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PREVENTION OF ORAL MUCOSITIS IN CANCER PATIENTS

by

PATRICIA E. BIEL

EVIDENCE-BASED PRACTICE PROJECT REPORT

Submitted to the College of Nursing and Health Professions

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Student Date Advisor Date

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DEDICATION

I would like to dedicate this project to my family and friends. My two children, Autumn and Roman, have served as my relentless cheerleaders through this entire project. My husband, who tolerated the frequent schedule changes, the late nights, and the work-life balance that was not always balanced. Thanks to my family that lives near that helped with childcare and other support, and to my family far who always opened their homes as a place to distress during breaks.

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ABSTRACT

Oral mucositis [OM] is one of the most severe non-hematological problems related to cancer treatments and can impact quality of life. It is linked to poorer outcomes due to the associated weight loss, pain, dehydration, and risk of developing life-threatening infections. The purpose of this evidence-based practice project was to determine if OM is preventable with the use of an oral care protocol and zinc supplementation when compared to use of oral care protocols alone. The Johns Hopkins Nursing Evidence-Based Practice Model was used to guide project implementation in an outpatient oncology office. Recommendations were developed from an exhaustive review of literature. Implementation of the project occurred in two phases. Phase one was establishment and implementation of an oral care protocol as the standard of care. Phase two included the standard of care and incorporated use of zinc supplements to select participants. Groups were selected by convenience sampling. A two-group pretest-posttest quasi-experimental design was applied. OM Symptoms were tracked using the Patient Reported Oral Mucositis Symptom (PROMS) survey, a visual analog scale consisting of ten questions. Participants (N=23) filled out baseline surveys and were followed over a six-week period. Independent t-test were used to analyze the data. Statistically significant results were noted in 8 out of 10 variables assessed using PROMS: Mouth pain, weeks 5 (2.91 vs. 8.75, p = .046) and 6 (2 vs. 8.91, p = .004), difficulty speaking, weeks 4 (2.7 vs. 7.33, p = .008) and 6 (1.18 vs. 3.36, p = .036), eating soft foods, weeks 3 (2 vs. 4.2, p = .024) and 5 (1.82 vs. 7.25, p = .008), restriction of eating week 6 (3.45 vs. 11.82, p = .017), difficulty drinking weeks 5 (2 vs. 5, p = .024) and 6 (1.36 vs. 3.73, p = .023, restriction of drinking week 3 (1.2 vs. 2.7, p = .033), difficulty swallowing weeks 4 (2 vs. 6.89, p = .048) and 5 (1.91 vs. 8.25, p = .027), and change in weeks 4 (6.3 vs. 14.33, p = .045) and 5 (4.55 vs. 16.88, p = .04)(Figure 4.8). There were no statistically significant differences in the groups with regards to restriction of speech or difficulty eating hard foods.

CHAPTER 1

INTRODUCTION

Background

Cancer is the collective name given to malignant processes that can start anywhere in the human body, occurring when some of the body's cells begin to divide without physical restrictions and can spread into other tissues (National Cancer Institute [NCI], 2015). Cancer can occur at any time during the lifespan. The second leading cause of death worldwide is cancer (WHO, 2018). In the United States, it is estimated that 38.4% of men and women will be diagnosed with cancer during their lifetime (NCI, 2018). Five-year survival rates for 2016 are 67% after treatment, however, data does not provide type of treatments given, nor distinguish route oncological methods are delivered (Miller et al., 2016). There are several methods of oncological treatment, such as chemotherapy, radiation treatment, surgery, hormonal therapy, and immune therapy (American Cancer Society [ACS], 2016). This paper addresses chemotherapy and radiation treatments as they are most commonly linked with oral mucositis (OM) with prevalence rates from 20-100% depending on cancer type and stage, characteristics of a tumor, the patient's age, and overall health status (ACS, 2016, Cidon, 2018 & Slade, 2017).

For many cancers, there are oncological treatments that can alleviate or cure specific cancer types. The cytotoxic effects of oncological therapies can disrupt normal tissues, especially those of the oral mucosa (Cullen et al., 2018). Oral mucositis is a complicated process of ulceration that involves many different factors and is considered one of the most severe non-hematological complications leading to pain, decreased quality of life, and life-threatening infections (Campos, Campos, Aarestrup, & Aarestrup, 2014 & Eilers, Harris, Henry & Johnson, 2014 & Slade, 2017). Preventing OM helps reduce the risk for several complications from oncological therapies, including oral infections, malnutrition, and dehydration in individuals. Discomfort is one common symptom that patients experience with OM: However,

clinical tools do not always capture the subjective experience. Inconsistency exists in the evaluation of OM and can vary significantly across tools, objective assessments, and documentation.

Pathophysiology of Oral Mucositis

Once thought to be a simple pathway that was unavoidable during oncological treatments, OM is now understood as a complex pathophysiological process (Eilers et al., 2014; Campos et al., 2014). This condition mostly affects nonkeratinized mucosa, particularly the buccal mucosa, soft palate, floor of the mouth, lateral edges of the tongue and lips (Carvalho, Medeiros-Filho, & Ferreira, 2018). This condition typically occurs in four stages: the initial stage, epithelia stage, ulceration stage, and healing stage.

The initial stage is triggered when the initial stimulus of the oncological treatment is introduced and causes a reactive oxygen species reaction within the oral mucosa (Campos et al., 2014; Panahi, Saadat, Shadboorestan & Ahmadi, 2016). A reactive oxygen species is an unstable molecule that easily interacts with other parts of the cell, and when there is a buildup of these molecules, they may cause damage to DNA, RNA, proteins, and cause cell death (Görlach et al, 2015).

In the epithelia stage, apoptosis has occurred in most of the epithelial cells lining the oral cavity. Furthermore, surviving cells are unable to be replicate due to errors in protein synthesis, leading to widespread denudation, inflammation, and ulceration (Campos et al., 2014; Eilers et al., 2016 & Panahi et al., 2016).

The next stage is known as the ulceration stage. This stage is marked by penetration damage to nonkeratinized mucosa causing exposure of the lamina propria, a thin layer of connective tissue under the mucosa, due to the epithelial loss (Campos et al., 2014 & Panahi et al., 2016). The ulceration stage is painful to patients because the epithelial loss results in nerve endings being exposed (Campos et al., 2014).

The final stage of the process is known as the healing stage. The healing stage is one of the longest stages and can last 12 to 16 days. The duration of healing can be extended based on patient age, nutritional status, stage of oral hygiene and health, oncological treatments given, renal and hepatic functions (Cidon, 2018 & Panahi et al., 2016). This stage is marked by lesion resolution, due to the submucosal extracellular matrix triggering that leads to cell proliferation, migration, and differentiation, healing the ulcers from the margins (Campos et al., 2014 & Panahi et al., 2016). Moslemi et al., (2014) noted that zinc is an important component of wound healing due to its anti-inflammatory effects, immune system modulator properties, and a necessity for synthesis of DNA.

Oncological treatments increase the risk of OM through the production of tremendous amounts of reactive oxygen species. It is estimated that at least 40% of patients receiving any oncological treatment will develop OM, while individuals receiving high doses of chemotherapy or radiotherapy of the head and neck will inevitably develop this condition (Campos et al., 2014; Eilers et al., 2014 & Panahi et al., 2016). Other factors that put a patient at risk for developing this condition include age, poor oral hygiene, impaired salivary function, neutropenia, and use of alcohol and tobacco (Eilers et al., 2014; Farrington, Cullen, & Dawson, 2013 & Panahi et al., 2016). It has also been proposed that genetic factors can increase the risk of OM (Eilers et al., 2014 & Panahi et al., 2016).

Prognosis of Oral Mucositis

The development of OM puts individuals at risk to develop treatment-related complications. The most life threating condition is the development of bacteremia or sepsis related to bacteria entering through the lamina propria and invading the vascular walls (Campos et al., 2014; Eilers et al., 2014; Moslemi, Babaee, Damavandi, Pourghasem & Moghadamnia, 2014; Obeid, 2018). Individuals with OM are also at risk for developing complications related to malnutrition. Ulcerations within the mouth and throat mark the ulceration stage of OM, limiting

the ability for oral intake due to pain and discomfort (Cullen et al., 2018; Moslemi et al., 2014; Obeid, 2018; Yarom et al., 2013).

Poorer outcomes related to withholding oncological treatments occur in patients who develop OM. Lee (2013) notes that is common for physicians to halt cancer treatments in attempts to lessen the oral pain and allow a period of healing. For patients receiving radiological interventions, development of OM can lead to less than optimal treatment due to reduced radiation dosages which negatively impacts survivorship (Cullen et al., 2018; Eilers et al., 2014; Moslemi et al., 2014 & Obeid, 2018). Other symptoms include xerostomia (dry mouth), fungal, and viral infections, impaired speech, and impaired swallowing (Cidon, 2018; Cullen et al., 2018; Eilers et al., 2014 & Slade, 2017).

For individuals receiving oncological treatments, pain can reduce a patient's quality of life. In the early stages of OM, pain occurs along with erythema and swelling and increases if the condition advances to ulcerations (Cidon, 2018 & Eilers et al., 2014). Pain is noted to be one of the factors that delays or reduces oncological treatments (Lee, 2015 & Cullen et al., 2018). Pain can also reduce the individual's quality of life (Da Cruz Campos et al., 2014; Huang et al., 2017; Lee, 2013; Obeid, 2018 & Yarom et al., 2013). Difficulties affect individual's ability to speak, swallow, and taste occur during an acute episode of OM (Cidon, 2018; Eilers et al., 2014 & Moslemi et al., 2014).

Financial Implications of Oral Mucositis

The development of OM can incur additional cost to individuals. In 2013, it was noted that the average price for individuals who developed OM was $1,700 depending on severity (Eilers et al., 2013). Individuals who experience secondary infections, sepsis, or who require nutritional support are all at risk for incurring higher costs related to hospitalization (Eilers et al., 2014, Da Cruze Campos, 2018 & Slade, 2018). Examples of other ways that OM can become a costly condition includes missed work days and expenses related to additional medication and treatments.

Standardized Assessment and Diagnosis of Oral Mucositis

No universal clinical standard exists when assessing OM. Subjective qualities of OM that can be significant patient concerns that affect the quality of life, are omitted in many objective tools designed to evaluate oral mucosa. Researchers conducting a systematic review of oral assessment instruments to find one appropriate for use in the pediatric and young teen populations noted there were 54 oral assessment tools at the time of their study, many of them untested for reliability and validity (Gibson et al., 2010). Most scales are noted to be objective. However, objectivity cannot be absolute due to human interpretation.

Individual disciplines often have their scale of preference (Panahi et al., 2016). One of the most frequently used tools is the World Health Organization (WHO) Oral Mucositis Grading Scale (Gibson et al., 2010 & Panahi et al., 2016). This tool measures soreness with or without erythema, ulcers, if a patient can swallow solid food, and if alimentation is possible. Although pain is a distressing concern for individuals experiencing OM, it is often omitted from objective OM assessment tools. Use of patient-reported subjective tools is suggested to capture this phenomenon (Cullen et al., 2018; Obeid, 2018 & Slade, 2017).

Another standardized assessment tool that has been used to measure the subjective effects OM is the Patient Reported Oral Mucositis Symptom (PROMS) survey. This tool measures mouth pain, speaking difficulties, and restriction of speech related to mouth sores (Kushner et al., 2008). The PROMS has some important advantages over other OM assessment tools, including measuring oral mucositis from the patient perspective. Use of this tool can allow the evaluation of both preventive or palliative treatment for OM, which is appropriate for this evidence-based project (Kushner et al, 2008).

Statement of the Problem

Data supporting the need for the project. The prevalence of OM in patients receiving treatment is 40-80% of those undergoing oncological treatments with some cancer treatments posing a higher risk up to 100% (Campos et al., 2014 & Panahi et al., 2016). If OM progresses

to the ulceration stage, patients are at risk for life threatening infection such as systemic sepsis (Yarom et al., 2013). It is important to that that greater than one-third of the United States population will be diagnosed with cancer sometime in their life, some of which will require treatments that are linked to the development of OM (NCI, 2018). Oncological treatments aimed at treating cancer can cause OM which is related to poorer patient outcomes, including malnutrition, dehydration, pain, difficulty communicating, infections of the oral cavity, and sepsis. Nursing professionals should understand how to prevent or reduce the effects of OM in a family practice setting. Moreover, these interventions should be effective, inexpensive, readily available, and easily transferable to the patient's home setting.

There are extensive studies that look at methods to prevent OM, however they are generally limited to head and neck cancer patients receiving oncological treatments due to OM developing nearly 100% of cases (Eilers et al., 2014). There is limited research on if prevention and symptom reduction is possible across a wide verity of cancer types. Ideally, this evidence-based project will explore if methods of prevention or symptom reduction are applicable to a wider patient base.

Additionally, people affected with OM often suffer from worse clinical outcomes. The development of OM can result in the need to reduce treatment doses, which then negatively impacts survivorship (Cullen, 2018). Quality of life is also negatively impacted by OM, due to the pain and the impact on diet (Cullen et al., 2018 & Yarom, 2013).

The clinical agency needs for the project. The clinical agency in which this project was implemented identified an increasing awareness of the need for better oral mucositis prevention and care. This need was described by patients, caregivers, and office staff. The EBP project arose from the understanding that it is possible to reduce the negative impact of OM on individual's quality of life while undergoing oncological treatments.

Providers at the clinical agency accepted this project with the understanding that oral care and assessment at the clinical agency was inconsistently provided and may not be based

on the most relevant evidence. Data about OM prevalence was difficult to find due to lack of consistency in charting across providers and no agreed upon scale of OM measurement. For example, one physician charted narrative subjective information provided by a patient while another provider documented objective findings without providing the patient experience. The office had no formal oral care protocol in place, and there was no standardized patient education about OM prevention or management.

Purpose of the Evidence-Based Practice Project

Oral mucositis is a distressing side effect that can occur when individuals receive oncological treatments, resulting in decreased quality of life, poorer outcomes, and increased risk for adverse effects. An extensive review of the literature has been performed to determine methods to prevent or reduce the impact of OM. The purpose of this project was to examine the effect of establishing an oral care protocol as the baseline standard of care, then adding zinc sulfate supplementation to determine if it reduced the prevalence and/or severity of OM within the project setting. Additionally, a patient-reported scale that measured the subjective OM experience, the PROMS survey, was identified and implemented to standardize the assessment and diagnosis of OM.

The harmful effects of OM can be avoided or minimized with the implementation of an oral care protocol that includes zinc sulfate supplementation. Oral care is a low-cost intervention that can be helpful in the prevention of OM (Farrington et al., 2013 & McGuire et al., 2013). While there is not a universal oral care protocol recommendation in current clinical practice guidelines, empirical evidence from single studies suggests that a standardized oral care protocol within a facility can prevent or reduce the duration and severity of OM (Carvalho et al., 2018; Eilers et al., 2014; Farrington et al., 2013 & McGuire et al., 2013). Even though universal oral care protocols do not exist, recommendations include that the structure of the protocol should be clear and contain information about oral rinses, include a suggested frequency with which to perform oral care, and have easy to read instructions (Cidon, 2018 & Huang et al.,

2018). Knowledgeable medical staff addressing oral care, assessing for signs and symptoms of OM and providing education to the individual about OM are also noted to be beneficial (Cullen et al., 2018; Da Cruz Compos et al., 2014 & Obeid, 2018).

There is supportive evidence that zinc sulfate can help prevent or reduce the duration of OM in patients receiving oncological treatments. In a meta-analysis looking at whether mineral derivatives helped prevent or reduce the symptoms of OM, data supported that zinc sulfate was helpful (Lee, 2015). In a systematic review of various types of studies, it was noted that zinc sulfate as a supplement might help prevent OM in individuals with oral cancers (Yarom et al., 2013). Moslemi et al., (2014) conducted a study where individuals were given zinc sulfate and found that it reduced oropharyngeal mucositis and delayed the initiation of oral mucositis. Formation of an EBP oral care protocol with the addition of zinc sulfate supplementation may be beneficial in preventing or reducing the severity of OM. Oral care protocols should be structured and teachable to both individuals receiving oncological treatments and the staff responsible for the administration of such. Assessment tools should be consistent throughout treatment with oncological interventions.

Anticipated effects are that the use of zinc sulfate, along with an oral care protocol, will prevent or reduce the severity of OM when compared to individuals who received oral care protocol education as a standard of care, reducing the effects of OM on the quality of life as measured by the subjective tools. The expected outcome is that patients receiving zinc will experience few distressing symptoms than individuals receiving the standard of care.

The PICOT question developed to guide the EBP project and develop a systematic approach was “In patients receiving oncological treatments, does an oral care protocol with zinc sulfate supplementation, compared to the standard of care (oral protocol alone), reduce complications related to oral mucositis as measured by a patient-reported assessment tool over a six week period?”

The significance of the EBP Project

For patients receiving oncological treatments, OM can be a distressing symptom. Best practices indicate possible measures that can help prevent or reduce the severity of OM. Not only will this improve quality of life for patients receiving oncological treatments, but it may also reduce life-threatening sequelae. The results of this EBP project may be useful in other areas such as radiology centers, inpatient hospital units that administer oncological treatments, and family practice. Other facilities that manage oncological treatment may be able to use these results to reduce patient distress and improve survival outcomes. This project was designed to apply EBP that focuses on patient quality of life.

CHAPTER 2

Oral mucositis (OM) is an adverse effect that often occurs in individuals receiving treatment for cancer that can compromise quality of life (Eilers, Harris, Henry & Johnson, 2014). OM is a complex inflammatory process that can progress to ulcerative lesions which may allow micro-organisms normally present in the oral cavity to enter the bloodstream resulting in life-threating infections (Collen et al., 2018; Eilers et al., 2014). The occurrence rate of this condition is estimated to be about 40% of individuals receiving chemotherapy and up to 100% of individuals receiving high-dose chemotherapy, radiation or both (Eilers et al., 2014; Harada et al., 2016). OM is the most common cause of non-hematological complications and morbidity in individuals undergoing oncological treatments (Campos et. al, 2014). This chapter describes the theoretical background and strength and quality of evidence for implementing selected interventions to manage OM. A model to guide the implementation of these interventions will also be described.

THEORETICAL FRAMEWORK, EBP MODEL AND REVIEW OF THE LITERATURE

Theoretical Framework

Self-care is identified as actions individuals and caregivers take for themselves and others to stay fit, manage long term conditions and maintain health and well-being (Williams, Mowlazadeh, Sisler, & Williams, 2015). Health can be conceptualized as simultaneously subjective, objective, comparative, classificatory, holistic, and/or a process occurring over time (Griffin, 2018). Because health is a highly multi-faceted construct, self-care is highly variable and individualized across demographics. Furthermore, self-care needs depend on societal values, including concepts of what is required for physical, emotional, mental, spiritual and social wellbeing (Griffin, 2018).

Self-care can be regarded in both positive and negative aspects. Self-care examples that carry positive implications include exercise, lifestyle change, nutrition, using prescribed medications, biological treatments and creation of meaningful relationships (Finley & Sheppard,

2017; Williams et al., 2015). Additionally, Self-care methods may also have negative connotations. In a study by Finley & Sheppard (2017) examining compassion fatigue in young oncology nurses some negative self-care skills included overindulging in alcohol, staying out late, binge-eating and sleep deprivation. Williams and colleagues (2015) noted “do nothing” as a self-care skill that can have a negative impact on health (p. 579). Inability to address self-care needs can result in poorer outcomes. In a study of U.S. veterans receiving outpatient cancer treatment, researchers noted that the inability to develop self-care behaviors to manage side effects resulted in delay or termination of their treatment regimens (Williams et al., 2015).

Research shows that self-care is a skill that can be built upon through preparatory education, cognitive restructuring, and building on current coping skills (Johnson, 2016). An example of preparatory education is educating individuals on what symptoms should be immediately reported and what to do in case of an emergency. Cognitive restructuring helps individuals identify maladaptive thought processes and dispute them through rational means. Enhancing current coping skills, such as humor or faith-based practices, is another example of self-care. Self-care aimed at prevention of OM may help improve quality of life and increase survivorship (Cullen et al., 2018).

The theory used to guide this project is Dorothea Orem’s Self-Care Nursing Theory. The theory of self-care postulates that individuals have the right and responsibility to care for themselves and maintain efforts towards health, and that nursing care is required when there is incapacity to meet the demands of self-care (Remeo, Deveraux, Detrick & Morris, 2018). The premise is composed of three interrelated concepts: self-care, self-care demands, and self-care agency (Griffin & Landers, 2014). Use of Orem’s self-care model allows nurses to judge a patient’s ability to meet their universal and developmental self-care requisites and address any health deviations.

Self-care. Orem defines self-care as comprised of the practice of activities that individuals initiate and perform throughout their life span in the interest of maintaining health,

functioning, development, and well-being by meeting self-care requisites (Orem, 2001). Orem's concept of self-care is rooted in an individual's desire to preform care on their own behalf (Remeo, Deveraux, Detrick & Morris, 2018). Blum (2014) notes common self-care activities include proper diet, exercise, and stress-reduction techniques. An example of self-care is to learn how to take a blood pressure at home and take medication prescribed to control hypertension.

Self-care demands. Self-care demands are defined as varied degrees, and kinds, of care required to meet an individual's need either at a specific point in time or across a duration of time (Remeo et al., 2018). Self-care demands can be thought of as the care activities that are necessary to control or manage self-care requisites (Orem, 2001). Orem addresses several aspects of self-care through what is called self-care requisites (Fawcett & DeSanto-Madeya, 2013).

Self-care requisites. Self-care requisites provide insight about actions that are known or assumed to be necessary in regulation of an aspect of human functioning or development along a continuum (Orem, 2001). Self-care requisites are best thought of as activities of daily living and apply to all individuals. Self-care requisites are divided into three categories based on universal, developmental, and health deviations (Griffin & Landers, 2014).

Universal self-care requisites are generalizable to all men, women, and children and address health goals that can be met through an individual's ability to promote positive human responses across the life span (Remeo et al., 2018). The universal self-care requisites are considered to be required by all people, regardless of age (Griffin & Landers, 2014). The universal self-care requisites addressed in Orem's theory, include: (a) the maintenance of sufficient intake of air, food, and water, (b) care associated with processes and excrements, (c) a balance between activities and rest, (d) balance between solitude and social interaction, (e) prevention of hazards to human life, human functioning and human well-being and (f) the promotion of human functioning and development within social groups (Orem, 2001).

Developmental self-care requisites are those that are considered requisites to be met at a particular stage in development, which refers to learning to perform self-care in a consistent and effective manner (Griffin & Landers, 2014; Orem, 2001). These requisites are divided into three categories: self-care requisites that focus on conditions that are met with the assistance of dependent-care agents, an individual's engagement in self-development, and ability to prevent or overcome conditions and life situations that can limit development. (Fawcett & DeSanto-Madeya, 2013; Orem, 2001). Developmental self-care requisites include providing and maintaining an environment that prevents both sensory deprivation and sensory overload, promoting positive mental health though deliberate efforts, and seeking to accept and explore feelings and emotions in relation to self, others, objects, and situations (Fawcett & DeSanto-Madeya, 2013).

Health-deviation self-care requisites address the essential requirements that need to be met during ill-health (Griffin & Landers, 2014). Two subcategories exist, one arising directly from disease, injury, disfigurement and disability with the other arising from the medical care measures that medical professionals preform or prescribe (Fawcett & DeSanto-Madeya, 2013). Examples of health-deviation self-care requisites include seeking out healthcare, being aware and attending to effects of pathological conditions such as seen with preventative care measures and learning to live with the effects of a chronic condition such as diabetes (Orem, 2001).

Self-care agency. Self-care agency addresses the individual's ability to engage in self-care (Orem, 2001). Several conditioning factors can affect an individual's ability to act as a self-care agent including factors such as age, developmental state, health state, sociocultural orientation, and environmental factors (Fawcett & DeSanto-Madeya, 2013). Self-care agency requires individuals to have sufficient power to complete self-care activities (Fawcett & DeSanto-Madeya, 2013). Research also shows that social support plays an important role in self-care agency. In a study among patients with a history of cardiac surgery, group participation

was shown to increase self-care agency through group social support (annual meetings), activities (planned physical activities), and reading newsletters (member-submitted stories and essays) (Noguchi-Watanabe, Yamamoto-Mitani, Arimoto, & Murashima, 2017). Orem (2001) believed that social support is an essential aspect of self-care agency because others can allocate power and other self-care resources to close the self-care gap for individuals who lack sufficient power and self-care agency on their own. Examples of individuals who can provide this social support include family members, neighbors, friends, social clubs and organizations, and healthcare professionals, particularly nurses.

Therapeutic self-care demands. Therapeutic self-care demands consist of the care measures needed, at a specific time or over a duration of time, to meet all an individual's known self-care requisites (Fawcett & DeSanto-Madeya, 2013). These demands encompass all required regulatory care (Orem, 2001). A clinical example that illustrates the concept of therapeutic self-care demand is the maintenance of the oral cavity while receiving oncological interventions. The self-care gap in this example is the knowledge of techniques to ensure adequate oral hygiene, referred to as a self-care deficit. Self-care deficit occurs when therapeutic self-care demands exceed self-care agency (Orem, 2001). In the provided example, the individual receiving oncological care has a self-care deficit because they do not yet have the ability or knowledge to perform correct oral care.

Nursing systems serve to address defects between self-care agency and therapeutic self-care (Griffin & Landers, 2014). To address deficiencies, nurses deliberately act to design, plan, implement and evaluate the systems of therapeutic self-care through the nursing process (Fawcett & DeSanto-Madeya, 2013). Nursing services can address self-care deficits through providing all of the essential care (i.e., a wholly compensatory system), providing some of the needed care (i.e., a partly compensatory system), or through cueing and prompting (i.e., a supportive-educative system; Griffin & Landers, 2014).

Application of Theoretical Framework to EBP Project.

Self-care serves to motivate individuals to seek out medical assistance, carry out medically prescribed treatments, and modify the self-image to fit the current state of health (Griffin & Landers, 2014). Self-care can be characterized according to specific clinical situations, such as undergoing oncological treatments. The flexible nature in which self-care can be defined makes Orem's Self-Care Theory especially potent to use with individuals who may develop painful oral mucositis after receiving oncological treatments. Since this EBP project is taking place in an outpatient cancer treatment setting, which requires participants to manage OM mainly on their own, their success will rely heavily on Orem's educative-supportive nursing system to address self-care deficits.

By including the self-care requisites within the theory, Orem addresses the importance of primary, secondary and tertiary care. For example, an oral care protocol can be implemented to help prevent OM or reduce symptoms once the condition occurs. The inclusion of requisites also makes the theory highly generalizable across demographics (Remeo et al., 2018). When addressing health-deviation self-care requisites, research shows that individuals must be aware of discomforting or uncomforting effects of medical care measures (Fawcett & DeSanto-Madeya, 2013). Since oncological therapies are well known to cause numerous side effects, including OM, it will be imperative for nurses to prepare their patients for the development of OM proactively.

Finally, this theory acknowledges the importance of situational life events, effects of age, developmental stage, gender, environment, learning style, and so forth as having effects on the ability to perform self-care (Fawcett & DeSanto-Madeya, 2013). Since cancer treatment can occur at any time in the lifespan, Orem's theory encourages that education is tailored to the developmental level of the client to maximize their self-care agency (Fawcett & DeSanto-Madeya, 2013). This is an appropriate topic to consider since the outpatient clinic addresses cancers that occur across the lifespan and treats a broad demographic.

Strengths and limitations of theoretical framework for EBP project. Orem's Self-Care Theory is well suited for cancer care because it guides situational self-care to reduce symptoms, enhance recovery, and promote overall well-being. Since cancer treatment can cause OM, which can have devastating effects on patient comfort and cancer recovery, this theory can be directly applied to the development of interventions to prevent OM. It can be used to design patient education, which facilitates patient-directed self-care, as well as supportive and restorative nursing care. (Fawcett & DeSanto-Madeya, 2013).

The primary limitation of this theory is that Orem focuses heavily on physical well-being, rather than emotional well-being. Because cancer has profound effects on all facets of health, including emotional health, this theory may be insufficient to develop nursing interventions geared toward enhancing emotional support in patients with cancer (Fawcett & DeSanto-Madeya, 2013). Furthermore, there are differences in cancer types and the oncological treatments required, resulting in some client groups being healthy and relatively asymptomatic (physically well) while also needing treatment to eliminate the malignancy or prevent its metastasis to other sites (cancer requiring intervention). Within this type of patient, there seems to be two diametrically opposed levels of self-care needs. However, further examination of the Self-Care Theory reveals that, while there are no symptoms (thus no need for symptom-relief self-care), there is still a physical illness requiring medical, surgical, or radiological treatment. Therefore, management of the cancer will still require the nurse to intervene to enhance the patient's self-care agency.

Evidence-based Practice Model

Evidence-based models serve as systematic frameworks to assimilate new evidence into nursing practice in an organized and methodical fashion. For this EBP project the Johns Hopkins Nursing Evidenced-Based Practice Model (JHNEBP Model) was chosen. This model was initially developed in 2002 by a team of nurses and facility at the Johns Hopkins Hospital (JHH) to simplify the EBP process and allow easier transition of EBP to nurses within the clinical

setting (Melnyk & Fineout-Overholt, 2015). Since its original publication, the model has been revised with the newest edition, the third, published in 2017 (Dang & Dearholt, 2017). The most current model, used with permission, will serve as the framework for the EBP project presented.

The JHNEBP Model is composed of an open system with three interrelated concepts: inquiry, practice, and learning. By having a model that is an open system, it allows and accommodates for both internal and external factors to be incorporated within the model. Internal factors include policies, organizational culture, values, believes, equipment, supplies, staffing, and offered services. Examples of external factors include local, state, and federal regulations, accreditation bodies, and external stakeholders (Dang & Dearholt, 2017). This makes the model highly adaptable across many care settings.

The first three concepts addressed by the JHNEBP Model are inquiry, practice, and learning. Inquiry is first step and it considered the starting point of EBP. This phase is hallmarked by inquisitiveness to examine a question, collect information in light of a concern, problem, or issue. It encourages addressing a problem and discovering solutions in novel and innovative ways. Following inquiry, comes practice which is the transition of putting what is known into what is done. Practice embraces the standards that are established by professional nursing organizations and help nurses operate within their scope of practice and meet professional performance standards. The next phase is the learning, which is when information is passed on and the one learning can understand it. For the JHNEBP Model learning is considered an ongoing process, keeping up with new information, technologies, skills and clinical practices. The JHNEBP Model holds learning as a lifelong process and project teams should be interprofessional and collaborative in nature (Dang & Dearholt, 2017).

Once the process of inquiry has started, individuals or teams can start to seek out the best evidence to address a problem. These groupings work systematically through the **p**ractice question that is being explored, the **e**vidence concerning the practice, and then the **t**ransition into practice which is referred by acronym, PET. Since the PET process is informed by practice

and an evolving understanding of solutions to the practice problem, new EBP processes can be triggered throughout this cycle (Dang & Dearholt, 2017).

Application of EBP model to EBP project. The current EBP project will follow the inquiry-practice-learning process and PET principles advocated in the JHNEBP Model. Because this chapter is limited to understanding the underlying problem and identifying potential solutions, this section will focus on the inquiry stage of the inquiry-practice-learning process and the practice and evidence principles of the PET acronym. The practice and learning stages and transition principle of PET will be described in subsequent chapters.

Inquiry and the practice problem. A problem-focused prompt was developed while working with a client who suffered from OM to a degree where admission to an acute care hospital was required for management of symptoms. Upon discussions with interdisciplinary team members, including an oncology and hematology physician, cancer nurse navigator, and oncology staff nurses, it was determined that prevention measures for OM were largely unexplored. Preventing OM for clients was considered an important priority and the project was approved by stakeholders who administered oncological therapies in an outpatient setting.

After the problem was defined, there was a discussion about where the gap was between current practice and desired practice. At the start of this project, there was no consistent information about whether OM could be prevented, and clients were provided minimal education on the topic. The compelling clinical question was then identified.

To address all appropriate stakeholders, a multidisciplinary team was formed that consisted of an oncology physician, clinical office manager, and a nurse practitioner. The team determined that at baseline there was no standard of care concerning OM and teaching was done inconsistently by point of care staff.

Evidence. Once the practice problem was identified, an exhaustive literature search was performed to explore possible interventions to prevent and treat OM. This evidence will be described in greater detail later in this chapter. After evidence was collected, appraised for level

and quality, and summarized, it was determined that an oral care protocol needed to be implemented as standard of care and that zinc sulfate should be initiated on clients to prevent or reduce the effects of OM.

Transition and learning. The transition plan will be described in chapter 3, along with the plan for evaluating the intervention. An explanation about what was learned through project implementation and evaluation will be provided in chapters 4 and 5.

The JHNEBP Model serves as an excellent framework to guide implementation of the EBP from inquiry of about best practice to dissemination of a project. The model guides users though a 19-step process and clearly explains what action is required to fulfil one step and move on to the next. The model is flexible enough to be used in acute care settings, outpatient clinics, and other point of care areas. It encourages users to identify all stakeholders in a systematic fashion and provides detailed spreadsheets to help organize the data. Using the JHNEBP Model to guide EBP project also helps establish the quality and grade of the data though comprehensive worksheets. This assisted in identifying high quality data that was useful for development of the protocol and clinical recommendations. The model also provided guidance on how to synthesize the overall findings of the evidence and how data should be transitioned into practice (Dang & Dearholt, 2017).

Strengths and limitations of EBP model for EBP project.

The primary strength of the JHNEBP Model is that it has been widely and successfully used in a variety of clinical contexts and to solve numerous practice problems. One of the reasons for its success is that it provides guidance to interprofessional project teams through well-defined steps. Moreover, it is one of the most often-used EBP models in nursing practice, and examples of its application abound in the peer-reviewed literature. It is a model that allows for flexibility while still providing adequate guidance to ensure that an EBP project is successfully completed.

Limitations noted for the JHNEBP Model included that the tools for appraising evidence were lengthy and subjective, especially with lower levels of research. The nonlinear format of the model encourages new EBP projects to be developed out of current EBP projects that are in progress, which can create confusion (Dang & Dearholt, 2017). There is no clear guideline on whether a new EBP project needs to be started or if the current one in progress can be modified. For example, during the implementation phase of the oral care protocol, the oral care of clients with dentures requires special attention. The JHNEBP Model provides little guidance about whether this should form a new EBP project altogether, or if the original oral care protocol should be adapted along the way to address the unique needs of clients who wear dentures.

Despite these limitations, the JHNEBP Model provides a powerful set of user friendly tools that work to move evidence into practice. From development of the question, to literature critique and evaluation, to implementation and evaluation the tools systematically address each step of the process. Additionally, this EBP model encourages users to concern both internal and external factors that the change might impact.

Literature Search

A search for evidence-based literature was conducted in efforts to find the best available evidence related to the prevention of OM in adult clients receiving oncological treatments. Databases searched for evidence included (a) CINAHL, (b) MedLine, (c) Cochrane, (d) Joanna Briggs Institute (JBI), (e) Nursing & Allied Health Database, and (f) National Guidelines Clearinghouse. In efforts to maintain consistency across the databases, terms used were “oral mucositis” and *prevent** were used across all databases. Additional search term of *cancer OR chemo** was included in the MedLine, CINAHL, Nursing & Allied Health Database and National Guidelines Clearinghouse databases. For the CINAHL database the word *adult* was added to search terms to assist in locating articles relevant to the population of the EBP project. Citation chasing was also performed in efforts to locate the best available data.

Inclusion criteria included studies that were (a) published between 2013 and 2018, (b) written in English, (c) peer reviewed and (d) focused on efforts to prevent OM. Studies that were excluded included (a) interventions that focused on pediatric populations, (b) prevention of OM using one specific chemotherapy agent, (c) studies that used drugs not approved for use in the United States, (d) failure to include results or recommendations and (e) studies that formed recommendations that were not based on timely data at the time of publication.

Search results. Complete search results from all data bases are depicted in table 2.1 CINAHL yielded a total of 35 articles, 27 of which were excluded by title alone. Four additional titles were eliminated after abstract review due to irrelevance to the purpose of this review, the remaining 4 articles were included in the review for further analysis. MedLine produced 270 results, after the removal of 3 duplicates, 255 articles were eliminated on title alone. The remaining 12 articles underwent abstract review and resulted in the elimination of 7 more article, leaving a total of 5 included in the review. A search was conducted in the Cochrane database and yielded a total of 5 results, 3 were irrelevant to the purpose of this review, and after abstract review of the remaining 2 articles, neither were determined to be appropriate for use in the project. Joanna Briggs Institute revealed 35 results with 6 articles reviewed, 2 were selected for inclusion. The Nursing & Allied Health Database yielded 18 results, 3 were reviewed but none were selected for inclusion. Finally, National Guidelines Clearinghouse was searched, revealed 16 results, after eliminating 15 due to irrelevancy, 1 underwent review and was not acceptable for inclusion. A detailed review of cited literature yielded a total of 5 pieces of evidence that were chased and all 5 were reviewed with 2 meeting inclusion perimeters. Altogether, 13 unique pieces of evidence were included.

Levels of evidence. Evidence for this EBP was assigned by following the stipulations presented in the evidence level and quality guide found in Appendix D of ©The Johns Hopkins Hospital/The John Hopkins University nursing EBP guide (Dang & Dearholt, 2017). Levels of evidence fall into five categories, listed as levels I – V. The tool describes level I evidence as

Table 2.1
Studies obtained from databases

Database	Initial Articles for Review	Duplicates	Abstracts Reviewed	Included in Review
CINAHL	35	0	8	4
MedLine	270	3	12	5
Cochrane	5	0	2	0
JBI	35	0	6	2
Nursing & Allied Health Database	18	0	3	0
National Guidelines Clearing House	16	0	1	0
Chased	5	0	5	2
Total				13

experimental, randomized control trails (RCTs), explanatory mixed method studies that include only other level I quantitative data, and systematic reviews of RTCs, with or without meta-analysis. Level II studies include individual quasi-experimental reports and mixed method designs that include only other level II studies, systematic reviews that are a combination of RCTs, quasi-experimental studies, or quasi-experimental studies alone, with or without meta-analysis. Level III studies are nonexperimental studies, systematic reviews including a combination of RCTs, quasi-experimental and nonexperimental studies, or nonexperimental studies alone with or without meta-analysis, exploratory, convergent, or multiphasic mixed method studies, explanatory mixed method designs that include only other level III quantitative studies and qualitative studies with meta-synthesis. Level IV data includes opinions of respected authorities, opinions of nationally recognized expert committees, or consensus panels based on scientific evidence. This level provides inclusion of clinical practice guidelines, consensus panels, and position statements. The lowest level of evidence provided by this method is level V, which is based on experiential and non-research evidence, including integrative reviews, literature reviews, quality improvement, programs, or financial evaluations, case reports, and opinions of naturally recognized experts based on experiential evidence (Dang & Dearholt, 2017).

Appraisal of relevant evidence. Quality ratings for the appraisal of evidence for each research article were assigned based on the quality ratings system found in Appendix D of ©The Johns Hopkins Hospital/The John Hopkins University EBP nursing guide (Dang & Dearholt, 2017). Quality ratings are assigned as A, A/B, B, or C to each article. The assigned grade of A indicates a research article is considered high quality and has features such as being consistent, having generalizable results, and making consistent recommendations based on exhaustive literature review that includes scientific evidence at level I. For level IV a grade of A indicates that materials were officially sponsored by professional, public, or private organizations, systematic literature search was completed, results were reported with sufficient

numbers of well-designed studies, and able to draw definitive conclusion. Level V assignment of grade A indicates clear aims and objectives, consistent results across various settings, evaluation of programs have been used, and definite conclusions and recommendations made with reference to scientific evidence (Dang & Dearholt, 2017).

At evidence levels II and III, the grade A/B indicates high/good quality studies, that discusses efforts made to evaluate the quality of the data, including transparency, diligence, verification, self-reflection, participant-driving inquiry and insightful interpretation. The A/B grade requires evidence of some or all of the qualities that are listed, though no calculated formula is provided by the tool (Dang & Dearholt, 2017).

Evidence graded at B indicates that the study is considered good quality. Features of good quality evidence included reasonably consistent results, sufficient sample sizes, some control, definitive conclusions, reasonable recommendations, and some reference to scientific reference at level I. For levels IV and V, good quality studies are expected to meet most of the features of grade A, but with reduced focus on key components. At grade B it can be expected that fairly definitive conclusions can be drawn, expertise is evidence, and some reference to scientific evidence is made (Dang & Dearholt, 2017).

Each level of evidence has a corresponding grade of C and these are considered low quality or majorly flawed studies. In this category, studies have little evidence, are inconsistence, or can not draw conclusions and lack many of the features noted for higher grading. The grade of C indicates that poorly defined improvement, evidence not revised within the past five years, or small sample size (Dang & Dearholt, 2017). In the following selection analysis and quality of each piece of evidence will be discussed (See Evidence Summary, Table 2.2).

Level I Evidence. Lee (2015) conducted a systematic review of RCTs with meta-analysis reviewing the effects of mineral derivatives, including zinc sulfate, in preventing or alleviating OM during oncological treatments. Their search was comprehensive including RCTs

from five large databases and specific keywords used in each database. Inclusion and exclusion criteria are clearly stated and applied to search studies appropriately. Lee (2015) provides a flow diagram that included the number of studies eliminated at each level of review. Sixteen studies were included in the meta-analysis and were analyzed for quality using Cochrane Collaboration guidelines. Trial and patient characteristics were also reviewed, finding a 1:2 female-to-male ratio in adults, with a mean age of 49. Other demographic information included percentile breakdowns of regions that the studies took place, percentages of oncological treatments, common chemotherapy combinations that appeared across the studies, and common radiation maximums. All data was pooled by outcome and results examined: Peak OM incidence, OM duration, time to OM onset, pain incidence, and analgesic use. Statistically significant findings were noted with participants who took mineral derivatives had reduced symptoms than those without treatment ($g = -0.47$, 95% CI −0.7 to −0.2, $p = 0.0006$, $I2 = 61\%$). Additionally, the time of OM onset was significantly delayed in those that took mineral derivatives ($g = -0.5$, 95% CI−0.8 to−0.2, $p = 0.0002$, $I2 = 35\%$). One limitation addressed was many of the RCTs were only conducted at single locations, making generalization questionable. High heterogeneity exists in this study due to diverse therapies and different OM measurement tools. Results suggest positive effects of mineral derivatives, chiefly zinc sulfate, in prevention and treatment of OM (Lee, 2015). Quality rating for this data is A due to the consistency, sufficient sample size at meta-analysis level, and strong recommendations based on comprehensive literature review.

Moslemi, Damavandi, Pourghasem, and Moghadamnia (2014) performed a randomized control trial in a medical university department of radiotherapy to evaluate the potential benefits of zinc sulfate in the prevention of OM in head and neck cancer patients. The literature review was current at the time of the study. Research type is described as a phase III, double blind, placebo-controlled RCT. Forty patients diagnosed with head and neck cancer were randomly divided into two equal groups, with one group receiving zinc sulfate while the other received the

placebo capsules which were filled with starch and designed to appear identical as capsules used in the experimental group. The intervention group received 30 mg of zinc sulfate starting 10 days before oncological treatment and 14 days after oncological treatment ended, while the control group received a starch filled placebo. No characteristic or demographic differences were noted between groups. Exclusion criteria were described in detail. Data were collected using the well-validated Oral Mucositis Assessment Scale (OMAS). Results were presented at various points throughout the treatment, including known peak times of OM. In weeks 2 through 7, eight patients scored lower on the OMAS scale in the zinc group, than they did the placebo group ($p<0.003$), indicating that patients in the treatment group had less severe OM. Limitations were omitted from the study, but small sample size and limited to one cancer type are noted. This study supported the hypothesis that use of zinc sulfate can reduce the severity of OM in groups receiving radiation (Moslemi et al.,2014). Quality rating of B was assigned to this study, due to small sample size for the study design.

In a randomized controlled trial conducted by Huang et al., (2018) a study exploring the effectiveness of a saline mouth rinse regimen and education program on OM symptoms and quality of life (QOL) in patients receiving oncological treatments. The study was conducted at a cancer center in northern Taiwan. Sample size grouping was not described. Participants were randomly divided into experimental or control group by casting of lots. Patients in the two groups differed in marital status, and this variation may have influenced the independent variable because of the differences between the physical and social-emotional quality of life could marital status may have had an influence but was not accounted for in the study. The intervention group was taught mouth care skills, provided face to face education, and given supportive care consisting of assessing patient concerns, emotional support, evaluation and response to the saline mouth care, and answering questions. Control group received the standard of care, which included education of mouthwashes made from boiled water for three to four-hour intervals after meals. Measurements were recorded using the World Health

Table 2.2 *Evidence summary*

Citation, Level of Evidence	Study Design	Setting, Sample	Purpose	Measurement	Results	Limitations	Conclusion, Recommendations
Carvalho, C. G., Medeiros-Filho, J. B., & Ferreira, M. C. (2018). Guide for health professionals addressing oral care for individuals in oncological treatment based on scientific evidence. *Supportive Care in Cancer, 26*(8), 2651-2661. doi:10.1007/s00520-018-4111-7 Level I, Grade B	Systematic reviews of randomized clinical trails (RCTs) and RCTs	Incorporated data from 17 Systematic reviews/meta-analyses of RCTs of high quality or well conduction RCTs or RCTs with a very low and low risk of bias 37 RCTs with diverse designs	To determine the best evidence based oral care for patient receiving oncological treatments	Multiple studies looking at preventive and therapeutic conduct for oral complications and addressing oral assessment, professional and home oral care	Before oncological treatments oral hygiene for home should be taught, brushing 3x daily with ultra-soft burhs and fluoride toothpaste and dental floss Lubrication and hydration of the oral mucosa in cases of xerostomia Periodic evaluation during and after oncological treatments and oral care	No standard oral protocol was able to be developed	Oral care minimizes oral complications during oncological treatments Assessment of oral condition is important during oncological treatments

					protocols can help prevent or minimize OM		
Cidon, E. U. (2018). Chemotherapy induced oral mucositis: prevention is possible. *Chinese Clinical Oncology, 7*(1), 6. doi:10.21037/cco.2017.10.01 Level II, Grade C	quasi-experimental cohort design	Medical oncology hospital in Bournemouth, UK N=68 Female breast cancer patients undergoing neoadjuvant or adjuvant treatment, who experienced OM during the past cycle	To explore if a special mouthwash (combination mouthwash with anti-inflammatories, antifungal and saline water) could help reduce the effects of OM in a patient population who had previously experienced OM during their treatment cycle	Patient survey consisting of 7 yes/no questions concerning OM Medical oncologist assessment using criteria stabled by WHO	A binomial test concluded probability of grade 2–3 OM after using this mouthwash was lower P=0.000087 (1-sided). And the probability of grade 2 OM was P=0.000015 (1-sided)	Data was limited to a female population and specific chemo regiments to treat breast cancer All participates were previously educated but protocol is not described Non-validated tool used to collect patient information Data not inclusive as to why	The special mouthwash, when used 3 times daily starting 3 days before expected episode of OM was effective in reducing the severity of OM in women who were already in good dental health and had previously been educated on oral care

						ingredients to special mouthwash were chosen and unclear if one ingredient of it was superior to others	
Cullen, L., Baumler, S., Farrington, M., Dawson, C., Folkmann, P., & Brenner, L. (2018). Oral care for head and neck cancer symptom management: Piloting an evidence-based practice change at a radiation oncology center. *AJN American Journal of Nursing*, *118*(1), 24-45. Level III, Grade A	Descriptive study	One radiation oncology center N=28 (n=23 responded) clinicians, and patients N=105 (n=20 usual care prior to intervention, n=85 intervention)	To Implement and study the effectiveness of EBP change designed to reduce the severity of oral mucositis in adults receiving radiation treatments for head and neck cancers	Pre and posttest of clinician knowledge on 4-point Likert scale before and after intervention Patient survey with questions concerning oral care practices, patient perceptions about oral care rated on a 4-point Likert scale and subjective oral mucositis symptoms rated on an 11-	Clinicians scores improved N=29 (n=20) preimplementation Correct response to knowledge assemsent from 71% preimplementation to 80% postimplementation Intervention patient reported less severity than usual care patients in	Study focused on a limited cancer type Preformed only in one clinical, generalization may not be possible All material needed for the study were provided to the patients	Implementation of an oral care protocol reduces the patient-reported perceptions of complications due to OM Implementation of an oral care protocol can improve clinician knowledge and assist in changing towards EBP

				point Likert scale collected prior to initiation of treatment, 4-5 week of treatment, and one month after treatment	various symptoms: mouth and throat soreness (3.9 versus 5), difficulty swallowing (4 versus 5.6), difficulty eating (4.9 versus 5.9), and difficulty talking (2.9 versus 4), less difficulty with xerostomia (3.1 versus 4.1)		
da Cruz Campos, M. I., Campos, N.C., Aarestrup, F.M., & Aarestrup, B. J. (2014). Oral mucositis in cancer treatment: Natural history, prevention and treatment. *Molecular and Clinical Oncology, 2*(3), 337-340. doi: 10.3892/mco.2014.253	Literature review	29 articles between 1994 and 2013	To review OM, it's causes and treatment in professional settings	PubMed, Lilacs, and MedLine used to retrieve articles, using keywords of *oral mucositis, prevention and control, pharmacological effects* and *immunosuppressive agents*	Professional oral examination should be performed prior to initiation of oncological treatments Preventive oral care program should be followed to	Inclusion and exclusion criteria not clearly described	Patients may benefit from professional instruction of oral hygiene

Level V, Grade B					reduce the complication of oncological treatments		
Eilers, J., Harris, D., Henry, K., & Johnson, L. A. (2014). Evidence-based interventions for cancer treatment-related mucositis: Putting evidence into practice. *Clinical Journal of Oncology Nursing*, *18(*6) *80*-96. doi:10.1188/14.CJON.S3.80-96 Level V, Grade A	Literature review	104 publications from 2008 to 2013	Review of evidenced-based interventions for OM and develop guidelines for nursing interventions	PubMed was searched for *Mucositis[ti]* OR *Mucositis[majr]* OR *"oral complication*"* with 635 articles yielded CINAHL search inclused (*MM "Mucositis"* OR *MM "Stomatitis"* OR *TI Mucositis* OR *TI stomatitis* OR *"oral complication*"*) AND (*cancer* OR *neoplasms* OR *oncolog** OR *chemotherap**) with 338 articles yielded	Recommended for practice: cryotherapy, low-level laser therapy, oral care protocols, palifermin, sodium bicarbonate mouth rinses. Likely to be effective: Benzydamine rinses, Lactobacillus lozenges, prophylactic chlorhexidine mouth rinses Effectiveness not established	Recommended for practice is not applicable to generalized cancer patients or can only be used with limited chemotherapies. Expense limits the effectiveness of the recommendations	Oral care protocols that provide frequent oral hygiene, prophylactic mouth rinses, and routine assessment can help decrease the incidence, duration and severity of OM. Structure and components of oral care are important Sodium bicarbonate month rinses are recommended.

				After review only 104 met inclusion perimeters	in 46 interventions Effectiveness unlikely for Isegana, traumell S, Wob-Mugos E Not recommended: Chlorhexidine as a nonprophylactic, Sucralfate		Zinc or Zinc supplements noted as effectiveness not established.
Farrington, M., Cullen, L., & Dawson, C. (2013). Evidence-based oral care for oral mucositis. *ORL-Head and Neck Nursing: Official Journal of The Society of Otorhinolaryngology and Head-Neck Nurses*, *31*(3), 6-15. Level V; Grade A	Literature review	Large academic medical center, all nurses	Development and implementation of an oral care protocol for use in adult and pediatric populations	Educational PowerPoint with new oral care policy for use in unit in-services and computer-based training.	3-month post-implementation knowledge assessment nurses (n=117) Topic knowledge: 100% - use of soft toothbrushes 97% Biotene toothpaste	Preformed at one facility No pre-test, posttest only	Prevention of OM should be addressed by routine oral care using evidenced based products

					55% correct assessment knowledge 56% correct flossing knowledge 46% correct lip care 52% correct rinses for OM		
Huang, B., Wu, S., Lin, C., Fan, K., Chang, J. T., & Chen, S. (2018). The effectiveness of a saline mouth rinse regimen and education programme on radiation-induced oral mucositis and quality of life in oral cavity cancer patients: A randomised controlled trial. *European Journal of Cancer Care, 27*(2), 1-10. doi:10.1111/ecc.12819 Level I, Grade B	RCT	Cancer center of a medical center in northern Taiwan N=91 n=48 intervention group of saline mouth rinse regimen with education program n=42 provided with standard of care	To test the effectiveness of a saline mouth rinse regimen and educational program on OM and quality of life in patients with oral cavity cancer post operation but before induction of treatment	Radiation-induced OM evaluated WHO Oral Toxicity Scale 7-item MSS-moo, an instrument that assesses radiation-induced OM-related symptoms UW-QOL; measures 12 domains of health: pain, appearance, activity, recreation,	No statistically significant findings in improvement in radiation-induced OM symptoms and overall QOL was find between the two groups; Physical function QOL significantly improved from pre-test to post-test (Fw = 3.468, p < .01)	Limited to oral cancer patients Intervention excluded patients with mild-to-moderate, radiation induced OM Patients who appeared to be in pain during recruitment were excluded.	Saline mouth rinses along with an educational program are effective interventions in increasing physician and social-emotional quality of life by improving the symptoms of OM when compared to standard of care.

				swallowing, chewing, speech, shoulder, taste, saliva, mood and anxiety with 2 global items reflecting health-related and overall QOL Baseline data collected across both groups, first postoperative clinical visit, and post-test at 8 weeks. ANOVA test	A statistically significant group × time interaction (Fin = 4.627, p < .05) indicated that social-emotional QOL in the experimental group (70.22–78.11) improved more significantly than in the control group (69.37–69.96) after 8 weeks.		
Lee, S. (2015). Mineral derivatives in alleviating oral mucositis during cancer therapy: A systematic review. *Peerj*,*3*e:765. doi:10.7717/peerj.765 Level I, Grade A	Systematic review of RCTs with meta-analysis	16 studies included, *n*=1120	The effects of using mineral derivatives in treating OM when compared to the standard of care or placebo in any cancer types, population of	Binary and continuous data synthesized Hedges' g in a random effects model Decision tree mapped sensitivity, specificity, pre-test and post-	Mineral derivatives were less likely to experience peak OM than those without treatment (g = −0.47, 95% CI −0.7 to −0.2, p = 0.0006, I2 =	No clear recommendations can be made based on the study Unable to make clinical practice recommendations	The meta-analysis suggests mineral-derivatives have a positive effect in reducing severity of OM for patient receiving cancer treatments

			all ages, undoing various cancer treatments	test Baybesian probability	61%). Treatment groups (n = 958) experienced peak OM less than controls (g = −0.47,95% CI −0.7 to −0.2, p = 0.0006) OM onset was significantly delayed in treatment than controls (g = −0.51, 95% CI−0.8 to −0.2, p = 0.0002;		Supports positive effects for Zinc sulfate in prevention and treatment of oral mucositis
McGuire, D. B., Fulton, J. S., Park, J., Brown, C. G., Correa, M. E. P., Eilers, J., ... & Lalla, R. V. (2013). Systematic review of basic oral care for the management of oral mucositis in cancer patients. *Supportive Care in*	Systematic Review	52 studies that included only primary research with a verity of designs	To evaluate research of oral care interventions and update EBP guidelines for preventing and treating OM	OVID/MEDLINE databases searched; search terms of *mucositis, stomatitis, cancer, oral care, oral care protocol, dental care,*	*n*=24 studies tested oral protocols found positive effects across various populations including children	Lack of evidenced for 7 interventions Guidelines unable to be developed	Use of oral care protocols in prevention of OM in all age groups and treatment modalities Chlorhexidine should not be used to

Cancer, *21*(11), 3165-3177. Level III, Grade A				*dental cleaning, oral decontaminatio n, oral hygiene, saline, sodium bicarbonate, baking soda, chlorhexidine, magic/ miracle mouthwash,* and *calcium phosphate* Articles from 1950 to 2010 52 studies met inclusion criteria	No recommenda tions for dental care, normal saline mouthwash, sodium bicarbonate mouthwash, chlorhexidine mouthwash, mixed medication mouthwash, and calcium phosphate mouthwash. Guidelines suggest against using chlorhexidine mouthwash in head and neck cancers	based on data	prevent OM in head and neck cancer patients Normal saline and sodium bicarbonate mouth rinses are viewed as harmless when included in routine oral care practices
Moslemi, D., Babaee, N., Damavandi, M., Pourghasem, M., & Moghadamnia, A. A. (2014). Oral zinc sulphate and prevention of radiation-induced oropharyngealmucosi tis in patients with	RCT	Babol University of Medical Sciences in the Department of Radiotherapy N=40	To research the potential benefits of zinc sulphate in the prevention of radiation induced OM in head and neck cancers	The Mann - Whitney, Fisher's exact, Pearson chi-square tests and Friedman variation analysis,	Weeks 2-8, the severity of oral and pharyngeal mucositis were lower in the zinc group, ($p<0.003$)	Specific cancer type; limited to head and neck Small sample size	Zinc sulphate (30 mg, TID) can reduce oropharyngea l mucositis, delays initiation of mucositis

head and neck cancers: A double blind, randomized controlled clinical trial. *International Journal of Radiation Research, 12*(3), 235-241. Level I, Grade B		Randomly divided *n*=20 experimental group, *n*=20 placebo group					
Slade, S. (2017). *Oral mucositis: Treatment [Evidence Summaries].* Retrieved from Joanna Briggs Institute database. (Accession No. JBI15068) Level V, Grade A	Evidence summary	Incorporated data from 8 systematic reviews, 2 Cochrane systematic reviews, 1 Evidenced-based clinical guideline, 7 RCTs, 1 controlled trail, and Included articles based on expert opinion, non-analytic studies, and relevant literature	Determine best practice guidelines for prevention of oral mucositis in patients receiving cancer treatments	RCT that included 24 participants RCT that included 225 participants 5 RCTs Cochrane systematic review that included 131 studies and 10,514 participants Cochrane systematic review that included 35 RCTs with a	Range of interventions found to be useful but advised benefits may apply to specific cancers/treatments Cryotherapy, Keratinocyte Growth Factor, in some cancer/treatment types are effective at reducing OM Low-lever laser therapy	Best practice recommendations are limited to some exclusive cancer or treatment types There is potential bias or lack of generalizability in the studies used.	Preventative oral care regimens should be in place Oral pain should be self-reported using a validated tool on a regular basis

total of 3,102 participants	is a good alternative for prevention of OM
Systematic review of 27 studies	
Systematic review of 52 published papers	Regular assessment of patient-reported oral pain using a validated tool is recommended
Systematic review 49 papers across 15 interventions	
Systemic review of 54 oral assessment instruments	Preventive oral care should be in place
Systematic review of 24 trials	Before starting cancer treatment, dental examinations and treatment should be carried out
Systematic review that included 64 clinical studies	
Systematic review of 22 clinical studies	Chlorhexidine mouthwash and glutamine

				and 2 meta-analyses Articles based on expert opinion, non-analytic studies and relevant literature.	preparations are not recommended for head and neck cancer patients		
Obeid, S. (2018). *Oral mucositis: Assessment [Evidence Summaries].* Retrieved from Joanna Briggs Institute database. (Accession No. JBI15067) Level V, Grade C	Evidence summary	2 systematic reviews 1 observational study	Determine best practice guidelines regarding the assessments of oral mucositis in patients	Systematic review of oral assessment instruments for children and young people including 53 studies Observational study with 33 participants Systematic review including 104 studies and evidenced-based recommendation	Healthcare professionals should educate people with cancer about OM Standardized oral assessment for all patients should occur using a validated tool prior to assessment and throughout treatment. Oral assessment	There is potential bias or lack of generalizability in the studies used.	Healthcare professionals need to discuss, inform, and educate patients about OM and its assessment

tool should have patient subjective experiences in order to address patient experience

Patient reported assessment tools may complement clinician-determined measures or as stand-alone assessments when addressing OM

OM assessment tools by clinicians should be standardized across all patients within a health service

					User should be trained in correct manner to use assessment tool.		
Yarom, N., Ariyawardana, A., Hovan, A., Barasch, A., Jarvis, V., Jensen, S. B., . . . Mucositis Study Group of the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO). (2013). Systematic review of natural agents for the management of oral mucositis in cancer patients. *Supportive Care in Cancer, 21*(11), 3209-3221. doi:10.1007/s00520-013-1869-5 Level II, Grade A	Systematic Review	49 papers, various types of studies	To systematically review current literature and construct clinical practice guidelines for use of natural agents in the prevention and treatment of OM	OVID/MEDLINE databases searched; search terms *alternative, complementary, homeopathic, aloe vera, beta-carotene, chamomile, chinese herbal, folic acid, glutamine, hydrolytic enzyme, MF 5232 (mucotrol), multivitamin, natural, polaprezinc, traumeel, tretinoin, vitamin, zinc, honey, manuka & kanuka oil,*	Glutamine is not recommended by IV for prevention of OM, no guidelines possible for other modes of intake No guidelines possible for various vitamin or combination of vitamin and supplements No guideline possible for honey Oral systematic	Guidelines unable to be developed for several interventions based on data Recommended guideline limited to one cancer type.	IV Glutamine is not recommended for prevention of OM in patients receiving cancer treatments Systemic zinc supplements may help prevent OM in oral cancer patients receiving oncological treatments

Rhodiola algida, vitamin A, vitamin E, Wobe-Mugos E, retinoid, and *indigo wood root.*	zinc supplements maybe of benefit in preventing OM in oncological treatments No guideline for aloe vera gel, chamomile mouthwash, or Chinese herbal drug mouthwash. No guidelines for indigowood root No guidelines for manuka and kanuka oils, Mucotrol, *R. algida,* Traumeel S, Wobe-mugo E/proteolytic enzymes

Organization Oral Toxicity Scale, interobserver reliability of 0.99, and MacDibbs Symptom Score – Modified for oral cavity care and University of Washington Quality of Life scale, both having Cronbach's scores higher than 0.90. Differences in the quality of life (QOL) indices for physical function and socio-emotional function were statistically significant between groups. Significant findings were noted the physical functioning quality of life scores when compared to interactions between groups and within the pre and post-test ($F_{in} = 4.114$, $p < 0.05$)- The social-emotional function of QOL in the experimental group improved more significantly than in the control group ($F_{in} = 4.627$, $p < 0.05$) after eight weeks. However, this study did not find improvement in OM symptoms overall. This may have been the result of delayed recruitment into the study, which occurred in week 5 of treatment. Limitations of the study included the restriction of eligibility to only those patients with clinically severe OM and the lack of assessment of family social support and nutritional status of patients. Despite these limitations, this study supports that saline mouth rinses with an educational program increases the physical and social-emotional quality of life in patients with OM (Huang et al., 2018). This RTC receive a quality rating of B due to results that were classifiable as reasonably consistent.

Carvalho, Medeiros-Filho, & Ferreira (2018) performed a systematic review without meta-analysis in efforts to evaluate the available evidence and draft a guide for medical professionals that involved oral care for oncological patients. Criteria for studies included only systematic reviews of RCTs and individual RCTs. Extensive database searches occurred across the Cochrane Library, MEDLINE/PubMed and EBSCOHost databases. Inclusion and exclusion criteria are clearly defined. A flow diagram is provided that provides detailed information on how studies were eliminated at each level of review. Methodological quality was determined based on the "Assessing the Methodological Quality of Systematic Review" (AMSTAR) and "Method for Evaluating Research and Guideline Evidence" (MERGE) by two independent researchers. Conclusions were discussed for the interpretation and systematic data review. Authors recommended that, prior to oncological treatments, oral hygiene best

practices should be taught, including the recommendation of brushing 3x daily with ultra-soft toothbrushes, fluoride toothpaste and dental floss. In the event of xerostomia education should include the practices of lubrication and hydration of the oral mucosa. Ongoing assessments should be done before, during, and after oncological treatments. Recommendations also include that a professional oral examination should be performed prior to initiation of oncological treatments. This study strongly supports that a preventive oral care program should be followed to reduce complications (Carvalho, Medeiros-Filho, & Ferreira, 2018). Quality rating for this article is a B because results lack generalizability across populations and analytical data is not present.

Level II Evidence. A systematic review conducted by Yarom et al., (2013) addressed the use of natural agents for the management of OM in patients receiving oncological treatments. A comprehensive database search was conducted and inclusive key terms relative to the topic were provided. The resulting evidence was reviewed by two independent reviewers and evaluated based on a list of major and minor flaws. The Somerfield criteria were used to assign the appropriate level of evidence. Systematic review did not include a flow diagram but did provide narrative on the inclusion and exclusion process. Yarom et al., (2013) included in the review 49 papers across 15 interventions in the systematic review. Conclusions flowed logically and based on the scientific data presented. However, one limitation noted in the studies included that the systematic review focused chiefly on head and neck cancers and not cancers in general. Two recommendations developed from the systematic review in reference to preventing OM: one against the use of glutamine and one supporting the use of zinc sulfate in head and neck cancer patients (Yarom et al., 2013). This evidence supports the use of zinc sulfate as a preventative in patients receiving oncological therapies in the treatment of head and neck cancers. The quality rating assigned to this study is A because it meets the standards of transparency, diligence, verification, and low risk of bias due to the use of an independent researchers screening data before inclusion.

Cidon (2018) conducted a prospective cohort study to examine if a specialty mouthwash that was composed of 100 milliliters of water, 5 milligrams of soluble prednisolone, 2 drops of nystatin and 2.3 mg of salt. The combination was suggested to help prevent reoccurrence of OM in breast cancer patients who had developed OM during previous chemotherapy cycles. It is noted that before the study, all patients had been educated to continue an oral hygiene protocol and were in good dental health. A total of 68 patients were included in the study; all women undergoing treatment for breast cancer with various oncological therapies. Other demographics are not provided and the research took place at a single institution in Bournemouth, UK. Data was obtained by professional visual assessment using the World Health Organizational (WHO) grading criteria for OM and a seven-question patient survey. Instrument validity was not discussed and was without Cronbach's alpha data. Findings were statistically significant based on binomial testing indicating the probability of grade 2 to 3 OM after using this mouthwash was lower (2.9% $p < 0.0001$) and the likelihood of grade 2 OM was significantly less severe in those that used the special mouthwash (11.7%, $p < 0.0001$). The main limitation of this study was the small sample size which may have been inadequate to detect a truly significant difference. Additionally, since all participants were females with breast cancer, findings may not be generalizable to men with breast cancer or patients of any gender with non-breast cancer. The authors did not describe the evidence they used to support rational of the choice of ingredients included in the mouthwash formulation, so the empirical underpinnings of their intervention are unclear. Finally, patients were noted to have previously had OM and had received oral care education, which is an independent variable that needed to be explored. This study provides weak, though statistically compelling, evidence to support mouthwash as a care strategy for prevention or reduction of OM and receives a quality rating of C due to the methodological flaws outlined above.

Level III Evidence. Cullen and colleagues (2018) conducted a descriptive study to evaluate the use of oral care kits and oral care education for patients receiving radiation therapy

for head and neck cancers at a large academic medical center. The study took place at an accredited comprehensive cancer center. Patients were divided into two groups by opportunity sampling, with the first 20 patients receiving the standard of care and the next 85 patients serving as the experimental group. Both groups were treated similarly with the comparison group receiving standard care, which included extensive oral care preparation: Oncologic dentist evaluation, fluoride treatments, provisions of oral care supplies, and tooth extraction when necessary. The intervention group received standard care plus an oral care kit and extensive instructions on how to use it. Data were collected at the same treatment points in both groups, with surveys being used for data collection. Cronbach's alpha and instrument validity were not discussed. Data to assess clinician knowledge was collected pre- and post-intervention by using a pre and post-test method. Correct response to knowledge assessment increased from 71% to 80% postimplementation (n=20/29). Patient data was collected pre-oncological treatment, at week 4-5 of treatment, and one month after treatment ended. Patients in the intervention group reported less severity than usual care patients in various symptoms: Mouth and throat soreness (3.9 versus 5), difficulty swallowing (4 versus 5.6), difficulty eating (4 versus 5.9), difficulty talking (2.9 versus 4), and less difficulty with xerostomia (3.1 versus 4.1) (Cullen et al., 2018). This study supports the use of evidence-based oral care, oral care kits, and educational materials on judicious oral care. The study is considered A on the quality rating, due to transparency, diligence, verification, self and instructional reflection, and participant-centered inquiry.

McGuire and colleagues (2013) conducted a systematic review without meta-analysis evaluating research focused on basic oral care interventions in efforts to update EBP guidelines for preventing and treating OM. OVID/MEDLINE database was searched using a comprehensive list of keywords. Accepted article types were research studies of various designs. Stringent inclusion and exclusion criteria were used to discover best evidence for the prevention or treatment of OM. A structured clinical review was conducted for each article, with

analysis using the Hadorn criteria for assessing flaws and the Somerfield schema for rating level of evidence. Included in the review were 52 studies across seven interventions; (a) oral care protocols, (b) dental care, (c) normal saline, (d) sodium bicarbonate, (e) chlorhexidine, (f) mixed medication mouthwash, and (g) calcium phosphate. Researchers concluded that oral care protocols in the prevention of OM in all age groups and across all cancer treatments are recommended. No recommendations could be made for normal saline or sodium bicarbonate mouthwashes; however, research supported bland rinses can be helpful for both patient comfort and oral hygiene maintenance by an expert panel (McGuire et al., 2013). Evidence supported the use of an oral care protocol as a method of preventing OM. Evidence provided met the criteria of A quality for a systematic review.

Level V Evidence. Ferrington, Cullen, & Dawson (2013) implemented EBP recommendations for the prevention and treatment of OM across a diverse population. Recommendations were based on a synthesis of the evidence, providing consistent results from different sources about oral care in patients receiving oncological treatment. Literature included in the synthesis was timely and relevant to the topic. Meaningful conclusions drawn from the information were presented. A web-based evaluation tool was distributed to nursing staff (n=117) three months after EBP oral care protocol was implemented to identify areas that needed additional education. Researchers found that nurses were knowledgeable in: (a) use of soft toothbrushes – 100%, (b) Biotene toothpaste – 97%, however, reinfusion was required for topics of (c) Assessment – 55%, (d) flossing knowledge – 56%, (e) correct lip care -46% and (f) correct rinses for OM. This quality improvement initiative supports frequent oral hygiene for populations at risk for OM and the implementation of an EBP policy for oral care as a preventive measure against OM (Ferrington, Cullen, & Dawson, 2013). The organization experience presented in review meets the quality rating of A, related to clear aims and objectives, formal improvement plan, evaluation methods and being based on scientific evidence.

Researchers da Cruz Campos, Campos, Aarestrup, & Aarestrup (2014) performed a literature review to critically evaluate OM, its causes, and treatments in efforts reduce patient suffering. The researchers provided meaningful data on known causes, risks, and contributors to OM in their review. Additionally, researchers presented evidence that supports the concept that professional oral care should be provided before oncological treatments and recommended treatments for OM. The literature review is aimed at dental professionals, but it includes supportive information applicable to nursing. Gaps are not fully explored, however, there is acknowledgment that further research is required. Recommendations supported by this review include instructing patients on oral hygiene and professional dental care prior to initiation of chemotherapy or radiotherapy (da Cruz Campos, Campos, Aarestrup, & Aarestrup, 2014). For this literature review, the researcher's expertise appears to be credible and reasonably definitive conclusions are drawn, meeting the quality ratings of B.

Eilers, Harris, Henry, & Johnson, (2014) conducted a systematic review, but due to the inclusion of expert opinions and other nonresearched evidence, it is addressed as a literature review under Appendix D of ©The Johns Hopkins Hospital/The John Hopkins University nursing EBP guide (Dang & Dearholt, 2017). Researchers searched PubMed and CINAHL databases, and after inclusion and exclusion criteria were addressed, 104 articles were included for review. This research was attached to a body of knowledge that appeared in a previous publication. Based on the literature reviewed, five recommendations for practice were made: (a) cryotherapy, (b) low-level laser therapy, (c) oral care protocols, (d) palifermin, and (e) sodium bicarbonate mouth rinses. Other interventions were categorized as likely to be effective or effectiveness not established. Gaps in research were discussed, and recommendations for practice were noted by the researchers (Eilers, Harris, Henry, & Johnson, 2014). This article met the criteria for a quality rating of A.

Slade (2017) developed an evidence summary that identified the best evidence regarding OM prevention for patients with cancer. Evidence was developed from Cochrane

systematic reviews with one that included 131 studies and 10,514 participants and another included 35 RCTs with a total of 3,102 participants, systematic review including 27 studies, systematic review of 52 published papers, systematic review 49 papers across 15 interventions, systematic review of 54 oral assessment instruments, systematic review of 24 trials, systematic review that included 64 clinical studies, systematic review of 22 clinical studies and 2 meta-analyses, and an unspecified amount of articles based on expert opinion, non-analytic studies and relevant literature. Analytical evidence was not provided in the summery, instead data points were assigned a grade of A or B for the strength of the recommendations. Best practice recommendations were:

> [a] The use of cryotherapy (ice chips) and Keratinocyte Growth Factor appear to be effective in preventing mucositis (Grade A). [b] The ease of use of low-level laser therapy, high patient acceptance, and the positive results achieved, suggest this therapy is a good alternative for the prevention of oral mucositis for people undergoing chemotherapy and radiotherapy (Grade B). [c] Regular assessment of oral pain using a validated tool that uses self-reporting is recommended (Grade B). [d] Preventative oral care regimens should be in place, with therapeutic oral care regimens in place if mucositis develops (Grade B). [e] Prior to beginning cancer therapy, dental examinations and treatment should be carried out, and continued during treatment (Grade B). [f] Chlorhexidine mouthwash and glutamine preparations are not recommended for patients undergoing treatment for head and neck cancer. (Grade A) (Slade, 2017, p 3).

The study did not include search, inclusion or exclusion materials, or gaps in literature. However, there are reasonably consistent findings, inclusion of well-designed studies, and definitive conclusions drawn, allowing the quality rating of B.

Obeid (2018) developed an evidence summary addressing the best evidence regarding the assessment of OM in patients with cancer receiving oncological treatments. Research included in developing the best practice recommendations included a systematic review of oral

assessment instruments for children and young people including 53 studies, observational study with 33 participants, and a systematic review including 104 studies. Analytical evidence was not provided but assigned a grade of A or B was provided for the strength of the recommendations. Best practice recommendations were:

> [a] Healthcare professionals should ensure that they discuss and educate each person with cancer about oral mucositis and its assessment. (Grade A). [b] Standardized oral assessments for all patients using an appropriate, validated tool should occur prior to treatment and then regularly throughout treatment (Grade A). [c] Oral assessments should include a separate measurement of pain and other symptoms to assess the patients' experience (Grade A). [d] Patient-reported assessment tools may be useful to both complement clinician-determined measures of oral mucositis or as standalone assessments when patients cannot undergo clinician-assessed assessments (Grade A). [e] The use of oral mucositis assessment tools by clinicians should be standardized across all patients within a health service(Grade A). [f] Users should be trained in the consistent and correct use of the chosen assessment tool (Grade A). (Obeid, 2018, p. 2)

The study did not include search, inclusion or exclusion materials, or gaps in literature. Though definitive conclusions are drawn, information was drawn from a relativity small pool of data, raising questions of whether recommendations are fully discernable. Due to this flaw, it was assigned a quality rating of C.

Construction of Evidence-based Practice

The foundation for EBP is the judicious examination and appraisal of the best available evidence. To develop this EBP project, synthesis of the evidence is required to allow the formation of best practice recommendations regarding OM prevention in patients receiving oncological treatments. The synthesis of the literature and best practice recommendations are examined in detail.

Synthesis of critically appraised literature. An in-depth appraisal of current and relevant literature exploring the best way to prevent OM in patients receiving oncological treatment allowed an intimate understanding of EBP measures. Evaluation of the literature produced evidenced-based themes and strategies to address the prevention of OM.

The appraisal of the literature revealed four objectives in the prevention of OM. These objectives included (a) having an oral care protocol in place, (b) use of subjective assessment tools, (c) professional clinical knowledge of OM, and (d) zinc sulfate as a preventive. Overwhelmingly, the need for structured oral care routine was noted throughout the literature, with seven studies referencing the importance of this measure (Carvalho et al., 2018; Cullen et al., 2018; da Cruz Campos et al., 2014; Eilers et al., 2014; Farrington et al., 2013, Huang et al., 2018; McGuire et al., 2013 & Slade, 2017). Tools to monitor and assess for complications of OM were noted as important themes in five studies (Carvalho et al., 2018; Cullen et al., 2018, Eilers et al., 2014; Slade, 2018 & Obeid, 2018). Five studies referenced the need for professional knowledge about OM in both reference to skillful assessment and divulging knowledge to patients (Cullen et al., 2018, da Cruz Campos et al., 2014; Eilers et al., 2014, Farrington et al., 2013 & Obeid, 2018). Three studies examining OM prevention concluded that zinc sulfate was effective as preventive measure (Lee, 2015; Moslemi et al., 2014 & Yarom et al., 2013).

An important prevention step, found in seven of the studies, was that structured oral care protocols should be in place before a patient starts oncological treatments. Four of the studies addressed the need for formalized oral care protocols to be in place prior to starting treatment (Eilers et al., 2014; Farrington et al., 2013, Huang et al., 2018 & McGuire et al., 2013). The other three studies addressed the need for education regarding routine or therapeutic oral care measures (Carvalho et al., 2018; Cullen et al., 2018 & Slade, 2017).

Examination of necessary components of structured oral care occurred. Four of the studies address mouth rinse (Cidon et al., 2018, Eilers et al., 2014, Huang et al., 2018 &

McGuire et al., 2013). Three of the studies (Cullen et al., 2018, Eilers et al., 2014; & Farrington et al., 2013) endorse a rinse of salt and baking soda, also called sodium bicarbonate. One study also notes salt water (Farrington et al., 2013) can be used. In one study, normal saline and sodium bicarbonate solutions were viewed as harmless when part of an oral care practice and may promote patient comfort (McGuire et. al., 2013). Oral cavity care, including lip care, tooth brushing, flossing (unless at high risk for bleeding), and oral rinses, were addressed in three studies (Cullen et al., 2018, Eilers et al., 2014; & Farrington et al., 2013). Two studies specified that the toothpaste used in oral care interventions needs to be both non-abrasive (Cullen et al., 2018) and free of pyrophosphates and sodium lauryl sulfate (SLS) (Farrington et al., 2013).

The next evidence-based strategy produced from analysis of the literature was the necessity of using a consistent assessment tool. Seven studies provided evidence that that an oral assessment tool should be used throughout treatment (Carvalho et al., 2018; Cidon, 2018; Cullen et al., 2018; Eilers et al., 2014, Huang et al., 2017; Obeid, 2018 & Slade, 2017). Suggestions for the types of tools that should be used to evaluate OM, three studies suggested use of a patient reported tool (Cullen et al., 2018; Obeid, 2018 & Slade, 2017) while the other two did not specify (Carvalho et al., 2018 & Eilers et al., 2014). Two experimental studies (Cidon, 2018 & Huang et al., 2017) used a combination of both subjective and objective assessment tools for collection of data.

The next EBP concept that emerged was importance of professional knowledge concerning teaching about and assessing OM. There was a total of five studies acknowledging the importance of the professionals' knowledge (Cullen et al., 2018, da Cruz Campos et al., 2014; Eilers et al., 2014, Farrington et al., 2013 & Obeid, 2018). In the study by da Cruz Campos et al., (2014) it was noted that a clinical dentist should instruct patients on oral hygiene methods. Two studies use it as an implementation measure and evaluation of nursing knowledge (Cullen et al., 2018 & Farrington et al., 2013). Two studies addressed it as an

indication for practice when working with patients who are at risk for developing OM (Eilers et al., 2014 & Obaid, 2014).

In efforts to prevent OM in patients undergoing oncological therapies, zinc sulfate was found to be beneficial in three studies (Lee, 2015; Moslemi et al., 2014 & Yarom et al., 2013). A meta-analysis of high quality RTCs found that mineral derivatives, especially zinc sulfate, were helpful in the treatment and prevention of OM (Lee, 2015). In a double-blind, randomized RTC, Moslemi (2014) found that zinc sulfate reduces OM and delays its onset of oropharyngealmucositis in head and neck cancers. In a systematic review addressed by Yarom et al., (2013), evidence supported the use of zinc sulfate, but recommendation was limited to oral cancers.

Best practice model recommendation. The EBP recommendations were developed from synthesis of the best available evidence. Oncological therapies are linked to the development of OM which can lead to diminished patient outcomes. This condition is one of the most severe non-hematological complication that occurs during oncological treatments (da Cruz Campos et al., 2014). Having preventive measures in place can lead to better patient outcomes. Therefore, due to evidence-based recommendations, an oral care protocol was developed as the standard of care for all patients in an outpatient facility that provided oncological treatments. Clinical team members were educated on the oral care protocol, use of a validated patient-reported tool, and key points of educational handouts provided to patients. Once the oral care protocol was in place and all patients were receiving the standard of care, zinc sulfate supplementation was introduced to patients under a select provider.

How the best practice model will answer the clinical question. The best available evidence concludes that having an oral care protocol in place, assessing patients through their oncological treatments with a valid tool, having clinicians knowledgeable in OM and OM prevention measures, and zinc sulfate supplementations are all evidence based measures to prevent OM. Utilization of preventive measures will lead to better outcomes for patients by

reducing the risk that OM poses to their health while they are receiving oncological treatments. The incorporation of an oral care protocol that includes zinc supplementation as suggested by evidenced-based recommendations was used to answer the clinical question: “In patients receiving oncological treatments, does an oral care protocol with zinc sulfate supplementation reduce complications related to oral mucositis at greater rates than an oral care protocol alone, as measured by a patient reported assessment tool over a six week period?”

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

The evidence presented in Chapter 2 supports the development of an oral care protocol as the standard of care along with additional zinc supplementation to prevent oral mucositis in cancer patients receiving oncological treatments. This chapter will describe the setting, participants, outcomes, intervention, data management, and analysis plan. Also included are the steps to protect human subjects. This EBP project serves to address to address the following PICOT question: “In patients receiving chemotherapy treatments, does an oral care protocol with zinc sulfate supplementation, compared to the standard of care (oral protocol alone), reduce complications related to oral mucositis as measured by a patient-reported assessment tool over a six-week period?”

Participants and setting

This EBP project occurred at an outpatient infusion center that provided oncology and hematology services. The group of providers at this office consists of four physicians who are experienced in medical oncology, hematology, and internal medicine and all have achieved board certification for these specialties. The daily staff is typically two or more physicians who rotate schedules between the two offices, a nurse practitioner, two oncology-certified nurses, three medical assistants, and a care technician. The office infuses between 30 and 50 oncological agents on an average day. The average patient age is 58. The most common type of cancer patients receive treatment for is lung cancer. Each physician has their patient care loads to which they do office visits, review labs, develop chemotherapy care plans and other tasks. The nurse practitioner reviews labs and adjusts chemotherapy plans as needed based on lab results and performs other administrative duties. The two oncology-certified nurses mix and administer oncological or hematological treatments. The medical assistants perform lab draws, monitor pumps, start peripheral intravenous access, run lab equipment, and deliver labs

to the correct personnel for review. The care technician sits in a central area surrounded by bays, monitoring individuals during treatments and responding to patient bells.

The office accepts most commercial and managed care insurance plans, including Medicare and Medicaid. Also, they have an onsite financial staff to assist patients through various billing arrangements. This office serves an area where the average median household income is less than the annual average wage in the United States (United States Census Bureau, 2016). The overall poverty rate for the community was over 16% which is above the national average of 14.7% (United States Census Bureau, 2016). When an individual cannot afford treatment, the office will apply for assistance from the pharmaceutical companies, obtain samples until insurance coverage can start, or in emergent cases, admit to the hospital to initiate treatment.

Participants eligible for this evidence-based practice project were ones who presented to the infusion center for their initial dose of chemotherapy and were willing to participate in the study. Participates were required to be fluent in English and mentally competent to fill out the survey tool independently. Patients groups underwent chemotherapy infusions that were customized to treat their specific cancers and managed by the oncologist and coordinating care team.

Design

The project used a two-group pretest-posttest quasi-experimental design. Participants were assigned to groups based on the oncologist that was managing their care at the time of the project. One provider provided their patients with zinc sulfate as part of the treatment plan with education that the supplement was being used to prevent OM during their course of treatment. The other providers, who did not provide zinc supplementation to their patient load, served as the comparison group. All participants were followed for six weeks through the course of their treatments, despite overall treatment length. All received the standard of care, which

was the oral care protocol with education to continue stringent oral care until the end of their chemotherapy regimen.

Outcome

The primary outcome for this project was to assess for the reduced incidence and severity of OM in patients receiving zinc compared to the standard of care alone. Oral mucositis is an adverse effect that often occurs in patients undergoing treatment for cancer. This condition is known to have negative impacts on nutrition, oral hygiene, quality of life, and can lead to significant weight loss, pain, dehydration, or life-threatening infections (Slade, 2017 & Yarom et al., 2013). Prevention and reduction of OM have been studied primarily in head and neck cancers. However, no studies found explored the reduction of OM in patients receiving oncological treatments for various cancer types. With incidence rates ranging from 40% to 100% and the increased complications related to OM, it is essential to see if preventive measures can reduce the occurrence across cancer types in an ambulatory setting while maintaining cost effectiveness (Slade, 2017; Farrington, Cullen, & Dawson, 2013).

Intervention

This project began as an effort to help prevent OM in patients, due to the high risk for infections, distress, and sepsis in these patients. Discussions with the oncologist, oncology navigators, and oncology certified nurses revealed that current preventive efforts were inadequate at the infusion center and that there were no evidenced-based solutions in place. The investigation revealed that oral care was taught on a provider preference level and varied widely in content and scientific backing. The initial practice question was, “What can be done to prevent OM?”

As described in chapter 2, the literature provided evidence that an oral care protocol needed to be in place as a standard of care. Also, health care professionals need education on OM as well as to be able to teach the OM protocol to patients. Finally, the literature also provided evidence that zinc sulfate may prevent or reduce the effects of OM.

The primary intervention for this project is zinc sulfate supplementation. Under the supervision of a collaborating provider, zinc sulfate supplementation was prescribed to all patients receiving oncological therapies under their care. Participants who were supervised under the care of other providers within the office served as the control group. For patients wishing to purchase zinc sulfate over the counter, a list of appropriate national brands was provided along with the stores that carried them. Zinc sulfate was dosed at 30 mg, three times a day, by mouth based on dosing recommended in a randomized controlled trial in a similar patient population (Moslemi et al., 2014). Participants started zinc sulfate treatment on the day of initiation of their chemotherapy after consent for participation was signed. All participates were educated on the oral care protocol, to maintain the standard of care. Although nausea and vomiting can occur with high doses of zinc sulfate, Moslemi and colleagues (2014) found that these side effects were not present at the dose used in the RCT.

The primary intervention was implemented after the facility adopted a standardized oral care protocol for all patients receiving oncological treatment. While many staff members at the infusion center chose to discuss oral care with their patients receiving oncological therapies, this practice was not yet considered standard care at the time of the project. Therefore, an evidence-based oral care protocol was developed (See Appendix B-C) and implemented as “Phase 1” of this EBP project. Foundation for the oral care protocol that was agreeable to the infusion center was developed based on current evidence.

Staff education about this protocol was delivered by a poster presentation in the staff break room, a lunch-and-learn session and example trifold handouts. Educational topics included: appropriate use of oral rinses, toothbrush types, suitable toothpaste for use, and timing of oral care. A knowledge quiz about the oral care protocol was used to determine if staff were adequately prepared to handle the oral care protocol in practice and assist with any question patients may present. Nursing knowledge was collected in a pre-and-posttest format the following week to ensure readiness and address any areas of weakness before initiation.

Staff knowledge about oral mucositis prevention was measured using a 10-item multiple-choice quiz developed by the project leader. The questionnaire focused on key points from the oral care protocol. Staff completed the questionnaire at baseline and after completing the oral care protocol education. Data concerning the pretest and posttest with the team were anonymously collected. One double-sided sheet was used, and names did not appear on the sheets. The full-time clinical staff manager assisted with distribution and collection of these quizzes. Performance on the questionnaires was measured using percentage correct out of the total number of quiz items. An average score of 90% indicated that the staff was ready to implement the protocol.

Trifold handouts and education were provided to all patients receiving chemotherapy. Trifolds were easy to read, offered visual cues, and offered follow up information about symptoms of OM. Dietary recommendations were added per request of clinical site. Additional trifolds were placed in visible areas for ease of access.

Planning

This project used the collection of survey data and employed anonymized data for patient tracking. The project received an expedited review process by the Valparaiso University Institutional Review Board (IRB), and informed consent was obtained from individual participants that met eligibility requirements. Written permission was obtained from both the facility and IRB.

Data measures

Reduction of oral mucositis complications was the primary outcome of this EBP project. Oral mucositis was measured using item one of the PROMS survey, which measures pain severity on a 100-mm visual analog scale. The PROMS has demonstrated high internal consistency (Cronbach's alpha 0.86 – 0.98) and convergent validity (Spearman's rho -0.43) with the Functional Assessment of Cancer Therapy (FACT-G) and the transplantation specific subscale (BMT). Divergent validity (Spearman's rho 0.72) for both ulceration and erythema at

seven-day post-treatment was analyzed by correlating the PROMS scale and the Affect Balance Scale (ABS) (Kushner et al., 2008). Also, Kushner et al., (2008) noted a correlation between the PROMS tool and the Center for Epidemiologic Studies Depression (CES-D) scale noting that on day seven (Spearman's rho 0.51) and day fourteen (Spearman's rho 0.39) there was statistical significant direct correlation between OM severity and depression severity.

Participants in this evidence-based project were assessed using the PROMS at baseline (time of treatment initiation) then weekly for an additional five weeks.

Data collection

Data concerning OM severity were anonymously collected using the PROMS survey. This survey was given to patient participants by the clinical infusion nurse who initiated their chemotherapy. The PROMS was printed on three single-sided sheets that capture measurements along a 100-millimeter visual analog scale. It took about 5 to 7 minutes for the patient to complete the survey. When the patient finished the PROMS survey, the tech who monitored the infusion areas would write down the number of the chemo bay, the letter of the seat the patient was in, and the year of birth. This number had no connection to the patient medical ID, nor did use of this combination of identifiers provide any meaningful information that could indicate a patient's private information. The assignment to chemo bays was not consistent which passively helped randomize data. In the charting system used at the facility, this information was easy to see and did not require additional burden of location. The date would also be placed on the paper for demographic information review. At the end of the clinic day, all completed PROMS surveys collected and placed in a locked filing cabinet in the clinical manager's office until data could be electronically entered.

Management and analysis

Data obtained from PROMS surveys was double entered into an Excel spreadsheet and stored on a password-protected USB drive to ensure the accuracy and security of the quantitative data. When a discrepancy occurred, the data was corrected for accuracy. When

the USB drive was not in use, it was stored in a locked filing cabinet that was under constant video surveillance monitoring for entrance and exit out of the nurse manager office. Original surveys where then destroyed using the facility provided secure shred service.

Descriptive statistics were used to describe the sample population. Data collected included age, sex, race, and type of cancer. The mean age and its standard deviation will be calculated, and age will be compared between treatment and control groups using independent sample t-test. Categorical variables (sex, race, ethnicity, cancer type) will be described using frequencies and percentages, and differences in these variables will be compared between groups using the chi-square.

Inferential statistics were used to examine the differences in PROMS scores between the two groups using independent sample t-tests. Between-group comparisons occurred at baseline (week zero) and at week six. Within-group comparisons occurred at baseline (week zero), between week one and week two, between week two and week three, between week three and week four, between week four and week five, and between week five and week six. All comparisons of PROMS scores were made using the independent samples t-test.

Protection of Human Subjects

Insurance of the protection of human rights occurred throughout the project. The project leader was required to undergo training in human rights protection and obtained a certificate of completion (NIH, 2018). All physicians within the practice were committed to complete the project, along with consideration to methods already in place. Additionally, Valparaiso University granted IRB approval before initiation of the project. The treatment center did not have a formal IRB process in place. Specific steps to maintain patient confidentiality and anonymity were previously described.

CHAPTER 4

FINDINGS

Oral mucositis is considered one of the most severe non-hematological complications that can occur in patients undergoing oncological treatments (Campos et. al, 2014). Development of OM can compromise quality of life and result in life-threating bloodstream infections (Collen et al., 2018; Eilers et al., 2014). This condition can affect anywhere from 40 to 100% of patients receiving various oncological treatments (Eilers et al., 2014; Harada et al., 2016). Currently there is no universally accepted protocol for the prevention of OM, though efforts to minimize its impact have been completed. This chapter describes the results of a quasi-experimental evidence-based practice project, which consisted of a standardized oral care protocol for all participants and a prescription for zinc sulfate (300 milligrams by mouth once daily) in half of the convenience sample of patients undergoing oncological treatment for cancer. The following chapter reviews demographic information and comparisons between the intervention (i.e., “zinc”) and control (i.e., “non-zinc”) groups.

Participants

Size. There was a total of 88 possible participants that met inclusion criteria to participate in this project. Of the eligible participants, 23 (26.1%) completed more than one survey over the 6-week period, resulting in a final sample size of 23 participants.

Characteristics. Most respondents were male (*n* = 14, 60.9%). Almost half of the participants were between the ages of 61 and 70 (*n* = 12, 52.1%), and the remaining 47.9% were either between the ages of 41 and 60 (*n* = 6, 26%) or 71 to 90 (*n* = 5, 21.7%). The most frequently occurring ethnic group was African-American (*n* = 12, 52.2%). Whites comprised 39.1% of the study (*n*=9). The remaining 47.8% of the sample were either White (*n* = 9, 39.1%), Asian (*n* = 1, 4.3%), or Hispanic/Latino (*n* = 1, 4.3%).

Most of the participants in the EBP project were receiving chemotherapies for lung cancers (*n* = 11, 47.8%), breast cancer (*n* = 3, 13.3%), or colorectal cancer (*n* = 3, 13.3%). Two participants were being treated for pancreatic cancer (8.7%), and one each (4.3%) for non-Hodgkin's lymphoma, leukemia, and laryngeal cancer. Metastases of these cancers were common, with 13 participants (56.5%) having cancers beyond the primary site.

Characteristics of the Treatment Groups. For this project, two groups were compared over the 6 weeks(See Figures 4.1 and 4.2). One group received the standard of care alone, and the other group received the standard of care plus a prescription for zinc supplementation. In the zinc supplementation group, there was a total of 12 participants (52.2%); in the non-zinc supplementation group, there were 11 participants (47.9%).

Chi-square statistics were used to compare the participants in the zinc group to the participants in the non-zinc group. At baseline, significantly more males were noted in the non-zinc group than in the zinc supplement group (*n* = 5 vs. 9, respectively, *p* = .049). No other significant differences were found in any patient characteristics between the zinc and non-zinc groups. See table 4.1.

Changes in Outcomes

The EBP project was divided into two phases. The first phase focused on implementation of a standardized oral care protocol and staff education. Knowledge was assessed before and after implementing the staff education using a 10-item oral care knowledge questionnaire. Registered nurses and medical assistants completed the same staff education and knowledge questionnaires. The mean pretest score was 64%, and the average posttest score was 90%, indicating an increase in staff knowledge about oral care for patients receiving oncological treatment.

The second phase of the project focused on differences in oral health symptoms (mouth pain, difficulty speaking, restricted speech, difficulty eating hard foods, difficulty eating soft

Table 4.1 *Demographics of participants*

Demographic	**Zinc** ***n*** **(%)**	**No zinc** ***n*** **(%)**	X^2	***df***	***p*-value**
Number of participants	12	11			
Gender					
Male	5 (41.7)	9 (81.8)	3.884	1	0.049
Female	7 (58.3)	2 (18.2)			
Age Range					
41-50	1 (8.3)	0	5.977	7	0.542
51-55	0	2 (18.2)			
56-60	2 (16.7)	1 (9.1)			
61-65	3 (25.0)	4 (26.4)			
66-70	3 (25.0)	2 (18.2)			
71-75	0	0			
76-80	2 (16.7)	1 (9.1)			
81-85	0	1 (9.1)			
86-90	1 (8.3)	0			
Race					
Asian	0	1 (9.1)	2.072	3	0.558
African-American	6 (50.0)	6 (54.5)			
Hispanic	1 (8.3)	0			
White	5 (41.7)	4 (36.4)			
Cancer Types					
Lung cancer	6 (50.0)	5 (45.5)	6.727	7	0.458
Breast cancer	2 (16.7)	1 (9.1)			
Colorectal cancer	1 (8.3)	2 (18.2)			
Non-Hodgkin’s lymphoma	1 (8.3)	0			
Leukemia	1 (8.3)	0			
Pancreatic cancer	0	2 (18.2)			
Other endocrine cancer	1 (8.3)	0			
Laryngeal cancer	0	1 (9.1)			
Metastases					
No Metastases	7 (58.3)	3 (27.3)	2.253	1	0.133
Metastases	5 (41.7)	8 (72.7)			

foods, restricted eating, difficulty drinking, restricted drinking, difficulty swallowing, and change in taste), measured weekly using a 100-millimeter visual analog scale for each symptom, between participants in the zinc and non-zinc groups over a 6-week period. Effectiveness of the intervention was evaluated by comparing the survey scores of the two groups as they reported on the survey. Data from the visual analog scale were entered and analyzed using SPSS version 25 (IBM, 2017).

Statistical Testing.

Independent *t*-tests were used to answer the PICOT question: In patients receiving oncological treatments, does an oral care protocol with zinc sulfate supplementation, compared to the standard of care (oral protocol alone), reduce complications related to oral mucositis as measured by a patient-reported assessment tool over a six-week period? A separate independent samples t-test was performed to compare mean scores of the zinc group and the non-zinc group each within each week (i.e., within-week between-group comparisons). Statistical significance was determined using a level of significance equal to .05.

Statistically significant differences were found in 8 out of 10 oral mucositis symptoms. These differences were more apparent towards the middle and the end of the six-week period, with the zinc supplementation group showing fewer symptoms than the control group. The symptoms with statistically significant improvement were mouth pain at weeks 5 and 6, difficulty speaking at weeks 4 and 6, difficulty eating soft foods at weeks 3 and 5, restriction of eating at week 6, difficulty drinking at week 5 and 6, restriction of drinking at week 3, difficulty swallowing and week 4 and 5, and change in taste at weeks 4 and 5.. Mean scores and test statistics are presented in Table 4.2 and displayed graphically in Figures 4.3 through 4.11. The only symptoms without any statistically significant differences were restricted speaking and difficulty eating hard foods.

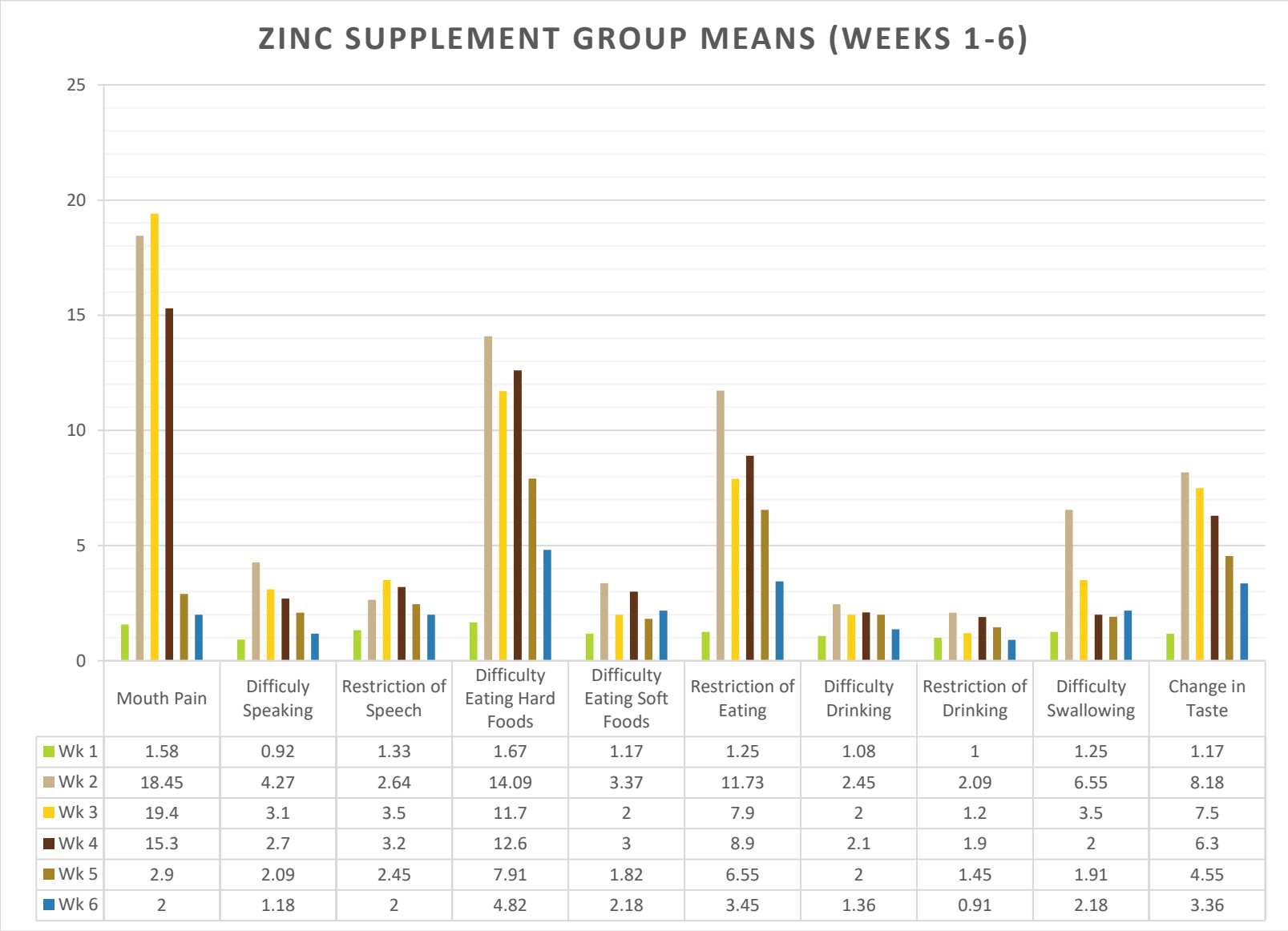
Table 4.2

Differences in Oral Health Symptoms Between Groups

	Zinc Group (*n* = 12)		Non-Zinc Group (*n* = 11)			
Symptom	*M*	*SD*	*M*	*SD*	*T*	*p*
Mouth Pain						
Baseline	1.58	1.676	4.36	8.629	-1.05	.124
Week 2	18.45	25.629	22.5	31.206	-.325	.252
Week 3	19.40	27.694	16.30	25.016	.263	.637
Week 4	15.30	19.961	17.22	27.399	-.173	.402
Week 5	2.91	3.113	8.75	17.169	-.951	.046
Week 6	2.00	1.549	8.91	15.751	-1.44	.004
Difficulty Speaking						
Baseline	0.92	1.564	2.27	2.832	-1.40	.394
Week 2	4.27	5.551	5.60	10.606	-.354	.191
Week 3	3.10	4.280	4.70	11.026	-.428	.212
Week 4	2.70	3.401	7.33	11.347	-1.17	.008
Week 5	2.09	2.023	5.00	7.819	-1.02	.086
Week 6	1.18	1.471	3.36	6.329	-1.11	.037
Restricted Speaking						
Baseline	1.33	1.723	2.64	3.585	-1.09	.451
Week 2	2.64	4.249	6.20	8.509	-1.19	.170
Week 3	3.50	6.621	5.20	9.508	-.464	.602
Week 4	3.20	3.048	5.22	6.037	-.906	.372
Week 5	2.45	2.841	3.38	4.069	-.550	.549
Week 6	2.00	3.464	3.09	4.763	-.614	.720
Difficulty Hard Foods						
Baseline	1.67	1.614	6.91	12.454	-1.38	.003
Week 2	14.09	13.620	18.40	24.158	-.497	.277
Week 3	11.70	9.499	18.80	22.125	-.932	.214
Week 4	12.60	9.891	14.67	15.851	-.337	.429
Week 5	7.91	5.338	15.13	17.932	-1.10	.138
Week 6	4.82	4.490	10.18	14.442	-1.17	.066
Difficulty Soft Foods						
Baseline	1.17	1.586	2.64	3.776	-1.19	.163
Week 2	3.73	5.985	3.70	2.497	.014	.241
Week 3	2.00	1.414	4.20	4.984	-1.34	.024
Week 4	3.00	4.422	3.44	2.651	-.269	.453
Week 5	1.82	1.471	7.25	10.011	-1.52	.008

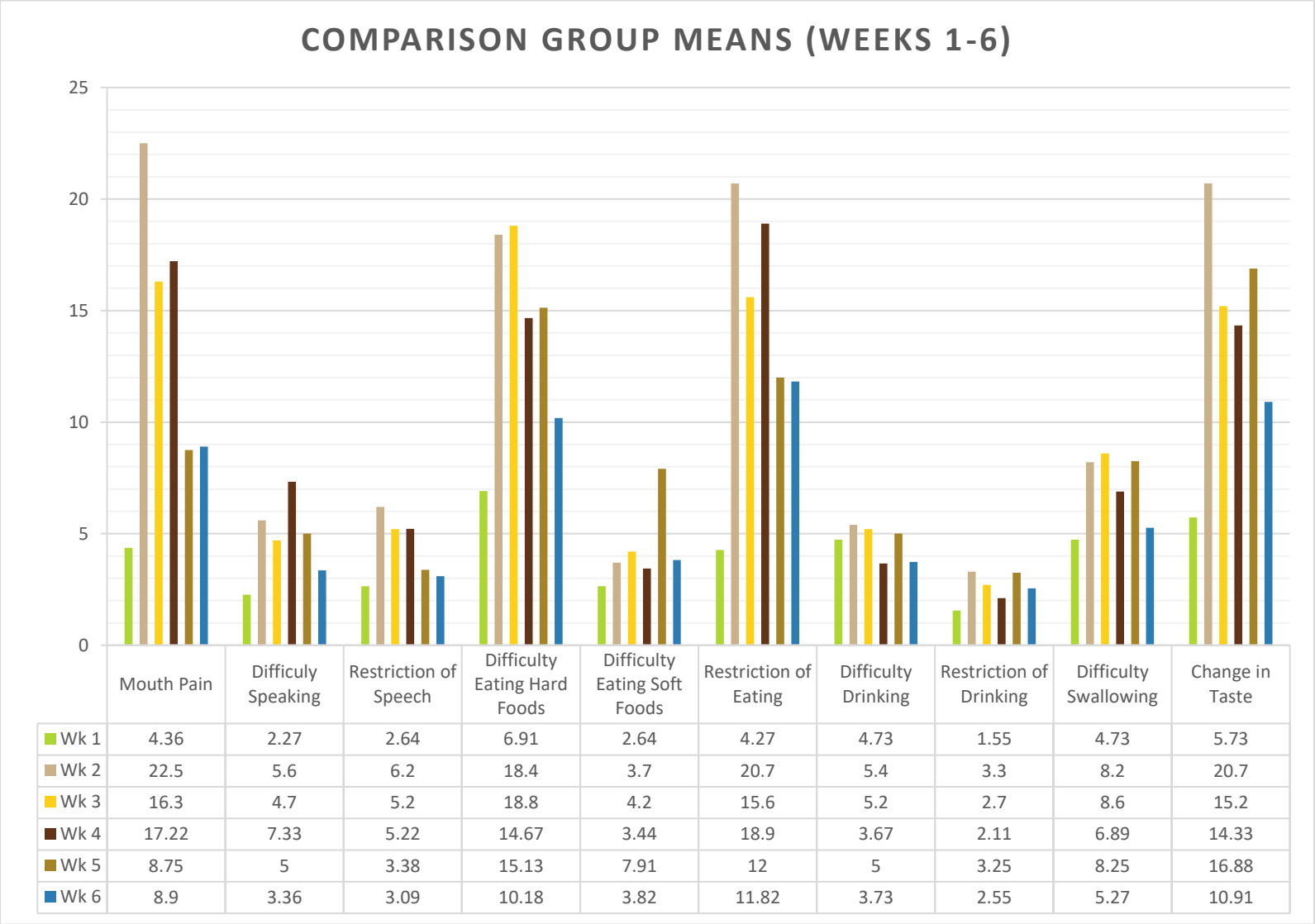
Week 6	2.18	1.779	3.82	4.644	-1.09	.151
Restricted Eating						
Baseline	1.25	1.765	4.27	6.958	-1.40	.024
Week 2	11.73	16.304	20.70	23.338	-1.01	.066
Week 3	7.90	13.585	15.60	21.214	-.967	.338
Week 4	8.90	10.640	18.89	24.096	-1.14	.073
Week 5	6.55	12.910	12.00	15.866	-.799	.429
Week 6	3.45	3.475	11.82	15.112	-1.78	.017
Difficulty Drinking						
Baseline	1.08	1.621	4.73	8.615	1.38	0.31
Week 2	2.45	3.588	5.40	5.835	-1.37	.097
Week 3	2.00	1.700	5.20	8.121	-1.22	.051
Week 4	2.10	1.912	3.67	3.240	-1.26	.095
Week 5	2.00	2.324	5.00	6.676	-1.21	.024
Week 6	1.36	1.859	3.73	5.101	-1.44	.023
Restricted Drinking						
Baseline	1.00	1.706	1.55	1.753	-.755	.827
Week 2	2.09	2.548	3.30	2.869	-1.01	.668
Week 3	1.20	1.033	2.70	3.234	-1.39	.033
Week 4	1.90	1.853	2.11	2.472	-.209	.430
Week 5	1.45	1.440	3.25	3.732	-1.29	.050
Week 6	0.91	1.044	2.55	2.162	-2.26	.251
Difficulty Swallowing						
Baseline	1.25	1.960	4.73	12.076	-.944	.093
Week 2	6.55	12.144	8.20	16.936	-.255	.642
Week 3	3.50	4.035	8.60	20.244	-.781	.103
Week 4	2.00	1.700	6.89	13.430	-1.08	.048
Week 5	1.91	1.375	8.25	17.409	-1.02	.027
Week 6	2.18	1.940	5.27	9.371	-1.07	.148
Change in Taste						
Baseline	1.17	1.801	5.73	15.730	-.956	.068
Week 2	8.18	12.360	20.70	25.708	-1.40	.053
Week 3	7.50	12.430	15.20	25.724	-.852	.215
Week 4	6.30	8.486	14.33	21.442	-1.05	.045
Week 5	4.55	7.090	16.88	28.723	-1.18	.040
Week 6	3.36	4.478	10.91	21.328	-1.14	.052

Figure 4.1 *Overall Zinc Supplement Group Means*



	Mouth Pain	Difficuly Speaking	Restriction of Speech	Difficulty Eating Hard Foods	Difficulty Eating Soft Foods	Restriction of Eating	Difficulty Drinking	Restriction of Drinking	Difficulty Swallowing	Change in Taste
Wk 1	1.58	0.92	1.33	1.67	1.17	1.25	1.08	1	1.25	1.17
Wk 2	18.45	4.27	2.64	14.09	3.37	11.73	2.45	2.09	6.55	8.18
Wk 3	19.4	3.1	3.5	11.7	2	7.9	2	1.2	3.5	7.5
Wk 4	15.3	2.7	3.2	12.6	3	8.9	2.1	1.9	2	6.3
Wk 5	2.9	2.09	2.45	7.91	1.82	6.55	2	1.45	1.91	4.55
Wk 6	2	1.18	2	4.82	2.18	3.45	1.36	0.91	2.18	3.36

Figure 4.2 *Overall Comparison Group Means*



	Mouth Pain	Difficuly Speaking	Restriction of Speech	Difficulty Eating Hard Foods	Difficulty Eating Soft Foods	Restriction of Eating	Difficulty Drinking	Restriction of Drinking	Difficulty Swallowing	Change in Taste
Wk 1	4.36	2.27	2.64	6.91	2.64	4.27	4.73	1.55	4.73	5.73
Wk 2	22.5	5.6	6.2	18.4	3.7	20.7	5.4	3.3	8.2	20.7
Wk 3	16.3	4.7	5.2	18.8	4.2	15.6	5.2	2.7	8.6	15.2
Wk 4	17.22	7.33	5.22	14.67	3.44	18.9	3.67	2.11	6.89	14.33
Wk 5	8.75	5	3.38	15.13	7.91	12	5	3.25	8.25	16.88
Wk 6	8.9	3.36	3.09	10.18	3.82	11.82	3.73	2.55	5.27	10.91

Figure 4.3 *Mouth Pain*

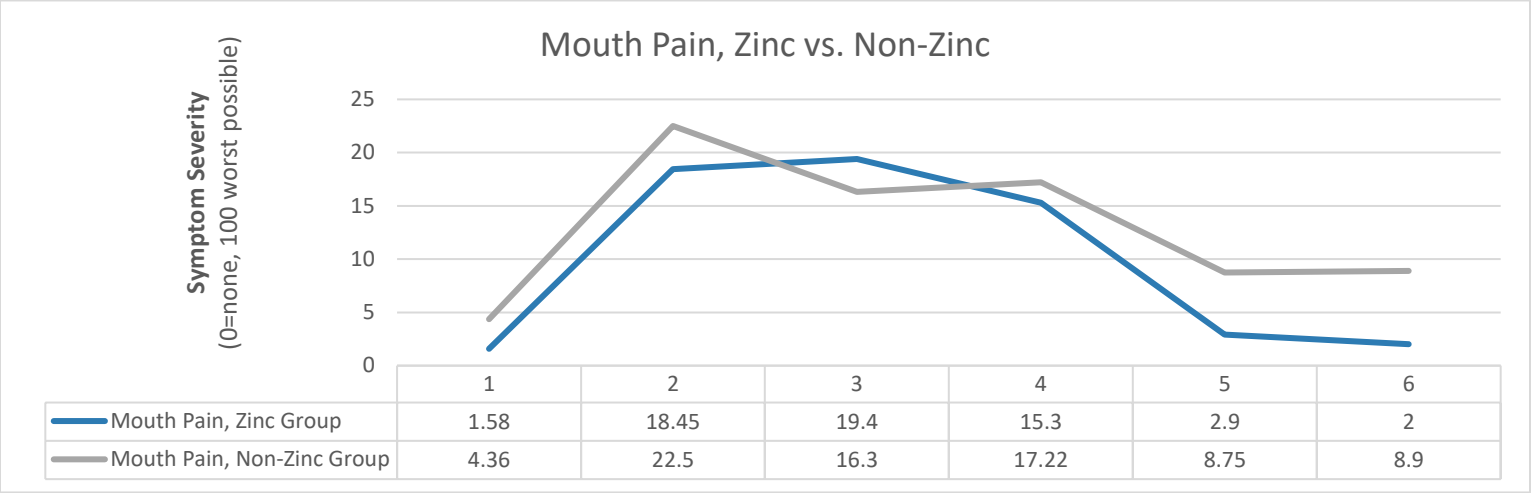


Figure 4.4 *Difficulty Speaking*

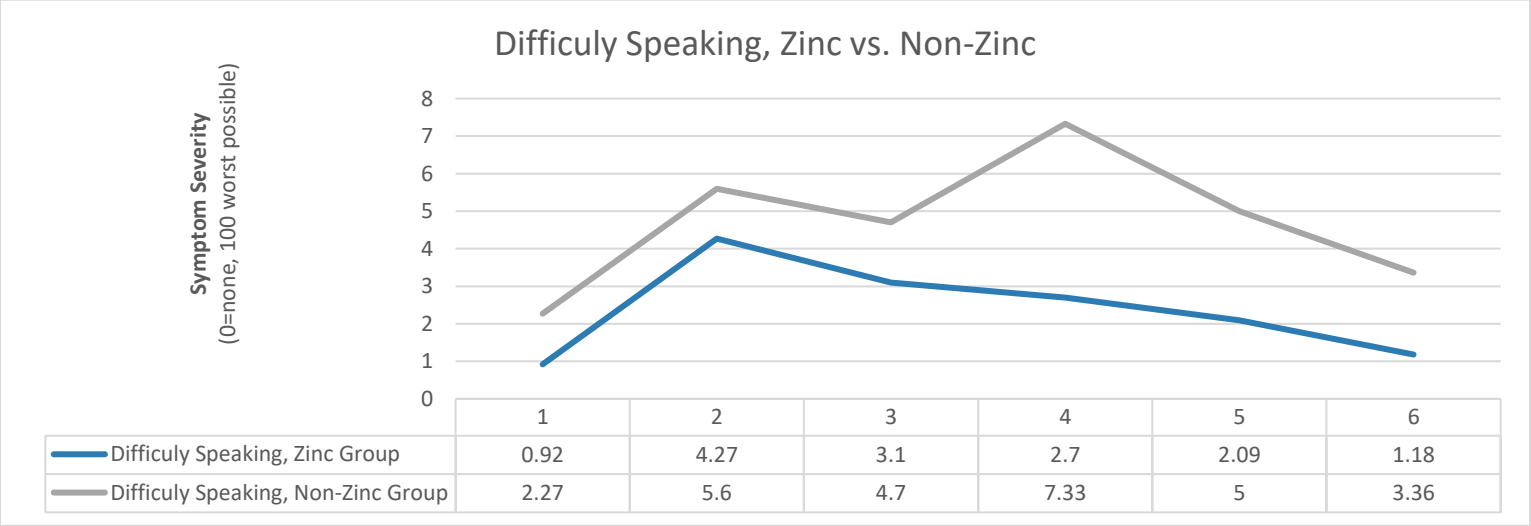


Figure 4.5 *Difficulty Eating Soft Foods*

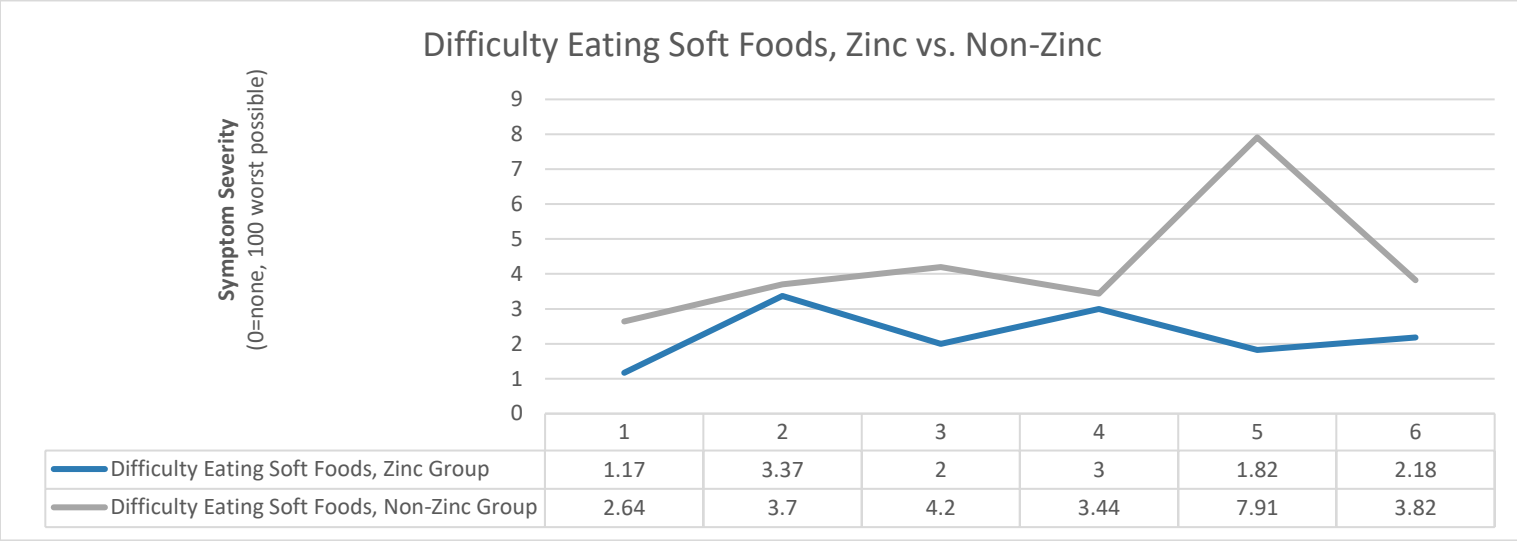


Figure 4.6 *Restrictions of Eating*

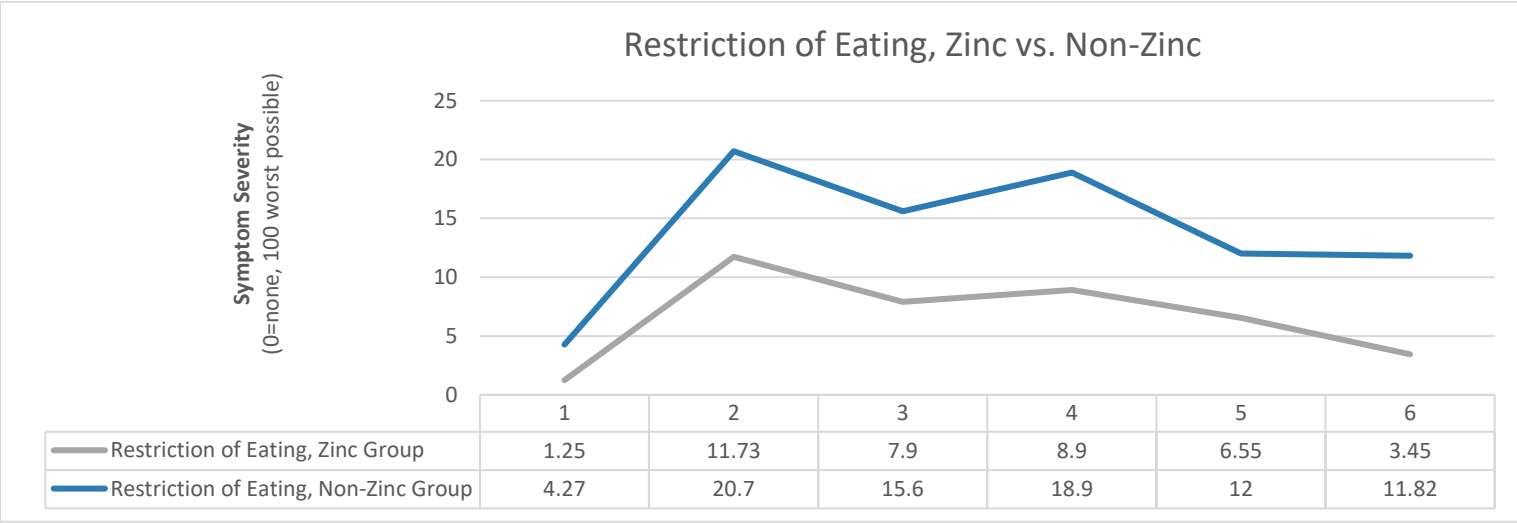


Figure 4.7 *Difficulty Drinking*

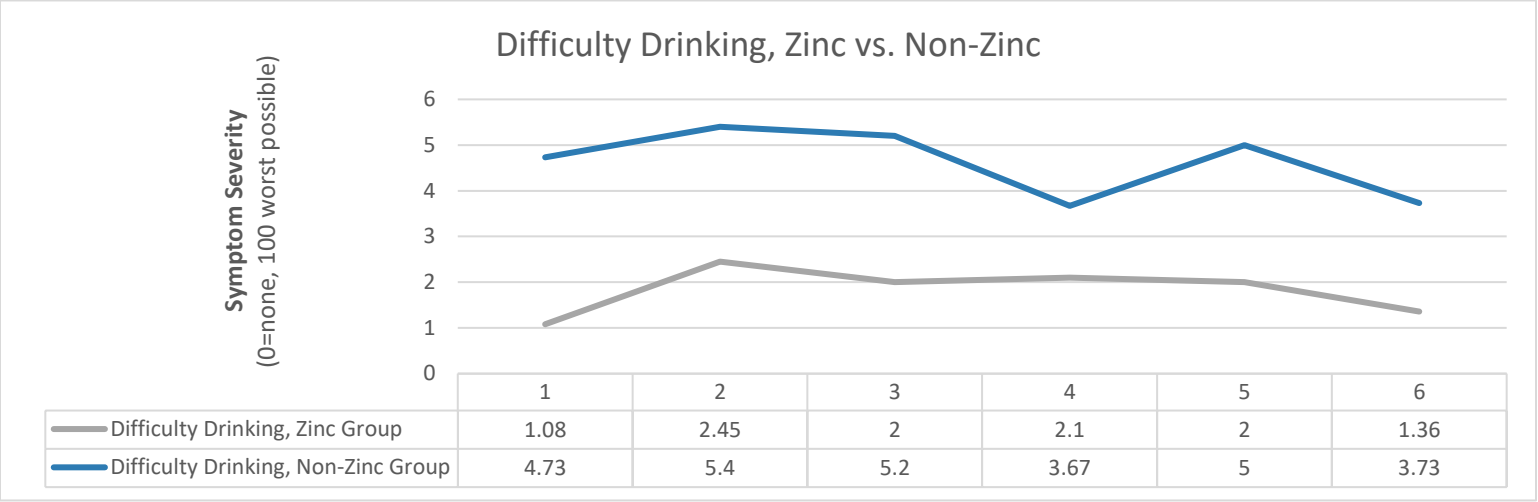


Figure 4.8 *Restrictions of Drinking*

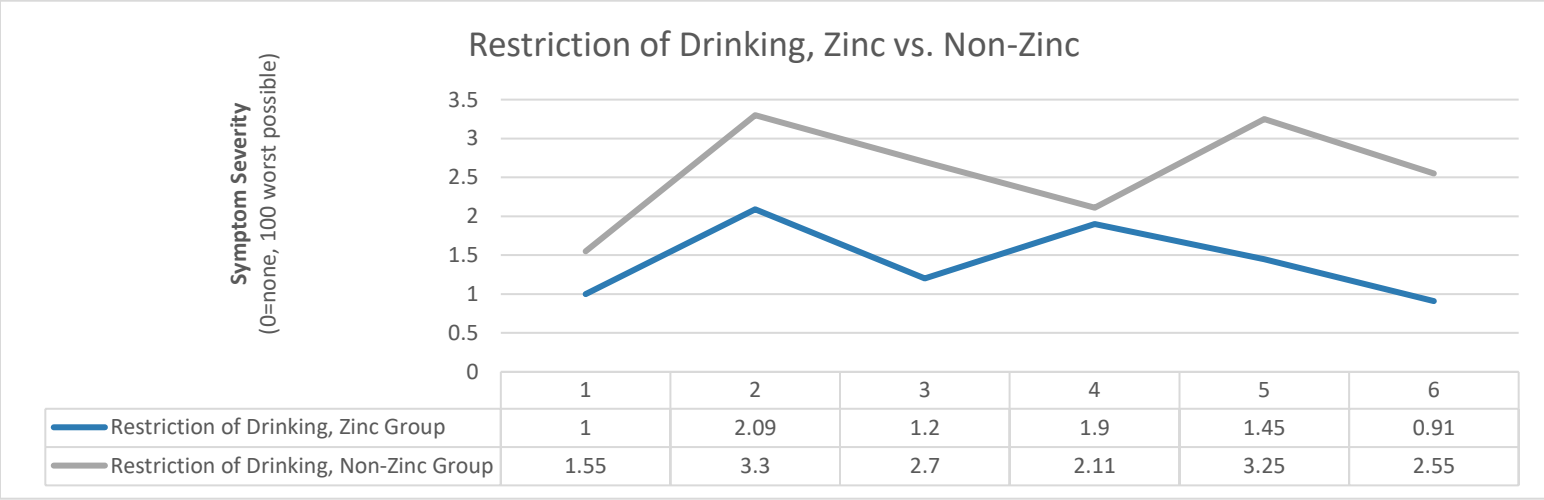


Figure 4.9 *Difficulty Swallowing*

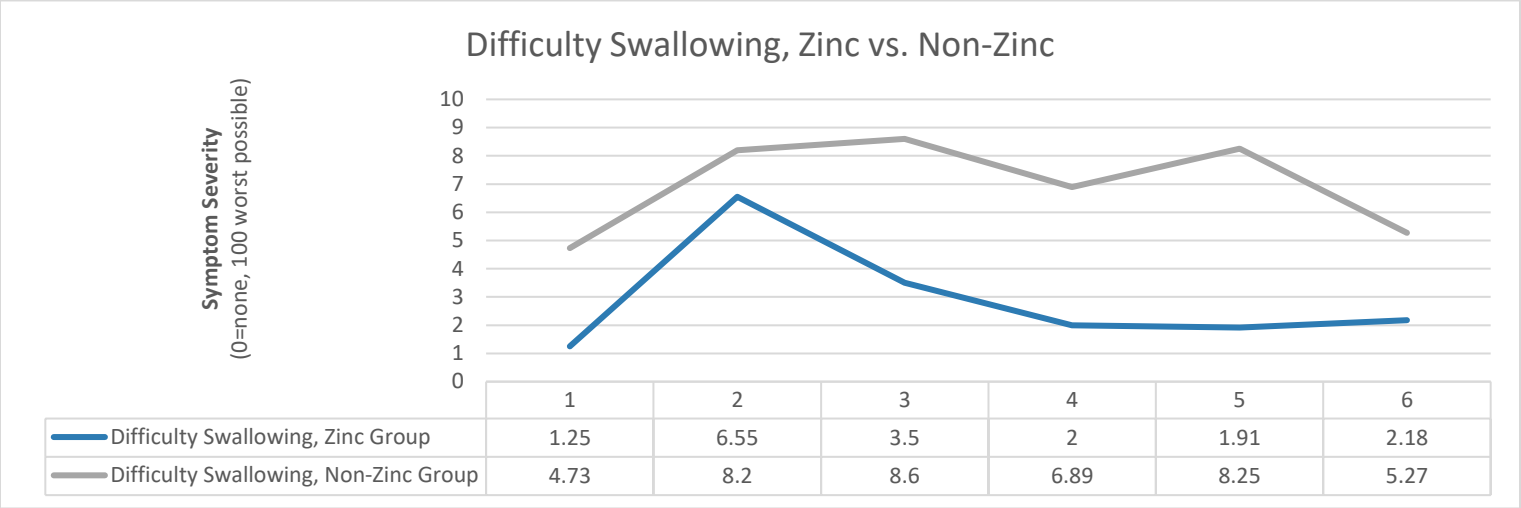
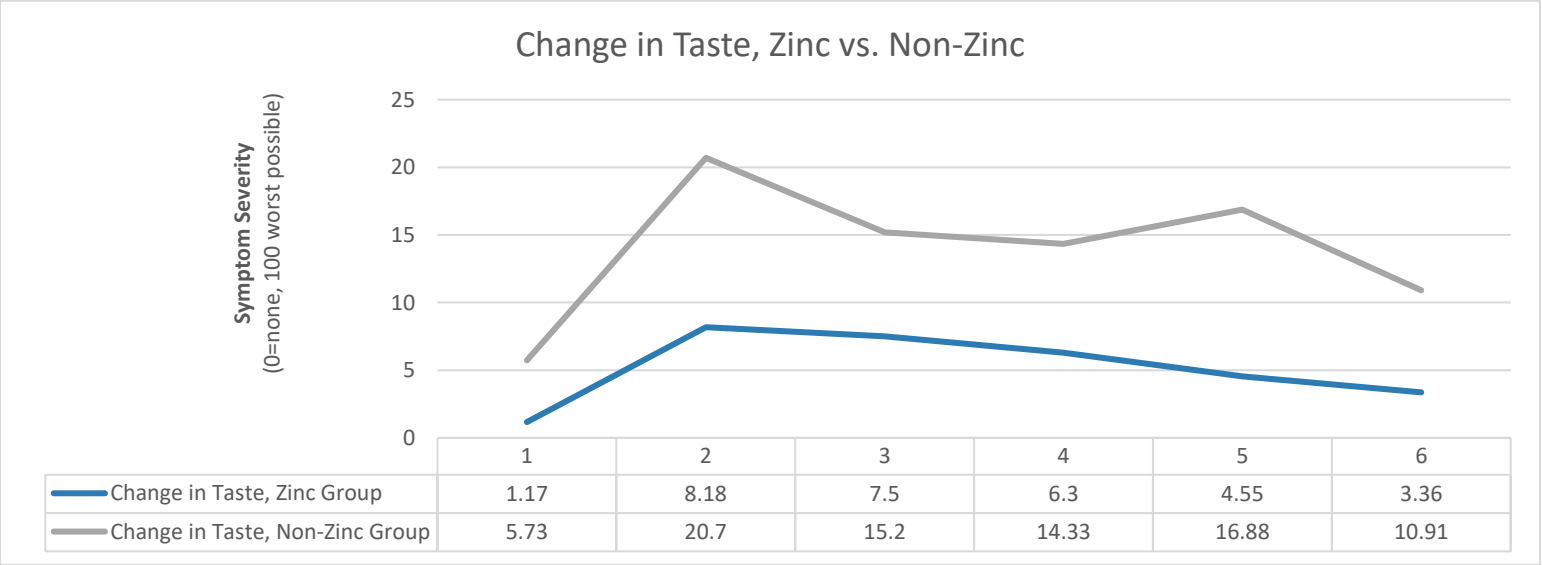


Figure 4.10 *Change in Taste*



CHAPTER 5

DISCUSSION

Oral mucositis (OM) is an adverse effect that is associated with several distressing symptoms in individuals receiving chemotherapy. This condition is a complex inflammatory process that can progress to ulcerative lesions, decrease the quality of life due to pain and eating restrictions, and promote the development of life-threatening infections (Collen et al., 2018; Eilers et al., 2014). OM is the most common cause of non-hematological complications and increases morbidity in individuals undergoing treatment (Campos et. al, 2014).

The purpose of this EBP project was to explore if zinc supplementation in addition to an oral care protocol reduced the complications of OM when compared to the oral care protocol alone. Participants filled out a subjective survey, the PROMS, weekly for six weeks. Data for both groups were recorded then tested for statistical significance. Statistical significance was found in 8 out of 10 symptoms that were tracked on the PROMS survey. The statistical significance was most prominent starting towards the middle of the six weeks and continued to the end of the six weeks data was collected.

Explanation of Findings. Results from the statistical analyses were provided in Chapter 4. Overall, the group that was treated with zinc sulfate had less severe symptoms at various time points during the six-week period, although these differences were not statistically significant for all symptoms or at all times. Instead, differences in symptom severity did not appear to be statistically significant until Week 4 for most symptoms. This is consistent with the existing literature on zinc supplementation, which found that patients receiving oncological treatment for head and neck cancers who were treated with zinc sulfate supplementation had a shorter duration and reduced OM symptoms (Moslemi et al., 2014).

No statistically significant differences were noted in the groups in relation to restriction of speech or difficulty eating hard foods when completing the independent *t*-test. This could be in

part due to the small sample size, which, given the presumably small effect size of zinc sulfate on oral mucositis symptoms, may not have provided adequate statistical power to avoid a type II error. However, shorter duration of symptoms may be linked to use of zinc, which is why finding a statically significant in week six is noteworthy (Eilers et al., 2014).

Significant findings between groups may have been diminished due to participants having freedom to choose their own zinc supplementation. Zinc is not a prescription medication and is common at many local retailers. Participants were not provided a preference list for brands since there are many price points and brands to choose from. Participants purchased brands based on their individualized preference. The use of multiple zinc supplement brands that were purchased from both retail and online market places could have varied in quality, purity, and even type of zinc used. Since there was little control over the independent purchases, and random error may have had a considerable effect on these analyses.

Zinc comes in many different formations, with the best-absorbed oral types of zinc including zinc citrate, zinc acetate, or zinc picolinate (Turner, 2013). However, best available evidence focused on use of zinc sulfate in studies (Moslemi et al., 2014 & Yarom et al., 2013). The literature supporting this EBP project failed to specify why zinc sulfate was chosen over formulations, so it is possible that the use of zinc sulfate rather than better-absorbed zinc salts could have contributed to a reduced treatment effect in this project.

Most of the participants were male for this EBP project (n = 14, 61%), but there were disproportionately more males in the control group (n = 9) than in the zinc group (n = 5), resulting in a statistically significant result (p=0.05). This was the only statistically significant difference at baseline in terms of patient characteristics, and it is unclear if this had any effect on the OM outcomes. Elder and colleagues (2013) found that men have less health confidence, which hinders their ability to fully engage in self-care at home. Since this EBP project required diligent self-care and a rigorous schedule of oral hygiene to complete several times throughout the day, it is possible that the high number of male participants in the non-zinc group (and thus

relied solely on following the self-driven oral hygiene protocol) were less comfortable managing self-care. More sophisticated analyses that looks at a mixed effect between sex and treatment group on OM symptoms may be useful in making this determination.

The types of cancers that this EBP project encountered differed greatly. The goal was to determine if zinc sulfate was a viable option across all cancer types, and it appears that there may be some benefit to using zinc sulfate for treatment of OM, regardless of the underlying type of cancer. However, it is not possible from this small sample to conduct more sophisticated analyses that would look for differences in outcomes between cancer types. Furthermore, the risk of developing OM varies based on cancer type and treatment modality, with some cancers having the risk of development for OM estimated at a minimum of 20% while cancer of the head and neck developing at a rate of almost 100% (Cullen et al., 2018; McGuire et al., 2013; Panachi et al., 2016 &Yarom et al., 2013). A larger sample size would make it possible to control for these variables, at least to differentiate “head and neck cancers” from “non-head and neck cancers”. Unfortunately, this was not possible in this project.

Cancer advancement or metastases may have contributed to the variation in mean OM severity between the two groups. The non-zinc group had a higher rate of participants with cancers that metastasized from their original location (*n* = 8, 72%) compared to the zinc group (*n* = 5, 41%). The type of oncological treatments or primary cancer site in the group with metastasis, and therefore the overall risk for developing OM at all, may have varied from those that did not present with metastasis. This may account for the mean symptom severity in the non-zinc group being consistently higher across all areas.

Evaluation of Applicability of Theoretical and EBP Frameworks

Theoretical Framework: Dorothea Orem’s Self-Care Nursing Theory. Dorothea Orem’s Self-Care Nursing Theory was used as the theoretical framework for this project. Orem’s theory involves three interrelated concepts: self-care, self-care demands, and self-care agency (Griffin & Landers, 2014). *Self-care* addresses the concept that individuals preform certain tasks

throughout their lives in the interest of maintaining their health, function, development, and well-being by meeting self-care requisites (Orem,2001). Self-care is the desire of one's willingness to preform care on their own behalf. *Self-care demands*, according to Orem's theory, include the degree and kinds of care that an individual may need at a specific point in time or across a duration of time (Remeo et al., 2018). Self-care requisites are the demands can be thought of as activities of daily care that help control or manage an individual's self-care. *Self-care agency* in Orem's theory addresses an individual's ability to complete tasks of self-care (Orem, 2001). There are several factors that contribute to self-agency: age, developmental state, health state, sociocultural orientation, and environmental factors (Fawcett & DeSanto-Madeya, 2013).

Since this project relied on all participants following an oral care protocol and the zinc supplement group requiring purchasing and taking zinc, this theory was appropriate. The primary investigator spent time educating participants on the oral care protocol. Part of the eligibility criteria for participating in this project was that the participant would have appropriate self-care agency by being able to functionally and cognitively preform oral care. Educational handouts were given to patients as reference, as a manner to help reinforce the educational points for the oral care protocol.

One reason why Orem's Self-Care Nursing Theory is appropriate is because it addresses situational illnesses, which occur for a specified period of time. Since cancer treatment is usually situational, the theory is appropriate to guide this self-care-based intervention.

EBP Framework: Johns Hopkins Nursing Evidenced-Based Practice Model (JHNEBP Model). The JHNEBP Model is an open system with three interrelated concepts: inquiry, practice, and learning. The open system allows and accommodates for both internal and external factors to be incorporated into the model (Dang & Dearholt, 2017). For this EBP project internal factors included organizational culture, beliefs, supplies, and staffing. The organizational culture for the EBP project was one that fostered learning. The physicians would often have

small meetings about changes that were occurring, both in office, but also new treatments and studies that were going on. They were receptive to questions and explained the rationales behind their support of the intervention or why the evidence did not convince them that zinc supplementation would change the course of OM. An open culture of information exchange among all staff helped the JHNEBP Model follow the required steps and plan as needed to fit the needs of their office.

External factors included external stakeholders, insurance companies and external influences on purchasing. Stake-holders included the patients who came there for chemotherapy treatments, the people that they brought for support, as well as the larger communities that they dwelled in. The JHNEBP Model helped the staff to be consistent in addressing oral care and zinc supplementation once the project was implemented, thus affecting all involved in the patient care. Due to the socioeconomical factors within the population the intervention as intentionally kept low cost. Insurance companies could also be considered stakeholders because the overarching goal was to prevent or reduce the complications of OM. It is possible that if sustainability is achieved, it could save on hospital admission cost.

Inquiry was the first step for this EBP project. It encouraged addressing a problem and discovering solutions in novel and innovative ways. For this EBP project, the question examined if there was a way to prevent or reduce the impact of OM in patients receiving outpatient chemotherapy treatments. The JHNEBP Model encouraged looking past old methods and becoming innovative based on the evidence. After the literature was evaluated, the interventions synthesized from the data strongly supported use of an oral care protocol and zinc supplementation, both of which were low cost, patient driven interventions. Patient involvement in their own care as well as their symptoms reported subjectively, help contain cost because it did not require more assessment or documentation on the providers and their staff who worked in the busy office, thus also working towards cost containment.

The next step is practice, which is the transition phase of putting what is already known into the task that is going to be done, while it addresses nursing standards and helps ensure that nurses operate within their scope of practice. Since the primary investigator was experienced in acute oncology care expectations for time in the facility had to be discussed. Due to the close association between the acute care and clinical outpatient site, the primary investigator was well known within the office. Three of the employees, including the nurse manager of the clinical site, had formally worked with the primary investigator. The expectations had to be outlined, so the outpatient clinical staff understood that I could not go above my role as a DNP student, and that I would not be able to assist with starting IVs, managing chemotherapy infusions, or other roles which I was not orientated to do within that office.

Part of the practice step was ensuring that the clinical staff was onboard with the intervention. Initially, when the project was presented, many of the employees expressed that oral care was not important and that they provided adequate oral care education. However, once the pretest score was provided the staff acknowledged that they needed more education and they became more receptive to the intervention. When they were educated on zinc sulfate, which is an over the counter supplement, the nurses did not feel comfortable discussing this with patients voicing concerns that the patients could overdose. They were educated on the amount needed, based on results from previous studies, and it was noted to be well within safe limits. Ultimately, the physician who overseen the intervention group provided them with an educational print out and the reassurance that they could safely take it while receiving chemotherapy. The participants were more receptive to hearing it from the overseeing physician than the primary investigator and office staff.

The next phase is the learning phase. The JHNEBP Model learning is considered an ongoing process and allows to change when there is new information, clinical practices or other factors that can improve current processes. This model for EBP practice establishes that learning is life long and project teams should be interprofessional and collaborative in nature

(Dang & Dearholt, 2017). The team for this EBP project consisted of multidisciplinary personal, all working towards the same goal.

For example, the development of the oral care protocol was an ongoing process between the primary investor and the physicians within the practice. The original version included only oral care information, however, they physicians felt it could be improved by adding dietary recommendations, suggested toothpaste brands, and more specific lip care instructions. Through various editing, this information was added, along with the recipe for making the mouth rinses for patients who could not afford saline solutions. Another example of change that took place during the learning phase was who would issue the surveys to the participants. Originally, it was proposed that the front desk provide the PROMS survey to patients at check-in, however, they did not know who participants were and were not able to distinguish if an appointment was for chemotherapy or another type of treatment. Working with office flow, the process changed to have the medical assistants give and collect the surveys to participants in the absence of the primary investor. By inclusion of all the roles in the office, it allowed the development of a more organic and easier to follow chain of events that ensured the standard of care and the intervention was being addressed.

The JHNEBP Model systematically addresses questions through the **p**ractice question that is being explored, the **e**vidence concerning the practice, and then the **t**ransition into practice. This process is referred to by the acronym PET. Since the model is open, new EBP processes can be triggered throughout this cycle (Dang & Dearholt, 2017). For this EBP project, the transition phase from Evidence Synthesis into the Practice took the longest due to requested changes in the oral care protocol and educational materials after the project had already been approved. Educational trifolds originally addressed only the oral care protocol, however, the multidisciplinary team requested dietary information be included as well. The later version also included recommended brands of toothpaste and two recipes for oral rinse solution.

A final revision was requested that included recommendations for lip care. The final education trifold for patients is presented in Figure 5.1.

There were several characteristics of the JHNEBP Model that made it a good fit for this project. First, it was flexible enough to withstand a variety of both internal and external factors that could have derailed the project. Second, the model prompted the investigator to solicit feedback and partnership from a multidisciplinary team at the implementation site. This turned out to be an essential key to the success of this project. Third, the JHNEBP Model also provides comprehensive tools for novices to follow, giving step by step guides that move towards project implementation including identification of stakeholders, steps of the PET process, evidence assessment and appraisal tools, action planning, and dissemination tools. In summary, the Model proved to be user-friendly, team-focused, and promoted deeper thinking about what would and would not work at the implementation site.

While the JHNEBP Model is highly utilized, it is not without limitations. Facilities that are not familiar with EBP must be taught some of the core principles and be provided with more information about sequences of steps. For example, developing a list of who could serve as change champions in their respected areas was a step that needed to be taken. Instead of accepting the idea that everyone would immediately adopt the interventions, it was important to have someone within their area to be able to reinforce the importance of the interventions. This allowed for two-way valuable feedback to the primary investigator about what was working well and about what processes needed to change. A notable time when feedback was helpful was when there was discussion of the clinic providing the zinc supplementation. After analysis, this plan was decided not to be incorporated because of fears of medications storage, counting, and meeting accreditation standards. **Strengths and Limitations of the EBP Project**

Strengths. There were several strengths attributed to this project. One strength was the implementation site, which proved to be large enough for participant recruitment, but small enough that workflows and processes were relatively straightforward. Moreover, the

organizational culture was one that fully supported evidence-based practice and embraced the self-care theoretical underpinnings of this intervention. Upon formal approval of the EBP project from the physician owner of the implementation site, the clinical providers, nurses, medical assistants, and human resources staff provided whatever support was necessary to implement and evaluate this project. For example, one physician within the site encouraged staff to attend the education sessions held prior to implementing the project. The nursing manager also held the staff accountable for completing knowledge questionnaires and collecting specific data (e.g. types of therapy) if the investigator was unavailable.

The second strength was the use of a validated measurement tool for oral mucositis symptom severity. The PROMS scale was easy for participants to understand and it used a 100-millimeter visual analog scale; both of these features served to minimize measurement error in this small sample, which allowed for the highest possible power during statistical analysis. Furthermore, the prepared survey could be completed at the participants chosen pace during their oncological treatment session, and it required no additional work for clinic staff.

The third strength of this project's findings was the high proportion of African-American participants, which comprised more than half of the sample. Current research has not been generalizable to clinics in areas with a large African-American population. However, this project has done so.

Limitations. This project had some important limitations. The original proposal included the distribution of oral care kits to participants, which included a soft-bristled toothbrush, a recommended tooth paste, and packets to make saline for oral rinses. However, the process of obtaining these items would have significantly delayed implementation due to the purchasing process of the facility, so this intervention was dropped due to it not being feasible.

There had also been consideration of providing the participants with zinc sulfate supplementation capsules and methods of replenishing them weekly basis. Concerns arose that there would need to be pill counts, additional materials to both identify and transport the pills

once out of labeled bottle and tracking system for who should receive the pills weekly. Nursing staff voiced concerns that this would create undue burden to their task flow and the office manager worried about meeting all the standards by regulatory bodies. This measure was also dropped due to the cumbersome process that would have needed to be established to meet various needs and requirements.

Perhaps the most important limitation was the small sample size. There was a total of 88 people who met the inclusion criteria for the project, yet only 23 filled out the informed consent and completed more than one survey. Throughout the recruitment process, it was noted that potential participants would often decline to enroll because they were tired or anxious during their first chemotherapy treatments. Therefore, a recruitment approaches that addresses these limitations is recommended in the future.

Convenience sampling may have also had an impact on results. Participants were grouped by provider managing their care in the office. However, this resulted in the comparison group having a higher number of participants with more advanced cancers due to metastasis, which made it unclear whether the worse symptom severity in this group was due to the absence of zinc supplementation, or to the advanced nature of the cancer.

Implications for the Future

Practice. Review of evidence indicated that zinc supplementation in addition to an oral care protocol may be more effective than and oral care protocol alone. The outcomes of this EBP project did show consistent statistically significant results in 8 out 10 areas assessed by the PROMS survey, especially towards the middle and end weeks. This is consistent with findings in the literature. This does not support that data that zinc sulfate may prevent OM symptoms, however, it could suggest that it reduces the duration of symptoms. More sophisticated investigation is needed to determine if zinc supplementation is appropriate to provide to all patients receiving chemotherapy. It is recommended to assess zinc sulfate as an OM prevention initiative in a more controlled setting, with a larger sample size, over a longer

duration, and with a more consistent distribution of participant sample groups to ensure that similar cancer types and cancer stages are equally represented. Based on the results from this project, zinc sulfate with an oral care protocol seems to help reduce the intensity and duration of OM systems when surveyed using the PROMS questionnaire, but results are not generalizable, therefor zinc should not be prescribed until further investigation is completed.

Theory. Dorothea Orem's Self-Care Nursing Theory was beneficial in that it helped develop information that focused on self-care. It allowed the primary investigator to interact with participants in a dynamic context, and it helped them develop the tools to engage in the self-care at home in efforts to prevent OM. The JHNEBP Model was helpful for the novice primary investigator. It provided tools, such as a stakeholder analysis that included the intended purpose of the tool, definitions and how to use the tool. The action planning tool was also helpful to a novice for project implementation. It served as a guide to ensure successful transitions of interventions into practice. The action plan tool, helped the novice primary investigator consider things such as barriers, how the change would affect the health record, workflow, or policies. It also referenced support and cost. The final page included documentation of milestones and related task. These tools are immensely helpful when working towards implementation of an evidence-based project.

Research. While exploring if zinc sulfate help prevent or reduce the incidents of OM was the foundation for this EBP project, the effectiveness of establishing an oral care protocol as a preventive measure was not explored due to it becoming the standard of care. The oral care protocol was the strongest supported finding in the evidence, however, the construct of the EBP project did not allow the exploration of if this step alone was enough to produce significant results. Future research should incorporate appropriate time to do pre-implementation measures of OM, thus making this project three phases instead of the two explored by this EBP project. There may also be benefits to investigating overall dietary textures and providing

education about restrictions to soft foods only since questions addressing soft foods had much lower mean scores in both groups and maybe of some benefit.

The two phased project implementations at the facility caused a significant delay in the initiation of the second phase which was where participant data was collected. Phase one consisted of development of the oral care protocol and the education of staff which were two of the major themes from the best available evidence. The largest delay, however, came from the development of oral care protocol trifold handouts which participants received as an educational reference. The trifold was developed by the primary investigator and then modified to meet the needs of the facility, however, this process took away from valuable time in which participants could have been recruited into the study.

More research could be applied to the dietary portion of oral care. Refining what constituted “soft food” or “hard food” seemed to be a patient specific experience. For example, toast was considered a soft food to some participants, and a hard food for others. One participant noted they considered hard foods items difficult to chew, such as meat but noted breaded chicken as a soft food. Using the oral care protocol from another facility may prevent delays such as this when future research is conducted.

Outcomes could have been affected by the demographics for the patients. For example, most of the participants were male. Another interesting characteristic this project captured was a high number of African American participants. Lung cancer was the most common kind of cancer to be treated in this project, which could have also affected the results. More sophisticated investigation is needed to see if these characteristics contributed to the results. Ideally, upon repeat investigation, these characteristics should be considered as an area of importance.

Education. Because OM can have such devastating effects on those that receive oncological treatments, prevention or reduction of OM symptoms should be incorporated as an important part holistic care. All outpatient facilities should establish an oral care protocol as a

cost effective, patient driven intervention to prevent OM. Oral care protocols should be taught to patients by staff, patients should receive easy to read instructions, and OM symptoms should be tracked through the duration of treatment by a subjective patient tool. More sophisticated investigation is needed to determine if zinc sulfate supplementation if viable to reducing OM. The small sample size, demographic characteristics, and convenience sampling does not allow this study to be generalizable to all patients receiving chemotherapy treatments.

Education of the clinical professional is also valuable. While many may know different parts of oral care, no standard oral care protocol exists. Clinicians in all fields may encounter persons who receive oncological type treatments and it is important to provide them with methods based in science to help reduce complications.

Conclusion

Oncological treatments result in cytotoxic effects that can lead to the development of OM. Oral mucositis is one of the most severe non-hematological problems related to chemotherapies. This condition can result in poorer quality of life, weight loss, pain, and increased risk for hospitalization and death related to sepsis. Review of evidence lead to four major themes which were incorporated into this EBP project: Use of an oral care protocol, use of patient reported OM tools, professional clinical knowledge OM, and zinc sulfate may be effective as a preventive supplement. This project found that zinc sulfate 300 milligrams by mouth once daily, plus a standardized oral care protocol, was more effective at reducing OM symptom severity than the standardized oral care protocol alone. The use of a standardized oral care protocol would be beneficial to any outpatient area that administers chemotherapy, however more research is needed to determine if zinc sulfate supplementation can be given to all patients receiving chemotherapy.

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BIOGRAPHICAL MATERIAL

Mrs. Biel graduated from Indiana University Northwest with a bachelor's degree in nursing in 2008. She has worked for Methodist Hospital since 2006. Her nursing career has included medical-surgical, cardiac intermediate care, oncology, and nursing management. She accepted a newly created role as a nurse liaison but quickly realized that her nursing passion was to care for oncology patients. She decided to leave this coveted position to return to the oncology unit at Methodist. Patty began to pursue her Doctor in Nursing Practice in 2015. Her evidenced based practice project focused on cost effective ways to prevent oral mucositis in patients receiving oncological treatments. After graduation she plans to continue her nursing practice providing care to oncology patients. Patty has an interest in improving the continuum of care for patients with cancer and hopes to become politically active to improve the quality of health teaching in secondary education. She is a member of the Oncology Nursing Society and Sigma Theta Tau International – Zeta Epsilon chapter. Patricia enjoys volunteer work and has worked in conjunction with local health departments. She assisted with lead testing the citizens of East Chicago and the transition of patient records after the closure of the Gary Maternal Child Health Clinic.

ACRONYM LIST

ACS: American Cancer Society

EBP: Evidence-based practice

JHNEBP Model: Johns Hopkins Nursing Evidenced-Based Practice Model

JBI: Joanna Briggs Institute

NCI: National Cancer Institute

NIH: National Institutes of Health

OM: Oral mucositis

OMAS: Oral Mucositis Assessment Scale

PET: practice, evidence, transition

PROMS: Patient Reported Oral Mucositis Symptoms survey

QOL: Quality of life

RCT: Randomized control trial

WHO: World Health Organization

Appendix A: *PROMS survey*

This questionnaire asks you to evaluate some situations you may have experienced in the past week.

All of the situations refer to the *condition of your mouth*. You can indicate the severity of the situation by placing a vertical mark along the lines below.

First, we will use this type of line to rate temperature as an example.
On a hot day in the middle of the summer, if we asked you to rate how warm it was today, you would probably mark the line as follows:

not warm at all — extremely warm

On a cool day in fall, you might indicate:

not warm at all — extremely warm

On a cold day in winter, you might indicate:

not warm at all — extremely warm

To practice: Please tell me how warm it is outside today by placing a mark on the line below:

not warm at all — extremely warm

Appendix A: *PROMS survey (continued)*

Now that you know how to use this scale, please indicate to what degree these situations have affected you in the past week.

Mouth pain

no pain		worst possible pain

Difficulty speaking because of mouth sores

no trouble speaking		impossible to speak

Restriction of speech because of mouth sores

no restriction of speech		complete restriction of speech

Difficulty eating hard foods (hard bread, potato chips, etc.) because of mouth sores

no trouble eating hard foods		impossible to eat hard foods

Difficulty eating soft foods (jello, pudding, ect.) because of mouth sores

no trouble eating soft foods		impossible to eat soft foods

Appendix A: *PROMS survey (Continued)*

Restriction of eating because of mouth sores

no restriction of eating		complete restriction of eating

Difficulty drinking because of mouth sores

no trouble drinking		impossible to drink

Restriction of drinking because of mouth sores

no trouble drinking		complete restriction of drinking

Difficulty swallowing because of mouth sores

not difficult to swallow		impossible to swallow

Change in taste

no change in taste		complete change in taste

Appendix B: *Oral care protocol trifold (front)*

Oral Mucositis

Individuals receiving chemotherapy treatments are at risk for developing oral mucositis. This condition can cause pain and ulcerations on the inside of the mouth and to the lips. If ulcerations develop, the risk for infection increases.

Thorough oral care can help reduce the risk of developing this condition.

To get started, you will need:

- New soft toothbrush
- Recommended toothpaste
- Measuring cups and spoons
- Baking soda
- Salt
- Petroleum-free lip care products

Toothpaste Brands Recommended:

- Tom's of Maine Sensitive formula
- Sensodyne Pronamel brands
- Biotene – especially you have dry mouth or are receiving radiation therapy to the head or neck.

Please see a staff member with any questions concering oral care

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ORAL CARE

while receiving chemotherapy.

Recommendations to reduce oral mucositis

Appendix C: *Oral care protocol trifold (back)*

Oral Rinses:

Oral rinses help keep the mouth clean, moisturized and healthy during chemotherapy treatments.

Do not use mouthwashes with alcohol in the ingredients

Well Water:

If you have **well water** on private property it is recommended that distilled water be used for drinking, oral care, and oral rinses.

Lip Care

Protect lips by using *petroleum-free products*.

Many organic lip moisturizers are free of petroleum but avoid ones with peppermint oils or additional colors.

Lanolin also work well, can be found in the baby care section, but must be removed before receiving any radiation treatments.

Oral care steps:

- Floss teeth with waxed floss after meals
  - If bleeding is noted, stop & address at your next visit
- Use the soft bristle brush
- Apply a pea size amount of toothpaste to brush
- Two minutes of brushing
  - Take about thirty seconds per quarter of your mouth
- Rinse with solution (See recipe below!)
- Allow toothbrush to dry before putting it into storage

While receiving chemotherapy it is important to brush and floss teeth after every meal, at least 2-3 times daily.

Oral rinses should be done every 3 hours while awake.

Oral Rinse Recipe

- 1 cup of warm water
- 1/4 tsp baking soda
- 1/8 tsp of salt

OR

Saline packets can be purchased for on the go and they are located by allergy medication, by the nasal wash at most drug stores.

Dietary tips:

Avoid foods that may cause mouth discomfort such as, hot, spicy, acidic or rough foods

Avoid alcohol and tobacco.

Choose foods that are soft, wet, and easy to swallow such as oatmeal, grits, mashed potatoes, cottage cheeses, baby foods, soups and scrambled eggs

Avoid citrus fruits such as oranges, lemons, and grapefruit

Soften foods with sauces and gravies

A blender can be used to pureed cooked foods so that they are easier to eat

If oral mucositis occurs:

Inform the staff at your next appointment of any oral issues that you may be experiencing and follow these recommendations:

- Keep preforming oral care per instructions, if it is too painful to brush, preform rinses only.
- Liquid nutritional supplements maybe useful to maintain calorie intake