DENTAL FLUOROSIS AND PARENTAL KNOWLEDGE OF RISK FACTORS FOR DENTAL FLUOROSIS

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ABSTRACT

Introduction: Dental fluorosis is a developmental disturbance of enamel that results from ingestion of high amounts of fluoride during tooth mineralization. Drinking water remains the main source of fluoride. Other sources of fluoride include infant formula, vegetables; canned fish as well as early, improper utilization of fluoridated toothpastes in children. Knowledge of risk factors in the causation of dental fluorosis may improve strategies to prevent dental fluorosis.

Objective: To determine the prevalence of dental fluorosis among children aged 12-15 years old in Athi River sub-county, Machakos County, Kenya and assess the level of knowledge on risk factors for dental fluorosis among their parents.

Methodology: This was a descriptive study with an analytic component. A total of 281 children aged 12-15 years attending public primary schools within Athi River sub-county, Machakos County were included. A self-administered questionnaire was sent to parents for socio-demographic characteristics and oral health practices. Children whose parents consented were examined and dental fluorosis scored according to the Thylstrup and Fejerskov index. Forty randomly selected children were requested to bring water samples from their homes. Retail stores located in the area were visited for purchase of six different brands of bottled water. These samples were sent to a certified laboratory for fluoride analysis and reported in milligrams of fluoride per litre.

Data analysis: Data was entered into SPSS version 20 and analysed for means, ANOVA of means and chi-square test of significance for categorical variables. All tests for significance were set at 95% confidence level ($\alpha \leq 0.05$).

Results: A total of 314 self-administered questionnaires were sent to parents together with consent forms for their children’s participation in the study. Two hundred and eighty six responded positively, giving a response rate of 91%. The overall prevalence of dental fluorosis among children aged 12-15 years was 93.4% with only 6.6% (n=19) recording a TFI score of 0. About one quarter 70(24.4%) of children had severe fluorosis with TFI scores of ≥5. The mean TFI score for all children was 3.09 (SD=2.0), with males recording a mean TF score of 3.01 (SD=2.11) and females a mean TF score of 3.16 (SD=1.88). Out of 44 water samples analysed, 29 (65.9%) had a fluoride content of less than 0.6mg/l, 5 (11.4%) had fluoride content of 0.7 - 1.5mg/l while 10 (22.7%) of samples had a fluoride content ≥1.5mg/l. The highest fluoride content recorded was 9.3mg/l, with another sample reflecting 8.9mgF/l. Three of the bottled water samples had a fluoride content of less than 0.6mg/l, while the other half of the bottled water reported 0.7 - 0.8mg/l fluoride. A majority (87.8%) of parents indicated that they had noticed children with brown staining of their permanent teeth in their community. About 80% of parents thought dental fluorosis was caused by salty water, while only 12.9% correctly identified water with high fluoride content as being responsible for the discolored teeth.

Conclusion: Although about one in five water sources sampled had fluoride content of ≥1.5mg/l, the prevalence of dental fluorosis in this community was very high. Parental knowledge on the risk factors for dental fluorosis was low. Further research is necessary to identify the water distribution networks to provide sound evidence for engaging with the county authorities on provision of safe drinking water to the community.
DECLARATION
I, the undersigned, hereby declare that the work contained in this thesis is my original work and that it has not been previously in its entirety or in part submitted at any university for a degree.

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8 March 2016

Dr. Regina Mutave James
Date
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ABBREVIATIONS
B.D.S- Bachelor of Dental Surgery

FRI - Fluorosis Risk Index

IBM SPSS Statistics – Statistical Package for Social Scientists

KEBS – Kenya Bureau of Standards

MRes – Master of Research in Health Geography

PGD-RM - Post-Graduate Diploma in Biomedical Research Methodology

TFI – Thylstrup and Fejerskov Index of fluorosis

TSIF – Tooth Surface Index of Fluorosis

WHO – World Health Organisation
Chapter 1

BACKGROUND

1.1 Introduction
Dental fluorosis is a developmental disturbance of enamel that results from ingestion of high amounts of fluoride during tooth mineralization. The marginal threshold of fluoride during the critical tooth development period for development of dental fluorosis has been documented at 0.03-0.1mg F/Kg body weight (Mascarenhas 2000). Consumption of higher than the documented levels of fluoride leads to disruption of secretory ameloblasts, resulting in increased porosity of the subsurface enamel. In milder forms, porosity is limited to the subsurface enamel, although in severe forms the porosity affects the surface enamel causing excessive pitting, chipping and subsequently, tooth decay (Fejerskov et al 1990, Mascarenhas 2000). The beneficial effects of consuming water with moderate levels of fluoride have been proven in studies that were summarized in a Cochrane review by Marinho and Sheiham (2004). The optimum dose of fluoride necessary for the prevention of dental caries has been determined to be in the range of 0.05-0.07mg F/Kg body weight (Dabeka et al 1982, Levy et al 1995).

In countries in Eastern Africa and parts of Asia including India, naturally occurring fluoride in water presents challenges with affected populations suffering severe forms of dental fluorosis. Nair et al (1984) sampled water from underground sources in Nairobi and found 50% of the water from boreholes to contain more than 1.5mg fluoride per litre. Studies done in Kenya and Ethiopia have reported that dental fluorosis is endemic in many geographical areas located along the Great Rift Valley (Ng’ang’a and Valdehaug 1993, Tekle-Haimanot et al 1995, Kloos and Tekle-Haimanot 1999).

There is a known dose-response relationship between fluoride in water and the occurrence of dental fluorosis. Other sources of fluoride that are considered risk factors for dental fluorosis include consumption of fluoride-rich in foods and beverages (Kahama et al 1997, Opinya et al 1991). Weaning practices including the use of fluoridated water for infant formula preparation has also been identified as a risk factor for dental fluorosis (Macarenhas 2000). Children who have an early introduction to tooth brushing using fluoridated dentifrice risk developing fluorosis
if parental supervision on the amount of paste dispensed is not appropriately done (Mascarenhas 200, de Almeida et al 2007, Alvarez et al 2009).

Population increase in urban centres in Kenya especially Nairobi city has not been matched by infrastructural developments. Consequently, rapidly growing suburban zones of Nairobi lack basic amenities like piped water, tarmac roads and central sewerage systems. Populations settling in these areas have often resulted in overreliance on underground water sources as most of the surface sources are contaminated by effluent from industries and informal settlements (Coertsiers et al 2008, Wambu and Muthakia 2011). The source of water may thus be shallow wells and boreholes, often consumed without monitoring of contaminants and mineral content. Machakos County borders Nairobi City County to the eastern and south-east. Some of the suburban settlements of Nairobi extend to occupy Athi River and Mlolongo towns, both located in Machakos County. Furthermore, parents practice of weaning and introduction of oral hygiene practices for young children in Kenya have not been previously studied or documented.

1.2 Problem statement
The impact of dental fluorosis on affected individuals ranges from esthetic, to social and even psychological (Wondwossen et al 2003a, Wondwossen et al 2003b). Poor esthetics may have unfavourable effects on individual’s personality, and may lead to stigmatization of the affected person even in the job market (Mwaniki et al 1994, Wondwossen et al 2003a). Due to the rough surface associated with pitting of enamel in severe fluorosis, research has reported a high prevalence of caries in individuals with severe dental fluorosis (Makhanu et al 2009). There is unequivocal evidence on the relationship between knowledge and health outcomes. Poor knowledge predisposes to poor health outcomes (Dewalt et al 2004, Vann et al 2010). Knowledge on the cause of fluorosis has been found deficient in a study carried out among residents of Njoro, who could not associate the brown staining of their teeth with the fluoride levels in water (Moturi et al 2002).

1.3 Justification
Dental fluorosis is a known public health problem. Investigations leading to identification of possible risk factors are warranted. Knowledge generated could assist in proposing various strategies for the prevention of dental fluorosis.
1.4 Aim
To determine the prevalence of dental fluorosis among children aged 12-15 years old in Athi River sub-county of Machakos county, and assess the level of knowledge on risk factors for dental fluorosis among their parents.

1.4.1 Objectives
1. To determine the prevalence of dental fluorosis among children aged 12-15 years old in Athi River sub-county of Machakos county.
2. To investigate the level of knowledge on risk factors for dental fluorosis among parents of children aged 12-15 years old in Athi River sub-county of Machakos county.
3. To determine the fluoride content of sampled drinking water in Athi River sub-county of Machakos County.
4. To compare risk factors for dental fluorosis reported by parents of children aged 12-15 years old in Athi River sub-county of Machakos County with the severity of dental fluorosis in their children.
Chapter 2

LITERATURE REVIEW

2.1 Risk factors for Dental Fluorosis

Studies have demonstrated that drinking water and diet are the main sources of fluoride (Opinya et al 1991, Levy et al 1995, Khan et al 2004, Malde et al 2004, Alvarez et al 2009). The benefits of fluoride in drinking water have been widely documented, and many developed countries have implemented water fluoridation policies for the prevention of dental caries. The World Health Organisation (WHO) provided a guideline of maximum fluoride content in drinking water of 1.5mgF/l (WHO 1984). However, many countries have revised this to suit their local needs depending on the annual mean temperature and availability of other sources of fluoride. The optimum level of fluoride for the prevention of dental caries without causing dental fluorosis has been set at 0.7 -1.2mgF/l in the United States (WHO 1994). Several other countries such as United Kingdom (UK), Pakistan, Senegal and Ghana have made adjustments to the level of maximum allowable fluoride concentration in drinking water to between 0.4-1.0mgF/l (Stephen et al 2002, Khan et al 2004, Brouwer et al 1988, Anongura 2002).

According to a study by Den Besten (1994), the severity of dental fluorosis depends on the timing of the overexposure to fluoride, individual response, body weight, degree of physical activity, nutritional factors and rate of bone growth. It is thus possible to have different levels of dental fluorosis from the same level of fluoride ingestion. Use of fluoridated drinking water, fluoride supplements, fluoride dentifrices and infant formula before the age of six years could lead to dental fluorosis (Mascarenhas 2000, Wong et al 2010). Furthermore, altitude, mean annual temperature, dietary habits and individual susceptibility may be responsible for different experience of dental fluorosis from populations consuming water with similar fluoride concentration (Yoder et al 1998, Khan et al 2004, Pontigo-Loyola et al 2008, Alvarez et al 2009). About 75-90% of fluoride ingested daily is absorbed readily from the stomach, and studies have found an inverse relationship between the pH of the gastric contents and fluoride absorption (WHO 1994). Ingestion of high fluoride concentration on an empty stomach leads to higher fluoride absorption rates, a factor that has been associated with severe degrees of fluorosis among malnourished populations (Ripa 1993, Alvarez et al 2009). Individual susceptibility may
further be influenced by renal insufficiency and the presence of other minerals in water including calcium and magnesium (Mascarenhas 2000, Malde et al 2004, Akosu and Zoakah 2008).

2.1.1 Infant formula and beverages as risk factors for dental fluorosis
The fluoride content ingested varies widely according to individuals’ dietary practices and socioeconomic status. The intake of water for infants is very low and more of fluoride in children is likely to be derived from infant formula and beverages. Levy et al (1995) reported that the total water by itself ingested by infants below 9 months was ≤473 millilitres. Infant formula preparations vary, with some being presented as ready-to-feed, while others are powdered concentrates to be constituted by addition of water. Powdered infant formula and baby cereal have been shown to contribute to higher fluoride ingestion by infants compared to the fluoride from water (Levy et al 1995, Hujoel et al 2009, Levy et al 2010). Osuji et al (1988) reported that prolonged use of infant formula beyond 13 months of age was associated with an increased risk of dental fluorosis. Levy et al (2010) reported that consumption of infant formula and beverages by children aged 3-9 months was associated with increased risk of dental fluorosis in the permanent dentition.

Other notable sources of fluoride are foods grown in fluoride-rich soils or prepared using water with high fluoride content. In a study done in Kenya, Opinya et al (1991) demonstrated that a regular cup of tea brewed from 3.9g of tea leaves contained about 5.0mg F/l. Other than tea, foods prepared using water with a high fluoride level as well as vegetables and fish protein have been shown to contribute significantly to available fluoride (Opinya et al 1991, Ripa 1993, Kahama et al 1997). There are currently many milk-based and non-milk-based beverages constituted using water, and they could be a source of fluoride if the water used in their preparation has high fluoride content. Furthermore, it’s worth noting that there is no requirement for manufacturers of beverages to declare the fluoride content (Levy et al 1995). Other studies have reported fluorosis to occur in communities consuming doses as low as 0.04mg F/Kg body weight (Manji et al 1986). Helderman et al (1999) identified the use of magadi. Magadi, also called Trona is primarily composed of Trisodium Hydrogendi carbonate dihydrate (Na₃(CO₃)(HCO₃).2H₂O, named after the place of its mining in Lake Magadi located in the Kenyan Rift Valley. It is added to food during the cooking process by communities living both in Kenya and in Tanzania.
2.1.2 Use of fluoridated tooth pastes and fluoride supplements
A study by Osuji et al (1988) reported that children who started brushing teeth before the age of 25 months were at increased risk for dental fluorosis. Similarly, Levy et al (2010) found an increased risk of fluorosis among children who used fluoridated dentifrice between the ages of 16-36 months. In another study conducted among Brazilian children aged 1-3 years, De Almeida et al (2007) concluded that swallowing of dentifrice was responsible for 81.5% of daily fluoride intake. Dabeka et al (1982) concluded that children under the age of 3 years swallow 30% of dentifrice during tooth brushing. Early introduction of fluoridated toothpaste and its inappropriate use in children is thus a recognized risk factor for dental fluorosis (Dabeka et al 1982, Osuji et al 1988, Mascarenhas 2000, Marinho and Sheiham 2004, De Almeida et al 2007, Wong et al 2010). Use of fluoride supplements has also been associated with increased prevalence of dental fluorosis. Currently, an assessment of sources of fluoride for children is advised before a recommendation for use of fluoride supplements (Levy et al 1995). Recommendations also exist for use of fluoride foam as the safer mode of topical fluoride in children due to its ability to adhere quickly to the tooth surface and a slow release which ensures reduced bioavailability when compared to conventional topical fluoride gels (Alvarez et al 2009, Wong et al 2010).

2.2 Prevalence of Dental Fluorosis
Kenya has a large geographical zone in the Great Rift Valley with high fluoride concentrations in water. This geographic feature extends from the Turkana area in the North, traverses through Kenyan highlands regions of Kericho, Nakuru and enters Tanzania just south-east of mount Kilimanjaro. Studies conducted among populations in these high fluoride zones reported that close to 100% of the populations had dental fluorosis (Manji et al 1986, Kahama et al 1997). Ng’ang’a and Valdehaug (1993), in a study carried out in Nairobi among children aged 13-15 years reported a prevalence of dental fluorosis of 76%, and there was a 40% prevalence of Thylstrup and Fejerskov (TF) score of ≥5, indicating a serious esthetic concern. In similar studies in Ethiopia conducted among 10-15 year olds, the prevalence of dental fluorosis ranged between 70-100%, with the majority of the study participants having severe fluorosis (Tekle-Haimanot et al 1995, Kloos and Tekle-Haimanot 1999, Wondwossen et al 2003a). Wondwossen et al (2003a)
further reported that 37% of children aged 12-15 years old in three Rift Valley villages in Ethiopia where fluorosis is endemic exhibited TF scores of ≥4.

Kenya is classified as a water-scarce country, with 80% of it being Arid and Semi-Arid land (Fitzgibbon 2012). With rapid urbanisation, ground and surface water is no longer able to satisfy the demand for drinking and domestic consumption. There has been increasing trend of relying on underground water sources including boreholes and shallow wells to supplement the surface water sources (Coertsiers et al 2008). In 2002, the ministry of water and natural resources had registered 16,000 boreholes, with 4,000 of these being in Nairobi alone (KEBS 2010). In a survey on the fluoride content of water, 50% of water sourced from boreholes in Nairobi, Nakuru, Narok, Baringo, Kajiado, Kericho and Laikipia contained fluoride levels above the WHO maximum guideline level of 1.5mgF/l (Nair et al 1984, KEBS 2010).

2.3 Impact of dental fluorosis
Dental fluorosis results in increased porosity of surface and subsurface enamel due to damage to secretory ameloblasts by excess fluoride. Although the resultant enamel has a normal structural arrangement of the hydroxyapatite and fluorohydroxyapatite crystals, the intercrystalline spaces increase, resulting in increased porosity of enamel (Fejerskov et al 1990). At the mildest forms dental fluorosis appears as thin white opaque lines corresponding to the perikymata and running across tooth surface with a symmetrical distribution within the oral cavity. The severity of dental fluorosis varies according to the type of tooth depending on the stage of tooth formation and mineralization. In severe forms, dental fluorosis may manifest as entire chalky white enamel which exhibits very high degrees of hypomineralization. Teeth with severe dental fluorosis may break-off post-eruptively especially along incisal edges and cuspal tips to lose tooth morphology and are susceptible to attrition and uptake of stains depending on the individuals dietary habits (Fejerskov et al 1990).

The impact of high fluoride in drinking water is mottled teeth with increased porosity which in severe forms may cause enamel breakdown with total loss of tooth morphology. Esthetically unacceptable staining commonly accompanies dental fluorosis while skeletal fluorosis can be crippling. Due to the rough surface associated with pitting of enamel in severe fluorosis, research
has reported a high prevalence of caries in individuals with severe dental fluorosis (Makhanu et al 2009). Individuals affected by dental fluorosis may face varying degrees of stigma and discrimination (Riordan 1993, Wondwossen et al 2003b).

Dental fluorosis in Kenya has been a source of concern and a research agenda since the mid-twentieth century, and no decisive government intervention has been implemented to date (Williamson 1953, Manji 1986, Ng’ang’a 1993, Makhanu 2009). Mechanisms of water defluoridation exist both at a domestic level, and at the large scale level targeting piped water networks and advocacy may be needed for implementation of prevention strategies for dental fluorosis (Mosha 1984, WHO 1994, Catholic Diocese of Nakuru 2007).

2.5 Bottled water consumption in Kenya
Consumption of bottled water was initially associated with workplaces and affluence. However, bottled water is consumed in virtually every sphere of the Kenya population. Kenya has over 400 brands of bottled drinking water in circulation and is among the countries with the fastest growth of the bottled drinking water industry. Some of the reasons given for increased consumption of bottled water include the lack of trust of safety of piped water as a result of contamination (Pip 2000, Bulcao and Rebelo 2009). Consumption of bottled drinking water in major urban centres may be reinforced by the belief that water sources in urban centres are contaminated. There is also a general perception among the public that any product which appears well packaged meets the highest standards. This may however not be so for bottled water as the country lacks strict standards as well as capacity to enforce compliance with adopted international standards. The Kenya Bureau of standards adopted the WHO guideline for fluoride content in safe drinking water of 1.5mgF/l even though the country has wide variations in mean annual temperature according to the Kenya department of meteorology. Brazil, which has an annual mean temperature in the range of 26.8-32.5°C has a recommended fluoride concentration in drinking water of 0.6-0.8mgF/l (Bulcao and Rebelo 2009). Depending on source of drinking water whether local or bottled, it is possible that bottled water in the Kenyan market reflects the fluoride concentration levels of the areas where the bottling plant is located. Parents trusting bottled water for its cleanliness may utilise it for preparing infants’ food, increasing the chances for dental fluorosis.
2.6 Community awareness of dental fluorosis

Dewalt et al (2004) in a systematic review of literacy and health outcomes concluded that poor literacy levels predispose to poor health outcomes. Vann et al (2010) undertook a study among female caregivers to assess the impact of oral health outcomes in early childhood. Irrespective of level of education, race, age and number of children, low knowledge was associated with worse oral health status. Moturi et al (2002) described a situation where the public was not able to link the brown staining of their community’s teeth with the water that they consumed.

Optimum levels of fluoride essential for the prevention of dental caries may result in some experience of dental fluorosis, usually mild forms of Thylstrup and Fejerskov Index (TFI) of ≤2. Stephen et al (2002) demonstrated that milder forms of dental fluorosis (TFI ≤2) did not have marked impact on the esthetic consideration of parents and children interviewed during their study. Communities that are themselves affected by dental fluorosis tend to be more tolerant with regard to cosmetic effects caused by dental fluorosis (Wondwossen et al 2003a, Wondwossen et al 2003b). However, there appears to exist differences as to whether mild forms of dental fluorosis (TF 1 &2) constitute a public health problem with most professional views taking the view that mild fluorosis is esthetically acceptable (Ripa 1991, Riordan 1993, Stephen et al 2002). Riordan (1993) concluded that fluorosis of even TF 3 was regarded by lay respondents as individuals’ neglect, and was likely to lead to stigmatization of affected children. Wondwossen et al (2003b) investigated the perception of dental fluorosis among Ethiopian children aged 12-15 years and their mothers. Adolescent children were sensitive to even mild forms of dental fluorosis and they described teeth with TF scores of 2 as unacceptable. The study further noted that children raised in high fluoride areas where dental fluorosis was endemic were more likely to be tolerant of the esthetic effects of dental fluorosis, while misunderstanding of the cause of dental fluorosis persisted among the study populations (Wondwossen et al 2003a, Wondwossen et al 2003b). Experience of dental fluorosis as displayed by high TF scores was stigmatized as resulting from a neglect of individuals’ oral health in this population too (Wondwossen et al 2003b).

In areas along the Great Rift Valley, the prevalence of dental fluorosis has been reported to affect 100% of the resident populations, with large proportions displaying severe fluorosis (Mosha 1984, Nganga and Valdehaug 1993, Tekle-Haimanot et al 1995, Kloos and Tekle-Haimanot.

2.7 Prevention of dental fluorosis
Controlling the fluoride intake in children between the age of 1-6 years is the best prevention for dental fluorosis (Abanto et al 2009). The modalities for controlling fluoride intake should be explored for each region and clinicians and public health personnel could be useful. Water defluoridation methods have been tried in various regions of Asia, Ethiopia and Kenya and may be available both in large –scale and small scale domestic units (Mosha 1984, Kloos and Tekle-Haimanot 1999, Catholic Diocese of Nakuru 2007). Mothers with young children need to receive advice and be sensitized to take their drinking water for analysis for fluoride content. Infant formula is one diet that would need to be prepared with water whose fluoride content may be unknown. In cases where a clinician intents to prescribe fluoride supplements, they should undertake to establish the fluoride content being used by the child before such a prescription (Mascarenhas 2000). Health education is key, and mothers must be educated on the appropriate age to introduce tooth brushing using fluoridated dentifrice. Parents should receive advice on the amount of tooth paste; which should not exceed pea-size. Alternative a children’s tooth paste which may contain 400-500ppm fluoride may be used for children (Abanto et al 2009, Wong et al 2010).

2.8 Measurement of Dental Fluorosis
Dental fluorosis has been measured using several indices since the Deans index of 1934 came into use (Rozier 1994). The original Deans index comprised of seven classes ranging from ‘0’ for normal, ‘0.5’ for questionable, ‘1.0’ for very mild, ‘2.0’ for mild, ‘3.0’ for moderate ‘3.5’ for moderately severe to ‘4.0’ for severe. This was later modified in 1942 to merge the moderate and the moderately severe categories and give a six-point classification (Rozier 1994). This index has been widely used in epidemiological studies due to its ease of use and became the standard for comparison with subsequently developed indices (Rozier 1994). This index has been criticized for lacking sensitivity, with some of the criteria especially the ‘0.5’ for questionable being unclear (Fejerskov et al 1990, Rozier 1994).
Tooth Surface Index of Fluorosis (TSIF) was developed in 1980 with the objective of assessing the esthetic appearance of teeth surfaces examined. Teeth are not dried during the examination with anterior teeth getting a score for the facial and lingual surfaces, while the buccal teeth get scores for buccal, lingual and occlusal surfaces. An 8-point scoring criteria with ‘0’ for no fluorosis, to ‘1’ representing areas of white-patches confined to incisal edges of anterior teeth and cusp tips of posterior teeth. Score ‘6’ has both discrete pitting and staining of intact enamel, while ‘7’ is confluent pitting of enamel surface with possible large areas of enamel missing and the anatomy of the tooth altered. Due to the large number of surfaces to be scored, including lingual surfaces which may not be easily visualized, the TSIF has not found wide acceptance and concern about examiner reliability has been raised (Rozier 1994). The utilization of this index of a category ‘6’ where staining is part of the criteria has been questioned since staining per se is not a manifestation of fluorosis, but rather a reflection of the dietary habits (Fejerskov et al 1990). It is however a good index that can record the esthetic concerns of individuals.

Fluorosis Risk Index (FRI) developed by Horowitz et al in 1984 and aimed at relating the time of exposure with the period when enamel can be said to be at risk (Fejerskov et al 1990, Rozier 1994). It is a good index for use in analytical epidemiological studies due to its clear criteria for association of age-specific exposure to fluoride, and the development of dental fluorosis (Rozier 1994). It is viewed as having improved the understanding of the importance of the secretory and maturation phases of enamel and the risk of development of fluorosis. In this classification, non-fluoride opacities are also provided for as a score of ‘7’, while a score of ‘9’ indicates an excluded surface zone. The main fluorosis classification has a 4-point scale with ‘0’ for normal translucent enamel, ‘1’ for questionable which covers area of white spots, striations, or fluorotic defects covering less than 50% of the surface. A score of ‘2’ indicates mild to moderate fluorosis with ‘3’ for severe fluorosis involving extensive pitting over more than 50% of the tooth surface, staining and deformity. The index is useful in understanding risk to fluorosis, but because it cannot easily be compared with any of the other indices, it may not be utilized for prevalence studies (Rozier 1994).

Thylstrup and Fejerskov index was developed decades after the Deans index in 1978 and later modified in 1988, with an objective of providing a more sensitive classification for dental fluorosis (Rozier 1994). The Thylstrup and Fejerskov Index (TFI) is based on a ten point ordinal
scale the classifies enamel changes associated with increasing fluoride exposure. Teeth surfaces are dried and examined and classified as ‘0’ if normal translucent enamel is observed. TFI score of ‘1’ indicates enamel with thin white opaque lines seen running across the tooth surface, and corresponding to the position of the perikymata. TFI Scores ‘2’, and ‘3’, indicate increasing areas of enamel opacities with TFI score of ‘4’ being marked opacity of entire tooth surface. Corresponding to Deans category of ‘severe’ are TFI scores ‘5’ through to ‘9’ which seek to record the wide variety of clinical changes associated with higher fluoride level consumption (Rozier 1994). TFI score ‘5’ depicts enamel with some round pits of less than 2millimetres in diameter, through ‘6’ where the pits may start to merge while a score of ‘9’ indicates loss of the major part of the outer enamel resulting in change of the shape of the tooth. The TFI index has been praised for its sensitivity by epidemiologists since it corresponds closely to histological changes and to enamel fluoride concentrations, giving it biological validity (Fejerskov et al 1990). In areas with fluoride concentration ≥5ppm, the TFI should be used because of its sensitivity when measuring severe form of fluorosis (Rozier 1994). Fejerskov et al (1990) indicates that the TFI is easier to use than Dean’s index, and allows for comparisons to be made between the two indices. Due to its further breakdown of what Deans index classified as severe to more groups of TFI 5-9, some clinicians have praised the TFI indicating its value to assist with treatment planning since treatment modalities for cases TFI 1-4 may require micro-abrasion and/or bleaching, while TFI 5-7 may benefit from veneers with TFI 8-9 being an indication for full coverage crowns (Alvarez et al 2009).
Chapter 3

METHODOLOGY

3.1 Study Design
This was a descriptive study with an analytic component.

3.2 Study sites
The study was conducted in Athi River, a suburban region of Nairobi, which is administratively located in the county of Machakos. Machakos county borders Nairobi to the south-east, and has seen a rapid urban population growth as a result of the expansion of Nairobi city. The town of Machakos is located 64 kilometres from Nairobi, off the Nairobi-Mombasa road. Two urban centres in this region have seen rapid population expansion as populations working in Nairobi seek cheaper accommodation. Mlolongo town is located 25 kilometres from Nairobi while Athi River town is 30 kilometres from Nairobi. Both towns are located along the busy Mombasa-Nairobi highway (Figure 1).

Administratively, Machakos County is divided into eight sub-counties, namely Machakos, Masinga, Yatta, Kangundo, Matungulu, Kathiani, Athi River and Mwala. The sub-counties are further subdivided into twenty two divisions, seventy one locations and two hundred and thirty three sub-locations. The current study was carried out in two sub-locations of Athi River sub-county namely Athi River township and Syokimau sub-locations of Athi River division, Athi River location. During the 2009 population census, the population of Machakos county was 1,098,554 people, with a population density of 224 persons per kilometer. In contrast, Athi River township sub-location had a population density of 1,260 persons per square kilometer while that of Syokimau sub-location was 1,130 persons per square kilometer. Mlolongo town is the main commercial centre in Syokimau sub-location while Athi River town is the commercial centre for Athi River township sub-location.
3.3 Sample size determination

A prevalence of dental fluorosis of 76% as recorded in the study by Ng’ang’a and Valdehaug (1993) was used in the study.

The sample size was calculated using the following formula:

\[
\text{Sample size: } N = \frac{Z^2 \times P \times (1-P)}{C^2}
\]

Where:

- \(N\) = Study population
- \(Z\) value = 1.96
- Prevalence is 76% (0.76)
- \(C\) = Confidence level 95% (0.95)
\[ N = (1.96)^2 \frac{0.76(1-0.76)}{(1-0.95)^2} \]
\[ = 280.2 \]
\[ N = 281 \]

3.4 Sampling
Currently, Athi-River sub-county has 35 public primary schools and 12 public secondary schools. Kenya runs an education system where children start primary school at the age of 6 years, and are expected to complete 8 years of basic education at the age of 14 years. It is normal for weak students to repeat classes and therefore some children may complete the 8 years of basic education when aged well over 15 years.

Seven public primary schools are located within Athi-River Township and Syokimau sub-locations. Random sampling was used to pick two public primary schools in Athi River Township and Syokimau sub-locations within Athi River sub-county. Two schools were selected randomly from a list of schools available, one to represent each sub-location resulting in selection of Athi River primary school and Mlolongo primary school (Appendix 5).

Only public schools were included to ensure that the sampled groups fall within the same socio-economic status. With the assistance of Deputy head teachers in each school, one stream of children in standard six (12 & 13 year olds), seven (13 & 14 year olds) and eight (14 & 15 year olds) were randomly selected. All eligible children from the selected class were registered using a specially designed form (Appendix 4), and were issued with consenting documents for themselves and their parents. Questionnaires that each child took for their parent were numbered and their identification number matched with the child’s serial number and oral examination form (Appendix 3 & 4). A total of 162 and 152 children satisfied the inclusion criteria in Athi river and Mlolongo primary schools respectively. The same teachers randomly assigned numbers 1-40 to eligible children who had already been picked for inclusion in the study using the registration list generated. These 40 children were each provided with a water sample bottle and instructed to carry water used for drinking in their homes. The identification
label of the bottle provided for sample collection was recorded against the child’s details in the form (Appendix 4).

A large retail store located in Mlolongo, was randomly selected and visited for purchase of six different brands of bottled water since retail stores in this area stocked similar brands of bottled water. A total of 8 brands of bottled water were on sale in the sampled shop. Water displayed in the shelves of the retail shop was picked consecutively until the sixth brand was picked. To ensure blinding of the analyzing laboratory personnel, bottled water was transferred to half litre plastic bottles that had been rinsed with de-ionised water and lids securely placed.

All water samples collected were stored in a dark carton, in a cool room before being transported for laboratory analysis for fluoride content. All samples were transported within 48 hours after collection. A total of 46 water samples were targeted for fluoride analysis.

3.5 Permissions and consenting procedures

Permission to involve sampled schools was sought from the Athi River sub-county education office, and the head teachers of the schools (Appendix 9). Information about the study together with parental consent forms was sent to parents/guardians of sampled children (Appendix 1 and 2). Upon returning of the parental consent forms, children of consenting parents were provided with questionnaires to deliver to their parents and assent forms were distributed to the same children. Children whose parents/guardians consented and who themselves assented to participate in the study were examined. Oral examination of the children was performed during break times to avoid disrupting the normal operations of the school.

3.6 Inclusion Criteria

- Children who lived in their current residence for six or more years
- Children within the age group 12-15 years of age
- Children whose parents consented for the oral examination
- Children who assented to undergo an oral examination

3.7 Data Collection

Self-administered questionnaires were sent to parents and guardians of sampled children upon completion of consenting procedures described above. The questionnaire was designed specifically for this study and was validated using a similar population at a primary school
within Nairobi City. All questions were tested for clarity and ease of self-interpretation. The questionnaire was also translated to Kiswahili to ensure that parents who could not understand English were accommodated.

All sampled children who assented to participate received an oral examination and findings were recorded in a specially designed clinical examination form (Appendix 3). The intra-oral examination followed a standard procedure with the child and operator seated, and natural lighting was used to detect the translucence of enamel and a wooden spatula used to retract oral soft tissues. Teeth were dried with sterile gauze, and the scoring was done according to the Thylstrup and Fejerskov (TF) dental fluorosis index (Thylstrup and Fejerskov 1978). All erupted and sound teeth were scored for fluorosis (Appendix 3). The highest recorded TF score in a child was regarded as the overall TF score for the child. Children who were diagnosed with any type of oral diseases/conditions had the information communicated to their parents through a referral form (Appendix 3) and a recommendation was made for their parents to take them for treatment at the Machakos Level V Hospital dental clinic.

Forty randomly selected children were requested to bring half a litre of water from their homes. Bottled water from six different brands was purchased in one litre containers and was stored in a cool place. All water samples were transferred to 500ml plastic bottles, which had been rinsed with de-ionized water and coded (Numbered 1 – 46) to avoid the bias of the analyzing laboratory staff. The Catholic Diocese of Nakuru water quality laboratory was used for analysis of all the water samples. The fluoride ion selective electrode analysis method was used and reporting of fluoride concentration was in milligrams per litre (APHA, 1995). Data capture sheets were used to record details of the selected children and matching of water bottles. (Appendix 4).

3.8 Validity and reliability of data
To ensure that the data is valid the researcher who is a qualified dental practitioner carried out all the examinations. The examiner was calibrated by a senior researcher in oral sciences and a kappa value reported for inter-examiner variability. The consistency was also controlled by repeating the scoring for every 10th child examined for intra-examiner reliability. A Kappa value is also reported for intra-examiner variability.
3.9 Quality assurance for fluoride in water
All samples of water were transported to the analyzing laboratory (Catholic Diocese Nakuru – CDN - water quality laboratories). During a previous water analysis exercise, this laboratory was calibrated against two other laboratories of international reputation. Results from AL Abotts and Kenya Bureau of Standards laboratories were comparable to those obtained from the CDN water quality laboratory. The laboratory is based within a water defluoridation plant, and is routinely used for monitoring fluoride content in water using a fluoride ion selective electrode method (APHA, 1995).

3.10 Data analysis
Data was entered into IBM SPSS Statistics version 20 and analysed for descriptive statistics including frequencies, means and standard deviation. Statistical significance tests were performed with chi-square test of significance for categorical variables and correlation coefficients. The relationship between parents’ response on risk factors for dental fluorosis, reported fluoride level of sampled water and the severity of their children’s dental fluorosis were investigated using analysis of variance (ANOVA), and independent sample t-test.
Chapter 4

RESULTS

A total of 314 self-administered questionnaires were send to parents together with consent forms for their children’s participation in the study. Two hundred and eighty six responded positively, giving a response rate of 91%. Forty water sample collection bottles were distributed to forty randomly sampled children. Thirty eight bottles were returned with water samples, giving a response rate of 95%.

4.1 Socio-demographic characteristics of children and parents

4.1.1 Parents socio-demographic characteristics

Majority (84.3%) of parents lived in rented houses, 12.6% lived in their own houses while 3.1% lived in houses provided by institutions or companies where they worked. Table 1 summarizes other characteristics of the parents.

Table 1 Parents socio-demographic characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residential Location</td>
<td>Athi River</td>
<td>113 (39.6)</td>
</tr>
<tr>
<td></td>
<td>Mlolongo</td>
<td>141 (49.5)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>31 (10.9)</td>
</tr>
<tr>
<td>Age categories</td>
<td>≤30 years</td>
<td>100 (35.1)</td>
</tr>
<tr>
<td></td>
<td>31 – 40 years</td>
<td>151 (53.0)</td>
</tr>
<tr>
<td></td>
<td>&gt;40 years</td>
<td>34 (11.9)</td>
</tr>
<tr>
<td>Source of drinking water</td>
<td>Borehole</td>
<td>36 (12.7)</td>
</tr>
<tr>
<td></td>
<td>County council piped</td>
<td>225 (78.7)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>25 (8.6)</td>
</tr>
</tbody>
</table>

Besides the two main sources of drinking water, rain water harvesting and bottled water were identified as the “other” source of drinking water reported by 8.6% of the parents. Other than the source of water declared in the Table 1, some of the parents (28.3%) also indicated that they regularly used other water sources including rain water harvesting (33.3%), bottled water (21%), other piped water from different suppliers (12.4%), other boreholes in the area (14.8%) and purchasing from local water vendors (18.5%) whose source was not always declared.
Table 2 Parental practices towards oral health of children and assessment of children at risk

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>Question</th>
<th>Yes (%)</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral hygiene practices for children</td>
<td>283</td>
<td>Did you brush child’s milk teeth</td>
<td>172 (60.8)</td>
<td>111 (39.2)</td>
</tr>
<tr>
<td>Feeding practices for children</td>
<td>284</td>
<td>Did you feed child on infant formula</td>
<td>167 (58.8)</td>
<td>117 (41.2)</td>
</tr>
<tr>
<td></td>
<td>167#</td>
<td>Boiled drinking water and used for preparation of infant formula</td>
<td>147 (88.0)</td>
<td>20 (12.0)</td>
</tr>
<tr>
<td></td>
<td>282</td>
<td>Have you used bottled water for drinking at home</td>
<td>111 (39.4)</td>
<td>171 (60.6)</td>
</tr>
<tr>
<td>Parents with young children*</td>
<td>227</td>
<td>Do you have a child less than one year old</td>
<td>17 (7.5)</td>
<td>210 (92.5)</td>
</tr>
<tr>
<td></td>
<td>246</td>
<td>Do you have a child between 1-4 years old</td>
<td>78 (31.7)</td>
<td>168 (68.3)</td>
</tr>
<tr>
<td></td>
<td>257</td>
<td>Do you have a child between 4-6 years old</td>
<td>88 (34.5)</td>
<td>169 (65.5)</td>
</tr>
<tr>
<td>Parents with young children</td>
<td>278</td>
<td>Do you have children aged less than 6 years of age</td>
<td>154 (55.4)</td>
<td>124 (44.6)</td>
</tr>
</tbody>
</table>

# only parents who answered in the affirmative when asked if they fed their children on infant formula answered this question. * The responses for this question varied widely and many parents did not answer.

The majority 172(60.8%) of parents cleaned their children’s deciduous teeth, and the practice of feeding children with infant formula was also common with 167(58.8%) of parents reporting to have fed their children on infant formula. About a third 78(31.7%) and 88(34.5%) of parents who responded having children in the age range 1-4, and 4-6 years respectively. Overall, 154(55.4%) of parents had children aged 6 years or below (Table 2).

4.2 Children’s experience of dental fluorosis

Examination for dental fluorosis was done by the researcher with natural lighting since both schools had well-lit areas. Children sat in front of the examiner, and a wooden spatula was used to retract the oral soft tissues. Teeth surfaces were dried using sterilized gauze which was later disposed of together with other clinical waste by burning. Calibration of the examiner was done by an experienced dental researcher and kappa value of 0.745 was recorded. During examination, repeat of TFI scoring was done for every 10th case, and the intra-examiner reliability was
obtained using the Kappa values. A kappa statistic of 0.760 which was considered good was obtained during this process for intra-examiner reliability.

### Table 3 Relationship of children’s Sex with mean TFI scores (n=285)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
<th>Mean TFI Score (SD)</th>
<th>Statistical test</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children’s Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>127 (44.6)</td>
<td>3.01 (2.11)</td>
<td>t= - 0.664</td>
<td>p=0.508</td>
</tr>
<tr>
<td>Female</td>
<td>158 (55.4)</td>
<td>3.16 (1.88)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>285 (100)</td>
<td>3.09 (2.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* t–statistic reported for independent t-test.

The overall prevalence of dental fluorosis among children aged 12-15 years was 93.4% with only 6.6% (n=19) recording a TFI score of 0. The mean TFI score for all children was TFI score of 3.09 (SD=2.0), with males recording a mean TFI score of 3.01 (SD=2.11) and females a mean TFI score of 3.16 (SD=1.88). The relationship between children’s sex and the TFI scores was not statistically significant (p=0.508, Table 3).

### Table 4 Relationship of children’s age with mean TFI scores (n=285)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
<th>Mean TFI Score (SD)</th>
<th>Statistical test</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children’s Age (Years)</td>
<td>12</td>
<td>64 (22.5)</td>
<td>3.95 (1.9)</td>
<td>F(3,281)=6.62</td>
</tr>
<tr>
<td>13</td>
<td>115 (40.4)</td>
<td>3.10 (2.05)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>59 (20.7)</td>
<td>2.68 (1.74)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>47 (16.4)</td>
<td>2.51 (1.85)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>285 (100)</td>
<td>3.09 (2.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* F statistic reported for analysis of variance (ANOVA)

The mean TFI scores were compared for different age groups using analysis of variance (ANOVA) and is presented in Table 4. There was a statistically significant difference at the p<0.05 level for the overall TFI scores for different age groups of children F (3,281) =6.62, p=0.0001 with a medium effect size of 0.07. Post-hoc comparison using the Tukey HSD test
indicated that the mean TFI score for 12 year old children (M=3.95, SD=1.9) was statistically different from all the other age groups.

### Table 5 Comparison of children’s mean age for different sex

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
<th>Mean Age in years (SD)</th>
<th>Statistical test</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children’s Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>127 (44.6)</td>
<td>13.53 (1.05)</td>
<td>t= 3.3</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Female</td>
<td>158 (55.4)</td>
<td>13.14 (0.93)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>285 (100)</td>
<td>13.31 (1.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

_t–statistic reported for independent t-test._

An independent t-test was performed to compare the ages of male and female children. There was a statistically significant difference in the ages of the males (M=13.53, SD=1.05) and females (M=13.14, SD=0.93; t=3.3, p=0.001) (Table 5).

**Figure 2. Comparison of severity of dental fluorosis for selected tooth types across different sex**

![Figure 2. Comparison of severity of dental fluorosis for selected tooth types across different sex](image-url)
Several teeth types were selected to compare the severity of dental fluorosis across gender (Figure 2). Males appeared to have slightly more severe dental fluorosis experience for lower first premolar (44) and the second maxillary molar (17). But this relationship was not statistically significant (Chi-square = 0.64, df=2, p=0.73; Chi-square =0.87, df=2, p=0.65 respectively).

The overall TFI score of a child was regarded as the highest TFI score obtained from any tooth in their mouth. Nineteen children (6.6%) recorded an overall TFI score of zero, a sign of no dental fluorosis, 110 (38.5%) has TFI scores of 1 and 2, while 87 (30.4%) children had TFI scores of 3&4. Seventy (24.4%) children had TF scores of 5 and above.

4.3 Fluoride content for samples of drinking water
A total of 38 (Sample ID 1 – 40) water samples were presented at the schools by children who were randomly selected and provided with sealable half litre plastic containers to take home on the first day of data collection. Two children did not turn up for school on the date of fluoride sample collections giving a response rate of 95%. Six bottled water samples were available for analysis (Sample I/D 41-46).

Out of 44 water samples analysed, 29 (65.9%) had a fluoride content of less than 0.6mg/l, 5 (11.4%) had fluoride content of between 0.7 -1.5mg/l while 10 (22.7%) of samples had a fluoride content of above 1.5mg/l. The highest local sourced sample had a fluoride content of 9.3mg/l, with another sample reflecting 8.9mg/l. Three of the bottled water samples had a fluoride content of less than 0.6mg/l, while the other 3 of the bottled water reported 0.7 - 0.8mg/l fluoride. A comparison of fluoride content sourced locally and bottled water is presented in Figure 3.
Information labeled on bottled water samples was used to compare the indicated fluoride content by the bottling company and the fluoride content obtained at analysis. Table 6 summarizes the observed values according to labels and a comparison with the content of fluoride as analyzed in the laboratory.

### Table 6 Bottled water fluoride analysis

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Declared fluoride content (mg/l)</th>
<th>Fluoride content as analysed (mg/l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maisha</td>
<td>0.22</td>
<td>0.2</td>
</tr>
<tr>
<td>Highlands</td>
<td>0.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Body coolant</td>
<td>0</td>
<td>0.06</td>
</tr>
<tr>
<td>Keringet</td>
<td>0.55</td>
<td>0.8</td>
</tr>
<tr>
<td>Grange park</td>
<td>0.42</td>
<td>0.8</td>
</tr>
<tr>
<td>Daima</td>
<td>0.2</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Three of the bottled water samples had very low fluoride content (0.06-0.2mg/l) (Table 6). The other 3 contained 0.7-0.8 mg/l of fluoride. Notably, two brands of bottled water have their declared content of fluoride closely matched by the current analysis; Maisha declared a fluoride
content of 0.22mg/l, while analysis obtained 0.2mg/l, Body Coolant declared a fluoride content of 0mg/l, while there was just a trace during analysis, which recorded 0.06mg/l of fluoride. There was variance between the reported fluoride values on the container labels and that obtained by analysis on three of the six bottled water samples.

4.4 Parental Knowledge and practices with regards to risk factors for dental fluorosis

Parents were asked if they had noticed permanent brown staining of children’s teeth among their community. The total number of parents who responded to this question was 286. A majority (87.8%) of parents indicated that they had noticed children with brown staining of their permanent teeth in their community. Parents were required to indicate what they thought was the cause of the brown discolored teeth prevalent in their communities. About 80% of parents thought it was salty water, while only 12.9% correctly identified water with high fluoride content as being responsible for the discolored teeth. A small number (7.5%) indicated that the brown discoloration was caused by among other things potatoes and eating unripe bananas. Parents perception of the proportions of children aged below 18 years who are affected by brown discoloration in their community is summarized in Table 7.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Categories</th>
<th>Parents perception of children affected by dental fluorosis in the community</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1 in ten n(%)</td>
<td>2-4 in ten n(%)</td>
</tr>
<tr>
<td>Age of Parent</td>
<td>≤30</td>
<td>17(20)</td>
<td>24(28.2)</td>
</tr>
<tr>
<td></td>
<td>31-40</td>
<td>12(8.9)</td>
<td>56(41.5)</td>
</tr>
<tr>
<td></td>
<td>&gt;40</td>
<td>4(13.3)</td>
<td>17(56.7)</td>
</tr>
<tr>
<td>Parents Residence</td>
<td>Athi River</td>
<td>16(16.5)</td>
<td>34(35.1)</td>
</tr>
<tr>
<td></td>
<td>Mlolongo</td>
<td>13(9.9)</td>
<td>59(45.0)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>4(18.2)</td>
<td>5(22.7)</td>
</tr>
<tr>
<td>Overal TF score of child</td>
<td>0-2</td>
<td>16(14.5)</td>
<td>46(41.8)</td>
</tr>
<tr>
<td></td>
<td>3-4</td>
<td>10(12.8)</td>
<td>31(39.7)</td>
</tr>
<tr>
<td></td>
<td>5-9</td>
<td>7(11.1)</td>
<td>21(33.3)</td>
</tr>
<tr>
<td>Declared source of water</td>
<td>County piped water</td>
<td>28(14.3)</td>
<td>75(38.3)</td>
</tr>
<tr>
<td></td>
<td>Borehole</td>
<td>2(6.5)</td>
<td>13(41.9)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>3(12.5)</td>
<td>10(41.7)</td>
</tr>
</tbody>
</table>

*p-value reported for chi-square test
There was a statistically significant difference between the age of parents and their perception of the proportion of children affected by dental fluorosis. Parents in the age group 31-40 years perceived dental fluorosis to affect more children than the other groups ($X^2=16.81$, df=8, $p=0.032$).

**Table 8 Parents’ socio-demographic characteristics and relationship with children’s overall TF score**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Frequency (%)</th>
<th>Mean TFI Score (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residential Location</td>
<td>Athi River</td>
<td>113 (39.6)</td>
<td>3.4 (1.9)</td>
<td>p=0.071</td>
</tr>
<tr>
<td></td>
<td>Mlolongo</td>
<td>141 (49.5)</td>
<td>2.9 (2.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>31 (10.9)</td>
<td>2.6 (1.7)</td>
<td></td>
</tr>
<tr>
<td>Age categories</td>
<td>≤30 years</td>
<td>100 (35.1)</td>
<td>3.3 (2.0)</td>
<td>p=0.51</td>
</tr>
<tr>
<td></td>
<td>31 – 40 years</td>
<td>151 (53.0)</td>
<td>3.1 (2.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;40 years</td>
<td>34 (11.9)</td>
<td>2.8 (2.0)</td>
<td></td>
</tr>
<tr>
<td>Source of drinking water</td>
<td>Borehole</td>
<td>36 (12.7)</td>
<td>3.1 (1.7)</td>
<td>p=0.96</td>
</tr>
<tr>
<td></td>
<td>County council piped</td>
<td>225 (78.7)</td>
<td>3.1 (2.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>25 (8.6)</td>
<td>3.2 (2.0)</td>
<td></td>
</tr>
<tr>
<td>Flouride content in</td>
<td>0 -0.6mg/l</td>
<td>26 (68.4)</td>
<td>3.4 (2.5)</td>
<td>p=0.695</td>
</tr>
<tr>
<td>sampled water</td>
<td>0.7 – 1.5mg/l</td>
<td>2 (5.3)</td>
<td>2.5 (2.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;1.5mg/l</td>
<td>10 (26.3)</td>
<td>2.7 (2.1)</td>
<td></td>
</tr>
</tbody>
</table>

*p-value reported for one way analysis of variance (ANOVA)*

Table 8 reflects the relationship between parents’ socio-demographic characteristics, and dental fluorosis experience of their children. There was no statistically significant difference between the mean TFI scores of children and parents residential location ($F(2,282) =2.7$, $p=0.071$). Similarly, there was no statistically significant difference between the age categories of parents and their children’s mean TFI scores ($F(2,282) =0.69$, $p=0.505$). The declared source of water also did not have a statistically significant relationship with the children’s mean TF scores ($F(2,283) =0.04$, $p=0.96$).
Table 9 Relationship of severity of dental fluorosis with child’s age, sex, residence and source of water

<table>
<thead>
<tr>
<th>Variable</th>
<th>Categories</th>
<th>Severity of dental fluorosis</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TFI 0-2 n(%)</td>
<td>TFI 3-4 n(%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td>18(28.1)</td>
<td>22(34.4)</td>
</tr>
<tr>
<td>13</td>
<td></td>
<td>52(45.2)</td>
<td>36(31.3)</td>
</tr>
<tr>
<td>14</td>
<td></td>
<td>31(52.5)</td>
<td>17(27.8)</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td>27(57.5)</td>
<td>12(25.5)</td>
</tr>
<tr>
<td>Children’s sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td>60(46.9)</td>
<td>35(27.3)</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>69(43.7)</td>
<td>52(32.9)</td>
</tr>
<tr>
<td>Parents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Athi River</td>
<td></td>
<td>40(35.4)</td>
<td>41(36.3)</td>
</tr>
<tr>
<td>Mlolongo</td>
<td></td>
<td>70(49.6)</td>
<td>38(27.0)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>19(61.3)</td>
<td>8(25.8)</td>
</tr>
<tr>
<td>Declared source of water</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>County piped water</td>
<td></td>
<td>104(46.2)</td>
<td>66(29.3)</td>
</tr>
<tr>
<td>Borehole</td>
<td></td>
<td>16(44.4)</td>
<td>11(30.6)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>9(36.0)</td>
<td>10(40.0)</td>
</tr>
</tbody>
</table>

*p-value reported for chi-square test

Dental fluorosis was further classified to three groups to enable improved cell numbers for statistical analysis. The categories used were TFI 0-2, TFI 3-4, and TFI 5-9. Table 9 summarizes the relationship of children’s age, gender, residential area, source of water with the severity of dental fluorosis. Children aged 12 years had significantly more cases with severe dental fluorosis compared with other age groups and this was statistically significant (p=0.035).

4.4.1 Other risk factors for dental fluorosis
Parents were asked if they cleaned their children’s deciduous teeth. A total of 172 (60.8%) of parents indicated that they cleaned their children’s teeth while 39.2% of parents did not clean their children’s deciduous teeth. The majority (53.6%) of those who cleaned their children’s started cleaning them when the children were aged 1 -3 years. While some parents (26%) used soft cloth-materials with water to clean their children’s deciduous teeth, 41.9% of them used tooth brush and toothpaste for their children aged 1-3 years, with another 28.4% used tooth brushes with water only. Parents were also asked if they had children aged 6 years and below. A total of 278 parents responded to this question, and 154 (55.4%) of the parents had children younger than 6 years. Further analysis was done to establish whether having children younger than 6 years may be associated with better knowledge or practices with regards to risk factors for dental fluorosis. The cross tabulations are presented in table 10 below.
Table 10 Relationship of having children younger than 6 years with knowledge and practices with regard to risk factors for dental fluorosis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Parents with children aged ≤6 years</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yes(%)</td>
<td>No(%)</td>
</tr>
<tr>
<td>Materials used for cleaning</td>
<td>Used soft cloth and water</td>
<td>26(24.8)</td>
<td>19(29.2)</td>
</tr>
<tr>
<td>deciduous teeth at 1-3 years</td>
<td>Used baby tooth brush only</td>
<td>32(30.5)</td>
<td>18(27.7)</td>
</tr>
<tr>
<td></td>
<td>Used baby tooth brush and tooth paste</td>
<td>44(41.9)</td>
<td>26(40)</td>
</tr>
<tr>
<td></td>
<td>Other cleaning aids</td>
<td>3(2.8)</td>
<td>2(3.1)</td>
</tr>
<tr>
<td>Fed baby on Infant formula</td>
<td>Yes</td>
<td>100(66.7)</td>
<td>65(52.4)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>50(33.3)</td>
<td>59(47.6)</td>
</tr>
<tr>
<td>Age of introduction of Tea</td>
<td>≤1 year</td>
<td>22(14.8)</td>
<td>9(7.6)</td>
</tr>
<tr>
<td></td>
<td>Between 1-6 years</td>
<td>107(71.8)</td>
<td>88(74.6)</td>
</tr>
<tr>
<td></td>
<td>&gt;6 years</td>
<td>20(13.4)</td>
<td>21(17.8)</td>
</tr>
<tr>
<td>Age that dental fluorosis may</td>
<td>≤1 year</td>
<td>1(0.7)</td>
<td>3(2.5)</td>
</tr>
<tr>
<td>develop deciduous teeth</td>
<td>Between 1-6 years</td>
<td>43(29.1)</td>
<td>32(26.7)</td>
</tr>
<tr>
<td></td>
<td>&gt;6 years</td>
<td>104(70.2)</td>
<td>85(70.8)</td>
</tr>
<tr>
<td>Cleaned deciduous teeth</td>
<td>Yes</td>
<td>105(68.2)</td>
<td>63(51.2)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>49(31.8)</td>
<td>60(48.8)</td>
</tr>
</tbody>
</table>

p-value reported for chi-square test

Parents with children aged less than 6 years were more likely to indicate they fed their children on infant formula, and also cleaned the children’s deciduous teeth. These two relationships were statistically significant (p=0.035 and 0.004 respectively).

The practices about infant formula for feeding young babies were also investigated. Parents who fed their children on infant formula mostly boiled water available in their homes (85.1%), which they then used for preparation of the infant formula. A small number (12.6%) indicated that they sourced for bottled water which they used for the preparation of infant formula (Table 11).
Table 11 Relationship of parental knowledge on the risk factors for dental fluorosis and severity of dental fluorosis in their children’s teeth.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Categories</th>
<th>Severity of dental fluorosis</th>
<th>Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TFI 0-2</td>
<td>TFI 3-4</td>
<td>TFI 5-9</td>
</tr>
<tr>
<td>Did you feed child with infant formula</td>
<td>Yes</td>
<td>75 (44.9)</td>
<td>51 (30.5)</td>
<td>41 (24.6)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>54 (46.2)</td>
<td>34 (29.1)</td>
<td>29 (24.8)</td>
</tr>
<tr>
<td>At what age did child start taking tea</td>
<td>Before 6 years</td>
<td>104 (58.8)</td>
<td>67 (37.9)</td>
<td>61 (34.5)</td>
</tr>
<tr>
<td></td>
<td>After 6 years</td>
<td>19 (45.2)</td>
<td>15 (35.7)</td>
<td>8 (19.1)</td>
</tr>
<tr>
<td>Did you brush child’s milk teeth</td>
<td>Yes</td>
<td>85 (49.4)</td>
<td>48 (27.9)</td>
<td>39 (22.7)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>43 (38.7)</td>
<td>37 (33.3)</td>
<td>31 (27.9)</td>
</tr>
<tr>
<td>Do you regularly use other sources of water</td>
<td>Yes</td>
<td>58 (53.7)</td>
<td>30 (27.8)</td>
<td>20 (18.5)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>69 (39.2)</td>
<td>57 (32.4)</td>
<td>50 (28.4)</td>
</tr>
<tr>
<td>What may cause brown discoloration in teeth</td>
<td>Water with high salt content</td>
<td>98 (44.1)</td>
<td>67 (30.2)</td>
<td>57 (25.7)</td>
</tr>
<tr>
<td></td>
<td>Water with high fluoride content</td>
<td>17 (47.2)</td>
<td>10 (27.8)</td>
<td>9 (25.0)</td>
</tr>
<tr>
<td></td>
<td>other</td>
<td>11 (52.4)</td>
<td>6 (28.6)</td>
<td>4 (19.0)</td>
</tr>
<tr>
<td>What did you use for cleaning child’s teeth at age 1-3 years</td>
<td>Cloth and water</td>
<td>22 (48.9)</td>
<td>15 (33.3)</td>
<td>8 (17.8)</td>
</tr>
<tr>
<td></td>
<td>Tooth brush only</td>
<td>30 (61.2)</td>
<td>11 (22.4)</td>
<td>8 (16.3)</td>
</tr>
<tr>
<td></td>
<td>Tooth brush and tooth paste</td>
<td>28 (39.4)</td>
<td>20 (28.2)</td>
<td>23 (32.4)</td>
</tr>
<tr>
<td></td>
<td>other</td>
<td>4 (66.7)</td>
<td>2 (33.3)</td>
<td>0</td>
</tr>
</tbody>
</table>

*p-value reported for chi-square test, ----No p-value reported as one cell has a zero

Regular use of other water sources was associated with significant differences in the severity of dental fluorosis (X=6.3, df=2, p=0.04). Observation during data collection revealed most water points were crowded with both hand and donkey drawn carts, a sign of perennial piped water shortage in the area. There were two boreholes located within Athi River and one located at Mlolongo which supplied water to most areas using water vendors.

4.5 Proposed community strategies to prevent dental fluorosis

Parents were asked to propose measures that their community could use to reduce the number of children being affected by the condition causing brown discoloration of their teeth. A total of 261 parents responded to this question and the responses are summarized in table 12.
<table>
<thead>
<tr>
<th>Response</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children in the community should avoid the use of salty water</td>
<td>73 (28.0)</td>
</tr>
<tr>
<td>The County government should provide clean/fresh drinking water to the residents</td>
<td>47 (18.0)</td>
</tr>
<tr>
<td>People should boil water for drinking</td>
<td>6 (2.3)</td>
</tr>
<tr>
<td>Children should undertake regular tooth brushing after meals</td>
<td>82 (31.4)</td>
</tr>
<tr>
<td>Children should avoid consumption of sweets and sugary foods</td>
<td>35 (13.4)</td>
</tr>
<tr>
<td>People should drink water with low fluoride content</td>
<td>5 (1.9)</td>
</tr>
<tr>
<td>Others (Included regular visits to the dentist, educating children on brushing their teeth, avoid eating unripe bananas)</td>
<td>13 (5)</td>
</tr>
</tbody>
</table>
Chapter 5

DISCUSSION

5.1 Choice of Study Population
Parents/guardians were identified as important since parents health literacy has a general influence on their children’s health outcomes (DeWalt et al 2004, Vann et al 2010). The outcome studied was experience of dental fluorosis. Parents’ knowledge of risk factors for dental fluorosis in key to reducing or even modifying this risk for their children. Dental fluorosis results from consumption of water high in flounce content between 1-6 years. Children at that age rely solely on their parents/carers for their oral health behaviours and practices. The response rate for the parents’ data capture questionnaire was 91% which was rated as good.

The choice of children aged 12 – 15years was made since typically these children are in classes 6-8 in primary schools, and have a good level of general literacy. They also have increased awareness of health issues affecting them. Dental fluorosis is associated with cosmetic concerns which may cause stigma. Children at puberty stage may therefore be keen to participate in a study about dental fluorosis since some maybe affected while others may be curious about it; furthermore their permanent teeth are erupted and may be causing concern if they show signs of dental fluorosis to both children and their parents.

5.2 Study Tools
Oral health literacy has not been studied in the chosen population. A structured, mainly closed ended questionnaire was used for data collection. This allowed for obtaining data on many variables with regard to oral health practices of parents/guardians for their children. A general overview may be obtained from the summary of these findings. Further research may be required to focus on some of the identified areas of concern with qualitative techniques to be able to obtain in depth information. The method used for sampling allowed only the population living in Athi River sub-county of Machakos county to participate in the study. Caution is advised in any attempt to generalize the findings of this study beyond this population.
5.3 Socio-demographic Characteristics
Athi river town was established following the construction of a railway station in 1920, and grew rapidly as an industrial town thereafter. It is currently home to six cement manufacturing companies. The export processing also located in the town employs a large number of workers, who reside in this town. Mlolongo town, located 14 kilometres from Nairobi developed around the weighbridge set up to regulate loading of heavy commercial vehicles. It is the new frontier of expansion of Nairobi city, with low-cost housing units, a factor that has attracted many workers to the area. It is located along the main Nairobi-Mombasa highway. The district is thus a centre of rural urban migration with relatively young population. Over 88% of the sample children had parents aged 40 years and below (Table 1). About 79% of the population indicated they received water from the local municipal supply.

5.4 Prevalence and severity of dental fluorosis
This study reported overall prevalence of dental fluorosis of 93.4%. The population suffers high levels of dental fluorosis and does not differ from levels reported previously in East Africa (Ng’ang’a and Valdehaug 1993, Manji et al 1986, Kahama et al 1997, Tekle-Haimanot 1999). About a quarter (24.4%) of children experienced severe dental fluorosis with TFI score ≥5. The mean TF score was 3.09(SD=2.0) with males recording a lower mean TFI(3.01, SD 1.88). Although the difference between the severity of dental fluorosis across gender was not statistically significant (P=0.508), the results indicate that males were significantly older than females (Table 5), p=0.001. Furthermore, younger children (Aged 12years), had higher TFI scores hence, higher severity of dental fluorosis (Table 4), p=0.0001(mean TFI 3.95, SD 1.9). This difference in severity of dental fluorosis may be due to the settlement pattern of populations as these urban centers have been rapidly expanding in the last decade. Older children may have migrated into the town when part of their dentitions was already mineralized. It may also point to a worsening problem of over reliance on underground water as new boreholes are constructed to cope with the rising demand of water in this area (Coertsiers et al 2008). Studies in Kenya have reported upto 50% of borehole water in Nairobi and in most of the Rift Valley to have fluoride content ≥1.5mg/l (Nair et al 1984, KEBS 2010). Further research may be needed to establish why the dental fluorosis situation seems to get worse in this sub-county.
5.5 Fluoride content of available drinking water

The WHO in 1984 provided guidelines for maximum allowable fluoride in drinking water as 1.5mg/l (WHO 1984). Due to beneficial effects of fluoride in caries prevention, minimum amounts necessary for caries prevention have also been established. Kenya had not established a minimum level but may benefit from adopting levels set out at 0.7mg – 1.2mg/l for (WHO 1994, Brouwer et al 1988, Anongura 2002). Majority (65.9%) of water samples tested contained fluoride content of ≤0.6mg/l. This water may not confer any benefits in caries prevention. Another 22.7% of water samples had fluoride of ≤ 1.5mg/l. Water containing fluoride content of 3-6mg/l may result in skeletal fluorosis. A fifth (20%) of all water samples had fluoride content ≤3mg/l and 3 of these had fluoride in excess of 7mg/l (Figure 3). There was no significant relationship between the declared source of drinking water and the severity of dental fluorosis among children. These findings differed from those reported in a study in Choma district in Zambia which reported that children who drank water from hot springs before the age of 7 years experienced moderate to severe dental fluorosis (Shitumbanuma et al 2007). The current study setting was an urban settlement and it was not possible to disaggregate the sources of water between families who settled here. However, the observation of high prevalence of dental fluorosis has been previously reported in studies in Kenya by Ng’ang’a and Valderhaug (1993), who also could not adequately explain the variation between the fluoride in drinking water of the population and the prevalence of dental fluorosis recorded. Some of the reasons advanced for this variation include altitude, temperature variation and presence of fluoride from other sources like vegetables, tooth paste and fish meal (Opinya et al 1991, Wong et al 2010).

Three out of six bottled brands of water on sale in the area had fluoride content between 0.7-0.8mg/l, while the other 3 had negligible fluoride content (0.06 – 0.2mg/l) (Table 6). Of importance too is the variance between the manufacturers reported fluoride content in bottled drinking water and the level detected during analysis for half of the samples. Kenya does not have guidelines and standards on fluoride content of bottled water and applies those provided by the WHO of maximum allowable fluoride of ≤1.5mg/l (WHO 1984). Parents indicated one of the regular sources of drinking water was bottled water (21%). There was also a tendency of parents with young children to use bottled water (12.6%) for preparation of their babies infant formula. This points to a developing trend where bottled water may be commonly used in homes for drinking due to the lack of trust of piped water (Bulcao and Rebelo 2009).
5.6 Parental knowledge and practices in relation to risk factors for dental fluorosis

While majority of parents (87.8%) were aware of the existence of dental fluorosis, and the effects it had on the appearance of their children, only 12.9% indentified dental fluorosis as being associated with consumption of water with high fluoride content. In their proposal for strategies to prevent dental fluorosis in their children, most parents displayed lack of understanding of dental fluorosis where 31.4% of parents seemed to think dental fluorosis results from individual carelessness of not cleaning their teeth properly, while another 28% simply thought children should stop consuming “salty” water with no alternative offered. This lack of knowledge has been reported previously among a population living in Njoro (Moturi et al 2002). There appears to be no efforts at collective community action to find solutions to the problem of poor quality of water available in the sub-county. Health education may assist the community to understand the issue of dental fluorosis, and begin to address it.

Some surprising findings included the no significant relationship reported between residential location (p=0.071), source of drinking water (p=0.96) and fluoride content of water (p=0.695) (Table 8). Kenya has been classified a water scarce country and Machakos county is both arid and semi-arid (Fitzgibbon 2012). Alternative water sources were used by 38% of the study population. The use of alternative water sources was associated with the severity of dental fluorosis (p=0.04) (Table 11). Without a reliable water supply source, a clear picture may not be obtained as families may supplement their usual water source frequently. Further studies are necessary to understand the exact water distribution networks.

5.6.1 Infant formula as a risk factor for dental fluorosis

Most parents (55.4%) had children less than 6years of age (Table 2). This group of children was still at risk of dental fluorosis. Majority of children (58.8%) were fed on infant formula (Table 11). While this seems to be a common practice in this population, it exposes children to danger of dental fluorosis as parents commonly boil available water (85.1%) and use it for preparation of infant formula. More parents with children less than 6years seemed to indicate they fed their older children on infant formula compared to parents who did not have children aged 6 years and
below (P=0.035) (Table 10). This finding may need to be cautiously interpreted as it may be as a result of recall bias with parents who had young children being more aware of their practices around childrens’ feeding while those without young children may not recall. These practices were however not statistically associated with severity of dental fluorosis (p=0.96) (Table 11). Infant formula has been identified as a source of high fluoride and a risk factor for dental fluorosis especially the use of powdered concentrate forms which are prepared by mixing with water (Levy et al 1995, Pendrys 2000, Hujoel et al 2009, Levy et al 2010). There is a misconception among parents that boiling water could remove excess undesirable minerals in this population and parents who fed their children on infant formula mostly boiled available water before use. Other infant feeds investigated in this study included the introduction of tea by parents to their young children. Majority (84.7%) of parents introduced their children to tea, a common beverage in Kenya before the age of 6 years (Table 11). Previous studies have reported that tea, often prepared by boiling water, adding tea leaves to the boiling water and probably some milk can contain substantial amounts of fluoride even when the low fluoride water was used for its preparation (Opinya et al 1991). Other beverages consumed by communities may also contribute to high fluoride as has been observed in a study by Opinya et al (1991b), who reported high TFI scores for deciduous teeth in a low fluoride water area. Many parents recommended that children should brush their teeth regularly as a means to preventing the brown discolouration of their teeth (Table 12). This points to a low level of awareness among parents on the potential causes and management of dental fluorosis.

5.6.2 Fluoridated toothpaste as a risk factor for dental fluorosis
Parents with children aged less than 6 years reported to have cleaned their children’s deciduous teeth and there was a statistically significant difference with parents who did not have children aged 6 years and below (P=0.004) (Table 10). The practice of cleaning deciduous teeth was associated with severity of dental fluorosis (p=0.04), (Table 11). Studies have reported that inappropriate use of toothpaste in young children before the age of 3 years could be responsible for increased risk of dental fluorosis in the permanent dentition (Osuji et al 1988, Pendrys 2000, Stephen et al 2002, Levy 2010). Pendrys (2000) reported increased risk of dental fluorosis reporting from reported brushing frequency of more than once a day as well as use of more than
pea-sized toothpaste during the first year of life. Caution is advised when fluoride supplements and toothpaste are introduced in young children below the age of 3 years (Levy et al 1995).
Chapter 6

CONCLUSION
The prevalence of dental fluorosis in children aged 12-15 years in Athi River sub-county was recorded at 93.4%. The majority of children experienced moderate levels of fluorosis with a mean TF score of 3.09(SD=2.0). About a quarter (24.4%) of children examined had severe dental fluorosis with TFI scores ≥5. Younger children aged 12 years in this study had significantly higher TFI scores, indicating a more severe dental fluorosis experience.

Water containing fluoride ≥1.5mg/l accounted for 22.7% of all samples collected. Half of the sampled bottled water on sale in Athi River sub-county had safe levels of fluoride for prevention of dental caries with minimal risk for dental fluorosis. The experience and severity of dental fluorosis were not associated with reported water sources as a result of irregular water supply patterns.

Majority (87.8%) of parents recognized that children in the area were affected by dental fluorosis. Parents were not aware of the causes of dental fluorosis and only 12.9% correctly identified water with high fluoride content as the main cause for dental fluorosis. Other risk factors for dental fluorosis were common as 58.8% of parents indicated that they fed their children on infant formula while out of 172(60.8%) of parents who cleaned their children’s teeth, 41.9% used toothbrush and tooth paste for their children aged ≤3 years.
Chapter 7

RECOMMENDATIONS

1. Water supplies in Athi River sub-county of Machakos county require to be quality-controlled to ensure they have safe levels of fluoride for the prevention of dental caries as well as dental fluorosis.

2. The low level of awareness of the community of the risk factors for dental fluorosis is one of the key reasons for lack of community mobilization to lobby for quality drinking water. It may thus not be possible to predict the time before the community awareness reaches a critical level. Health education and advocacy by other stakeholders may be required to demand for action from county authorities.

3. There is need for longitudinal studies to establish the water supply networks and patterns through appropriate mapping. This may assist in providing advice to the population on sources that are safe for domestic use and also advise on water defluoridation for affected supplies.

4. Parents need to be educated on other practices prevalent in this community which constitute risk factors for dental fluorosis including the use of infant formula, and fluoridate tooth pastes for their children aged ≤3 years.

5. The county government may need to consider strategies of using both the water sources with high fluoride content and those with low fluoride and directing them to a common treatment and storage facility to enable the population to obtain a final product of water that is both safe to drink and can help in caries prevention. This would also address the issue of high fluoride and the occurrence of dental fluorosis in this population.
8.0 REFERENCES


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APPENDICES: DATA COLLECTION TOOLS

Appendix 1: Parental Information and Consent form

APPENDIX 1: CONSENT FORM - ENGLISH

PURPOSE OF THE STUDY
I am ................................................................., a researcher from the University of Nairobi and would like to seek your consent to participate in a study aimed at assessing the knowledge on dental fluorosis and parental knowledge of risk factors associated with dental fluorosis. The data I collect will enable me to identify major risk factors responsible for dental fluorosis in your community.

HOW YOU PARTICIPATE
You will be issued with a questionnaire to assess your knowledge of the risk factors for dental fluorosis. Your child will have a dental examination to determine if their teeth are affected by dental fluorosis. You may also be required to provide a half-litre of water in the provided bottle from the water used for domestic purposes which will be send for laboratory analysis to determine the level of fluoride.

EXPECTED BENEFITS
At the end of this study, I expect to communicate to you on the experience of dental fluorosis among children who will be examined. The fluoride level of water used for domestic purposes will also be communicated to the community. All children who will undergo examination will have referral for any dental diseases and this information will be send to you if your child is found to require any such referral.

ANTICIPATED RISKS
No risk is anticipated for participating in the study.

CONFIDENTIALITY
The information collected during the researcher will be kept in strict confidence. No confidential information will be revealed, released or published.
If you are satisfied with my explanation and are willing to participate, please sign the consent form below.

You are also free to refrain from participating in the study or withdrawing at any point in time without fear of victimization.

RESEARCHER,

Signed:……………………………………… Date:…………………………………………………

Dr. Regina Mutave James BDS (Nbi), MRes (St. Andrews), PGD-RM (Nbi)

Department of Periodontology/ Community and Preventive Dentistry

School of Dental Sciences, University of Nairobi

P.O Box 19676, 00202; Tel 0722 754481. Email mutave@uonbi.ac.ke

This research has been cleared by the Kenyatta National Hospital/ University of Nairobi ethics committee. For further clarification on this matter you may use the contact below.

ETHICS AND RESEARCH COMMITTEE

Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke
Link: www.uonbi.ac.ke/activities/KNHUoN

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 code 00202

Telegrams: varsity
(254-020) 2726300 Ext 44355
CONSENT FORM

I, ……………………………………………… of …………………………………(COUNTY),
do hereby give my consent to participate in the study on “Dental fluorosis and parental
knowledge of risk factors for dental fluorosis”

I do confirm that the nature of the study has been explained to me by …………………… and at
no time have I been coerced to participate in the study.

Signed: ………………………………………………………………………………………(SELF/ GUARDIAN).

I, ……………………………………………………………………………………… hereby confirm that the
nature and purpose of the study has been explained and understood by the participant.

Signed: ………………………………………………………………………………………(INVESTIGATOR).
KIAMBATISHO 1: FOMU YA IDHINI - KISWAHILI

LENGO LA UTAFITI
Mimi………………………………………………………………., ni mtafiti kutoka Chuo kikuu cha Nairobi na ningependa kupata idhini yako ya kushiriki katika utafiti wenye lengo la kutathmini kiwango cha uuzi kuhusiana na madini ya fluoride na jinsi inavyoadhiri meno na kusababisha meno ya rangi ya hudhurungi. Mawaidha nitakayo kusanya yataniwawezesha kutambua njia bora za kuzuia madhara yanayosababishwa na maji yenyewe madini ya fluoride.

JINSI YA KUSHIRIKI
Utapewa fomu ya kutathmini uuzi wako katika swala la meno ya hudhurungi, na mambo yanayochangia kusababisha meno haya. Mtoto wako atakaguliwa kwa mdono kutathmini kama meno yake yameathirika. Unaweza kuishiriki kwa kiasi cha nusu lita ili yapelekwe kwa mahabara kwa uchunguzi zaidi kubaini kiwango cha madini ya fluoride.

FAIDA ZINAZOTARAJIWA

HATARI YA UTAFITI
Hakuna hatari za kutarajia kwa kushiriki katika utafiti huu.

USIRI
Taarifa zitakazokusanywa wakati wa utafiti zitawekwa na kuhifadhiwa vyema. Hakuna habari za siri zitakazofunuliwa, kutolewa au kuchapishwa.

Kama umeridhika na maelezo haya na uko tayari kushiriki, tafadhali tia sahihi fomu ya idhini iliyo chini .

Pia uko huru kujiepusha na kushiriki katika utafiti huu au kujiondoa wakati wowote bila hofu ya uonevu.

MTAFITI MKUU,
Dk. Regina Mutave James BDS (Nbi), MRes (St. Andrews), PGD-RM (Nbi)
Shule ya Sayansi ya meno, Chuo Kikuu cha Nairobi

SLP 19676, 00202; Simu 0722754481. Barua pepe mutave@uonbi.ac.ke

Utafiti huu umeidhinishwa na kamati ya maadili ya Hospitali ya Taifa ya Kenyatta na Chuo Kikuu cha Nairobi. Kwa ufanuzi zaidi juu ya utafiti huu unaweza kuwasiliana kupitia njia zifuatazo.

ETHICS AND RESEARCH COMMITTEE
Baruapepe: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke
Fungo: www.uonbi.ac.ke/activities/KNHUoN

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
SLP 19676, 00202
Simu ya maandishi: varsity
(254-020) 2726300 Ext 44355
KIBALI CHA UTAFITI

Mimi ……………………………………….kutoka ……………………………………….(KAUNTI) ninakubali kuhusika katika utafiti wakuchunguza “Kiwango cha kuadhirika na meno ya hudhurungi na ujuzi wa jinsi meno huadhirika baina ya wazazi”.

Nina hakikisha yakwamba nimeelezwa kikamilifu kuhusu utafiti huu na …………………. Na hakuna malipo yoyote nimeahidiwa kwa kuhusika katika utafiti huu.

Sahihi: ……………………………………………………………………………………………………………………………… (MWENYEWE/ MSIMAMIZI)

Mimi, …………………………………………………………………………………………………………………………………nakahikisha ykwamba, nimemuelezea mshiriki kikamilifu juu ya utafiti huu.

Sahihi: …………………………………………………………………………………………………………………………………………(MTAFITI).
Appendix 2: Self-administered questionnaire

S/No_______

Please answer the following questions

1. What best describes the location of your residence

   (1) Athi River town
   (2) Mlolongo town
   (3) Syokimau
   (4) Other ____________________________

2. What is your age bracket?

   (1) Below 30 years
   (2) Between 31-40 years
   (3) Between 41-50 years
   (4) 51 or more years

3. What best describes your occupancy status of your current house

   (1) Own house
   (2) Rented house
   (3) Other (Company, institution etc..)

4. What is your source of water for domestic use (drinking, cooking)?

   (1) Well
   (2) Spring
   (3) Borehole
   (4) County council piped
   (5) Dam
   (6) Other (specify) ________________________________________
5. Do you regularly use any other sources for drinking water

   (1) Yes

   (2) No

   If YES above state which source______________________________

6. Do you currently have children in the following age categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1 year old</td>
<td>Yes</td>
</tr>
<tr>
<td>Between 1-4 years of age</td>
<td>Yes</td>
</tr>
<tr>
<td>Between 4-6 years of age</td>
<td>Yes</td>
</tr>
</tbody>
</table>

7. Have you noticed any children with brown discolouration in their teeth in your local area?

   (1) Yes

   (2) No

8. If yes to No. 7 above, about what proportion of children below 18 years of age do you estimate to be affected by this condition?

   (1) Less than 1 child in every 10 children

   (2) Between 2-4 children in every 10 children

   (3) About half of all children in the area

   (4) Between 6-8 children in every 10 children

   (5) More than 8 children in every 10 children
9. What may be the main cause of the brown discolouration in teeth?
   (1) Drinking water with high fluoride content
   (2) Drinking water with high salt content
   (3) Others (specify) ____________________________________________

10. Did you brush your children’s milk teeth?
    (1) Yes
    (2) No

11. If Yes to Q10 above, at what age did you start brushing your child’s teeth
    (1) Before the baby reached 1 year of age
    (2) When the baby was between the age of 1-3 years of age
    (3) When the baby was older than 3 years of age
    (4) Other ____________________________________________

12. Which of the following describes what you used for cleaning your child’s teeth between the ages of 1-3 years?
    (1) I used a clean cloth with water to clean the teeth
    (2) I used a baby toothbrush only to clean the teeth
    (3) I used a toothbrush and toothpaste to clean the teeth
    (4) Other ____________________________________________

13. Did you feed your young child on infant formula?
    (1) Yes
    (2) No

14. If Yes to Q13 above, what best describes the handling of the infant formula feed?
    (1) I boiled our drinking water, cooled it and mixed it with the baby formula
    (2) I bought bottled water specifically for mixing the baby formula
    (3) Other ____________________________________________
15. Have you used bottled water for drinking in your home?
   (1) Yes
   (2) No

16. If your answer to Q15 is yes, how long have you used bottled water in your home?
   (1) Less than 6 years
   (2) More than 6 years

17. What best describes the consumption of tea by your child?
   (1) My child started taking tea when they were less than 1 year of age
   (2) I introduced tea to my child between the ages of 1-6 years of age
   (3) I introduced tea to my child after the age of 6 years

18. At what age in a child's development may the condition causing brown discolouration of teeth occur?
   (1) Below the age of 1 year
   (2) Between the ages of 1-6 years
   (3) Between the ages of 6-10 years

19. Do you know any measures a community may take to stop more children from developing the brown discolouration of their teeth? Name them

THANK YOU
Kiambatisho 2: Fomu ya kukusanya mawaidha

Tafadhali jibu maswali yafuatayo

1. Eneo lako la makazi ni
   1) Mji wa Athi River
   2) Mji wa Mlolongo
   3) Syokimau
   4) Nyingine _____________________________

2. Uko katika kifungo cha umri gani?
   1) Chini ya miaka 30
   2) Kati ya miaka 31 – 40
   3) Kati ya miaka 41 – 50
   4) Miaka 51 na zaidi

3. Nyumba unapoishi kwa sasa ni
   1) Nyumba yangu
   2) Nyumba ya kukodesha
   3) Nyingine kama nyumba ya Kampuni, Shirika ninayofanyia kazi

4. Unayapata wapi maji yako ya matumizi ya nyumbani (kunywa, kupikia)?
   1) Kisima cha kufukua (Well)
   2) Maji ya machipuko
   3) Kisima cha kuchimba (Borehole)
   4) Maji ya mfereji ya kaunti
   5) Bwawa
   6) Nyingine (bainisha)__________________________

5. Unatumia maji mengine ya kunywa mara kwa mara?
   1) Ndio
   2) La

Kama jibu ni NDIO, ni maji ya wapi?___________________________
6. Kwa sasa uko na watoto wa viwango vya umri zifuatazo?

<table>
<thead>
<tr>
<th>Kiwango</th>
<th>Jibu</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chini ya umri wa mwaka 1</td>
<td>Ndio</td>
</tr>
<tr>
<td>Kati ya umri wa mwaka 1 – 4</td>
<td>Ndio</td>
</tr>
<tr>
<td>Kati ya umri wa mwaka 4 – 6</td>
<td>Ndio</td>
</tr>
</tbody>
</table>

7. Umeona watoto ambao meno yao yamebadilika rangi hudhurungi (Brown) katika eneo lako?
   1) Ndio
   2) La

8. Kama swali la saba ni NDIO, unaweza kusema ni kiasi gani cha watoto chini ya mwaka 18 ambao huathiriwa na hali hiyo ya meno?
   1) Chini ya mtoto 1 katika kila watoto 10
   2) Kati ya watoto 2 – 4 katika kila watoto 10
   3) Karibu nusu ya watoto wa eneo langu
   4) Kati ya watoto 6 – 8 katika kila watoto 10
   5) Zaidi ya watoto 8 katika kila watoto 10

9. Je, ni nini kinaweza kuwa chanzo cha meno kubadilika rangi na kuonekana hudhurungi?
   1) Kunywa maji yenye madini mengi ya florini
   2) Kunywa maji yenye madini mengi ya chumvi
   3) Nyingine (bainisha)__________________________________________

10. Je, ulipiga mswaki meno ya maziwa ya mtoto wako?
    1) Ndio
    2) La

11. Kama swali la 10 ni NDIO, ulianza kupiga mswaki mtoto wako akiwa umri mgani?
    1) Kabla mtoto afikishe mwaka 1
    2) Mtoto akiwa kati ya mwaka 1 – 3
    3) Mtoto akiwa zaidi ya mwaka 3
    4) Nyingine ___________________________________________
12. Ni lipi lifuatalo linajeza kile ulichotumia kusafisha meno ya mtoto wako akiwa kati ya umri 1 – 3?
   1) Nilitumia kitambaa kisafi na maji safi kusafisha meno
   2) Nilitumia mswaki wa mtoto pekee kusafisha meno
   3) Nilitumia mswaki na dawa ya meno kusafisha meno
   4) Nyingine ________________________________

13. Ulilisha mtoto wako akiwa mchanga na fomyula ya watoto wachanga?
   1) Ndio
   2) La

14. Kama swali la 13 ni NDIO, ni lipi lifuatalo linajeza kamili jinsi ulivyo shughulikia fomyula ya kulisha mtoto wako mchanga?
   1) Nilichemsha maji yetu ya kunywa, nikapoesha kisha nikachanganya na fomyula ya kumlisha mtoto
   2) Nilinunua maji maalum ya chupa ya kuchanganya fomyula ya kulisha mtoto
   3) Nyingine ________________________________

15. Umewahi tumia maji ya chupa kwa matumizi ya kunywa nyumbani?
   1) Ndio
   2) La

16. Kama swali la 15 ni NDIO, umetaumia maji ya chupa kwa muda mgani nyumbani?
   1) Chini ya miaka 6
   2) Zaidi ya miaka 6

17. Ni lipi linajezea kamili jinsi mtoto wako anatumia chai?
   1) Mtoto wangu alianza kunya chai akiwa chini ya mwaka 1
   2) Nilimuanzisha mtoto kunywa chai akiwa kati ya mwaka 1 – 6
   3) Nilimuanzaisha mtoto kunywa chai baada ya mwaka wa 6

18. Meno ya mtoto yanaweza kuadhirika na kupata meno ya rangi ya hudhurungi mtoto akiwa na umri gani?
   1) Chini ya mwaka 1
   2) Kati ya mwaka 1 – 6
   3) Kati ya mwaka 6 – 10
19 Unajua hatua zozote jamii inaweza chukua kuzia kuongezeka kwa meno ya watoto kubadilika rangi ya hudhurungi? Zitaje

AHSANTE
Appendix 3: Clinical examination form and TFI scoring criteria
Dental Fluorosis (Thylstrup and Fejerskov index¹)

Name_________________________ Sex __________
Questionnaire Number ____________ Year Of Birth________________________

<table>
<thead>
<tr>
<th>Tooth</th>
<th>17</th>
<th>16</th>
<th>15</th>
<th>14</th>
<th>13</th>
<th>12</th>
<th>11</th>
<th>21</th>
<th>22</th>
<th>23</th>
<th>24</th>
<th>25</th>
<th>26</th>
<th>27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
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<tr>
<td>Tooth</td>
<td>47</td>
<td>46</td>
<td>45</td>
<td>44</td>
<td>43</td>
<td>42</td>
<td>41</td>
<td>31</td>
<td>32</td>
<td>33</td>
<td>34</td>
<td>35</td>
<td>36</td>
<td>37</td>
</tr>
</tbody>
</table>

# - Highest TF surface score recorded for any tooth will be the individuals TF score.

Overall TF Score _________

CHILD REFERRAL FOR DENTAL TREATMENT

Dear Parent/ Guardian,

Your child ____________________________, has received a dental examination in school and has been found to have Tooth decay/ Gum disease/ Malaligned teeth or ____________________________ which requires urgent treatment. I recommend that you take the child to Machakos Level V hospital dental clinic or a private facility of your choice for management. Please note that you will bear the full cost of your child’s treatment.

Yours Faithfully,

Dr. Regina M. James
Dental Researcher
### Scoring Criteria for dental fluorosis using the Thylstrup and Fejerskov Index

<table>
<thead>
<tr>
<th>SCORE</th>
<th>CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal translucency of enamel after air-drying</td>
</tr>
<tr>
<td>1</td>
<td>Narrow white lines corresponding to the position of the perikymata.</td>
</tr>
<tr>
<td>2</td>
<td>More pronounced lines of opacity corresponding to perikymata. May merge to form small cloudy areas scattered over whole tooth surface. Opacity of cusp tips and incisal edges common</td>
</tr>
<tr>
<td>3</td>
<td>Merging of white lines with cloudy areas spread through the tooth surface.</td>
</tr>
<tr>
<td>4</td>
<td>Entire surface has marked opacity and may appear chalky white</td>
</tr>
<tr>
<td>5</td>
<td>Entire surface displays opacity with focal loss of outermost enamel (Pits of less than 2mm in diameter)</td>
</tr>
<tr>
<td>6</td>
<td>Pits are regular, arranged in horizontal bands less than 2mm in vertical extension. Teeth may exhibit marked attrition.</td>
</tr>
<tr>
<td>7</td>
<td>Loss of outermost enamel in irregular areas involving less than ½ of entire surface</td>
</tr>
<tr>
<td>8</td>
<td>Loss of outermost enamel involving more than ½ of the surface. Remaining enamel is opaque</td>
</tr>
<tr>
<td>9</td>
<td>Loss of main part of enamel, resulting in change of tooth anatomy. Cervical rim of opaque enamel noted.</td>
</tr>
</tbody>
</table>

### TFI SCORING CRITERIA

<table>
<thead>
<tr>
<th>TF 0</th>
<th>TF 1</th>
<th>TF 2</th>
</tr>
</thead>
</table>

---

**UNIVERSITY of the WESTERN CAPE**
Appendix 4: Data capture sheet: Child register and fluoride content in drinking water

NAME OF SCHOOL__________________________________

DENTAL FLUOROSIS DATA COLLECTION REGISTER

CLASS IDENTIFICATION______________________________

<table>
<thead>
<tr>
<th>S/NO</th>
<th>NAME</th>
<th>SEX</th>
<th>DATE OF BIRTH</th>
<th>PARENTS’ QUESTIONNAIRE NUMBER</th>
<th>WATER SAMPLE NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
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WATER SAMPLES BY CHILDREN

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<th>Type of source</th>
<th>Geographic Location</th>
<th>Fluoride content</th>
<th>Comment (&gt; or &lt; than 1ppm)</th>
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BOTTLED WATER SAMPLES

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<tr>
<th>Brand Name</th>
<th>Lot number and expiry</th>
<th>Fluoride content – Label</th>
<th>Fluoride content – Lab report</th>
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Appendix 5: List of Public Primary Schools in Athi-River Township and Syokimau Sub-Locations of Athi-River sub-county.

Public Primary School

1. St. Francis of Assissi Primary school
2. KMC DEB Primary School
3. Mavoko Primary School
4. Mlolongo Primary School
5. St Pauls primary school
6. Athi River Primary school
7. Ngwata Primary school
Appendix 6 Ethical clearance and permission to conduct research

Office of the Deputy Dean
Research
Faculty of Dentistry & WHO Collaborating Centre for Oral Health
UNIVERSITY OF THE WESTERN CAPE
Private Bag X1, Tygerberg 7505
Cape Town
SOUTH AFRICA

Date: 24th October 2014

For Attention: Dr RM James
Department of Community Oral Health
Faculty of Dentistry
Tygerberg Campus

Dear Dr James

STUDY PROJECT: Dental fluorosis and parental knowledge of risk factors for dental fluorosis

PROJECT REGISTRATION NUMBER: 14/9/8

ETHICS: Approved

At a meeting of the Senate Research Committee held on Monday, 27th October 2014 the above-mentioned project was approved. This project has therefore now been registered and you can proceed with the study. Please quote the above-mentioned project title and registration number in all further correspondence. Please carefully read the Standards and Guidelines for Researchers below before carrying out your study.

Patients participating in a research project at the Tygerberg and Mitchell's Plain Oral Health Centres will not be treated free of charge at the University of the Western Cape Health. The University of the Western Cape does not support research financially.

Due to the heavy workload auxiliary staff of the Oral Health Centres cannot offer assistance with research projects.

Yours sincerely

Professor Sudeeshni Naidoo

Tel +27-21-937 3148 (w); Fax +27-21-931 2287 e-mail: suenaidoo@uwc.ac.za
STANDARDS AND GUIDANCE FOR RESEARCHERS

Research should only be performed by persons with scientific and clinical qualifications appropriate to the project, who are familiar with the ethical standards applicable to the research, who submit the necessary applications and protocols to the UWC Faculty and Senate REC to review, and who carry out research in compliance with the requirements established by the UWC Senate REC and Research Policies.

1. Submitting an Application

1.1 An application for review of the ethics of proposed biomedical or other research should be submitted by a qualified researcher, who is directly responsible for the ethical and scientific conduct of the research.

1.2 Student proposal should be submitted under the responsibility of a qualified supervisor/faculty member involved in the oversight of the student’s work.

1.3 All documentation required for a thorough and complete review of the ethics of the proposed research should be submitted as specified in the UWC SRC and Research Policy procedures.

2. Conduct of Research

2.1 The research should be conducted in compliance with the proposal approved by the UWC SRC.

2.2 No deviations or changes should be made to the approved proposal, or in following it, without prior approval of the SRC, except where immediate action is necessary to avoid harm to the research participant(s). In such a case, the SRC should be informed promptly of the changes/deviations made, and the justification for doing so.

2.3 The SRC should be informed of any changes at the research level that significantly affect the conduct of the research/ trial, and/or increase the risk of harm to participants.

3. Safety Reporting

3.1 All serious adverse events as defined in the proposal and any unexpected adverse events should be promptly reported to the SRC as described in the proposal and according to the procedures established by the SRC and UWC Research Policy.

3.2 Any recommendations provided by the SRC (or other pertinent committee) should be immediately implemented.

4. Ongoing Reporting and Follow-up

4.1 Progress reports have to be submitted annually for all registered research projects.

4.2 In the case of early suspension/termination, the investigator should notify the REC of the reasons for the suspension/termination; provide a summary of the results obtained prior to prematurely suspending or terminating the study; and describe the manner in which enrolled participants will be notified of the suspension or termination and the plans for care and follow-up for the participants.

4.3 Researchers should inform the Faculty and SRC when the study is completed or cancelled.

4.4 If the SRC terminates or suspends it approval, the investigator should inform the institution under whose authority the research is being conducted, the sponsor of the research or any other applicable body.

5. Information to research participants

The researchers have an obligation to keep the research participants and their communities informed of the progress of the research at suitable timeframes in simple, non-technical language. Notification is particularly important when:

- The research is modified, suspended, terminated or cancelled.
- Any changes occur in the context of the research that alters the potential benefits or risks.
- The research project is completed.
- The research project is completed.

Tel: 27-21-937 3148 (w); Fax: 27-21-931 2287 e-mail: sue@uwc.ac.za
Dr. Regina Mutave James
Dept. of Periodontology/Community and Preventive Dentistry
School of Dental Sciences
University of Nairobi

Dear Dr. Mutave,

Research Proposal: Dental fluorosis and parental knowledge of risk factors for dental fluorosis (P43/01/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 24th April 2015 to 22nd April 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.

b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.

c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.

d) Any changes, anticipated or otherwise that may increase the risks or affect 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.

e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period.

(f) Clearance for export of biological specimens must be obtained from KNH/UoN Ethics & Research Committee for each batch of shipment.

g) Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website www.erc.uonbi.ac.ke

24th April, 2015
TO WHOM IT MAY CONCERN

Dear Sir/ Madam,

RE: RESEARCH AUTHORIZATION

The office of the DEO Athi-river authorizes Dr. Regina J. Munuve a researcher from the University of Nairobi to carry out a study aimed at ‘assessing the knowledge on dental fluorosis and parental knowledge of risk factors associated with dental fluorosis’ in primary and secondary schools Athi-river district.

Thank you

Joseph Kiema
DISTRICT EDUCATION OFFICER
ATHI RIVER