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Oncology Patients Oral Hygiene Education Intervention Mapping among Nursing Staff: A Repeated Measure Non-experimental Design

Maura Poleon
*Florida International University*, mpole006@fiu.edu

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Oncology Patients Oral Hygiene Education Intervention Mapping among Nursing Staff: A Repeated Measure Non-experimental Design

A Scholarly Project Presented to the
Faculty of the Nicole Wertheim College of
Nursing and Health Sciences

Florida International University

In partial fulfillment of the Requirements for the Degree of
Doctor of Nursing Practice

By
Maura Poleon, DNP(ABD)

Supervised by
C. Victoria Framil, DNP, FNP-BC

Approval Acknowledged

DNP Program Director: ______________________________________________

Date:  ______________________________________________
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Abstract

OBJECTIVE: Oral health conditions mainly cavities, and tooth decay had been implicated in oral cavities neoplasm incidence, complications, prognosis and survival. The current study aimed to assess the knowledge and skills of oncology nurses, prior to the application of the training and education module on oral hygiene, and thereafter re-assessment.

MATERIALS & METHODS: A repeated measure, non-experimental design was used to assess the knowledge and skills of nursing staff. The study was conducted at 5 Hope, 6Hope, and 5 Clarke, Baptist Hospital of Miami, with 145 nurse participants in the pretest assessment, while 63 nurses completed the post test. A paired sample *t*-test was applied in assessing the contribution of training and education module in oral hygiene knowledge and skills enhancement among oncology nurses.

RESULTS An estimated 145 nurses completed the pretest prior to the education intervention module, while 63 completed the post-test (43.4%), indicative of 56.6% attrition rate. With respect to study characteristics, female represented (84.1%), males (15.9%), day shift (71.4%) and night shift,28.6%. In addition, age group, 21-40 years represented 76.2%, advanced and expert nurses, 51.6%, bachelor’s degree, 76.2%, while 6-Hope represented 54%. The pretest mean score was 11.8, SD 3.4, 95% Confidence Interval (CI), 11.0-12.6., while the posttest mean score was 10.8, SD= 4.6, 95 % CI, 9.6-12.0, *p* = 0.04.

CONCLUSION. This study, due to participants’ low concentration after exposure to the oral hygiene education observed no improvement in knowledge of the nursing staff in this training module.
Introduction/ Problem Statement/Significance

Nurses are primary caregivers and the first line of contact with patients in many healthcare institutions, particularly in inpatient hospital settings. Therefore, they can assume a significant role to screen for oral complications and implement evidence-based oral care interventions to mitigate and or eliminate oral problems (Pai, et al., 2019). In current practice, there is a gap in the documentation of oral assessment and oral hygiene interventions in hospitalized oncology patients. During hospitalization, significant changes occur in a patient’s microbial flora and ability to perform basic hygienic functions, such as performing oral hygiene. Proper and timely oral care done by the patient, or the medical staff can decrease opportunistic infections in the already immunocompromised oncology patient.

Globally, approximately 500,000 new cases of head and neck cancers are forecasted. Treatment modalities for head and neck cancers are primarily surgery, radiotherapy, and chemotherapy as monotherapy or in combination. Radiotherapy and chemotherapy for head and neck cancers and other cancers, in general, are notorious for adverse side effects on the oral cavity such as mucositis (inflammation of oral mucosa), oral candida infections (oral thrush), Xerostomia (commonly referred to as cotton mouth/ dry mouth), loss of taste sensation(ageusia), radiation caries (tooth decay induced by radiation-induced xerostomia) and osteochemo/radio-necrosis (Pai & Ongole, 2015).

The mouth is a host to a wide range of microorganisms. Oral mucositis leads to a disruption in oral mucosa in patients who are immunocompromised which significantly increases the risk of infection and sepsis. The local bacterial flora
having that epithelial barrier in the mouth freely enters the bloodstream leading to a possible systemic infection. Standard-dose chemotherapy or head-and-neck radiotherapy patients can experience an incidence of 15% to 40% of oral mucositis (Pai, et al., 2019).

A clinical correlation exists between a patient’s normal flora, subsequent contamination with gram-negative pathogens, biofilm/plaque formation, xerostomia, and mucositis development, and the increased risk for hospital-acquired pneumonia and other life-threatening infections in immunosuppressed patients. The lack of or absence of oral hygiene can result in a myriad of debilitating and deadly complications, increased length of hospital stays, and astronomically costly preventable treatments. Hospital-acquired pneumonia (HAP) is the most common healthcare-associated infection (HAI) in the United States, with many of the cases occurring in non-ventilated patients. But many hospitals track HAP only in ventilated patients due to the complexity and subjectivity of conducting surveillance for large numbers of non-ventilated patients (Ji, et al., 2019).

According to the Joint Commission, 2021 saw a national call to action aimed at highlighting the hidden harm of non-ventilator hospital-acquired pneumonia (NVHAP). The call to action was issued by the National Organization to Prevent Hospital-Acquired Pneumonia (NOHAP), the Centers for Disease Control and Prevention (CDC), and the Veterans Health Administration (VHA). The Joint Commission, the American Dental Association (ADA), and several other organizations are collaborating to support healthcare organizations to focus efforts on this preventable precursor for many other health complications (Munro, et al., 2021).
Summary of the Literature Related to the Clinical Question

A literature search was performed in OVID MEDLINE, PubMed, and CINAHL for articles in the English language for 2015-present using the search terms “importance of oral hygiene, blood and bone marrow transplant patients, oral hygiene protocol, mouth care, cancer patients.” These terms were combined with staff nurses, patient care technicians, awake, non-ventilated patients, and independent; 29 unique articles were found with 12 relevant to this study. Evidence is lacking for the application of an oral hygiene protocol on this specific patient population group as an evidence-based nursing intervention. Although most of the relevant articles found were generalized to the oncology patient the findings are also pertinent to the blood and bone marrow patient.

A cross-sectional convenience study was conducted in Jordan to evaluate oncology nurses’ knowledge and compliance with oral mucositis (OM) management guidelines. Cancer is a life-altering health problem in Jordan with an increase in incidence. Patients diagnosed with cancer undergo different treatment modalities including chemotherapy, radiotherapy, surgery, and bone marrow transplantation and as a result they experience a wide range of long-term and short-term complications, such as oral complications. Oral complications affect the quality of life, disrupt/delay treatment plans, alter the nutritional status, and can result in pain (Abu Sharour, 2019).

In summarizing this study, it was discovered that an improvement in knowledge and skills through continued training is required to improve oral care and minimize the risk of OM. This study examined the oncology nurses’ knowledge and compliance with OM management guidelines and provided concrete evidence that there is a need for the establishment of a structured educational oral hygiene program.
A non-randomized control trial supports the basis that oral hygiene is fundamental in the care of the oncology population and begins with the performance of regular, thorough assessment of the oral cavity in addition to keeping the oral cavity moist and free of disease-causing organisms (Coke, et al., 2015). The main aim of the article was to assess patient knowledge, practices, and staff documentation practices on oral assessment and performance of oral hygiene care. Limitations of the study in this article included that; participants were obtained from a non-randomized convenience sample, the sample size was small, and there was no knowledge pretest or overall evaluation of the educational module.

This article sought to highlight the importance of integrating an evidence-based oral hygiene model as best practice in the care of hematology/oncology patients to prevent mucositis. Again, the importance of consistency in the assessment and performance of oral hygiene is highlighted by this article. The deviation from performing oral assessment and maintaining consistency in the performance or oral hygiene may be associated with infections which may result in longer hospitalization and impact a patient's nutritional status.

One of the most relevant studies in the literature garnered is an internet-based survey among 30 transplant centers in the Eastern Mediterranean region. Questions ranged from demographics of the transplant center, current center-based oral care protocol in use, type of collaboration with dental service, use of standardized oral assessment tools and grading systems for mucositis, consultations for management of oral complications and oral health needs at the center (Mawardi, et al., 2021).

It was concluded that the magnitude and implementation of oral care protocols before and during hematopoietic stem cell transplantation varied among the
different centers. And the lack of a universal protocol contributes to gaps in the oral healthcare needs and management of this specific patient population. Oral care during transplant should be a standard component of transplant protocols.

This cross-sectional descriptive survey was conducted in India to determine the nurses’ practice and barriers regarding oral care in cancer patients undergoing chemotherapy and radiation therapy. Lack of standard operating procedures, manpower, and maintenance of records were some of the major barriers to providing oral care. The documentation audit revealed that oral care was documented in the chart only when the order was present in the care sheet, but oral problem assessment was not recorded at all and there was no protocol specifically designed for oral care of cancer patients. The participants of this study verbalized that oral care in cancer patients was one of the most ignored aspects of oncology nursing (Pai, Ongole & Banerjee, 2019). The conclusion derived from this research study again accentuates the need to conduct and publish more research findings to support the need to develop evidence-based oral care intervention protocol and staff education and motivation to attend continuing education regularly to keep themselves abreast of the latest trends to render comprehensive care to the patients.

Before 2015 one of the earliest published articles is a descriptive case design for the implementation and evaluation of oral assessments and oral hygiene. Although this study focused on ventilated patients in intensive care units, it was found to be relevant as it can be adapted for use in the oncology patient or any inpatient population. The goal of the study was to introduce the Bedside Oral exam (BOE) and the Barrow Oral Care (BOCP) to guide oral care for intensive care unit patients and to explore quality improvement for the incidence of Ventilator-associated pneumonia (VAP), the cost-effectiveness of oral hygiene supplies and staff response
to change in practice. Cost-effective, comprehensive oral care appears to be effective in reducing VAP (Prendergast, Kleinman & King, 2013).

**PICO Question**

Is there any difference in knowledge of nursing staff in Baptist Hospital of Miami (5 Hope, 6 Hope and 5 Clarke) exposed to the Oral Hygiene Education and training Module? This study was designed to examine whether or not the involvement of nursing staff within this intervention enhances their knowledge and skills in caring for cancer patients with oral pathology. Below are the dimensions in the actualization of this study:

**Population:** Nurses on the Oncology Unit

**Intervention:** introduction of a pretest/posttest and an educational module specific to the importance of an oral regimen in oncology patients on 5 Hope, 6 Hope, and 5 Clarke

**Comparison:** current practice (observation of or care not being done routinely)

**Outcome:** increased oral care knowledge

**Time:** within 12 weeks

The purpose of this research study is to evaluate the impact of a mouth care educational module on the documentation of assessment of the oral cavity and performance of oral hygiene whether done independently by the patient or assisted by nursing staff. Thus, bridging the gap between research and the implementation of an evidence-based nursing staff-focused educational module aimed at improving the documentation of oral assessment and performance of oral hygiene in the focused population- the hospitalized oncology patient.
Primary DNP Project Goals

The Primary DNP Project Goal is to gain leadership skills that will enable an advanced practitioner to assume complex and advanced leadership roles to initiate and guide change through the development of an Oral Hygiene Protocol on the Oncology unit at Baptist Health South Florida. Collaborating with various stakeholders such as dentist, oral hygienist, bedside nurses, patients, floor clinicians, patient care supervisors and Director of Oncology services (preceptor) to implement evidence-based project.

Gain in-depth knowledge of the dynamics in a healthcare organization specifically policy/protocol development and implementation in healthcare systems by evaluating the relationship among access, cost, quality and safety and their influence on healthcare. Also evaluating how organizational structure, care processes, finance, marketing, and Policy decisions impact the quality of healthcare.

Objectives

SMART goals represent specific, measurable, attainable, realistic, and timely objectives. The attainment of the objectives supports the ultimate progression towards project goals. The desired outcome involved multiple goals the identification of objectives for advancement of goals may require prioritization. (Zaccagnini & White, 2014).

Specific- The PICO clearly stated the improvement process, population, setting and time Frame. Measurable- Pre and posttest 17 item questionnaire which was conducted via REDCap as soon as IRB approval was obtained. Attainable and Realistic- The research study was deemed feasible secondary to the availability of staff to participate in the pretest, posttest, and education module. The education module as an intervention was proposed to increase oncology nursing staff knowledge and skills
with respect to oral hygiene. Timely- The research study was completed within the expected timeframe.

**Definition of Terms**

**Pneumonia:** Defined as an infection of the pulmonary parenchyma caused by various organisms; it is not a single disease but a group of specific infections, each with its epidemiology, pathogenesis, presentation, and clinical course. The American Thoracic Society (ATS) and Infectious Diseases Society of America (IDSA), pneumonia is defined as the presence of new lung infiltrates and clinical evidence that the infiltrate is of an infectious origin, such as the new onset of fever, purulent sputum, leukocytosis and decline in oxygenation (Levison, 2001).

**Hospital-acquired Pneumonia (HAP):** Pneumonia that occurs more than 48 hours after hospital admission and was not incubating at the time of admission.

**Healthcare-associated pneumonia (HCAP):** Defined as pneumonia acquired by an individual with a specific type of healthcare contact in the recent past, including hospitalizations for 2 or more days within the preceding 90 days, residence in a long-term facility or extended care facility, receipt of home infusion therapy, chronic dialysis treatment within 30 days, or round care. These individuals were once thought to be at increased risk of infection caused by multi drug-resistant organisms.

**Non-ventilated Hospital-acquired pneumonia (NV-HAP):** Pneumonia that occurs more than 48 hours after hospital admission and was not incubating at the time of admission in patients not requiring mechanical ventilation.

**Oral health:** According to the Centers for Disease Control and Prevention (CDC), oral health encompasses the state of health of the teeth, gums, and entire oral-facial system that allows individuals to smile, speak and chew. Some of the most common diseases that impact oral health include cavities (tooth decay), gum (periodontal) disease, and oral
cancer (CDC, n.d.)

**Radiation caries:** tooth decay caused as a result of radiation-induced dry mouth

**Nursing Staff:** Nursing staff means registered nurses, licensed practical nurses, and licensed vocational nurses providing services at a facility currently licensed to the extent required by the State to deliver those health services they have undertaken to provide.

**Chemotherapy:** Treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.

**Oral health:** Oral hygiene is the practice of keeping your mouth clean and disease-free. It involves brushing and flossing your teeth as well as visiting your dentist regularly for dental X-rays, exams, and cleanings.

**Radiation:** Radiation therapy (also called radiotherapy) is a cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumors.

**Education:** Education is both the act of teaching knowledge to others and the act of receiving knowledge from someone else.

**Mucositis:** Inflammation of the lining of the mouth

**Xerostomia:** A dry mouth

**Leukoplakia (white/red):** Lesions that cannot be scrapped off or attributed to any other cause **Candidiasis (oral thrush):** Yeast-like fungus, candida albicans, which normally inhabits the vagina and digestive system. It commonly manifests as soft white plaques on the mucosa and tongue.

**Gingivitis:** Inflammation of the gums leading to swelling and bleeding caused by plaque which attacks the tissue causing damage.
Conceptual Underpinning and Theoretical Framework of Project

Lewin’s Change Model, Jean Watson’s Human Caring theory and the Nola Pender’s Health Promotion Model are two of the theorists underpinned that will be used in the development and implementation of this project. Lewin’s Change Model which explains the steps in human reaction and response to change will assist me in anticipating potential barriers or problems with the implementation of this project. Jean Watson’s theory will be used as a guide to enrich the human-human interaction between the nurse and patient thus fostering a caring-healing environment. Watson defines “caring” as the moral ideal of nursing whereby the end is protection, enhancement, and preservation of human dignity.” Nola Pender’s Health Promotion Model affects both the nurse and patient in this project as the nurse will be motivated to engage the patient in health promotion to improve their health or to prevent negative outcomes and the patient will be eager to engage in any activity that will improve or maintain their health

Materials & Method

Materials and Methods components as the methodology in this study reflect the following components: Institutional Review Board (IRB) Approval: This study was approved by Baptist Hospital of Miami IRB prior to its conduct. Study Design: This is a non-experimental repeated measure design. This design allows for the utilization of pre and post-test approaches in the assessment of knowledge and skills in an educational intervention project. The current design is very appropriate and reliable, given the utilization of oral hygiene education and training module in knowledge acquisition during this study. Study Sample/Population: This study involved the recruitment and participation of Oncology Registered nurses working on 5 Hope, 6 Hope, and 5 Clarke at Baptist Hospital of Miami (BHM). Sample size and power estimations: To determine the sample size in this study, the following parameters were utilized: (a) power (1-beta), which is the ability of a study to
detect the minimum difference, should such a variance exists, comparing the pre and posttest, and was estimated at 80% (0.8), (b) Type 1 Error tolerance which was estimated at (d) $t$ 5% (0.05), (c) effect size, classified as delta, which was set at 20% (0.20), and (d) repeated measure design. With these parameters, the sample size was estimated as $n=60$.

**Study eligibility:** This study involved inclusion and exclusion criteria as eligibility. (I) **Inclusion Criteria:** This criterion reflects the following: (a) Oncology registered nurses who are currently employed full-time, part-time, or per diem in either department at Baptist Hospital, (b) academic achievements of nurses with nursing degrees (c) Nurses in the oncology units: 5 Hope, 6 Hope, and 5 Clarke, (II) **Exclusion criteria:** The study ineligibility, implying exclusion criteria requires the following: (a) nurses without nursing degrees (Licensed Practical Nurses), (b) nurses not performing care in 5 Hope, 6 Hope, and 5 Clarke.

**Instruments/Surveys/Questionnaires:** **Oral Health Hygiene Survey for Oncology Nursing (OHSON)** was a 25-item Likert-type survey to assess oncology nurses’ attitudes, beliefs, and perceptions of knowledge/skills, resources, and logistics related to providing oncology patients with oral hygiene/care (Appendix The instrument was developed by the researcher using current available literature and assistance from the DNP preceptor and a Baptist Health Nurse Scientist. The Likert-type items are rated on a five-point scale (1= Strongly Disagree, 2= Disagree, 3 = Neither Agree nor Disagree, 4= Agree, and 5= Strongly Agree). The OHSON also included two open-ended questions. **Pretest/Posttest Instrument.** The same test was used for the pretest and posttest. The questionnaire contained 17 multiple-choice questions that assessed the participants’ knowledge of oral hygiene/care before and after the education intervention (Appendix C). The order of the pretest and post-test questions was altered to minimize recall bias.
Recruitment, Procedures, Consent Process, and Intervention: Oncology nurses on 5 Hope, 6 Hope, and 5 Clarke were recruited via email using Baptist Health email distribution groups. The email invitation (Appendix D) included the study’s title and purpose, researcher information, the participant’s estimated time commitment, and the Research Data Capture (REDCap) universal locator (URL) address and quick response (QR) code for direct access to the demographic information and OHSON, pretest/posttest, and educational module. The REDCap cover page Appendix E) will include statements to address (1) study title/purpose, (2) voluntary participation, (3) the right to withdraw participation without penalty, (4) assurance of anonymity confidentiality, (5) risks/benefits, and (6) procedure for participation. Completion of the survey implies consent to participate. The participants will complete (1) the demographic information page (2) the OHSON survey, (3) a pretest, (4) the education module (Appendix F), and (5) a posttest. The estimated time to complete the surveys was 15 minutes.

Data Collection and Variable Ascertainment: The data in this study were collected using the survey on the REDCap platform. The participants were required to provide information on socio-demographics as well as the geographic location and the units within the hospital. Additionally, the pre and post-test examinations were conducted using the REDCap data collection tool. The required variables in this study involved the following: age, gender, RN level, unit/department, shift, and nursing experience. The outcome variable was the posttest whilst the independent variable was the pretest. These variables were characterized as dependent due to the design as a repeated measure (dependent t-test).

Education Intervention Mapping: The approximate time to complete the OHSON was 10 minutes, the pretest was 10-15 minutes, as well as the post-test. The education module took approximately 30 minutes to complete. Statistical Analysis: The pre-analysis screening was performed to examine the collected data for outliers and missing variables. The summary
statistics were performed using frequency and percentages. This assessment described the study characteristics using frequencies and percentages. With respect to the assessment of the knowledge based on the oral hygiene education module, a pretest was performed using a \( t \)-test evaluation which was conducted after the normality assumption test. After the education module, a posttest assessment was performed. This posttest required testing the normality assumption prior to its conduct.

In the assessment of the knowledge and skills gained or marginalized during the education intervention, a dependent \( t \)-test was used, implying a paired sample \( t \)-test. This test allowed for the assessment of the t value, the pretest means, the standard deviation (SD), and the 95% Confidence Interval (CI). Similarly, the posttest mean and SD as well as the 95% confidence interval were obtained. Additionally, the difference between the posttest and the pretest mean value, standard deviation, and 95% confidence interval were obtained. The test error tolerance (\( p \)-value) was set at 5% (0.05), while the measure of precision, CI was set at 5% (95% CI). The entire data were analyzed using STATA statistical software, STATA Corporation, College Station, Texas.

**SWOT Analysis**

The SWOT analysis tool was utilized to provide a methodical guide for identification of strengths and weaknesses of an organization, project or even a process (Moran, Burson & Conrad, 2020). SWOT, an acronym which describes: Strengths, Weaknesses, Opportunities and Threats. Conducting a SWOT analysis prior to the conduction of the research study was necessary to ensure measures were taken to address potential issues that could be mitigated prior to study implementation. The SWOT analysis is outlined in Table 1 for review.
### TABLE 1: SWOT Analysis of Baptist Hospital

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Magnet Hospital that promotes nursing research.</td>
<td>- New research study requiring multi-layered approval</td>
</tr>
<tr>
<td>- PhD and Doctoral prepared Nurse scientist</td>
<td>- FIU and Baptist Internal Review Board approval necessary prior to commencement</td>
</tr>
<tr>
<td>- Dedicated leaders who can change focus and direction of organization and units once a current direction is proved not to be working.</td>
<td>- Shifts in staffing specifically high rate of novice nurses</td>
</tr>
<tr>
<td>- PI and team members are all employed at clinical site.</td>
<td>- High staff turnover rate</td>
</tr>
<tr>
<td>- Optimization of resources to enhance patient centered care</td>
<td>- Shortage of nurses leading to increased Nurse: Patient ratio.</td>
</tr>
<tr>
<td></td>
<td>- Increased vulnerability of staff leading to callouts and leaving.</td>
</tr>
<tr>
<td></td>
<td>- Staff engagement recruitment and retention of participants.</td>
</tr>
<tr>
<td></td>
<td>- Inability to control all variables (especially time constraints)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Opportunities</td>
<td>Threats</td>
</tr>
<tr>
<td>- Improvement in staff retention. Currently there is minimal focus on staff retention and key members leave for more lucrative opportunities.</td>
<td>- Loss of skilled personnel. Many nurses left for hospitals in the area (example University of Miami) knowledge left with them to another competitor.</td>
</tr>
<tr>
<td>- Expansion of the unit with many future opportunities for success. Currently 5 &amp; 6 Hope (oncology floors) have the capability for 63 beds to be remotely monitored by EICU but does not match the number of nurses capable of caring for high acuity patients.</td>
<td>- Competitors (example Sylvester Cancer Institute) changing their marketing strategies or merging with another competitor can wipe out the position in the market that Miami Cancer Institute has achieved. Or they may copy a service that we provide at a cheaper price.</td>
</tr>
<tr>
<td>- High staff turnover rate which can affect quality of patient care.</td>
<td>- Adaptation of developments in technology may change the market beyond the unit capability to absorb the changes.</td>
</tr>
<tr>
<td>- Creating a Med Surg power plan that includes oral care for all admitted patients.</td>
<td>- Current economic/financial conditions such as high inflation rate, increased fuel prices can create instability in market</td>
</tr>
<tr>
<td>- Incentive for staff to participate in more research studies</td>
<td>- Competition for time/services of available personnel to support study</td>
</tr>
<tr>
<td>- Team members onsite for data collection and education</td>
<td>- Sustainability of recommendations from results of research finding</td>
</tr>
<tr>
<td>- Monthly benchmark oral care compliance report</td>
<td></td>
</tr>
</tbody>
</table>

The Principal Investigator, team members and nursing management are experienced, knowledgeable, approachable, and supportive of the initiative for improvement in patient care. The introduction of any research study requires recruitment/enlistment and retention of research participants/subjects. The identified stakeholders with interest in the outcome of this research study are the Principal Investigator, Director of Oncology Services, Chief Nursing Officer of Baptist Hospital oncology nursing staff and other affiliated research members (Nurse Scientist and Dentist). Potential strengths may be recognized with early stakeholder
enlistment whereas weaknesses may be a result of time constraints and availability of staff during the active phase of the study.

Findings/Results

This study was conducted to enhance knowledge and skills of nurses providing care to oncology patients with oral health conditions. With this education intervention in oral health improvement among cancer patients, the module involved information on oral hygiene, oral pathologies prevention as well as treatment. An estimated 145 nurses completed the pretest prior to the education intervention module, while 63 completed the post-test (43.4%).

Table 1A and 1B illustrate the characteristics of nurses in this study based on demographics, education, and units. Most of the participants were females (84.1%) relative to male (15.1%). With respect to the age group of nurses in this study, majority were 21-31 years (44.4%), followed by the age group 31-40 years (31.8%). The age group, 41-50 years represented an estimated 15.9%. The smallest proportion of nurses in this study were characterized as older than 50 years, representing the lowest percentage, 7.9%.
Table 1A. Study Characteristics, Oral Hygiene Education Intervention Module Baptist Hospital, (5- Clarke, 5-Hope, 6-Hope), 2022

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>53</td>
<td>84.1</td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
<td>15.9</td>
</tr>
<tr>
<td>Age Group (Years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21-30</td>
<td>28</td>
<td>44.4</td>
</tr>
<tr>
<td>31-40</td>
<td>20</td>
<td>31.8</td>
</tr>
<tr>
<td>41-50</td>
<td>10</td>
<td>15.9</td>
</tr>
<tr>
<td>&gt; 50</td>
<td>05</td>
<td>07.9</td>
</tr>
<tr>
<td>Professional Level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expert</td>
<td>14</td>
<td>22.6</td>
</tr>
<tr>
<td>Advanced</td>
<td>18</td>
<td>29.0</td>
</tr>
<tr>
<td>Proficient</td>
<td>20</td>
<td>32.3</td>
</tr>
<tr>
<td>Novice (Resident)</td>
<td>10</td>
<td>16.1</td>
</tr>
<tr>
<td>Nursing Experience (Years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1</td>
<td>10</td>
<td>15.9</td>
</tr>
<tr>
<td>1-5</td>
<td>28</td>
<td>44.4</td>
</tr>
<tr>
<td>6-10</td>
<td>10</td>
<td>15.9</td>
</tr>
<tr>
<td>&gt; 10</td>
<td>15</td>
<td>23.8</td>
</tr>
</tbody>
</table>

The professional levels were classified as, Novice (residents), Proficient, Advanced, Expert. Most of the nurses who participated in this study were classified as Proficient (32.3%), Advanced (29.0%), Expert (22.6%). The smallest percentage of nurses in this study were observed as Novice Residents (16.1%). The nursing experience was characterized by years of working in the nursing area less than 1 year, 1-5 years, 6-10 years and greater than 10 years. With respect to this nursing experience, an estimated 44.4% were in the 1-5 years cohort, while those greater than 10 years represented 23.8% of the study participants. With respect to less than 1 year and 6-10 years’ experience, the proportions were similar, 15.9%. Concerning the nursing academic qualifications as a degree, an estimated 76.2% were associated with bachelor’s degree, whilst Associate degree represented 15.9%. Master’s and Doctorate degrees represented 6.4% and 1.4% respectively.
Table 1B. Study Characteristics, Oral Hygiene Education Intervention Module Baptist Hospital, (5- Clarke, 5-Hope, 6-Hope), 2022

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (n)</th>
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<tbody>
<tr>
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<td>76.2</td>
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<tr>
<td><strong>Care Unit</strong></td>
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<td>5 Hope</td>
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<td><strong>Work Shift</strong></td>
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<td>Day</td>
<td>45</td>
<td>71.4</td>
</tr>
<tr>
<td>Night</td>
<td>18</td>
<td>28.6</td>
</tr>
</tbody>
</table>

The care units associated with this study were 5 Clarke, 5 Hope and 6 Hope. Most of the study participants were 6 Hope unit (54.0%) 5 Hope, 30.2% while the smallest proportion of participants were affiliated with 5 Clarke 15.9%. Regarding the work shift of nurses in this study majority were classified as dayshift (71.4%), while night shift was observed with a lower percentage (28.6%).

Table 2A-1 and 2A- 2 describe the pretest of the study participants by demographics as well as professional experience and academic achievement. This pretest utilizes the mean, standard deviation, interquartile range in characterizing the scores obtained prior to the education intervention. The mean score for all the subjects in this study was 11.8, whilst the standard deviation was 3.4, median (12.0), interquartile range (5.0). The pretest mean score differed by the age group upon which the age group older than 50 years were observed with the highest mean score, 14.2, (SD= 0.2), age group 41-50, (mean=13.4, SD= 3.0), age group 21-30 (mean, 11.7, SD= 3.3), while the lowest mean score was observed in the age group 31-40 years (mean ,10.5, SD= 3.7). The pretest score by sex of the participants was higher among female nurses.
with respect to the mean 12.1 (SD=3.4). The pretest mean score for male nurses was 10.5, (SD=3.4).

Table 2A-I. The Pretest Score of Nurses in Oral Hygiene Training and Education Module in Cancer Care and Management Units, Baptist Hospital, (5-Clarke, 5-Hope, 6-Hope), 2022

<table>
<thead>
<tr>
<th>Participants</th>
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<th>SD</th>
<th>Median</th>
<th>IQR</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Subjects</td>
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<td>3.4</td>
<td>12.0</td>
<td>5.0</td>
<td>63</td>
</tr>
<tr>
<td>Age Group</td>
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</tr>
<tr>
<td>21-30</td>
<td>11.7</td>
<td>3.3</td>
<td>12.0</td>
<td>5.0</td>
<td>28</td>
</tr>
<tr>
<td>31-40</td>
<td>10.5</td>
<td>3.7</td>
<td>11.0</td>
<td>5.0</td>
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</tr>
<tr>
<td>41-50</td>
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<td>13.5</td>
<td>4.0</td>
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<tr>
<td>&gt; 50</td>
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<td>0.2</td>
<td>14.0</td>
<td>0.0</td>
<td>10</td>
</tr>
<tr>
<td>Sex</td>
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<td></td>
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<tr>
<td>Male</td>
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<td>11.0</td>
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<tr>
<td>Female</td>
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<tr>
<td>Experience</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1-5 Years</td>
<td>10.5</td>
<td>3.4</td>
<td>11.0</td>
<td>5.0</td>
<td>28</td>
</tr>
<tr>
<td>6-10 Years</td>
<td>12.9</td>
<td>2.3</td>
<td>13.5</td>
<td>4.0</td>
<td>10</td>
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<tr>
<td>&lt; 1 Year</td>
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<td>3.3</td>
<td>13.5</td>
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<td>10</td>
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<tr>
<td>&gt; 10 Years</td>
<td>12.9</td>
<td>3.6</td>
<td>14.0</td>
<td>4.0</td>
<td>15</td>
</tr>
</tbody>
</table>

Notes and Abbreviations: SD = Standard deviation, IQR = Interquartile range. Since the normality assumption was violated in this data, scientific evidence discovery requires the utilization of the median and IQR in these findings. The study participants are all nurses in the units providing care to oncology patients.

With respect to the nursing experience, nurses with an experience of greater than 10 years were observed with the highest posttest mean score (mean =12.9, SD= 2.9), while the lowest posttest mean score was observed in 1-5 years’ experience (mean= 8.5, SD= 5.2). The 6-10 years’ experience (mean=12.6, SD=2.7) and less than 1 year experience (mean= 12.2, SD= 4.0) were observed with comparable post mean scores.
### Table 2A-II  The Pretest Score of Nurses in Oral Hygiene Training and Education Module in Cancer Care and Management Units, Baptist Hospital, (5- Clarke, 5-Hope, 6-Hope), 2022

<table>
<thead>
<tr>
<th>Participants</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>IQR</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Subjects</td>
<td>11.8</td>
<td>3.4</td>
<td>12.0</td>
<td>5.0</td>
<td>63</td>
</tr>
<tr>
<td><strong>Professional Level</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Novice(Residents)</td>
<td>12.3</td>
<td>3.1</td>
<td>8.5</td>
<td>3.0</td>
<td>46</td>
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<tr>
<td>Advanced</td>
<td>11.9</td>
<td>3.3</td>
<td>8.0</td>
<td>3.0</td>
<td>50</td>
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<tr>
<td>Expert</td>
<td>12.2</td>
<td>3.9</td>
<td>8.0</td>
<td>3.0</td>
<td>07</td>
</tr>
<tr>
<td>Proficient</td>
<td>11.2</td>
<td>3.5</td>
<td>6.5</td>
<td>3.0</td>
<td>12</td>
</tr>
<tr>
<td><strong>Nursing Degree</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Associate</td>
<td>11.2</td>
<td>3.9</td>
<td>11.0</td>
<td>5.0</td>
<td>10</td>
</tr>
<tr>
<td>Bachelor’s</td>
<td>11.8</td>
<td>3.4</td>
<td>12.0</td>
<td>4.5</td>
<td>48</td>
</tr>
<tr>
<td>Master’s</td>
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<td>2.9</td>
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<td>4.0</td>
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<td>Doctorate</td>
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<td>00.0</td>
<td>0.0</td>
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</tr>
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<td><strong>Department (Unit)</strong></td>
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<td></td>
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</tr>
<tr>
<td>5 Hope</td>
<td>11.8</td>
<td>3.2</td>
<td>12.0</td>
<td>6.0</td>
<td>19</td>
</tr>
<tr>
<td>6 Hope</td>
<td>12.3</td>
<td>3.7</td>
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<td><strong>Shift Work</strong></td>
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<td>Day</td>
<td>11.4</td>
<td>3.5</td>
<td>12.0</td>
<td>5.0</td>
<td>45</td>
</tr>
<tr>
<td>Night</td>
<td>12.7</td>
<td>3.1</td>
<td>13.0</td>
<td>4.0</td>
<td>18</td>
</tr>
</tbody>
</table>

**Notes and Abbreviations:** SD = Standard deviation, IQR = Interquartile range. Since the normality assumption was violated in this data, scientific evidence discovery requires the utilization of the median and IQR in these findings. The study participants are all nurses in the units providing care to oncology patients.

Concerning the professional level, the highest posttest mean score was observed in the Advance level (mean = 12.3, SD= 3.0), while the lowest posttest mean score was observed in the Proficient level (mean =8.6, SD= 3.5). However, the Expert level nurses indicated 12.8 post mean score, SD= 3.8, while Novice were observed with a posttest mean score of 10.8, SD= 4.9.

Regarding the academic accomplishment, Master’s degree participants in this study were observed with the highest posttest mean score (mean =12.8, SD =4.7), while the least posttest mean score was observed in a Doctorate nurse (mean = 8.0, SD= 0.0). However, the Associate
and bachelor’s degree nurses were observed with comparable mean score (mean = 10.7, SD= 4.8).

The 6 Hope Unit indicated the highest posttest mean score (mean = 12.0, SD= 4.4), while the moderate mean score was observed in 5 Hope (mean =10.2, SD 4.5). The 5 Clarke unit was observed with the lowest posttest mean score (mean = 7.7, SD= 4.6). With respect to shift work, the posttest mean score was higher in nurses in night shift, (mean =11.4, SD= 5.0), while day shift indicated a posttest mean score of 10.6, SD=4.5.

Table 3. Baseline and Post Intervention Scores Assessment on Oral Hygiene in Cancer Care and Management Training

<table>
<thead>
<tr>
<th>Test Score (Variable)</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
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<td>Pretest</td>
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<td>11.8</td>
<td>3.4</td>
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<td>11.0-12.6</td>
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<tr>
<td>Post test</td>
<td>63</td>
<td>10.8</td>
<td>4.6</td>
<td>0.6</td>
<td>09.6-12.0</td>
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<tr>
<td>Differences</td>
<td>63</td>
<td>0.98</td>
<td>3.8</td>
<td>0.5</td>
<td>0.03-02.0</td>
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</table>

Notes and Abbreviations: SD = standard deviation, SE = standard error; CI = Confidence Interval; p = type 1 error tolerance that was set at 5% (0.05). t =2.10 and df = degree of freedom, 62 (n-1). The p value for the mean difference = 0, 04.

Table 3 demonstrates the comparison of the overall score in this study using the pretest and posttest model of paired or dependent t-test. The pretest mean was 11.8, (SD 3.4), 95% confidence interval (CI), 11.0 – 12.6. The posttest mean score was 10.8, (SD 4.6), 95 % CI, 9.6-12.0. The t – value = 2.10, degree of freedom(df) = 62, p=0.04.

Discussion

This study was conducted to assess the impact an oral hygiene training and educational module would have on the knowledge and skills in oral care of oncology nurses at Baptist Hospital. This study applied the pre and post intervention knowledge regarding oral hygiene
among patients with malignant neoplasm. The nurses in the training reflected 5 Hope, 6 Hope and 5 Clarke and were provided with accurate and reliable information in the process of understanding this pathway (oral hygiene). The approach in this direction involved the utilization of a statistical tool namely dependent or paired t-test.

The following results were obtained: First, there were differences with respect to the study characteristics by sex, age group, nursing experience (years of work), academic accomplishment (nursing degree), unit and work shift. Secondly, there was a small differential with respect to the pre and posttest. Thirdly in the overall sample, the pretest was slightly higher than the posttest, implying the posttest scores were lower than the pretest, indicative of limited attention and marginalized focus on the education module by the participants.

The current study observed some differences in the pretest with respect to the study characteristics. For example, female did better than male nurses with respect to the pretest score. The rationale behind this performance is not very fully understood. However, it is difficult to imagine whether there exists a comparable finding in a different circumstance or situation. Additionally, the dayshift was observed with a lower pretest score compared with the night shift.

The observed variance in this study does not imply nursing staff concentration or attention during the dayshift but maybe explained by other factors which is not fully understood at this time. With respect to the care unit, the pretest was lowest in 5 Clarke and highest in 6 Hope. The variance in this pretest score is not very well understood, but maybe explained by nursing experience and limited of exposure to oncology patients (5 Clarke recently joined the oncology service line). In addition, there were fewer participants from 5 Clarke which might in part explain this variance in this pretest score. Further, the pretest score did vary with respect to the age group of the nurses in the study. The observed differential may be driven
by professional experience, implying the number of years spent working in the nursing field.

Although majority of the research participants had a degree of experience (of the nurses who participated in this study Proficient had the highest percentage, Advanced with the second highest followed by Expert nurses with the smallest percentage of nurses in this study being observed as Novice/Residents) that experience was not reflected neither in the pretest nor the posttest results. Furthermore, nursing years of experience did not positively influence the results of neither the pretest nor posttest scores.

The posttest score variance was higher in females, relative to their male counterparts, which reflect the pretest comparison as well. Specifically, the lower pretest among males may implicate the lower posttest among male nurses in this study, which is quite understandable. With respect to work shifts, the post test score was higher in the night shift. The observed variability is in part explained by the pretest score. However, this variance may be explained by nursing degree (academic attainment) years of experience as well as a specific unit).

Concerning the units, the post test was very comparable with the pretest scores, upon which 5 Clarke performed the least in the post test score. The observed variance may in part be explained by the limited exposure of nurses to oral hygiene in 5 Clarke. Further, the posttest score in nursing experience, age group as well as academic achievement was comparable to the pretest score. With these observations it is very difficult to provide an adequate and reliable explanation to the observed differentials.

Finally, this study illustrated a lower posttest score compared with the pretest score in the overall sample. The observed differential is not explained by the relevance and importance of the oral hygiene and education module in this study. However, a possible explanation may be due to the inability of the participants to focus and concentrate on the posttest materials.
assessment which is explained by an estimated 43.6% that completed the post test. Specifically, an estimated 133 initiated the pretest but only 53 completed the posttest, implying more than 50% did not complete the post test. Clearly, the higher attrition rate, greater than 50% reflects the marginalized post test score of participants. This very observation explains in part the poorer performance in the post test score. Additionally, with respect to the number of questions in the pre and posttest these quantities may not explain the poor performance in the post test compared to the pretest.

Furthermore, the present study showed that most of the staff nurses had poor knowledge of oral care in oncology patients possibly due to a lack of exposure to continuing education and training. It would therefore be appropriate to implement annual mandatory continuing education and training for all nursing staff working in oncology units regarding oral care and ensure effective implementation of oral care practices with frequent documentation audits.

**Limitations**

Execution of the SWOT analysis prior to the commencement of the study helped predict some of the possible obstacles that would be encountered during the study. The initiation of the research was impacted by the delay in obtaining IRB approval from multiple sites (FIU and Baptist IRB approval were both necessary) due to the inexperience of a novice researcher in navigating the IRB process. Recruitment and retention of participants was affected by allostatic overload (reflects situation/circumstance upon which an individual due to stressful environment is unable to concentrate, as well as experience marginalized orientation and memory degradation).

Despite the strength of the study implying a reliable and objective oral hygiene education and training module and the application of a paired or dependent t test in intervention mapping there are some limitations. First, the attrition rate was significantly high, reflecting the incompleteness of the posttest (55.6%). Secondly, it is highly likely that the participants
were unable to complete the posttest due to marginalized concentration as well as distractibility. Thirdly, due to the digital approach the feedback with respect to the posttest was adversely affected.

**Advanced Nursing Practice Implications**

**Cultural change.** When nursing staff understand the implications of poor oral hygiene implying abnormal cellular proliferation particularly in the oncology patient there would be a cultural change where they can anticipate appropriate evidence-based practice. Despite an abundance of evidence that oral hygiene in the intubated patient has tremendously decreased the incidence and prevalence of ventilator associated pneumonia (VAP), there is a need for more research on non-ventilator associated pneumonia (NVHAP). The results of the research study indicate a need for cultural change. Oral hygiene has been viewed as a comfort measure rather than a standard of care. There needs to be a shift in that perception. It must be reprioritized as an infection control measure.

Oncology nursing staff are in strategic positions as health care providers, they play a key role in infection control and prevention. Creating awareness is key to creating a cultural change. Initially that change might be difficult to implement especially when caring for complex patients in even more complex environments. *Lewin’s change theory* will be used during the change process. Involvement of key stakeholders (nurses, physicians, nursing administration) will make the change successful.

Oral hygiene would be incorporated into the standard of care for every patient and not viewed as simply a task. Oral care of the hospitalized patient should be an essential component of the comprehensive plan of care particularly in the oncology population. In theory, the provision of oral care for the hospitalized patient should be on three levels: assessment of oral health, promotion of oral health by educating patients and providing
primary oral care to maintain oral health. An innovative approach to making oral care a standard of care would be to integrate a barcode for oral care kits in the MAR section of the Electronic Health Record (EHR) and a prechecked order for oral care at least twice daily.

**Patient and family education and involvement.** Empowering patients, family members and caretakers on the importance of oral care in infection prevention especially during any period of hospitalization which increases the risk of opportunistic infections. Empowering patients to optimize healthy outcomes increases patient satisfaction and decreases hospital length of stay and the cost associated with acquiring a hospital acquired infection (HAI) such as pneumonia.

**Conclusion and Recommendations**

In summary, the oral hygiene education module based on the concept and application was very accurate and reliable in improving knowledge and skills of nurses providing care and management to cancer patients. However, the variance between the pre and posttest did not reflect the information provided in this module, indicative of the application of this training and education module in a very reliable environment. Based on this finding comparing the pre and posttest, this study suggests the application of a reliable and useful environment in order to improve the nurses’ knowledge and skills in the application of the information in this module in oral care enhancement with respect to cancer patients. Regarding the posttest performance in this study, there is recommendation for an annual oral hygiene competency by nursing staff. Also, general medicine admission power plans to include orders for *Oral Care BID* (twice daily).
References


Appendices

Appendix A

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<tr>
<th>Age (years)</th>
<th>Gender</th>
<th>Unit/Department</th>
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</tr>
<tr>
<td>□ 31-40</td>
<td>□ Male</td>
<td>□ 6 Hope</td>
</tr>
<tr>
<td>□ 41-50</td>
<td>□ Other</td>
<td>□ 5 Clarke</td>
</tr>
<tr>
<td>□ ≥ 51</td>
<td>☐ Prefer not to answer</td>
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PARTICIPANT DEMOGRAPHICS

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<tr>
<td>□ Night</td>
<td>□ 1 – 5 years</td>
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</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
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<td>□ Doctorate</td>
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<tr>
<th>RN Level</th>
<th>Average time you spend providing oral care/hygiene for each patient:</th>
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<tr>
<td>□ No vice (Residents)</td>
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</tr>
<tr>
<td>□ Proficient</td>
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</tr>
<tr>
<td>□ Advanced</td>
<td>□ 5 – 6 minutes</td>
</tr>
<tr>
<td>□ Expert</td>
<td>□ 7 – 8 minutes</td>
</tr>
<tr>
<td></td>
<td>□ 9 – 10 minutes</td>
</tr>
<tr>
<td></td>
<td>□ Greater than 10 minutes</td>
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APPENDIX B

Oral Health-Hygiene Survey for Oncology Nursing (OHSON)

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<tr>
<th>Statements</th>
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<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
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<td>1. My nursing responsibilities include assessment of my oncology patients’ oral health and status. (B)</td>
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<tr>
<td>2. I feel that oral health/hygiene is a high priority when caring for my oncology patients. (A)</td>
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<td>3. I feel that cleaning the oral cavity is a pleasant task. (A)</td>
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<td>4. I feel that performing oral care/hygiene is a time-consuming task (takes too long). (A)</td>
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<td>5. I need additional training to provide oral care. (PKS)</td>
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<td>6. Oral care/hygiene guidelines would help me provide quality oral care. (PKS)</td>
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<td>7. I am comfortable selecting the appropriate oral care/hygiene supplies/equipment based on my oncology patient’s specific oral hygiene needs. (PKS)</td>
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<td></td>
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<td>8. I believe that I should assess my oncology patients’ oral health routinely. (B)</td>
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<td></td>
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<tr>
<td>9. I am confident with my ability to perform oral health assessments. (PKS)</td>
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<tr>
<td>10. I am comfortable with performing oral care/hygiene for my patients. (PKS)</td>
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</tr>
<tr>
<td>11. I believe it is important to perform an initial oral health assessment on oncology patients admitted or transferred to my unit. (B)</td>
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<tr>
<td>12. On my unit, I have the supplies/equipment needed to provide quality oral care. (R)</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>13. I provide oral care/hygiene to my oncology patients per nursing standard of practice or as prescribed by the healthcare provider via a Power Plan. (PKS)</td>
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<tr>
<td>14. I believe oral care/hygiene for my oncology patients is a key element in</td>
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</tbody>
</table>
In your opinion, what is the main barrier preventing you from *performing a good oral health assessment* on the oncology patients on your unit?

In your opinion, what is the main barrier preventing you from *providing good oral care* to oncology patients on your unit?

<table>
<thead>
<tr>
<th>Question</th>
<th>Option</th>
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<th>Option</th>
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<tbody>
<tr>
<td>Preventing hospital-acquired infections.</td>
<td>☐</td>
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<tr>
<td>15. There are enough nursing staff in my unit to preserve my patients’ oral health.</td>
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<tr>
<td>16. I am confident with my ability to identify changes in my oncology patients’ oral health.</td>
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<tr>
<td>17. I have access to an oral health assessment tool/guide on my unit.</td>
<td>☐</td>
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<tr>
<td>18. I know where to document the oral health assessment in the electronic health record (i.e., Cerner).</td>
<td>☐</td>
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<tr>
<td>19. I discuss my patients’ oral status and management of oral deficits during handoff reports.</td>
<td>☐</td>
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<tr>
<td>20. I believe that oral discomfort affects my patient’s nutritional status.</td>
<td>☐</td>
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<tr>
<td>21. I believe that oral health assessment and oral care/hygiene of the oncology patient should be a part of annual educational competencies on my unit.</td>
<td>☐</td>
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<tr>
<td>22. I believe it is my nursing duty to help oncology patients maintain good oral health.</td>
<td>☐</td>
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<tr>
<td>24. I consistently document performance of oral care/hygiene for my oncology patients’</td>
<td>☐</td>
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Appendix C

Pretest / Posttest

1. Which part of the oral cavity should the nurse/patient clean as part of oral hygiene/care?
   a. Teeth
   b. Gums
   c. Tongue
   d. All the above

2. A patient is undergoing chemotherapy. What oral complications may the patient experience?
   a. Dental caries
   b. Oral mucositis
   c. Periodontitis
   d. Halitosis

3. What is the recommended frequency for professional dental checkups by a dentist or hygienist?
   a. At least every 2 years
   b. At least once a year
   c. Only when oral pain is experienced
   d. Every 6 months and before Chemotherapy or radiotherapy

4. The healthcare team member is explaining why brushing the teeth is important. What common oral problem may occur if the tongue is not brushed?
   a. Periodontitis
   b. Dental caries
   c. Halitosis
   d. Gingivitis

5. An oncology patient who is undergoing radiation has severe oral mucositis. The nurse should encourage the patient to provide moisture to the oral cavity by taking which action?
   a. Decrease fluid intake
   b. Eat a popsicle
   c. Eat hot and spicy foods
   d. Eat foods the patient enjoys

6. An oncology patient is newly admitted to the unit. During patient assessment/teaching which type of toothbrush should the nurse recommend?
   a. Electric
   b. Hard
   c. Soft
   d. Toothette sponge
7. When assessing oral health, which of the following is indicative of a potential oral health issue?
   a. Dental plaque
   c. Dry mouth
   d. Bleeding gums
   e. Reddened gums
   f. Oral ulcers
   g. All the above

8. Which practice may contribute to oral hygiene problems?
   a. Replacing toothbrush every 3 to 4 months
   b. Brushing teeth twice a day
   c. Flossing teeth once a day
   d. Rinsing with a cosmetic mouthwash

9. Which signs and symptoms best describe grade 3 mucositis?
   a. Very painful erythema, ulcers, inability to drink
   b. Soreness, no erythema, no ulcerations, able to eat
   c. Diffuse hemorrhage leading to hemodynamic instability, inability to tolerate oral intake
   d. Moderately painful erythema, edema, isolated white patches or ulcers, ability to eat

10. Which statement from the patient best indicates understanding of the nurse’s teaching regarding proper oral hygiene care?
    a. “I will brush my teeth with a firm toothbrush twice a day.”
    b. “I will rinse my mouth with a mouthwash containing alcohol twice a day.”
    c. “When my lips get dry, I will wash them with soap and water.”
    d. “I will rinse my mouth with a non-alcoholic mouthwash twice a day.”

11. Which phase of mucositis development includes observable changes in the mucosa but little to no patient symptoms?
    a. I
    b. II
    c. III
    d. IV

12. What should the oral assessment documentation of an oncology patient health record include:
    a. Within normal limits (WNL)
    b. No documentation is needed, document only if the patient has an oral complaint
    c. Assessment of mouth, teeth, gums, throat, and presence of pain.
    d. Ability of patient to perform oral care independently or with assistance
    e. Both C and D
13. What are the **basic supplies** a patient would need to perform mouth care?
   a. Toothbrush from home
   b. Hard toothbrush that would remove all plaque
   c. Soft toothbrush provided on admission
   d. Soft toothbrush provided on admission, fluoride/sodium bicarbonate toothpaste, antiseptic mouthwash, and mouth moisturizer

14. What is the **minimum** recommended times one should perform mouth care to prevent the occurrence of oral complications?
   a. Daily
   b. Every other day
   c. Twice a week
   d. Twice a day

15. A 50-year-old female newly admitted to the unit for commencement of chemotherapy. Which of the following oral complications is most likely to occur?
   a. Dental caries
   b. Oral mucositis
   c. Halitosis
   d. Gingivitis

16. Robert, a 50-year-old male schoolteacher, was transferred to the oncology unit for severe neutropenia. On arrival to the unit, Robert unpacks his toiletries from home. What education should the nurse caring for Robert provide him?
   a. Discard toothbrush from home and provide a new soft bristle toothbrush.
   b. It's okay to allow him to use his favorite toothbrush from home.
   c. He does not need education because he is knowledgeable about oral hygiene.
   d. Wait until Robert asks questions about oral care.

17. Mrs. Jones a 35-year-old female recently commenced radiation therapy for breast cancer, complains of "dry mouth". Which intervention below is the BEST to treat her symptoms?
   a. Sucking on ice chips or popsicle
   b. Performing an oral assessment and ensuring that the patient performs oral care with soft toothbrush and antiseptic mouthwash twice daily. Notify physician, Monitor symptoms every shift and documenting findings in electronic health record.
   c. Symptoms are temporary and should resolve with time.
   d. Wash mouth with soap and water
   e. Gargle with antiseptic mouth wash
APPENDIX D

Participant Invitation Email

Dear Valued Baptist Nurse,

My name is Maura Poleon, and I am a Doctor of Nursing Practice (DNP) student at Florida International University (FIU). I am currently conducting a research study, The Prevention of Oral Complications in Oncology Patients by the Introduction of an Oral Hygiene Education Module Targeting Oncology Nurses.

The goal of this study is to improve the nurses’ knowledge of oral complications in the oncology patient and their role in the prevention of such complications.

You are eligible to participate in this project because you are a registered nurse at Baptist Hospital of Miami and provide care to oncology patients on 4 Hope, 5 Hope, or 6 Clarke.

If you decide to participate in this study, you will complete a demographic information sheet, the Oral Care Survey for Oncology Nurses, and an oral care/hygiene pretest. Then you will review an oral care/hygiene education module, followed by completion of an oral care/hygiene posttest. Your estimated participation time is 30 to 45 minutes.

Thank you for your time and consideration of participating in this very important study.

If you choose to participate, please click on the link provided below or scan the QR code:

https://redcap.baptisthealth.net/surveys/?s=WYWN89PACENWNED9

If you have any questions about the study, please contact me via mpole006@fiu.edu or 786-326-8917. You may also contact my Faculty Mentor, Dr C. Victoria Framil via cframil@fiu.edu or 305-348-7230.

Sincerely,
Maura Poleon, MSN, APRN-BC
FIU DNP Student
Appendix E

Study Information for Participants

Hello, I am Maura Poleon, the principal investigator (PI) for the following study: The Prevention of Oral Complications in Oncology Patients by the Introduction of an Oral Hygiene Education Module Targeting Oncology Nurses. The purposes of this study are to:

(1) evaluate nurses’ attitudes and knowledge of related to oral assessment and oral care in the oncology patients, and
(2) the impact of a self-learning education module on nurses’ oral care/hygiene knowledge.

As a nursing professional at Baptist Health South Florida (BHSF), you are an integral member of the healthcare team. Therefore, your input and participation in this research study are greatly valued.

On the following web page is a demographics survey to collect participant characteristics followed by the Oral Hygiene Survey for Oncology Nurses (OHSON), which takes approximately 10 minutes to complete, and an oral hygiene/care pretest, which is expected to take approximately 10 to 15 minutes. Thereafter, you will be asked to review an oral hygiene/care education module, which takes approximately 30 minutes. After the module, you will be asked to complete an oral hygiene/care posttest, which takes approximately 10 to 15 minutes.

Below are your rights as a research study participant:
1. Your participation is voluntary, so you may decline to answer any or all the questions without penalty.
2. Your responses will be anonymous, and all data collected will remain confidential.
3. You will not be asked to give your name, employee number, or any other identifying information.
4. There will be no attempt to link information to you personally.
5. All survey data collected using Redcap will be password-protected, only accessible to the PI and/or designated research team member.
6. Participating or not participating in this study will in no way affect your employment at Baptist Health.
7. You will not receive compensation, monetary or otherwise, for participating in this study.
8. There is minimal risk of confidentiality breach as the survey contains no identifiable information and data will be reported numerically.
9. Data collection for the research study will occur over approximately a 2–3-month period.
10. Your records may be reviewed for audit purposes by BHSF employees or other agents, who will be bound by the same provision of confidentiality.

Through this study, the researcher is seeking to validate the importance of oral hygiene in the oncology population and the need for more research in this area. Although it is not a direct benefit, the data you provide will assist the PI in gathering information useful to promote further research with respect to oral hygiene/care.

Click on the word “Next Page” below to complete the survey. By clicking on “Next Page” you are giving your consent to participate in the collection of any survey responses you provide.

When you have answered the statements and questions to your satisfaction, please click on the word “Submit” at the end of the screen. This will automatically submit your responses.
Thank you for your interest in this study!

If you have any questions about your rights as a research participant, please contact the IRB, Florida International university coordinator: Maria Melendez-Vargas at (305) 348-8311 or email maria.melendez2@fiu.edu

For further information or questions about the study please contact Maura Poleon, Tel: 786 326 8917 or email: maurap@baptisthealth.net or mpole006@fiu.edu or Dr C. Victoria Framil at Tel: 305 439 9041 or email: cframil@fiu.edu.
Appendix F

Nursing and Health Sciences Research
Research Leadership Collaborative Approval

Maura Poleon
Registered Nurse | Emergency Department
Baptist Hospital of Miami | Baptist Health South
Florida 8900 N. Kendall Drive | Miami, FL 33176

September 7, 2022

RE: The Prevention of Oral Complications in Oncology Patients by the Introduction of an Oral Hygiene Education Module Targeting Oncology Nurses

Dear Ms. Poleon,

The Baptist Health South Florida (BHSF) Research Leadership Collaborative (RLC) thanks you for electronically presenting your application to conduct research at Baptist Hospital of Miami. This letter is to inform you that the BHSF RLC has put your study, “The Prevention of Oral Complications in Oncology Patients by the Introduction of an Oral Hygiene Education Module Targeting Oncology Nurses” through a facilitative review process examining clinical significance, professional significance, logistics, and protection of human subjects in research. The BHSF RLC believes that, pending major revisions as outlined on the Primary Reviewer Checklist, your study should move onto the IRB for approval. Thank you for addressing all the comments provided by the members of the BHSF RLC.

To proceed with data collection at the BHSF hospitals, you must seek and receive administrative support and BHSF Institutional Review Board (IRB) approval to conduct your study. Please contact the BHSF IRB at 786-527-9280 if you have any questions.

The study cannot be initiated until you receive a final verification letter from the BHSF IRB. It is your responsibility to maintain a binder for your study. Please consult a Nurse Scientist if you need to make any changes once your study documents have
been submitted. At the completion of your research study, you are required to submit a final report to the BHSF IRB.

The BHSF RLC wishes you well as you progress on your research project. If you have any questions or concerns, please contact me

Sincerely,

Natalie Bermudez, PhD, RN Chairperson
Baptist Health South Florida Research Leadership Collaborative

Appendix G

Research Proposal

1. Title: The Prevention of Oral Complications in Oncology Patients by the Introduction of an Oral Hygiene Education Module Targeting Oncology Nurses

0. Baptist Health Research Personnel

1. Principal Investigator: Maura Poleon, MSN, RN (DNP Student/BHM Staff RN)
2. Key Personnel:
   1. Shelli Chernesky, DNP, RN (BHM, Director/DNP Preceptor)
   2. Natalie Bermudez, PhD, RN (Nurse Scientist)

Florida International University Personnel
a. Dr. C. Victoria Framil (Faculty Mentor)

0. Purpose, Hypothesis(ases), and/or Objectives

The overarching objective is to ensure that oncology nurses acquire a substantial amount of education in ensuring adequate dental care for oncology patients. The following specific aims were proposed: Specific Aim I: To evaluate the attitude and knowledge of nursing of the importance of oral assessment and oral care in the oncology patient. Specific Aim II: To promote best practices related to prevention and early intervention and treatment of frequent complications associated with various treatment modalities in the cancer patient.

Since this project is not of an experimental design, hypothesis testing is not applicable in addressing the above specific aims. However, a descriptive approach, implying a non-inferential approach is utilized in this education module.
0. **Background and Significance**

Dental education in care provision for patients with malignant neoplasm among nurses have not been structured nor adequately applied in care provision for this patient population. Since oral pathology such as teeth decay, gum bleeding and dental cavities predispose to several pathologies, there is a need to understand the risk and predisposing factors in dental hygiene and oral diseases.

With this observation as a gap in knowledge there is a need to educate nurses for knowledge acquisition as well as skills development in providing dental care to patients with malignant neoplasms.
A literature search was performed in OVID MEDLINE, PubMed and CINAHL for articles in English language for 2015-present using the search terms importance of oral hygiene, blood and bone marrow transplant patients, oral hygiene protocol, mouth care, cancer patients. These terms were combined with staff nurses, patient care technicians, awake, non-ventilated patients, independent; 29 unique articles were found with 12 relevant for this study. Evidence is lacking for application of an oral hygiene protocol on this specific patient population group as an evidence-based nursing intervention. Although most of the relevant articles found were generalized to the oncology patient the findings are also pertinent to the blood and bone marrow patient.

The year 2021 observed a national call to action to confront the hidden harm of non-ventilator hospital acquired pneumonia (NVHAP). The National Organization to Prevent Hospital Acquired Pneumonia (NOHAP) collaborated with a joint task force that includes the Veterans Health Affairs (VHA), the Centers for Disease Control and Prevention (CDC), the Joint Commission (TJC), the American Dental Association (ADA), and several other organizations to beseech healthcare organizations to mobilize efforts to eradicate this preventable complication. In the Oncology patient oral examination, oral care and continuous oral assessment is crucial to prevent complications such as NVHAP. Whereas there are both observations from NOAHP as well as CDC, which is indicative of oral pathologies among patients within the healthcare system and oncology patients, there is no substantial data on the incidence and prevalence of oral disease among cancer patients. Furthermore, there is no data on the application of education intervention with respect to oral pathology among cancer patients by the healthcare providers, namely oncology nurses.

The oral cavity remains an entrance to the biologic system that tends to reflect the highest portal of entry to the human system and organs that may result in either gastrointestinal disorder, esophageal disease, splenic disease, hepatic disorders as well as renal insufficiencies. The understanding of the risk’s determinants in gum bleeding, oral cavities, tooth decay as well as other buccal pathologies allows for systemic disease prevention as well as control. The current research study, based on the ongoing knowledge of oral pathology aims at allowing the healthcare provider to acquire knowledge and skills in preventing oral diseases among cancer patients. With this directive, cancer patients will benefit from several comorbidities as well as increase remission during cancer therapeutics.
Methods

Study Design: Cross-sectional quasi-experimental (pretest/posttest) design.

Target Population: Oncology registered nurses (RN) working on oncology (4 Hope, 5 Hope, and 6 Clarke) at Baptist Hospital of Miami (BHM).

Sample Size & Setting: The researcher will use convenience sampling techniques to recruit RNs working on oncology units 5 Hope, 6 Hope and 5 Clarke at BHM; the minimum target sample size is 82 with a maximum of 150.

Inclusion and Exclusion Criteria: The principal investigator (PI) will review demographic data to confirm participant eligibility based on the following inclusion/exclusion criteria:

1. Inclusion Criteria:
   1. Oncology registered nurses (RN) who are currently employed full-time, part-time, or per diem on enter departments here at Baptist Hospital of Miami (BHM).

2. Exclusion Criteria:
   1. None.

Data Collection/Study Timeline: Following Baptist Health (BH) institutional review board (IRB) approval, data collection and management will begin using the surveys on the Research Data Capture (REDCap) platform until at least a minimum sample size of 82 is achieved, not to exceed 150, for a maximum period of four (4) months.

Variables

1. Independent variables: Participant characteristics (Appendix A)
2. Categorical variables:
   1. Age
   2. Gender
   3. RN level
   4. Unit/department
   5. Shift
   6. Nursing experience
   7. Nursing degree
8. Oral care duration time
   1. Intervention: Self-learning education module
   2. Dependent variables
2. Self-assessment of oral hygiene/care skills/knowledge (OHSON scores)
   2. Actual oral hygiene/care knowledge (pretest/posttest scores)

5. Subject Participation Timeline:

2. The Oral Hygiene Survey for Oncology Nurses (OHSON) takes approximately 10 minutes to complete.

2. The approximate time to complete the pretest is 10 to 15 minutes and the posttest is 10 to 15 minutes.
   1. The learning module takes approximately 30 minutes to complete.

6. Researcher Timeline:
2. The estimated time frame is maximum of 4 months for the investigators to complete this study (complete data collection and primary analyses)

ii. Instruments/Surveys/Questionnaires

2. Oral Health-Hygiene Survey for Oncology Nursing (OHSON) is a 25-item Likert-type survey to assess oncology nurses’ attitudes, beliefs, perceptions of knowledge/skills, resources, and logistics related to providing oncology patients with oral hygiene/care (Appendix B). The instrument was developed by the researcher using current available literature and assistance from the DNP preceptor and a Baptist Health Nurse Scientist. The Likert-type items are rated on a five-point scale (1=Strongly Disagree, 2=Disagree, 3=Neither Agree nor Disagree, 4=Agree, and 5=Strongly Agree). The OHSON also includes two open-ended questions.

Pretest/Posttest: The same test will be used for the pretest and posttest. The questionnaire has 17 multiple-choice questions to assess the participants’ knowledge of oral hygiene/care before and after the educational intervention (Appendix C). The order of the pretest and posttest questions will be randomized to minimize recall bias.

iii. Recruitment Procedures, Consent Process, and Intervention:

Oncology nurses on 5 Hope, 6 Hope, and 5 Clarke will be recruited via email using Baptist Health email distribution groups. The email invitation (Appendix D) will include the study’s title and purpose, researcher information, participant’s estimated time commitment, and the Research Data Capture (Redcap) universal resource locator (URL) address and quick response (QR) code for direct access to the demographic information and the OHSON, pretest/posttest, and educational module. The REDCap cover page (Appendix E) will include statements to address
1) study title/purpose, 2) voluntary participation, 3) right to withdraw participation without penalty, 4) assurance of anonymity/confidentiality, 5) risks/benefits, and 6) procedure for participation. Completion of the surveys implies consent to participate. The participants will complete 1) demographic information page, 2) OHSON survey, 3) pretest, 4) education module (Appendix F), and 5) posttest. Estimated time to complete the surveys is 30 minutes. A waiver of consent will be requested because there are no anticipated risks of physical harm associated with the study. However, there is minimal risk related to breach of confidentiality (see Data Management and Confidentiality section).

iii. Data Analysis Plan: Data will be analyzed using Statistical Package for Social Sciences (SPSS) version 27.0 and Microsoft Excel 2016. Descriptive statistics will be used to determine frequencies, mean (averages), median, standard deviation, and ranges for all survey items. Tables and graphs will be used to display and report survey item frequencies and averages. Pearson’s or Spearman’s correlation coefficient, depending on normalcy of data distribution, will be used to examine relationships between variables. An a priori power analysis (two-tailed) resulted in a minimum of 82 participants to achieve a power of .80 with probability set at .05 and a medium effect size of .30. Dependent t test or Whitney Mann U test (depending on normality of distribution) will be used to examine differences between pretest/posttest scores. An a priori power analysis (two-tailed) showed a minimum of 34 participants are needed to achieve an estimated power of .80 with probability set at .05 and a medium effect size of .50.

iii. Data Management and Confidentiality: Data collected via REDCap is password-word protected and only known to the PI and/or designee. Data will be stored in password-word protected programs such as REDCap, IBM SPSS, and Microsoft Excel. The PI, the PI’s
Florida International University (FIU) faculty mentor, the PI’s Baptist Health preceptor, and BH Nurse Scientist will know the passwords

a. **Resources:** The researcher is a masters-prepared registered nurse and Doctor of Nursing practice (DNP) student working collaboratively with a DNP-prepared Florida International University faculty member, as well as a DNP-prepared preceptor employed at BHM. Participants have received ethical conduct in research training via CITI Program (www.citiprogram.org). The researcher also has guidance from a PhD-prepared BH Nurse Scientist, with expertise in conducting research. The researcher has sufficient resources to successfully conduct and complete this study within the specified timeframe.

   a. **Compensation:** Participants will not receive compensation, monetary or otherwise, for participating in this study.

   a. **Withdrawal of Participants:** Participants will be provided with a written statement on the cover page that they are voluntarily participating in this study, and they may decline participation, or if they initially agreed to participate, they may terminate participation at any time for any reason without penalty. Declining to participate or withdrawing participation will not negatively affect the participant’s employment at BHM.

1. **Risks and Benefits**

   1. **Risks:** There are no foreseeable physical risks associated with the study. However, there is minimal risk related to potential breach of confidentiality. However, the PI has ensured measures to protect the participants’ identity (see above).

   2. **Benefits:** There are no direct benefits to the participants in this study. However, the participants may have increased awareness of their own strengths and weaknesses related to their oral hygiene/care knowledge and skills.

   1. **Ethical Considerations:** This study has been approved as an exempt study by FIU Institutional Review Board (IRB). The study will undergo the BH IRB review process as an external IRB submission. This includes initial assessment by the peer facilitated review process and final review and approval by IRB. Data will be entered into a protected database on password protected BHSF computer until the study is completed. Upon finalization of the study and the record-keeping requirements are attained, the retention and destruction of records (hard copies of survey and Excel spreadsheet) will be done in accordance with BHSF Research Uses and Disclosures policy and procedures (Policy No.: BHSF-100-8085-401.00).
Appendix H

MEMORANDUM

To: Dr. Carmen V. Framil
CC: Maura Poleon
From: Carrie Bassols, BA, IRB Coordinator
Date: July 26, 2022
Proposal Title: “The Prevention of oral complications in oncology patients by the introduction of an oral hygiene education module targeting oncology nurses.”

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the Exempt Review process.

IRB Protocol Exemption #: IRB-22-0345 IRB Exemption Date: 07/26/22
TOPAZ Reference #: 111987

As a requirement of IRB Exemption, you are required to:

1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
1) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N

For further information, you may visit the IRB website at http://research.fiu.edu/irb.
MEMORANDUM

To: Dr. Carmen V. Framil
CC: Maura Poleon
From: Maria Melendez-Vargas, MIBA, Coordinator
Date: September 15, 2022

Proposal Title: “The Prevention of oral complications in Oncology patients by the introduction of an Oral hygiene education module targeting oncology nurses.”

Approval # IRB-22-0345-AM01
Reference # 111987

The Florida International University Office of Research Integrity has approved the following modification(s):

- 1. Start date October 10 and not August 1, 2022. Pending Baptist IRB approval.
- 2. Educational intervention platform is REDCAP and not BHU (Baptist Health University) as previously stated.
- 2. Informational/ Participant letter converted to cover letter therefore waiver of consent.
- 3. Posttest will be done immediately after educational module and not 2 months after as previously stated (due to time constraints).

Special Conditions: N/A.

For further information, you may visit the FIU IRB website at http://research.fiu.edu/irb.

MMV/em
Appendix J

ACKNOWLEDGEMENT OF SITE AGREEMENT TO CEDE IRB REVIEW AND REVIEWING IRB TO PROVIDE OVERSIGHT

This form documents that:

1) Florida International University will serve as the Reviewing IRB for Baptist Hospital of Miami, Inc. for the study noted below.

and

2) Baptist Hospital of Miami, Inc. has agreed to cede IRB review to Florida International University for the study noted below.

<table>
<thead>
<tr>
<th>Study Title:</th>
<th>The prevention of oral complications in oncology patients by the introduction of an oral hygiene education module targeting oncology nurses.</th>
</tr>
</thead>
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<tr>
<td>FIU IRB Protocol Number:</td>
<td>111987</td>
</tr>
<tr>
<td>FIU PI:</td>
<td>Carmen Framil</td>
</tr>
<tr>
<td>Relying Site Investigator:</td>
<td>Maura Poleon, MSN, FNP-BC</td>
</tr>
</tbody>
</table>

IRB review will be ceded under the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement.

Digitally signed by Christopher Grayson
Date: 2022.10.11 15:36:29 -04'00'
Christopher Grayson, MBA, CIP, CIM

Date Director, FIU Research Integrity Reviewing IRB Designee

Amanda Coltes-Rojas
Digitally signed by Amanda Coltes-Rojas
Date: 2022.10.10 19:24:28 -04'00'
Amanda Coltes-Rojas, MPH, CIP, CHRC

Date Director, BHSF Office for Research Integrity Relying IRB Designee
Appendix K

Dear Maura Poleon,

As Principal Investigator for this study at BHSF, it is your responsibility to submit the following to the Baptist Health South Florida Institutional Review Board Office:

1. A copy of the FIU IRB initial approval letter and approved consent form(s) for this site.
2. Accrual status (open, closed to accrual, suspended, accrual hold, etc.).
3. Copy of the final report when the study is completed.
4. Notification of any actions by FIU IRB affecting their approval to conduct the study, including suspension, expiration, or termination of approval.
5. Notification if changes to study personnel are to be made. The BHSF IRB Office must approve new study personnel before they can be added to the study.

It is your responsibility to maintain compliance with all FIU IRB and BHSF
institutional requirements. If you have any questions or require further information, please contact the BHSF IRB office at 786-527-9280 or via email at IRBOffice@baptisthealth.net. Sincerely,

Amanda Coltes-Rojas, MPH, CIP, CHRC Director, Research Integrity Baptist Health South Florida Institutional Review Board ACR/nj

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Baptist Health South Florida's records.