

The Influence of Family Functioning in Adolescent Dental Caries

by

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Abstract

Objective: Dental caries affect most of the world's population and although great strides have been made to reduce caries prevalence, it still remains a persistent health issue. Many components of this complex disease are well elucidated; however, family functioning is one area that has not yet been explored. Family functioning refers to how a family organizes itself to accomplish tasks and involves the relationships within the family. Understanding the influence of family functioning on dental caries has public health significance as caries impact the majority of individuals in industrialized nations. Using data from the first cohort from the Center for Oral Health Research in Appalachia, we examined the predictive relationship of selected family functioning dimensions on the number of dental caries in adolescents.

Methods: To assess the selected family functioning dimensions, the Family Assessment Measure was used and consists of three sections: (1) General, (2) Self, and (3) Dyadic. A total DMFT (decayed, missing, and filled teeth) index served as the dependent variable, which included primary plus permanent dentition. Linear regression analyses were performed between each family functioning dimension and the dependent variable for each of the three sections. The only dyadic relationship assessed in this thesis was the adolescent-mother dyad and their responses were analyzed separately. The analyses were done with and without adjustment for covariates (age, income, race, sex, and site).

Results: No statistically significant relationships were found in the general assessment. In the self assessment, the dimensions involvement and values and norms were significant predictors of the adolescent's total DMFT index. The adolescent's dyadic rating of values and norms was also found to be a significant predictor of their total DMFT index. Both control and values and norms were significant predictors in the mother's rating of the relationship.

Conclusions: This study yielded support for family functioning dimensions being statistically significant predictors of an adolescent's total DMFT index. Based off these findings, future studies investigating family functioning and dental caries merit further exploration. Studies such as this contribute to the overall understanding of the disease and may serve to inform future public health interventions.

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Preface

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1.0 Introduction

Oral health is a crucial element of overall health and well-being. However, oral health was largely ignored until the Surgeon General published the first report on oral health in 2000. Dental disease was referred to as a “silent epidemic” affecting the most vulnerable populations in the United States (i.e. the elderly, individuals with intellectual disabilities, and children).¹ Once the report was published, greater attention was given to this worldwide health issue. Furthermore, particular attention has been focused on children and the burden of dental caries on this at-risk population. Although, largely preventable, dental caries remains the most common chronic childhood disease.² Dental caries has both short- and long-term impacts on a child’s life. Research has shown caries have a detrimental impact on a child’s psychological well-being, school performance, and cause difficulties with eating and sleeping.³ The US Department of Health and Human Services found 51 million hours of school are lost each year due to dental-related illness.¹ Caries can also affect children into adulthood by requiring lifelong maintenance and repair, as well as negatively affecting overall health and well-being.

The dental caries disease process is considered multifactorial, which means it is influenced by environmental, genetic, and behavioral factors. Some of the biggest and most understood contributors to dental caries are a high sugar diet, lack of fluoride treatment, and low socioeconomic status.^{4,5} Although many risk factors have now been discovered, the impact of family functioning on childhood dental caries is not yet understood. Family functioning concerns the social and organizational properties of the family environment and assesses many intangible dimensions of family life.⁶ Family functioning looks at specific relationships and the ability of the family to complete tasks. Studies examining child development and health have revealed the

family has a significant and influential role in the habits and routines a child develops and takes onto adulthood.^{7,8} Proper oral hygiene habits are no different. For example, tooth brushing is one of the first tasks a child completes on his or her own, which means this habit is formed within the context of the family.

The aim of this study is to explore the relationship between family function and adolescent dental caries in children 11-17 years old. For the purpose of this thesis, family functioning is limited to the following dimensions: task accomplishment, communication, involvement, control, and values and norms. Data from the first cohort of the Center for Oral Health Research in Appalachia (COHRA1) was used to achieve the following aims:

- Assess the adolescent's rating of general family functioning and determine if it can predict the level of dental caries in the adolescent
- Assess an adolescent's perception of his or her own functioning in the family and determine if it can predict the level of dental caries in the individual
- Assess family functioning for the dyadic relationship between adolescent and mother
 - Determine if the mother and the adolescent assess the relationship in a similar manner
 - Determine if the adolescent's and/or the mother's assessment of the dyadic relationship can predict the level of dental caries in the adolescent

Despite strides in lessening the number of dental caries in children living in the United States, caries continue to be a persistent public health problem.⁹ The results of this study will help to provide a deeper understanding of how family functioning impacts the number of dental caries in children. The hope is for this information to contribute to the creation of more effective oral health interventions with the overall goal of improving oral health in children.

2.0 Literature Review

2.1 Dental Caries

2.1.1 Overview

Dental caries is a continuous disease process with multifactorial etiology. Biofilm, such as plaque, sits on the surface of the teeth, which metabolizes consumed carbohydrates. This generates acids which have the ability to enter the different layers of the tooth causing demineralization.¹⁰ If this area of the tooth surface does not undergo remineralization, it will begin to decay (caries formation). According to the Centers for Disease Control and Prevention (CDC), dental caries “remain the most common chronic disease of children aged 6 to 11 years and adolescents aged 12 to 19 years”.² Despite research illuminating the caries formation process, risk factors, and protective factors, dental caries continue to be a global public health burden.

2.1.2 Tooth Anatomy

To understand the dental caries process, it is important to understand the anatomy of the tooth. The tooth structure consists of four different layers: enamel, dentin, pulp, and cementum.¹¹ Enamel is the outermost layer of the tooth serving as a protective barrier against physical, chemical and thermal forces.^{12,13} Enamel is formed by epithelial cells and contains no collagen, which means that once enamel is formed, it is unable to remodel itself.¹⁰ Dentin makes up the bulk of the tooth structure, enclosing the pulp of the tooth and is more susceptible to caries-causing bacteria than

enamel.¹¹ Dentin is made up of dentinal tubules, which are microscopic tubes that lead to the pulp of the tooth.¹¹ The pulp is the part of the tooth that contains the nerves and blood vessels. It is responsible for providing blood flow and nutrients to keep the tooth alive and healthy.¹¹ The pulp is extremely sensitive and if damaged by decay or trauma, a bacterial infection may occur requiring restoration to save the tooth. The cementum covers the root surface and serves to prevent the tooth from fusing or being reabsorbed by the alveolar bone.¹⁴

These components and structures form early on during fetal development during a process called odontogenesis, which begins in the 6th week of fetal development.¹⁵ Tooth development consists of three stages: the bud stage, the cap stage, and the bell stage.¹⁵ After these stages are complete, hard structures form to make the crown of the tooth.¹⁵ Humans have two sets of teeth known as the primary and the permanent dentition and both develop during fetal development. On average, individuals develop 20 primary teeth. These are eventually replaced by the permanent dentition, which normally consists of 32 teeth.

Teeth have different structures, surfaces, and sizes depending on their function. For example, incisors and canine teeth are chisel-shaped for cutting while molars have two or more cusps for grinding food. Due to their differences, certain teeth are more susceptible to caries than others. A study in 1941 by Klein and Palmer found molars were the most susceptible to caries while incisors and canines were least susceptible.¹⁶ A follow up study which utilized the methods of the Klein and Palmar study also found molars to be more susceptible to caries than other tooth types.¹⁷ The most susceptible tooth type was the mandibular second molar.¹⁷ Molars and premolars have more pits and fissures (grooves), which are more suitable for biofilm colonization and thus are more susceptible to caries than flat or smooth surfaces.^{18,19}

2.1.3 Dental Caries Formation

Previously dental caries was thought to be a simple linear progression, from enamel demineralization to a carious lesion. However, the caries process is now understood to be dynamic and continuous throughout an individual's lifetime. The process is considered multifactorial or complex but requires the ingestion of dietary carbohydrates or sugars.²⁰⁻²³ Consumption of sugar has been shown to cause significant changes in the biochemistry and physiological environment of the oral cavity biofilms (such as plaque on the surfaces of the teeth), which makes teeth more vulnerable to caries.²¹ For example, sucrose fermentation induces a drop in pH that changes the plaque microflora to be more cariogenic.²⁰⁻²³ Despite being the strongest substance in the human body, the cariogenic environment has the capacity to demineralize dental enamel.¹⁰ Demineralization causes calcium and other minerals to leach out of the enamel creating a subsurface carious lesion, which may appear as a white spot on the tooth.²⁰⁻²⁴ Remineralization occurs when there is a high concentration of calcium and phosphate ions thus restoring calcium and other minerals to the pre-carious lesion and stopping the disease process.²⁵ This process of demineralization and remineralization occurs throughout the day, eventually leading to either cavitation of the tooth or repair and reversal of the carious lesion.

2.1.3.1 Microbiome in Dental Caries

The human oral cavity contains various microorganisms, which are rich in diversity and number. The term microbiome was put forward by Joshua Lederberg to refer to a "group of microorganisms living in a certain habitat" and "metagenome" refers to the genomes of all microorganisms inhabiting a particular habitat.^{26,27} The oral microbiome contains various microorganisms including viruses, fungi, and bacteria.²⁶ To date, the expanded Human Oral

Microbiome Database (EHOMD) holds information on 770 microbial species that have been identified in the human aerodigestive tract, which includes the oral cavity.²⁸ The bacteria in the oral cavity have the ability to become a biofilm on the surface of the teeth, such as plaque. Again, the presence of plaque and other types of biofilms on the tooth surface make teeth susceptible to dental caries.²¹ However, the presence of a biofilm alone is not sufficient to start the caries process, rather the ingestion of carbohydrates or sugars is necessary.²⁰⁻²³

Progress has been made in understanding the biofilms responsible for the dental caries process. The identification of streptococci bacteria in carious lesions had a significant impact on the field in the 1960s to 1970s.²⁹ It is believed that *Streptococcus mutans* is essential for the initiation of the caries process and *Lactobacilli* is also required for the carious lesion to form.^{24,30} *S. Mutans* and *Lactobacilli* produce organic acids, such as lactic acid, acetic acid, formic acid, and propionic acid.³¹ These acids have all been shown to dissolve tooth enamel and dentin by breaking down calcium phosphate stored in the tooth.^{31,32} Lactic acid is especially prolific at dissociating calcium phosphate, which in turn quickly lowers the pH allowing the different acids to diffuse quickly into the enamel and/or dentin. If the demineralization process is not stopped or reversed through remineralization, a carious lesion will form. Newer studies have identified other bacteria found in carious lesions or in individuals with a high caries burden: *Streptococcus sobrinus*, other *mutans Streptococci*, *Selenomonas* species, *Neisseria* species, and three species of *Veillonella* to name a few.³³⁻⁴²

2.1.3.2 Environmental and Behavioral Factors in Dental Caries

Caries formation is also influenced by environmental and behavioral factors. This includes an individual's dietary choices, eating behaviors, and family socioeconomic status. One of the most significant contributing factors to dental caries, is an individual's eating habits. Studies have

demonstrated that children who consume cariogenic foods or drinks between meals and before bed have a higher rate of caries compared to children the same age who do not have these eating behaviors.^{43,44} A study by Marshall et al. found regular soda pop ingestion between the ages of 1 and 5 years old, was the strongest predictor for the extent of caries.⁴⁵ Furthermore, regular soda pop and regular drinks made from powder are more strongly associated with caries risk compared to juice drinks including 100% fruit juice.⁴⁵ The consumption of foods and drinks high in sugar is not the only risk factor for caries, but when an individual consumes such foods and drinks at a high frequency, they are put at increased risk for caries.^{43,46,47} The increase in frequency of consuming high sugar foods and drinks can result in the pH of the oral cavity remaining acidic, which provides a cariogenic environment.⁴³ Nonetheless, the dental caries process is continuous and the effects of sugar consumption at a young age may not present until the child is older. This is supported by rates of dental caries in primary dentition increasing as individuals age.⁴⁸⁻⁵¹

Additionally, individuals who brush their teeth infrequently are at a greater risk for the incidence of new carious lesions compared to those who brush more frequently.^{52,53} However, there have been inconsistencies between the association of oral hygiene habits and caries. This could be due to self-reported tooth brushing data which is not indicative of the quality or effectiveness of an individual's brushing ability. Also, assessing the effectiveness of toothbrushing on its own has proven difficult because fluoridated toothpaste is often used in tandem. However, research does support the regular use of fluoridated toothpaste in protecting against caries.^{52,54-56}

A child's social environment also has an impact on their oral health. For example, caries is more prevalent in lower socioeconomic statuses when compared to higher socioeconomic status.⁵⁷⁻

⁶¹ Socioeconomic status (SES) is generally measured by income, education, and occupational

position or level.⁶² The impact of the family environment is discussed further in the sections 2.3.1 and 2.3.2 and is the major focus of the current study.

2.1.3.3 Genetics of Dental Caries

Environmental and behavioral factors related to dental caries may be the most apparent in the disease process; however, the genetic component should not be disregarded. Individuals with similar environmental exposures display different amounts of susceptibility to dental caries, which indicates a genetic component of the disease. Twin and family studies have illustrated the genetic contribution with estimated heritability rates between 40-70% and heritability is greater in the primary dentition.⁶³⁻⁶⁵ Despite recognizing the importance of genetics, specific genes are not yet well known or understood. Shaffer et al. performed the first genome wide association study (GWAS) on the primary dentition and while it did not find any statistically significant single nucleotide polymorphisms (SNPs), it did find three loci which were suggestive of association: 1q42-q43, 11p13, and 17q23.1.⁶⁶ Other GWAS studies have been done; however, not much overlap exists between findings, implying there is still much to be learned about the genetics of dental caries. In addition to GWAS studies, researchers have begun to explore the possible relationship between known genes and dental caries risk. A study by Wendell et al. investigated markers within taste pathway genes for associations with dental caries.⁶⁷ A significant association of the GGC nucleotide substitution in TAS2R38 gene conferred protection against caries in the primary dentition. Individuals with this substitution are characterized as “supertasters” (bitter sensitivity). This result was further supported by associations with the haplotypes GGC, GGX (X being any nucleotide), and XGC in TAS2R38, which also conferred protection against dental caries.⁶⁷ The opposite haplotypes CAT and CAX were associated with caries risk and individuals with these changes are known as “non-tasters” (bitter insensitivity).⁶⁷ The results of this study

emphasize the importance of understanding the role taste preference plays in dental caries and how it could contribute to more effective intervention strategies based on taste preferences.⁶⁷ Research has also explored the possible relationship between gene-by-sex interactions and the dental caries process. A study which looked into this relationship found that the amount of influence genes have on the primary dentition does vary between males and females, while different sets of genes altogether may influence the permanent dentition in the sexes.⁶⁸ The study by Shaffer et al. served to fill gaps in GWAS literature with its results suggesting the “missing heritability” could be due in part to gene-by-sex interactions.⁶⁸

2.1.3.4 Prevention of Dental Caries

Despite being an ongoing process, dental cavities can be prevented. Early epidemiological studies found an inverse relationship between fluoride exposure in drinking water and caries prevalence.⁶⁹ The most well-known caries prevention strategy is fluoridated water programs. Due to the success at reducing dental caries, fluoridated water was named one of the ten greatest public health achievements of the 20th century.⁷⁰ According to the CDC, drinking fluoridated water strengthens teeth and reduces caries by about 25% in both children and adults.⁷⁰ As of 2014, 66.3% of the United States population receives fluoridated water.⁷¹ Fluoride works to reduce caries at different time points of tooth development. During enamel formation, fluoride ions are incorporated at low levels making the enamel more stable and therefore improving enamel’s resistance to acids.¹⁰ After tooth eruption, fluoride ions can still be incorporated into the enamel by replacing or substituting hydroxide molecules that are lost as a result of demineralization.¹⁰ The application of topical fluoride is an effective approach to quicken the remineralization process and stop the progression of carious lesions.^{10,20}

Overall, fluoride has the ability to act as an inhibitor to acid-mediated demineralization when the pH in the oral cavity becomes more acidic (decreases) and as a promoter of remineralization when the pH becomes more basic (increases).⁷² During demineralization it restores the concentration of calcium and phosphate ions.^{10,72} However, there is a limitation to the positive effects of fluoride on enamel. Once the outer layer of enamel is lost, it cannot be restored through remineralization and the tooth will require restoration.

In addition to using fluoridated toothpaste, the American Dental Association (ADA) and the Centers for Disease Control (CDC), recommend brushing teeth twice a day.^{2,73} Toothbrushing is a mechanical method of removing plaque. However, many studies have found patients of various ages are not able to remove plaque effectively.⁷⁴⁻⁷⁷ Additionally, the ADA recommends the use of dental sealants on all primary and permanent molars of all children and adolescents.⁷⁸ Sealants reduce the risk of caries up to 80% for two years when placed on permanent molars compared to having no sealant at all.⁷⁹ Despite the effectiveness of dental sealants, studies have shown they are still underused. In the United States, dental sealant prevalence in children and adolescents aged 5 to 19 living below 200% of the poverty level was only 20-22% compared with 32% for children who were living at or above 200% of the poverty line.⁸⁰ Furthermore, a study done in the Appalachian region found dental sealant usage on select permanent teeth in children aged 5 to 17 years old was greater than the national rate, however, the rate of caries in these children were still higher than the national average.⁸¹ Results such as these, raise the question of what else could be contributing to the high caries rates in children.

Saliva can also act to prevent dental caries. Saliva plays a vital role in the maintenance of the oral cavity; it is needed to maintain the oral mucosa tissues and the teeth.⁸² Because it contains bicarbonate, saliva acts as a buffer to restore the pH in the oral cavity making the environment less

acidic and less cariogenic.⁸³ When the pH of the oral cavity is no longer acidic (above 5.5), the saliva and plaque are super saturated with ions that can begin to repair the damage caused by demineralization.⁸⁴ Furthermore, the stimulation of saliva flow increases the washing out of acids and increases the quantity of bicarbonate buffer and ions involved in the remineralization process. Consistent with this fact, research has found that individuals who have a decreased flow rate of saliva are associated with an increased caries risk while those who have a high flow rate are at a reduced risk.^{82,85,86}

2.1.4 Epidemiology of Dental Caries in Children and Adolescents

2.1.4.1 Prevalence

Dental caries continue to be a silent epidemic for both developing and industrialized nations alike. According to the World Health Organization (WHO), dental caries affects 60-90% of school aged children and the majority of adults in industrialized nations.⁸⁷ The rate of caries in developing nations remains relatively low; however, it is predicted to rise as consumption of processed and sugary foods becomes more common in these countries.⁸⁷ Particular attention has been given to children who are significantly affected by dental caries. Dental caries in children is five times more common than asthma and seven times more common than hay fever.¹ According to the National Health and Nutrition Examination Survey (NHANES), the prevalence of total dental caries, both treated and untreated, in children aged 2-19 years in the United States in 2015-2016 is 45.8%.⁹ The prevalence of dental caries did increase with age with it being 21.4% in children aged 2 to 5 years old to 50.5% in children aged 6-11 years old to 53.8% in children aged 12-19 years old.⁹ On a global scale, research has shown approximately 50% of preschool aged children from various countries have experienced dental caries.⁸⁸

However, the distribution of dental caries in children is not even throughout populations. According to the NHANES survey, dental caries (treated and untreated) were the highest among children of Hispanic descent at 57.1% compared to 40.4% in non-Hispanic Caucasian children in the United States. Furthermore, the prevalence of untreated dental caries was the highest in non-Hispanic Black children at 17.1% compared to Hispanic children at 13.5% and non-Hispanic Asian children at 10.5%.⁹ A cross-sectional study examined racial and ethnic differences in dental caries experiences among children in kindergarten in North Carolina. The study found 51.7% of Hispanic children and 39% of Black children had experienced dental caries by the time they enrolled in kindergarten compared to 30.4% of Caucasian children.⁸⁹ The study also completed multi-level regression models and after controlling for other variables, Hispanic children were 1.57 times more likely to have experienced dental caries than Caucasian children.⁸⁹ Black children were 1.23 times more likely to have experienced dental caries when compared to Caucasian children.⁸⁹ High prevalence rates of dental caries amongst children of ethnic minority groups have likewise been seen in other parts of the world. A cross-sectional study done in the Netherlands found children from other ethnic backgrounds had higher dmft indices compared to native Dutch children.⁹⁰ The dmft index stands for decayed, missing, and filled teeth. Dmft being written in lower-case letters means only the primary dentition is being considered. Moreover, these ethnic and racial disparities still exist amongst adults. A study by Delgado-Angulo et al. found ethnic disparities in adults, even when controlling for location and environmental exposure.⁹¹ The study selected adults who lived in a deprived region of the United Kingdom and found ethnic disparities for lifetime caries experience.⁹¹ Asian adults had 42% lower DMFT scores compared to Caucasian adults.⁹¹ Black adults had 45% lower DMFT scores compared to Caucasian adults.⁹¹ Again, DMFT stands for decayed, missing, and filled teeth. DMFT being written in upper-case letters means only the

permanent dentition is being considered. This study also found significant differences within ethnic groups. For example, Caucasian East Europeans had 22% higher DMFT indices compared to Caucasian British adults.⁹¹ This suggests other factors contribute to the differences in dental caries experience.⁹¹ Disparities also exist by income level. The prevalence of both treated and untreated dental caries increased from 34.8% for children whose family income level is greater than 300% of the federal poverty level to 56.4% for children whose family income was below the federal poverty line.⁹

Adolescence, defined as the period between 10 and 19 years old, is a crucial time period in an individual's life. This time period typically involves adolescents becoming more independent from their parents, which can cause changes in behaviors including oral hygiene habits. As the adolescent develops their own independent behaviors it can impact their oral health and well-being both for the short- and long-term. Research has shown that caries rates remain high in adolescence.^{9,80} This increase in caries may be due to environmental factors such as oral hygiene being a low priority for the adolescent, dietary choices, or the choice to avoid dental care.⁹² For these reasons, it is important to gain a better understanding into the mitigating and inciting factors of dental caries in adolescents.

2.1.4.2 Impact on Childhood and Adolescent Quality of Life

The impact of dental caries on children is long reaching. One area of particular significance is academic performance. A national study which utilized data from the National Health Interview Survey data found that 117 school hours are lost per every 100-school-aged-children because of dental problems or visits.⁹³ A study that focused on disadvantaged children in the Los Angeles County school district, found a total of 16,431 school days were missed each year due to dental problems.³ This is “equivalent to 58 school hours missed each year per 100 elementary school-

aged children and 80 school hours missed each year per 100 high school-aged children”.³ Children missing school hours is significant because it may have impact on their academic achievement and their social relationships/interactions. A study done on school aged-children in Brazil found that children with dental caries or children who had experienced dental trauma had lower mean school performance than other children.⁵⁸ A study conducted on children from North Carolina’s Child Health Assessment and Monitoring Program, also found a significant relationship between poor school performance and absences related to dental pain or infection.⁹⁴ In this study, 1,049 school days were missed by their study population of 2,120 children due to any dental care reason.⁹⁴ It was further elucidated that 17.3% of the days were specifically due to dental pain or infection.⁹⁴ Additionally, children with good, fair, or poor oral health were nearly 3 times more likely to miss school as a result of dental pain compared to those children with very good or excellent oral health.⁹⁴ Furthermore, a relationship between poor school performance and poor oral health independent of school attendance was determined.⁹⁴ A child experiencing poor oral health may have a more difficult time concentrating and performing in school compared to a child who has good oral health.

Caries can also have a negative impact on a child’s overall quality of life.⁹⁵⁻⁹⁷ Children may experience a variety of physical and emotional issues. Studies have shown that dental caries impact functions that are needed for overall quality of life such as sleeping, normal social activities, talking, and overall good general health.^{95,97} However, a study done by Feldens et al., found that adolescent quality of life was impacted only when dental caries went untreated.⁹⁸ Two other studies of adolescents found similar results, while another study found the opposite to be true.⁹⁹⁻¹⁰¹ Pain is a common theme when interviewing children about their experience with dental caries.⁹⁵ Pain

not only causes difficulties while eating but may result in a language delay due to restricting facial movement.⁴⁴

2.2 Family Environmental Factors and Functioning – the Example of Childhood and Adolescent Obesity

The term family can be defined many ways depending on its societal meanings. Generally, family refers to individuals related by marriage, ancestry, adoption, or choice.¹⁰² An individual's family serves as a primary source of social support and has influence of their health and well-being.¹⁰² The family environment, which includes composition of the home, parenting style, socioeconomic status, parental habits, and family functioning, has been linked to health outcomes in children.¹⁰³⁻¹⁰⁶ Due to the influential role families have over their child's long-term health outcomes, research is trying to gather a stronger understanding of the relationship between the family and health outcomes.

2.2.1 Family Environmental Factors

As previously mentioned, the family environment is composed of many different factors including composition of the home and caregiver characteristics. For the purpose of this document, family functioning will be discussed in a later section and the influence of the family environment will be limited to a specific example and its effect on child and adolescent health outcomes. The specific example was chosen due to its similarities to dental caries. The relationship between SES and childhood obesity is explored below. Eating habits, much like oral health habits, are shaped

within the context of the family environment. Because of this, and obesity being a multifactorial and largely preventable disease, it is similar to the dental caries disease process.

The family's SES is one of the most well understood and thoroughly researched aspects of the family environment. SES is a measured or self-reported value that is meant to be reflective of the social and economic status of the household. The concept of the social gradient refers to observation that individuals with the lowest SES have worse health outcomes while individuals with higher SES have better health outcomes.¹⁰⁷ This social gradient is present in obesity risk for children and adolescents. A study by Fradkin et al. examined the association between SES and obesity risks in 4,824 participants aged 10 to 13 years old from diverse racial and ethnic groups in the United States.¹⁰⁵ The study found an inverse relationship between SES and obesity risk in this population when race and ethnicity was not included.¹⁰⁵ However, the risk was not consistent when looking within ethnic groups. For example, they found no difference in risk for obesity with SES in African American individuals. However, within the Hispanic study population a higher SES reduced the risk of obesity.¹⁰⁵ The NHANES survey on obesity and SES in children and adolescents from 2005-2008 found similar findings as the Fradkin et al. study.¹⁰⁸ The study found children and adolescents who are part of low-income households are more likely to be obese than children and adolescents at higher income statuses, however, these findings too were not consistent across race and ethnic groups.¹⁰⁸ Although, these health issues are less directly related to dental caries, higher infant mortality rates, higher rates of depression and anxiety among adolescents, and higher rates of behavior and emotional difficulties, among others, have been linked to lower SES.¹⁰⁹⁻

2.2.2 Family Functioning Factors

Family functioning is an important component of a family's unique environment. Family functioning refers to the structural organization of a family and the relationships between individuals.¹⁰² This includes emotional, physical, and psychological activities between family members. According to the family systems theory, the family is an emotional unit and a single individual cannot be understood in isolation.¹⁰² Furthermore, each family member helps to shape the other. This means family functioning has a global influence, affecting things such as decision making, communication, and day-to-day problem solving. While each family is unique, certain characteristics can be used to assess every family's health and level of family functioning through assessment tools focused on capturing the unique relationships and patterns of a family.

Family functioning assessments can either be observational survey tools (e.g. the Family Health Scales and the Beavers Interactional Competence Scale) or self-report questionnaires (e.g. the McMaster Family Assessment device, the Beavers Self-Report Family Inventory, and the Family Assessment Measure), each having its own strengths and limitations based on the perspective of each tool.¹⁰² Assessment tools have the ability to investigate the family at different levels such as the general or global scale or within dyadic relationships such as marital/partner relationships, sibling relationships, and/or parent-child relationships.¹⁰² Evaluating the family on various levels allows for a richer look into family functioning. Furthermore, these tools evaluate the family using different dimensions and while they do not all assess the same dimensions the majority assess: communication, problem solving ability, organization, and affective environment.⁶

A family with "functional" (healthy) family functioning would display clear communication, demonstrate well-defined family roles, and be cohesive allowing them to achieve

family goals and tasks.^{6,102} In contrast, a family with “dysfunctional” (unhealthy) family functioning would display ineffective communication, have high levels of conflict, and have poor affective and behavioral control causing them to struggle to achieve family goals and tasks.^{6,102} Family functioning has become a topic of public health due to its implications in childhood health and well-being. The influence of family functioning on childhood health can be explored using the overall score of family functioning or by looking at specific dimension scores. Both methods have value allowing researchers to better understand the influence of the family environment and therefore create more effective health intervention strategies.

For the purpose of this thesis, the Family Assessment Measure was used. This is a self-report model based on the process model of family functioning.¹¹² It focuses on the interaction between family functioning dimensions, which include task accomplishment, role performance, communication, affective expression, involvement, control, values and norms.¹¹² Definitions for these terms can found in Appendix A of this document.

2.2.2.1 Current Understanding of the Impact of Family Functioning on Childhood and Adolescent Obesity

Most research on family functioning has been centered around chronic and often life-threatening diseases. Furthermore, families of affected children are most commonly assessed with the goal of better understanding how the disease impacts family relationships. Due to these being chronic conditions, it would be expected for family functioning to be negatively impacted, however, it is difficult to prove this as prospective studies are often not possible. For the purpose of this thesis, family functioning research will be limited to the specific example of childhood and adolescent obesity. Again, this disease was selected due to the similar role parents or caregivers play in the formation of healthy habits for their children. Understanding how family functioning

impacts the eating habits children form, may allow for a more global understanding of how family functioning impacts a child's health. This too could allow for more effective intervention strategies aimed at targeting the family dynamic.

Berge et al. explored the relationship of family functioning and eating behavior in adolescents in the Minneapolis and St. Paul metropolitan area of Minnesota.¹¹³ The study included 2,793 adolescents with a mean study population age of 14.4 years.¹¹³ Amongst adolescent girls, higher family functioning was significantly associated with more frequent breakfast consumption and more frequent family meals after controlling for age, SES, and ethnicity/race.¹¹³ Additionally, higher family functioning was associated with a greater daily intake of fruits and vegetables and lower BMI z scores.¹¹³ In adolescent boys, higher family functioning was also associated with more frequent family meals after controlling for age, SES, and ethnicity/race.¹¹³ It did not find a significant association between higher family functioning and servings of fruits and vegetables or BMI z scores.¹¹³ However, a study conducted on children between the ages of 4 and 12 years-old living in the state of Victoria, Australia found a relationship between eating habits and poor family functioning in both boys and girls.¹¹⁴ It found poor family functioning to be associated with inadequate fruit and vegetable intake in both sexes.¹¹⁴ In addition to poor eating habits, studies have found an association between the perception of poorer family functioning and obesity rates in children.¹¹⁵⁻¹¹⁷ Another study focused on adolescents found an association between better family functioning and the consumption of a healthier diet.¹¹⁸ A better understanding of how family functioning impacts a child's behaviors and habits has the potential to lead to more effective interventions to benefit children.

2.3 Family Environmental Factors and Functioning in Dental Caries

Dental caries is a multifactorial disease, which means it has a multitude of contributing factors including an individual's family and family environment. As with the diseases summarized above, the family plays a role in the dental caries disease process. With respect to preventing the disease process, family members play a significant role in the creation of daily habits for children, including oral health maintenance. In the context of managing and treating the disease, family members help to provide dental health services for their children and support positive daily habits. As dental caries continues to plague the majority of the world's children, researchers should look beyond conventional risk factors and explore new disease mediators such as family functioning.

2.3.1 Family Environmental Factors

It has long been known that the family environment impacts a child's oral health status. Oral health behaviors, such as twice daily tooth brushing and flossing, are established and promoted by a child's parent(s) or caregiver(s). The child will learn and adopt health-related attitudes and behaviors as their own through a process known as primary socialization.¹¹⁹ These habits are created early on in a child's life subsequently creating a crucial role for the child's family. Researchers continue to explore the relationship of the family environment with caries from various viewpoints, including caregiver characteristics some of which are related to SES. For example, studies have elucidated a relationship between parents with lower occupation levels and higher prevalence rates of caries in young children.^{57,61,120} Lower occupation levels were defined as blue collar occupations versus white collar^{57,61,120} or employee/non-professional or unemployed versus employer/professional.⁶¹ Moreover, lower family income is associated with higher

prevalence and severity of dental caries in children.^{57-59,121-124} A parent's education level is also linked to a child's oral health outcome. Children of parents with lower education levels were seen to have higher risks for dental caries compared to children of parents with higher education levels.^{58,60,61,122,125-128} This association was seen regardless if both parents were assessed or just one.^{61,125,128}

Caregiver characteristics specific to mental health, well-being, or psychosocial attributes have been implicated in child oral health outcomes. A study by Al-Jewair and Leake explored the association between parental or caregiver depression and the presence of early childhood caries using a study population previously collected by the Toronto Perinatal and Child Health Survey.¹²¹ The study found children with parents or caregivers who suffered from depression had significantly higher prevalence rates of early childhood caries compared to children whose parents or caregivers were not affected by depression.¹²¹ A cross-sectional study of 235 children under 6 years of age and their parents showed a statistically significant positive correlation between a parent's experience with depression and anxiety and the prevalence of dental caries in the child.¹²⁹ A cross-sectional study by Dos Santos Pinto et al. found the presence of maternal depression disorder increased the chance of the mother's child exhibiting caries.¹³⁰

Moreover, a caregiver's oral health status has been explored to see if a relationship exists between the two and in fact, a number of studies have found a correlation. A study by Kawashita et al. conducted a cross-sectional study on children 3 years of age, with and without dental caries, and their caregivers.¹³¹ It found that a child's def (decayed, extracted, and filled teeth) score was positively correlated to the mother's DMFT.¹³¹ Another study by Bhat et al. looked at children 3-5 years old and found a positive correlation between maternal DMFT and a child's caries prevalence.¹³² Furthermore, a statistically significant relationship between history of dental

problems in parents and the dmft score of their children was found, along with a significant relationship between the amount of plaque a child has and their parent having a history of dental problems.¹³³

It is important to consider the oral health behaviors of parents because they are reflected in their own oral health statuses and parents are responsible for establishing a child's behaviors. A study done on children aged 8 to 12 years old in suburban Nigeria, found the odds of a child brushing their teeth two or more times a day increased by over 21-fold when their mother brushed their teeth twice a day or more.¹¹⁹ Furthermore, if the mother used fluoridated toothpaste, the odds of the child doing the same increased by 39-fold.¹¹⁹ Other studies have found a relationship between parental toothbrushing habits and a child's oral health. For example, if a mother brushed her teeth irregularly, an association was found with her child's dmft being greater than 0.¹³⁴ The same association was found with a child's dmft score when the father brushed his teeth irregularly.¹³⁴ Another study revealed a significant relationship between a parent's frequency of tooth brushing and a child's frequency of tooth brushing, which is expected since children learn oral health behaviors from their parents.¹³³

Beyond characteristics of caregivers, the influence of family structure on dental health has been explored. A descriptive cross-sectional study by Wellaplu and Amarasena found statistically significant relationships between different aspects of family structure and caries experience.¹³⁵ For example, individuals who belonged to families with more than 2 children had significantly higher mean dmft compared to children who belonged to families with 2 or less children.¹³⁵ A similar study has also observed higher rates of caries in children who live in crowded houses.¹³⁶ Moreover, birth order and the age of parents when a child is born have been associated with dental caries experience.¹³⁵

2.3.2 The Current Understanding of Family Functioning and Dental Caries

As described above, the majority of studies have focused on attributes related to the parent or caregiver such as cognitive level and psychosocial attributes. However, researchers have not fully explored the relationship of dental caries with family functioning. A study by Duijster, Verrips, and Cor van Loveren aimed to “evaluate the association between family functioning dimensions and childhood dental caries in a sample of 5- to 6-year-old children in the Netherlands”.¹³⁷ This study used the Gezinragenlijst (Family Questionnaire), which is a validated family functioning assessment tool.¹³⁷ The Gezinragenlijst assesses family functioning through five dimensions: communication, organization, partner-relation, responsiveness, and social network. The study found children from families with normal scores for communication, organization, responsiveness, and social network had significantly less dental caries than children from families with subclinical and/or clinical scores in these dimensions.¹³⁷ The children with these same subclinical or clinical scores were found to engage in less favorable oral hygiene behaviors than those from normal functioning families.¹³⁷ A study by Renzaho and de Silva-Sanigorski examined the association between a child’s (aged 1-12 years-old) oral health and certain aspects of the home environment including family functioning.¹³⁸ The authors concluded the odds of a child having good oral health were lower as parental psychological distress and poor family function increased.¹³⁸ This relationship was found across all age groups.¹³⁸

In summary, there is a link between the family environment and a child’s risk for dental caries. Although, progress has been made to reduce the burden of dental caries, it still remains a persistent public health issue, which only shows the importance of investigating potential influencing factors. It is important to note, for the scope of this study, family functioning dimensions were limited to: task accomplishment, communication, involvement, control, and

values and norms. These dimensions were selected for based on the research by Duijster et al., which suggested domains of involvement, control, organization, communication, and parenting style be assessed.⁴ By looking more into family functioning and its potential relationship to caries in adolescents, we can better understand the complex relationship between the two with the purpose of creating more effective public health interventions.

3.0 Manuscript

3.1 Background

Dental caries impacts the majority of the world's children and adults.⁸⁷ Considered a multifactorial disease process, great strides have been made to understand its different components, which include environmental, genetic, and behavioral factors. One necessary component for the disease process to occur is the consumption of carbohydrates or sugars.²⁰ When these are broken down by the biofilms in the oral cavity, it causes a shift in the pH making the environment cariogenic.²⁰⁻²³ The enamel of the tooth can be demineralized in this environment leading to a precarious lesion.²⁰⁻²⁴ If the lesion is not repaired through remineralization, the process of restoring calcium and other minerals, then cavitation will occur and the tooth will require repair.²⁵ Despite making progress in reducing the prevalence of dental caries through public health interventions such as public water fluoridation, caries remain the most common chronic childhood disease.^{2,9,70}

3.1.1 The Family Environment and Dental Caries

Research efforts have focused on understanding the impact of the family environment on oral health outcomes. For example, toothbrushing is one of the first independent tasks a child performs on his or her own, which means caregivers are vital in creating and reinforcing this habit. Furthermore, research has examined the oral health behaviors of parents and its relationship to their child's behaviors. A study found the odds of a child brushing his/her teeth two or more times

a day increased by over 21-fold when his/her mother practiced this same habit.¹¹⁹ Additionally, if the mother used fluoridated toothpaste, the odds of the child having the same practice increased by 39-fold.¹¹⁹ Another study found a significant relationship between the frequency of parental toothbrushing and the frequency of toothbrushing in their children.¹³³ These study findings are not surprising when it's known that dental hygiene habits are shaped within the context of the family. Another aspect of the family environment that has been studied in association with dental caries is socioeconomic status (SES). Studies have found an association between lower family income and higher prevalence rates and severity of dental caries in children.^{57-59,121-124} Another dimension of SES is occupation and studies have shown young children whose parents have blue collar occupations or are unemployed have higher prevalence rates of caries.^{57,61,120}

3.1.1.1 Family Functioning and Dental Caries

Family functioning is another component of the family environment; however, it has not been fully explored in the context of oral health. Family functioning refers to how a family organizes itself and also involves its interpersonal and intrapersonal relationships.¹⁰² Research has explored the link between family functioning chronic diseases such as childhood obesity.¹¹⁵⁻¹¹⁷ For example, a study explored the relationship between family functioning and eating habits of children and found poor family functioning to be associated with inadequate fruit and vegetable intake.¹¹⁴ As with other health conditions, assessing the relationship between family functioning and childhood dental caries has the potential to inform future intervention strategies. By understanding how families work together to accomplish tasks, it is possible to create more personalized intervention strategies that result in more effective dental caries prevention. In order to explore family functioning, a variety of assessment tools have been created which include both observational and self-assessment tools.¹⁰² These assessment tools can vary on the dimensions of

family functioning they assess; however, the majority assess communication, affective environment, organization, and problem-solving abilities.⁶ In this study the Family Assessment Measure was used to examine the following dimensions: task accomplishment, communication, involvement, control, and values and norms.^{112,139} We hypothesize that these family functioning dimensions affect the number of dental caries in adolescents. Two dimensions assessed by the FAM – affective expression and role performance – were not examined in this analysis.

3.2 Methods

This study was reviewed and approved through the University of Pittsburgh Institutional Review Board (IRB) and West Virginia University IRB. IRB approval letters can be found in Appendix B. Informed consent was obtained for study participants.

3.2.1 Study population

The data analyzed for this thesis were previously collected by the Center for Oral Health Research in Appalachia (COHRA) as part of the first research cohort (COHRA1). COHRA is a collaboration between the University of Pittsburgh and West Virginia University.¹³⁹ COHRA1 recruited families living in the Appalachian region from 2002 and 2009. The Appalachian region consists of 13 states: Alabama, Georgia, Kentucky, Maryland, Mississippi, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Virginia, and West Virginia.¹⁴⁰ The Appalachian region is unique when compared to the rest of the United States because 42% of the Appalachian population is rural, compared to 20% of the national population.¹⁴⁰ Residents of this

region are impacted more by caries and other oral diseases than many other areas in the United States.⁸¹ With the Appalachian population having some of the worst oral health indicators, the COHRA project was created to gain a greater understanding of the region's unique and shared risk factors for oral disease.¹³⁹ In order to be eligible for the COHRA1 study, at least one child-parent pair had to reside within the home and the child had to be between the ages of 1 and 18 years-old.¹³⁹ Households were recruited from Webster and Nicholas counties in West Virginia and Allegheny, Washington, and McKean counties in Pennsylvania.¹³⁹ Several study variables were collected from study participants, including microbiology samples, standardized caries screenings, and self-report forms.¹³⁹ Information on the complete COHRA1 study methods are outlined by Polk et al.¹³⁹

Specific data used for this thesis project were chosen based upon a child's eligibility to complete the Family Assessment Measure. According to the study protocol, children under the age of 11 were not provided the Family Assessment Measure and were therefore not included in this study.¹³⁹ Family Assessment Measure scores were requested for children between the ages of 11 and 17 years. Additionally, three sections of the Family Assessment Measure were used to gain a greater understanding of the family environment: General, Self, and Dyadic. For each section, the adolescent's answers were used for analysis. The mother's responses for the dyadic relationship with her child were also included. Each section of the Family Assessment Measure was analyzed separately. The study population was further refined using the method outlined in Figure 1.

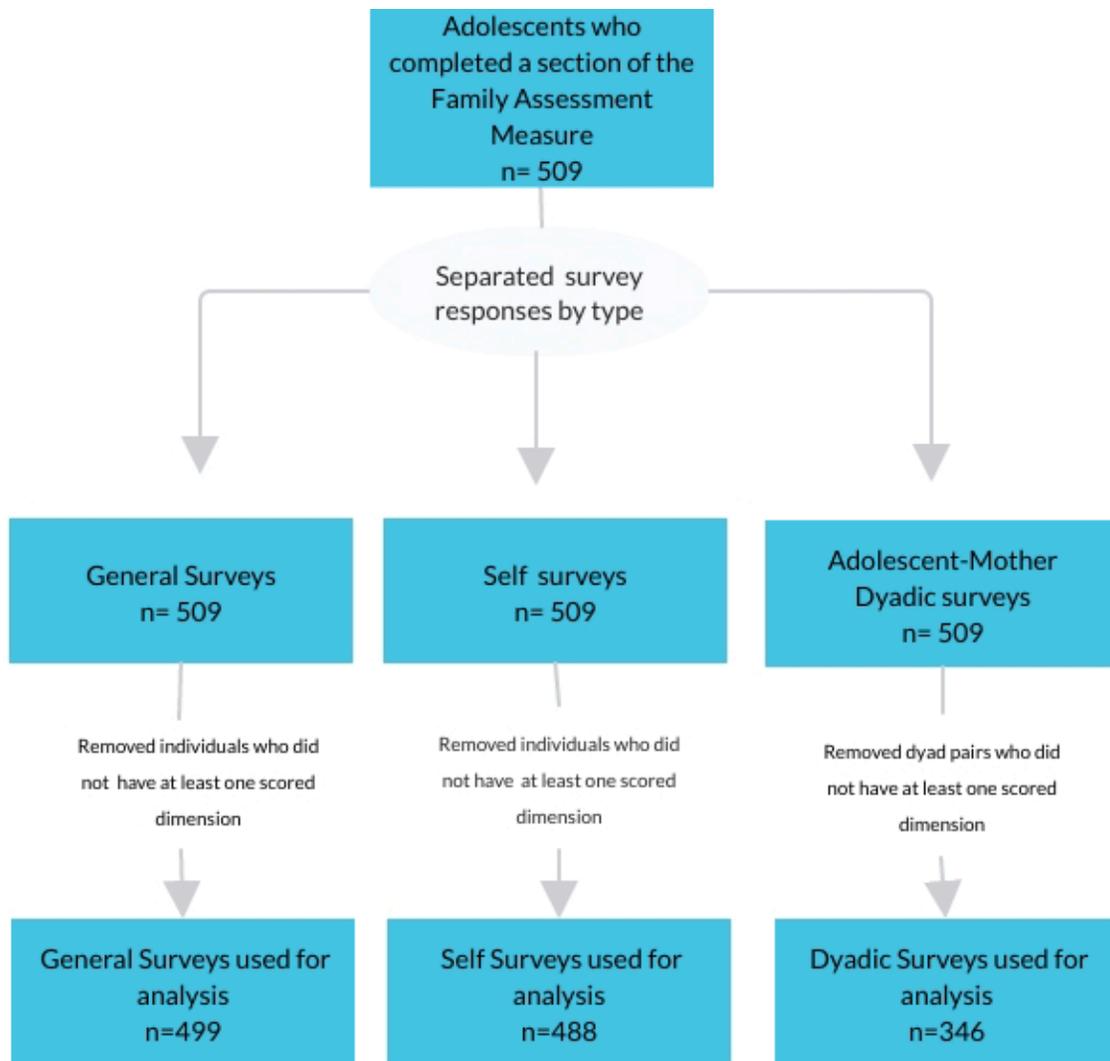


Figure 1. Refinement of the Family Assessment Measure Surveys for Analyses

3.2.2 Family Assessment Measure

The Family Assessment Measure is a self-report tool used to assess family functioning. It is based on the Process Model of Family Function, which examines family functioning from a family systems approach.¹¹² The focus of the Process Model is on the family’s ability to accomplish various tasks and it does this by assessing seven constructs or dimensions related to

the family unit: (1) task accomplishment, (2) role performance, (3) communication, (4) affective expression, (5) involvement, (6) control, and (7) values and norms.¹¹² The Family Assessment measure was developed to assess these seven dimensions. It consists of three that assess family functioning on different levels within the family: General, Self, and Dyadic.¹¹² The General section focuses on the whole family as a system and consists of 50 questions.¹¹² The Self section assesses an individual's perception of his or her own functioning within the family and consists of 42 questions.¹¹² The Dyadic section assesses specific relationships or dyads within the family and also has 42 questions.¹¹² For each section, the individual reads a statement and rates it on a four-point scale (1 = strongly agree, 2 = agree, 3 = disagree, 4 = strongly disagree).¹¹² A raw score was generated for each dimension by a member of the COHRA research team. The raw score for each dimension in the General section ranges from 0 to 15 and from 6 to 24 for the Self and Dyadic sections. Lower scores indicate better family functioning; however, these scores have not yet been transformed to their standard score values and therefore cannot be compared to outside populations or characterized as normal, subclinical, or clinical.¹¹² For the purpose of this thesis, the scores are analyzed in their raw form.

3.2.3 Caries Screening Exam

A standardized caries screening was performed by COHRA1 research staff members, one being either a dentist or dental hygienist.¹³⁹ The coronal surfaces of each tooth were assessed for the presence of dental carries and classified as either sound, decayed, filled, or missing.¹³⁹ For the purpose of this thesis, a total DMFT (decayed, missing, and filled teeth) index was used, which includes both the primary and permanent dentition. For more information on how the caries

screening was completed and the calibration of research staff members, please see the study protocol by Polk et al.¹³⁹

3.2.4 Data Acquisition

Once approved, the COHRA1 data request was sent to the data management team. Only the data necessary for this thesis were compiled along with the appropriate data dictionaries. Data dictionaries include relevant information such as coding definitions, questions asked for the Family Assessment Measure, and scoring algorithms used for the Family Assessment Measure. A deidentified data set was provided for analysis.

3.2.5 Data Analysis

The three sections of the Family Assessment Measure were analyzed separately. Linear regression models were used to test the relationship between an adolescent's DMFT index and the different family functioning dimensions. Models were run using the family functioning dimensions as the predictors for the dependent variable (i.e. total DMFT). Each dimension was analyzed individually, both with and without adjustment for covariates of sex, age, site, and race/ethnicity. These covariates were selected for due to differences seen in previous studies.^{9,48,51,57,59-61,68,89,91,141} For the purpose of data analysis, race and ethnicity was collapsed into two groups: Caucasian and Other. This decision was made because there was only a small number of individuals who did not identify as Caucasian; however, complete race and ethnicity information for each section of the Family Assessment Measure can be found in Table 1, Table 3, and Table 5 below. The linear regression models were performed in STATA.¹⁴² Missing values were present in each section of

the Family Assessment Measure and therefore not all individuals were included in the analyses (see Figure 1). Leverage-versus-residual-squared plots were generated along with Cook's distance to investigate outliers and influential data points in order to refine the regression models. To control for familywise error rate the Bonferroni correction (α/n , where n is the number of statistical tests) was applied making the alpha level 0.00125 for study-wide significance.¹⁴³ The Bonferroni correction will control for the increase in type I error due to multiple analyses being done on the same data set.¹⁴³ However, it is important to note that this correction reduces type I error (false positives) at the expense of type II error (false negatives) and is considered conservative.¹⁴³ For the Dyadic Family Assessment Measure, the level of agreement between adolescent and mother was calculated. Agreement was defined as having no difference in the score for the specific family functioning dimension.

3.3 Results

This study explored the relationship between family functioning dimensions as predictors of the amount of dental caries in adolescents. The sections of the Family Assessment Measure were analyzed separately and the results from each analysis can be found below in its corresponding section.

3.3.1 Family Assessment Measure – General

The General Family Assessment Measure included 499 adolescents aged 11 to 17 years from COHRA1. A summary of sample characteristics for this portion of the Family Assessment

Measure is shown in Table 1. The sample consisted of nearly equal amounts of females (53.71%) and males (46.29%). Further, the sample was predominantly Caucasian (84.91%). The majority of the sample population was from West Virginia (67.54%). The mean total DMFT index was 3.062 with a standard deviation of 3.429. The family functioning dimension raw scores were previously calculated by the COHRA1 research team and range from 0-15. The distribution of the scores for each dimension are shown in Figure 2. The mean scores for the dimensions assessed during the analysis were: 6.015 for communication, 4.692 for involvement, 5.945 for task accomplishment, 6.063 for values and norms, and 6.472 for control.

Table 1. Population Characteristics of the General Family Assessment Measure

Population Characteristic	N	Mean (SD) or Percent
Adolescent's Age	499	13.76 (1.85)
Adolescent's Sex		
Male	231	46.29%
Female	268	53.71%
Adolescent's Race & Ethnicity		
Caucasian	422	84.91%
Other	75	15.09%
African American	63	12.63%
Asian	3	0.60%
Hispanic	3	0.60%
More than one race	6	1.20%
Household Income		
<\$24,999	210	56.00%
>\$25,000	165	44.00%
Site		
West Virginia	337	67.54%
Bradford, PA	25	5.01%
Burgettstown, PA	65	13.03%
Braddock, PA	72	14.43%
Total DMFT (primary plus permanent dentition)	499	3.062 (3.429)
Family Functioning Dimensions		
Communication	477	6.015 (2.578)
Involvement	474	4.692 (2.830)
Task Accomplishment	475	5.945 (2.394)
Values and Norms	473	6.063 (2.680)
Control	475	6.472 (2.656)

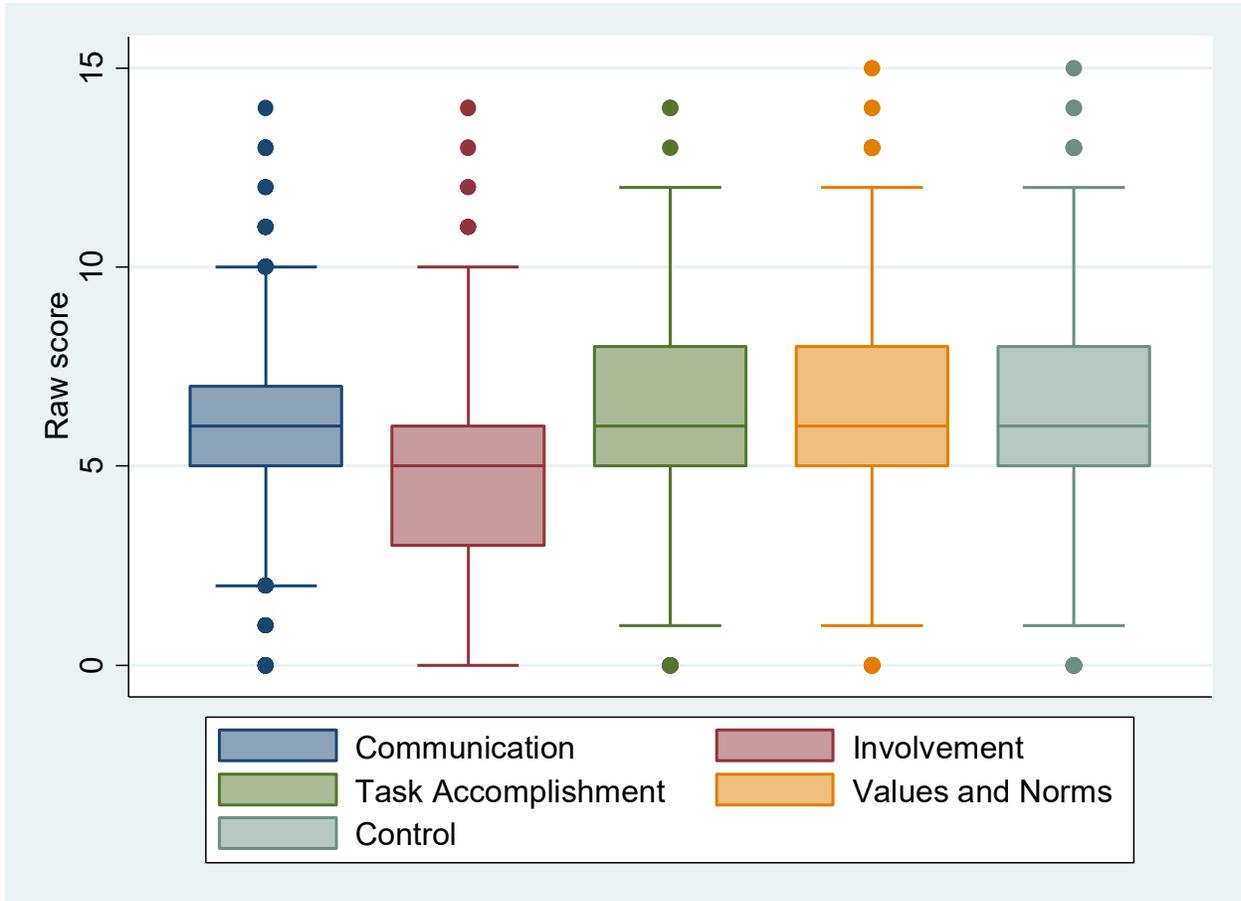


Figure 2. Distribution of the General Family functioning Raw Scores by Dimension

Table 2 summarizes the relationships between the general family functioning dimensions and the adolescent's total DMFT index. No statistically significant relationships were found in any of the family functioning dimensions for either the unadjusted or the covariate-adjusted model.

Table 2. Relationship between Family Functioning Dimensions for the General Family Assessment Measure and Total DMFT

Dependent Variable	Predictor	Unadjusted			Adjusted		
		Beta Coefficient	Standard Error	p-value	Beta Coefficient	Standard Error	p-value
Total DMFT	Communication	0.076	0.052	0.106	0.038	0.057	0.484
Total DMFT	Involvement	0.082	0.046	0.082	0.012	0.047	0.842
Total DMFT	Task Accomplishment	0.093	0.052	0.048	0.119	0.055	0.030
Total DMFT	Values and Norms	0.013	0.050	0.787	-0.027	0.052	0.621
Total DMFT	Control	0.109	0.050	0.021	0.144	0.050	0.008

^a Adjusted models include age, sex, race, site, and income.
Total DMFT includes decayed missing filled teeth for both the primary and permanent dentition.

3.3.2 Family Assessment Measure – Self

The Self Family Assessment Measure included 488 adolescents aged 11 to 17 years from COHRA1. The mean age of the sample was 13.76 and was predominantly Caucasian (84.98%). It included a relatively equal number of females (52.87%) and males (47.13%) and the mean total DMFT score was 3.035. A complete summary of sample characteristics is shown in Table 3. The raw scores for the family functioning dimensions range from 6-24 and the distribution can be seen for each dimension in Figure 3. The mean scores for each dimension assessed during the analysis were as followed: 12.82 for communication, 12.02 for involvement, 12.55 for task accomplishment, 13.39 for values and norms, and 13.39 for control.

Table 3. Population Characteristics for the Self Family Assessment Measure

Population Characteristic	N	Mean (SD) or Percent
Adolescent's Age	488	13.76 (1.853)
Adolescent's Sex		
Male	230	47.13%
Female	258	52.87%
Adolescent's Race & Ethnicity		
Caucasian	413	84.98%
Other	73	15.02%
African American	64	13.11%
Asian	2	0.41%
Hispanic	1	0.20%
More than one race	6	1.23%
Household Income		
<\$24,999	205	56.32%
>\$25,000	159	43.68%
Site		
West Virginia	331	67.83%
Bradford, PA	17	3.48%
Burgettstown, PA	64	13.11%
Braddock, PA	76	15.57%
Total DMFT (primary plus permanent dentition)	488	3.035 (3.436)
Family Functioning Dimensions		
Communication	455	12.82 (2.497)
Involvement	460	12.02 (2.438)
Task Accomplishment	460	12.55 (2.635)
Values and Norms	463	13.39 (2.454)
Control	463	13.39 (2.454)

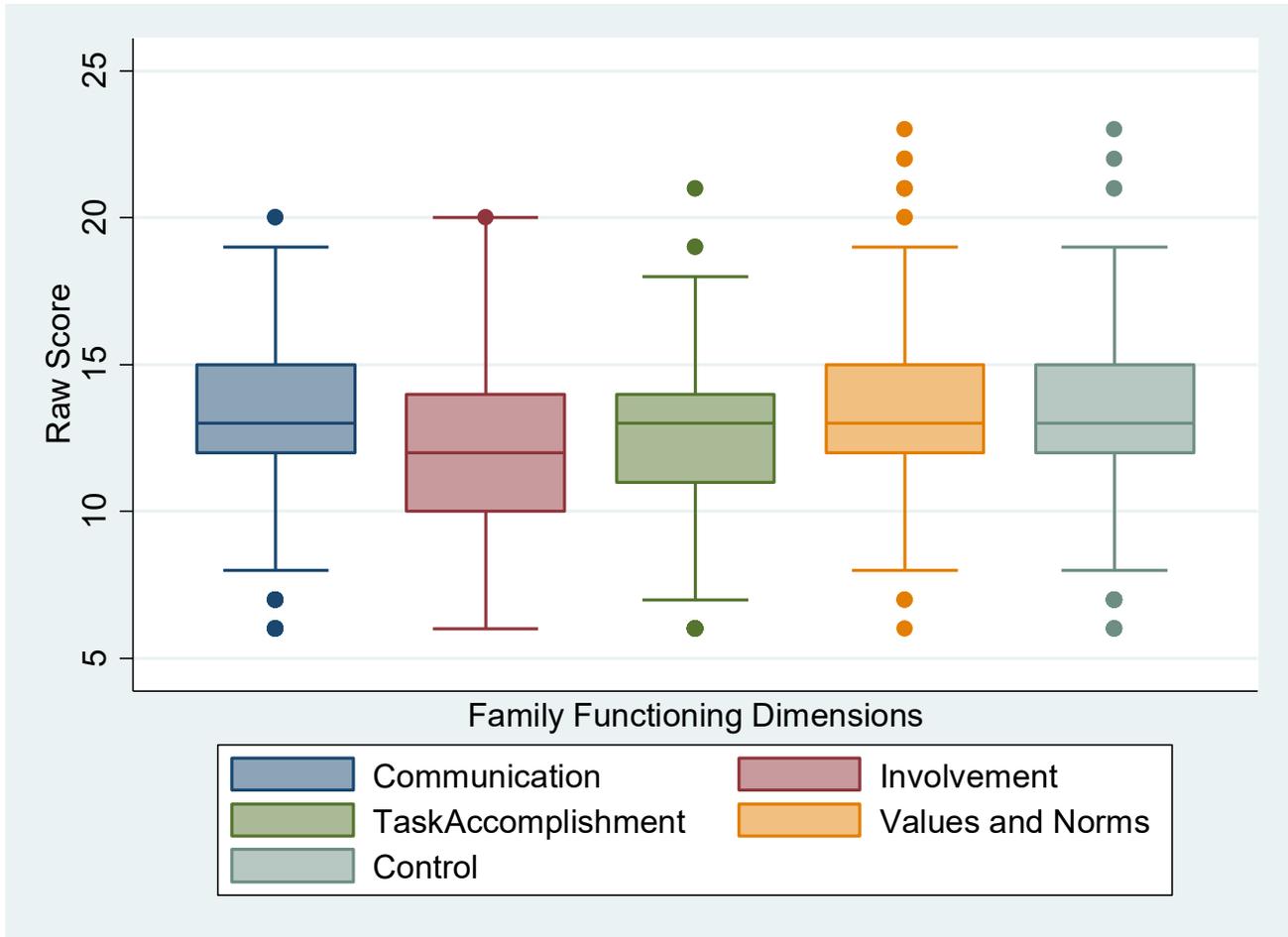


Figure 3. Distribution of the Self Family Functioning Raw Scores by Dimension

Statistically significant relationships were found in the univariate analyses and the covariate-adjusted analyses for the Self Family Assessment Measure. A statistically significant relationship was found between an adolescent’s score for involvement and total DMFT index (p-value=0.000) in the univariate analysis and remained statistically significant after the model was adjusted for age, sex, race, site, and income (p-value=0.000). The dimension values and norms was also statistically significant in the unadjusted model with a p-value of 0.000, however, the dimension did not remain significant once it was adjusted for covariates. The dimensions

communication, task accomplishment, and control were not significant in either model (see Table 4).

Table 4. Relationship between Family Functioning Dimensions for the Self Family Assessment Measure and Total DMFT

Dependent Variable	Predictor	Unadjusted			Adjusted		
		Beta Coefficient	Standard Error	p-value	Beta Coefficient	Standard Error	p-value
Total DMFT	Communication	0.139	0.054	0.004	0.085	0.053	0.127
Total DMFT	Involvement	0.184	0.054	0.000	0.220	0.053	0.000
Total DMFT	Task Accomplishment	0.135	0.049	0.005	0.139	0.050	0.013
Total DMFT	Values and Norms	0.182	0.055	0.000	0.122	0.059	0.027
Total DMFT	Control	0.132	0.051	0.006	0.147	0.049	0.007

^a Adjusted models include age, sex, race, site, and income.
 Total DMFT includes decayed missing filled teeth for both the primary and permanent dentition.
 Bold font indicates a p-value less than 0.00125

3.3.3 Family Assessment Measure – Dyadic

The Dyadic Family Assessment Measure included 386 adolescents aged 11 to 17 years with a mean age of 13.90. The demographics of the mothers are not reported; however, information such as income and site are representative of both the adolescent and his/her mother. The majority of the study participants was from West Virginia (63.58%) and 82.90% identified as Caucasian. The average total DMFT index was 2.864 with a standard deviation of 3.334. The distribution of raw scores for the Dyadic family functioning dimensions of the child and mother relationship can be seen in Figure 4 and range from 6-24. A complete summary of sample characteristics is provided in Table 5. The adolescent and mother’s family functioning scores were also assessed to

determine congruency. 13.17% of the adolescent-mother pairs were in agreement about the dimension communication. 48.27% of the adolescents in the study rated communication for the dyad worse than the mother and 38.56% of the adolescents rated communication better than the mother. Similar proportions were seen for each of the dimensions and can be found in Figure 5 below.

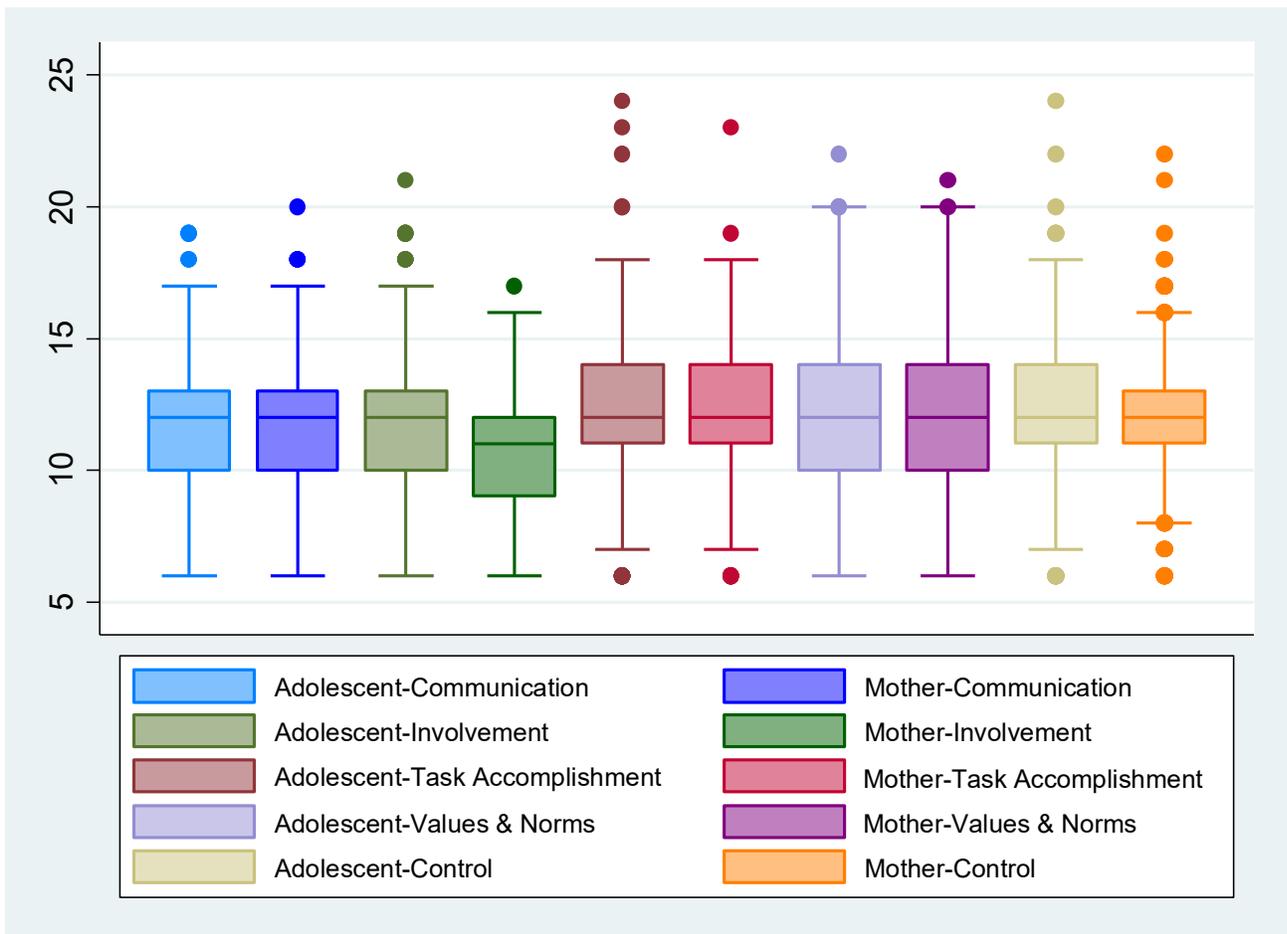


Figure 4. Distribution of the Family Functioning Dimension Raw Scores for the Adolescent-Mother Dyad Pairs by Dimension

Table 5. Population Characteristics for the Dyadic Family Assessment Measure

Population Characteristic	N	Mean (SD) or Percent
Adolescent's Age	346	13.90 (1.850)
Adolescent's Sex		
Male	172	49.71%
Female	174	50.29%
Adolescent's Race & Ethnicity		
Caucasian	286	82.90%
Other	59	17.10%
African American	52	15.03%
Asian	2	0.58%
Hispanic	1	0.29%
More than one race	4	1.16%
Household Income		
<\$24,999	162	54.73%
>\$25,000	134	45.27%
Site		
West Virginia	220	63.58%
Bradford, PA	16	4.62%
Burgettstown, PA	44	12.72%
Braddock, PA	66	19.08%
Total DMFT (primary plus permanent dentition)	346	2.864 (3.334)
Family Functioning Dimensions		
Communication (adolescent's rating)	329	11.78 (2.770)
Communication (mother's rating)	339	11.67 (2.586)
Involvement (adolescent's rating)	323	11.69 (2.898)
Involvement (mother's rating)	337	10.89 (2.302)
Task Accomplishment (adolescent's rating)	326	12.17 (3.010)
Task Accomplishment (mother's rating)	336	12.06 (2.625)
Values and Norms (adolescent's rating)	323	11.90 (2.835)
Values and Norms (mother's rating)	335	12.17 (2.811)
Control (adolescent's rating)	328	12.36 (2.908)
Control (mother's rating)	336	12.11 (2.566)

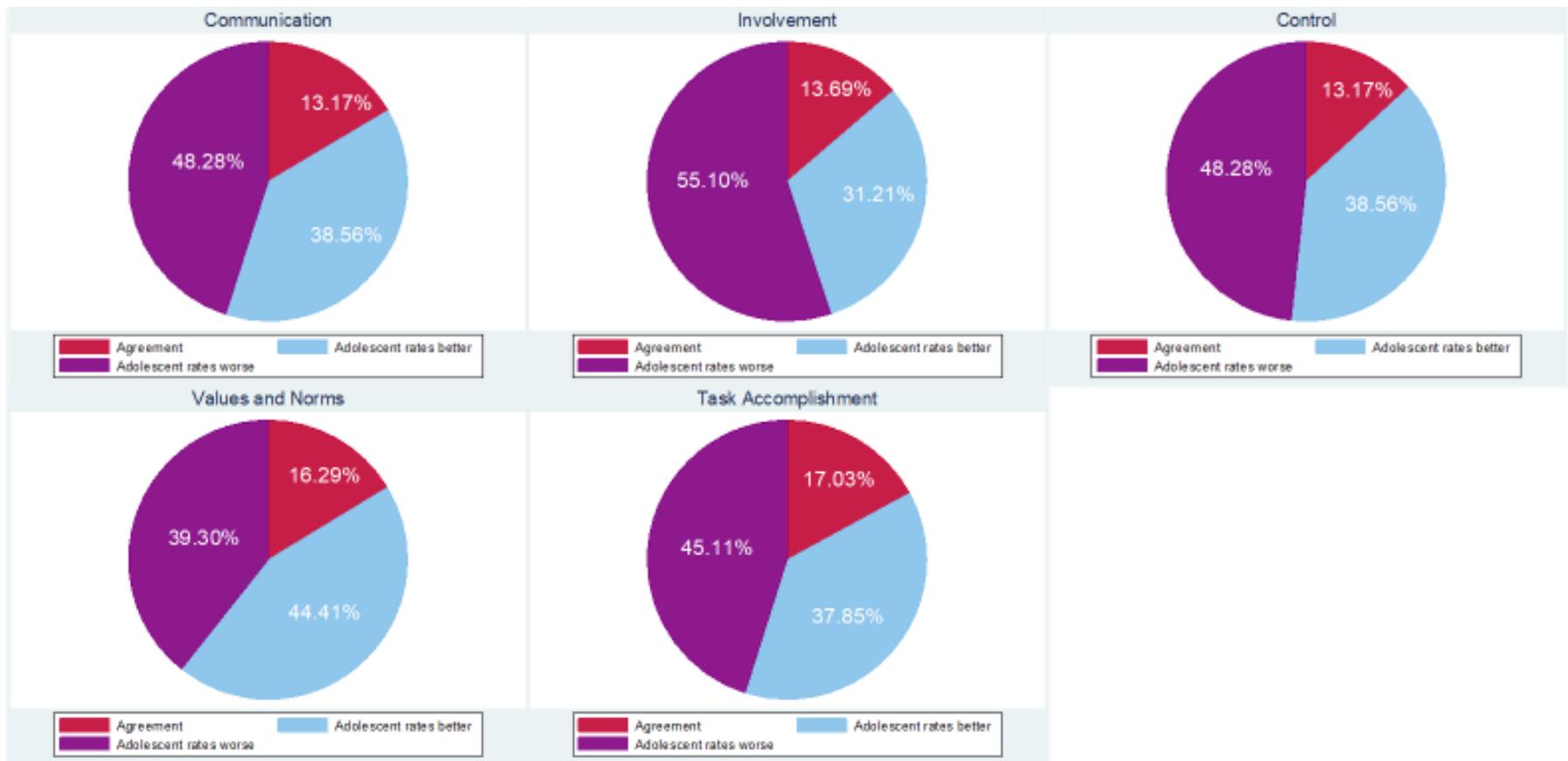


Figure 5. Score Differences by Dimension for the Adolescent-Mother Dyad Pairs

The dyadic raw scores for the adolescent and their mother were analyzed separately. For the adolescent's rating of the dyadic relationship, the dimension values and norms was determined to be a statistically significant predictor of the adolescent's total DMFT index. In the unadjusted model values and norms had a beta coefficient of 0.2274 and a p-value of 0.000. In the covariate adjusted model values and norms had a beta coefficient of 0.2408 and a p-value of 0.000. In the adolescent's rating of the dyadic relationship, the dimensions communication, involvement, task accomplishment, and control were not found to be statistically significant predictors of the total DMFT index. For the mother's rating of the dyadic relationship, the dimension values and norms was also determined to be a statistically significant predictor of her adolescent's total DMFT index. For the unadjusted model, the p-value was 0.001 and the beta coefficient was 0.1901, however, the dimension did not continue to be significant in the adjusted model (see Table 6). Additionally, the dimension control was determined to be a statistically significant predictor of her (the mother) adolescent's total DMFT index with a beta coefficient of 0.2105 and a p-value of 0.000 in the adjusted model.

Table 6. Relationship between Family Functioning Dimensions for the Dyadic Family Assessment Measure and Total DMFT

Dependent Variable	Predictor	Unadjusted			Adjusted		
		Beta Coefficient	Standard Error	p-value	Beta Coefficient	Standard Error	p-value
Adolescent's rating							
Total DMFT	Communication	0.0691	0.0559	0.223	0.0884	0.0540	0.153
Total DMFT	Involvement	0.1614	0.0516	0.005	0.0758	0.0508	0.224
Total DMFT	Task Accomplishment	0.1467	0.0541	0.010	0.1322	0.0505	0.031
Total DMFT	Values and Norms	0.2274	0.0538	0.000	0.2408	0.0525	0.000
Total DMFT	Control	0.0876	0.0534	0.124	0.0239	0.0507	0.698
Mother's rating							
Total DMFT	Communication	0.1317	0.0575	0.018	0.1676	0.0527	0.005
Total DMFT	Involvement	0.1410	0.0605	0.011	0.0943	0.0578	0.116
Total DMFT	Task Accomplishment	0.1028	0.0574	0.066	0.1490	0.0543	0.014
Total DMFT	Values and Norms	0.1901	0.0498	0.001	0.1497	0.0488	0.013
Total DMFT	Control	0.1453	0.0588	0.009	0.2105	0.0560	0.000
<p>^a Adjusted models include age, sex, race, site, and income. Total DMFT includes decayed missing filled teeth for both the primary and permanent dentition. Bold font indicates a p-value less than 0.00125</p>							

3.4 Discussion

The aim of this study was to explore the relationship of family functioning dimensions as predictors of the adolescent caries experience. The COHRA1 cohort that was used was representative of the adolescent age group, albeit, younger ages were more represented than older ages with the mean age in all Family Assessment Measures being approximately 13 years. In each of the analyses (General, Self, and Dyadic), males and females were approximately equally represented. However, not all study demographics were equal in the analyses. The majority of the study sample was from West Virginia and identified as Caucasian. Although, a predominantly Caucasian sample is not representative of the United States, it is representative of the Appalachian region. According to the 2000 U.S. Census, 88% of the Appalachian population identified as Non-Hispanic White, 8% identified as Non-Hispanic Black, 2% identified as Hispanic, and 2% identified as other races, which include non-Hispanic American Indians, Pacific Islanders, Asians, and multiracial persons.¹⁴⁴ In our study sample, the percentage of individuals who identified as Caucasian ranged from approximately 83%-85%, ~13%-15% of individuals identified as African American, ~0.40%-0.60% of individuals identified as Asian, and ~0.20%-0.60% identified as Hispanic.

3.4.1 Family Assessment Measure – General

The General Family Assessment Measure examines the family on a global level. This survey allows the study participant to rate how their family interacts and achieves goals as a whole.¹¹² None of the family functioning dimensions were found to be a statistically significant predictor of the adolescent's total DMFT index after applying the Bonferroni correction. Note

though that there are family functioning dimensions that reach suggestive statistical significance (p -value < 0.05), such as task accomplishment and control. Both these dimensions are suggestive in the unadjusted and the adjusted models. An increase in the dimension score is indicative of worse family functioning.¹¹² Therefore, a possible explanation of how an increase in the score for task accomplishment may increase the adolescent's total DMFT index is by the family struggling to complete tasks related to oral hygiene such as, regular trips to the dentist and daily oral hygiene habits. Regular dental visits allow the dentist to continue to aid in the development and education of healthy oral hygiene habits.¹⁴⁵ Furthermore, individuals who brush their teeth infrequently are at a greater risk for a new carious lesion compared to individuals who brush regularly.^{52,53}

The other dimension that was a suggestive predictor of the adolescent's total DMFT index was control. Control refers to how family members influence one another.^{112,146} According to the Process Model of Family Functioning, family members influence one another in two distinct conditions.¹⁴⁶ The first condition is to maintain current functioning to achieve day-to-day tasks and the second condition is to allow the current functioning to shift in order to meet changing demands.¹⁴⁶ It is possible that an increased score in this dimension may cause an adolescent's total DMFT index to increase because the family is experiencing challenges with maintenance functioning, which hamper the completion of day-to-day tasks such as oral hygiene habits.¹⁴⁶ Another explanation is that there is a change in the household structure such as, a two-parent household becoming a single-parent household. Such changes could also result in poorer toothbrushing behaviors for the children and adolescents residing in the home and perhaps poorer eating habits (i.e. an increase in sugar consumption).

Furthermore, choosing to only analyze the adolescent's assessment of the General Family Assessment Measure has limitations as there may be discrepancies in other family member's

ratings of the dimensions that are unknown at this time. Studies examining family functioning in families that have a child with an eating disorder have demonstrated that including all family members in the evaluation process is critical, as viewpoints vary across family members. For example, research has shown that mothers tend to view family functioning as healthier and less disordered compared with their affected daughters, while others have found no difference in the perceptions of family functioning between fathers and affected daughters.^{104,147,148}

3.4.2 Family Assessment Measure – Self

The Self Family Assessment Measure allows the adolescent to rate his or her own functioning within the context of the family.¹¹² As an adolescent, the individual is beginning to establish their own oral hygiene habits and has assumed different roles within the family. For these reasons, assessing how the adolescent views himself/herself is important in trying to understand the family dynamic. Two of the five family functioning dimensions analyzed were found to be significant predictors of the adolescent's total DMFT index. The dimension involvement had the highest beta coefficient in the unadjusted model at 0.184. This means with every one standard deviation increase in the adolescent's raw score for involvement, results in a 0.184 standard deviation increase in their total DMFT index. The dimension values and norms was also found to be statistically significant in the unadjusted model with a beta coefficient of 0.182. In the covariate-adjusted model, involvement was the only statistically significant predictor of the adolescent's total DMFT index with a beta coefficient of 0.220. Again, this would mean with every one standard deviation increase in the adolescent's raw score for involvement, a 0.220 standard deviation increase in their total DMFT index would occur. The dimension involvement "refers to the degree and quality of family members' interest and concern for one another".¹⁴⁶ In the context of the Self

Family Assessment Measure, this would refer to how the individual feels about their own interest in family members. With this in mind, it is possible that an increase in an adolescent's score for involvement may lead to an increase in their total DMFT index because the individual may not be interested in other family members and therefore feels a sense of pseudo-autonomy and therefore does not feel the need to complete oral hygiene tasks.¹⁴⁶ On the other hand, an individual could have an increase in their involvement score because they have a strong interest in the family and therefore are too involved in helping others complete their tasks at the expense of their own.

Furthermore, in the unadjusted models the dimensions communication, task accomplishment, and control reach suggestive significance (p values < 0.05) for predicting adolescent's total DMFT index. A possible explanation of how an increase in the dimension communication could result in an increase in the adolescent's total DMFT index is the adolescent could be struggling to deliver clear messages about their personal needs to family members.¹⁴⁶ For example, as an adolescent becomes more independent certain tasks may be transferred to him/her and less reminders are given by the parents. The adolescent may then be in charge of providing reminders to the parent about scheduling dental appointments. If a child cannot deliver this message to a parent or is trying to pass the message indirectly, it is possible the dental appointment will be missed and therefore the adolescent's oral hygiene cannot be assessed and corrected if needed.¹⁴⁶ In the adjusted model, dimensions that are suggestive of being predictors of an adolescent's total DMFT index are task accomplishment, values and norms, and control.

3.4.3 Family Assessment Measure – Dyadic

The Dyadic Family Assessment Measure allows individuals within the household to rate different dyadic relationships. In this thesis, the dyadic assessments were limited to the relationship

between adolescent and mother. The mean rating for each dimension was relatively similar for the adolescent-mother dyad. For example, the mean score of communication as rated by the adolescent was 11.78 and 11.67 as rated by the mother. The scores of the dimensions imply the adolescent and the mother perceive their relationship in a similar manner. Adolescents' assessment of their relationship with their mother did yield a single family functioning dimension that was predictive of their total DMFT index: values and norms. The dimension values and norms was significant in both models. In the unadjusted model, the beta coefficient indicates that with every one standard deviation increase in the raw score for values and norms results in a 0.2274 standard deviation increase in the adolescent's total DMFT index. In the adjusted model, the beta coefficient indicates that with every one standard deviation increase in the raw score for values and norms, a 0.2408 standard deviation increase in the adolescent's total DMFT index occurs.

The mother's assessment of the dyadic relationship also had statistically significant family functioning dimensions. In the unadjusted model, the dimension values and norms was also found to be a statistically significant predictor of the adolescent's total DMFT index with a beta coefficient of 0.1901. In the models adjusted for age, income, race, sex, and site, the dimension control was a statistically significant predictor of the adolescent's total DMFT index. Control's beta coefficient of 0.2105 means that with every one standard deviation increase in the mother's raw score for control, an increase of 0.2105 standard deviations occur in their adolescent's total DMFT index. The dimension control again refers to the techniques used by family members to influence one another's behavior.^{112,146} Additionally, control lends insight into an individual's internal sense of responsibility.¹⁴⁶ With this in mind, it is possible that an increase in the mother's rating of control causes an increase in her adolescent's total DMFT index because the adolescent

has not yet achieved his/her own sense of internal responsibility. A mother may feel that she often has to remind her child to complete their tasks such as brushing his/her teeth.

The dimension values and norms was a statistically significant predictor in both the adolescent's and the mother's rating of their dyadic relationship. As explained by the Process Model of Family Functioning, values and norms help to provide context for individuals when going through the decision-making process.^{112,146} An example of how an increase in this score could explain an increase in the total DMFT index would be the assigned value to dental health and habits by the family. Studies have shown that when a parent or caregiver values or implements positive oral hygiene habits, their child is more likely to do the same.^{119,133,134} If dental health is not part of a family's values and norms, it could have impact on the dental hygiene habits of the family. However, without exploration into the relationship of family functioning dimensions, oral hygiene habits, and DMFT index, it cannot be said if one of these mediates or influences the other. The study by Duijster et al. found all family functioning dimensions to be significantly associated with oral hygiene behaviors.¹³⁷ Furthermore, they found children who were from normal functioning families were more likely to start brushing their teeth at a younger age when compared to children from families who had clinical or subclinical family functioning.¹³⁷ These findings suggest the importance of exploring the possible relationship of family functioning and oral hygiene habits.

Other family functioning dimensions reached suggestive levels of statistical significance (i.e. p values < 0.05) for predicting the adolescent's total DMFT index. In the adolescent's rating of his/her dyadic relationship, the dimensions involvement and task accomplishment in the unadjusted model were suggestive with a p-value of 0.005 and 0.010 respectively. In the adjusted model, task accomplishment remained suggestive with a p-value of 0.031. In the mother's rating

of her dyadic relationship, the dimensions communication, involvement, and control were suggestive in the unadjusted model. In the adjusted model, communication remained suggestive with a p-value of 0.005. The dimensions task accomplishment and values and norms were also suggestive.

3.4.4 Limitations and Directions for Future Research

This study has several limitations that can be addressed in future studies. It will be critical to transform the family functioning dimensions into their final T-scores in order to characterize each dimension as a weakness or a strength for the family. This will allow for more descriptive studies of the COHRA1 cohort. For example, separating families into high and low functioning groups will allow exploration into possible differences between the two groups. Furthermore, fully scoring the dimensions will allow the comparison to outside study populations that also utilize the Family Assessment Measure.

This study only explored the relationship between the mother and the adolescent. While historically more research has focused on the mother, it is critical to gather more information about the influence of the father (and other types of caregivers) on a child's oral health. Additionally, each member in the household also completed the General and Self section of the Family Assessment Measure in addition to the Dyadic section. Exploring the caregiver's perspective of the general family environment and how they perceive their own functioning would allow for a more thorough understanding of the family environment. Although there was agreement in the dyadic relationship, it is possible there is differences in perceptions of general family functioning. It would be interesting to explore these surveys and to see if there was any relationship between them and dental caries experience. It would also be beneficial to explore all the dimensions

assessed by the Family Assessment Measure. Due to the nature of the thesis project, the dimensions were limited for scope, however, it is possible other dimensions are also predictive of dental caries.

Although covariates were included to adjust for influence, it is possible not all predictors were included in the regression model. It would be important to explore the relationship of family functioning dimensions on oral hygiene habits such as how often an adolescent brushes his or her teeth. As mentioned earlier, the Duijster et al. study found that the relationship between childhood dental caries and family functioning may have been mediated by oral hygiene behaviors.¹³⁷ Information on oral hygiene habits was collected on the COHRA1 sample and would be important to explore in future studies.

3.5 Conclusion

This study demonstrates that select family functioning dimensions are statistically significant predictors of an adolescent's total DMFT index, and several other reach suggestive significance. The three sections of the Family Assessment Measure were analyzed independently. No statistically significant dimensions were found in the General Family Assessment Measure. The dimensions involvement and values and norms were significant predictors of the dependent variable in the Self Family Assessment Measure. Values and norms was significant in both the adolescent's and the mother's Dyadic Family Assessment Measure, along with the dimension control for the mother's dyadic assessment. These results support the hypothesis that family functioning dimensions have an impact on an adolescent's total DMFT index, however, additional research is needed to understand the relationship further. Understanding of how family functioning

impacts an adolescent's, or a child's, DMFT index would be useful in strategizing public health interventions to more efficiently prevent dental caries and thereby reduce its public health impact.

4.0 Research Significance to Genetic Counseling and Public Health

Strides have been made to reduce the burden of dental caries; however, it remains a global health problem affecting 60-90% of school-aged children in industrialized nations.⁸⁷ In the United States alone, the prevalence of treated and untreated dental caries in children aged 2-19 years old was approximately 45% in 2015-2016.⁹ Due to the prevalence of dental caries in the United States and it being considered a largely preventable disease, it is considered a significant public health issue.^{1,2,9} Currently, oral health is one of the 2020 Healthy People Initiatives.¹⁴⁹ A goal of this initiative is to prevent and control dental caries, along with other oral and craniofacial conditions, and improve access to preventative dental services and care.¹⁴⁹

The core functions of public health services are assessment, policy development, and assurance.¹⁵⁰ Research such as this thesis project contributes to the assessment function of public health and supports the Healthy People 2020 Initiative. Assessment includes monitoring and diagnosing health problems in communities.¹⁵⁰ Although the COHRA1 cohort is not wholly representative of the United States population, the results of this study indicate that family functioning may be an important social determinant of health worth studying in other populations in connection to dental caries. The aim of this study was to assess and better understand the predictive relationship of family functioning dimensions for adolescent total DMFT index through the use of the Family Assessment Measure. The three sections of this assessment tool were analyzed separately in order to assess the impact of different relationships and levels within family functioning (e.g. how the adolescent sees his or her own functioning within the context of the family and its impact on the total DMFT index). By exploring the relationship of the predictor variables on the dependent variable, the study further assessed the problem of dental caries and

studies like these may also inform future intervention strategies aimed at preventing or reducing the oral health burden.

Further, this study also has implications for the field of genetic counseling. Dental caries is considered a chronic disease and managing the carious lesions has impacts on the family and the family has impact on the disease process. Many of the diseases that impact genetics patients are also chronic and progressive similar to dental caries.^{113-118,137} For this reason, it is important to continue to recognize the importance of family and support assessment during genetic counseling sessions. With recognizing this research and others that has focused on childhood chronic diseases, family functioning has impacts on disease outcome and management. Therefore, recognizing possible predictors of disease outcomes could inform future clinical practices.

Appendix A Definitions of Family Functioning Dimension

Task Accomplishment: Achieving tasks is the overall goal of the family and includes a variety of tasks ranging from basic to crises tasks. In order to accomplish tasks, the family must organize itself in order to achieve its goals. According to the Process Model, “the process by which tasks are accomplished includes: (1) task or problem identification, (2) exploration of alternative solutions, (3) implementation of selected approaches, and (4) evaluation of effects”.¹¹²

Communication: In order to achieve tasks, roles must be assigned to family members and these roles must be communicated effectively. Skinner et al. describes effective communication as the “achievement of [a] mutual understanding”.¹¹²

Involvement: This refers to the quality and the amount of family members’ interest in one another.¹¹² The type of involvement family members have with one another may support or inhibit the process of task accomplishment.

Values and Norms: A family’s values and norms may influence how a family proceeds in accomplishing different tasks. A family will use its values and norms to provide information or context for the different choices it has to make. There are different aspects of this dimension that may be more influential, such as how much autonomy does a family member have to determine their own attitude or behavior.¹¹²

Control: According to Skinner et al., “control is the process by which family members influence each other”.¹¹² Traits or characteristics of the family are critical to control. For example, is a family constructive or destructive. Combinations of traits can give rise to four styles of control: chaotic, laissez-faire, rigid, or flexible.¹¹²

Appendix B IRB Approval Documentation

5/9/2018

<https://www.osiris.pitt.edu/osiris/Doc/0/6J7MP8T7H724FCL40FNL3GMV7B/fromString.html>

University of Pittsburgh Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
<http://www.irb.pitt.edu>

Memorandum

To: [Mary Marazita](#), PhD
From: [IRB Office](#)
Date: 5/9/2018
IRB#: [REN18050059](#) / IRB020773
Subject: Genetic Factors Contributing to Oral Health Disparities in Appalachia.

Your renewal for the above referenced research study has received expedited review and approval from the Institutional Review Board under:

45 CFR 46.110.(9)

Please note the following information:

Approval Date: 5/9/2018
Expiration Date: 5/17/2019

This approval is for analysis of data only.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month** prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.



Approval of Protocol Renewal

06/25/2018

To: Daniel McNeil

From: WVU Office of Research Integrity & Compliance

Protocol Type: Expedited

Approval Date: 06/25/2018

Submission Type: Renewal

Expiration Date: 06/24/2019

Funding: University of Pittsburgh

WVU Protocol #: 1309099825R005

Protocol Title: Genetic Factors Contributing to Oral Health Disparities in Appalachia

The West Virginia University Institutional Review Board has reviewed and granted your request for re-approval of Expedited protocol 1309099825R.005, in accordance with the Federal regulations 45 CFR 46, 21 CFR 50, and 21 CFR 56 (when applicable). Additional details concerning the review are below:

- Category 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

The following documents were reviewed and approved for use as part of this submission. Only the documents listed below may be used in the research. Please access and print the files in the Notes & Attachments section of your approved protocol.

- COHRA-1 BRAAN approval letter 10-22-12.pdf
- Form H017.2012.12.04 - Continuing Review Form COHRA1 10-2-2014.docx
- HIPPA document H-24094.docx
- COHRA-1 BRAAN protocol 9-27-13.pdf
- List of personnel 6-26-17.pdf
- List of personnel 6-26-17.pdf

Protocol #: 1309099825R005

Phone: 304-293-7073

FWA: 00005078

Fax: 304-293-3098

ICRG: 0000194

Email: IRB@mail.wvu.edu

- COHRA1 KC Amendment Form 10-13-14.docx
- BriefUpdate for IRB 6-13-2018.pdf

WVU IRB approval of protocol 1309099825R005 will expire on 06/24/2019.

Once you begin your human subjects research, the following regulations apply:

1. Unanticipated or serious adverse events and/or side effects encountered in this research study **must** be reported to the IRB within five (5) days using the Notify IRB action in the electronic protocol.
2. Any modifications to the study protocol or informed consent form must be reviewed and approved by the IRB prior to implementation. These modifications should be submitted as an amendment.
3. You may not use a modified informed consent form until it has been reviewed and approved by the WVU IRB. **Only consent forms with the WVU+kc watermark may be used to obtain informed consent from participants.**

The Office of Research Integrity and Compliance will be glad to provide assistance to you throughout the research process. Please feel free to contact us by phone, at 304.293.7073 or by email at IRB@mail.wvu.edu.

Sincerely,



Johnathan M. Herczyk
IRB Administrator

Protocol#: 1309099825R005

PWA: 00005078

ICRC: 0000194

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University of Pittsburgh
Institutional Review Board

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Memorandum

To: [Mary Marazita, PhD](#)
From: [IRB Office](#)
Date: 11/9/2018
IRB#: [REN18100311](#) / IRB0506048
Subject: Coordinating Center for Genetic Factors Contributing to Oral Health Disparities in
Appalachia

Your renewal for the above referenced research study has received expedited review and approval from the Institutional Review Board under:

45 CFR 46.110.(9)

Please note the following information:

Approval Date: 11/9/2018
Expiration Date: 11/17/2019

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month** prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

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<https://www.osiris.pitt.edu/osiris/Doc/0/66HGL6NPFOFK54V7GFO5D1E3C1/fromStrin...> 11/14/2018

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