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The purpose of the current research was to examine the prevalence of middle ear disease, specifically chronic otitis media (OM) in racial/ethnic non-minority (NM) and racial/ethnic minority (REM) children. Previous studies (Fleming-Dutra et al., 2014; Smith & Boss, 2010) have reported Black and Hispanic children were less likely to be diagnosed with OM. In addition, the likelihood of NM and REM children with non-syndromic cleft lip (CL), cleft palate (CP), cleft lip and palate (CLP), being diagnosed with chronic OM and then receiving pressure equalization (PE) tube treatment was investigated. Finally, the use of PE tube treatment in NM and REM children with CL/P based on the expected payer source was explored.

The analysis was limited to children birth to five-years, 11-months of age who received medical care in NC as reported to the Healthcare Cost and Utilization Project (HCUP) program during 2016. A total of 319,682 patient files were accessed for the study. Patients with a primary diagnosis of CL/P were identified using ICD-10-CM codes.

REM children were under-identified in the diagnosis of chronic OM. The findings of this study were consistent with previous studies by Fleming-Dutra et al., (2014) and Smith and Boss (2010) in which REM children were less likely to be diagnosed with OM compared with NM children. Though not significant, REM children were less likely to be born with CP and CLP. These results are consistent with Canfield et al., (2006) and Williams et al., (2003) who reported rates of oral clefts were higher in NM infants. This study did not identify significant differences in the prevalence of chronic OM, PE tube treatment, or the expected payer source for PE tube treatment for NM and REM children with CL/P. Future studies should continue to investigate

what causes delays in seeking or complying with recommendations and how caregivers communicate the frequency and severity of OM symptoms.

THE PREVALENCE OF RACIAL/ETHNIC AND SOCIOECONOMIC FACTORS IN PRESSURE-EQUALIZATION TUBE TREATMENT AMONG PRESCHOOL-AGE CHILDREN WITH NON-SYNDROMIC CLEFT LIP/PALATE IN NORTH CAROLINA

by

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APPROVAL PAGE

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LIST OF ABBREVIATIONS

ACPA	American Cleft Palate-Craniofacial Association
AHRQ	Agency for Healthcare Research and Quality
CL	Clefts of the lip
CLP	Clefts of both the lip and palate
CL/P	Cleft of the lip with or without a cleft of the palate
CP	Cleft palate
CPT	Current Procedural Terminology
ET	Eustachian Tube
HCUP	Healthcare Cost and Utilization Project
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
NBDPN	National Birth Defects Prevention Network
NC	North Carolina
NM	Racial/ethnic non-minority
OFC	Oral facial clefts
OM	Otitis Media
OME	Otitis Media with Effusion
PE tube	Pressure Equalization tube
REM	Racial/ethnic minority
SASD	State Ambulatory Surgery and Services Databases
SE	Standard Error
SES	Socioeconomic status
US	United States

CHAPTER I

STATEMENT OF THE PROBLEM

Annually, healthcare providers in the United States (US) treat more than 7.8 million children under the age of six-years for a primary Otitis Media (OM) visit (Marom et al. 2014). In preschool-aged children, OM has been reported as the most common diagnosis for medical visits, with 50% of all children in the US diagnosed with OM before their first birthday and 90% diagnosed with OM by their fifth birthday (Smith & Boss, 2010; Teele, Klein &, Rosner, 1989). It has been estimated that 40% of children will have six or more recurrences of OM by seven-years of age (Casselbrant & Mandel, 2003; Vergison et al., 2010). Otitis Media with Effusion (OME) and acute otitis media (AOM) are among the most commonly occurring childhood illnesses, with OME occurring more frequently than AOM (Chonmaitree, 2000; Rosenfeld et al., 2013). More recently, Kawai and colleagues (2018) have reported a reduction of six million ambulatory visits for OM in children, as a result of the impact of pneumococcal conjugate vaccines. This decline was not dependent upon gender, racial/ethnic identification, health insurance status (expected payer source), or geographic region.

Research has shown that racial/ethnic differences exist in the diagnosis of OM. At six-months of age, Black and Asian infants are less likely to be diagnosed with OM, compared to White infants (Vernacchio et al., 2004). Similarly, Smith and Boss (2010) noted fewer Black and Hispanic children ranging from less than two-months to 18 years of age, were diagnosed with OM, compared to White children. More recently, research conducted by Fleming-Dutra et al., (2014) reported the percentage of diagnosis of OM for Black children 14-years of age and

younger was significantly lower than non-Black children (White, Asian, American Indian/Eskimo/Alaskan, Native Hawaiian/Pacific Islander, other). In short, disparities exist in the diagnosis of OM based on racial/ethnic identification. It is unclear if the variations exist based on Black children receiving more appropriate care that is consistent with national guidelines as suggested by Fleming-Dutra et al. (2014) or Vernacchio and colleagues' (2004) suggestion that Black and Asian children were less likely to receive specialty care or surgery compared to White children with recurrent OM.

The Impact of OM

OM, the inflammation and/or infection of the middle ear, compromises the traditional air-conduction sound pathway, creating a mild to moderate degree of conductive hearing loss (Northern, Downs & Hayes, 2014). OM is delineated as OME or AOM. OME, as defined in the clinical practice guideline developed jointly by the American Academy of Otolaryngology – Head and Neck Surgery Foundation, the American Academy of Pediatrics, and the American Academy of Family Physicians (Rosenfeld et al., 2016), is the presence of fluid in the middle ear space without signs or symptoms of an acute ear infection (ear fluid). AOM is the result of rapid onset of signs and symptoms of inflammation of the middle ear (ear infection) and typically refers to the first few weeks of the pathology being present. Chronic OME develops when OME persists for at least three months from the onset date or the diagnosis date of OME (Rosenfeld et al., 2016).

Untreated OM may result in short-term implications for the child, including ear pain, temporary conductive hearing loss (Northern et al., 2014), or tympanic membrane (eardrum) perforation (Bennett et al., 2016; Jung et al., 2013; Klein, 2001; Marom et al., 2014). Repeated episodes of OM are costly to both the child and their parents/caregivers. Often, caregivers who

work outside of the home need to be absent from their paid job to tend to the child with OM, leading to a reduction in their income (Barber et al, 2014). On average, children with AOM have twice as many office-based and emergency facility visits compared to same-age peers without AOM. In addition, children with AOM receive more than twice the number of prescriptions. This results in an increase of $314 per child annually in outpatient health care costs to families and/or the US healthcare system (Ahmed et al., 2014).

Untreated OM may also result in long-term sequelae. Mastoiditis, the second most common OM related complication (Marom et al., 2014), occurs as a result of a bacterial infection that can cause damage such as inflammation within the temporal bone, meningitis, or a brain abscess (Lieberthal et al., 2014; Mattos et al., 2014). Children with repeated or untreated OM may experience hearing thresholds that ranges from normal hearing to a moderate hearing loss (Rosenfeld et al., 2013). The loss can be conductive in nature due to a stiffening of the tympanic membrane and ossicle bones in the middle ear (Grindle & Correa, 2016) or sensorineural, as a result of infection or inflammation in the inner ear (Klein, 2001).

The impact of chronic OM is not limited to audiological damage. Chronic OM often results with the child experiencing fluctuating hearing loss over time, thus increasing the risk of speech and language delays in young children (Rosenfeld et al., 2013). Fluctuating hearing, because of intermittent ear fluid could interfere with speech and language development of preschoolers four-years of age or younger (Jung et al., 2013). Deficits have been noted in the speech production, speech perception, receptive language, and expressive language skills in children with OM (Gravel & Wallace, 2000). Northern et al., (2014) noted speech intelligibility is directly proportional to the degree of hearing loss and all children with hearing loss will show delays in receptive and expressive language skills.

Clefts of the Lip, Palate, or both Lip and Palate

Clefts of the lip and palate are among the most common of all congenital craniofacial anomalies (Parker et al., 2010). Worldwide, it is estimated that clefts of the lip (CL), cleft palate (CP), or both the lip and palate (CLP) occur in approximately 1 out of every 600 births (Berkowitz, 2013; Dixon et al., 2011; Rahimov et al., 2022). In the US, approximately 7,090 children are born each year with a cleft of the lip with or without a cleft of the palate (CL/P) (Centers for Disease Control and Prevention, 2015) resulting in CL/P occurring in an estimated 1 per 1,000 live births (Parker et al., 2010; Wehby et al., 2012).

Individual states are not required to provide data on the number or prevalence rates of birth defect cases. According to the National Birth Defects Prevention Network (NBDPN), not all states provide statewide data. For example, Georgia only provides metropolitan Atlanta area data for children born with CP and CL/P while Minnesota provides such data for children in metropolitan Minneapolis (NBDPN, 2017). North Carolina provides statewide data of the number of children born with CL, CP, and CLP to the NBDPN (Stallings et al., 2019). Refer to Table 1 for the average annual number of cases in North Carolina (NC) and the US during 2012-2016.

Table 1. Total Cases of Children Born With CL, CP and CLP in NC and the US

Total Counts for 2012-2016[+]		
Diagnosis	NC	US
CL	218	4,797
CP	307	8,608
CLP	327	9,799
Total	852	23,204

[+]estimates based on pooled data from birth years 2012-2016
Prevalence per 10,000 Live Births

Previous studies have demonstrated the prevalence of CL/P varies by racial group. Generally, individuals of Asian and Native American descent have the highest reported birth prevalence rate of CL/P with rates as high as 1 in 500. The prevalence rates of Caucasian children are lower with reported rates of nearly 1 out of 1,000; while individuals of African American descent were reported to have the lowest rates of roughly 1 out of 2,500 (Arosarena, 2007; Dixon et al., 2011; Vanderas, 1987).

According to Canfield et al. (2006), the prevalence of CL/P also differs according to ethnicity. Infants of non-Hispanic Black mothers had a significantly lower birth prevalence of CP and CL/P compared to infants of non-Hispanic White mothers. Similarly, infants born to Hispanic mothers had a significantly lower birth prevalence of CP compared with infants born to non-Hispanic White mothers. These results are similar to outcomes obtained by Williams et al. (2003) in which the rates of oral clefts were higher in White than in non-Hispanic Black and Hispanic-White infants.

OM and CL/P

Middle ear infection is one of the many conditions that may affect children with CL/P, specifically OM with and without effusion. The likelihood of middle ear disease and hearing loss in infants with CP has been noted for more than 50 years (Stool & Randall, 1967; Paradise et al., 1969). OME is generally recognized as a universal complication in children with CP (Paradise, 1980). More recently, Heidsieck et al., (2016), noted OME continues to occur frequently in children with CP. Similarly, Rosenfeld and colleagues (2016) concluded the prevalence of OME in children with CP ranges from 60% to 85%. As a result, dysfunction of the Eustachian Tube (ET) is believed to be responsible for the majority of OME in individuals with CP (Berkowitz, 2013).

The American Cleft Palate-Craniofacial Association (ACPA) acknowledges children with craniofacial anomalies are subject to an increased occurrence of ear disease (ACPA, 2009). Children with CL/P have been reported to have significantly increased incidence of Pressure Equalization (PE) tubes inserted for management of chronic OM (Flynn et al., 2009; Sheahan et al., 2003). Szabo and colleagues (2010) reported 98% of children with CP had at least one set of PE tubes inserted by five years of age. Short- and long-term benefits have been reported as a result of early insertion of PE tubes in these children (Kuo et al., 2014) including the prevention of short-term hearing loss and improved long-term language outcomes (Tunçbilek et al., 2003).

Treatment for OM

In the US, there are seven million annual episodes of reported OM with an estimated cost of $5 billion (Forrest et al., 2011). Treatment for OM includes nonsurgical and surgical interventions. Nonsurgical options include watchful waiting and medical therapy such as steroids, antibiotics, antihistamines or decongestants, which provide short-term benefits (Rosenfeld et al., 2016). When these treatments fail to eliminate chronic OM, the surgical insertion of PE tubes, which ventilate the middle ear space, can be used to alleviate the adverse effects of negative pressure on middle ear function and provide a means for middle ear fluids from OM to drain (Rosenfeld et al., 2013; Wallace et al., 2014).

Insertion of PE tubes is the most common ambulatory or outpatient surgery performed on children in the US (Rosenfeld et al., 2013). By three years of age, nearly 7% or 1 in 15 children will have had PE tubes placed (Kogan et al., 2000). Typically, PE tubes are inserted due to persistent middle ear fluid, frequent ear infections, or ear infections that persist after antibiotic therapy. The insertion of PE tubes reduces the prevalence of effusion, provides a mechanism for

drainage, and may reduce the likelihood of recurrent AOM (Browning et al., 2010; Rosenfeld et al., 2013).

Few studies suggest OM is more common in children from lower socioeconomic status (SES) families (Ah-Tye, Paradise et al., 2001; Damiano et al., 2009; Paradise et al., 1997). In contrast, Lieu and Feinstein (2002) concluded the diagnosis of OM was directly correlated with increasing income levels. Thus, SES disparities in the prevalence of OM in children has not been thoroughly explored (Smith & Boss, 2010). To fill this gap in the literature, the present study compared the prevalence of chronic OM in racial/ethnic minority (REM) and racial/ethnic non-minority (NM) preschool children with CL/P in the state of NC. The study also compared the prevalence of PE tubes in REM and NM preschool children and whether PE tube insertion was influenced by the expected payer source of private or public insurance. These findings will indicate whether REM preschool children with CL/P and a diagnosis of chronic OM are under-identified relative to NM preschool children with CL/P and a diagnosis of chronic OM and whether they are less likely to get PE tubes. The information gained from this study will assist stakeholders including speech-language pathologists, audiologists, medical personnel, educators, caregivers, healthcare policymakers/influencers, and when applicable, members of the Cleft Palate-Craniofacial Team who are involved in the care of preschool-age children.

CHAPTER II

LITERATURE REVIEW

It has been reported that racial/ethnic disparities exist in the diagnosis of OM with White children more likely to receive a diagnosis of OM compared to children of Black, Asian, and Hispanic descent (Fleming-Dutra et al., 2014; Vernacchio et al., 2004). The aim of this literature review is to provide an overview of the function of the ET paying special attention to the impact on children with clefts of the palate. Next will be a description of OM and CL/P including the impact of SES on children with non-syndromic CL/P. Finally, there will be a discussion of access to PE tubes, one of the most common treatment options for OM for not only this population but for all children.

Function of the ET and OM

The function of the ET in the human auditory system includes ventilation, pressure regulation, protection from sound, and drainage of secretions in the middle ear (Berkowitz, 2013). The ET is normally closed (Sharma & Nanda, 2009). When the ET opens, typically during chewing and swallowing, air pressure equalizes between the outer and middle ear, thereby ventilating the middle ear. This equalization of the air pressure between the outer and middle ear allows optimal transmission of sound through the eardrum. The ability to transmit sound is reduced if the air pressure between the outer and middle ear is unequal, forcing the eardrum outward or inward, resulting in discomfort (Sharma & Nanda, 2009). In children younger than three years of age. The ET is shorter, floppier, and more horizontal, which makes it less effective in ventilating and protecting the middle ear than the ET in the adult (Rosenfeld et al., 2016).

An underlying palatopharyngeal musculature contributes to the function of the ET. Thus, the primary function of the tensor veli palatini muscle, one of the palatal muscles, is to open the ET (Perry, 2011). In individuals with cleft, displacement of muscles due to the palate not fusing during fetal development also affects the function of the soft palate. The levator veli palatini muscle plays a role in elevating the velum posteriorly, thereby assisting in opening the ET (Kuehn & Moller, 2000). In children with CP, the tensor veli palatini has an abnormal course and insertions due to defects in the anatomic structure (Broen et al., 1996). Opening of the ET allows equalization of air pressure across the eardrum as well as drainage of middle ear fluids to occur (Leider et al., 1993). For children with CP, the ET is assumed to be in a horizontal position, permitting fluid to freely pass from the oropharynx into the nasopharynx as well as into the ET (Rood & Stool, 1981). Children with CP have been found to have severe functional obstruction of the ET. This obstruction appears primarily related to the inability of the tensor veli palatini muscle to dilate the ET actively during swallowing and seems to be the major factor responsible for the pathogenesis of OME in this population (Doyle et al., 1980). This impaired function of the ET in children with CLP may increase the risk of frequent ear infections and fluctuation of the child's hearing status over time due to the increased incidence of OM resulting in higher rates of mild to severe hearing loss (Kuo et al., 2013).

It has long been noted that the presence of recurrent OME has been attributed to abnormalities of ET function, affecting the child's hearing ability (Paradise et al., 1969). Additionally, children with oral clefts such as clefts of the hard and/or soft palate have an increased risk for incidences of ear disease that may be related to structural conditions, which affect the function of the ET (ACPA, 2009; Heidsieck, Smarius et al, 2016; Paradise et al., 1969; Stool & Randall, 1967). Early intervention and treatment of middle ear disease is vital in reducing

or eliminating the potential adverse impact of hearing, social, and psychological effects in individuals born with non-syndromic CL/P.

In most children, AOM and OME will resolve spontaneously or after medical intervention. Children with untreated OM may experience ongoing earache pain (McCormick, 2016). Rosenfeld and colleagues (2013) noted behavioral complaints such as distractibility, withdrawal, frustration, or aggressiveness. Additionally, some children or their caregivers reported motor complications including unexplained clumsiness, balance problems, or delayed motor development.

OM negatively affects sound transmission in the middle ear, possibly increasing the risk of speech and language delays in young children (Rosenfeld et al., 2013). Fluctuating hearing as a result of intermittent ear fluid could interfere with speech and language development of children younger than seven-years (Jung et al., 2013). Although the results have been inconclusive, deficits have been noted in the speech production, speech perception, receptive language, and expressive language skills in children with OM (Gravel & Wallace, 2000; Northern et al., 2014).

Cleft Lip and Palate

Oral-facial clefts (OFC) including CL, CP, and CLP occur early in the first trimester of pregnancy, when the child's lip, palate or other facial structures do not completely fuse (CDC, 2015). CL and CLP occur either unilaterally or bilaterally. In contrast, CP only appears in the midline of the hard and/or soft palate (Peterson-Falzone, 2011). Oral clefts are often categorized as either non-syndromic or syndromic type. Non-syndromic or isolated type is the most common oral cleft. This type of cleft is not related to a known syndrome or other chromosomal abnormalities (Wehby et al., 2014). Individuals with syndromic or non-isolated type of oral clefts also present with additional anomalies.

People with OFC frequently require healthcare services beyond the initial surgery to repair the cleft. In fact, individuals with oral clefts may require medical and dental care from birth into adulthood. Furthermore, the effect of an OFC has been identified as having an influence on the acquisition of speech sounds (Root, 2012); hearing outcomes (Knight et al., 2015; Skuladottir et al., 2015); academic progress and use of special education services (Collett et al., 2014; Richman et al., 2012; Wehby et al., 2014; Yazdy et al., 2008). Also, the development of peer relationships (Norman et al., 2015; Klein et al. 2014; Wehby et al., 2012) and mental health, including issues of body image and self-esteem (Hamlet & Harcourt, 2015; Hunt et al., 2007; Stock et al., 2015) have been reported to be impacted with individuals born with an OFC.

The impact of an OFC is not limited to the individual with the cleft. Even in the presence of prenatal diagnosis, the initial parental experience of shock, fear, and the need for emotional support may occur. Additional responsibilities and challenges caregivers might face as a result of having a child born with an OFC may include parent-child interactions (Nidey et al., 2016; Stock & Rumsey, 2015; Zeytinoglu & Davey, 2012), financial costs (Cassell et al., 2008; Razzaghi et al., 2015), and demands on time to travel to medical and dental appointments (Cassell et al., 2014; Cassell et al., 2013).

The resulting impact of an individual having a CL/P extends beyond the individual and their family/caregivers. Individuals with a CL/P also have an influence on society as a whole. Individuals with OFC typically require ongoing medical interventions to minimize developmental complications that occur later in life (Phua et al., 2009; Weiss et al., 2009). Financial costs extend beyond the toddler years for children with CL/P to include salaries for teachers and clinicians to provide academic support (Cassell et al., 2014; Wehby et al., 2014), as well as speech and language services (Wehby et al., 2012; Yazdy et al., 2008). Increased attention has focused on the

need to provide mental health support to address overall health and quality of life for individuals with CL/P (Munz et al., 2011; Sinko et al., 2005; Stock et al., 2015; Strauss & Cassell, 2009).

The Impact of SES and CL/P

Inconsistent findings have been reported on the impact of SES and CL/P. In a nationwide study of infants born during 1997-2000, researchers concluded children from households with the lowest SES had the greatest risks of being born with CL/P (Yang et al., 2008). Similarly, Carmichael et al., (2009) noted lower SES was associated with an increased risk of CL/P and CP. On the other hand, discrepant results were obtained in a study conducted by Root (2012), in which SES did not affect the likelihood of a child being born with CL/P as determined by the poverty and unemployment rates of the neighborhood.

Access to PE Tube Treatment

PE tube insertion is the most common ambulatory or outpatient surgery performed on children in the US (Rosenfeld et al., 2013). This procedure is typically performed because of persistent middle ear fluid, frequent ear infections or ear infections that persist after antibiotic therapy (Rosenfeld et al., 2013). This cost-effective treatment for OM costs on average $769 per surgery as determined by Sjogren and colleagues (2016).

Research over the past twenty years has shown that intervention for OM with PE tube treatment differs by race, with White children being more likely than Black children to receive this surgical procedure (Fleming-Dutra et al., 2014). White children and children in the South region of the US were more likely to receive PE tube treatment by three years of age, compared with African American/Black children (Kogan et al., 2000). Simon and colleagues (2017) reported similar results in that it was more common for White children to receive PE tube insertion surgery compared to Black and Hispanic children. Furthermore, African

American/Black children were less likely to receive surgical or antibiotic treatment compared to White children. Thus, disparities in access to PE tubes exists due to the structure of the respective healthcare systems and social factors, including access to regular care and insurance type (Baerg et al., 2017).

Medicaid, a joint federal and state program, is the single largest source of health coverage in the United States. The Children's Health Insurance Program (CHIP) serves uninsured children in families with incomes too high to qualify for Medicaid. Combined these two programs provide health coverage to more than 72.5 million Americans (Centers for Medicare & Medicaid Services, n. d). The Patient Protection and Affordable Care Act (Affordable Care Act) which was signed into law in March 2010 included provisions on affordable healthcare. By 2016, it was estimated an additional 20 to 24 million people were insured as a result of this Act (Uberoi et al., 2016).

The cost of inserting PE tubes may be a prohibitive factor for some uninsured families. For 2016, the federal poverty threshold level for a family of four with two children was $24,339. In NC of the 2,241,156 children living in the state 532,742 or 24% were living with poor families, compared to the national average of 19%. The race/ethnicity of these children living in poor families were 14% White, 37% Black, 12% Asian, 36% Native American, and 40% Hispanic. To sum up, 27% of all children under the age of 6-years lived in poor families in the state, according to the National Center for Children in Poverty (n.d.).

The Impact of Socioeconomic Disparities and PE Tube Treatment

Individuals from low SES backgrounds often experience barriers to accessing many types of healthcare in the US, resulting in substantial healthcare disparities (Bornstein et al., 2010; Like, 2011; Roseberry-McKibbin, 2000). Researchers have reported that children with chronic OME

were more likely to be from high poverty areas or lower neighborhood median household income levels. On the other hand, children from neighborhoods that experienced lower incidences of poverty or higher neighborhood median household income levels were more likely to receive PE tubes for recurrent AOM. Researchers also noted children with recurrent AOM were more likely to be privately insured compared to those who were publicly insured (Nieman et al., 2016).

In the US, disparities in the prevalence of OM in children have not been thoroughly explored (Smith & Boss, 2010). Few studies suggest OM is more common in children from lower SES families (Ah-Tye, Paradise et al., 2001; Damiano et al., 2009; Paradise et al., 1997). In contrast, Lieu and Feinstein (2002) concluded the diagnosis of OM was directly correlated with increasing income levels.

It has long been reported that children with CL/P have an increased risk for incidences of OM (Paradise et al., 1969). Previous research has reported conflicting results of the impact of SES and the diagnosis of OM in children. While studies have demonstrated Black children are less likely to be diagnosed with OM and receive surgery for PE tube insertion (Fleming-Dutra et al., 2014), few studies have explored the access REM children with CL/P have to this hearing healthcare intervention.

Purpose of the Current Research

The purpose of this study was to examine the prevalence of middle ear disease, specifically chronic OM. Also, the probability of being born with non-syndromic CL, CP, CLP in preschool-age REM children in NC was explored. In addition, the likelihood of REM children with CL/P being diagnosed with chronic OM and then receiving PE tube treatment was investigated. Finally, this study will report any differences of PE tube treatment in NM and REM children with CL/P based on the expected payer source. Files from the State Ambulatory Surgery

and Services Databases (SASD) of the Healthcare Cost and Utilization Project (HCUP) sponsored by the Agency for Healthcare Research and Quality (AHRQ) (AHRQ, 2016) were analyzed.

The specific research questions and hypotheses are listed below:

1. Are there significant differences in the prevalence of chronic OM in NM and REM preschool-age children?

    Hypothesis: REM preschool-age children are less likely to be diagnosed with chronic OM than NM preschool-age children.

2. Are there significant differences in the prevalence of CL, CP, and CLP in NM and REM preschool-age children?

    Hypothesis: REM preschool-age children are more likely to be diagnosed with CL than NM preschool-age children whereas REM preschool-age children will be less likely to be diagnosed with CP and CLP than NM preschool-age children.

3. Are there significant differences in the prevalence of chronic OM in NM and REM preschool-age children with diagnoses of CP and CLP?

    Hypothesis: REM preschool-age children with CP and CLP are less likely to be diagnosed with chronic OM than NM preschool-age children with CP and CLP.

4. Are there significant differences in the prevalence of receiving PE tube treatment in NM and REM preschool-age children with diagnoses of CP and CLP?

    Hypothesis: REM preschool-age children with CP and CLP are less likely to receive PE tube treatment than NM preschool-age children with CP and CLP.

5. Are there significant differences in the expected payer source for PE tube treatment for NM and REM preschool-age children with CP and CLP?

Hypothesis: NM preschool-age children are more likely to have an expected private payer source (private insurance) for PE tube treatment than REM preschool-age children whereas REM preschool-age children are more likely to have an expected public payer source (e.g. Medicare, Medicaid, no charge, etc.) for PE tube treatment than NM preschool-age children.

CHAPTER III

METHOD

The overall purpose of this study was an examination of the prevalence of middle ear disease, specifically chronic OM in NM and REM preschool-age children in North Carolina. In addition, the likelihood of NM and REM children with non-syndromic CL, CP, CLP being diagnosed with chronic OM and then receiving PE tube treatment was investigated. Finally, the use of PE tube treatment in NM and REM children with CL/P based on the expected payer source was explored. The study was reviewed and approved by the University of North Carolina Greensboro Institutional Review Board. Data were purchased and obtained through data use agreement with HCUP and the AHRQ.

Secondary Data Files

Existing data was derived from restricted use files from the SASD of HCUP sponsored by the AHRQ (AHRQ, 2016). HCUP is part of a federal, state, and industry partnership sponsored by the AHRQ and includes information from inpatient and outpatient hospitals. Thirty-five participating states and the District of Columbia voluntarily report patient-level hospital stay data to HCUP following the standardized International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. HCUP includes the largest collection of longitudinal hospital care data in the US and includes all-payer types (AHRQ, 2016). The SASD is comprised of encounter data, or information on the services provided, for ambulatory surgery as well as other outpatient services from hospital-owned facilities. This dataset includes aggregated clinical and demographic information including the patient's age on the procedure

date, gender, racial/ethnic identity, payer type, zip codes, and medical diagnoses for patients (AHRQ, 2016).

Study Design

SASD data for North Carolina was accessed and analyzed. A descriptive quantitative design was used for this records review study. The design was non-experimental and cross-sectional. This research was completed using the most recent de-identified data provided from HCUP. Relevant ICD-10-CM codes were identified from inpatient and outpatient hospital visits of preschool-aged children during the 2016 calendar year.

Participants and Coding

The analysis was limited to children birth to five-years, 11-months of age who received medical care in NC as reported to the HCUP program during 2016. A total of 319,682 patient files were accessed for the study. Patients with a primary diagnosis of CL/P were identified using ICD-10-CM codes for cleft lip and cleft palate. The use of these primary ICD-10-CM oral cleft codes was to control for non-syndromic CL/P. Refer to Table 2 for additional details on ICD-10-CM codes used to identify children with CL/P.

Table 2. ICD-10-CM Codes for Cleft Lip and Cleft Palate

Q35 Cleft Palate	
Q35.1	Cleft hard palate
Q35.3	Cleft soft palate
Q35.5	Cleft hard palate with cleft soft palate
Q35.9	Cleft palate, unspecified
Q36 Cleft Lip	
Q36.0	Cleft lip, bilateral
Q36.1	Cleft lip, median
Q36.9	Cleft lip, unilateral
Q37 Cleft Palate with Cleft Lip	
Q37.0	Cleft hard palate with bilateral cleft lip
Q37.1	Cleft hard palate with unilateral cleft lip
Q37.2	Cleft soft palate with bilateral cleft lip
Q37.3	Cleft soft palate with unilateral cleft lip
Q37.4	Cleft hard and soft palate with bilateral cleft lip
Q37.5	Cleft hard and soft palate with unilateral cleft lip
Q37.8	Unspecified cleft palate with bilateral cleft lip
Q37.9	Unspecified cleft palate with unilateral cleft lip

ICD-10-CM codes H65 (Nonsuppurative otitis media) and H66 (Suppurative and unspecified otitis media) were used to identify children with diseases of middle ear and mastoid process. The 80 codes were categorized as either acute or chronic OM. Northern et al., (2014) stated chronic suppurative OM is long-term and recurrent; for this reason, suppurative OM was identified as chronic and nonsuppurative OM as acute. See Appendix A for a complete list of all ICD-10-CM codes for diseases of middle ear and mastoid process. Table 3 presents the Current Procedural Terminology (CPT) procedure codes (Centers for Medicare & Medicaid Services, 2004) used to identify the PE tube treatment.

Table 3. Description of CPT Codes

Code	Diagnostic Service for PE tube insertion surgery
69433	Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia
69436	Tympanostomy (requiring insertion of ventilating tube), general anesthesia

Data Extraction

The data was purchased through the HCUP Central Distributor after completing a web based HCUP Training Course and Data Use Agreements with the AHRQ. The database was delivered via computer disc. The study data included racial/ethnic identification, expected payer source, diagnosis of CL/P, diagnosis of diseases of middle ear, CPT codes for the tympanostomy procedure, and the patient's zip code of residence. Case information on 319,682 patient files were extracted from SASD's software using a coding system (See Appendix B) and then saved on an SPSS spreadsheet.

Variables of interest for the study were identified from the SASD database. Recoding of data allowed grouping of ICD-10-CM codes that contained a greater level of detail; therefore, a group of conditions were transformed into one code. For example, the three ICD-10-CM codes used to identify bilateral CL (Q36.0), median CL (Q36.1), or a unilateral CL (Q36.9) were collapsed into one variable (DX_Cleft Lip). Recoding was also performed for the 80 ICD-10-CM codes to identify a diagnosis of acute or chronic OM; four ICD-10-CM codes to identify a diagnose of CP; eight ICD-10-CM codes to identify a diagnose CLP; two CPT codes to identify PE tube treatment (tympanostomy surgery); NM or REM identification, and the expected primary payer source of private (private insurance or self-pay) or public (Medicare, Medicaid, no charge, or other government programs) insurance. The data was saved on UNCG Box.

Descriptive Characteristics of the Sample

A total of 319,682 children birth to five-years, 11-months of age received medical care in NC during 2016 as reported to the HCUP program and identified in the SASD database. It is important to note that children could have participated in multiple visits in the same calendar year; however, that information was not contained in this dataset. Table 4 lists the demographic

data accessed for this study. There were 176,914 male (55.3%) participants in this study (Figure 1). With respect to racial/ethnic identification, 164,347 (51.4%) subjects identified as NM. There were 19,663 (6.2%) cases missing racial/ethnic identification (Figure 2). No REM child with chronic OM had a diagnosis of CL, whereas 45.5% of REM children diagnosed with chronic OM had CLP. A total of 15,631 (4.9%) of medical care visits were for PE tube treatment. Public insurance was the expected primary payer source for 207,597 (64.9%) of the children.

Table 4. Selected Characteristics of Preschool-Age Children Who Received Medical Care in NC in 2016

Characteristic	n	%
Racial/Ethnic Identification		
NM	164,347	51.4
REM	135,672	42.4
Missing	19,663	6.2
CL/P Diagnoses		
CL Diagnosis	131	< 0.01
CP Diagnosis	337	< 0.01
CLP Diagnosis	382	< 0.01
OM Diagnoses		
Acute OM	7,662	2.4
Chronic OM	17,757	5.6
Procedure		
PE Tube Treatment	15,631	4.9
Expected Primary Payer Source		
Private Insurance	110,599	34.6
Public Insurance	207,597	64.9
Missing	1,486	.5

Figure 1. Children by Gender Identification

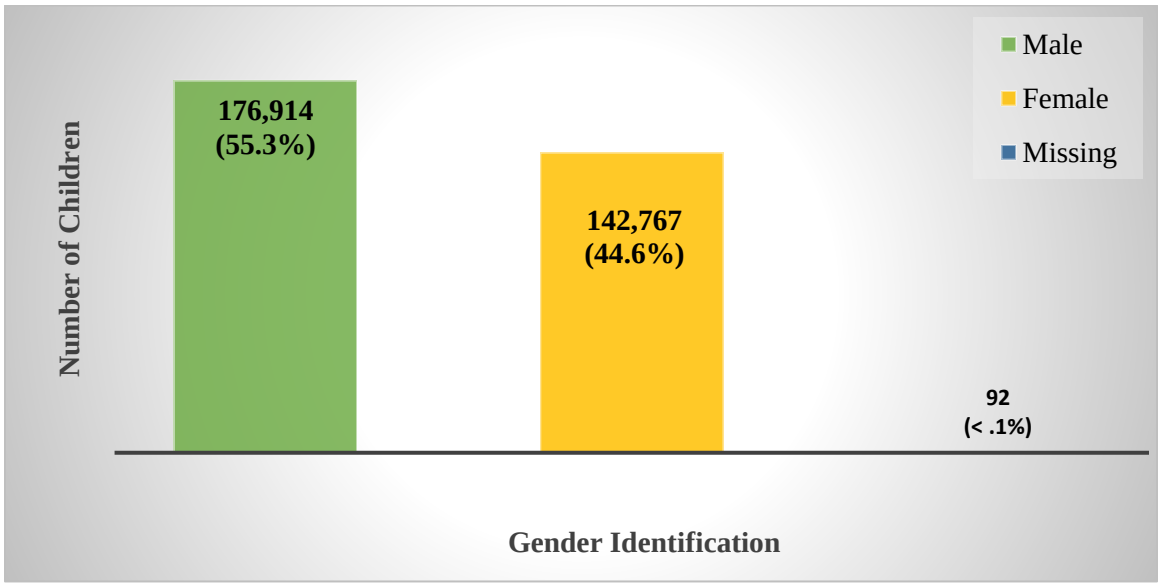
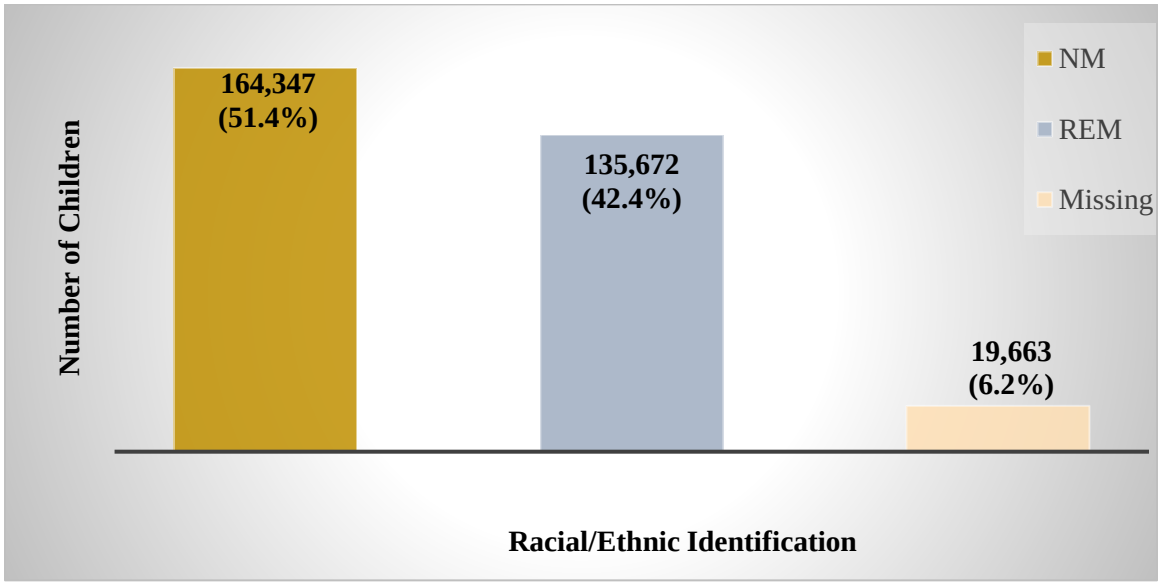


Figure 2. Children by Racial/Ethnic Identification



Access to Medical Care

Most of the medical care provided was to residents of NC. The North Central (26.4%), Piedmont-Triad (20.0%), and Southwest (18.0%) regions had the most preschool-age children to receive medical services; whereas, the Northeast (3.9%), Northwest (6.2%), and Western (6.3%) regions had the least number of children accessing medical care. These geographical regions were selected as the expectation would be for children to enroll in a public, charter, private, or non-public (homeschool) setting within one of the eight educational regions of the NC State Board of Education Districts, based on the zip code of their residence.

Access to medical services was not restricted to residents of NC. Of the preschool-age children who received medical care, approximately 8,300 (2.5%) resided outside of the state or country. Table 5 lists the range of the number of medical care visits for the preschool-age children who were non-residents of NC. Of the children who lived in one of the 46 states, territories or another country, many lived in the neighboring states of Virginia (2,463) or South Carolina (4,293).

Table 5. Range of Number of Medical Care Visits for Non-Residents of NC

Number of medical care visits	Residential State or Territory Within the US
1-25	Alaska, Alabama, Arizona, Colorado, Connecticut, District of Columbia, Hawaii, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, North Dakota, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Dakota, Utah, Vermont, Washington, Wisconsin
26-50	Arkansas, Illinois, Ohio, Pennsylvania
51-75	California, Minnesota, Texas
76-100	New Jersey
101-150	Georgia, Maryland, Tennessee, West Virginia

Table 5. Cont.

Number of medical care visits	Residential State or Territory Within the US
151-200	Florida, New York
1,000-2,000	Invalid/Missing
2,000-4,000	Virginia
4,001-5,000	South Carolina
Number of medical care visits	**Country of Residence**
1-25	Brazil

Data Analysis

For each research question, prevalence data or the total number of children with the existing condition (e.g. chronic OM, CL/P, PE tube treatment, private or public insurance) was calculated to determine the likelihood of the condition or situation occurring. The number of children in the sample with the characteristic of interest (e.g. children with a diagnosis of chronic OM) was divided by the total number of children in the sample (children with and without chronic OM) to determine the prevalence. Next the odds ratio with 95% confidence intervals were calculated. Odds ratio represent the strength of exhibiting the characteristic compared to the odds of not having the characteristic. Odds ratio compares the relative odds of the occurrence of the outcome (e.g. diagnosed with chronic OM) given the variable of interest (e.g., REM). An odds ratio = 0 indicates the variable does not affect odds of outcome. Odds ratio > 1 suggest the associated variable has higher odds of outcome; whereas an odds ratio < 1 implies lower odds of outcome. Binary logistic regression analyses were used to determine whether the odds ratio was significant. A p-value < 0.05 was the criteria for statistical significance.

CHAPTER IV

RESULTS

The first research question addressed the prevalence of chronic OM in NM and REM preschool-age children. Chronic OM was diagnosed in 16,915 (6%) of the 300,019 children with racial/ethnic information. Due to missing racial/ethnic identification, this number is lower than the overall number of children in the study. As can be seen in Figure 3 and Table 6, there were 12,129 NM and 4,786 REM children diagnosed with chronic OM. The prevalence for chronic OM in NM children was .074 (12,129/164,347) compared with .035 for REM children (4,786/135,672). The odds ratio was 2.18, indicating NM children were twice as likely to be diagnosed with chronic OM than REM children. A binary logistic regression analysis indicated that this difference was significant ($p < .001$) (Table 7).

Figure 3. **Diagnoses of Chronic OM by Racial/Ethnic Identification**

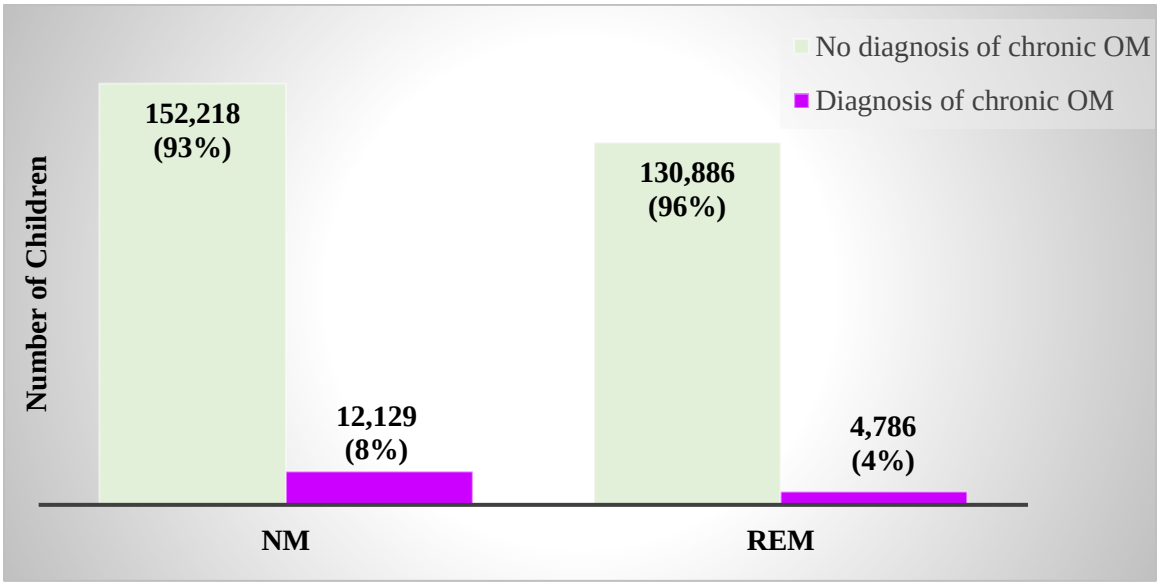


Table 6. Children Diagnosed With Chronic OM by Racial/Ethnic Identification

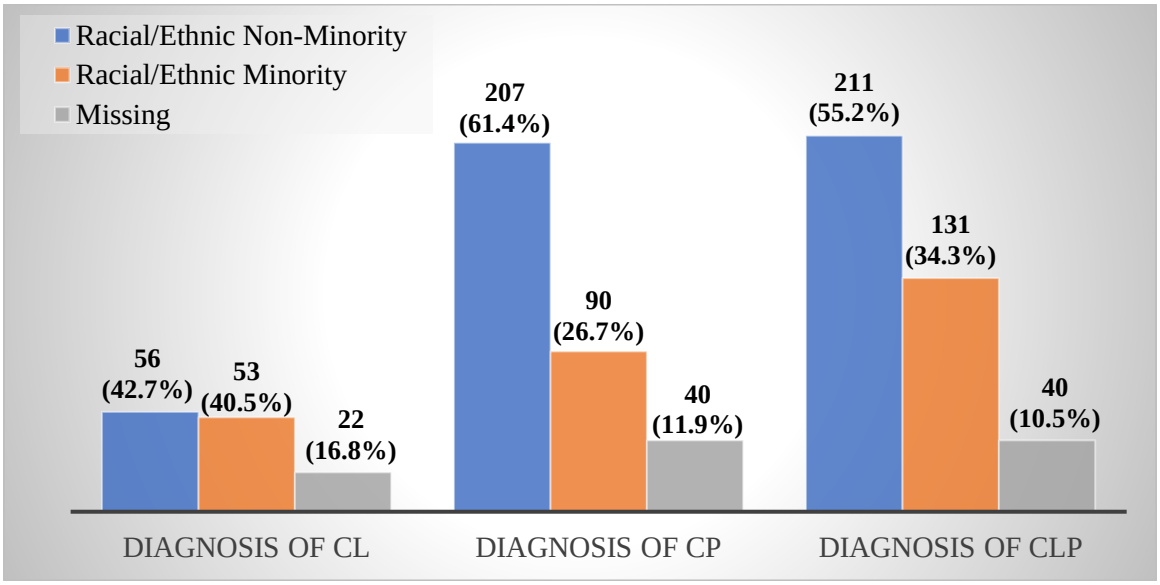
	NM	REM	Total
No diagnosis of chronic OM	152,218	130,886	283,104
Diagnosis of chronic OM	12,129	4,786	16,915
Total	164,347	135,672	300,019
Prevalence for diagnosis of chronic OM	12,129 / 164,347 = .0738	4,786 / 135,672 = .0353	

Table 7. Odds of Receiving a Diagnosis of Chronic OM According to Racial/Ethnic Identification

					95% CI	
	B	S.E.	p - value	Odds Ratio	Lower	Upper
Race/Ethnicity	.779	.017	< .001	2.18	2.106	2.255
Constant	-3.309	.015	< .001	.037		

The second research question addressed the prevalence of CL, CP and CLP in NM and REM preschool-age children. A total of 850 children had CL/P. CL was diagnosed in 131 of the children; however, due to 22 cases missing racial/ethnic identification, only 109 of the children with CL included racial/ethnic identification. NM children were diagnosed with 56 cases of CL and REM children were diagnosed with 53 cases of CL. Of the 337 children diagnosed with CP, 40 were missing racial/ethnic identification. NM children were diagnosed with 207 cases of CP while REM children were diagnosed with 90 cases of CP. Similarly, 40 children with CLP were missing racial/ethnic identification. There were 211 NM children diagnosed with CLP and REM children were diagnosed with 131 cases of CLP (Figure 4).

Figure 4. Children by CL/P and Racial/Ethnic Identification



As can be seen in Table 8, the prevalence for NM children being diagnosed with CL was .0003 (56/164,347) compared with .0004 (53/135,672) for the REM children. The odds ratio was 1.15 indicating that the two groups were equally likely to be diagnosed with CL. The difference was not significant ($p > .05$) (Table 9).

Table 8. Children Diagnosed With CL by Racial/Ethnic Identification

	NM	REM	Total
No diagnosis of CL	164,291	135,619	299,910
Diagnosis of CL	56	53	109
Total	164,347	135,672	300,019
Prevalence for diagnosis of CL	56 / 164,347 =.00034	53 / 135,619 = .00039	

Table 9. Odds of Receiving a Diagnosis of CL According to Racial/Ethnic Identification

	B	S.E.	p - value	Odds Ratio	95% CI Lower	95% CI Upper
Race/ Ethnicity	.137	.192	.476	1.147	.787	1.669
Constant	-7.984	.134	< .001	.000		

As can be seen in Table 10, the prevalence for NM children being diagnosed with CP was .0013 (207/164,347) compared to .0007 (90/135,672) for the REM children. The odds ratio was 1.90, indicating NM children were about twice as likely to be diagnosed with CP than REM children. This difference was significant ($p < .001$) (Table 11).

Table 10. Children Diagnosed With CP by Racial/Ethnic Identification

	NM	REM	Total
No diagnosis of CP	164,140	135,582	299,722
Diagnosis of CP	207	90	297
Total	164,347	135,672	300,019
Prevalence for diagnosis of CP	207 / 164,347 = .00126	90 / 135,582 = .00066	

Table 11. Odds of Receiving a Diagnosis of CP According to Racial/Ethnic Identification

	B	S.E.	p - value	Odds Ratio	95% CI Lower	95% CI Upper
Race/ Ethnicity	.642	.126	< .001	1.90	1.483	2.434
Constant	-7.318	.105	< .001	.001		

Table 12 provides the prevalence data for CLP. As can be seen in this table, the prevalence for NM children being diagnosed with CLP was .0012 (211/164,347) compared to .001 (131/135,672) for the REM children. The odds ratio was 1.3, which means the NM children

were about 30% more likely to be diagnosed with CLP than the REM children. This higher likelihood, though small, was significant ($p < .05$) (Table 13).

Table 12. Children Diagnosed With CLP by Racial/Ethnic Identification

	NM	REM
No diagnosis of CLP	164,136	135,541
Diagnosis of CLP	211	131
Total	164,347	135,672
Prevalence for diagnosis of CLP	211 / 164,347 = .00128	131 / 135,672 = .00097

Table 13. Odds of Receiving a Diagnosis of CLP According to Racial/Ethnic Identification

					95% CI	
	B	S.E.	p - value	Odds Ratio	Lower	Upper
Race/ Ethnicity	.285	.111	.010	1.330	1.069	1.654
Constant	-6.942	.087	< .001	.001		

The third research question addressed the prevalence of chronic OM in NM and REM preschool-age children with a diagnosis of CP and CLP. Only one NM child had a diagnosis of CL and chronic OM, so the analyses in this section focuses on CP and CLP. As shown in Table 14, there were 207 NM and 90 REM children diagnosed with CP. The prevalence for chronic OM in NM children with CP was .145 (30/207) compared to .122 for REM children (11/90). The odds ratio was 1.22, indicating NM children were 22% more likely to be diagnosed with chronic OM than REM children. This difference was not significant ($p > .05$) (Table 15).

Table 14. Children Diagnosed With CP With and Without Chronic OM

	NM children with CP	REM children with CP
Diagnosed with chronic OM	30	11
No diagnosis of chronic OM	177	79
Total	207	90
Prevalence for diagnosis of chronic OM	30 / 207 =.1449	11 / 90 = .1222

Table 15. Odds of Receiving a Diagnosis of Chronic OM by CP Diagnosis

	B	S.E.	p - value	Odds Ratio	95% CI Lower	95% CI Upper
Race/ Ethnicity	.197	.378	.603	1.217	.581	2.551
Constant	-1.972	.322	< .001	.139		

Table 16 shows that the prevalence for the NM children being diagnosed with CLP was .114 (24/211) compared to .153 (20/131) for the REM children. REM children with CLP were 40% more likely to be diagnosed with chronic OM than NM children with CLP. As can be seen in Table 17, the difference was not significant ($p > .05$).

Table 16. Children Diagnosed With CLP With and Without Chronic OM

	NM children with CLP	REM children with CLP
Diagnosed with chronic OM	24	20
No diagnosis of chronic OM	187	111
Total	211	131
Prevalence for diagnosis of chronic OM	24 / 211 = .1137	20 / 131 = .1527

Table 17. Odds of Receiving a Diagnosis of Chronic OM by CLP Diagnosis

	B	S.E.	p - value	Odds Ratio	95% CI Lower	95% CI Upper
Race/ Ethnicity	-.339	.326	.297	1.404	.742	2.658
Constant	-2.053	.217	< .001	.128		

The fourth research question addressed the prevalence of receiving PE tube treatment in NM and REM preschool-age children with diagnoses of CP and CLP. As can be seen in Table 18 and Table 19, there were 12 NM and 7 REM children diagnosed with CP who received PE tube treatment. The prevalence for receiving PE tubes in NM children with CP was .058 (12/207)

compared to .078 for REM children (7/90). The odds ratio was 1.37, indicating REM children with CP were 37% more likely to receive PE tubes than NM children. The difference was not significant ($p > .05$) (Table 19).

Table 18. Children Diagnosed With CP and Receiving PE Tube Treatment

	NM children with CP	REM children with CP
No PE tube treatment	195	83
PE tube treatment	12	7
Total	207	90
Prevalence for receiving PE tube treatment	12 / 207 = .058	7 / 90 = .0778

Table 19. Odds of Receiving PE Tube Treatment by CP Diagnosis

					95% CI	
	B	S.E.	p - value	Odds Ratio	Lower	Upper
Race/ Ethnicity	.315	.493	.523	1.370	.521	3.604
Constant	-2.788	.297	< .001	.062		

Table 20 shows that the prevalence for NM children with CLP receiving PE tube treatment was .076 (16/211) compared to .038 (5/131) for the REM children with CLP. The odds ratio was 2.07 indicating NM children with CLP were twice as likely to receive PE tube treatment than REM children with CLP. As can be seen in Table 21, although preschool NM children were twice as likely to receive PE tubes treatment than REM children, the difference was not significant ($p > .05$).

Table 20. Children Diagnosed With CLP and Receiving PE Tube Treatment

	NM children with CLP	REM children with CLP
No PE tube treatment	195	126
PE tube treatment	16	5
Total	211	131
Prevalence for receiving PE tube treatment	16 / 211 = .0758	5 / 131= .0382

Table 21. Odds of Receiving PE Tube Treatment by CLP Diagnosis

					95% CI	
	B	S.E.	p - value	Odds Ratio	Lower	Upper
Race/ Ethnicity	.726	.525	.166	2.068	.739	5.785
Constant	-3.227	.456	< .001	.040		

The fifth research question addressed the prevalence of the expected payer source for NM and REM preschool-age children with CP or CLP receiving PE tube treatment. As shown in Table 22, there were 10 NM and two REM children with CP or CLP who received PE tube treatment with the expected payer source of private insurance. The prevalence for private insurance paying for PE tube treatment in NM children with CP or CLP was .357 compared to .167 for REM children. This odds ratio was 1.755 indicating NM children with CP or CLP who received PE tubes were more likely to have private insurance than REM children. The difference was not significant (p = > .05) (Table 23).

There were 18 NM and 10 REM children with CP or CLP who received PE tube treatment with the expected payer source of public insurance (Table 22). The prevalence for public insurance paying for PE tube treatment in NM children with CP or CLP was .643 compared to .833 for REM children. The odds ratio was 1.373 indicating NM children with CP or

CLP who received PE tubes were more likely to have public insurance than REM children. The difference was not significant (p = > .05) (Table 24).

Table 22. Children Diagnosed With CP or CLP Who Received PE Tube Treatment by Payer Source

	NM children with CP or CLP	REM children with CP or CLP
Private Insurance	10	2
Public Insurance	18	10
Total	28	12
Prevalence for private insurance as expected payer source	10 / 28 = .3571	2 / 12 = .1667
Prevalence for public insurance as expected payer source	18 / 28 = .6429	10 / 12 = .8333

Table 23. Odds of Being Diagnosed With CP or CLP and Receiving PE Tube Treatment by Private Payer Source

					95% CI	
	B	S.E.	p - value	Odds Ratio	Lower	Upper
Race/ Ethnicity	.563	.788	.475	1.755	.375	8.220
Constant	-2.976	.324	.000	.051		

Table 24. Odds of Being Diagnosed With CP or CLP and Receiving PE Tube Treatment by Public Payer Source

					95% CI	
	B	S.E.	p-value	Odds Ratio	Lower	Upper
Race/ Ethnicity	.317	.406	.435	1.373	.620	3.040
Constant	-2.976	.324	.000	.051		

CHAPTER V

DISCUSSION

Summary of Findings

Five research questions were examined in this study. The first one questioned the prevalence of chronic OM in NM and REM preschool-age children. It was hypothesized that REM children would be less likely to be diagnosed with chronic OM than NM children. NM children were more than twice as likely to be diagnosed with chronic OM than REM children. These results indicate REM children were significantly less likely to be diagnosed with chronic OM than NM children. The results are consistent with previous research showing fewer REM children are diagnosed with chronic OM than NM children (e.g., Fleming-Dutra et al., 2014; Smith & Boss, 2010).

The second research question addressed the prevalence of CL, CP, and CLP in NM and REM preschool-age children. It was hypothesized that REM children would be more likely to be diagnosed with CL than NM children. Previous research reported the prevalence rates for children of Asian and Native American descent were the highest, with Caucasian children higher than those of African American descent (Arosarena, 2007; Dixon et al., 2011; Vanderas, 1987). The data set analyzed for this study combined African American/Black, Asian or Pacific Islander, Native American and Hispanic as REM. In the current study, though not statistically significant, REM children were diagnosed with CL at a slightly higher rate than NM children. It was also hypothesized REM children would be less likely to be diagnosed with CP and CLP than NM children. Statistically significant results found NM children were more likely to be diagnosed

with CP (about twice as likely) and CLP (approximately 30% higher) than REM children. These results agree with those of Canfield and colleagues (2006) in which infants of non-Hispanic Black mothers had significantly lower birth prevalence of CP and CLP compared to infants of non-Hispanic White mothers. Likewise, Williams et al., (2003) reported rates of oral clefts were higher in White infants compared to non-Hispanic Black and Hispanic-White infants.

The third research question investigated the prevalence of chronic OM in NM and REM preschool-age children with diagnoses of CP and CLP. It was hypothesized REM children with CP and CLP would be less likely to be diagnosed with chronic OM than NM children with CP and CLP. Only one child with CL was diagnosed with chronic OM. Although 20% more NM children with CP were diagnosed with chronic OM than REM children, the results were not significant. NM children with CLP were more likely (40%) to be diagnosed with chronic OM than REM children; however, the results were not significant. This could be because of the small number of children with CP and CLP diagnosed with chronic OM.

The fourth research question probed the prevalence of receiving PE tube treatment in NM and REM preschool-age children with diagnoses of CP and CLP. It was hypothesized REM children with CP and CLP would be less likely to receive PE tube treatment than NM children with CP and CLP. Though not significant, approximately 37% more REM children with CP received PE tubes compared to NM children with CP. Fewer than 15 children with CP received PE tubes and less than 20 children with CLP received PE tubes. Although numerically the NM children received more PE tube treatment than REM children, statistically REM children were more likely to receive PE tubes. The results differ from Fleming-Dutra et al., (2014) in which White children were more likely than Black children to receive PE tubes.

The final research question explored the expected payer source for PE tube treatment for NM and REM preschool-age children with CP or CLP. It was hypothesized NM children would be more likely to have an expected private payer source for PE tube treatment than REM children. Even though NM children with CP or CLP who received PE tube treatment had private insurance as the expected payer source 37% more than REM children, the results were not significant. It was also hypothesized REM children with CP or CLP would be more likely to have an expected public payer source for PE tube treatment than NM children. Although REM children were 75% more likely to have public insurance as the expected payer source than NM children, the results were not significant. Whereas there were 30 NM children with CP or CLP who received PE tube treatment, fewer than 15 REM children with CP or CLP received PE tube treatment.

Interpretation of Study Findings and Practice Implications

Disparities in healthcare treatment outcomes have historically occurred with groups that actually or perceptually vary from the expected norms or group that typically represents the majority. Therefore, variations from expected norms can occur with racial/ethnic identification or SES (Carter-Pokras, & Baquet, 2002). It has been projected that by 2044, more than half of all Americans will not identify as racial/ethnic non-minorities (US Bureau, 2015); as a result, the racial/ethnic diversity of US residents, including preschool-age children is expected to continue to increase.

This study confirmed an area of disparity related to the hearing healthcare of NM and REM preschool-age children. REM children in NC were less likely to be diagnosed with chronic OM than NM children, indicating REM children are under-identified in the diagnosis of chronic OM. Additionally, REM children in NC have a lower risk of being born with CP and CLP. These

results are consistent with previously reported racial/ethnic variation in the occurrence of CL/P (Arosarena, 2007; Dixon et al., 2011; Vanderas, 1987).

A crucial step in eliminating the disparate outcomes for racial/ethnic minority children is to acknowledge the existence of disparities and collectively work towards finding solutions to ensure all children receive quality care based on implementation of respective clinical practice guidelines. Perhaps the explanation is found in social factors, such as access to care, reporting of the severity of symptoms, or complying with medical recommendations. There may be misunderstandings by caregivers (biological parents, legal guardians, foster parents, immigrants, refugees, etc.) in reporting the presence of concerns; as well as, the frequency and severity of symptoms. These miscommunications may result in over- or under-reporting of symptoms, leading to racial/ethnic disproportionate diagnosis for chronic OM. On the other hand, if stakeholders including caregivers, speech-language pathologists, audiologists, medical personnel, educators, and healthcare policymakers are mindful of these issues, accurate caregiver reporting and when appropriate, questioning of children's symptoms may reduce over- or under-referrals for chronic OM, thereby increasing accurate diagnosis and effective treatment. Given these points, stakeholders should make a concerted effort to identify at-risk children regardless of their racial/ethnic identification or socioeconomic factors. The Clinical Practice Guideline: Otitis Media with Effusion (Rosenfeld et al., 2016) suggests multidisciplinary recommendations including evaluating at-risk children for OM at the time of diagnosis of an at-risk condition; providing education for caregivers regarding the natural history of OM and the need for follow-up; and recommending PE tube treatment when appropriate.

The impact of not receiving early hearing healthcare intervention may negatively impact the child's educational future. Also, the effects of an OFC may influence acquisition of speech

sounds (Root, 2012); academic progress; and use of special education services (Collett et al., 2014; Richman et al., 2012; Wehby et al., 2014; Yazdy et al., 2008). Preschool-age children may experience temporary or permanent hearing loss due to not receiving early hearing interventions; such as PE tubes, in a timely manner. Reduced hearing can also interfere with appropriate opportunities of stimulation, social development, and pre-literacy skills, which are all instrumental for developing school readiness. As a result, these children will be at greater risk academically. School districts are responsible for obtaining and allocating financial resources to hire and/or train personnel to remediate these delays. In NC the financial burdens of caring for those children who are at greater risk based on previous diagnoses of OM or CL/P, are concentrated in the North Central, Piedmont-Triad and the Southwest educational regions of the NC State Board of Education Districts. Four of the five Cleft Palate-Craniofacial Teams located in the state are within these three educational regions (ACPA, 2020). The remaining Cleft Palate-Craniofacial Team is in the Southeast region of the state. The smaller numeric and geographic educational regions may not have the infrastructure needed to accommodate young children diagnosed with OM or CL/P. Smaller communities may also lack quality early intervention opportunities and readily available therapeutic services in community agencies or school systems. Providing assessible medical care to treat children who receive an early diagnosis of OM may reduce long-term financial costs and increased educational outcomes.

In addition, the current study did not find significant differences in the prevalence of chronic OM in preschool-age children with diagnoses of CL, CP, and CLP; PE tube treatment in children with CL/P; or the expected payer source for PE tube treatment with NM and REM children with CL/P. Results of the present study also indicated REM children were more likely to use public insurance. This is consistent with previous reports that Black children (without CL/P)

were more likely to have public insurance (Baerg et al., 2017). Although disparities did not exist in NM and REM children receiving PE tube treatment based on the expected payer source, it is crucial to be cognizant of potential socioeconomic factors. For one thing, families who utilize public insurance for their children's medical bills may have other financial barriers. Equally important, these families may be less likely to request time off from work to seek early medical care if they are required to take unpaid leave. Families who use public insurance may avoid scheduling or following through with doctor recommendations to treat OM due to out-of-pocket costs. Not to mention, families from lower SES backgrounds may not have insurance with cost-free options to seek second opinions when they disagree with the recommendation or lack of recommendation of their medical provider. Additionally, some families may not have reliable transportation or must access public transportation which could add costs and time for travel to and from the medical appointment. To address these and other challenges families may experience, social workers could provide resources for families to access to assist in overcoming potential barriers which may be preventing or delaying children from receiving hearing healthcare in a timely manner. Information on satellite healthcare providers who may be able to shorten the distance for families to travel to locations to receive services, may be an option to explore. Another possible solution to reduce the time for travel would be to offer telehealth to reduce travel while allowing patient and healthcare provider(s) opportunities to discuss symptoms, possible treatment options, and provide early hearing healthcare education.

Limitations and Future Research

The major strength of this study is that it utilized state-wide encounter data for inpatient and outpatient hospital visits in the state of NC. This study does however have several limitations. One limitation is the use of quantitative data which is not descriptive; therefore, it was difficult to

make decisions based solely on the restricted information that was collected. Another limitation is the use of secondary data prohibits direct observation that might have provided important insights into the interactions between caregivers and medical personnel. As this study was intentionally limited to patient data in the state of NC, it is possible some of these findings may not easily translate to other states or territories in or outside of the US.

Future studies should consider including the demographic characteristics of care providers and medical personnel in addition to the children receiving medical services. This could include but not be limited to racial/ethnicity identification and knowledge of the geographic area. As the racial/ethnic diversity of NC and the US increases, medical personnel may not be familiar with cultural/home remedies or ease of access to traditional medicine which may delay families from seeking or complying with recommendations from providers of modern medicine. Future research also needs to examine the economic impact on families based on the method, distance and time traveled to the doctor's office or Cleft Palate-Craniofacial Team site as well as other pertinent but less obvious reasons that delay or prevent the identification of chronic OM as well as resources for families of children diagnosed with CL/P.

Medical personnel may not be familiar with the ability or difficulty for families to access and ultimately comply with recommendations based on geographical barriers which may exist in both urban and rural areas. Additional information could provide increased opportunities to investigate communications between the patient – caregiver – medical personnel triad; as well as, an understanding of how caregivers communicate concerns of their child's frequency and severity of symptoms. One strategy that can be implemented to identify early hearing healthcare needs is the use of a community health assessment to determine the current needs and issues, as well as how and where to allocate resources. This or other collaborative efforts would allow stakeholders

including caregivers, audiologists, social workers, Cleft Palate-Craniofacial Team members, speech-language pathologists, educators and others to discuss successes and challenges including over- and under-identification of OM, access to medical care, identifying and communicating OM symptoms, as well as following recommendations.

Summary and Conclusions

The purpose of this study was an examination of the prevalence of middle ear disease, specifically chronic OM in NM and REM preschool-age children. In addition, the likelihood of NM and REM children with non-syndromic CL, CP, CLP being diagnosed with chronic OM and then receiving PE tube treatment was investigated. Finally, the use of PE tube treatment in NM and REM children with CL/P based on the expected payer source was explored. There were significant differences in the prevalence of chronic OM in NM and REM preschool-age children, with REM children under-identified in the diagnosis of chronic OM. Furthermore, REM children were less likely to be born with CP and CLP. This study did not identify significant differences in the prevalence of chronic OM in preschool-age children with diagnoses of CL, CP, and CLP; PE tube treatment in children with CL/P; or the expected payer source for PE tube treatment for NM and REM children with CL/P. It was noted that fewer REM children were identified with CL/P; therefore, more NM children were identified with CL/P, resulting in the opportunity for more frequent need for PE tube treatment.

This study may be the first to address preschool-age children diagnosed with CL/P who received PE tube treatment by expected payer source in addition to racial/ethnic identification. Future studies should not only examine the reporting of OM symptoms by caregivers to medical personnel but also the access to quality early hearing healthcare interventions across racial/ethnic identification, geographic location, and payer source. The collaborative efforts of stakeholders to

increase effective communication between caregivers and medical personnel could increase the likelihood that all children receive quality early hearing healthcare. Consistent application of respective clinical practice guidelines is crucial to assist all children in achieving optimal school readiness skills and speech/language developmental milestones. Early identification of at-risk children, regardless of racial/ethnic identification or socioeconomic factors, is crucial to reduce and possibly eliminate existing hearing healthcare disparities. It is important to note that although some of the results were not statistically significant, the reported differences should be addressed to ensure no child is denied access to early hearing healthcare interventions.

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APPENDIX A

ICD-10-CM CODES DISEASES OF MIDDLE EAR AND MASTOID PROCESS CODES INFORMATION

Variable	*ICD-10-CM Code*
Acute serous otitis media	H65.00, H65.01, H65.02, H65.03, H65.04, H65.05, H65.06, H65.07
Acute and subacute allergic otitis media (mucoid) (sanguinous) (serous)	H65.111, H65.112, H65.113, H65.114, H65.115, H65.116, H65.117, H65.119
Other acute nonsuppurative otitis media	H65.191, H65.192, H65.193, H65.194, H65.195, H65.196, H65.197, H65.199
Chronic serous otitis media	H65.20, H65.21, H65.22, H65.23
Chronic mucoid otitis media	H65.30, H65.31, H65.32, H65.33
Chronic allergic otitis media	H65.411, H65.412, H65.413, H65.419
Other chronic nonsuppurative otitis media	H65.491, H65.492, H65.493, H65.499
Unspecified nonsuppurative otitis media	H65.90, H65.91, H65.92, H65.93
Acute suppurative otitis media without spontaneous rupture of ear drum	H66.001, H66.002, H66.003, H66.004, H66.005, H66.006, H66.007, H65.009
Acute suppurative otitis media with spontaneous rupture of ear drum	H66.011, H66.012, H66.013, H66.014, H66.015, H66.016, H66.017, H66.019
Chronic tubotympanic suppurative otitis media	H66.10, H66.11, H66.12, H66.13
Chronic atticoantral suppurative otitis media	H66.20, H66.21, H66.22, H66.23
Other chronic suppurative otitis media	H66.3X1, H66.3X2, H66.3X3, H66.3X9
Suppurative otitis media	H66.40, H66.41, H66.42, H66.43
Otitis media	H66.90, H66.91, H66.92, H66.93

APPENDIX B

CODING SYSTEM

Name	Description	Values	Missing
Gender	Indicator of sex	0 = Male 1 = Female	999
PE_T_ Treatment	CPT codes: PE Tube treatment: 69433 or 69436	0 = No PE Tube Treatment 1 = Received PE Tube Treatment	999
DX_Cleft_ Lip	Primary I10-D-CM diagnosis of CL	0 = No Diagnosis of CL 1 = Diagnosis of CL	999
DX_Cleft_ Palate	Primary I10-D-CM diagnosis of CP	0 = No Diagnosis of CP 1 = Diagnosis of CP	999
DX_CLP	Primary I10-D-CM diagnosis of CLP	0 = No Diagnosis of CLP 1 = Diagnosis of CLP	999
DX_CL_ and_or_P	DX of Clefts of the Lip and/or Palate	0 = No Diagnosis of CL/P 1 = Diagnosis of CL/P	
DX_OM_ Acute	Primary diagnosis of acute otitis media	0 = No Diagnosis of Acute OM 1 = Diagnosis of Acute OM	999
DX_OM_ Chronic	Primary diagnosis of chronic otitis media	0 = No Diagnosis of Chronic OM 1 = Diagnosis of Chronic OM	
Expected_ Primary_ Payer	Expected primary payer source	0 = Private Insurance or Self-Pay 1 = Public: Medicare, Medicaid, No charge, Other (gov programs)	999
Race_ Ethnicity	Identification of patient's race/ethnicity	0 = Racial/Ethnic Non-Minority (White/Caucasian) 1 = Racial/Ethnic Minority (Black/ African American; Hispanic; Asian/ Pacific Islander; Native American; Other	999
Zip Code	Zip Codes by Region	Northeast: Southeast: North Central; Sandhills; Piedmont Triad; Southwest; Northwest; Western; Outside of NC	