DENTAL CARIES, ORAL MUCOSITIS AND ORAL-HEALTH RELATED-QUALITY-OF-LIFE IN CHILDREN UNDERGOING CANCER THERAPY AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

I, Dr. Diana Okello, declare that this dissertation is my work and has not been submitted for any award in any other institution.

Signed  .....

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DEDICATION

To my loving husband, Samora

Who believes in me and calms every storm.

To my dearest children, Svetlana and Mikhail

Whose hugs fade the struggles of any day.

And, to my parents and brother

Who taught me the value of education and endurance.

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TABLE OF CONTENTS

LEGEND OF FIGURES

LIST OF TABLES

LIST OF APPENDICES

LIST OF ABBREVIATIONS

CT	Chemotherapy
CPQ	Child Perception Questionnaire
DMFT	Decayed Missing Filled Teeth in permanent dentition
dmft	decayed missing filled teeth in primary dentition
ERC	Ethical Research Committee
HSCT	Haematopoietic Stem Cell Treatment
KNH	Kenyatta National Hospital
MTRH	Moi Teaching and Referral Hospital
OHRQoL	Oral Health-Related Quality of Life OM
	Oral Mucositis
PPE	Personal Protective Equipment
RIM	Radiation-Induced Mucositis
RT	Radiation Therapy
SPSS	Statistical Package for Social Sciences
UOL	University of London
UON	University of Nairobi
WHO	World Health Organization

DEFINITION OF TERMINOLOGIES

Cancer therapy	The use of surgery, chemotherapy, radiotherapy, haematopoietic stem cell transplant and/or immunotherapy to treat cancer.
Caregiver	A biologically related adult family member who primarily provides care and supervision of the child at home and/or in the hospital.
Children undergoing cancer therapy	In this study, these are hospitalized children undergoing cancer therapy.
Dental Caries	A biofilm mediated infection resulting in demineralization and destruction of inorganic and organic tooth structure.
Immunotherapy	Biological cancer therapy that aids the immune system response.
Haematopoietic Stem Cell Transplantation	A special therapy that may be applied to individuals with cancer, that involves the transfer of healthy stem cells to replace unhealthy bone marrow cells.
Oral Mucositis	Inflammation of the oral mucosa caused by cancer therapy.
Oral Health	A state of being free from chronic orofacial pain, infection, tooth decay, or gum disease that limits the child's ability to perform day to day functions.
Oral Health-Related Quality of Life	A person's comfort when performing ordinary activities while eating, sleeping, and socializing while maintaining satisfaction and self-esteem in respect to their oral health.

ABSTRACT

Background: Children with cancer undergo various complex treatment modalities that predispose them to oral complications. Little is known about the prevalence of these manifestations and how they affect a child's Oral Health-related Quality of Life (OHRQoL).

Study objectives: The study sought to determine the prevalence of dental caries, oral mucositis and oral hygiene status among 3-12-year-old hospitalized children undergoing cancer therapy, and their association with the children's OHRQoL.

Study area: The study was conducted at the Kenyatta National Hospital (KNH), the specific sites being the children's oncology wards.

Study design: This was a descriptive cross-sectional study.

Study population: The study population consisted of one hundred and two paediatric oncology patients aged 3-12 years who were undergoing various forms of cancer therapy at KNH.

Materials and methods: The study participants were selected by purposive sampling. The inclusion criteria was all children aged 3-12-years, admitted in the oncology wards at KNH and undergoing cancer therapy. Data was collected using the WHO questionnaire on oral health surveys and clinical examination of the patients. The presence of dental caries and oral mucositis was determined using the dmft/DMFT and WHO Oral Mucositis scale indices. A validated 8-item Child Perception Questionnaire $_{8\text{-}10}$ ($CPQ_{8\text{-}10}$) was used to collect data on OHQoL among the 8-12-year-old children in the study.

Data analysis and presentation: Data was analysed using SPSS version 25. The results were then subjected to descriptive and inferential statistical tests. $P<0.05$ was considered statistically significant. The confidence interval was set at 95%. The results were presented in the form of tables and text.

Results: The prevalence of dental caries was 58.8%. Age was statistically significantly associated with dental caries experience with children aged 6 – 12 years having a higher

odds of having dental caries compared to those aged 3 – 5 years (p=0.025). The prevalence of mucositis was 28.4%. Grade I and Grade II were the most prevalent in terms of severity, mostly affecting children who had increased chemotherapy circles. While dental caries was not associated with OHRQoL, children with oral mucositis had significantly poor OHRQoL.

Conclusion: Children undergoing cancer therapy were found to suffer from a higher prevalence of dental caries than those in the general Kenyan population. They also displayed significant levels of oral mucositis which affected negatively, several domains of the children's OHRQoL. The likelihood of developing oral mucositis increased with the increase in cancer treatment modalities and increase in number of chemotherapy cycles.

Recommendation: There is a need to pay closer attention to the oral health needs of children undergoing cancer therapy. This may require the involvement of a paediatric oral health team. Information from this study may be used in the development of appropriate oral healthcare protocols for use among hospitalized children.

CHAPTER ONE: INTRODUCTION

1.1 Background

Paediatric malignancies are uncommon and are less than 1% of new cancer cases globally.[1,2] Nonetheless, 80% of the worldwide cases occur in developing nations.[3] Notably, 4.6% of cancers in sub-Saharan Africa occur in children younger than 14 years owing to the young age structure in Africa, compared to only 0.5% in high-income countries.[3] There is a dearth of data on the true cancer incidence in Africa, due to the inadequate number of cancer tumour registries.[4] In 1987, South Africa established the only national paediatric tumour registry in Africa.[5] Kenya has three cancer registries in Nairobi, Kisumu and Eldoret.[6] The Kenya National Cancer Strategy of 2017 – 2022 reports 37,000 new cancer cases per annum with an annual mortality of over 28,000. Of these cases, the annual incidence of childhood cancer in Kenya is 2500.[7]

Leukaemia is the most common childhood cancer in North America.[8] Nigeria reported lymphomas, and Uganda reported Kaposi sarcoma as the most common paediatric cancer.[9,10] Earlier studies reported lymphoma, leukaemia, nephroblastoma and rhabdomyosarcoma as the most prevalent paediatric malignancies in Kenya.[11]

Genetic factors, pre-natal and post-natal exposure to radiation or viruses are known risk factors for some childhood cancers, but mostly, the aetiology remains unknown.[8] Nearly a third of the total cancer cases in Kenya is attributed to infectious agents.[12]

The treatment of childhood cancers is complex and most children are treated using chemotherapy (CT), radiotherapy (RT), surgery, or a combination of cancer treatment modalities.[9] Before the discovery of CT and RT, surgery was the standard treatment of childhood solid tumours, but only a few cases cured by surgery alone.[13] Cancers such as osteosarcoma can be cured with surgery followed by CT to prevent micrometastasis.[14] RT is paramount in the treatment of soft tissue tumours and paediatric brain tumours, conversely with increased risk of impaired growth, development or secondary cancers.[15,16,17] Currently, a multimodal treatment significantly improves the survival rates for children with malignancies.[18] Cancer therapy is rapidly advancing with haematopoietic stem cell transplant (HSCT) and immunotherapy emerging as leading therapies for certain cancers.

The potential side effects of cancer therapy in the oral cavity include mucositis, xerostomia, candidiasis, ulcers, and gingival bleeding which increase the disease burden for children with cancer.[4] Children undergoing CT have a higher prevalence of dental caries which is believed to be due to the toxicity of methotrexate and its toxic effects on the oral mucosa resulting in poor oral hygiene.[19] Additionally, nausea and vomiting, which are common side effects of chemotherapy, result in children having smaller but frequent food intake therefore further increasing their caries risk.[19]

Children and adolescents express reduced autonomy, low self-esteem and depression, especially during the first three to six months after a cancer diagnosis.[20-22] Key determinants of Quality of Life deterioration in children with cancer appear to be painful clinical interventions, cancer therapy and hospitalization.[23] Good oral hygiene practices during cancer therapy help prevent and treat complications such as dental caries and oral mucositis that may arise.[24] However, an assessment of how dental problems influence the quality of life is impossible using traditional methods of dental health evaluation.[25] These clinical parameters evaluate oral and dental disorders in the viewpoint of the professionals and consequently fail to capture the consequences of these conditions in the day-to-day life of the child. Parents and caregivers have been used as proxy informants in some studies that evaluate the Quality of Life of children.[26] However, according to child development experts, children from the age of six years are capable of conveying a range of emotions such as anxiety and happiness, as well as cultural values such as beauty.[27] Good oral care is imperative in managing these toxic effects of cancer therapy and is seldom emphasized in clinical practice.[28]

The study is intended to find out the prevalence of dental caries and oral mucositis in children undergoing cancer therapy, to contribute to literature, and provide baseline data. Furthermore, the study aimed to get the impact of dental caries and oral mucositis in these children.

CHAPTER TWO: LITERATURE REVIEW

2.1 Dental Caries

2.1.1 Aetiology of dental caries

Dental caries is a multifactorial, biofilm-mediated, diet modulated, non-communicable, disease resulting in mineral loss of dental hard tissues determined by behavioural, psychosocial, biological, and environmental factors.[29] The WHO reported that the prevalence of dental caries among children ranges from 60% to 90%.[30]

Streptococcus mutans bacteria is linked to dental caries initiation, while *Lactobacilli species* is linked to the progression of dental caries.[31] Frequent consumption of fermentable carbohydrates results in lengthy contact between sugars and these cariogenic bacteria on the teeth resulting in a drop in pH in the dental plaque from neutrality to pH 5.5 or below.[32,33] The Ecological Plaque Hypothesis (1994) by Phillip D. Marsh, proposes that disease results from an imbalance in the microflora leading to an upsurge of certain disease-related micro-organisms.[34] Therefore, bacteria such as *Streptococcus mutans* and *Lactobacillus* spp., lower the pH, resulting in dental caries.[35-37] The Ecological Plaque Hypothesis is also supported by the caries-protective role of the host factors such as salivary properties.[38]

2.1.2 Pathogenesis of dental caries during cancer therapy

Dental caries is a preventable disease, and caries prevention is one imperative aspect of oral care for children undergoing cancer therapy.[39,40,41] Dental caries is not an alteration directly derived from anticancer therapies.[42] A hospital-based Chinese study by Wang et al. enrolled 39 children receiving chemotherapy for Acute Lymphoblastic Leukaemia and matched them to healthy counterparts.[19] The study found that dental caries accounts for 69.2% of all oral diseases which was believed to be due to the toxic and adverse effects of methotrexate on the oral mucosa leading to poor oral hygiene. The study also found that nausea and vomiting caused by CT drugs resulted in the children consuming smaller but frequent food portions therefore significantly increasing their risk for dental caries. The same study sampled supragingival plaque microbiota composition and

found an abundance of *Lactobacillus* spp. compared to the healthy group of children, thereby further putting them at risk for progression of dental caries. Therefore, poor oral hygiene, increased frequency of eating, high sugar consumption, and shift in the microbiome resulted in the development and progression of dental caries. A study by Hong et al. concurred that leukaemia patients indeed tend to drink sugar-rich drinks to relieve oral dryness caused by cancer therapy which further increases caries risk in these children.[43]

A university-based Finish study by Pajari et al. enrolled 55 children with cancer who are either acute or cured, and 103 healthy participants aged 5, 8 and 11 years as well as adults.[44] The children with cancer were receiving either chemotherapy, radiotherapy or a combination of both for management of leukaemia or solid malignancies. The findings of the study were that the salivary pH values were considerably lower in children with cancer, in those undergoing cancer therapy, and in those cured of their malignancy, than in their age-matched healthy controls. The study also showed an increased number of *Streptococcus mutans* and *Lactobacilli* species in the oral microbiome of children with cancer or undergoing cancer therapy. The reduced pH, as well as the microbial shift, increased their dental caries risk. In addition, during chemotherapy, there is a reduction in saliva flow rate and a concurrent increase in the concentration of microorganisms in saliva.[19]

A Sudanese hospital-based study by Mohammed et al. enrolled 87 children, younger than 15 years, with leukaemia.[45] The patients were grouped into three categories: newly diagnosed patients, patients who were undergoing CT, RT or combination therapy and patients who were in the maintenance phase. The study found that 93.1% of the participants had never received dental health care, 67.9% had poor oral hygiene and 37.9% had untreated dental caries. In this population, the proportion of children with dental caries was found to be higher than that described previously among healthy 12-year-old Sudanese schoolchildren.[46]

Xerostomia describes the subjective symptoms of a dry mouth originating from a lack of saliva.[47] Hyposalivation is a direct consequence of chemotherapy and can persist for up to five years after CT.[48] It may also affect up to 80% of those who require

radiotherapy as their primary treatment.[49] It is the most frequent oral complication in patients who undergo head and neck RT and may appear during or after RT.[50,51] RT-induced xerostomia depends on the cumulative amount of the radiation doses on the head and neck region with salivary flow decreasing by 50-60% in the first week and it diminishes to about 20% at 7 weeks, and continues to decline for many months after RT.[52] During irradiation, there is a reduction of bicarbonate concentration in saliva and a microbial shift towards cariogenic bacteria namely *S. mutans*, and *Lactobacillus* species, correlated to decreased plaque pH.[53,54] Further increasing the dental caries risk in irradiated patients.

Antineoplastic CT and RT are associated with dental caries development and its high incidence during cancer treatment due to the increased intake frequency of sugar-rich food, poor oral hygiene and xerostomia. In addition, radiation therapy in children may lead to enamel demineralization which also increases the paediatric oncology patient's susceptibility to dental caries.[55] This is because pre-secretory odontoblasts undergo rapid cell division and are predominantly susceptible to the toxic effects of CT and RT.[56]

2.2 Oral Mucositis

2.2.1 Aetiology and pathogenesis of oral mucositis

Oral mucositis describes the effects of CT and RT-induced inflammation of the oral mucosa.[57] Young age, poor oral care during cancer treatment, poor nutritional status, neutropenia, and type of malignancy are the major risk factors for developing oral mucositis.[58] Nearly 40% of all patients receiving CT will present with oral side effects [59], and this rate increases exponentially to more than 90% among children younger than 12 years.[57] CT is a commonly prescribed cancer therapy for childhood cancers, and the toxic effects of the CT primarily affect biological areas with a high cell turnover, such as the oral mucosa.[60] Up to 80% - 100% of patients receiving direct RT on the oral cavity during the treatment of head and neck cancers develop Radiation-induced mucositis (RIM).[61,62] Moreover, concomitant chemotherapy increases the chances of developing RIM.[63]

Oral mucositis may either be direct and indirect.[58] Direct mucositis, as a result of CT or RT, can cause changes in normal turnover and cell death of epithelial cells. On the other hand, indirect oral mucositis may be caused by bacterial or fungal infections.[58] Sonis et al.[63] developed a pathobiological model of oral mucositis as illustrated in **Figure 1**.

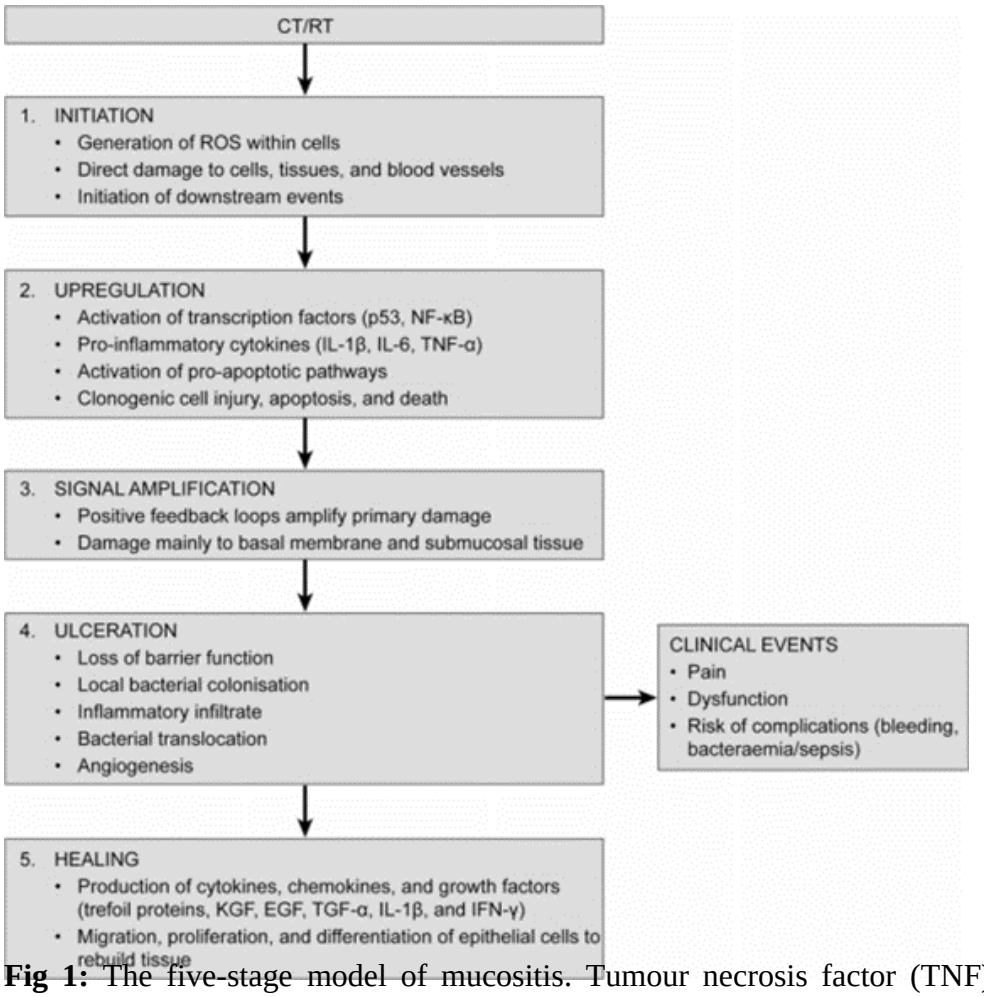

Fig 1: The five-stage model of mucositis. Tumour necrosis factor (TNF);Reactive Oxygen Species (ROS); interferon (INF); epidermal growth factor (EGF); interleukin (IL); keratinocyte growth factor (KGF); nuclear factor (NF); transforming growth factor (TGF). (Adapted from Sonis et al.[63])

2.2.2 Clinical Features of oral mucositis

CT-induced mucositis is the most common complication resulting from antineoplastic CT.[63] A Brazilian study by Ribeiro et al. found that oral mucositis appears

approximately 5-7 days after the commencement of CT and may persist over the entire therapy period which was similar to findings in a Chinese study by Chen et al.[65,66] Clinically, the mucosa is oedematous, erythematous and friable, which results in pain or discomfort and dysphagia.[67] Ulcers develop after 7-10 days,[68] have little inflammatory infiltration in the margins and take two weeks to heal.[69] However, they may gradually merge and form large shallow ulcerated zones with a necrotic base.[70]

On the contrary, oral lesions of radiation-induced mucositis (RIM) usually appear two weeks after the initiation of radiation and heal about 3-4 weeks after RT.[64] It commonly occurs in individuals treated with 200 cGy of daily fractionated RT programs.[71] Side effects and sequelae of RIM include oral pain (69%), dysphagia (56%), opioid use (53%), weight loss of 3–7 kg, and adjustment or disruption of treatment in 11–16% of oncology patients.[72-74]

Ulcers occurring in oral mucositis differ from those associated with either aphthous stomatitis or any dental trauma, with one major feature being undefined borders which lack an erythematous ring, usually affecting the soft palate, buccal mucosa, floor of mouth; and rarely on the dorsum of the tongue or the gingiva.[64] These painful ulcers compromise nutrition, and oral plaque control and increase the risk for infection.[73] The rapid turnover of taste cells makes them sensitive to chemotherapy agents, which may result in dysgeusia, in addition to oral mucositis.[74,75] A Swedish hospital-based study, found that the parents of the younger children perceived oral pain and altered taste as the most important causes of their child's reduced food intake; while the children viewed food aversions, nausea, vomiting and oral pain as important causes of reduced food intake.[76]

2.3 Oral Health-Related Quality of Life

Locker and Allen's concept of OHRQoL describes it as the impact of oral conditions on daily functioning and well-being.[77] Conventional dental indices of assessing oral health focus on the presence or absence of oral diseases excluding the oral well-being in terms of feelings or ability to chew and enjoy food.[78]

In 2005, Ferrans et al. developed an OHRQoL conceptual framework illustrated in **Figure 2** which suggested that the biological function, symptoms and functional status complex are influenced by both the personal and external characteristics which together influence the overall OHRQoL and health.[79]

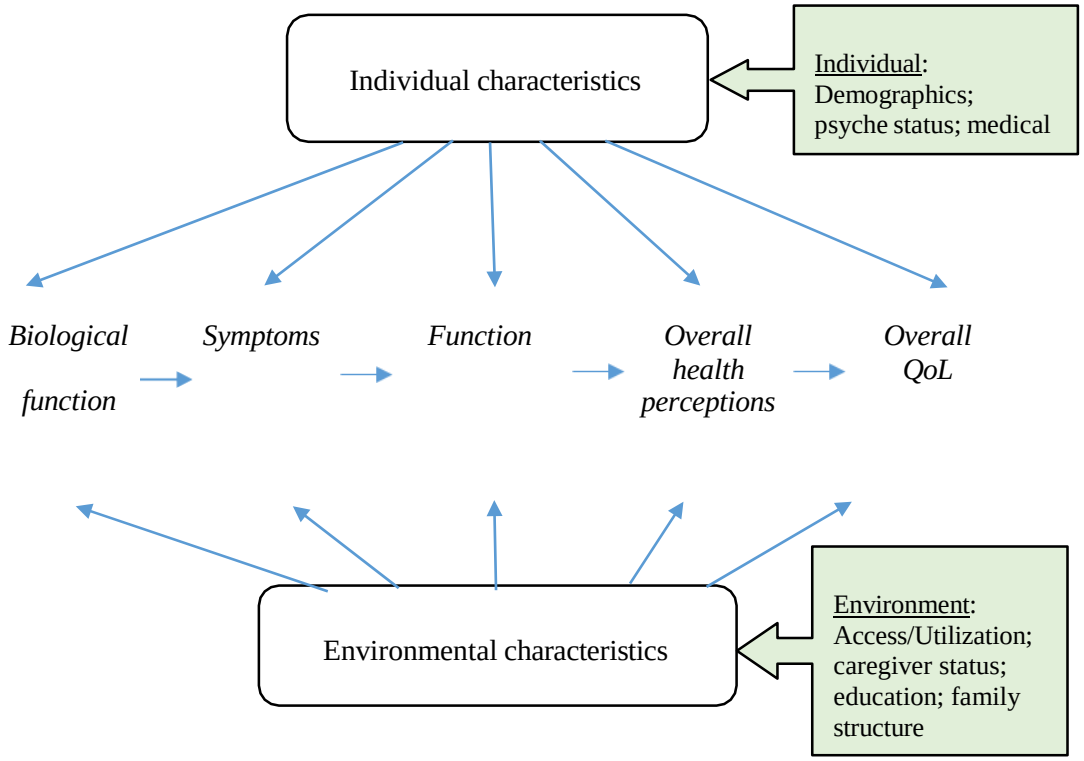

Fig 2: Determinants of Health-related Quality of Life. (Adapted from Ferrans et al.[79])

2.3.1 OHRQoL in children

Oral complications that arise during cancer therapy include dental caries and oral mucositis which affect how the child eats, talks, chews or swallows.

A 2012 multicentre study by Cheng et al., enrolled one hundred and forty children (age 8-18 years) in Singapore.[65] The study aimed to determine the range of oral symptoms, their severity, and their effect on the QoL during CT. Participants completed the Oral Mucositis Daily Questionnaire and Oral Mucositis-specific Quality of Life Measure. The study found oral mucositis affected their ability to eat (82.4%), swallow (78.9%), drink (75.4%), sleep (71.9%), and talk (43.9%).

The 2020 Moroccan hospital study by Bensouda et al., enrolled 40 children (aged 11 - 14 years) to assess the OHRQoL among children with acute leukaemia.[80] Data was collected via the Child - Oral Impacts on Daily Performance Questionnaire. The study

found that the overall prevalence of oral problems impacting daily activities over the last 3 months was 52.5%. The most frequently affected daily activity was eating (45%).

Masiga et al., carried out a study to determine the impact of dental caries on the Quality of Life among HIV-infected children attending the comprehensive care centre outpatient clinic at KNH. The study concluded that there was high dental caries experience predominately in the primary dentitions and dental caries had a negative impact on the QoL.[18] However, there is a dearth of information regarding the OHRQoL of children undergoing cancer therapy in developing countries.

Xu et al., developed and validated an 8-item child OHRQoL instrument.[81] The Child Perception Questionnaire (CPQ_{8-10} and CPQ_{11-14}) comprises the following four conceptual domains: oral symptoms, functional limitations, emotional well-being and social wellbeing. This instrument is more applicable in studies of children's wellbeing.[81]

As a function of the aforementioned, chronic illnesses such as malignancies, and antineoplastic therapy, affect the OHRQoL of children. Incorporating OHRQoL in management creates a shift in patient assessment and care that emphasises social, emotional and physical functioning.

2.4 Advances in cancer therapy

2.4.1 Haematopoietic Stem Cell Transplantation

Hematopoietic stem cell transplant (HSCT) is well-defined as the infusion of stem cells, derived from the bone marrow, cord blood, or peripheral blood to reconstitute the hematopoietic system.[82,64] HSCT is used to treat both malignant and benign diseases in the paediatric population.[83] HSCTs in Africa, as shown in **Figure 3**, represents only 3% of the total global transplant activities described.[84]

Fig 3: African countries where HSCT is available. (Adapted from Baldomero et al.[84])

Complete body irradiation and/or chemotherapy may be administered to children treated with HSCT leading to a prolonged immunosuppressed period that can last at least 100 days.[85] This, therefore, makes it impossible to perform dental treatment during this period before the transplant.[85] As high as 80% of patients receiving HSCT will develop oral mucositis, oral dryness, dysgeusia, and local and systemic infections.[86,87]

2.4.2 Immunotherapies for childhood malignancies

Cancer immunotherapy is now considered to be the "fifth pillar" of cancer therapy.[88] Immunotherapy drugs have been used for the treatment of advanced solid tumours refractory classic Hodgkin lymphoma in children.[89] The most predominant immune-related adverse events associated with anti-cancer immunotherapies are cutaneous toxicities. Common oral toxicities associated with immunotherapy include xerostomia, dysgeusia, lichenoid reactions and low-grade stomatitis.[90,91]

Toxic oral effects of cancer therapy are evident and have an impact on the social, emotional and physical functioning of the child undergoing treatment. This study shall serve to build on literature.

2.5 Problem statement

Studies conducted on the prevalence of oral complications resulting from antineoplastic therapy show that dental caries and oral mucositis (OM) are the most common oral problems. These oral problems subsequently increase the disease burden for these children. However, the majority of the studies describing the prevalence of dental caries and OM in children undergoing cancer therapy have been carried out in high-income countries. Furthermore, a majority of the global childhood cancer cases occur in sub-Saharan Africa, therefore, the actual impact of these oral complications is yet to be quantified owing to the paucity of data. Consequently, little is known about how dental caries and oral mucositis affect the Kenyan child's routine activities such as eating, smiling or socializing with friends. This study aimed at filling the gap in knowledge on the prevalence of dental caries and OM, and their impact on routine activities such as chewing, smiling or socializing with friends, in children undergoing cancer therapy.

2.6 Justification

Culturally and environmentally, cancer may affect children differently as we do not have much information about it in our population. The study was intended to contribute to the literature and provide baseline data regarding the most common oral complications of cancer therapy in addition to shedding light on the OHRQoL of life in children receiving cancer therapy. It was perceived that the results of the study may contribute useful information to health workers attending to paediatric oncology patients thereby assisting them in understanding the consequences of cancer and cancer therapy in children receiving treatment. Additionally, the study may also contribute to the development of a protocol for the oral healthcare of these children and its intergration into the existing medical care pathway thereby standardizing the quality of healthcare they receive.

2.7 Objectives of the study

2.7.1 Broad objectives

To determine the prevalence of dental caries, oral mucositis and the oral health-related quality of life in 3-12-year-old children undergoing cancer therapy at KNH.

2.7.2 Specific objectives

1) To determine the prevalence of dental caries among 3-12-year-old patients undergoing cancer therapy at KNH.
2) To determine the prevalence of oral mucositis among 3-12-year-old patients undergoing cancer therapy at KNH.
3) To determine the oral hygiene status of 3-12-year-old patients undergoing cancer therapy at KNH.
4) To determine the association between dental caries, mucositis and the OHRQoL in 3-12-year-old patients undergoing cancer therapy.

2.8 Study variables

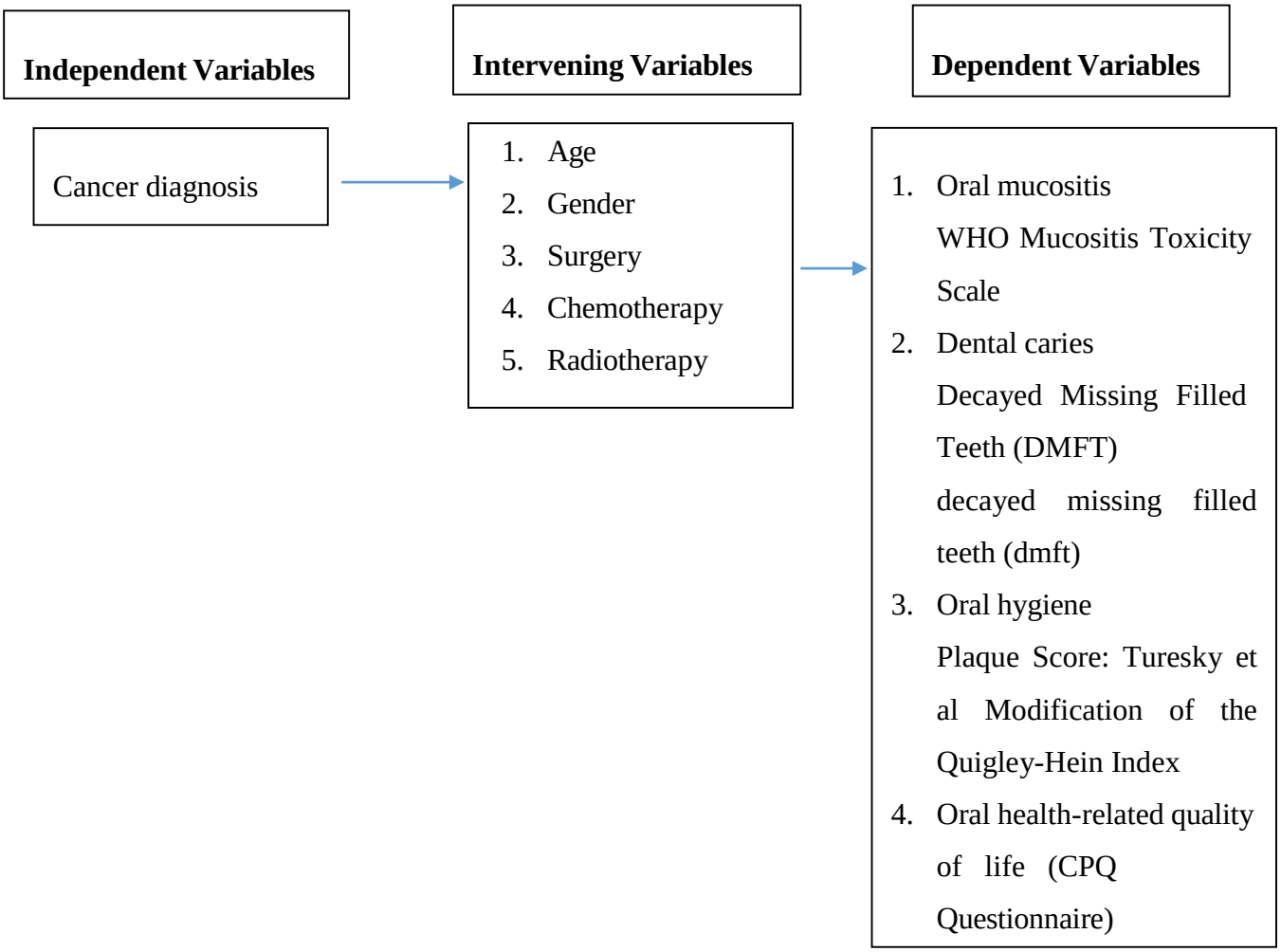

Fig 4: Study variables

2.9 The hypothesis of the study

There is no association between dental caries, oral mucositis and the oral health-related quality of life in children undergoing cancer therapy.

CHAPTER THREE: METHODS AND MATERIALS

3.1 Study design

The study was a descriptive cross-sectional study.

3.2 Study area

The study was conducted in KNH, which is Kenya's largest public referral hospital located in Nairobi City County, equipped to provide the three major cancer treatment modalities namely: chemotherapy, surgery and radiotherapy. The hospital has a total bed capacity of 1800 with an estimate of 400 beds for paediatric patients, however, due to congestion, the number of total inpatients can rise to 3000 patients. The following inpatient wards accommodate paediatric oncology patients – 1E, 1C, 3A, 3B, 3C and 3D. There is an average of 140 paediatric cancer cases at any one time of year. The paediatric wards where the study was carried out admit patients younger than 12 years of age, as per the hospital policy.

3.3 Study population

The study population was children aged 3 – 12 year olds diagnosed with cancer and undergoing cancer therapy at KNH.

3.4 Inclusion Criteria

1. Children that are aged 3 - 12 years, diagnosed with cancer and undergoing cancer therapy.
2. Children whose parents provided consent.
3. Children who assented to the study.

3.5 Exclusion Criteria

1. Children who were too ill or in isolation.

3.6 Sample size determination

Considering the study design, the sample size was determined using Cochran's formula (Z test) and computed as follows: [92]

$$\boldsymbol{n = \frac{(Z_{1-\frac{\alpha}{2}})^2 p(1-p)}{d^2}}$$

Where:

n = sample size

Z = value from the standard normal distribution for 95% confidence level = 1.96

p = prevalence of dental caries & mucositis among paediatric oncology patients = 0.5

d = allowable error (absolute) = 0.05

Therefore:

$$\boldsymbol{n = \frac{(1.96)^2 0.5(1-0.5)}{0.05^2}}$$

$$\boldsymbol{n = 384}$$

Nonetheless, the sample size calculated is for a study population > 10,000 and the desired sample size is for a study population < 10,000, the sample size was corrected for a study population < 10000 :

$$\boldsymbol{n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}}$$

Where:

n = desired sample size for a study population < 10000

n_0 = sample size derived for a study population > 10000

N = estimated size of the study population (patients) = 140

Therefore:

$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

$$n = \frac{384}{1 + \frac{(384 - 1)}{140}}$$

$$n = 102$$

Therefore, a sample size of **102** paediatric oncology children were enrolled into the study.

3.7 Sampling technique

A purposive sampling technique was used.

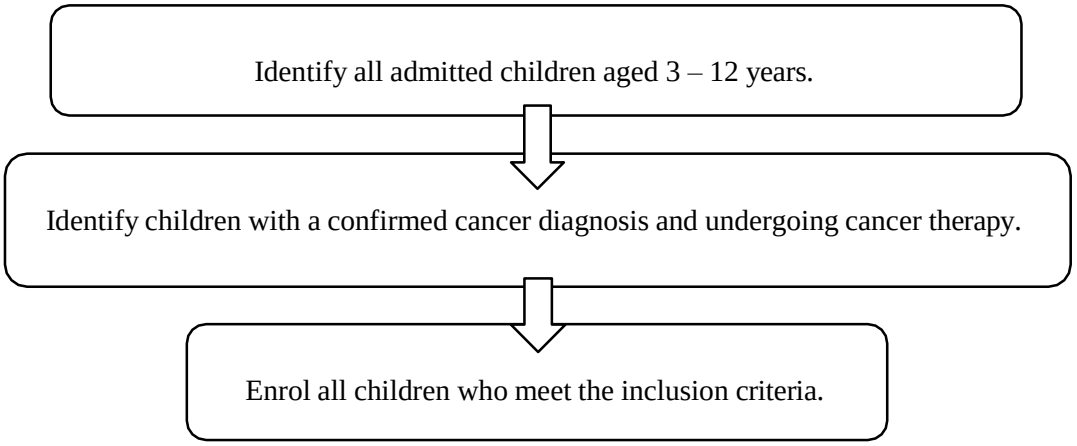

Fig 5: Flow chart showing the sampling method

3.8 Data collection technique and instruments

The Principle Investigator obtained consent from the parents/guardians (Appendix 4) and assent from the children (Appendix 5) at the point of recruitment.

3.8.1 Personal Protective Equipment measures

To prevent infection and nosocomial spread of coronavirus disease 2019 (COVID-19), the PI will ensure effective infection prevention and control procedures,[93] as detailed in Appendix 1.

3.8.2 Questionnaire

The study was conducted using an interviewer-administered structured questionnaire available in the official national languages of Kenya, English and Kiswahili (Appendix 2 and Appendix 3 respectively). The questionnaire was adapted and modified from the WHO Simplified Oral Health Questionnaire for Children[94] and the 8-item Child Perception Questionnaire.[80] The Questionnaire was divided into three parts namely Part I, Part II and Part III.

Part I included the medical history of the child retrieved from the hospital file. Information collected included the age and gender of the child, cancer diagnosis, method used in diagnosis, type and duration of cancer therapy(ies), and any dental interventions. The parents/guardians were the key informants for Part II, with some of the information being sought including socio-demographic data, oral hygiene practices and food intake frequency. Only children who are eight years and above completed Part III, which pertained to their OHRQoL, in a face to face interview with the PI. This was used to obtain information on difficulties in eating, emotional status and wellbeing, and social interaction. The PI conducted all the interviews.

The Questionnaire (Appendix 2) was pretested among 10 children in ward 1E at KNH and subsequently excluded from the study. The responses were assessed and any adjustments such as “feeling frustrated” were rephrased to “unable to be happy or joyful”. The data clerk was trained on how to fill the questionnaire during the pretesting. Every assessment form was filled out by the data clerk and checked for completeness and every score was verified after the examination of the child.

3.8.3 Clinical examination

The Principal Investigator (PI) examined each child to assess for dental caries, oral mucositis and oral hygiene status, under field conditions using natural light and the data

recorded in Appendix 3. The child was requested to sit on a chair or the edge of their beds for the examination. PPE and sterile dental instruments (mouth mirror, probe, gauze, sterile gloves) were used during the clinical examination. The teeth were identified using FDI nomenclature.

Dental caries status was determined by visualization and tactile sensation using the WHO Oral Health Assessment form for Children, 2013. The teeth were dried using gauze before the examination. Dental caries was diagnosed when there was a white chalky area in the cervical area or when there was detectable loss of tooth substance or when such loss has been treated with dental fillings or extraction.

The PI examined for oral mucositis by retracting the child's lip and buccal tissue to examine the non-keratinized surfaces. To evaluate the occurrence and severity of mucositis, the WHO criteria of 1979,[19] was followed.

Oral hygiene status was assessed by determining the amount of plaque present. The PI instructed each child to chew a disclosing tablet for one minute and use their tongue to transfer it to all parts of their teeth, followed by a brief rinse with water to remove the excess particles. The six index teeth were selected according to Silness and Löe criteria.[95] Turesky et al. modification of the Quigley-Hein Index was used to quantify plaque deposition on the buccal and lingual aspects.[96]

The used dental instruments were then decontaminated and placed in a container with water then disinfected with a polyenzymatic detergenent. The cleaned instruments were then packed in sterilization pouches and sterilized at the University of Nairobi Dental Hospital CSSD. The instruments were then re-used in the next session.

3.9 Reliability and validity

One of the supervisors calibrated the PI on the diagnosis of dental caries, oral mucositis and the presence of plaque among children in ward 1E of KNH. Every child was re-examined to determine intra-examiner consistency and reproducibility during data collection. Cohen's Kappa coefficient (*k*) statistic was used to measure the inter-examiner and intra-examiner reliability of the study. The Cohen Kappa statistic value of 0.82 for dental caries, 0.90 for mucositis and 0.86 for the plaque score was obtained

to measure the degree of agreement and reproducibility. During the period of data collection, every 10th child was re-examined by the PI to determine intra-examiner consistency. The intra-examiner Cohen Kappa statistic value was 0.90 for dental caries, 0.96 for mucositis and 0.85 for plaque score. A data clerk was trained and calibrated by the PI on proper data recording of the findings during the examination.

3.10 Data management

3.10.1 Quality assurance protocol

The collected data was reviewed for completeness, accuracy, errors and double entered for quality control before analysis using SPSS version 25. Additionally, once data entry was been done, 15% of the records were sampled for double entry to ensure quality control and accuracy. The data set was also checked for any logical or typographical errors. Computer data was password protected and the research tool was kept under lock and key.

3.10.2 Data analysis and presentation

Data analysis was done using IBM SPSS version 25 to determine the descriptive and inferential statistical characteristics. Descriptive statistics such as mean, median and standard deviation were applied to continuous data variables. Thereafter, data was subjected to statistical tests such as Pearson's Chi-square test, Rank-Order correlation coefficient and linear regression model to compare and relate variables. 95% Confidence Interval (CI) was calculated to measure the different factors. These results were presented in tabular format and in text.

3.11 Ethical consideration

Ethical approval and clearance to conduct the study were obtained from the University of Nairobi - Kenyatta National Hospital Ethics Research Committee. The authorisation was sought from the University of Nairobi, Department of Paediatrics and Child Health, Department of Ophthalmology, Radiotherapy Department, Health Records and Information, as well as the Nurses in Charge of the various KNH wards. Only participants who satisfied the inclusion criteria were included in the study and the participation was voluntary, without any incentives and with the right to withdraw at

any point. The children received free dental consultation and oral health education, while those who required dental treatment were referred to KNH dental department (Appendix 6). Patient confidentiality was ensured by excluding the patient names and by the allocation of identification numbers.

3.12 Perceived Benefits of the Study

The findings provided baseline information on the prevalence of dental caries, mucositis, and the OHRQoL in paediatric oncology patients which may contribute to the development of a protocol to ensure standardized comprehensive quality healthcare.

CHAPTER 4: RESULTS

4.1 Socio-demographic characteristics

A total of 102 children, 55(53.9%) male, and 47(46.1%) female participated in the study, a ratio of 1.2:1. The age range of the participants was 3 – 12 years, with a mean age of 6.08 years $\pm$ 3.1 SD.

About one-third of the children's caregivers, {39(38.2%)}, had completed primary school, 31(30.4%) secondary education, 22(21.6%) technical college and university, and 10(9.8%) had no formal education. Majority of the caregivers, 82(80.4%), were married and 20(19.6%) were single.

The participants were from varied geographical locations. The geographical counties of origin were then grouped into the regions of Kenya. About a quarter of the children, 26(25.5%), were from Nairobi. The rest were from Eastern 20(19.6%), Central 18(17.6%), Rift Valley 14(13.7%), Nyanza 11(10.8%), Coast 8(7.8%), North-Eastern 4(3.9%) and 1(1%) from Western Kenya.

4.2 Cancer treatment modalities at KNH

The study participants were undergoing various cancer therapies at KNH. Chemotherapy, radiotherapy and surgery were the cancer treatment modalities available at the time of the study; HSCT and immunotherapy were not available. More than half of the children, 61(59.8%), were undergoing chemotherapy only. The distribution of treatment modalities is presented in **Table 1**.

Table 1: Frequency distribution of cancer treatment modalities

Treatment combination	**n = 102**	**%**
Chemotherapy alone	61	59.8
Chemotherapy and surgery	24	23.5
Chemotherapy and radiotherapy	7	6.9
Surgery, radiotherapy and chemotherapy	6	5.9
Surgery alone	3	2.9
Radiotherapy alone	1	1.0
Haematopoietic Stem Cell Transplant	0	0.0
Immunotherapy	0	0.0
Overall	**102**	**100.0**

The distribution of childhood cancers among the study participants was variable. The most common childhood malignancy was the Leukaemias, cumulating at 35(34.3%). The childhood malignancies were categorised according to the International Classification of Childhood Cancers [97] and comprehensively presented in **Table 2**.

Table 2: Distribution of children by cancers

Malignancy	n = 102	%
Leukaemia		
Acute Lymphocytic Leukaemia	24	23.5
Acute Myeloid Leukaemia	9	8.8
Chronic Myeloid Leukaemia	2	2.0
Lymphomas and Reticuloendothelial Neoplasms		
Non-Hodgkin's lymphoma	12	11.8
Hodgkin's lymphoma	5	4.9
Mediastinal lymphoma	1	1.0
Retinoblastoma		
Retinoblastoma	16	15.7
Renal Tumours		
Nephroblastoma	12	11.8
Soft Tissue Sarcomas		
Rhabdomyosarcoma	4	3.9
Fibrosarcoma	1	1.0
Synovial sarcoma	1	1.0
Sympathetic Nervous System Tumours		
Neuroblastoma	4	3.9
CNS and Miscellaneous Intracranial and Intraspinal Neoplasms		
Medulloblastoma	2	2.0
Pineoblastoma	1	1.0
Craniopharyngioma	1	1.0
Carcinomas and other Malignant Epithelial Neoplasms		
Malignant Mesothelioma	1	1.0
Metastatic Neuroendocrine Tumour	1	1.0
Nasopharyngeal Carcinoma	1	1.0
Spindle cell carcinoma	1	1.0
Other unspecified malignant tumours		
Malignant Teratoma	2	2.0
Malignant Bone Tumours		
Osteogenic sarcoma	1	1.0
	102	**100.0**

The study participants were all at various phases of cancer therapy. The distribution of children by chemotherapy phase was assessed for the most prevalent cancer in our study population. The distribution of children with Acute Lymphocytic Leukaemia (ALL) undergoing various phases of chemotherapy is presented in **Table 3**.

Table 3: Distribution of children with ALL by phases of chemotherapy

Phases of chemotherapy	n=24	%
Induction	16	66.7
Consolidation	3	12.5
Interim maintenance	2	8.3
Delayed intensification re-induction	2	8.3
Long term maintenance	1	4.2
Total	**24**	**100.0**

The children on chemotherapy were undergoing various cycles of chemotherapeutics such as: methotrexate, doxorubicin, vincristine, L-Asparaginase, carboplastine, etoposide, daunorubicin, cytarabine, Actinomycin-D and others, as part of the various regimens based on their diagnoses.

4.3 Dental caries

For purposes of clinical evaluation, the children were stratified into two groups according to their dentition. Those in primary dentition were 3-5-year-olds, 57(55.9%), and those in mixed and permanent dentition were 6-12-year-olds, 45(44.1%).

4.3.1 Prevalence of dental caries

The overall prevalence of dental caries among the study participants was 58.8%. The prevalence of dental caries among the 3 – 5-year-olds was 49.1% while among the 6 – 12-year-olds was 71.1%. Age was statistically significantly associated with dental caries experience with children aged 6 – 12 years having a higher odds of dental caries compared to those aged 3 – 5 years (χ^2=5.020, df=1, p=0.025). With regards to gender, the male participants had a higher prevalence of dental caries (63.6%) than female participants (χ^2 =1.141, df = 1, p=0.285) as presented in **Table 4**.

Table 4: Prevalence of dental caries

Characteristic	Category	Caries prevalence				Pearson's Chi-Square		
		Present		Absent		χ^2	df	p-value
		n	%	n	%			
Gender	Male	35	63.6	20	36.4	1.141	1	0.285
	Female	25	53.2	22	46.8			
	Overall	**60**	**58.8**	**42**	**41.2**			
Age categories (years)	3 - 5	28	49.1	29	50.9	5.020	1	**0.025**
	6 - 12	32	71.1	13	28.9			
	Overall	**60**	**58.8**	**42**	**41.2**			

Statistical significant results with p-value ≤0.05

4.3.2 Dental caries experience by dentition

The dmft/DMFT was evaluated by the dentition. The mean dmft in the deciduous dentition was 2.33 while the mean dmft in mixed and permanent dentition was 2.78. The mean DMFT in permanent dentition was 0.33. With regards to gender, the mean dmft/DMFT was higher among the male participants as presented in **Table 5**.

Table 5: Dental caries experience

Characteristic	Category	d	m	f	dmft	ANOVA
		M ±SD	M ±SD	M±SD	M±SD	
Gender	Male	3.02 ±3.76	0.0	0.0	3.02±3.76	F(1,100)=2.38, p=0.126
	Female	1.94 ±3.07	0.0	0.02±0.15	1.96±3.08	
Characteristic	**Category**	**D**	**M**	**F**	**DMFT**	**ANOVA**
		M±SD	M±SD	M±SD	M ±SD	
Gender	Male	0.13 ±0.61	0.04±0.27	0.00	0.16±0.66	F(1,100)=0.67, p=0.796
	Female	0.06±0.32	0.0	0.06±0.44	0.13±0.74	

M±SD represents Mean ± Standard Deviation; dmft (decayed, missing, filling, teeth [primary]); DMFT, (Decayed, Missing, Filling, Teeth [permanent]). Statistical significant results with p value ≤0.05

Decayed teeth accounted for the highest component of the dmft and DMFT indices in both dentitions. This indicated that most teeth with dental caries were left untreated especially in the primary dentition as presented in **Table 6**.

Table 6: Distribution of decayed, missing or filled teeth per dentition

Category	DMFT components	N	%
		N = 429	
	D	10.00	2.33
Permanent dentition	M	2.00	0.47
	F	3.00	0.70
		N = 1787	**%**
	d	257.00	14.38
Primary dentition	m	0.00	0.00
	f	1.00	0.06

4.3.3 Prevalence of dental caries in relation to the cancer treatment

The prevalence of dental caries was evaluated in relation to the modality of cancer treatment. The children undergoing chemotherapy had a high prevalence of dental caries, although these were the majority of children. The prevalence of dental caries by cancer treatment modality is presented in **Table 7**.

Table 7: Dental caries prevalence by cancer treatment modalities

Characteristic	Category	Caries prevalence				Pearson's Chi-Square		
		Present		Absent		χ^2	df	p-value
		n	%	n	%			
Treatment modalities	CT alone	35	57.4	26	42.6	0.992	5	0.963
	CT and RT	4	57.1	3	42.9			
	RT alone	1	100	0	0.0			
	CT and Surgery	14	58.3	10	41.7			
	Surgery alone	2	66.7	1	33.3			
	CT, RT, & Surgery	4	66.7	2	33.3			
	Overall	**60**	**58.8**	**42**	**41.2**			

Statistical significant results with p value ≤0.05. CT – Chemotherapy , RT – Radiotherapy

4.4 Oral mucositis (OM)

OM is one of the most common complications of cancer therapy. For purposes of evaluation, the children were stratified into two age groups of 3 – 5 years and 6 – 12 years.

4.4.1 Prevalence of oral mucositis

The overall prevalence of mucositis was 28.4%. With regards to gender, the male participants had a slightly higher prevalence. However, this was not statistically significant ($\chi^2 = 0.026$, df =1, p=0.0873). With regards to age, 15(26.3%) of the children aged 3 – 5 years and 14(31.1%) of the 6-12-year-olds had mucositis as presented in **Table 8**.

Table 8: Bivariate comparisons of mucositis with gender and age

Characteristic	Category	Mucositis				Pearson's Chi-Square		
		Present		Absent				
		n	%	n	%	χ^2	df	p-value
Gender	Male	16	29.1	39	70.9	0.026	1	0.873
	Female	13	27.7	34	72.3			
	Overall	**29**	**28.4**	**73**	**71.6**			
Age categories (years)	3 – 5	15	26.3	42	73.7	0.284	1	0.594
	6 – 12	14	31.1	31	68.9			
	Overall	**29**	**28.4**	**73**	**71.6**			

Statistical significant results with p value ≤0.05

4.4.2 Prevalence of oral mucositis by cancer treatment modalities

The children were receiving varied cancer treatment modalities either in combination or on their own. Oral mucositis was most prevalent among the children receiving chemotherapy alone, 16(55.2%), followed by children who had undergone both surgery and chemotherapy, 5(17.2%)

The likelihood of developing OM increased with an increase in chemotherapy cycles received as presented in **Table 9** which shows 12(41.4%) children, who underwent more than six chemotherapy cycles had an increased incidence of OM. However, this was not statistically significant (p=0.856).

Table 9: Prevalence of mucositis by cancer treatment modalities

Characteristics	Category	Mucositis				Pearson's Chi-Square		
		Present		Absent				
		n	%	n	%	χ^2	df	p-value
Treatment combination	Chemotherapy alone	16	26.2	45	73.8	9.562	5	0.089
	Radiotherapy and Chemotherapy	4	57.1	3	42.9			
	Radiotherapy	0	0.0	1	100.0			
	Surgery and Chemotherapy	5	20.8	19	79.2			
	Surgery	0	0.0	3	100.0			
	Surgery, Radiotherapy and Chemotherapy	4	66.7	2	33.3			
	Overall	**29**	**28.4**	**73**	**71.6**			
Number of chemotherapy cycles	≤ 2	9	25.7	26	74.3	0.311	2	0.856
	3 - 5	8	29.6	19	70.4			
	6+	12	31.6	26	68.4			
	Overall	**29**	**28.4**	**73**	**71.6**			

Statistical significant results with p value ≤0.05

4.4.3 Severity of mucositis by WHO Mucositis Scale

The WHO Mucositis scale was used to grade the severity of mucositis. Most of the children with OM fell within Grade I and Grade II. Fourteen (13.7%) children had Grade II, 13(12.7%) had Grade I and 2(2%) had Grade III mucositis as presented in **Table 10**.

Table 10: Distribution of mucositis severity among the children

WHO grade of mucositis	Age categories (years)				Chi-square	
	3 - 5		6 - 12		χ^2 (df)	p-value
	N = 57	%	N = 45	%		
Grade 0	42	57.5%	31	42.5%	3.514 (3)	0.319
Grade I	6	46.2%	7	53.8%		
Grade II	9	64.3%	5	35.7%		
Grade III	0	0.0%	2	100.0%		
Grade IV	0	0.0%	0	0.0%		

Statistical significant results with p value ≤0.05

4.4.4 Oral mucositis severity in relation to cancer treatment modalities

The mucositis severity was higher among the study participants who were undergoing only chemotherapy which is presented in **Table 11**.

Table 11: Distribution of mucositis severity by cancer treatment modalities

	Cancer treatment combinations											
Mucositis Severity Grade	Chemotherapy only		Chemotherapy Radiotherapy		Radiotherapy only		Chemotherapy Surgery		Surgery only		Chemotherapy Radiotherapy Surgery	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Grade 0	45	61.6	3	4.1	1	1.4	19	26.0	3	4.1	2	2.7
Grade I	7	53.8	2	15.4	0	0.0	2	15.4	0	0.0	2	15.4
Grade II	7	50.0	2	14.3	0	0.0	3	21.4	0	0.0	2	14.3
Grade III	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade IV	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Overall	**61**	**59.8**	**7**	**6.9**	**1**	**1**	**24**	**23.5**	**3**	**2.9**	**6**	**5.9**

Spearman's rank-order correlation found no statistical significance between mucositis severity and cancer treatment among the children, ($\rho = 0.048$ and $p = 0.629$).

4.5 Oral hygiene status

In regards to the oral hygiene aids, the majority of the children, 84(84.8%), used a toothbrush and fluoridated toothpaste to clean their teeth, 15(14.3%) used a cloth and warm salty water, 2(2.2%) used a chew stick and 1(1.0%) child used wooden toothpicks.

The oral hygiene status was assessed by the presence of plaque. Turesky et al. modification of the Quigley-Hein Index was used to quantify plaque deposition on the buccal and lingual aspects. The plaque severity was then categorized as either mild 12(11.8%), moderate 57(55.9%), or severe 33(32.2%) depending on the amount of plaque covering the tooth surface

4.5.1 Plaque severity

All children 102(100%) had some level of plaque. More than half of the children, 57(55.9%) had moderate plaque accumulation as presented in **Table 12**.

Table 12: Plaque severity of the children

Characteristic	Category	n	%
Plaque severity	Mild plaque	12	11.8
	Moderate plaque	57	55.9
	Severe plaque	33	32.2
	Overall	**102**	**100.0**

4.5.2 Plaque score

The mean plaque score was evaluated by age and by gender. The plaque score was found to be slightly higher among the 3- 5 year olds (p=0.661). The plaque score was slightly lower among the female participants as presented in **Table 13**. However, gender was not statistically significant (p=0.246).

Table 13: Mean plaque score

Age categories (years)	Mean	Standard Deviation	ANOVA
3 - 5	3.91	0.99	ANOVA
6 - 12	3.82	1.07	F(1,100) = 0.194,
Total	3.87	1.02	p = 0.661
Gender	**Mean**	**Standard Deviation**	**t-Test**
Male	4.00	1.06	t= -1.167,
Female	3.76	0.98	df=100, p=0.246

Statistical significant results with p value ≤0.05

4.5.3 Plaque severity in children with mucositis

Eleven (37.9%) children with mucositis demonstrated high levels of plaque. However, plaque severity was not statistically significantly related to mucositis (χ^2=1783, df=4, p=0.776) as presented in **Table 14**.

Table 14: Plaque severity in children with mucositis

Characteristics	Category	Mucositis				Pearson's Chi-Square		
		Present		Absent				
		n	%	n	%	χ^2	df	p-value
Plaque severity	Mild	3	25.0	9	75.0	1.783	4	0.776
	Moderate	15	26.3	42	73.7			
	Severe	11	33.3	22	66.7			
	Overall	**29**	**28.4**	**73**	**71.6**			

Statistical significant results with p value ≤0.05

4.5.4 Plaque severity in children undergoing various cancer therapies

Children who were undergoing a combination of chemotherapy and surgery had poorer oral hygiene than their counterparts as presented comprehensively in **Table 15**.

Table 15: Oral hygiene status in children undergoing cancer treatment

Treatment combination	Plaque severity					
	Mild plaque		Moderate plaque		Severe plaque	
	n	%	n	%	n	%
Chemotherapy only	9	14.8	34	55.7	18	29.5
Radiotherapy and Chemotherapy	0	0.0	5	71.4	2	28.6
Radiotherapy only	0	0.0	1	100.0	0	0.0
Surgery and Chemotherapy	3	12.5	10	41.7	11	45.8
Surgery only	0	0.0	2	66.7	1	33.3
Surgery, Radiotherapy and Chemotherapy	0	0.0	5	83.3	1	16.7
Overall	**12**	**11.8**	**57**	**55.9**	**33**	**32.4**

4.6 Oral Health-Related-Quality of Life among 8 – 12 year olds

This aspect of the study was carried out among the 8-12-year-old children who were selected because of their age-related ability to speak, read, write, and think in abstract terms.[37] A total of 31 children, 22(71%) male and 9(29%) female, with a mean age of 10.3 $\pm$ 1.25 SD, answered the 8-item validated Child Perception Questionnaire regarding their perceived oral health.

4.6.1 Cancer treatment modalities

The most prevalent cancer within this age group was Acute Lymphocytic Leukaemia 6(19.4%). Most of the children, 24(77.4%), were undergoing only chemotherapy while

the rest, were undergoing combined cancer therapy such as chemotherapy in combination with surgery and/or radiotherapy.

4.6.2 Dental caries, oral mucositis and oral hygiene status

4.6.2.1 Dental caries

The prevalence of dental caries among the 8 – 12 year olds was 64.5%. The mean dmft was 2.23 ± 2.75 SD and DMFT was 0.48 ± 1.21 SD.

4.6.2.2 Oral mucositis (OM)

The prevalence of OM among the 8 – 12 years olds was 35.5%. These children had OM of varying degrees, with 6(19.4%) having Grade I, 4(12.9%) having Grade II mucositis and 1(9%) having Grade III; there was no child with Grade IV.

4.6.2.3 Oral hygiene status

Regarding their oral hygiene status, the majority, 20(64.5%), had moderate plaque accumulation with a mean plaque score of 3.59 ± 0.91 SD and 3.56 ± 1.42 SD among the male and female participants, respectively.

4.6.3 Perceived OHRQoL among the 8 – 12 year olds

The study participants were initially required to describe the state of their teeth and mouth as either very good, good, okay or poor. In regards to the state of their teeth, 12(38.7%) children described their teeth as very good, 5(16.1%) as good, 14(45.2%) as okay and no child reported the state of their teeth as poor. In regards to the state of their mouth, 10(32.3%) children described the health of their mouth as being very good. The rest of the responses were: 3(9.7%) good, 14(45.2%) okay and 4(12.9%) poor. The children then proceeded to answer the 8-item validated Child Perception Questionnaire regarding their perceived oral health in the domains of oral symptoms, functional limitation, emotional well-being and social wellbeing.

4.6.3.1 Oral Symptoms

The oral symptoms evaluated were pain in the teeth or mouth, and whether the child experienced food stuck in their teeth. In regards to experiencing pain in teeth or mouth, 13(41.9%) children never experienced pain in their teeth or mouth. In regards to experiencing food stuck in their teeth, 12(38.7%) reported that food stuck in their teeth sometimes.

4.6.3.2 Functional Limitation

The functional limitations evaluated were the child's difficulty in chewing hard food and the duration the child required to chew their food. Fourteen (45.2%) children never experienced a hard time biting or chewing food like carrots or meat, while 2(6.5%) children experienced a hard time very often. In regards to the duration required to chew food, 15(48.4%) children did not need a longer time than other to eat their meals, however, 2(6.5%) required a longer time very often. The distribution of responses in the two domains of oral symptoms and functional limitation are comprehensively presented in **Table 16**.

Table 16: Distribution of responses: oral symptoms and functional limitation

Characteristic	Category	n	%
Oral symptoms			
Pain in your teeth or mouth	Very often	6	19.4
	Often	4	12.9
	Sometimes	5	16.1
	Once or twice	3	9.7
	Never	13	41.9
Food stuck in your teeth	Very often	2	6.5
	Often	4	12.9
	Sometimes	12	38.7
	Once or twice	5	16.1
	Never	8	25.8
Functional limitation			
Had a hard time biting or chewing food like carrots or meat?	Very often	2	6.5
	Sometimes	9	29.0
	Rarely	3	9.7
	Once or twice	3	9.7
	Never	14	45.2
Needed longer time than others to eat your meal	Very often	2	6.5
	Often	5	16.1
	Sometimes	4	12.9
	Once or twice	5	16.1
	Never	15	48.4

4.6.3.3 Emotional wellbeing

The child's emotional well-being was evaluated by whether they were upset or unhappy with the state of their teeth or mouth. Sixteen (51.6%) children were never upset because of their teeth or mouth while 3(9.7%) children were upset often. Six (19.4%) children were often unhappy because of their teeth or mouth.

4.6.3.4 Social wellbeing

The social well-being was evaluated by the child's school attendance and their desire to speak to their peers as a result of the state of their teeth or mouth. Twenty three (74.2%) children missed school. Tha majority of children, 22(71%), reported that they never lacked the desire to talk to other children because of their teeth or mouth. The distribution of emotional and social well-being reponses are comprehensively presented in **Table 17**.

Table 17: Distribution of responses: emotional and social wellbeing

Characteristic	Category	n	%
Emotional wellbeing			
Been upset because of your teeth or mouth	Very often	3	9.7
	Often	4	12.9
	Sometimes	4	12.9
	Once or twice	4	12.9
	Never	16	51.6
Felt unhappy or lacked joy because of your teeth or mouth?	Very often	3	9.7
	Often	6	19.4
	Sometimes	0	0.0
	Once or twice	4	12.9
	Never	18	58.0
Social wellbeing			
Missed school because of pain, appointments or surgery related to your mouth or teeth	Very often	23	74.2
	Often	3	9.7
	Sometimes	0	0.0
	Once or twice	0	0.0
	Never	5	16.1
Not wanted to talk to other children because of your teeth or mouth	Very often	2	6.5
	Often	3	9.7
	Sometimes	3	9.7
	Once or twice	1	3.2
	Never	22	71.0

4.6.4 Dental caries, OM, cancer therapy and OHRQoL

Pearson's product-moment correlation showed no statistical significance between dental caries and oral symptoms (r = -0.105, p = 0.53), dental caries and functional limitation (r = 0.053, p = 0.776), dental caries and emotional wellbeing (r = 0.013, p = 0.943) and dental caries and social wellbeing (r = -2.03, p = 0.273). Overall, dental caries (r=-0.097, p=0.604) and OHRQoL were not statistically significant. Therefore, the null hypothesis that there is no association between dental caries and oral health-related quality of life in children undergoing cancer therapy is accepted. Moreover, the correlation between cancer therapy (r=-0.300, p=0.101) and the OHRQoL had no statistically significance as presented in **Table 18**.

Table 18: Pearson's product-moment correlation with OHRQoL

	n	Pearson's r	p-value
Dental Caries	31	-0.097	0.604
Oral Mucositis	31	-0.498	**0.004***
Cancer therapy	31	-0.300	0.101

Shows statistical significant results with p value ≤0.05

Spearman's correlation showed that there was a negative correlation between mucositis severity and oral symptoms (ρ = -0.426, p = 0.017), increasing mucositis severity was correlated with worse oral symptoms. There was a negative correlation between mucositis severity and emotional wellbeing (ρ = -0.486, p = 0.006), and a negative correlation between mucositis severity and social wellbeing (ρ = -0.540, p = 0.002).

Overall, mucositis (0=absent, 1=present), had a negative correlation with OHRQoL (r=-0.498, p=0.004) as illustrated in **Figure 6**. Therefore, the null hypothesis that there is no association between oral mucositis and OHRQoL was rejected.

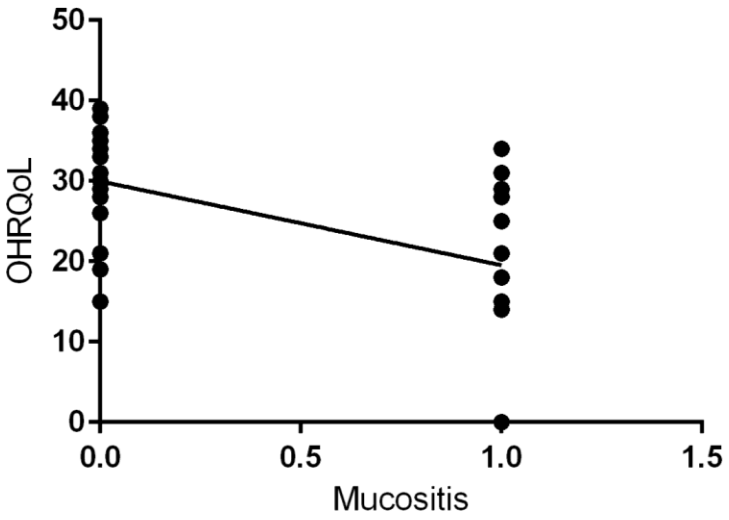

Fig 6: Linear Regression Model where R^2=0.2714, F(1, 29)=10.80, p=0.0027

CHAPTER 5: DISCUSSION

Children undergoing cancer therapy are reported to experience adverse and toxic oral effects as a result of their cancer treatment. The most common oral conditions in these children are dental caries and oral mucositis.[44,48,57] The current study evaluated the prevalence of dental caries, oral mucositis (OM) and the OHRQoL in children 3 – 12 years undergoing cancer therapy at KNH.

The most common malignancy among the children in this study was Acute Lymphocytic Leukaemia (23.5%), findings which mirrored American and North African studies.[8,98] However, this differed with an earlier Kenyan study done at MTRH that reported Non-Hodgkin's Lymphoma, of which Endemic Burkitt's lymphoma (eBL) falls under, as the most prevalent.[99] Epstein-Barr virus and *Plasmodium falciparum* malaria are considered co-factors that increase the risk of developing eBL and skewing of the geographical distribution of eBL cases.[100] In the present study, most of the children were from Nairobi, which is not malaria endemic. A subjective inference can then be made on the reduced number of eBL cases in this study based on great strides taken in malaria preventive strategies and geographical distribution of the study participants.[101]

The treatment of cancer is complex. Most children in the present study were undergoing chemotherapy alone or in combination with other modalities such as radiotherapy and/or surgery. Chemotherapy is a globally accepted cancer treatment modality for children with ALL as reported in studies.[102] According to the current KNH Paediatric oncology protocol, the children with ALL undergo 2 – 3 years of cancer treatment in the following phases of therapy: *Induction of remission* (1 month), *Consolidation of remission* (1.5 months), *Interim maintenance* (2 months), *Delayed intensification – re-induction* (1 month), *Delayed intensification – re-consolidation* (1 month), and *Maintenance* (2 years for females, 3 years for males).[103] In the present study, most children were in the induction phase of therapy. An explanation for this may be supported by literature. Remission induction is the first block of chemotherapy and patients are usually admitted for their initial treatment and laboratory investigations, but once complications have stabilized they may be discharged before the completion

of this phase with close outpatient follow-up and continuation of treatment as in the clinic.[104]

In the current study, 58.8% of the children had dental caries. This is higher than the 2015 Kenya National Oral Health report (23.9%), which assessed children in the general population. Similarly, a Sudanese study found the prevalence of dental caries in children undergoing cancer therapy to be 37.9%, a figure that was higher than the prevalence among children in the general Sudanese population (24%). [45,105] The findings of the current study were similar to a cross-sectional Caribbean study carried out among 71 paediatric oncology patients attending a national children's hospital in Trinidad. [106] The mean age of that study was 6 years with a range of 1 year to 15 years. Similarly, the most common malignancy was Acute lymphocytic leukaemia (39.1%), and patients were at varying stages of cancer treatment. The prevalence of visible dental caries was 54.3%, which is similar to findings in the current study.

Studies have shown that oral healthcare needs were the number one unmet health care need in children with systemic illnesses.[107] Children with cancer are more likely to develop dental caries for various reasons.[108] Certain risk factors were evident in this study. Only 2.9% of the children had a dental evaluation during cancer therapy. The children, therefore, had minimal access to preventive or therapeutic dental services. Dental caries is a dynamic biofilm-mediated infection. All the children had plaque of varying degrees with the majority having moderate plaque. Studies have shown that poor oral hygiene during cancer therapy[54] and microbial shift to cariogenic bacteria leads to reduced pH and decalcification of tooth structure.[19] Additionally, a majority of the children were on various chemotherapeutic agents, such as vincristine, cyclophosphamide, and fluorouracil which may cause a reduction in saliva flow.[109] The current study did not examine the changes in salivary flow rate, however, it can be inferred from the literature that CT and RT-induced xerostomia greatly increases a patient's risk for developing dental caries. Chemotherapy-induced febrile neutropenia is a severe hematological toxicity of cancer chemotherapy which blunts the inflammatory response of the innate immune system and allows bacterial multiplication and invasion.[109,110] Several studies have shown that neutrophils are recruited from saliva in individuals with dental caries due to the rise in Gram positive bacteria.[111,112,113] A study by McLachlan et al., reported an increased level of pro-inflammatory

cytokines, IL-1β and IL-8, in carious dental pulp.[114] It can be presumed that study participants with neutropenia may have a decreased immunological response to cariogenic and periogenic bacteria found in the dental biofilm further increasing their susceptibility to dental caries and gingival diseases.

The current study found the prevalence of oral mucositis at 28.4%. A wide variation of results has been obtained by several other investigators. Wahlin et al., found a higher percentage of oral mucositis (69%) in paediatric cancer patients.[115] In their prospective study, 26 children with acute leukaemia were all in the induction phase of chemotherapy at the University Hospital of Umea, Sweden. Ulcers were seen after 5- 10 days in hospital in five patients (23%), which then increased in number and severity as induction of chemotherapy progressed. The investigators, however, did not grade the severity of the lesions. A prospective study by Mendonça et al. enrolled seventy-one Brazilian children (mean age 7.8 years) with ALL who were undergoing cancer therapyand reported a 40% prevalence of oral mucositis.[59] The higher prevalence of oral mucositis in the two studies may have been higher than our study since they were prospective studies in design and recorded all the occurrences of mucositis during the study duration. The pattern of occurrence and resolution of mucositis is due to its pathophysiology. Oral mucositis arises 5 – 7 days after initiation of chemotherapy and certain chemotherapy drugs, such as doxorubicin, fluorouracil, or methotrexate, commonly cause oral mucositis.[116] Additionally, the current study included children with various cancers and at various phases of their cancer therapy, which may, to some extent, be responsible for the lower prevalence of mucositis. Whereas, the studies mentioned above solely concentrated on patients with leukaemia, who generally speaking, have a higher prevalence of oral manifestations during treatment.[117] In accordance to the KNH Paediatric Oncology Protocol, children have rest periods in between the phases of therapy which can last up to 2 weeks. Therefore, it is possible that some children were in the rest period of their cancer therapy, where mucositis would have resolved owing to its pathophysiology, or were in severe myelosuppression or had severe infection and therefore chemotherapy halted until the child is physiologically optimized to continue with cancer treatment. In the Caribbean study, the prevalence of oral mucositis was lower than in the present study, at 3%.[106] This demonstrates the wide variation in the results being obtained by authors further

demonstrating the pathophysiology, occurrence and resolution of oral mucositis during cancer treatment.

During the study, it was observed that all the children undergoing cancer treatment were on betadine mixed with normal saline for the prevention of OM. Additionally the children were on a mouth wash termed “magic mouthwash” which contains: lidocaine, chlorpheniramine, relcer gel (Aluminium, Magnesium , Simethicone, and deglycyrrhizinated liquorice) and dexamethasone. Dexamethasone is an anti-inflammatory agent.[118] It therefore reduces the levels of proinflammatory cytokines, such as TNF-α and IL-1β, thus contributing to reducing the occurrence of cancer therapy induced oral mucositis.[119] This may have contributed to the reduced prevalence of oral mucositis, at 24%.

In general, the occurrence oral mucositis and its severity of worsened as the number cancer treatment modalities and cancer treatment cycles received increased. A study by Ramon et al., reported the incidence of oral mucositis increased with the number of modalities used in cancer therapy.[120] An explanation for this may be the extensive mucosal injury due to combined chemotherapy and radiotherapy, further compounded by poor oral hygiene after surgery. In the current study, about a quarter of the children suffered from varying degrees of oral mucositis, the most prevalent being Grade I and Grade II. This was also reported in a Mexican study.[120] The highest frequency and severity of oral mucositis occurred in the 3-5-year age group in the current study. Younger children have higher odds of occurrence of chemotherapy-induced oral mucositis.[121] This phenomenon may be related to the rapid epithelial mitotic rate in the paediatric population as well as their immunosuppression. The variability in the severity of mucositis is one reason there may be under-reporting of its prevalence in cancer patients.

Oral care is the practice of keeping the oral cavity clean and healthy.[122] All children in the present study had plaque accumulation of varying severity and 89.7% of the children with oral mucositis had moderate to severe plaque accumulation. Dontasky et al., reported that the oral health status of hospitalized children diagnosed with cancers is generally poor.[123] In the present study, this could be associated with poor oral hygiene practices of the hospitalized children as well as the effects of the cancer treatment. A

study by Yan et al., assessed the oral health of children undergoing chemotherapy and found that the adverse effects of methotrexate had negative effects on oral hygiene.[124] Therefore, the poor oral hygiene among the children undergoing cancer therapy may be explained by them being hospitalized, having pain in their mouth due to the cancer therapy, and that the oral health needs are often left unmet in children with systemic illnesses.

This study also evaluated the OHRQoL among a selected group of patients. Thirty-one children (age 8 – 12 years) answered the CPQ_{8-10} questionnaire which assessed four domains: oral symptoms, functional limitations, emotional and social wellbeing. Children commonly begin abstract thinking from the age of six years and this allows self-reporting from this age on.[125]

In the current study, dental caries was not statistically associated with a reduced OHRQoL among the children (p=0.604). This result may be explained by its dynamic nature. A painful tooth may stop hurting if it becomes necrotic or the occurrence of a fistula may relieve the pressure and pain at the time of the study. Therefore the painful acute phase may have already passed at the point when data was collected. Additionally, when children live with a morbid condition such as cancer, they may disregard a slightly uncomfortable tooth as not painful since dental illness assumes a lower priority within the context the other health problems. Most children reported to have missed school. This may be due to the complexity of cancer treatment that necessisates hospitalization which results in missed school days.

There was a negative correlation between oral mucositis and OHRQoL (p=0.004), findings similar to Hendrawati et al., and Cheng et al., which confirm that mucositis worsens the quality of life of children with cancer in comparison to children with no oral mucositis. [126,127] Oral mucositis considerably affects the OHRQoL in terms of pain, ability to eat, swallow, and talk.[128] The symptoms of OM consist of objective symptoms (erythema,lesions), subjective changes (pain, sensitivity, dry feeling) and functional adjustment (changes of voice, gnawing and swallowing).[129] The findings of the present study echoed Sonis et al., who reported that severe mucositis had a major effect on well-being, and quality of life.[64] Children who experienced oral mucositis were disturbed physically, emotionally and socially. Interestingly, the study participants still had the

desire to socialize with their peers even while experiencing some of these adverse toxic oral effects. The study positis that playing and socializing with their peers may be a coping mechanism among these.

5.1 Conclusion

1. The overall prevalence of dental caries was 58.8%.
2. Age was associated with dental caries experience with children aged 6 – 12 years having a higher odds of dental caries and the mean dmft (2.33) was higher than the mean DMFT (0.33).
3. The prevalence of oral mucositis of 28.4%, with Grade I and Grade II being the most prevalent.
4. The likelihood of developing oral mucositis increased with the increase in cancer treatment modalities and increase in number of chemotherapy cycles.
5. Oral mucositis was associated with poor OHRQoL.

5.2 Recommendations

1. The sample size in the present study was small, therefore it is recommended that larger multi-centre studies may be carried out.
2. It would be beneficial for a dentist to be included in the multidisciplinary team in order to perform a pre-cancer treatment oral health status evaluation and provide preventive and curative oral health services to the hospitalized children.
3. Baseline data from the current study may help in the formulation of an oral health care protocol in order to provide preventive and curative oral health services for the hospitalized children undergoing cancer therapy.

5.3 Study Limitations

It was difficult to know the pre-existing dental and oral conditions before the commencement of cancer therapy as well as the rate of disease progression due to the cross-sectional nature of the study and the fact that nearly all children had not undergone dental evaluation before the commencement of cancer therapy. Consequently, a direct association between the malignancy or cancer therapy and the development or progression of dental caries could not be substantiated. The sample size

was small, therefore the results may not be generalized to all paediatric cancer patients undergoing cancer therapy in other institutions. Additionally there may have inter-proximal dental caries which were not clinically diagnosed due to the lack of x-rays.

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APPENDICES

Appendix 1: PROCEDURE FOR DONNING AND DOFFING PPE

Step 1: Hand hygiene: The Principal Investigator (PI) will perform hand hygiene using hospital alcohol-based solutions before wearing PPE while following the recommended WHO Steps of hand hygiene.

Step 2: PPE Gown – Before examining participants in a selected ward, the research PI will unpack individually packed re-usable water-resistant long-sleeved gown and shall don.

Step 3: Mask and Goggles - The PI shall then wear either an FFP (class 2 or 3) respirator mask or two surgical masks which they will adjust to fit at the nose followed by googles.

Step 4: Gloves - After the goggles, the gloves are next. The PI will wear gloves and extend them to cover the wrist over the gown's cuffs. These will be discarded and changed after examining each participant.

Step 5: Safe removal of gloves – The PI will remove the gloves, perform hand hygiene followed by wearing a new pair of gloves to prevent self-contamination and either continue with the next participant in the ward or further continue the doffing procedure.

After examining participants in each ward, the PI will remove (doff) the PPE as follows:

Step 6: Safe removal of the gown - With a new pair of gloves on, the gown should be removed. Removal is done by pulling the gown away from the body, keeping the contaminated front part inside the gown and then placed in a yellow biohazard bag for safe transportation to the University of Nairobi Dental Hospital CSSD unit for disinfection.

Step 7: Safe removal of goggles - After the gown, the goggles should be removed for disinfection with cotton and surgical spirit.

Step 8: Safe removal of gloves – The PI will then use an alcohol-based hand sanitiser first and then remove the gloves following the procedure described above. After glove removal, hand hygiene will be performed again.

Appendix 2: QUESTIONNAIRE

Modification of the WHO Oral Health Questionnaire for Children and the Child Perception Questionnaire (CPQ_{8-10}).

Date: ……... Identification number | | | |

PART I: PATIENT MEDICAL INFORMATION

To be completed by Principle Investigator.

1. Ward _____
2. Sex *(Tick one)* BOY ___ GIRL ___
3. Date of Birth Date ____Month____Year ____
4. Age in years _____
5. County of Origin _____
6. Primary malignancy of the child _____
7. Date of confirmed diagnosis Date ____Month____Year ____
8. Method of confirmation _____
9. Cancer therapies received *(Tick those received)*
   Surgery ____
   Radiotherapy _____
   Chemotherapy ____
   Other _____
   (Name the procedure/therapy)
10. Name of the Surgical procedure ……
    (Applies ONLY to those who have undergone surgical cancer therapy)
11. Chemotherapy regimen ……
    (Applies ONLY to those who are undergoing chemotherapy. Name of medications and number of cycles) ……
    ……
    ……
    ……
12. Radiotherapy regimen
    (Applies ONLY to those who have received radiotherapy)
    a. Radiotherapy cycles
    Number of cycles received ____out of___
    Within 10 days ☐
    10 – 21 days ☐
    More than 21 days ☐

b. Date of Last Radiation cycle week ……

c. Dosage of Radiotherapy per cycle ….

d. Total Dosage of RT ……..

13. Dental Evaluation by a Dentist before cancer therapy *(Tick one)*
    Performed _____
    Not performed _____

If not referred, skip to number 16.

14. Reason for Dental Evaluation
    Pain ____
    Swelling ____
    Cavity ____

15. Referred by:
    Doctor ____
    Nurse ____
    Clinical Officer ____
    Other (Please state)
    _____

16. Dental Evaluation by a Dentist during cancer therapy (Tick one)
    Performed _____
    Not performed _____

17. Neutropenia (Tick one)
    Most Recent Full Haemogram Y _ N _

First, I would like to ask you a few questions about yourself and your family. Please tick (✓) the most appropriate option.

PART II: SOCIO-DEMOGRAPHIC AND FOOD INTAKE (ENGLISH)

1. **Caregiver:** Mother ☐ Father ☐ Aunty ☐
   Uncle ☐ Grandparent ☐ Other ☐

2. Marital status of the caregiver:

Married ..... ☐
Single ..... ☐
Separated ..... ☐
Divorced ..... ☐
Widowed ..... ☐

3. Caregiver level of education?

No formal education ☐ Primary School ☐
Secondary School ☐ Technical College ☐ University ☐

4. Does your child use any of the following to clean their teeth? (State each item)

	Yes (1)	No (2)
Toothbrush	☐	☐
Wooden toothpicks	☐	☐
Plastic toothpicks	☐	☐
Thread (*dental floss*)	☐	☐
Charcoal	☐	☐
Chew stick/mswaki	☐	☐
Other	☐	☐

5. Does your child use toothpaste while cleaning their teeth?

Yes ..... ☐ 1
No ..... ☐ 2

6. **How often does your child eat or drink any of the following foods, even in small quantities?** *(Read each item and tick ✓)*

	Several times a day	Every day	Several Times a week	Once a week	Several times a month	Never
	6	5	4	3	2	1
Fresh fruit	☐	☐	☐	☐	☐	☐
Biscuits, cakes, cream cakes, ngumu, buns etc.	☐	☐	☐	☐	☐	☐
Juice, soda or other soft drinks	☐	☐	☐	☐	☐	☐
Jam/honey	☐	☐	☐	☐	☐	☐
Chewing gum containing sugar	☐	☐	☐	☐	☐	☐
Sweets/candy	☐	☐	☐	☐	☐	☐
Milk with sugar	☐	☐	☐	☐	☐	☐
Tea with sugar	☐	☐	☐	☐	☐	☐

Children above 8 Years to complete Part III:

Now, we would like you to answer some questions concerning yourself and your teeth.

PART III: ORAL HEALTH-RELATED QUALITY OF LIFE

7. How would you describe the state of your teeth and mouth?

	Teeth	Mouth
Very Good.....	☐	☐
Good	☐	☐
Okay….	☐	☐
Poor	☐	☐

During the last 3 months, how often have you had:

8. Oral Symptoms:

a. Pain in your teeth or mouth?

Very often..... ☐
Often……..... ☐
Sometimes..... ☐
Once or twice..... ☐
Never……..... ☐

b. Food stuck in your teeth?

Very often..... ☐
Often……..... ☐
Sometimes..... ☐
Once or twice..... ☐
Never……..... ☐

9. Functional Limitation:

a. Had a hard time biting or chewing food like carrots or meat?

Very often..... ☐
Sometimes……..... ☐
Rarely ..... ☐
Once or twice..... ☐
Never……..... ☐

b. Needed a longer time than others to eat your meal?

Very often..... ☐
Often……..... ☐
Sometimes..... ☐
Once or twice..... ☐
Never……..... ☐

10. Emotional wellbeing:

a. Been upset because of your teeth or mouth?

Very often..... ☐
Often……..... ☐
Sometimes..... ☐
Once or twice..... ☐
Never……..... ☐

b. Felt lack of joy or happiness because of your teeth or mouth?

Very often..... ☐
Often……..... ☐
Sometimes ..... ☐
Once or twice..... ☐
Never……..... ☐

11. Social Wellbeing:

a. Missed school because of pain, appointments, or surgery related to your mouth or teeth?

Very often..... ☐
Often……..... ☐
Sometimes ..... ☐
Once or twice..... ☐
Never……..... ☐

b. Not wanted to talk to other children because of your teeth or mouth?

Very often..... ☐
Often……..... ☐
Sometimes ..... ☐
Once or twice..... ☐
Never……..... ☐

That completes our interview thank you very much for your cooperation.

HOJAJI

Hojaji ya WHO iliyorekebishwa kuhusu Afya ya Meno kwa watoto na Hoaji ya Mtazamo wa Mtoto (CPQ_{8-10}).

Tarehe: ……... Nambari ya utambulisho | | | |

SEHEMU YA I: TAARIFA ZA MATIBABU YA MGONJWA

Kukamilishwa na mtafiti mkuu.

1. Wodi ya hospitali _____
2. Uana wa mtoto Mvulana ___ Msichana ___
3. Tarehe ya kuzaliwa Tarehe ___Mwezi_____Mwaka ____
4. Umri (miaka) _____
5. Nchi ya asili _____
6. Uovu wa msingi wa mtoto _____
7. Tarehe ya utambuzi uliothibitishwa Tarehe _____Mwezi_____Mwaka ___
8. Njia ya uthibitisho _____
9. Tiba ya saratani imepokelewa
   (Bainisha kila kimoja)
   Upasuaji ____
   Radiotherapy _____
   Chemotherapy _____
   Nyingine _____
   (Taja utaratibu / tiba)
10. Jina la utaratibu wa upasuaji
    (Inatumika kwa wale tu ambao wamepata tiba ya saratani ya upasuaji)
    ……..……..……
11. Aina ya Chemotherapy
    (Inatumika kwa wale tu ambao wanapata chemotherapy. Jina la dawa na idadi ya mizunguko (cycles))
    ……
    ……
    ……
    ……
    ……
12. Radiotherapy
    (Inatumika kwa wale tu ambao wamepokea matibabu ya radiotherapy)
    Idadi ya mizunguko iliyopewa_ idadi kamili ___
    e. Radiotherapy cycles
    Ndani ya siku 10 ☐
    10 – 21 (siku) ☐
    Zaidi ya siku 21 ☐
    f. Tarehe ya matibabu ya mwisho _____

g. Kipimo cha Radiotherapy kwa kila mzunguko _____

h. Kipimo cha jumla cha RT _____

13. Tathmini ya meno na Daktari wa meno kabla ya tiba ya saratani (chagua moja)
Imefanywa _____
Haikutekelezwa _____

Ikiwa haikutajwa, ruka kwa nambari 16.

14. Sababu ya Tathmini ya Meno
Maumivu ___
Kufura ___
Shimo kwa meno ___

15. Mtaalamu ambaye alielezea:
Daktari ___
Muuguzi ___
Afisa wa Klinic (Clinical officer)___
Nyingine (Tafadhali taja)_____

16. Tathmini ya meno na Daktari wa meno wakati wa tiba ya saratani (chagua moja)
Imefanywa _____
Haikutekelezwa _____

17. Neutropenia (chagua moja)
Matokeo ya Hivi Karibuni ya Full Haemogram Ndio _ La _

Mwanzo, ningependa ujibu maswali kadhaa kuhusiana nawe na familia yako. Tafadhali onyesha alama ya (✓) kwa jibu unalokubaliana nalo zaidi.

SEHEMU YA II: DATA KUHUSU TAARIFA ZA KIJAMII NA MARUDIO YA ULAJI WA CHAKULA

1. **Mlezi:** Mama ☐ Baba ☐ Shangazi ☐

   Mjomba ☐ Babu/Nyanya ☐ Mwingine ☐

2. Hali yako ya ndoa:

Nimeoa ..... ☐

Sijaoa..... ☐

Tumetengana ..... ☐

Tumetalikiana..... ☐

Mjane ..... ☐

3. Kiwango cha uhitimu wa masomo cha mlezi?

Sina elimu ya shule ☐ Shule ya msingi ☐

Shule ya sekondari, ☐ Chuo anuawai ☐ Chuo Kikuu ☐

4. Je, wewe hutumia gani kati ya vifuatavyo kusafisha meno yako? (*Bainisha kila kimoja*)

	Ndiyo (1)	La (2)
Brashi ya meno	☐	☐
Vichokonoo vya mti	☐	☐
Vichokonoo vya plastiki	☐	☐
Uzi (*Dental floss*)	☐	☐
Mkaa	☐	☐
Mswaki (*Chew stick*)	☐	☐

Nyingineyo …….

5. Je, wewe hutumia dawa ya kusugua meno unaposafisha meno yako?

Ndiyo ☐ 1

La ☐ 2

6. Ni kwa mara ngapi wewe hula au kunywa aidha mojawapo ya vyakula vifuatavyo, hata kama ni kwaviwango vidogovidogo?

(Soma kila jibu na kuweka ala ya ✓)

	Mara nyingi kwa siku	Kila siku	Mara nyingi kwa wiki	Mara moja kwa wiki	Mara moja kwa mwezi	Hamna kamwe
	(6)	(5)	(4)	(3)	(2)	(1)
Sharubati ya matunda mapya	☐	☐	☐	☐	☐	☐
Biskuti, keki, keki za krimu, "ngumu", mandazi n.k	☐	☐	☐	☐	☐	☐
Juisi, Soda, ama vinywaji vingineyo baridi/vitamu	☐	☐	☐	☐	☐	☐
Jamu/asali	☐	☐	☐	☐	☐	☐
Chingramu za kutafuna za sukari	☐	☐	☐	☐	☐	☐
Switi/peremende	☐	☐	☐	☐	☐	☐
Maziwa yenye sukari	☐	☐	☐	☐	☐	☐
Chai yenye sukari	☐	☐	☐	☐	☐	☐

Watato waliopita miaka 8 kujaza sehemu ya III:

Sasa tungependa ujibu maswali kadhaa yanayokuhusu wewe na meno yako.

SEHEMU YA III: UBORA WA MAISHA KUAMBATANA NA HALI YA AFYA YA MDOMO

10. Unaweza kuelezea meno na mdomo wako kuwa katika hali gani?

	Meno	Mdomo
Nzuri zaidi.....	☐	☐
Nzuri	☐	☐
Bora ….	☐	☐
Duni	☐	☐

Katika miezi 3 iliyopita, ni kwa mara ngapi umekumbana na:

11. Dalili zinazodhihirika katika mdomo:

a. Uchungu kwenye meno au mdomo?

Mara kwa mara..... ☐
Sana……..... ☐
Wakati mwingine..... ☐
Mara moja au mbili..... ☐
Hamna kamwe..... ☐

b. Vyakula vinavyobaki kweny meno yako?

Mara kwa mara ……..... ☐
Sana ……..... ☐
Wakati mwingine …..... ☐
Mara moja au mbili ..... ☐
Hamna kamwe..... ☐

12. Upungufu/chanagamoto katika utendaji

a. Umetatizika kuuma ama kutafuna vyakula kama karoti au nyama?

Mara kwa mara..... ☐
Wakati mwingine..... ☐
Kwa nadra ……..... ☐
Mara moja au mbili..... ☐
Hamna kamwe..... ☐

b. Ulihitaji muda mrefu zaidi ya wengine kula chakula chako?

Mara kwa mara ..... ☐
Sana ……..... ☐
Wakati mwingine..... ☐
Mara moja ama mbili ..... ☐
Bado kamwe……..... ☐

13. Ustawibora kwa kigezo-hisia:

a. Umesikitika kwa sababu ya meno au mdomo wako?

Mara kwa mara ..... ☐
Sana ……..... ☐
Wakati mwingine..... ☐
Mara moja ama mbili..... ☐
Bado kamwe ..... ☐

b. Umehisi kufadhaika kwa sababu ya meno au mdomo wako?

Mara kwa mara..... ☐
Sana ……..... ☐
Wakati mwingine..... ☐
Mara moja ama mbili..... ☐
Bado kamwe ……..... ☐

14. Ustawibora kwa kigezo-jamii:

a. Umekosa kuhudhuria masomo kutokana na maumivu, miadi ya daktari, au upasuaji kwa sababu ya meno au mdomo wako?

Mara kwa mara ..... ☐
Sana ……..... ☐
Wakati mwingine..... ☐
Mara moja ama mbili..... ☐
La hasha…..... ☐

b. Hukujihisi kutaka kuwaongelesha watoto wengine kwa sababu ya meno au mdomo wako?

Mara kwa mara ..... ☐
Sana ……..... ☐
Wakati mwingine ..... ☐
Mara moja ama mbili ..... ☐
Bado kamwe ..... ☐

Na huu ndio mwisho wa mahojiano yetu, ahsante sana kwa ushirikiano wako

Appendix 3: CLINICAL EXAMINATION FORM

(Modified from WHO Oral Health Assessment form for Children, 2013)

Date: ……. **Identification Number:** | | | |

DENTAL CARIES ASSESSMENT

Indicate the code in the shaded regions.

17	16	15	14	13	12	11	21	22	23	24	25	26	27
		55	54	53	52	51	61	62	63	64	65		
		85	84	83	82	81	71	72	73	74	75		
47	46	45	44	43	42	41	31	32	33	34	35	36	37

TOOTH STATUS	CODE FOR DECIDUOUS TEETH	CODE FOR PERMANENT TEETH
Sound	A	1
Decayed	B	2
Filled with D=decay	C	3
Filled with no decay	D	4
Missing as a result of caries	E	5
Sealant varnish	F	6
Bridge abutment or special crown	G	7
Unerupted	H	8
Not recorded	I	9

ORAL MUCOSITIS ASSESSMENT

The World Health Organization Oral Toxicity Scale measures the anatomical, symptomatic, and functional elements of Oral Mucositis shown in **Table 19** and Fig 7.[19]

Table 19: Grading of Oral Mucositis

Score	Description
Grade 0	Absence of mucositis.
Grade 1	Erythema and generalized oedema of the mucosa, but no pain.
Grade 2	Deep ulcerative lesions are not extensive and cause slight pain; the swallowing of solids is still possible.
Grade 3	Ulcers are extensive, the gums are markedly oedematous, and the saliva is very thick; there is moderate pain and only liquids can be swallowed.
Grade 4	Ulcers are more extensive, bleeding gums and infection are observed, saliva is absent, pain is very intense, and discomfort prevents the patient from ingesting solids and liquids

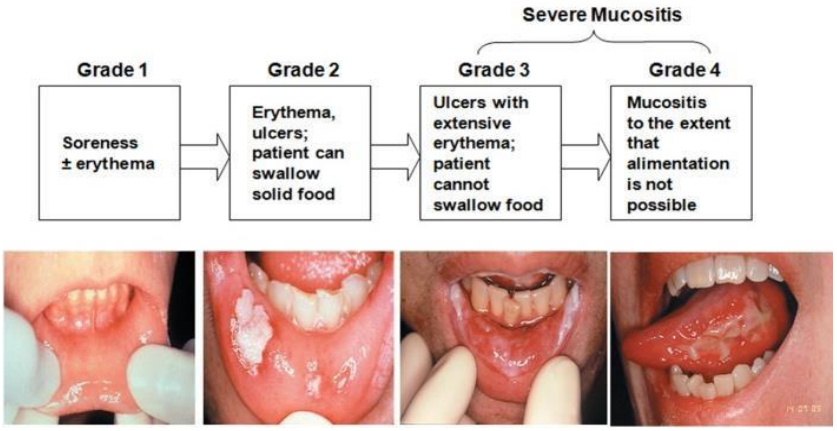


Fig 7: WHO Oral Toxicity Scale

1. Select the Cancer therapy received within the last 6 weeks **(Select <u>all</u> that apply ✓)**

Chemotherapy ☐ **Radiotherapy** ☐ **Surgery** ☐ **Other** _____

2. WHO Grade of mucositis **(Select <u>one</u> option ✓)**

Grade 0 ☐

Grade I ☐

Grade II ☐

Grade III ☐

Grade IV ☐

ORAL HYGIENE STATUS ASSESSMENT

(Plaque score - Turesky et al. Modification of the Quigley-Hein Index)

	R		A		L	
F						
L						
F						
L						

R – Right

A – Anterior

L – Left

F – Facial

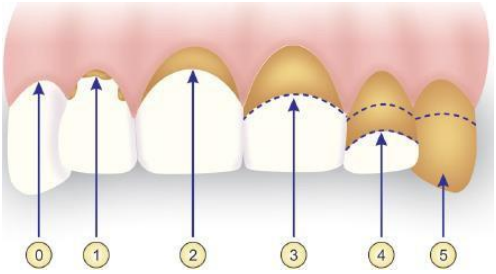
L – Lingual

TOTAL SCORE _____

MEAN SCORE _____

PLAQUE SCORE _____

KEY: Criteria for classifying debris



0	No plaque
1	Separate flecks of plaque at the cervical margin
2	Thin continuous band of plaque of 1mm at the cervical margin of the tooth
3	Plaque covering more than 1mm but less than 1/3 of the tooth
4	Plaque covering 1/3 but less than 2/3 of the tooth
5	Plaque covering 2/3 or more of the tooth

Appendix 4: CONSENT FORM

Date: ……. **Identification Number: ……..**

PRINCIPAL INVESTIGATOR'S STATEMENT

I, Dr. Diana Okello, am pursuing a Masters of Dental Surgery in the department of Paediatric Dentistry and Orthodontics, at the University of Nairobi, Kenya. I would like to seek your consent for your child's participation in a study aimed at determining the prevalence and effect of dental caries and oral mucositis on the daily activities of your child. Dental caries and oral mucositis are very common oral complications in children undergoing cancer therapy. The information I get will be useful in providing baseline clinical information. It may also assist health workers to consider the oral health quality of life of children undergoing cancer therapy. Ethical approval to carry out this project will be sought from Kenyatta National Hospital and UON Ethics and Research Committee (KNH – UON ERC).

STUDY PROCEDURES

I will record the child's medical history in a patient medical datasheet. The parent/guardian will be asked some questions regarding the family as well as the food frequently consumed. The Children above 8 years of age will be asked a few questions about the mouth and teeth and how these problems interfere with his/her day to day activities. I shall then examine your child's mouth and record some observations. The examination will be carried out here in the ward, using clean and sterile instruments and no invasive procedure shall be done. Any child who requires dental treatment shall be referred to the Dental clinic at Kenyatta National Hospital.

ANTICIPATED RISKS

There are no foreseeable risks in participating in this study.

CONFIDENTIALITY

The information in the study will be kept in strict confidence. No information, by which your child's identity can be revealed, will be released or published.

VOLUNTARISM OF PARTICIPATION

Your child's participation in this study is voluntary.

RIGHT OF WITHDRAWAL

After you sign the consent form, you are still free to withdraw at any time and without giving a reason.

CONSENT

I, ... have read, and I understand the provided information and have had the opportunity to ask questions. I hereby consent that my child may participate in the proposed research. I understand that my child's participation is voluntary and that I am free to withdraw him/her at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form.

Parent's / Guardian's signature **Date**

_____ _____

For more information, please contact:

Dr. Diana Alice Okello
Principle Investigator
Telephone: +254712133980
Email: dr.dianaokello@gmail.com

Dr. Marjorie Muasya
Supervisor
Telephone: +254714575258
Email: marjoriemuasya@gmail.com

The Chairperson,
Kenyatta hospital/ University of Nairobi Ethics
and Research Committee,
Email: uonknh_erc@uonbi.ac.ke
Tel: 00202 726300-9

FOMU YA IDHINI

Tarehe: …… Nambari ya utambulisho: ……..

TAARIFA YA MTAFITI MKUU

Mimi Dkt. Diana Okello, nasomea shahada ya Uzamili katika Tiba na Upasuaji wa meno kwenye idara ya Utabibu wa meno na Uzuiaji/urekebisho wa matatizo ya ukuaji usio wa kawaida wa meno (orthodontics) ya watoto katika Chuo Kikuu cha Nairobi, Kenya. Ningependa kuomba idhini yako ya kumruhusu mwanao kushiriki katika utafiti ambao unalenga kutathmini kiwango enezi cha uozo wa meno na vidonda vinavyomonyosha viungo vya ndani mwa mdomo (mucusitis) na athari zao katika shughli za kila siku kwa mwanao. Uozo wa meno na vidonda vinavyomonyoa viungo vya ndani mwa mdomo (mucusitis) ni matatizo ya mara kwa mara miongoni mwa watoto wanaopitia tiba ya saratani. Taarifa nitakayokusanya itakuwa muhimu kwa uendelezaji wa taarifa msingi za kimatibabu. Inaweza pia kuwasaidia wafanyikazi wa afya kukadiria kiwango cha ubora wa afya ya meno kwa watoto wanaoendelea na tiba ya saratani. Idhini ya kimaadili ya kuendeleza utafiti huu itaombwa kutoka Hospitali ya Kitaifa ya Kenyatta na Kamati ya Kimaadili na Utafiti ya Chuo Kikuu cha Nairobi (KNH – UoN ERC).

TARATIBU ZA UTAFITI

Nitaandika historia ya matibabu ya mtoto kwenye karatasi ya data ya matibabu ya mgonjwa. Mzazi / mlezi ataulizwa maswali kadhaa juu ya familia na pia chakula kinachotumiwa mara kwa mara. Watoto walio juu ya miaka 8 wataulizwa maswali machache juu ya mdomo na meno na jinsi shida hizi zinaingiliana na shughuli zake za kila siku. Uchunguzi utafanywa hapa kwenye wodi kwa kutumia vyombo safi kabisa na vilivyokingwa na uambukizi wowote. Mtoto yeyote atakayehitaji matibabu ya meno, atatumwa kwenye kliniki ya meno ya Hospitali ya Kitaifa ya Kenyatta.

HATARI ZINAZOTAZAMIWA

Hamna hatari zinazotarajiwa kukukumba kwa kushiriki kwako katika utafiti huu

USIRI

Taarifa kutokana na utafiti huu zitahifadhiwa kwa usiri wa hali ya juu. Hamna habari zozote zinazowezesha kumtambulisha mwanao zitakazowekwa wazi, kutolewa wala kuchapishwa.

HIARI YA KUSHIRIKI

Ushiriki wa mwanao katika utafiti huu ni wa kujitolea kwa hiari.

HAKI YA KUJIONDOA

Baada ya kutia sahihi fomu ya idhini, ungali huru kujiondoa na pasipo/bila ya kutoa sababu.

IDHINI

Mimi,…..... nimekwishaso ma, na kuelewa taarifa zilizotolewa na kupata fursa ya kuuliza maswali. Hivyo natoa idhini kuwa mwanangu anaweza kushirikishwa katika utafiti unaopendekezwa. Ninaelewa kuwa ushiriki wa mwanagu ni kwa hiari na niko huru kumwondoa wakati wowote ule bila ya kutoa sababu yoyote na bila ya kulipia gharama. Ninaelewa kwamba nitapokezwa nakala ya fomu hii ya idhini.

Sahihi za mzazi/mlezi _____ **Tarehe** _____

Kwa taarifa zaidi, wasiliana na:

Dkt. Diana Alice Okello
Mtafiti mkuu
Simu: +254712133980
Anwani pepe: dr.dianaokello@gmail.com

Dkt. Marjorie Muasya
Msimamizi
Simu: +254714575258
: marjoriemuasya@gmail.com

Mwenyekiti,
Kenyatta hospital/ University of Nairobi Ethics and Research Committee,
Anwani pepe: uonknh_erc@uonbi.ac.ke
Simu:: 00202 726300-9

Appendix 5: CHILD ASSENT FORM

Date: ……. Identification number: ……...

My name is Dr. Diana Okello. I would like to learn more about how the cavities in your teeth and how the pain in your mouth affect you. If you would like, you can be in my study. If you decide to be in my study, I will ask some questions about yourself and your parent/guardian, and then I will look into your mouth and write down what I see. I will use a clean mirror to look at your teeth and you will not experience any pain. I will also check your hospital file to know more about your illness. The process will help you because I will be able to identify the problems in your mouth and advice you on how to care for your teeth and your mouth. If I find problems, I will refer you to the Kenyatta National Hospital dental clinic where you can be treated. Other people will not know that you are in my study. I will not use your name. Your parents have to permit me to include you in my study. After they decide, you get to choose if you want to do it or not. If you do not want to be in the study, no one will be mad at you. If you want to be in the study and later change your mind, that is ok. You can stop at any time. Before you say YES to being in the study, I will answer whatever questions you may have. I will also give you a copy of this form in case you want to ask questions later.

VOLUNTARISM OF PARTICIPATION

Your participation in this study is voluntary.

RIGHT OF WITHDRAWAL

You are still free to withdraw at any time and without giving a reason.

AGREEMENT

I have decided to be in the study even though I know that I don't have to do it.

Finger print of Study Participant ……...… Date ……

Signature of Researcher …….. Date ……

For more information, please contact:

Dr. Diana Alice Okello
Principle Investigator
Telephone: +254712133980
Email: dr.dianaokello@gmail.com

Dr. Marjorie Muasya
Supervisor
Telephone: +254714575258
Email: marjoriemuasya@gmail.com

The Chairperson,
Kenyatta hospital/ University of Nairobi Etl ics and Research Committee,
Email: uonknh_erc@uonbi.ac.ke
Tel: 00202 726300-9

FOMU YA KUMTATHMINI MTOTO

Tarehe: ……. Nambari ya utambulisho: ……...

Jina langu ni Dkt. Diana Okello. Ningependa kujifahamisha zaidi na namna vijishimo kwenye meno yako na uchungu mdomoni mwako zinavyokuathiri. Kama unakubali unaweza kushiriki katika utafiti wangu. Ikiwa umeamua kushiriki katika utafiti wangu, nitakuuliza maswali kadhaa kukuhusu wewe na pia mzazi/mlezi wako, kisha ntatazama ndani mwa mdomo wako na kunakili yale amabayo nitayaona. Nitatumia kioo safi kuyatazama meno yako na hutahisi uchungu wowote. Pia nitaangalia faili yako ya hospotali ili kuelewa zaidi kuhusu kuugua kwako. Mchakato huu utakusaidia kwakuwanitaweza kubainisha matatizo mdomoni mwako na kukushauri jinsi ya kutunza meno na mdomo wako. Ikiwa nitatambua matatizo, nitakutuma kwenye kliniki ya meno katika Hospitali ya Kitaiifa ya Kenyatta. Watu wengine hawatapata kujua ya kwamaba wewe unashiriki katika utafiti wangu. Sitalitumia jina lako. Wazazi wako ni sharti wanipatie idhini ya kukushirikisha katika utafiti wangu. Baada ya wao kuamua, basi utachagua ikiwa unataka kushiriki au sivyo. Ikiwa hutaki kushiriki katika utafiti, hamna mtu atakayekukufokea. Ikiwa unataka kushiriki katika utafiti na hatimaye ubadilishe wazo lako, itakuwa tu sawa. Unaweza kujiondoa wakati wowote. Naam, Kabla hujakubali NDIYO kushirikishwa katika utafiti huu, nitajibu swali lolote ambalo huenda ukawa nalo. Nitakupatia pia nakala ya fomu hii, iwapo ungependa kuuliza maswali baadaye.

HIARI YA KUSHIRIKI

Ushiriki wako katika utafiti huu ni wa kujitolea kwa hiari.

HAKI YA KUJIONDOA

Ungali huru kujiondoa na pasipo/bila ya kutoa sababu.

MAAFIKIANO

Nimeamua kushiriki katika utafiti ingawa najua sio sharti.

Alama za vidole vya mshiriki wa utafiti: …… Tarehe:……

Sahihi ya mtafiti: …….. Tarehe:……

Kwa taarifa zaidi, wasiliana na:

Dkt. Diana Alice Okello
Mtafiti mkuu
Simu: +254712133980
Anwani pepe: dr.dianaokello@gmail.com

Dkt. Marjorie Muasya
Msimamizi
Simu: +254714575258
: marjoriemuasya@gmail.com

Mwenyekiti,
Kenyatta hospital/ University of Nairobi Ethi cs and Research Committee,
Anwani pepe: uonknh_erc@uonbi.ac.ke
Simu:: 00202 726300-9

Appendix 6: REFERRAL FORM

Dear Parent/Guardian of .....(Name of child),

Having seen your child during this oral health survey, he/she would benefit from a more detailed examination/evaluation.

We found that he/she has _____ and will need further evaluation. Kindly arrange and take him/her to the Kenyatta National Hospital Dental department to seek dental care.

Principal Investigator: …… Date: ……

Appendix 7: KNH-ERC APPROVAL

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/453

24th November 2021

Dr. Diana Alice Okello
Reg. No.V60/11167/2018
Paediatric Dentistry and Orthodontics Unit
Dept.of Dental Sciences
Faculty of Health Sciences
University of Nairobi

Dear Dr. Okello

RESEARCH PROPOSAL: PREVALENCE OF DENTAL CARIES, MUCOSITIS AND ORAL-HEALTH-RELATED-QUALITY 0F-LIFE IN 3-12 YEAR-OLD CHILDREN UNDERGOING CANCER THERAPY AT KENYATTA NATIONAL HOSPITAL (P796/010/2021)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P796/10/2021.** The approval period is 24th November 2021 – 23rd November 2022.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely

PROF. M.L. CHINDIA
SECRETARY, KNH-UON ERC

c.c. The Dean-Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Dept. of Dental Sciences, UoN
Supervisors: Prof. Mary A. Masiga, Paediatric Dentistry and Orthodontics Unit, UoN
Dr. Marjorie Muasya, Paediatric Dentistry and orthodontics Units, UoN

Appendix 8: NACOSTI RESEARCH PERMIT

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **506245**

Date of Issue: **07/December/2021**

RESEARCH LICENSE

This is to Certify that Dr.. DIANA Alice OKELLO of University of Nairobi, has been licensed to conduct research in Nairobi on the topic: PREVALENCE OF DENTAL CARIES, MUCOSITIS AND ORAL-HEALTH-RELATED- QUALITY-OF-LIFE IN 3 – 12-YEAR-OLD CHILDREN UNDERGOING CANCER THERAPY AT KENYATTA NATIONAL HOSPITAL for the period ending : 07/December/2022.

License No: **NACOSTI/P/21/14808**

506245

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

Appendix 9: AUTHORITY TO COLLECT DATA

KENYATTA NATIONAL HOSPITAL
P.O. BOX 20723, 00202 Nairobi

Tel.: 2726300/2726450/2726550
Fax: 2725272
Email: knhadmin@knh.or.ke

Ref: KNH/PAEDS-HOD/48 Vol.II

Date: 1st December 2021

Dr. Diana Okello
Department of Paediatrics and Child Health
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Okello

RE: AUTHORITY TO COLLECT DATA IN PAEDIATRICS DEPARTMENT

Following approval of your Research proposal by the KNH/UON-Ethics & Research Committee and subsequent filing of the Study Registration Certificate, this is to inform you that authority has been granted to collect data in ***Paediatrics Department***, on your study titled ***"Prevalence of Dental caries, mucositis and oral health related quality of life in 3-12 year old children undergoing cancer therapy at Kenyatta National Hospital.***

Kindly liaise with the Senior Assistant Chief Nurse, (SACN) Paediatrics for facilitation.

You will also be required to submit a report of your study findings to the office of the undersigned after completion of your study.

Dr. Juliana Muiva-Gitobu
Head of Department, Paediatrics

Copy to: SACN, Paediatrics

24/08/2022

DENTAL CARIES, ORAL MUCOSITIS AND ORAL-HEALTH RELATED- QUALITY-OF-LIFE IN CHILDREN UNDERGOING CANCER THERAPY AT KENYATTA NATIONAL HOSPITAL

ORIGINALITY REPORT

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2	erepository.uonbi.ac.ke Internet Source	1%
3	Xiangqun Ju, Pedro Henrique Ribeiro Santiago, Loc Do, Lisa Jamieson. "Validation of a 4-item child perception questionnaire in Australian children", PLOS ONE, 2020 Publication	<1%
4	hdl.handle.net Internet Source	<1%
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6	MA Masiga, JM M'Imunya. "Prevalence of Dental Caries and its Impact on Quality of Life (QoL) among HIV-infected Children in Kenya", Journal of Clinical Pediatric Dentistry, 2013 Publication	<1%