30) prior to PC consultation which is T1 and two subsequent visits T2 & T3 (Koesel et al., 2019). A retrospective cohort study focused on system outcome, impact of ESAS use on unplanned Emergency Department (ED) visit evaluated in patients with breast cancer (n=2,541) (Barbera et al., 2015). Another retrospective cohort study examined ESAS score data in the final year of life in patients with gastrointestinal cancer at the PC visit between 2003 to 2015 (n=11,242) (Merchant et al., 2019). The symptoms were categorized from mild (score 0-3) to moderate-severe (score 4-10). Semi-structured audiotaped interviews were conducted from June through December 2018 and ESAS data from patient as part of routine care in addition to ESAS data completed by provider was collected during the study period (Brooks et al., 2020).

The use of online eRAPID system was developed to allow patients to report symptoms electronically outside the traditional clinical setting (Basch et al., 2018). The internal pilot study (n=87) over 6-month period with total of five hundred forty online symptom reports were completed by these patients with eleven severe symptom alerts to provider (Basch et al., 2018). The Improving Patient Experience and Health Outcome Collaborative (iPEHOC) at multisite cancer clinics to enable use of PRO data to evaluate if innervation group differed in their healthcare utilization (Doris Howell et al., 2020).

Summary of Results

PRO effect on patient outcome. Fatigue was the most common symptom measured in this study with improvement in the ESAS score for fatigue ($p<0.001$) (Ghoshal et al., 2017). The HRQoL score at T1 was similar for both group but overall use of ESAS did not lead to improvement in HRQoL except for cognitive function (Diplock et al., 2019). Statistically significant lower ESAS score for pain ($p=0.005$), fatigue ($p=0.001$), and anxiety ($p=0.001$) were reported with decrease in two or more points of all symptoms from baseline to second follow up

visit (Koesel et al., 2019). Systematic review Van Egdom et al. (2019) reported decreasing symptom prevalence or symptom distress over time and increased reporting of new or change in the symptom severity when PRO tool was used. Additionally, increased reporting was noted when electronic application was used verses paper-based tool to report symptoms (Van Egdom et al., 2019). Patients experienced statistically significant reduction in ESAS score for anxiety, nausea, pain, and lack of well-being after first PC visit (Merchant et al., 2019). Six out of thirty studies in the evidence review by Howell et al. (2015) evaluated impact of routine use of HRQoL tool on overall well-being, only one reported significant effect on patient well-being but better symptom management can be achieved using PROMs.

Patient-Provider Communication. The important facilitator for the patient was seeing how the provider used the ESAS-r findings during the clinic visit, and outside the clinic setting patient received algorithmic feedback on immediate advise based on severity of the symptom reported on eRAPID (Basch et al., 2018). The use of PRO allows early recognition symptoms and can improve patient-provider communication (D Howell et al., 2015). The ESAS was helpful in forming urgencies of symptom control and guide the PC provider visit (Brooks et al., 2020).

System Outcome. The ED utilization was 43% lower amongst patients that were previously screened with ESAS in compare to control group and for each additional previous ESAS screening, there was a decline of 17% in ED visits (Barbera et al., 2015). Howell et al. (2020) reported slightly lower ED visits compared to control group, increased opioid and antidepressant prescription, lower psychosocial oncology visits, and lower PC visits (Doris Howell et al., 2020)

Conclusion

Studies evaluated impact of routine use of HRQoL instruments on overall patient's well-being with increased frequency on discussion of HRQoL related issues ($P < 0.05$) in comparison

to control group (Hilarius, Kloeg, Gundy, & Aaronson, 2008; Nicklasson, Elfström, Olofson, & Bergman, 2013; Seow et al., 2011; Velikova et al., 2004). Challenges in implementing ESAS as routine practice in patient with cancer diagnosis were lack of agreement on the select tool, lack of resource and guidance to address high scores, incorporating the data into the electronic medical record (EMR), resistance to change, and challenges to the traditional care model (Dudgeon et al., 2012). The facilitators of implementation of ESAS were centralized project management, a person assigned to the implementation process, clinical champions, clearly identified aims for the project, monthly data reporting, and implementation of quality improvement with expectations for performance (Dudgeon et al., 2012). The increased PRO score may prompt more actions taken by providers as the study by Seow et al. demonstrated routine use of ESAS with a higher score for pain and shortness of breath were associated with higher rates of pain documentation and symptom-specific actions in patients with breast and lung cancer (Seow et al., 2011).

Use of ESAS can reduce additional healthcare utilization such as emergency department visits, PC visit, and psychosocial oncology visit (Barbera et al., 2015; Doris Howell et al., 2020). Granted this is just an association not a causality. Greater reduction in positive symptoms such as pain, and nausea as they can be addressed with medications in comparison to tiredness, and lack of well-being (Merchant et al., 2019) Although the ESAS score and clinical action by the provider can be interpreted as interconnected, it does support the notion that use of ESAS tool may increase provider's actions toward symptom management. These studies support that palliative care can provide improved symptom management to these patients. Hence, we should consider utilizing this tool in the outpatient setting of adults with cancer.

CHAPTER 3: THEORETICAL FRAMEWORK

This DNP project focused on implementation of ESAS-r + 1 QoL tool using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework (Glasgow, Vogt, & Boles, 1999; Graham & Logan, 2004). The RE-AIM is a five component framework (Glasgow, Vogt, & Boles, 1999) used for planning, implementation, and evaluation process with attention on elements to promote implementation and sustainable adoption of an intervention (Glasgow et al., 1999). RE-AIM was developed to address key issues faced with implementation and evaluation in the public health domain (Gaglio, Shoup, & Glasgow, 2013). The framework helps implement the research and guidelines developed under control settings into the real world (Gaglio et al., 2013). The framework can be applied to assess the problem and intervention process; consequently, the RE-AIM was examined in-depth for this DNP project because RE-AIM provides flexibility.

From the review of the literature, RE-AIM has proven to be a versatile framework that can be applied at to individuals, organizations, systems, or communities based on the need. The framework originated to expedite the process of implementation from research to the real world in public health, but since publication, it has been used in health care, education, community, and public health.

CHAPTER 4: PROJECT METHODOLOGY

The clinic site for this project was evaluated for possible strengths and weaknesses. The site visit was performed on April 11, 2019 for approximately four hours with the palliative care team. This was organized and guided by PC nurse clinical coordinator Jennifer Hanspal. The visit included interacting with patients, nursing staff, PC providers, and healthcare unit coordinators. The site assessment provided a better understanding of clinic workflow and helped craft the implementation process to fit the clinic workflow.

Procedures for Project Implementation

Reach. The number of patients seen by the UNC-OOPC clinic during the DNP project time October 07, 2019 to December 29, 2019. The baseline benchmark at the end of initial PDSA cycle was set at 50% for each clinic. The goal for each cycle thereafter was to continue to look for ways to maintain or surpass the previously reached compliance rate, or 50%, whichever was highest.

Effectiveness. The Plan-Do-Study-Act (PDSA) cycles did facilitate effective piloting of the ESAS-r + 1 QoL item. The PDSA cycles gave the opportunity to make necessary changes to address noted barriers.

Adoption. The clinicians (PC advanced practice providers, PC physicians, clinical pharmacists, and PC nurse clinical coordinators) and support staff (healthcare unit coordinators (HUCs), certified medical assistants (CMAs), and nurses) received project information via staff meetings and group email. The contact information of the DNP student was included in the email for further questions. At the end of each PDSA cycle, the DNP student performed a site visit to

interact with support staff to assess barriers, if any. Adjustments were made to the implementation plan based on feedback from clinicians and support staff.

Implementation. A total of four PDSA three-week cycles were completed during the project time period. The Institute of Healthcare Improvement recommends choosing the end date for cycles based on the total project timeline (Provost, n.d.). Provost (n.d.) suggests dropping down two timeframes to complete a minimum of three complete cycles. The DNP student monitored the number of completed ESAS-r + 1 QoL forms and patient visits by OOPC team on a weekly basis, keeping data separate for each clinic. The student re-educated clinicians and support staff, provided resources, and made adjustments as needed for each clinic that did not meet the set benchmark as described above at the end of each PDSA cycles. Education and changes to the pilot project took place in the first week of new PDSA cycles.

Maintenance. This DNP project did not include the maintenance portion of the framework within the project timeline but instead plans to present maintenance as a recommendation for the future.

Study Design

The quality improvement project was aimed to improve the practice of measuring HRQoL and self-reported symptom severity in an outpatient PC clinic. The UNC-HC outpatient PC clinic did not have a standardized process in place for symptom assessment prior to this project. The quality improvement project was designed to incorporate the ESAS-r + 1 QoL form to help standardize the process of assessing symptom and QoL at each clinic visit. The methodology for the pilot project included the use of PDSA cycles. The Institute for Healthcare Improvement Model for Improvement PDSA was used to help facilitate this process by providing the structure for testing the change at a small scale prior to implementing it widely (Taylor et al., 2014). The first step was the “Plan,” which defined a clear purpose, formulated the

desired outcome, and established a means of putting the plan into action (Taylor et al., 2014). The second step was the “Do,” during which the implementation plan was rolled out into action (Taylor et al., 2014). The third step was the “Study,” in which the DNP student monitored the outcomes to assess progress and barriers to implementation (Taylor et al., 2014). The last step was “Act,” in which the thorough evaluation of barriers and lessons learned were examined to adjust future PDSA cycles (Taylor et al., 2014). The successful PDSA planning does not guarantee a successful project outcome; rather, it is a continuous cycle that improves the process (Reed & Card, 2016). The primary goal of this DNP project was to pilot the use of the ESAS-r + 1 QoL form in three clinics for all UNC-OOPC patients. The expected outcome was continuous improvement in compliance of ESAS-r + 1 QoL form uptake by end of the 12-week pilot project in all three clinics.

Plan. The approval from the clinic nurse managers was obtained prior to proceeding with the project planning. The project introduction, project timeline, and instructions were shared via information flyer with the HUCs, CMAs, nurses, and clinicians that were involved in caring for the patients seen by UNC-OOPC (see Appendix A). Flyers were posted at the HUCs’ desk and nurses’ station to serve both as a resource and as a reminder to complete the ESAS-r + 1 QoL form for each PC patient appointments. The HUCs were able to see on their worklist if the patient was scheduled to see a PC provider at the time of check-in.

Do. The piloting of the ESAS-r + 1 QoL form took place in each clinic at the same time. The existing HUC workflow was used to pilot the form. There were already several different forms distributed at the time of the clinical appointment. For example, a yellow symptom inventory form was given to patients with breast cancer in the clinic. The same workflow was used to distribute the ESAS-r + 1 QoL form for all patients coming in for the palliative care

appointment.

Study. The data was collected at regular intervals and tracked using an excel spreadsheet. The data was kept separate for each clinic. At the end of each cycle, the data was analyzed. The DNP student met in person or via phone call with HUCs to assess barriers and facilitators at the end of each PDSA cycle.

Act. The assessment of barriers was performed for the clinic that did not maintain or surpass the set compliance benchmark. Changes to the pilot project process were made to address barriers observed during assessment. Staff input was incorporated when making these changes.

Setting and Population

The project took place at UNC-OOPC, located on the second floor of North Carolina Cancer Center in Chapel Hill, NC. This was a complex setting, as the PC did not have a designated clinic area, however, patients were seen in three Oncology clinics located on the second floor: Surgical Oncology; Multi-disciplinary Oncology; and Hematology-Oncology. The PC team includes multiple physicians, two fellows, one nurse practitioner, one clinical pharmacist, and a nurse clinical coordinator. The PC team shared nursing and support staff with the primary oncology clinics. The project population consisted of all patients seen by the UNC-OOPC in these three clinics during the 12-week pilot period. There were three check-in desks staffed with a HUCs to check in patients. HUCs handed patients forms to complete while they waited to be seen. Each HUC had a different workflow. The majority of the patients seen were located in either the Multidisciplinary clinic or the Hematology Oncology clinic. The HUC at the hematology clinic did not support the idea of distributing the form to the patient while they were waiting, but rather preferred to attach the form to the check-in sheet for CMAs or nursing staff to hand it to the patient while getting them to their room.

Measurements

The primary outcome for this project was the continuous improvement in uptake of the ESAS-r + 1 QoL form in the three clinics.

Tools

The ESAS-r was available publicly for use. The only requirement for use was to list the two references on the form. The two references were added in the footnote of the form to comply with this requirement. The form was initially printed on white printer paper but was later changed to green printer paper to help distinguish from other papers in the clinics. The DNP project used a hard copy of the ESAS-r + 1 QoL form to be given to the patient at the time of clinic check-in by HUC or during rooming by CMAs or nursing staff. Clipboards with attached pens were already available at the HUC desk and the exam rooms. The completed ESAS-r + 1 QoL forms were collected by the support staff at the time of rooming and placed in a bin outside the room. Additional time was allowed to a patient who had not completed the questionnaire at the time of rooming. Those forms remained in the exam room and were collected by PC clinicians at the time of the visit. All ESAS-r + 1 QoL items were to be collected from the patient the end of the visit, regardless of completion status.

Data Collection

Prior to rolling out the DNP project, the DNP student worked with the UNC-OOPC clinics to secure a designated area to store completed assessment forms. The student added up the total number of completed ESAS-r + 1 QoL forms and compared it with the total number of completed visits under palliative care service in a given time period. The denominator was set as the total number of patient visits. If a patient visited the clinic twice in a given time period, then each visit was counted independently in the denominator. The nurse coordinator for the palliative care team agreed to keep a printed list of appointments for the day and to cross out “no show”

patients or patients seen outside the three-clinic area listed above. This information was collected by the DNP student weekly during the pilot period. An Excel data sheet was used to track this data for each clinic. No personal identifier of patients was logged into the data sheet.

Stakeholders

It was important to engage stakeholders in many different roles at UNC-OOPC clinic. Gaining not only cooperation but also the support from all of the clinic staff was critical for the success of this DNP project. The stakeholders of the intervention included the organization's executive directors, unit manager, administration personnel, and clinicians that provide direct interventional care to the patient (including the physician, advanced practice providers, clinician pharmacist in the PC team, nursing staff, and patients/caregivers). The HUCs handed out the ESAS-r + 1 QoL form to the patient when they checked in. The ongoing update on the progress and data collected up to that point was shared with stakeholders at the end of each PDSA cycle via e-mail.

Evaluation

The data was collected by the DNP student at a weekly interval during the project timeline by counting completed ESAS-r + 1 QoL forms. The DNP student used a Microsoft Excel spreadsheet to organize the number of completed ESAS-r with SI-QoL tool and the number of completed appointments in the three clinics. The data was organized separately for each clinic. The number of completed ESAS-r with SI-QoL tool was the numerator and number of completed appointments by PC team was the denominator. The following formula—[(number of assessment tools completed per clinic / number of patient appointments completed per clinic) X 100]—was used to obtain percentage of adherence with ESAS-r with SI-QoL form.

Ethical Considerations

The project was submitted to and approved by the University of North Carolina at Chapel Hill Institutional Review Board (IRB) on August 26, 2019 (See Appendix C). Because data collection was solely based on number of completed ESAS-r + 1 QoL forms with no identifying patient information used, the project was approved as “exempt” by the IRB. The UNC-MC Institutional Nursing Research Council (NRC) is an organization level committee that reviews all nursing research conducted at UNC-MC. Prior to implementation, this DNP pilot project was approved by NRC (September 11, 2019) (see Appendix D).

CHAPTER 5: RESULTS

The pilot project occurred in four rounds of 3-week PDSA cycles. Cycle 1 consisted of 3-weeks, including a kick-off day (first day of the project) to acquaint the HUC staff with the ESAS-r + 1 QoL tool distribution process. The initial introduction was given at a staff meeting during September 2019. Unfortunately, HUCs are not present at these staff meetings because they focus on checking in patients that arrive early for their scheduled oncology visits. The project was also introduced to the OOPC during their Thursday team meetings in April and July 2019. The DNP student was heavily involved supervising and supporting the front-line staff with distribution of ESAS-r + 1 QoL tool in the first cycle. The support included the following: 1) daily reminders of how many patients were scheduled to see OOPC provider in a specific clinic for the day, 2) the names of providers covering OOPC patients for the day, and 3) follow-up with HUC to see if patient received the ESAS-r + 1 QoL form at the time of check-in whenever the DNP student was in the clinic. A total of 54 ESAS-r + 1 QoL tools were completed by patients in the first PDSA cycle. This accounted for 66% of all OOPC completed visits during this period. The Overview of each PDSA cycle and associated modifications to the process were logged (see Appendix E, Table 2).

PDSA Cycle 2 began immediately after the end of cycle 1. This cycle was particularly challenging because the DNP student was unavailable in-person due to personal reasons. The cycle consisted of ongoing remote engagement with support staff via phone. The data collection process continued uninterrupted because the DNP student was able to educate the OOPC providers to collect the form after each visit and place this in the bin labelled completed ESAS-r

+ 1 QoL in the OOPC office. A total of 58% of patients completed the ESAS-r + 1 QoL during Cycle 2. There was a 29% increase in number of total OOPC visits completed in Cycle 2 when compared to Cycle 1. The percentage change of compliance between Cycle 1 and Cycle 2 decreased by 12.1%. Of note, compliance significantly dropped for the Surgical Oncology clinic from 50% Cycle 1 to 14% in Cycle 2 (see Appendix E, Table 1).

PDSA Cycle 3 consisted of ongoing HUC education and engaging with OOPC clinicians on how to input the patient selected value from the ESAS-r + 1 QoL form into the encounter progress note using Epic SmartPhrase, “ESAS.” All oncology clinics distributed various forms and surveys to patients at the time of check-in, depending on the patient’s clinic visit. Based on provider input at the beginning of Cycle 3 about difficulty locating the ESAS-r + 1 QoL tool outside the examination room because it blended in with other white forms used by the clinic, the color of the form was changed from white to dark green. To help standardize the process throughout all three clinics, a HUC assisted the DNP student with changing the form color. The ESAS-r + 1 QoL tool completion percentage had a 52% average between all three clinics. There was another 10.2% decrease in compliance in Cycle 3 when compared to Cycle 2 data. The total number of completed OOPC clinic visits were similar: the number of patients in Cycle 3 increased by only 2.8% from the number who participated in Cycle 2.

PDSA Cycle 4 began with face-to-face meetings with two of the PC clinicians and the clinical nurse coordinator for an assessment of Cycle 3. The clinicians noted that there had been a decrease in the Cycle 3 compliance due to hefty staff turnover throughout the month of November 2019 in both the Multi-Disciplinary clinic and the Hematology Oncology clinic. There was also a HUC who served as a project champion who notified DNP student the first week of Cycle 4 that it would be her last day at this clinic. No new champion was recruited for

the remainder of the 2 weeks of Cycle 4. The focus was placed on creating a process that would not be heavily dependent on routine staff. On the second day of Cycle 4, each clinic received a laminated sheet with a list of providers covering OOPC patient visits and instructions for the process to follow for each visit. The percentage of compliance at the end of Cycle 4 was 65% for all three clinics. There was a 25% increase in compliance when compared to Cycle 3, but there was a 31.2% decrease in the number of patients seen by OOPC clinic during Cycle 4. The contributing factors were the following: clinic being closed for three days in last week of the cycle due to Christmas and generally low census in the last weeks of Cycle 4. When compared to Cycle 3, the number of patients seen by OOPC was not affected by the clinic being closed for two days due to Thanksgiving holiday. There was an increased number of patients seen four days prior the Thanksgiving holiday closing.

Figure 2. PDSA Chart of Cycles 1-4

Engagement

Handwritten notes were taken periodically when making in-person visits during the project process to document observations throughout the PDSA cycles. Week one of Cycle 1 was

met with resilience from HUC and frontline staff members stating “we are doing all we can” and “cannot add one more thing to my workload.” As Cycle 1 progressed, staff became more receptive to the new process but often missed distributing ESAS-r + 1 QoL tool to patients stating “Oh, I forgot about the sheet.” Engagement during Cycle 2 was done remotely via phone. The phone conversations were brief in nature, with minimum feedback from the HUC staff during Cycle 2.

At the end of Cycle 3, the HUCs and PC clinicians shared the concern that another service provider had a similarly colored form to the ESAS-r + 1 QoL tool (a Spanish version of the yellow symptom inventory form for breast cancer patients). This was accidentally completed by one of the Spanish speaking OOPC patient. To address this concern, a different color folder was provided to the HUC to help differentiate between the two green sheets. During the Cycle 3 field visit, the DNP student noted two patients refused to complete the form because it was their second visit to OOPC clinic for severe symptom management in less than two weeks. New floating HUC staff were noted at the front desk of the Multi-Disciplinary Oncology clinic when making an in-person visit during Cycle 4. Brief interaction between the DNP student and frontline staff consisted of reminders about where the forms were placed, checking for adequate supply, and asking about barriers to the process.

CHAPTER 6: DISCUSSION

As previously noted, the purpose of this Doctor of Nursing Practice (DNP) project is to: 1) pilot the ESAS-r with an added single global QoL question from EORTC-QLQ-C15-PAL in the UNC-OOPC, and 2) assess barriers and facilitators to improve future implementation of the tool in other OOPC setting for better feasibility and sustainability. Overall, this project did not achieve its goal of surpassing or maintaining ESAS-r + 1 QoL form compliance benchmark of 66% set at the end of PDSA cycle 1. Although subsequent PDSA cycles 2-4 maintained compliance rate between 52% to 65% with overall project compliance of 59%. This was due to a number of factors, clinic staff (HUCs, CMAs, nurses, and clinicians), and patient perceptions along with clinic setting played a central role in lower compliance rate. Also, an unpredictable higher than normal staff turnover in the PDSA cycle 3 and 4 was also a contributing factor.

Clinic Staff Perception

The clinic staff made significant impact on compliance rate were HUCs at the front desk of each three clinics. Initially, the supporting staff displayed resilience stating, “we are so busy, and now we have to do this?” but with continuous education on importance of practice change led to more buy-in. The HUC at the Surgical Oncology appointment often reported forgetting to hand the form at the time of check in to the patient. This clinic had a total of two to eight completed appointments per PDSA cycle in comparison to 40 to 50 appointments at the Hematology Oncology clinic and 40 to 55 appointments at the Multi-Disciplinary clinic. Among HUCs who encountered higher number of PC appointments, they were more likely to complete the process to distributing the ESAS-r + 1QoL tool, when compared to HUCs who encountered

lower number of PC appointment in their clinic.

Patients' Perceptions

Patients' perceptions were an important aspect of this project. Generally, patients reported that the form was easy to navigate through and required less than five minutes to complete. The lack of compliance from patients arose when the patient with severe symptoms were asked to complete ESAS-r + 1QoL form multiple times in a week or on weekly basis. One patient reported that the form was redundant to complete it twice in a single week. This patient didn't see the value in completing the form.

Clinic Setting

The three adult oncology clinics were part of this pilot project. The UNC-OOPC operates out of an office located in the Hematology Oncology clinic. Patients are scheduled throughout these clinics. The UNC-OOPC provider template is available in the Multi-Disciplinary clinic and Hematology Oncology clinic but not present in the Surgical Oncology clinic. This was the biggest barrier for the Surgical Oncology clinic. These patients were seen in the clinic as an add-on. The HUC in this clinic were unaware of which patients were scheduled for a PC appointment after their oncologist appointment. This was not the case for the other two clinic that had provider templates. Hence, the better compliance rate and higher number of scheduled appointments in the multi-disciplinary and hematology oncology clinics.

Exploring facilitators and barriers to implementation of PROs in palliative care setting can help guide the process of implementation and its effect of routine use of PROs on patient outcomes in the outpatient clinics. Despite the palliative care guidelines, the adoption of PROs in PC clinical practice has been slow due to lack of appropriate instruments, time and financial/professional incentives; lack of consensus regarding what outcome domains to include and what assessment measures to use; and providers remaining unconvinced of the benefits of

routinely monitoring outcomes (Antunes, Harding, Higginson, & EUROIMPACT, 2014; Greenhalgh, Long, & Flynn, 2005; Howell et al., 2015). The integration of PROs into PC clinical practice has three phases: preparation, education, and providing timely feedback (Antunes et al., 2014). It is important to recognize the ongoing behavioral and emotional processes of individuals when change is being implemented (Antunes et al., 2014). Facilitators to implementation may include integration with clinical practice guidelines, auto identification of higher than defined scores, incorporating the service-user perspective when going electronic with the tool, and longitudinal interpretation of change in PRO data (Howell et al., 2015).

This pilot project supports the need for spotting barriers and incorporating strengths when implementing the use of ESAS-r + 1 QoL tool to OOPC clinic. There is a high need for obtaining patient and staff feedback at regular intervals. This will assist in addressing a barrier at the early stage before it creates a negative impact on the compliance rate. The appropriate use of ESAS-r + 1 QoL tool can help initiate symptom management conversations and determine patient's course of treatment and follow-up. Ongoing training and education are recommended for all clinic staff at set intervals. Small presentation or education material should be included in the new hire orientation package to acclimate the process during staff training.

UNC-OOPC team is caring for wide range of complex patient populations with different stages of cancer diagnosis. The range of symptoms and intensity varies from patient to patient, creating higher need for patient symptom reporting system. Future implementation for ESAS-r + 1QoL tool needs to be distributed and completed electronically. This will allow more readily available data to be collected over time and trending the symptom severity.

APPENDIX A: ESAS-r + 1 QoL FORM

UNC Outpatient Oncology Palliative Care	Patient Label: _____
Edmonton Symptom Assessment System: (revised version) (ESAS-R)	

Please circle the number that best describes how you feel NOW:

No Pain	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Pain
No Tiredness <i>(Tiredness = lack of energy)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Tiredness
No Drowsiness <i>(Drowsiness = feeling sleepy)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Drowsiness
No Nausea	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Nausea
No Lack of Appetite	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Lack of Appetite
No Shortness of Breath	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Shortness of Breath
No Depression <i>(Depression = feeling sad)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Depression
No Anxiety <i>(Anxiety = feeling nervous)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Anxiety
Best Wellbeing <i>(Wellbeing = how you feel overall)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Wellbeing
No _____ Other Problem <i>(for example constipation)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible _____

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

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

Very Poor	1	2	3	4	5	6	7	Excellent
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(EORTC-QLQ-C15-PAL)

ESAS-r

Revised: November 2010

1. Watanabe SM, Nekolaichuk C, Beaumont C, Johnson L, Myers J, Strasser F. A multicentre comparison of two numerical versions of the Edmonton Symptom Assessment System in palliative care patients J Pain Symptom Manage 2011; 41:456-468.

2. Bruera E, Kuehn N, Miller MJ, Selinger P, Macmillan K. The Edmonton Symptom Assessment System (ESAS): a simple method for the assessment of palliative care patients. J Palliat Care 1991; 7:6-9.

Patient Name: _____

Date & Time: _____ Provider Signature: _____

APPENDIX B: INFORMATION FLYER

Who

The Outpatient Oncology Palliative Care team will be piloting ESAS-r with 1 Global Quality of Life Question for all patients seen under their care.

What

ESAS-r is a valid and reliable assessment tool to assist in the assessment of nine common symptoms experienced by patients with cancer. It is one of the key assessment tools used in the Palliative Care Integration Project.

When

The implementation will start in mid-September and a DNP student will be collecting data through mid-December. The goal is to make the assessment tool standard of care for OOPC patients.

Why

Patients with cancer typically experience multiple symptoms throughout their disease trajectory. The oncology palliative care patient has even higher symptom burden. This tool will help identify the severity of these symptoms from the patient's perspective and help address them during the appointment.

Where

The implementation of OOPC ESAS-r will take place in three outpatient oncology clinics located on the second floor of NC Cancer Hospital

- Surgical Oncology Clinic
- Multi-Disciplinary Oncology Clinic
- Hematology Oncology Clinic

If you have questions about this quality improvement project, you can contact Mallika Patel, RN, BSN, DNP student at UNC School of Nursing at mbp827@email.unc.edu or 919-444-1833

APPENDIX C: UNIVERSITY OF NORTH CAROLINA IRB APPROVAL

To: Mallikaben Patel and Ashley Bryant
School of Nursing

From: Office of Human Research Ethics

Date: 8/26/2019

RE: Determination that Research or Research-Like Activity does not require IRB Approval

Study #: 19-1157

Study Title: Improving Patient Care by a Piloting Self-Reported Symptom Assessment Tool in Outpatient Oncology Palliative Care Clinics at NC Cancer Hospital

This submission, Reference ID 245917, was reviewed by the Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (e or l) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description:

Purpose: To improve patient care by incorporating a consistent method of routinely assessing symptoms using Edmonton Symptom Assessment System -Revised (ESAS-r) with single-item quality of life (SI-QoL) question in Outpatient Oncology Palliative Care Clinic.

Participants: Patients coming in for an appointment to be seen by Outpatient Oncology Palliative Care Team at three clinics located at the NC Cancer Hospital.

Procedures (methods): The healthcare unit coordinators (HUCs), certified medical assistants (CMAs), registered nurses (RNs), and licensed practical nurses (LPNs) will receive information on the implementation of this assessment tool with a brief introduction via group email. The contact information including telephone number and email address of the DNP student will be provided for questions or comments. The assessment tool will be handed out to patients using one of the following method:

- 1) Given at the time of check in on the second floor. This will give the patient an opportunity to complete the form while waiting to be seen.
- 2) The blank paper ESAS-r + 1 Global QoL form will be placed with other forms with check in paper for rooming staff. This will be handed to patients after being placed in the examination room. The patients can complete assessment tool while being roomed or while waiting for the provider.

The data will be collected on number of assessment tools completed in given period of time and compared with number of completed palliative care appointments in each of these three clinics during this time period.

The Plan-Do-Study-Act (PDSA) model will be used at every 3 weeks interval for total of 4 cycles. The adjustments will be made and staff encouragement will be based on success rate. The goal will be to reach greater than 80% completion rate.

APPENDIX D: UNC-MC NRC APPROVAL

09/11/2019

To: Mallikaben Patel

Re: Proposal Number 8/21/19_79

Dear Mallikaben,

Thank you for submitting your proposal to the UNCH Nursing Research Council (NRC). The NRC has approved your proposal, *Piloting a Self-Reported Symptom Assessment Tool in Three Outpatient Oncology Palliative Care Clinics at NC Cancer Hospital*. Mengdan Liu will be the NRC contact to assist you. You may reach her at Mengdan.Liu@unchealth.unc.edu. If you have any questions, please do not hesitate to contact either Mengdan or Jennifer Myers, NRC Chairperson.

Because your project may be included as part of Magnet site visit materials, you are required to do the following:

1. Keep the NRC updated on the progress of your study.
2. Include “*submit a final report to UNCH Nursing Research Council*” as part of the “Dissemination” plan in your IRB application.
3. Submit your NRC Final Report Form to nursingresearch@unchealth.unc.edu when your data analysis and conclusions are completed. If you have questions about the final report form, please email the Nursing Research Council email address listed above.

Thank you for choosing UNCH as the site for your project and we appreciate the opportunity to review. We look forward to hearing the results of your project and would enjoy having you present at an NRC meeting to share your findings. If you have any questions about the above requirements, please do not hesitate to contact me.

We wish you the best.

Kind Regards,

Jennifer P. Myers, BSN, RN, BMTN | CNIV

Chair, UNCMC Nursing Research Council

Jennifer.Myers@unchealth.unc.edu

Mary Kime RN, PhD

Nursing Research Council Application Coordinator

mary.kime@unchealth.unc.edu

APPENDIX E: TABLES OF DATA FINDINGS

Table 1. PDSA Data Collection Overview

PDSA 3-week Cycles			
Cycle 1	# Appt	# ESAS-r + 1 QoL	Compliance %
Surg-ONC	2	1	50%
Multi-D	40	23	58%
Hem/Onc	40	30	75%
Total	82	54	66%
Cycle 2	# Appt	# ESAS-r + 1 QoL	Compliance %
Surg-ONC	7	1	14%
Multi-D	49	26	53%
Hem/Onc	50	34	68%
Total	106	61	58%
Cycle 3	# Appt	# ESAS-r + 1 QoL	Compliance %
Surg-ONC	8	1	13%
Multi-D	55	30	55%
Hem/Onc	46	26	57%
Total	109	57	52%
Cycle 4	# Appt	# ESAS-r + 1 QoL	Compliance %
Surg-ONC	3	1	33%
Multi-D	40	27	68%
Hem/Onc	32	21	66%
Total	75	49	65%
Total	# Appt	# ESAS-r + 1 QoL	Compliance %
Surg-ONC	20	4	20%
Multi-D	184	106	58%
Hem/Onc	168	111	66%
Total	372	221	59%

Table 2. PDSA Cycle Overview (10/07/2019-12/29/2019)

PDSA Cycle	Problem	Plan (P)	Do (D)	Study (S)	Act (A)
Cycle 1 Dates: 10/07/19 to 10/27/19	The OOPC team is not administering any self-reported symptom severity tool such as ESAS-r with 1QoL. The data can help provider guide the focus for the visit for that day and help assess quality of care.	Distribute ESAS-r +1 QoL tool to patients scheduled for New/Routine OOPC clinic visit	Distribute ESAS-r + 1 QoL tool to three clinics and provide staff direction of the flow	2/3 of the clinic HUC thought ESAS-r +1 QoL tool should be given to returning patients only and not new encounters. Lack of HUC knowledge regarding who should receive the ESAS-r + 1 QoL Patients comfort level when rating symptom severity listed on the ESAS-r + 1 QoL	Written instruction posted at each desk with the image of the form and who should receive it. Distribution process effective (50% or greater) for two weeks under direct daily supervision and guidance and third week via phone.
Cycle 2 Dates: 10/28/19 to 11/17/19	Can the pilot site sustainably distribute ESAS-r + 1 QoL tool as part of 3 cancer clinics front desk process with supervision and guidance?	Provide support to HUC via phone.	Call in the morning to remind them of number of appointments for two consecutive days.	Lack of HUC knowledge regarding ESAS-r + 1. QoL clinical significance	Distribution process partially sustainable for three weeks under remote supervision via phone.
Cycle 3 Dates: 11/18/19 to 12/08/19	Can the pilot site sustainably distribute ESAS-r + 1 QoL tool as part of 3 cancer clinics front desk process without supervision and guidance?	No in person reminder or calls for the HUC.	The ESAS-r + 1 QoL tool form color was changed dark green color to easily recognize.	The clinic was using pink, yellow, and light blue color for other providers. There was another provider with green form but it was a Spanish version of the	Different color folder with printed instructions taped to the front of the folder to differentiate forms.

PDSA Cycle	Problem	Plan (P)	Do (D)	Study (S)	Act (A)
				yellow symptom inventory form.	
Cycle 4 Dates: 12/09/19 to 12/29/19	Changing front line staff lack education on ESAS-r + 1 QoL related process.	Provide frontline staff update regarding modification to process and form appearance.	Laminated sheet given with name of providers and process given was placed at the HUC desk.	Similar process was being used by one of the HUC in the clinic. This helps to standardize the process throughout the three clinics.	Laminated sheet improved sustainability as it provided floating HUC and new HUC with information for workflow. Since clinic staff are not connected to the OOPC team directly, a member from OOPC team will need to update the HUC when new provider is hired.

REFERENCES

- American Cancer Society. (n.d.). Cancer Facts & Figures 2020 | American Cancer Society. Retrieved June 20, 2020, from <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2020.html>
- Arraras, J. I., de la Vega, F. A., Asin, G., Rico, M., Zarandona, U., Eito, C., ... Dominguez, M. A. (2014). The EORTC QLQ-C15-PAL questionnaire: validation study for Spanish bone metastases patients. *Quality of Life Research*, 23(3), 849–855. doi:10.1007/s11136-013-0511-9
- Barbera, L., Sutradhar, R., Howell, D., Sussman, J., Seow, H., Dudgeon, D., ... Krzyzanowska, M. K. (2015). Does routine symptom screening with ESAS decrease ED visits in breast cancer patients undergoing adjuvant chemotherapy? *Supportive Care in Cancer*, 23(10), 3025–3032. doi:10.1007/s00520-015-2671-3
- Basch, E., Barbera, L., Kerrigan, C. L., & Velikova, G. (2018). Implementation of Patient-Reported Outcomes in Routine Medical Care. *American Society of Clinical Oncology Educational Book / ASCO. American Society of Clinical Oncology. Meeting*, 38, 122–134. doi:10.1200/EDBK_200383
- Brooks, J. V., Poague, C., Formagini, T., Sinclair, C. T., & Nelson-Brantley, H. V. (2020). The Role of a Symptom Assessment Tool in Shaping Patient-Physician Communication in Palliative Care. *Journal of Pain and Symptom Management*, 59(1), 30–38. doi:10.1016/j.jpainsymman.2019.08.024
- Clark, D. (2015). A report for the Scottish Parliament by Professor David Clark: International comparisons in palliative care provision: what can the indicators tell us?
- Cohen, S. R., Sawatzky, R., Russell, L. B., Shahidi, J., Heyland, D. K., & Gadermann, A. M. (2017). Measuring the quality of life of people at the end of life: The McGill Quality of Life Questionnaire-Revised. *Palliative Medicine*, 31(2), 120–129. doi:10.1177/0269216316659603
- Conrad, R., Mücke, M., Marinova, M., Burghardt, A., Stieber, C., Cuhls, H., & Radbruch, L. (2017). Measurement of Quality of Life in Palliative Care: Evidence for Criterion-Oriented Validity of a Single-Item Approach. *Journal of Palliative Medicine*, 20(6), 604–610. doi:10.1089/jpm.2016.0218
- Costantini, M., Rabitti, E., Beccaro, M., Fusco, F., Peruselli, C., La Ciura, P., ... Higginson, I. J. (2016). Validity, reliability and responsiveness to change of the Italian palliative care outcome scale: a multicenter study of advanced cancer patients. *BMC Palliative Care*, 15, 23. doi:10.1186/s12904-016-0095-6
- Dans, M., Smith, T., Back, A., Baker, J. N., Bauman, J. R., Beck, A. C., ... Scavone, J. L. (2017). NCCN guidelines insights: palliative care, version 2.2017. *Journal of the National Comprehensive Cancer Network*, 15(8), 989–997. doi:10.6004/jnccn.2017.0132

- De Meij, J. S. B., Chinapaw, M. J. M., Kremers, S. P. J., Van der Wal, M. F., Jurg, M. E., & Van Mechelen, W. (2010). Promoting physical activity in children: The stepwise development of the primary school-based JUMP-in intervention applying the RE-AIM evaluation framework. *British Journal of Sports Medicine*, 44(12), 879–887. doi:10.1136/bjsm.2008.053827
- De Roo, M. L., Leemans, K., Claessen, S. J. J., Cohen, J., Pasman, H. R. W., Deliens, L., ... EURO IMPACT. (2013). Quality indicators for palliative care: update of a systematic review. *Journal of Pain and Symptom Management*, 46(4), 556–572. doi:10.1016/j.jpainsymman.2012.09.013
- Diplock, B. D., McGarragle, K. M. C., Mueller, W. A., Haddad, S., Ehrlich, R., Yoon, D.-H. A., ... Ellis, J. W. M. (2019). The impact of automated screening with Edmonton Symptom Assessment System (ESAS) on health-related quality of life, supportive care needs, and patient satisfaction with care in 268 ambulatory cancer patients. *Supportive Care in Cancer*, 27(1), 209–218. doi:10.1007/s00520-018-4304-0
- Dy, S. M., Kiley, K. B., Ast, K., Lupu, D., Norton, S. A., McMillan, S. C., ... Casarett, D. J. (2015). Measuring what matters: top-ranked quality indicators for hospice and palliative care from the American Academy of Hospice and Palliative Medicine and Hospice and Palliative Nurses Association. *Journal of Pain and Symptom Management*, 49(4), 773–781. doi:10.1016/j.jpainsymman.2015.01.012
- Dzingina, M., Higginson, I. J., McCrone, P., & Murtagh, F. E. M. (2017). Development of a Patient-Reported Palliative Care-Specific Health Classification System: The POS-E. *The Patient*, 10(3), 353–365. doi:10.1007/s40271-017-0224-1
- Echteld, M. A., Deliens, L., Onwuteaka-Philipsen, B., Klein, M., & van der Wal, G. (2006). EORTC QLQ-C15-PAL: the new standard in the assessment of health-related quality of life in advanced cancer? *Palliative Medicine*, 20(1), 1–2. doi:10.1191/0269216306pm1090ed
- El-Jawahri, A., Greer, J. A., Pirl, W. F., Park, E. R., Jackson, V. A., Back, A. L., ... Temel, J. S. (2017). Effects of Early Integrated Palliative Care on Caregivers of Patients with Lung and Gastrointestinal Cancer: A Randomized Clinical Trial. *The Oncologist*, 22(12), 1528–1534. doi:10.1634/theoncologist.2017-0227
- Forman, J., Heisler, M., Damschroder, L. J., Kaselitz, E., & Kerr, E. A. (2017). Development and application of the RE-AIM QuEST mixed methods framework for program evaluation. *Preventive Medicine Reports*, 6, 322–328. doi:10.1016/j.pmedr.2017.04.002
- Gaglio, B., Shoup, J. A., & Glasgow, R. E. (2013). The RE-AIM framework: a systematic review of use over time. *American Journal of Public Health*, 103(6), e38-46. doi:10.2105/AJPH.2013.301299
- Gesme, D., & Wiseman, M. (2010). How to implement change in practice. *Journal of Oncology Practice / American Society of Clinical Oncology*, 6(5), 257–259. doi:10.1200/JOP.000089

- Ghoshal, A., Salins, N., Deodhar, J., Damani, A., & Muckaden, M. (2017). Impact of symptom control on fatigue improvement in patients with advanced cancer: A prospective observational study. *Progress in Palliative Care*, 25(2), 63–74. doi:10.1080/09699260.2016.1200818
- Glare, P. A. (2013). Early implementation of palliative care can improve patient outcomes. *Journal of the National Comprehensive Cancer Network*, 11 Suppl 1, S3-9.
- Glasgow, R E, Vogt, T. M., & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American Journal of Public Health*, 89(9), 1322–1327. doi:10.2105/AJPH.89.9.1322
- Glasgow, Russell E, Nelson, C. C., Strycker, L. A., & King, D. K. (2006). Using RE-AIM metrics to evaluate diabetes self-management support interventions. *American Journal of Preventive Medicine*, 30(1), 67–73. doi:10.1016/j.amepre.2005.08.037
- Graham, K., & Logan, J. (2004). Using the Ottawa Model of Research Use to implement a skin care program. *Journal of Nursing Care Quality*, 19(1), 18–24; quiz 25.
- Groenvold, M., Petersen, M. A., Aaronson, N. K., Arraras, J. I., Blazeby, J. M., Bottomley, A., ... EORTC Quality of Life Group. (2006). The development of the EORTC QLQ-C15-PAL: a shortened questionnaire for cancer patients in palliative care. *European Journal of Cancer*, 42(1), 55–64. doi:10.1016/j.ejca.2005.06.022
- Harden, S. M., Gaglio, B., Shoup, J. A., Kinney, K. A., Johnson, S. B., Brito, F., ... Estabrooks, P. A. (2015). Fidelity to and comparative results across behavioral interventions evaluated through the RE-AIM framework: a systematic review. *Systematic Reviews*, 4, 155. doi:10.1186/s13643-015-0141-0
- Haun, M. W., Estel, S., Rücker, G., Friederich, H.-C., Villalobos, M., Thomas, M., & Hartmann, M. (2017). Early palliative care for adults with advanced cancer. *Cochrane Database of Systematic Reviews*, 6, CD011129. doi:10.1002/14651858.CD011129.pub2
- Hearn, J., & Higginson, I. J. (1999). Development and validation of a core outcome measure for palliative care: the palliative care outcome scale. *Quality and Safety in Health Care*, 8(4), 219–227. doi:10.1136/qshc.8.4.219
- Heckel, M., Bussmann, S., Stiel, S., Weber, M., & Ostgathe, C. (2015). Validation of the German Version of the Quality of Dying and Death Questionnaire for Informal Caregivers (QODD-D-Ang). *Journal of Pain and Symptom Management*, 50(3), 402–413. doi:10.1016/j.jpainsymman.2015.03.020
- Howell, D, Molloy, S., Wilkinson, K., Green, E., Orchard, K., Wang, K., & Liberty, J. (2015). Patient-reported outcomes in routine cancer clinical practice: a scoping review of use, impact on health outcomes, and implementation factors. *Annals of Oncology*, 26(9), 1846–1858. doi:10.1093/annonc/mdv181

- Howell, Doris, Li, M., Sutradhar, R., Gu, S., Iqbal, J., O'Brien, M. A., ... Barbera, L. (2020). Integration of patient-reported outcomes (PROs) for personalized symptom management in “real-world” oncology practices: a population-based cohort comparison study of impact on healthcare utilization. *Supportive Care in Cancer*, 28(10), 4933–4942. doi:10.1007/s00520-020-05313-3
- Kamal, A. H., Gradison, M., Maguire, J. M., Taylor, D., & Abernethy, A. P. (2014). Quality measures for palliative care in patients with cancer: a systematic review. *Journal of Oncology Practice / American Society of Clinical Oncology*, 10(4), 281–287. doi:10.1200/JOP.2013.001212
- Kessler, R. S., Purcell, E. P., Glasgow, R. E., Klesges, L. M., Benkeser, R. M., & Peek, C. J. (2013). What does it mean to “employ” the RE-AIM model? *Evaluation & the Health Professions*, 36(1), 44–66. doi:10.1177/0163278712446066
- Kiely, F., Cran, A., Finnerty, D., & O'Brien, T. (2017). Self-Reported Quality of Life and Symptom Burden in Ambulatory Patients With Multiple Myeloma on Disease-Modifying Treatment. *The American Journal of Hospice & Palliative Care*, 34(7), 671–676. doi:10.1177/1049909116646337
- Koesel, N., Tocchi, C., Burke, L., Yap, T., & Harrison, A. (2019). Symptom distress: implementation of palliative care guidelines to improve pain, fatigue, and anxiety in patients with advanced cancer. *Clinical Journal of Oncology Nursing*, 23(2), 149–155. doi:10.1188/19.CJON.149-155
- LeBlanc, T. W., & El-Jawahri, A. (2015). When and why should patients with hematologic malignancies see a palliative care specialist? *Hematology*, 2015, 471–478. doi:10.1182/asheducation-2015.1.471
- Lien, K., Zeng, L., Nguyen, J., Cramarossa, G., Culleton, S., Caissie, A., ... Chow, E. (2011). Comparison of the EORTC QLQ-C15-PAL and the FACIT-Pal for assessment of quality of life in patients with advanced cancer. *Expert Review of Pharmacoeconomics & Outcomes Research*, 11(5), 541–547. doi:10.1586/erp.11.64
- Lyons, K. D., Bakitas, M., Hegel, M. T., Hanscom, B., Hull, J., & Ahles, T. A. (2009). Reliability and validity of the Functional Assessment of Chronic Illness Therapy-Palliative care (FACIT-Pal) scale. *Journal of Pain and Symptom Management*, 37(1), 23–32. doi:10.1016/j.jpainsymman.2007.12.015
- McGee, S. F., Zhang, T., Jonker, H., Laurie, S. A., Goss, G., Nicholas, G., ... Wheatley-Price, P. (2018). The Impact of Baseline Edmonton Symptom Assessment Scale Scores on Treatment and Survival in Patients With Advanced Non-small-cell Lung Cancer. *Clinical Lung Cancer*, 19(1), e91–e99. doi:10.1016/j.clcc.2017.05.018
- Meier, D. E. (2011). Increased access to palliative care and hospice services: opportunities to improve value in health care. *The Milbank Quarterly*, 89(3), 343–380. doi:10.1111/j.1468-0009.2011.00632.x

- Merchant, S. J., Brogly, S. B., Booth, C. M., Goldie, C., Nanji, S., Patel, S. V., ... Baxter, N. N. (2019). Palliative Care and Symptom Burden in the Last Year of Life: A Population-Based Study of Patients with Gastrointestinal Cancer. *Annals of Surgical Oncology*, 26(8), 2336–2345. doi:10.1245/s10434-019-07320-z
- Nipp, R. D., El-Jawahri, A., Moran, S. M., D'Arpino, S. M., Johnson, P. C., Lage, D. E., ... Temel, J. S. (2017). The relationship between physical and psychological symptoms and health care utilization in hospitalized patients with advanced cancer. *Cancer*, 123(23), 4720–4727. doi:10.1002/cncr.30912
- Provost, L. (n.d.). How Long Should a PDSA Cycle Last? Retrieved June 14, 2019, from <http://www.ihl.org/education/IHIOpenSchool/resources/Pages/Activities/Provost-HowLongShouldAPDSACycleLast.aspx>
- Rabin, B. A., McCreight, M., Battaglia, C., Ayele, R., Burke, R. E., Hess, P. L., ... Glasgow, R. E. (2018). Systematic, multimethod assessment of adaptations across four diverse health systems interventions. *Frontiers in Public Health*, 6, 102. doi:10.3389/fpubh.2018.00102
- Reed, J. E., & Card, A. J. (2016). The problem with Plan-Do-Study-Act cycles. *BMJ Quality & Safety*, 25(3), 147–152. doi:10.1136/bmjqs-2015-005076
- Shamieh, O., Khamash, O., Khraisat, M., Jbouri, O., Awni, M., Al-Hawamdeh, A., ... Hui, D. (2017). Impact of outpatient palliative care (PC) on symptom burden in patients with advanced cancer at a tertiary cancer center in Jordan. *Supportive Care in Cancer*, 25(1), 177–183. doi:10.1007/s00520-016-3395-8
- Steinhauser, K. E., Clipp, E. C., Bosworth, H. B., McNeilly, M., Christakis, N. A., Voils, C. I., & Tulsky, J. A. (2004). Measuring quality of life at the end of life: validation of the QUAL-E. *Palliative & Supportive Care*, 2(1), 3–14. doi:10.1017/S1478951504040027
- Stiel, S., Psych, D., Kues, K., Krumm, N., Radbruch, L., & Elsner, F. (2011). Assessment of quality of life in patients receiving palliative care: comparison of measurement tools and single item on subjective well-being. *Journal of Palliative Medicine*, 14(5), 599–606. doi:10.1089/jpm.2010.0473
- Tai, S.-Y., Lee, C.-Y., Wu, C.-Y., Hsieh, H.-Y., Huang, J.-J., Huang, C.-T., & Chien, C.-Y. (2016). Symptom severity of patients with advanced cancer in palliative care unit: longitudinal assessments of symptoms improvement. *BMC Palliative Care*, 15, 32. doi:10.1186/s12904-016-0105-8
- Taylor, M. J., McNicholas, C., Nicolay, C., Darzi, A., Bell, D., & Reed, J. E. (2014). Systematic review of the application of the plan-do-study-act method to improve quality in healthcare. *BMJ Quality & Safety*, 23(4), 290–298. doi:10.1136/bmjqs-2013-001862
- Temel, J. S., Greer, J. A., Muzikansky, A., Gallagher, E. R., Admane, S., Jackson, V. A., ... Lynch, T. J. (2010). Early palliative care for patients with metastatic non-small-cell lung cancer. *The New England Journal of Medicine*, 363(8), 733–742. doi:10.1056/NEJMoa1000678

- U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research. (2006). Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: draft guidance. *Health and Quality of Life Outcomes*, 4, 79. doi:10.1186/1477-7525-4-79
- Ulas, S., Eyigor, S., & Caramat, I. (2018). Quality of life and neuropathic pain in hospitalized cancer patients: A comparative analysis of patients in palliative care wards versus those in general wards. *Indian Journal of Palliative Care*, 24(3), 325–333. doi:10.4103/IJPC.IJPC_12_18
- UNC Outpatient Oncology Palliative Care - UNC Lineberger. (n.d.). Retrieved March 26, 2019, from <https://unclineberger.org/ccsp/other-services/supportive-care/>
- van Dongen-Leunis, A., Redekop, W. K., & Uyl-de Groot, C. A. (2016). Which Questionnaire Should Be Used to Measure Quality-of-Life Utilities in Patients with Acute Leukemia? An Evaluation of the Validity and Interpretability of the EQ-5D-5L and Preference-Based Questionnaires Derived from the EORTC QLQ-C30. *Value in Health*, 19(6), 834–843. doi:10.1016/j.jval.2016.05.008
- Van Egdom, L. S. E., Oemrawsingh, A., Verweij, L. M., Lingsma, H. F., Koppert, L. B., Verhoef, C., ... Hazelzet, J. A. (2019). Implementing Patient-Reported Outcome Measures in Clinical Breast Cancer Care: A Systematic Review. *Value in Health*, 22(10), 1197–1226. doi:10.1016/j.jval.2019.04.1927
- Albers, G., Echteld, M. A., de Vet, H. C. W., Onwuteaka-Philipsen, B. D., van der Linden, M. H. M., & Deliens, L. (2010). Evaluation of quality-of-life measures for use in palliative care: a systematic review. *Palliative Medicine*, 24(1), 17–37. doi:10.1177/0269216309346593
- Watanabe, S. M., Nekolaichuk, C., Beaumont, C., Johnson, L., Myers, J., & Strasser, F. (2011). A multicenter study comparing two numerical versions of the Edmonton Symptom Assessment System in palliative care patients. *Journal of Pain and Symptom Management*, 41(2), 456–468. doi:10.1016/j.jpainsymman.2010.04.020
- World Health Organization. (n.d.). WHO | WHO Definition of Palliative Care. Retrieved August 15, 2019, from <https://www.who.int/cancer/palliative/definition/en/>