2016

Risk of Maternal Smoking on Breastfed Infants and the Development of Otitis Media

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Abstract

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Abstract

Despite advances in health promotion through efforts to reduce tobacco smoking, tobacco-related health conditions have continued to be significant. Exposure to secondhand smoke has been identified as a health risk also in addition to infant health risks related to maternal smoking. In contrast, breastfeeding has been found to promote infant health and is strongly encouraged. Despite literature supporting both of these statements, the combined effects of both breastfeeding and maternal smoking on infant wellbeing have not been delineated. Otitis media represents a common health problem among infants and young children. Tobacco exposure has been shown to increase its incidence while breastfeeding has been shown to reduce its occurrence. In the current study, a consecutive sample of all infants less than 5 years of age with otitis media and breastfed for at least 6 months was collected from a busy urban clinic for analysis. A survey tool was administered to those meeting study criteria. Primary analysis examined the odds ratio of developing otitis media among breastfed infants between those whose mothers smoked tobacco and those whose mothers did not. As a result, the association between the protective effects of breastfeeding and the detrimental effects of maternal smoking was evaluated in relation to the development of otitis media. Secondary variables including demographics, family history, past medical and birth history, and secondhand smoke exposure were also assessed. Results failed to demonstrate a significant difference in otitis media between the 2 cohorts in this study, and of the secondary variables, only cranio-facial deformities and/or a family history of these conditions resulted in higher otitis media occurrence. Further study with larger populations with higher tobacco use rates may offer additional insights into this matter.

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Dedication

I dedicate this degree to my children, mother and brother as well as my mentors and friends. I couldn't have done it without all of you. Thank you for all of your support along the way.

Acknowledgments

This project would not have been possible without the support of many people. Many thanks to my chair, Dr. Patrick Tschida, who read my numerous revisions and helped make some sense of the confusion. Also thanks to my committee member, Dr. Kai Stewart, who offered guidance and support. Thanks to the Walden University Graduate School of Public Health for awarding me a Dissertation Completion. Finally, thanks to my children, mother, brother and friends who were always offering support and love as they endured this long process with me.

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Chapter 1: Introduction to the Study

Introduction

Among leading issues involving public health, the effects of tobacco use and exposure continue to be serious concerns. According to the Centers for Disease Control and Prevention (CDC), tobacco continues to be a leading cause of morbidity and mortality among adults, with approximately 44.5 million individuals smoking regularly (defined as smoking at least weekly) and 36.1 million individuals smoking daily (defined as daily use for 30 days or more) (CDC, 2004). Using a more liberal definition of tobacco smoking thus captures a greater percentage of individuals affected by negative health effects. While direct costs of use of tobacco are substantial for individuals, costs to society related to health and medical interventions are tremendous. The social medical costs are estimated to be in excess of $260 million per day in the United States (US) alone (CDC, 2009).

Tobacco-related health issues are not limited to adults. They also involve children as well as infants. According to CDC, in 2012 approximately 6.7% of all middle school students were current smokers, while 23.2% of higher school students actively smoked (CDC, 2013). With regard to infants, exposure to tobacco-related products during pregnancy and after birth has been associated with numerous negative health effects. Among these conditions are colic, gastroesophageal reflux, low birth weight, cognitive delay, developmental delay, asthma, respiratory infections, and sleep dysfunction (Chantry, Howard, & Auinger, 2006; Julvez, Ribas-Fitó, Torrent, Forns, Garcia-Esteban,

& Sunyer, 2007; Laurberg, Nøhr, Pedersen, & Fuglsang, 2004; Mennella, Yourshaw, & Morgan, 2007; Reijneveld, Brugman, & Hirasing,2000; Shenassa & Brown, 2004).

Relative to infant health, breastfeeding has been shown to be protective against many adverse conditions. The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for infants for the first six months as a result (Chantry et al., 2006). In relation to tobacco exposure, breastfeeding has been shown to be protective for infants (Karmaus et al., 2008). Karmaus et al. (2008) demonstrated that breastfeeding specifically attenuated the risk of recurrent lower respiratory tract infections if continued for periods of three months or longer (Karmaus et al., 2008). Kull similarly showed protective benefits of breastfeeding in the development of a variety of allergic diseases (Kull et al., 2002). Others have demonstrated similar effects of breastfeeding on gastrointestinal health and the development of colic (Reinjneveld et al., 2000). Breastfeeding has even been shown to reduce the negative effects of tobacco on infants (Karmaus et al., 2008). Theories about why breastfeeding offers such protections involve the passive transfer of maternal antibodies, maturational effects on the infant's immune system, positive immunomodulatory effects and direct antimicrobial benefits (Chantry et al., 2006).

Thus, while exposure to tobacco-related substances has a negative effect on infant health, breastfeeding has been shown to be protective. These findings led some key professional and regulatory agencies to remove nicotine and tobacco from the banned list of drugs that may be used during breastfeeding (Pulley & Flanders-Stepans, 2002).

Specifically, the U.S. Food and Drug Administration (FDA) and the AAP both removed tobacco from their banned list of drugs during breastfeeding in 2001, stating that the importance of breastfeeding was more important and should be encouraged even among women choosing to smoke tobacco (Pulley & Flanders-Stepans, 2002). Unfortunately, policymakers and professional organizational leaders determining these decisions may have neglected to fully appreciate the effect maternal smoking has on the initiation and duration of breastfeeding itself. Multiple researchers have demonstrated that maternal smoking during and after pregnancy significantly reduce the chances of starting breastfeeding and promote early weaning (Ever-Hadani, Seidman, Manor, & Harlap, 1994; Giglia, Binns, & Alfonso, 2007; Liu, Rosenberg, & Sandoval, 2006; Napoli, Lallo, Pezzotti, Forastiere, & Porta, 2007; Weiser, Lin, Garikapaty, Feyerharm, Bensyl, & Zhu, 2005). While breastfeeding may protect infants from tobacco-related effects, maternal smoking decreases the chances of breastfeeding by approximately 50% (Liu et al., 2006). With this information regarding effects of tobacco during breastfeeding in mind, social policy may not accurately align with the best interests of public health especially for infants.

In addition to the negative effects maternal smoking has on adherence to current breastfeeding guidelines; few researchers have examined the direct effects of maternal smoking solely on populations of infants who are breastfed according to those guidelines. A paucity of evidence exists regarding the effect that smoking has on a population of breastfed infants only. This may seem, in part, from the relatively few mothers, who

smoke tobacco and complete six months or more of breastfeeding (Giglia et al., 2007). Regardless, this is an important area for study since significant effects of maternal smoking on breastfed infants could alter current FDA recommendations and social policies.

In the current study, a population of breastfed infants was assessed via a combined prospective-retrospective, cohort design to determine the effects that maternal smoking has on the occurrence of otitis media. The significance of factors that contribute or do not contribute to otitis media was assessed using logistic regression for a sample of breastfed infants. The subsequent sections of this chapter provide a more thorough background summary of the current literature relevant to maternal smoking, infant exposure to tobacco-related products, tobacco-related health disorders, information regarding breastfeeding effects, and the interrelationships of these topic areas as well as gaps in the current literature. Also the study will be described in greater detail along with its intent, terminologies, relevant research questions and hypotheses, methodologies, and foundational theories. Lastly, the overall scope and limitations of the study will be discussed to provide a working framework of references in relation to past literature and future research. This chapter thus provides an overview as a means to gain a foundational understanding of the planned research involved.

Background Information

In order to evaluate potential factors that may contribute to otitis media for infants being breastfed, a background analysis of information relevant to tobacco exposure,

infant illness, and breastfeeding was required. A detailed analysis of the current literature concerning these subjects was covered in Chapter 2, but a summary of the literature is provided here. Tobacco consists of over 4,000 compounds of which 60 or more have been associated with cancer (Mennella et al., 2007). Major constituent toxins found in cigarette smoke include nicotine, carbon monoxide, ammonia, formaldehyde, hydrocyanide, nitrous oxides, phenols, and sulfur dioxide (Best, 2009). Currently more than one in five Americans over the age of 18 years smokes with one in eight smoking in excess of a pack a day (CDC, 2004). Also notable is that of all women who smoke, half continue to smoke to some extent during their pregnancies. When considering pregnancies of all women (both smokers and nonsmokers), births to mothers who continued to smoke during their pregnancy represents approximately 12% of all births (Shenassa & Brown, 2004). These statistics reflect the large population of mothers and infants exposed to the potential ill effects of tobacco.

Tobacco Effects on Infants

Tobacco effects on infants can contribute to a variety of ill effects. Maternal use of tobacco during pregnancy is associated with low infant birth weight, preterm labor, and increased infantile respiratory distress (Weiser et al., 2009). Some researchers also have also shown that fetal brain exposure to nicotine during development causes an up regulation of nicotine receptors leading to a theorized increased potential for nicotine addiction later in life (Best, 2009). This demonstrates that the health effects on infants from smoking can perpetuate negative health habits and conditions later in life.

Gastrointestinal effects have also been hypothesized as a result of fetal nicotine exposure. Increased motilin, a hormone responsible for powerful gastric smooth muscle contractions, is increased in neonates in mothers smoking during pregnancy. Motilin is associated with gastrointestinal health risks which include colic as well as neonatal cramps and diarrhea (Shenassa & Brown, 2004). Based on a review of the literature, maternal smoking can therefore affect multiple systems during fetal development.

Secondhand smoke (SHS) has been associated with increased respiratory illness, early onset asthma and sudden infant death syndrome (SIDS) in infants (Best, 2009; Kull et al., 2002; Weiser et al., 2009). A reduced capacity for cognitive development has also been associated with maternal smoking in infants affecting verbal, executive, and memory functions (Julvez et al., 2007). In rare cases, this developmental delay may be related to an impairment of iodide transfer into breast milk (Laurberg et al., 2004). Other associations between maternal smoking and infant health effects have included increased risk for obesity (Toschke, Montgomery, Pfeiffer, & Von Kries, 2003); impaired sleep ability (Mennella, et al., 2007); and reduced sperm development in male infants (Jensen, Mabeck, Toft, Thulstrup, & Bonde, 2005). Therefore, risks of maternal smoking involving tobacco not only pertain to the fetus but to an infant as well.

Otitis Media and Tobacco Exposure

Several researchers have examined the association between tobacco exposures in children to the development of otitis media and supported a positive risk (Alpert, Behm, Connolly, & Kabir, 2011; Csákányi, Czinner, Spangler, Rogers, & Katona, 2012;

Hawkins & Berkman, 2011; Jensen, Koch, Homøe, & Bjerregaard, 2013; Yilmaz, Caylan, & Karacan, 2012). Some have examined the risk of tobacco exposure in causing recurrent otitis media, which demonstrated parental smoking doubles the risk of developing otitis media (Csakanyi et al., 2012; Hawkins & Berkman, 2011). Jensen et al. (2013) examined 222 children between the ages of 4 and 10 years and found current maternal smoking raises the risk of otitis media by 2.47 while previous smoking raised the risk 2.00 (2013). Additionally, Alpert et al. (2011) in assessing trends, found that reductions in secondhand smoke paralleled reductions in otitis media occurrences over a thirteen-year span in both inpatient and outpatient facilities.

These findings have been supported by systematic reviews, which assessed the correlation between middle ear disease and secondhand smoke. However, maternal smoking and household smoking of tobacco correlated with higher otitis media risk while paternal smoking and prenatal smoking did not (Jones, Hassanien, Cook, Britton, & Leonardi-Bee, 2012). In considering the effects of breastfeeding on otitis media occurrence, Yilmaz et al. (2012) identified the infection rate for upper respiratory infections in general declines five-fold in the presence of breastfeeding but increases 23-fold with maternal smoking and 15-fold with paternal smoking. However, Yilmaz et al. (2012) did not examine otitis media specifically.

Protective Effects of Breastfeeding

Statistics regarding breastfeeding, conversely, have supported benefits to infants with positive effects directly proportional to duration up to six months and to exclusivity

of breastfeeding. Breastfeeding has been shown to reduce the incidence of asthma, atopic dermatitis, allergic rhinitis, and other types of allergic diseases (Kull et al., 2002). Breastfeeding has likewise reduced the incidence of pneumonia and otitis media in children younger than 24 months of age (Chantry et al., 2006). Breastfeeding has also been found to reduce gastrointestinal infections (Chantry et al., 2004). Even among infants exposed to maternal smoking of tobacco, health protections have been identified with breastfeeding which include reduction of respiratory illness and asthma (Karmaus et al., 2008) and a reduction in the occurrence of colic (Reinjneveld et al., 2000). These protective effects resulted in FDA changes to remove tobacco from a contraindicated substance during the postpartum period (Pulley & Flanders-Stepans, 2002).

Researchers have also extensively addressed the effects of maternal smoking on the decision to initiate and maintain breastfeeding. Light and heavy maternal smokers have been found less likely to start breastfeeding while these individuals as well as mothers who quit during the pregnancy often wean earlier than non-smokers (Weiser et al., 2005). In an Australian study, maternal smokers weaned on average at 11 weeks compared to nonsmokers at 28 weeks (Giglia et al., 2007). Ever-Hadani and colleagues similarly found tobacco use had detrimental effects by reducing the rate that mothers who smoked chose to initiate breastfeeding (Ever-Hadani et al., 1994). While breastfeeding may be protective, a significant reduction in the number of mothers initiating and maintaining breastfeeding occurs in the presence of tobacco use after delivery.

While the literature is extensive in the aforementioned areas, the isolated effects of breastfeeding in protecting infants in the setting of tobacco exposure in comparison to absence of exposure has not been extensively researched. Researchers have supported protective effects of health from breastfeeding, and negative effects of tobacco on infant health and choices to breastfeed are evident. However, the degree to which breastfeeding protects infants of mothers who smoke tobacco has been poorly defined. This reflected a significant gap in the literature. Some researchers have supported that breastfeeding reduces the risk of asthma in the presence of maternal smoking (Karmaus et al., 2008). However, no researchers have examined the risk maternal smoking imposes on infants and children for developing otitis media in the presence of breastfeeding. The reason such a study was needed is to compare the degree of risk smoking adds to infants and children receiving breastfeeding in comparison to children not exposed to maternal smoking. If the risk is substantial, social policy change would be encouraged to redefine tobacco as a potentially contraindicated substance during the post-partum period. In this study I sought to define this risk in greater detail as it pertains to the development of otitis media.

Problem Statement

In the past 10 years, progress has been made in regards to the use of tobacco during pregnancy with a 50% decline over the last fifteen years (Best, 2009). Despite this, in 2009 the use of tobacco during pregnancy averaged above 10% during pregnancy in the United States with some states approaching 20% (Weiser et al., 2009). Even among mothers who do not smoke tobacco, secondhand smoke continued to represent a threat to

infant health (Shenassa & Brown, 2004). Otitis media has also been noted to be more common in children as a result of secondhand smoke exposure (Brooks et al., 2010). The risk of developing otitis media if parents smoke or if someone in the household smokes is increased significantly (Alpert et al., 2011; Csakanyi et al., 2012; Hawkins & Berkman, 2011; Jensen et al., 2013). Presumably, the immunologic and respiratory effects related to tobacco results in a greater susceptibility to infection of the upper as well as lower airways (Chantry et al., 2006). Despite this knowledge, the degree of protection from breastfeeding against developing otitis media in the presence of maternal smoking or in secondhand smoke environments has not been well studied. Some researchers have supported the protective effects of breastfeeding in relation to tobacco exposure. However, this effect has not been studied across multiple disease entities and the risk of protection of breastfeeding has not been well quantified. This lack of information represents an important gap in the current knowledge. Identification of a significant risk for an illness like otitis media with maternal smoking despite breastfeeding when compared to breastfeeding mothers who do not smoke could have profound effects on social policy and secondarily infant health.

Therefore, a research study was needed to evaluate this information by comparing the risk of developing illness among breastfeeding infants who are exposed to tobacco and compare its occurrence with breastfeeding infants who were not exposed to tobacco.

Purpose of the Study

The purpose of this study is to examine the risk of maternal smoking on infants who are breastfed during the first six months of life in regards to the development of otitis media. The study will be a quantitative study, which will identify the incidence of otitis media among the selected participants during their first six months of life and compare the incidence of otitis media for infants exposed to maternal smoking compared to infants without such exposure. This study examined otitis media incidence among infants who differed with regarding to (a) exposure to second-hand smoke, (b) maternal factors of education, marital status, and age, and (c) maternal, family, and infant medical conditions. By performing this research, an assessment of risk of maternal smoking was evaluated as it pertains to breastfed infants.

Research Question and Hypotheses

Based on literature gaps, the research questions involved in this study pertain to the risk of maternal smoking on infants who are breastfed during the first six months of life. The AAP supports exclusive breastfeeding during the first six months of life (Chantry et al., 2006). Therefore, in this study I sought to define any risk for the development of ear infections among different populations of infants which are and are not exposed to maternal smoking. The research question and hypotheses are thus as follows:

Primary Research Question and Hypotheses

Research Question 1: Is there a difference in otitis media incidence in breastfed infants during the first six months of life whose mothers are or are not tobacco smokers?

$H_0$1: The exposure of maternal tobacco smoking to breastfed infants during the first six months of life does not result in any significant risk in developing otitis media.

$H_1$1: The exposure of maternal tobacco smoking to breastfed infants during the first six months of life does result in a significant risk in developing otitis media.

The independent variables were represented by the presence or absence of maternal tobacco smoking exposure; presence or absence of exposure to secondhand smoke; mother's educational level; mother's relationship status; mother's age; difficulty experienced during delivery; presence of pre-existing cranio-auditory medical conditions; and family history of immunologic, and/or cranial disorders, and the dependent variable will be the diagnoses of otitis media during the first six months of life.

From a public health perspective, hypothesis testing can be used to determine the differences between two proportions in a health outcome that are due to, or can be attributed to, the exposure or risk factor (Creswell, 2009). The above reflect the hypotheses for this study and specifically help aim to address the research question formulated.

Secondary Research Questions and Hypotheses

In addition to the primary research question in this study, several secondary research questions were addressed to evaluate the effect of confounding variables on the development of otitis media. Each of these secondary research questions have null and alternative hypotheses which are be listed as follows:

Research Question 2: Are infants who are breastfed and exposed to secondhand smoke at significantly higher risk for developing otitis media?$H_0$1: The exposure of secondhand smoke to breastfed infants during the first six months of life does not result in any significant risk in developing otitis media.

$H_1$1: The exposure of secondhand smoke to breastfed infants during the first six months of life does result in a significant risk in developing otitis media.

Research Question 3: Are infants who are breastfed from mothers with lower education at significantly higher risk for developing otitis media?

$H_0$1: Breastfed infants of mothers of lower educational levels do not experience any significant risk in developing otitis media compared to those of mothers of higher educational levels.

$H_1$1: Breastfed infants of mothers of lower educational levels experience a significantly greater risk in developing otitis media compared to those of mothers of higher educational levels.

Research Question 4: Are infants who are breastfed from single mothers at a significantly higher risk for developing otitis media?

$H_0$1: Breastfed infants of single mothers do not experience any significant risk in developing otitis media compared to those of mothers who are not single.

$H_1$1: Breastfed infants of single mothers experience a significantly greater risk in developing otitis media compared to those of non-single mothers.

Research Question 5: Are infants who are breastfed from younger mothers at a significantly higher risk for developing otitis media compared to older mothers?

$H_0$1: Breastfed infants of younger mothers do not experience any significant risk in developing otitis media compared to those of older age mothers.

$H_1$1: Breastfed infants of younger mothers experience a significantly greater risk in developing otitis media compared to those of older age mothers.

Research Question 6: Are infants who are breastfed and who have difficulties during delivery at a significantly higher risk for developing otitis media?

$H_0$1: Breastfed infants with difficulties during delivery do not experience any significant risk in developing otitis media compared to breastfed infants without difficulties during delivery.

$H_1$1: Breastfed infants with difficulties during delivery experience a significantly greater risk in developing otitis media compared infants without difficulties during delivery.

Research Question 7: Are infants who are breastfed and who have pre-existing cranio-auditory medical conditions at a significantly higher risk for developing otitis media?

$H_0$1: Breastfed infants with pre-existing medical conditions do not experience any significant risk in developing otitis media compared to breastfed infants without pre-existing medical conditions.

$H_1$1: Breastfed infants with pre-existing medical conditions experience a significantly greater risk in developing otitis media compared infants without pre-existing medical conditions.

Research Question 8: Are infants who are breastfed and who have a family history of auditory, immunologic, and/or cranial disorders at a significantly higher risk for developing otitis media?

$H_0$1: Breastfed infants with family histories of auditory, immunologic, and/or cranial conditions do not experience any significant risk in developing otitis media compared to breastfed infants without such family histories.

$H_1$1: Breastfed infants with family histories of auditory, immunologic, and/or cranial conditions experience a significant risk in developing otitis media compared to breastfed infants without such family histories

Theoretical Framework

The underlying framework involved in this research study supports Pender's health promotion model (HPM) (Rich, 2010). This model was originally conceived in 1982 with subsequent revisions in 1996. Through a holistic view of health, aspects and segments can be examined within the context of the whole. Underpinnings of this model are based on expectancy value theory, which states individuals pursue activities as a means to achieve goals (Pender, 2011). Likewise, social cognitive theory is a foundation of this model identifying thoughts, behaviors and environment as areas of interaction where thought directs behavior. Health providers can thus direct health through a variety of individual, social and contextual factors to bring about behaviors which promote health (Pender, 2011). At the foundation of these are knowledge that serves to redirect thought and subsequently behaviors in relation to situations and environments (Pender, 2011). Thus, identifying knowledge concerning maternal smoking and breastfeeding effects on infant health can serve to aid providers in promoting positive health behaviors.

The focus of this study involves a study of the health effects of maternal smoking on infants. The choice of a mother to smoke during breastfeeding is an individual behavior and experience which can be modified. By investigating the degree of risk maternal smoking has on the development of otitis media in breastfed infants, a positive correlation between the individual experience of smoking tobacco and poor infant health (in this case otitis media) can be used to provide knowledge which can change maternal

behaviors (see figure 1). This model was intended to alter maternal tobacco use in this regard, and similarly, social policy change may also result from this behavior specific knowledge resulting in an increase in health promoting behavior more broadly (Rich, 2010).

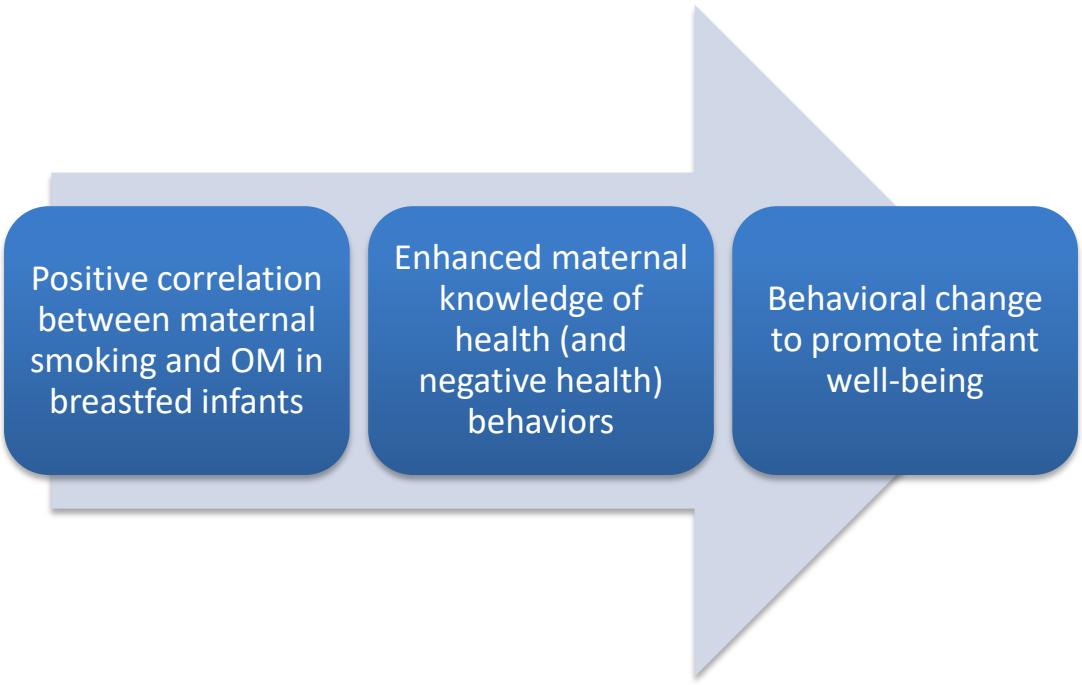

Figure 1: Health promotion model application to study

As part of the health promotion model and conceptual framework, in this study I sought to expand the knowledge available regarding infant health. Through the investigation, the risk of developing otitis media in infants who are breastfed was compared between mothers who do and do not smoke during the first 6 months after delivery. By selecting mothers who have chosen to breastfeed, a presumed level of self-autonomy exists. This is presumed due to the assumption that they believe breastfeeding offers them a better chance of control over the infant's health (Rich, 2010). In terms of

the health promotion model, this was pursued to provide individuals and providers with knowledge so better health goals can be advocated, and it sought to secondarily improve health behaviors and social environments as a result (Pender, 2011). Therefore, under this framework, being able to demonstrate better infant health among maternal nonsmokers during early infant life is hoped to result in more effective modifying factors within this subset of mothers.

In relation to maternal smoking as well as breastfeeding, modifying factors do exist. For example, low socioeconomic status has been associated with increased rates of maternal smoking and reduced rates of breastfeeding (CDC, 2004). The data regarding educational levels differ slightly from socioeconomic status in that both low and high educational levels have supported increased breastfeeding (Ever-Hadani et al., 1994). Some studies have supported a biological influence of nicotine on prolactin and dopamine which reduces the quality and quantity of breast milk production (Weiser et al., 2009). The results of this study were adjusted for these variables so in order to examine an isolated assessment of maternal smoking on the development of otitis media in infants.

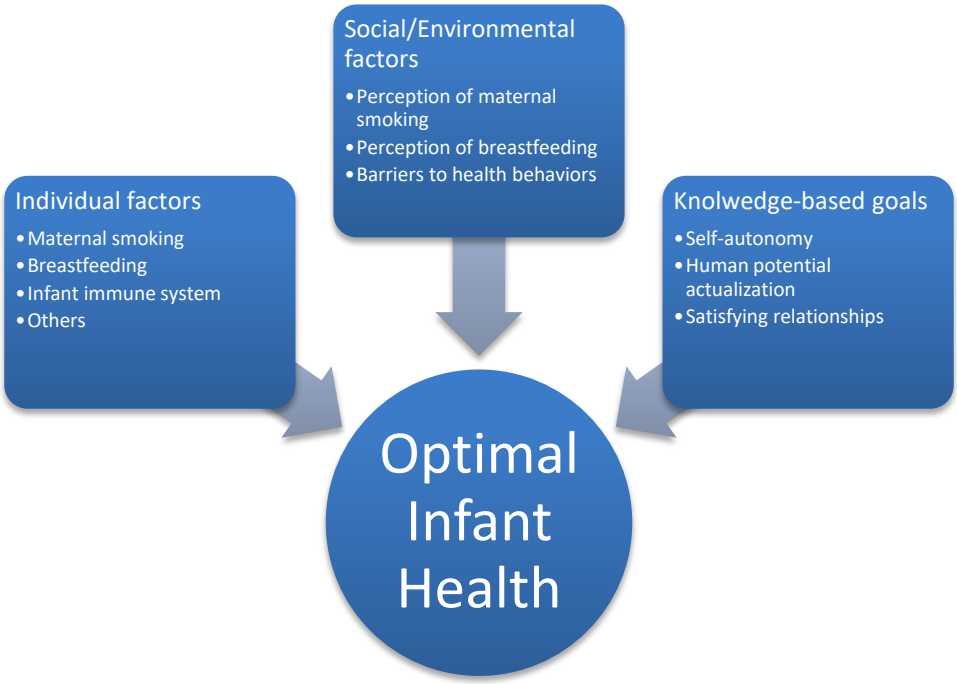

Figure 2: Pender health promotion model in relation to study framework

Despite this, Pender's health promotion model provided a logical framework conceptually for this study as described. In his model, health was viewed as a dynamic state of wellness which is multidimensional (See Figure 2). As such, health is a complex process with many variables, and the current research study sought to simplify this complex state to better define risk and benefit of specific behaviors (Rich, 2010). While some variables of behavior and influence were controlled, key variables involving maternal smoking, breastfeeding, and otitis media were addressed. This offers a degree of specificity with which cognitive factors and modifying factors were better defined in terms of health. Secondarily, this information could be used to positively influence behavior specific knowledge and health outcome goals in the future (Rich, 2010).

Nature of the Study

In this study, the design chosen for evaluation of the independent and dependent variables was a combined prospective-retrospective, observational, no experimental cohort study. This specific design was selected for the purpose of efficient resource utilization due to limited financial, human and time resources. Retrospective data involving basic demographics and clinical diagnosis of otitis media were obtained from clinics in addition to retrospective data obtained from participant surveys.

In terms of sampling, inclusion criteria included breastfed infants. Likewise, only infants exclusively breastfed for the entire six months of life will be enrolled. Exclusion criteria were defined as infants who were not exclusively breastfed (although introduction of solid foods at 4 months of age is permitted), and those who received formula supplements. The subsequent sample of participants in the study completed a study survey tool relevant to this research questions described.

The variables considered primarily involved the presence of breastfeeding during the first six months of infant life, the presence or absence of maternal smoking during the same time period, and the number of separate diagnosed conditions of unilateral or bilateral otitis media. Maternal smoking was identified by survey instruments where mothers self-reported whether they smoke tobacco or not. Secondary variables captured also included demographic information, past medical history relevant to ear and respiratory systems, family history relevant to congenital ear infections and deformities, maternal characteristics, exposure of infant to secondhand smoke in the absence of

maternal smoking if information available, and information regarding birth and delivery. Secondary variables were collected for purposes of statistical adjustments of primary variable analysis. This allowed better isolation of the effect maternal smoking had on the occurrence of otitis media in breastfed infants.

Definitions

For the sake of specificity and consistency, definitions were provided for comparison to past and future research using similar terms. Variable definitions concerning maternal smoking have ranged from requirements for daily use, the absence of use, or partial use with detailed quantification of the amount of tobacco used. Definitions of this variable and other concepts used in this current research study however are as follows:

Breastfeeding: Exclusive breastfeeding where infants receive only breast milk for nutrition during the first four to six months of life. The only other permitted substances included vitamins, minerals, hydration salts and medications prior to four months of age (WHO, 2013). After four months of age, solid food introduction was allowed for purposes of this study. However, no supplementation with cow's milk, goat's milk or formula was permitted during the entire six months for participants. There was not any distinction made in this study between mothers who pumped breast milk for infant feeding later and those who actively breastfed.

Maternal smoking: Tobacco smoking by mothers of infants, and by definition, it meant daily use of cigarettes or other regular inhaled tobacco products (Gilman et al., 2008).

Lower respiratory tract infections: Infection of the trachea, bronchus, bronchioles, and/or alveoli of the respiratory system (Thomas, 1989).

Otitis media: Acute otitis media suggesting acute infection and inflammation of the middle ear occurring during the first three weeks of infection. It may have been viral or bacterial on nature. Either of these may have been as a result of tobacco exposure due to impairment of immune function associated with tobacco.

Sociodemographic data: Information regarding poverty and economic status, educational status, ethnicity, race, marital status, and employment status. Gender issues are not relevant since all interviewees will be mothers.

Upper respiratory tract infection: Infection of the nares, sinuses, naso-pharynx, oropharynx, and/or larynx (Thomas, 1989).

Assumptions

Several key assumptions were made as part of this research study, which must be highlighted. From a definition standpoint, maternal smoking was defined in this study as daily inhaled tobacco use during the first six months while breastfeeding. This assumed that quantification of tobacco use beyond daily use is not necessary; however, this may not be the case. Light smokers and heavy smokers have been shown to have some differences in early weaning from breastfeeding in some research (Liu et al., 2006). Due

to a lack of definitive characterization of maternal smoking in the literature, any daily inhaled tobacco use defined maternal smoking in this study. The use of e-cigarettes will not meet the daily inhaled tobacco use criteria, however, since preliminary effects on air quality and others appears to be less (McAuley, Hopke, Zhao & Babaian, 2012)

The assumption that lighter smoking among breastfeeding mothers imparted a similar risk to infants as heavier smokers neglects a dose-dependent risk of tobacco exposure among the participants. This aspect was not addressed in the present study as the primary focus will be on determining the degree of protection infants are provided by being breastfed in relation to any tobacco exposure. In addition, this study did not address the variety of tobacco products on the market or e-cigarettes. The majority of mothers who smoke were presumed to smoke regular cigarettes or other common tobacco products. Therefore, only mothers smoking these tobacco products were considered in the study, and only these products were used to calculate frequency of use.

Secondly, while exclusive breastfeeding was defined according to accepted standards, the ability to distinguish quantity and quality of breastfeeding was not included in this study. Potentially, varying aspects of breastfeeding could influence potential protective effects for infants exposed to maternal smoking. However, the constraints of this study demanded an assumption that exclusive breastfeeding among all mothers regardless of quantity and nutritional quality offers comparable infant protections. This may not be the case since different levels of health protection have been shown between partial and exclusive breastfeeding (Kull et al., 2002). Different amounts (quantity) and

nutritional consistencies of breast milk (quality) may have resulted in similar discrepancies. Regardless, the assumption that exclusive breastfeeding of infants if comparable regardless of quantity and quality was made due to considerations of resource utilization and practicalities of the study.

Common among many mothers who do exclusively breastfeed were practices where pumped breast milk is administered to an infant for later use or by other caregivers. This may reduce the exposure to secondhand smoke for these infants and affect results of this study. However, since the quantification of tobacco smoke exposure (other than daily use) was not being measured, this distinction was addressed in this study. Therefore, infants fed pumped breast milk were allowed to meet inclusion criteria as long as they remain exclusively breastfed.

Assumptions were also made regarding the ability to select a representative sample of the population despite the use of non-probability sampling. Similar concerns over resources and practicalities existed here as well, and efforts were made to attempt sample selection so that socio-demographic groups represented the country's typical population distribution (Polit & Beck, 2012). It is also assumed that the administrative aspects of the clinics selected will provide accurate and efficient means by which data can be captured and reviewed. By screening first by diagnosis of otitis media, the assumption was that all potentially qualifying infants for the study would be available for review in each clinic. This assumption may have missed some infants who have more than one diagnosis or who receive miscoding for their diagnosis. Regardless, the

sampling methodology proposed provided the most efficient and comprehensive means of obtaining an accurate sample in each clinic setting.

Scope and Delimitations of the Study

In considering this research study from a perspective of internal and external validity, efforts were made to design the study to optimally narrow the relationship being studied into a cause and effect association. By adjusting for other variables, an association between maternal smoking and the development of otitis media were isolated. Otitis media was selected as the dependent variable for several reasons. First, research has supported that otitis media increases in occurrence in the presence of maternal smoking (Chantry et al., 2006; Haberg et al., 2011; Jones et al., 2012; Yilmaz, Caylan & Auinger, 2012). Likewise, otitis media has been associated with increased incidence from maternal secondhand smoke (Jones et al., 2012). Otitis media represents a type of upper respiratory tract infection since access to the middle ear cavity occurs through the Eustachian tube from the oropharynx and nasopharynx. Therefore, otitis media simply reflects one type of upper respiratory infection (Chantry et al., 2006). Secondly, otitis media represents a common and frequent infection among infants which would provide adequate population numbers for statistical assessment (Brooks et al., 2010). Thirdly, mothers of infants with otitis media symptoms routinely seek medical care in the majority of cases unlike less acute or significant infections which may be monitored at home (Haberg et al., 2011). The combination of these three characteristics resulted in the

selection of otitis media as a target measurement to assess health risks among infants of mothers who may or may not smoke tobacco.

As identified in the research analysis, this study sought to fill a gap in the current understanding of the risk imposed on infants who are breastfed by mothers who smoke. Therefore, the generalizability of the study's results was applicable mainly to infants who are breastfed and are in their first six months of life. Additional generalizations were assumed for other infant populations and other age children, but this exceeds the scope of the current study. Because the intent was to define the risk of maternal smoking among breastfed infants more precisely, this naturally limited the population to which the results can be applied. This study was not designed to explore larger conceptual aspects of maternal smoking such as effects during pregnancy or long term health effects of children. Likewise, long term benefits from breastfeeding were not a focus of investigation either. For purposes of this research, the conceptual framework was limited to the first six months of infant life as it related to exposure to maternal smoking in the presence of breastfeeding and the associated health effects that result.

Limitations of the Study

In assessing the limitations of the current research project, some considerations required explanation. The study was designed to evaluate the association between maternal smoking in breastfed infants and the occurrence of otitis media. With this in mind, other variables may have affected the recognized occurrence of otitis media (see Figure 5). Internal validity of this association was attempted to be enhanced by adjusting

for other variables which may have affected the occurrence of otitis media. Social environments including lower socioeconomic status, poverty situations, and others could arbitrarily increase or decrease health illness in general and tobacco related illness specifically (CDC, 2004). Likewise, individual variables such as educational level can influence these effects as well (CDC, 2004). By utilizing statistical means to adjust results based on socio-demographic factors and other secondary variables as defined in the research questions, an effort to analyze potential social and individual threats was attempted.

Another concern of internal validity was inherent anatomical or physiological differences between infants who do and don't suffer from otitis media. Anatomical differences in Eustachian tube structures and physiological differences in immune system function could make some infants more or less susceptible for otitis media. This naturally would affect the cause and effect relationship between maternal smoking and the development of the condition. However, such internal validity risks exist in most complex, multifactorial medical illnesses. By sampling medical histories and exams, efforts to identify outliers in this regard were performed to screen for such anomalies. This increased the internal validity associated between maternal smoking the otitis media occurrence in the study's results.

Internal validity was also potentially affected by single group threat since only breastfeeding mothers were selected. By nature of the study design, this intentionally excluded non-breastfeeding mothers, which narrowed the scope of the study and

increased the threat to the cause and effect association between maternal smoking and otitis media occurrence (Polit & Beck, 2012). While single group threat is acknowledged, this group of participants remains quite broad and varied in many other attributes. If this were not the case, adjustments for other variables would be less important. Despite the selection of a single group for study, it was felt this group still reflects an adequate diversity to allow strong internal validity between the independent and dependent variables.

External validity was threatened predominantly through the sampling methods used for this study. Because the study sought to generalize its findings to populations throughout the U.S., a representative sample of varied socio-demographics was needed. Resources did not exist to allow probability sampling, so non-probability sampling was used, which inherently threatened external validity (Polit & Beck, 2012). In an effort to reduce this threat, sample selection attempted to identify pediatric clinics with comparable populations to national populations (Polit & Beck, 2012). Using a sample from Tallahassee, Florida, may also hinder external validity to an extent when considering regional and national generalizations; but by comparing infants of both non-smoking and smoking mothers in this region, these hindrances were likely to be minimal.

Additional limitations involved aspects of construct validity. In capturing all infants with physician-made diagnoses of otitis media, misdiagnosis could result in some cases. This may occur genuinely as a result of medical error, or it may involve administrative choices to code a patient visit under otitis media when a more accurate

diagnostic code is lacking. Likewise, different clinics may encode diagnoses differently within charting systems at times. Because of this, infants with multiple conditions may have failed to be coded as having otitis media in favor of their other diagnoses. By having adequate sample numbers of both groups being compared, these relatively infrequent occurrences are expected to be minimized and statistically irrelevant. Prior research otherwise supported the diagnosis of otitis media as an appropriate measure of maternal smoking risk (Chantry, Howard & Auinger, 2006). Therefore, from a conceptual perspective, this measure was a reasonable construct to assess maternal smoking risk.

In addition to sociodemographic variables, other confounding variables included secondhand smoke (SHS) exposure from other household members and the presence of other undiagnosed health conditions. These could have affected quality of results and/or prevented the protocol exclusion of a participant. This limitation may be most relevant to SHS since this may not be captured during routine pediatric office visits on all visits. This was investigated by the study survey tool however.

In regards to the second confounding variable of undiagnosed conditions, this was presumed to be an uncommon occurrence. Given that infants will be examined in a pediatrician's office in specific relation to complaints of otitis media, the rate of missing important related conditions is believed to be low. Therefore, this confounding variable was not likely to significantly influence overall results. Adequate sample numbers also diluted any potential effect this confounding variable may have had through statistical analysis.

The last consideration concerning the limitations of the study involved a discussion of biases. Sampling biases have been discussed in addition to minimize such biases. Likewise, in the discussion of assumptions, biases may have existed in definitions of maternal smoking and exclusive breastfeeding, which failed to recognize variations in quantitative and qualitative aspects of each of these variables. One additional bias was inherent to the study's design and focus. By insisting all mothers involved in the study exclusively breastfeed for the first six months of their infant's life, this natural selection process isolated specific types of mothers which likely have their own set of biases. This may have affected the ability to generalize risks of maternal smoking to other groups, and it may have affected the occurrence of otitis media due to maternal effects unrelated to breastfeeding.

While this could be a threat to internal validity, the comparison of only breastfeeding mothers in this study eliminated that as a particular concern here. However, this could have resulted in an exaggerated bias in favor of breastfeeding protection assessments since other maternal factors in this particular group may be poorly recognized or defined. While this bias did not significantly affect the conclusions of this study, absolute value assessment of breastfeeding protection would need to take this into consideration for future study.

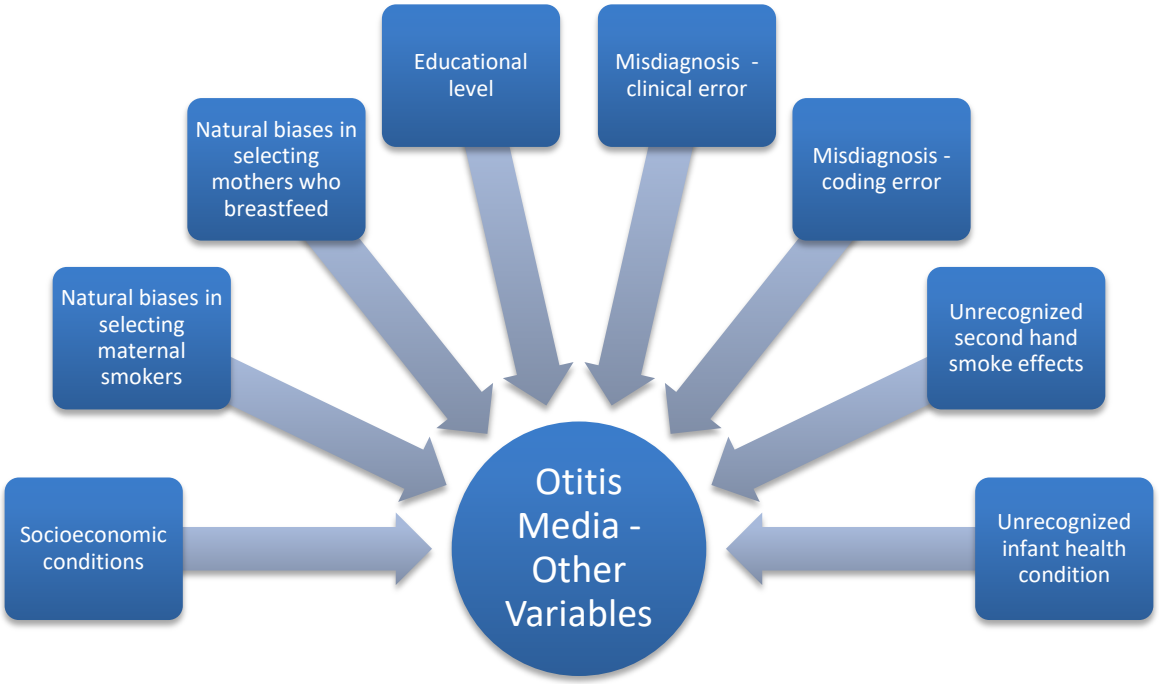

Figure 3: Potential variables affecting the recognized occurrence of otitis media

Significance of the Study

Strong support within the literature through prior research is present documenting the potential harm tobacco exposure can have on a fetus, an infant and children resulting in a range of health problems. Respiratory infections, asthma, colic, cognitive delay, gastroesophageal reflux disease, and sleep disturbances are among the more common (Chantry et al., 2006; Julvez et al. 2007; Lamberg et al., 2004; Mennella et al., 2007; Pulley & Flanders-Stepans, 2002; Reinjneveld et al., 2000; Shenassa & Brown, 2004). Researchers also support the benefits of breastfeeding through the first six months of life for infants as this enhances health through a variety of immunologic means and can even to some extent protect against harmful effects of tobacco (Karmaus et al., 2008). However, gaps in the research existed that involve the exact assessment of tobacco

exposure risk to infants while being breastfed. In other words, the degree of protection breastfeeding offers such infants and the degree of harm imposed by tobacco exposure while breastfeeding was not well-defined. This study hoped to add to current literature by better defining these two specific areas of interest.

Better information regarding the risks of tobacco exposure for infants through maternal smoking can offer objective evidence to guide better individual and social decisions among consumers. If the risk for developing otitis media among infants exposed to maternal smoking is significant compared to infants of non-smoking mothers, this information could deter maternal smoking during this time. Likewise, such information could initiate social changes within the culture and the way tobacco smoking is perceived among society members. Also, policies established by health organizations including the FDA could be affected by this data resulting in new restrictions on maternal smoking. And finally, this could lead to similar studies assessing the risk for other health disorders for maternal smoking in breastfed infants.

The overall significance of the study thus had potentially multi-layered effects depending on whether significant risk among breastfeeding mothers are found for maternal smoking. Even if significant risk was not defined, the information from this research will be beneficial in examining the overall protective effects of maternal breastfeeding in this setting. Through better quantification of the health risks and benefits specific to the participants' setting in this study, a more comprehensive approach to individual and social health can be pursued from a public health perspective.

Implications for Positive Social Change

Currently, the prevalence of tobacco use among mothers with infants remains high with estimates between 10 and 20% based on literature review (Weiser et al., 2009). Similarly, numerous infants are exposed to secondhand smoke based on the percentages of adults exposed (Shenassa & Brown, 2004). Both maternal smoking of tobacco and secondhand smoke have been found repeatedly to be associated with various health related problems including otitis media, lower respiratory infections and asthma (Brooks et al., 2010; Haberg et al., 2011; Jones et al., 2012; Yilmaz, Caylan & Karacan, 2012). At the same time, maternal breastfeeding has been shown to offer some protections against the development of these health disorders (Chantry et al., 2006). However, current shortcomings in the literature involved identification of the degree to which maternal breastfeeding offers protections for infants exposed to maternal smoking and its protection in specific health disorders.

With these issues in mind, the current study sought to better quantify the degree of infant protection that maternal breastfeeding provides in relation to the development of otitis media. In defining and quantifying these protections to a better extent, the current study offered potential benefits at individual, community and societal levels. The availability of this information can better guide maternal and infant behaviors while also serve to establish more effective community practices and public policies. Thus widespread implications existed from this study that could positively affect healthcare outcomes.

At an individual level, potential benefits from this study could affect mothers and infants as well as family members. Evidence that breastfeeding offered significant protections against otitis media naturally, encouraged breastfeeding among mothers and provided infants with better health care during infancy. The study demonstrated this protections, it will significantly reduce the presence of maternal smoking and secondhand smoke. Also motivations to change individual behaviors among mothers and family members will surface encouraging better infant protections. Each of these behavioral changes among individuals allows improved health primarily for infants and secondarily for mothers and others as better knowledge is gained. Thus cognitive-behavioral effects represent key implications for this study among individuals.

At a community level, this study had the potential to alter community health programs, social group advocacy, and local healthcare measures. With positive associations between maternal breastfeeding and infant health evident in protecting against otitis media, advocacy, education and awareness programs can be established to better serve communities. Likewise, if this protection was significantly curbed by tobacco exposure, additional programs may be developed in line with social cognitive theory to positively affect community behaviors. Also local healthcare measures and provider advocacy for breastfeeding and against infant tobacco exposure would likely evolve. These reflect likely implications from this study and potentially if the hypothesis is supported.

Finally, this study had larger societal implications. In the setting of preventative care, healthcare policy changes in addition to changing advocacy recommendations could also include incentive structure development to reward breastfeeding behaviors while discouraging maternal smoking and infant exposure to secondhand smoke. Public policy statements and decisions similarly could change reflecting stronger statements against tobacco use by mothers during infancy and/or exposure of infants to secondhand smoke environments. Just as many states have prohibited use of tobacco in restaurants, similar legislative acts could ban use of tobacco around infants. Each of these could evolve depending on the results of this study in combination with other supportive research.

Summary

In summary, tobacco exposure represented an ongoing public health issue with more than 20% of the population actively smoking tobacco by recent assessments (CDC, 2004). These figures were even more alarming based on the number of adolescents who actively smoke tobacco. Roughly 40% described themselves as current smokers, and this figure has not changed in recent years (CDC, 2013). To further complicate public health issues, secondhand smoke likewise poses serious health risks for those who do not smoke. In relation to infants, secondhand smoke from maternal smoking and others in the household has been associated with SIDS, respiratory disorders, otitis media, and cognitive decline (Best, 2009). Lastly, the effects of e-cigarette vapors on infant health were still unknown despite indoor air quality studies which suggest little harm to human

health (McAuley et al., 2012). For this reason, maternal smoking represented an area of health interest for society.

The literature has also strongly supported the protective benefits of breastfeeding among mothers and their newborn infants. Through presumed immunomodulatory effects and enhanced nutrition breast milk has been shown to enhance infant health (Chantry et al., 2006). Breastfeeding has also been shown to attenuate some negative health effects from maternal smoking on infants (Karmaus et al. 2008). Though the literature did not define the extent of this protection against maternal smoking, these findings have affected health policies and social perceptions (Pulley & Flanders-Stepans, 2002). This study, therefore, sought to fill this knowledge gap in the literature and provide significant information to help better guide public health policies and decisions.

Through an observational and quantitative study, infants being exclusively breastfed and diagnosed with otitis media during the first six months of life will be enrolled through selected pediatric clinics in Tallahassee, Florida. The presence or absence of maternal smoking served as an independent variable while the number of diagnosed events of otitis media will represent the dependent variable. Statistical adjustments were made for other secondary variables which may confound results. Enrollment will occur with sampling performed by convenience and purposive efforts, and a combined prospective-retrospective cohort review of all qualifying participants will be performed for data collection and analysis. A sample of 402 participants provided adequate numbers for statistical power analysis.

While some limitations existed regarding the study design and sampling procedures, limited resources were employed in practical manners to reduce error and bias while maximizing internal and external validities. The results have the potential to add significant value to the current public health knowledge base regarding maternal smoking and breastfeeding by quantifying the degree of risk and protection of each one respectively. With a HPM as a guiding conceptual model, this information can have the potential to assist individuals and society in making healthier choices based on evidence which could potentially result in healthier behavioral outcomes. As a result, public health advancements can be achieved for the population under investigation.

In the subsequent chapter, a detailed survey of the existing and current literature concerning maternal smoking, breastfeeding benefits, and tobacco effects on infants was explored and described. This established the current foundations of knowledge and understanding while also further delineating existing gaps in the literature where additional research is needed. In addition, the literature reviews supported the rationale for the current study and highlight any potential challenges, which may have been experienced by other researchers in this area.

Chapter 2: Literature Review

Introduction

Numerous epidemiological and experimental studies have identified negative health effects associated with tobacco smoking. A variety of systems can be affected including respiratory, gastrointestinal, endocrine, reproductive and urinary systems (Jensen et al., 2005; Karmaus et al., 2008; Lisboa, de Oliveira & de Moura, 2011; Reinjneveld et al., 2000). Despite this, approximately one-fifth of the population smokes tobacco with the highest rates being in nations that are poorly modernized (WHO, 2013). Given these statistics reflecting such a high number of active tobacco users, additional public health risks involve the effects from secondhand smoke or passive tobacco exposure. Multiple studies have likewise demonstrated the negative effects from passive exposure in individuals on their health which has resulted in progressive legislation and social policies banning tobacco smoking in some public locations (Best, 2009; Jones et al., 2011; Pulley & Flanders-Stepans, 2002). While secondhand smoke has the potential to affect anyone, children and infants are particularly vulnerable when they reside in a household with tobacco users or have parents who smoke (Jones et al., 2012).

A number of poor health outcomes in children and infants have been associated tobacco exposure. These included an increase in lower and upper respiratory infections, asthma, gastroenteritis, allergies, growth suppression, and obesity rates (Karmaus et al., 2008; Kull et al., 2002; Reinjneveld et al., 2000; Toschke et al., 2003). Some studies have also supported additional effects on sleep quality, cognition and reproductive health in

relation to maternal smoking during infancy (Jensen et al., 2005; Julvez et al., 2007; Mennella et al., 2007). Despite these findings, a number of women smoke during pregnancy. Estimates reported that half of all women who smoke prior to pregnancy continue smoking during pregnancy (Shenassa & Brown, 2004). In addition, even higher numbers of women smoke after delivery as cessation rates after birth decrease due to maternal smoking relapse. Proposed mechanisms of ill health effects in infants during this time resulted from secondhand exposure to smoke as well as direct effects from breast milk alterations (Best, 2009; Laurberg et al., 2002).

While the researchers widely supported these negative health effects from tobacco use by infant mothers, restrictions in maternal smoking were not in place. Likewise, while maternal smoking during pregnancy had negative social perceptions, the same perceptions were not as strong for post-partum mothers. In addition, mothers who smoke tobacco and breastfeed were felt to offset the negative effects of tobacco through breastfeeding protections (Lucero et al., 2009; Pulley & Flanders-Stepans, 2002). The literature supported that breastfeeding indeed protects infants from a variety of health problems including negative effects from tobacco. However the extent to which breastfeeding offers protection from tobacco exposure is not well defined (Guedes & Souza, 2009; Lauria, Lamberti & Grandolfo, 2012). Additionally, maternal smoking has been shown to reduce the number of women who breastfeed and breastfeeding duration as well (Ever-Hadani et al., 1994; Giglia et al., 2006; Napoli et al., 2007; Weiser et al., 2005).

The literature had gaps in defining the degree of protection breastfeeding offers infants who are exposed to tobacco from maternal smoking. This information was important in providing accurate knowledge to affect individual and social behaviors in promoting better public and infant health. While examining this issue demands additional study, the scope of the negative effects caused by tobacco exposure would require utilization of vast resources of time and expense. Instead, this study sought to examine the risk of maternal smoking on infants in relation to the development of otitis media during the six months of life in mothers who exclusively breastfeed. Rates of otitis media in infants who are breastfed by mothers who smoke tobacco were compared to rates among infants of breastfeeding mothers who do not smoke. Through a retrospective, non-experimental, observational study, medical record review, an examination of this data was done along with potential confounding variables in order to compare otitis media rates. In this way, the degree of protection provided by breastfeeding during the first six months of life can be estimated in relation to maternal smoking.

The information obtained from this study hopefully added to the current knowledge base regarding maternal smoking, breastfeeding and poor infant health effects. In turn, this information has the potential to change individual behaviors, social norms, and public health policies (Lucero et al., 2009). In the subsequent sections of this chapter, a comprehensive literature review relevant to this subject was provided in addition to literature search strategies and database evaluations. In addition, theoretical and conceptual aspects were discussed in relation to maternal smoking, breastfeeding and

infant health. These were considered in relation to existing literature and in relation to the current study. After detailing all of these aspects of literature assessment and application, a summary was provided to support the current study and its intentions. In essence, this chapter served as a foundation of knowledge and theory supporting the current methodologies, design, and interpretations of the study's results.

Literature Search Strategy

In order to provide a thorough literature search relevant to the scope of this subject matter, multiple databases and search strategies were utilized. The specific databases through which the literature search was performed include Google, Google Scholar, PubMed/NCBI, EBSCO (Academic Search Premier), SAGE, ELSEVIER, and Questia. Some articles, reports, and literature documents were available through these sites directly. In other instances, abstracts only were identified with the full document relocated through one of the other accessible databases mentioned. The subject matter specific to the literature journals and sites identified varied and covered a broad range of materials. Subjects of the literature journals included pediatrics, obstetrics and gynecology, maternal and neonatal medicine, endocrinology, otolaryngology, allergy and immunology, infectious disease, respiratory disorders and asthma, lactation, physiology, epidemiology, public and community health, clinical nutrition, addictions, nicotine research and nursing research. In addition, general health sites were accessed including the Centers for Disease Control (CDC) and the World Health Organization (WHO). The

spectrum of this wide range of information provided a comprehensive perspective concerning the topics reviewed.

The search terms utilized within the various databases were several. These primary search terms included the following: maternal smoking, prenatal maternal smoking, postnatal maternal smoking, postpartum maternal smoking, tobacco effects, tobacco risks in infancy, infant tobacco risk, passive tobacco exposure, secondhand smoke, breastfeeding and maternal smoking, breastfeeding protection in infants, tobacco cessation and breastfeeding, infant respiratory effects of tobacco, otitis media in infants, otitis media and maternal smoking, otitis media and breastfeeding, recurrent otitis media in infants, and maternal smoking treatment. Selection of articles, reports and studies as well as secondary web sites were chosen based on relevance of information, currency of information, and the ability to provide additional insights. A secondary search was performed relative to the theoretical and conceptual frameworks upon which this current study is based. These search terms included the following: Pender's Health Promotion Model, health promotion and maternal smoking, health promotion and breastfeeding, health promotion and infant health, and health promotion and tobacco use. Again literature selected from these search term results was based on relevance, currency and ability to provide pertinent insights.

The majority of the literature evaluated represented a current assessment of the known data and research concerning maternal smoking, breastfeeding, tobacco risks, and infant health. More than two-thirds of the literature was published in 2009 or later. Less

than a fifth of the surveyed literature reflected studies in 2004 or earlier. The oldest year of publication was 1991, and this study along with a few others was included due to the importance of the content provided in relation to the current study. The type of literature examined varied greatly. In addition to secondary web sites such as the CDC and WHO, other literature included systematic reviews, meta-analyses, cross-sectional studies, retrospective studies, cohort studies, and observational studies, randomized controlled studies, prospective assessments, and sectionalized study reviews. In addition, epidemiological and experimental studies were included as were qualitative and quantitative designs and methodologies. A minority were mixed in nature of their design. While some studies and reports offered editorials and opinions, these were not routinely included in the literature review analysis.

Theoretical Foundation

The approach of this research study was founded within a theoretical foundation related to social cognitive theory (SCT). Originally developed in the late 1970s by Albert Bandura, SCT examined human behavior as an outcome of the interaction between an individual and the environment (Crosby, Salazar, & DiClemente, 2011). In this regard, SCT did not place emphasis on nature or nurture independently but on a combination of complex interactions which involved the individual, social factors and situational contexts. SCT supports a bidirectional influence and effect between an individual's perceptions and cognitions, social behaviors and norms, and specific contexts related to a particular scenario (Crosby et al., 2011). Instead of adhering to prior theories that

environment alone influence behavioral outcomes, SCT also supports an ability for the individual to exert influences over the environment. Likewise, SCT identifies a distinction between learning and behavior. In other words, cognitive learning may occur but may not result in behavioral change due to a variety of other factors. These may involve the ability to adapt learned information to practical knowledge, values, conceptual shifts, and behavioral skills (Crosby et al., 2011).

Based upon the foundation of SCT, Pender developed the HPM a few years later in 1982 and revised it again in the late 1990s (Rich, 2010). In addition to health protection, the HPM Pender proposed added health promotion as a key component to pursuing optimal health and changing human behaviors. This holistic approach to health focused on multiple dimensions of influences that resulted in the complex outcome of human behaviors as they relate to health (Rich, 2010).

Pender separated influences into individual characteristics and experiences, behavior specific cognitions and affect, and resultant behavioral outcomes. Each interacted with the other to determine whether behaviors were continued or altered. Pender proposed positive health behaviors could be influenced favorably through understanding these interactions (Rich, 2010). Personal influences involved past behaviors of the individual as well as biologic, psychological and sociocultural influences. Behavior specific thoughts and emotions were influenced by perceptions about benefits of an action, barriers to act, degree of self-efficacy, and affect concerning the activity. Likewise, interpersonal and situational influences affected these thoughts and

feelings. Finally, competing demands and a commitment to act represented a final component in determining the behavioral outcome (Hansen & Wambach, 2011). As evident in this explanation, the relationship of SCT to the formation of the HPM was clear as individual and environmental factors interacted to determine behaviors.

Relative to the current study, several authors have used the HPM and SCT as theoretical frameworks for the evaluation of maternal smoking, breastfeeding and infant health in examining aspects of public health promotion (Fowles, Cheng & Mills, 2012; Noonan & Duffy, 2012). Some authors have applied the HPM to breastfeeding behaviors among Hispanic mothers (Schlickau & Wilson, 2005). Noonan and Duffy examined the various personal, psychological and behavioral factors involved among operator engineers in their behavioral decision to use smokeless tobacco (Noonan & Duffy, 2012). Examining each of these areas of influence, they determined younger age and reduced use of cigarettes were the primary variables in choosing to use smokeless tobacco among this population (Noonan & Duffy, 2012).

In another study, Fowles and colleagues critiqued eleven randomized controlled studies in the literature using the HPM (Fowles et al., 2012). The studies assessed a variety of interventions to improve behavioral outcomes of maternal smoking rates. The critique however revealed several problems among the studies based on the HPM comparison. Incomplete interventional descriptions were prevalent as were inconsistencies in sampling, examination of confounding variables, degree of effectiveness and duration of interventions (Fowles et al., 2012). The authors'

conclusions were that studies concerning interventions to change maternal smoking behavior in postpartum mothers provided poor data and failed to consider the key influences as defined by the HPM framework (Fowles et al., 2012). As evident in these relevant studies, the HPM and SCT are commonly used as theoretical foundations for study in comparable subject matter.

Correlating this theoretical foundation to the current study involved pursuing a cross-sectional observational study to assess the degree of protection provided by breastfeeding in relation to maternal smoking and the development of otitis media. The findings could have significant effects on behavior as depicted by SCT and the HPM through effects on individual factors and behavior specific cognitions and affect. For example, a minor degree of breastfeeding protection in the presence of maternal smoking in the development of otitis media could change perceived benefits of tobacco cessation, affect related to maternal smoking, and commitment to stop smoking postpartum. Likewise, the information could influence situational contexts and interpersonal influences if social norms and policies are altered as a result of new findings. In an effort to promote better infant and maternal health, the study used the HPM to identify specific considerations in changing eventual behavioral outcomes.

For the reasons stated above, the theoretical foundations used in this study provide practical means for better behavioral understanding and targets to promote positive behaviors related to both breastfeeding and maternal smoking.

Conceptual Framework

The conceptual framework for the current study is relatively straightforward. Key concepts involved maternal smoking during the postpartum period through six months of infant life, exclusive breastfeeding during the first six months of life, and the development of physician-diagnosed otitis media. Defining and discussing each of these primary concepts as they pertained to this study will help elucidate their importance in adding to the existing literature while also demonstrating consistency in how these concepts are being approached.

Postpartum maternal smoking was defined for the purposes of this study as any daily use of tobacco by mothers after the delivery of their infant through six months of age of the infant. The literature supports that even small amounts of daily nicotine use can have profound changes in the breast milk of nursing mothers (Laurberg et al., 2004; Shenassa & Brown, 2004; Santos-Silva et al., 2011). Likewise, daily smoking exposes infants to secondhand smoke as well. Some studies in the literature have graded the degree of maternal smoking based on volume of daily cigarettes consumed, and these have demonstrated an increasing gradient of effect on health outcomes (Weiser et al., 2005; Wen, Shenassa & Paradis, 2012; Xu et al., 2010). However, for the current study, access to this degree of information from chart review was not possible given the availability of research resources. Also numerous other studies have chosen to define this central concept as it is defined here (Ever-Hadani et al., 1994; Giglia et al., 2006; Karmaus et al., 2008; Liu et al., 2006; Reinjneveld et al., 2000). This allowed for

adequate consistency in study-to-study comparisons for the majority of the literature concerning this subject.

Exclusive breastfeeding represented a second key concept and was defined by infants receiving only breast milk for nutritional purposes. Water, vitamins and medications were allowed and do not exclude infants and mothers from study participation. Likewise, as recommended by the American Academy of Pediatrics (AAP) and the WHO, six months of breastfeeding were be required for study inclusion (Lucero et al., 2009; WHO, 2013). These two components were selected in order to comply with standard professional recommendations for infant nutrition so aspects of breastfeeding protection could be elucidated in accordance with typical maternal behaviors. As a result, the degree of protection provided by breastfeeding could be better applied to the public.

The last main concept involved the development of otitis media in the contexts of maternal smoking and breastfeeding. Otitis media represents one of the most common diagnoses among infants in pediatric clinics, and it also reflects an infection involving the upper respiratory tract. Maternal smoking has been identified as a risk factor for increased upper respiratory tract infections as well as a risk for otitis media development (Yilmaz, Caylan & Karacan, 2012). Likewise breastfeeding has been identified as reducing the risk of these same two conditions (Yilmaz et al., 2009). In order to narrow the scope of study to manageable means that fits within resource availability, the selection of otitis media was felt to be an appropriate diagnosis for study. This concept was supported by other studies which have selected otitis media for study in relation to

the other variables examined here (Haberg et al., 2010; Jones et al., 2012; Yilmaz et al., 2009). By requiring physician-diagnosed verification of otitis media, validity was believed to be increased over self-reporting. While the concept of otitis media may not allow extrapolation to all negative health effects of tobacco exposure, it may be used to extrapolate risks and protections of breastfed infants regarding upper respiratory infections when exposed to tobacco during their first six months of life.

The concept of otitis media being linked to tobacco exposure among infants first occurred in 1983, and studies have since supported tobacco as a risk factor among infants for developing this condition (Yilmaz et al., 2012). In addition, the absence of breastfeeding has also been identified as a risk factor for otitis media in this population (Yilmaz et al., 2009). The current gap in the literature, however, was the information which detailed the degree of risk and protection related to these two behaviors among new mothers during the six months postpartum. The current study by utilizing common concepts regarding maternal smoking, exclusive breastfeeding and physician-diagnosed otitis media aimed to reduce these gaps and provide a better understanding of the risks and protections involved.

Literature Review

Literature search strategies and databases assessed have been described. As a means to present the literature review in a constructive fashion, literature results were presented via two primary presentation tactics. First, literature pertinent to specific topics and subjects related to maternal smoking, breastfeeding, otitis media and infant health

were described in a progressive fashion allowing one subject to develop a foundation for the next and eventually provide a comprehensive overview of the current understanding of these concepts and their interrelations. Secondly, specific studies were detailed within the scope of this presentation framework in order to summarize key research in the field. This strategy was adopted for the sake of thoroughness and in order to provide sound rational for the current study being undertaken.

Literature foundations supporting the current study began with investigations regarding the overall effects of tobacco exposure on public health in general. Both systematic reviews and secondary data sites were utilized in accessing this information. One major source of data regarding tobacco-related health effects provided a detailed systematic overview of the current understanding regarding the effects of tobacco exposure including secondhand smoke on infants during the prenatal period (Best, 2009).

Associations between tobacco exposure and several negative health effects in infants were defined including low birth weight, sudden infant death syndrome (SIDS), lower respiratory infections, acute otitis media, allergies, and asthma (Best, 2009). Some studies reviewed in the analysis also identified early tobacco exposure as increasing tobacco addiction risk later in life among infants and an increased rate of breast cancer among female infants as adults (Best, 2009). The effects of tobacco are potentially widespread regarding health in infants, and otitis media has been consistently linked to its exposure (Alpert et al., 2011; Csakanyi et al., 2012; Hawkins & Berkman, 2011; Jensen et al., 2013).

Trends involving tobacco use defined the relevance of any study in this area, and use of tobacco within the population demonstrates variable results in this regard. According to the CDC and the 2004 National Health Interview Survey, which examined over 30,000 individuals, 20.9% of the U.S. population is active smokers while 12.1 percent smoke heavily as defined by more than a 25 cigarettes daily (CDC, 2004). Worldwide, one billion individuals smoke tobacco which includes approximately 10 percent of all women (Yilmaz et al., 2012). Likewise, 12% of all women giving birth actively smoke tobacco (Shenassa & Brown, 2004). However, the number of women choosing to smoke during pregnancy has declined 50% over the last two decades, and the overall rate of smoking in the U.S. has fallen 43% since 1991 (Best, 2009). This is offset by trends among adolescents which fail to show a decline in smoking with 11.7% of middle schoolers and 28% of high schoolers actively smoking (CDC, 2005). In addition, rates of tobacco use within developing countries were markedly high with approximately a third of these populations choosing to use tobacco (Yilmaz et al., 2012). Thus while some optimism may be evident in population trends, overall progress is slow worldwide in terms of reducing tobacco exposure and risk to health. These findings demonstrated the importance and relevance of the current study and its subject matter.

In addition to direct exposure to tobacco through use, secondhand smoke has been recognized as an indirect public health risk for individuals including infants. Researchers in China conducted a prospective study assessing hospital admissions among infants involving 8,327 participants comparing admission rates between those exposed and not

exposed to secondhand smoke (Leung, Lai-Ming & Lam, 2004). The results of the study demonstrated a significant increase in hospital admissions among exposed infants by 2.8% accounting for 616 additional admissions over the control group (Leung et al., 2004). Best noted in a literature review that studies attributed secondhand smoke to the presentation of new asthma cases among children estimated to be between 8,000 and 26,000 cases per year (Best, 2009). Jones and colleagues in a systematic review and meta-analysis of 61 epidemiological studies found one-third of all otitis media cases in children were due to secondhand smoke (Jones et al., 2012). Yilmaz and coworkers in a cross-sectional study involving 254 infants found paternal smoking alone increased the risk of lower respiratory infections 40-fold compared to infants without tobacco exposure at all, and upper respiratory infections were increased 15-fold as well (Yilmaz et al., 2009). The literature supported that indirect tobacco exposure is a serious factor in ill health effects, and infants and children appear to be particularly vulnerable in this regard.

Given the literature support for the negative health effects of tobacco in both direct and indirect forms as it pertains to infants and children, the issue of maternal smoking deserved close consideration. Tobacco itself contains over 4,000 compounds of which 60 or more have been found to be potential carcinogens (Mennella et al., 2007). Potential components affecting health include nicotine, carbon monoxide, ammonia, formaldehyde, hydrocyanide, nitrous oxides, phenols and sulfates (Best, 2009). While direct exposure of tobacco components occurs via passive exposure during maternal smoking, changes to the actual breast milk composition also represents a source of

negative health effects. Smoking more than 10 cigarettes daily has been reported to reduce breast milk production among lactating mothers and alter breast milk composition (Mennella et al., 2007). Lamberg and coworkers examined levels of cotinine, a nicotine metabolic byproduct, in 50 breastfeeding mothers who smoked tobacco and in 90 who did not smoke. Cotinine was found to correlate with reduced iodine levels in breast milk and increase thiocyanate levels which could serve to promote iodine deficiency and thyroid dysfunction in countries with marginal nutrition (Lamberg et al., 2004).

Increases in nicotine in breast milk have been associated with other effects in infants as well. Immediate increases of nicotine in breast milk within hours have been demonstrated to cause reduced sleep duration and quality compared to infants receiving breast milk from non-smoking mothers (Mennella et al., 2007). Breast milk changes from nicotine use are also suspected of causing increased rates of colic among infants of mothers smoking tobacco through mechanisms which augment motilin levels in the gastrointestinal system (Reinjneveld et al., 2000; Shenassa & Brown, 2004). Maternal smoking during breastfeeding thus reflects additional mechanism by which tobacco exposure can affect infant health.

Maternal smoking has been extensively studied by numerous researchers in relation to negative health effects on infants and children. The most common health effect conferred by tobacco exposure among infants involves respiratory illnesses. Cross-sectional studies examining infants at 6 months of age demonstrated maternal smoking increases the risk of lower respiratory infections 9.1-fold and the risk for upper

respiratory infections by 23-fold. In addition, maternal smoking increased otitis media rates by 9.4-fold (Yilmaz et al., 2009). Jones and colleagues found similar findings with maternal smoking having an odds ratio of 1.62 in causing otitis media in infants compared to non-smoking mothers based on a large systematic review of the literature (Jones et al., 2012). Haberg and others as part of the Norwegian Mother and Child Study involving 32,077 children found increased risk of otitis media among mothers who smoked tobacco compared to non-smoking mothers as well (Haberg et al., 2010).

Maternal smoking has been repeatedly linked to childhood asthma directly and indirectly. Maternal smoking increases asthma rates with a relative risk of 1.17 compared to non-smoking mothers, and it indirectly increases asthma rates at a relative risk of 4.16 by causing recurrent lower respiratory tract infections (Karmaus et al., 2008). Among the various effects on infant health attributed to maternal smoking, respiratory illnesses are among the best studied and supported by the literature. Otitis media is a common neonatal problem affecting many infants. Large studies have demonstrated that 70% of all children experience at least one bout of otitis media before the age of 2 years, and the peak incidence of the condition is between age 3 and 18 months (Paradise et al., 1997).

Therefore, the occurrence of otitis media reflect a condition which can be readily assessed in regards to its frequency. In relation to the development of otitis media, tobacco exposure has been identified as a risk factor. In one study involving 412 children, Csakanyi and colleagues assessed participants with a 22 item questionnaire (2012). Among these, 38% had parents who smoked tobacco. Multivariate logistic regression

analysis demonstrated that parental smoking more than doubled the risk for recurrent otitis media in these children (Csakanyi et al., 2012). In a much larger review involving 90,961 children, Hawkins and Berkman found that 26.2% of households used tobacco, and in children between the ages of 12 and 17 years, the risk of recurrent otitis media increased by a factor of 1.67 (2011). Thus the link between tobacco exposure in children and the development of otitis media has been well established.

The importance of tobacco smoking in causing otitis media has been quantified as fairly significant. Jensen and coworkers in a study examining 222 children ages 4 to 10 years found that both current and prior maternal smoking had a significantly higher risk for otitis media development than family history of otitis media or than having others who smoke in the house (2013). Likewise other studies have supported that reductions in otitis media occurrence in children between 1993 and 2006 coincided with reduced incidence of secondhand smoke exposure (Alpert et al., 2011). Yet while tobacco exposure has been liked to increased occurrence of otitis media, the distinction between this risk in mothers who breastfeed and the risk in mothers who don't has not been examined extensively based on literature review. Likewise, the relationship between maternal smoking and the risk of otitis media in infants under six months has not been examined either. Given this gap in the literature, the association of otitis media and tobacco exposure in all children, and the frequency of otitis media occurrence in general, this clinical condition can serve as beneficial dependent variable to assess the protective effects on breastfeeding on this specific population.

Maternal smoking has been linked to several other negative health effects in infants in children as well. With recent evidence supporting how environmental agents can affect metabolic programming through DNA methylation, histone acetylation, and interfering RNA expression, mechanisms by which tobacco can affect metabolic and endocrine functions have been postulated (Lisboa et al., 2011; Santos-Silva et al., 2011). A systematic review of animal epidemiological studies and experiments revealed rats exposed to tobacco during gestation and lactation have increases in serum letpin which in turn may promote insulin resistance, thyroid dysfunction and adrenal dysfunction (Lisboa et al., 2011). Increased rates of obesity have also been linked to maternal smoking. Toschke and colleagues performed a cross-sectional analysis of 4,974 children at ages between 5 and 6 years and correlated obesity to maternal smoking (Toschke et al., 2003). Their findings noted a statistically significant increase in obesity rates between non-smoking mothers (1.9 percent of children obese) and mothers who smoked throughout the prenatal period (5.9 percent of children obese) (Toschke et al., 2003). Wen and colleagues in examining historical data of 21,063 mother-child pairs as part of the U.S. Collaborative Perinatal Project found increasing dosages of tobacco use among postpartum mothers resulted in progressive rates of obesity in children at age 7 years (Wen et al., 2012). Other experimental studies have shown maternal smoking also has effects on cognitive performance among children later in life (Julvez et al., 2007). While respiratory effects may be the most common and best studied effects related to maternal

smoking, numerous other effects on health systems appears to be well supported in the literature.

Maternal smoking has also been examined in the literature in relation to the initiation and duration of breastfeeding performed by postpartum mothers. Notably breastfeeding provides health protections to infants in growth and development, immune function and other health capacities (Chantry et al., 2006). Therefore any deterrent to breastfeeding initiation and duration to the recommended first six months of infancy from maternal smoking represents additional health risks to a child (Pulley & Flanders-Stepans, 2002). The literature has supported a negative association between maternal smoking and breastfeeding for some time. In 1994, Ever-Hadani and coworkers reviewed hospital records in 8,486 mothers in Jerusalem and found maternal smoking resulted in a significant reduction of individuals choosing to start breastfeeding after delivery (Ever-Hadani et al., 1994).

Similarly a 12-month longitudinal study in Western Australia showed a decreased prevalence of breastfeeding among mothers who smoked tobacco compared to those who did not. The mean duration of both groups was 11 weeks and 28 weeks postpartum respectively (Giglia et al., 2006). A large cohort study in China showed maternal smoking significantly reduced breastfeeding after 3.5 months of infancy (Xu et al., 2010). As part of the Oregon Pregnancy Risk Assessment Monitoring System, maternal smoking in pregnancy and postpartum increased the risk of early weaning from breastfeeding (defined as less than 10 weeks) by 2.18-fold compared to non-smoking mothers (Liu et

al., 2006). And finally, the Missouri Pregnancy Related Assessment and Monitoring System conducting phone surveys of 1,789 mothers found both light and heavy tobacco smokers were less likely to initiate breastfeeding and more likely to wean from breastfeeding early compared to non-smokers (Weiser et al., 2005).

Maternal smoking combined with paternal smoking has an even greater deterrent effect on the initiation and continuation of breastfeeding (Napoli et al., 2007). Based on this large compilation of data, it appears maternal smoking not only has immediate negative health influences on infants and children but also affects other health promoting behaviors which may serve to offer protection.

Interestingly, several authors have taken a different perspective on the association between maternal smoking and breastfeeding. Instead of perceiving maternal smoking as a deterrent to breastfeeding initiation and continuation, several studies have suggested breastfeeding is a deterrent itself for maternal smoking (Higgins et al., 2010; Kendzor et al., 2010; Lauria et al., 2012). Kendzor and colleagues examined 251 postpartum women enrolled in a tobacco abstinence program and found 79.1% planned to breastfeed but only 40.2 percent still did so at 8 weeks postpartum (Kendzor et al., 2010). Subsequent analysis demonstrated that the presence of breastfeeding was strongly associated with tobacco abstinence in these women at 8 and 26 weeks postpartum (Kendzor et al., 2010).

In a larger prospective study involving 2,546 postpartum women, the prevalence and relapse rate of tobacco smoking was assessed in relation to breastfeeding. Though prevalence and relapse rates increased between birth and 6 months postpartum,

breastfeeding mothers had reduced prevalence and relapse rates overall compared to non-breastfeeding mothers (Lauria et al., 2012). Finally, Higgins and coworkers performed a randomized controlled experiment of 158 postpartum mothers who were incentivized to quit smoking and found tobacco cessation rates among those who breastfed were nearly double those who did not at 12 weeks postpartum (Higgins et al., 2010). Based on the literature, it is ambiguous whether maternal smoking deters breastfeeding alone, whether breastfeeding reduces maternal smoking rates, or whether both work in combination.

The literature does support that breastfeeding provides protection to infants in terms of the many conditions maternal smoking may cause particularly in respiratory infections risk and gastroenteritis (Kramer & Kakuma, 2012). Chantry and fellow researchers performed a cross-sectional survey of 2,277children between the ages of 6 and 24 months to examine the occurrence of pneumonia and recurrent otitis media (Chantry et al., 2006). When compared to mothers who breastfed only 4 to 6 months, mothers who breastfed for a full 6 months provided greater protection to their children from developing both pneumonia and otitis media (Chantry et al., 2006). Another study involving 4,089 Scandinavian infants showed exclusive breastfeeding reduced asthma rates, atopic dermatitis and allergic rhinitis compared to infants being bottle-fed (Kull et al., 2002). Another study involving 926 infants followed for 12 months demonstrated that exclusive breastfeeding for six months significantly reduced a variety of infections including acute respiratory infections, acute otitis media and oral thrush (Ladomenou et al., 2010). Yilmaz and colleagues in a cross-sectional study of 254 infants similarly

showed breastfeeding reduced lower respiratory infections 3.3-fold and upper respiratory infections (including otitis media) 5-fold (Yilmaz et al., 2009). Consistently research supports the benefits of exclusive breastfeeding for 6 months duration in promoting health among infants.

The literature was specifically searched for details regarding the degree by which breastfeeding attenuates the detrimental effects of maternal smoking among infants. Two studies in particular addressed this aspect of health promotion and protection. In one, 1,360 children born between 1989 and 1990 were followed prospectively in a longitudinal study for ten years. Three variables were examined in relation to the development of asthma which included maternal smoking during pregnancy, breastfeeding in excess of three months, and the presence of recurrent lower respiratory tract infections (Karmaus et al., 2008). Among the children followed, 25.3% had mothers who smoked during their pregnancy, 44.7% were breastfed in excess of three months, and 7.4% suffered recurrent lower respiratory tract infections. Though recurrent infections were the greatest predictor of the development of asthma, maternal smoking had a relative risk of 1.17 of increasing the presence of asthma while breastfeeding reduced asthma with a relative risk of 0.83 (Karmaus et al., 2008). The failure to delineate infants exclusively breastfed for 6 months limits the results of this study as does the lack of a control group. In a second study in Brazil, 268 children were followed through five years of age in a prospective cohort study examining the development of asthma and rhinitis (Guedes & Souza, 2009). The results demonstrated that exclusive breastfeeding for 6

months or more offered protective effects in developing these respiratory conditions with an overall odds ratio of 0.33 compared to an odds ratio of 2.5 for infants receiving less than 6 months of breastfeeding. More importantly, a logistic regression analysis showed controlling for maternal smoking further reduced the protection offered by breastfeeding to an odds ratio of 0.30 (Guedes & Souza, 2009). This study provided some measure of risk reduction for breastfeeding for asthma and rhinitis development in relation to maternal smoking, but only 35 children of the total 268 had mothers who smoked (Guedes & Souza, 2009). Overall these studies are limited in defining the degree of protection offered by breastfeeding in the presence of maternal smoking, and neither examines the effects in otitis media.

Risk factors for otitis media in infancy and childhood are multiple and include age, male sex, race, lower socioeconomic status, number of siblings, season of birth, daycare attendance and the presence of allergies (Ilia & Galanakis, 2012; Yilmaz et al., 2012). Genetics has also been found to influence otitis media (Hafren et al., 2012). However numerous authors have identified maternal smoking and tobacco exposure as also being a risk factor (Jones et al., 2012; Ladomenou et al., 2010; Yilmaz et al., 2012; Yilmaz et al., 2009). Likewise several studies support the protection of breastfeeding in deterring the development of otitis media (Chantry et al., 2006; Ladomenou et al., 2010; Yilmaz et al., 2012; Yilmaz et al., 2009). The key issue that has yet to be defined is the extent of risk of maternal smoking in causing otitis media in relation to the protection offered by breasting in the literature.

Otitis media represents an extremely common condition of infancy and childhood and is stated to be the most frequent disease of young children with a peak incidence between 6 and 18 months (Yilmaz et al., 2012). In a study examining 926 infant-mother pairs at 1, 3, 6, 9 and 12 month intervals during the infants' first year of life, 28.6% were found to suffer from otitis media at some point of observation (Ladomenou et al., 2010). Of the total number of children, 16.5% had single episodes of otitis media while 5.94% and 6.16% had two episodes and three or more episodes respectively (Ladomenou et al., 2010). Based on these figures, the ability to reduce the incidence of otitis through a better understanding of maternal smoking and breastfeeding effects offers significant promise in promoting greater infant health and reducing healthcare costs. Given the shortcomings in the literature pertaining to this subject, the current study hopes to contribute to the existing literature so greater public health promotion may occur.

In addition to promoting health and encouraging better health behaviors among individuals, the purpose of this study seeks to influence public policy as well. Since 2001, the AAP removed tobacco from the list of agents deemed to be contraindicated during breastfeeding (Pulley & Flanders-Stepans, 2002). The rationale of this decision reported by the AAP was to encourage discussions between mothers and providers about the benefits of breastfeeding even in the presence of maternal smoking since studies have demonstrated marked benefits for infants with breastfeeding (Lucero et al., 2009). However, since that time, additional negative effects of active tobacco exposure on children have been elucidated in the literature, and bans of tobacco use in many public

places, restaurants, and childcare settings have been established through legislation (Best, 2009; Jones et al., 2011). The literature currently supports that maternal smoking causes health risks among infants and children to a degree directionally proportional to use.

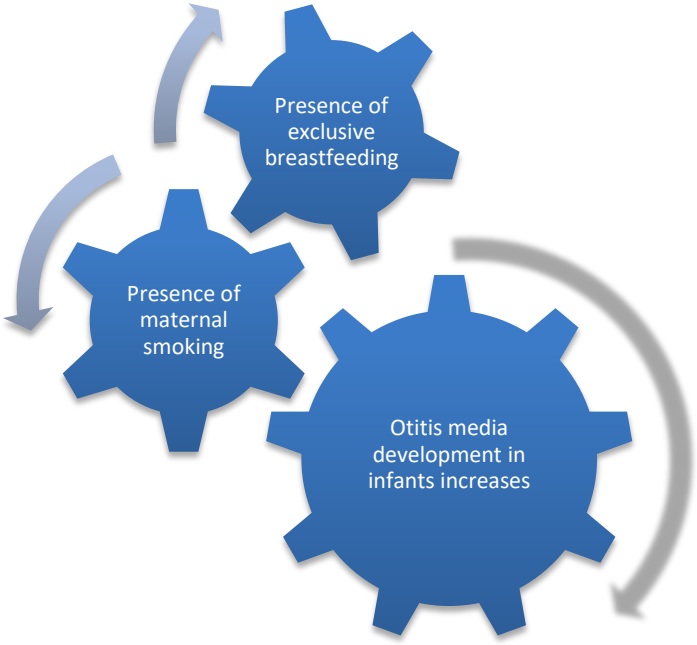

Figure 4: Positive and negative effects of study variables on otitis media

While breastfeeding has been shown to attenuate this risk, its degree of effect is unknown. The crux of this research investigation is to attempt to define the relationship between breastfeeding and maternal smoking. By comparing the occurrence of otitis media among infants of mothers who do and do not breastfeed in a population of maternal smokers, this attenuation effect can be better defined. Findings which reveal breastfeeding provides substantial attenuation effects will serve to strengthen public messages and policies which encourage breastfeeding. Likewise, demonstrating that this protective effect is inadequate through findings in the current study offers an opportunity

for professional organizations and public health agencies to reconsider their position on maternal smoking during breastfeeding and early infancy.

Summary and Conclusions

The literature concerning tobacco risks related to public health with specific attention to infants and children demonstrates many key concepts relevant to the current investigation. From a global health perspective, tobacco reflects a major environmental influence which serves to reduce health outcomes in multiple ways. Tobacco abstinence has been identified as the predominant behavioral outcome to eliminate this risk, but health promoting efforts have been complex and challenging in accomplishing this goal. As indicated by Social Cognitive Theory and the Health Promotion Model, individual characteristics, behavior specific cognitive and affective aspects, and actual behavioral feedback provide a bidirectional interaction resulting in complicated analyses (Hansen & Wambach, 2011). For this reason, additional information regarding specifics about tobacco-related health risks are sought so influences on this interactive set of personal and environmental dynamic may lead to more favorable health actions.

With this theoretical foundation and overall purpose in mind, the current study focuses on three key concepts in relation to tobacco exposure and health. These include maternal smoking postpartum, exclusive breastfeeding during infants' first 6 months of life, and the rate of development of otitis media during this period of time. Maternal smoking as defined in this study refers to any daily use of tobacco resulting from smoke inhalation. Though some of the literature has graded the dosage of tobacco use per day in

relation to outcomes, the current study will not make such a distinction as the majority of the literature uses a similar definition of maternal smoking as used here (Ever-Hadani et al., 1994; Giglia et al., 2006; Karmaus et al., 2008; Liu et al., 2006; Reinjneveld et al., 2000). Likewise, exclusive breastfeeding will refer to complete dependence on breastfeeding for infant nutrition during the first 6 months of life in accordance with AAP and WHO recommendations (Lucerno et al., 2009; and WHO, 2013). Finally, otitis media will be the dependent variable outcome and will be validated by physician verification and diagnosis. These concepts will be used for the current investigation to determine the degree of health protection that breastfeeding provides for infants in mothers who smoke tobacco.

The major themes identified in the literature review include support that maternal smoking in the postpartum period significantly increases infant risk for respiratory infections as well as for otitis media (Yilmaz et al., 2009). Likewise breastfeeding attenuates this risk to a degree when performed exclusively for the first 6 months of an infant's life (Yilmaz et al., 2009). However gaps in the literature fail to define precisely the degree of protection breastfeeding provides in this situation (Guedes & Souza, 2009). This lack of information is important due to current policies by professional agencies and health agencies which have removed tobacco from banned lists of substances to be used while breastfeeding. Evidence that breastfeeding protection is small in scale compared to maternal smoking risks has the potential to alter public policy and evoke behavioral change (Lucero et al., 2009; Pulley & Flanders-Stepans, 2002). The goal of this

investigation is to therefore provide additional information related to maternal smoking and infant health risks by better defining the degree of protection awarded by breastfeeding so educated decisions about behavior and policy can be made.

Chapter 3: Research Design and Methodology

Introduction

As is evident from the literature review, maternal smoking has been identified as a significant risk factor for infants during the first six months of life in terms of negative health effects. Negative health effects involve a variety of systems of which the respiratory system is most common (Karmaus et al., 2008). In addition, otitis media is a respiratory disorder which is common among all infants and has been shown to be more prevalent among infants whose mothers smoke tobacco (Yilmaz et al., 2012).

The literature also supported that exclusive breastfeeding during the first six months of infancy provides positive health effects and protections to infants. These protections include reduction in respiratory illnesses and infections based on prior research (Ladomenou et al., 2010). While these two findings have been well supported in various studies over the years, the interaction between maternal smoking risks and breastfeeding protections is not well defined. In other words, the degree of protection breastfeeding provides to infants in the setting of maternal smoking versus its protection in mother's who do not smoke tobacco is not well quantified (Yilmaz et al., 2009).

The degree to which breastfeeding attenuates the risk of otitis media among mothers who both breastfeed and smoke tobacco needs further examination and clarification. Comparing odds ratios of the development of otitis media between infants exposed to tobacco that breastfeed and those who do not breastfeed can provide insights into the degree of the protective effects breastfeeding provides. This information represents a gap in the current knowledge concerning maternal smoking and breastfeeding in relation to infant health. Further understanding and delineation of this information could have significant effects on social and health related behaviors and policies (Pulley & Flanders-Stepans, 2002).

The purpose of the current study was to examine the association between maternal smoking and otitis media in infants who are exclusively breastfed during their first six months of life. The occurrence of otitis media in breastfed infants of mothers who smoke tobacco will be compared to the occurrence of otitis media in infants whose mothers also breastfeed but do not smoke tobacco. By comparing these two groups of infants, an evaluation of the degree of protection breastfeeding provides infants exposed to maternal smoking can be determined, if any.

Depending on the results of this study, a potential to influence social and public health policy exists. Likewise, contributions to knowledge in the field of public health and infant health may encourage additional studies to advance understanding further. This study was a combined retrospective and prospective cohort study, which collected infant and maternal data from large pediatric clinics in Tallahassee, Florida. A

combination of sampling strategies were used including consecutive sampling of participants based on inclusion and exclusion criteria, convenience sampling in select larger clinics within Tallahassee, and purposive sampling in the selection of representative clinics within this city. Statistical analysis was performed to compare groups for incidence of otitis media in the setting. By collecting an adequate sample size of participants, measures to determine if statistical significance exists between these independent and dependent variables was possible. As a secondary evaluation, other variables such as socio-demographic information, relevant past medical history, relevant family history, birth history and the presence of secondhand smoke exposure was examined to further refine the statistical analysis and interpretation results.

In the subsequent sections of this chapter, specific details of the research design, methodology and validity threats were described. Explanations for the rationale for choosing these designs and methods as well as potential limitations and biases which may result were described. These discussions included explanations of how these limitations will be addressed. Finally, ethical procedures in handling the data and efforts to ensure ethical practices were summarized. Given the available time and other resources for this investigation, an understanding was able to be gained in relation to the design and methodology selection.

Research Design and Rationale

In determining the research design for the current investigation, several factors were considered. These included the availability of various resources, the ability to

identify causal relationships, ethical considerations and comprehensiveness of data. This information was combined with the purpose of the study in determining the optimal design with which to investigate the research questions posed. In each decision, the effort to maximize access to objective information while minimizing bias and subjective influence was attempted. Likewise, efforts to best clarify the relation between the independent and dependent variables were made through research design and subsequent analysis techniques (Polit & Beck, 2012).

Independent variables for the investigation included primarily the presence or absence of maternal smoking and breastfeeding during the first six months of infancy. Based on the literature review, this variable has a direct influence on otitis media occurrence which in the current study reflects the dependent variable (Haberg et al., 2010). However, the risk of otitis media in infants of mothers who smoke tobacco and breastfeed had not been defined. Breastfeeding has been shown to have direct protective effects in the development of otitis media in infants according to research (Ladomenou et al., 2010). Based on this established research data, all mother-infant dyads were required by inclusion criteria to have been exclusively breastfed during the first 6 months of the infant's life.

Other variables exerting a causal relationship to the development or prevention of otitis media also exist and have been demonstrated within the literature as well. For example, variables involving maternal age, socioeconomic class, maternal educational level, and the number of siblings affect occurrence of otitis media (Yilmaz et al., 2012).

Similarly, other health problems affecting the ears or respiratory system, family history of frequent otitis media, and birth complications may also represent covariate variables (Hafren et al., 2012; Ladomenou et al., 2010).

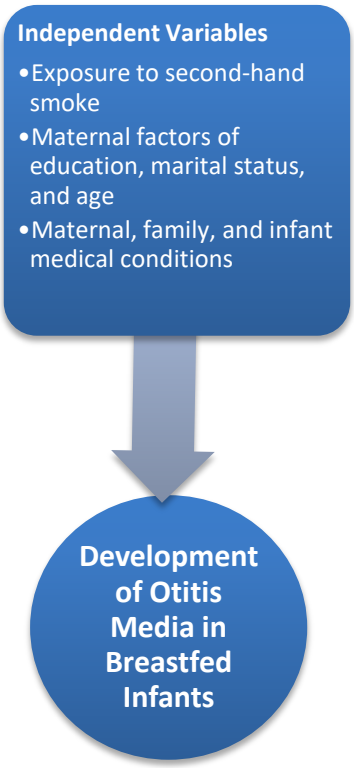

Figure 5: List of variables related to otitis media development

The primary research question in this investigation asked whether breastfed infants who are exposed to maternal smoking during the first six months of life are at a significantly higher risk for developing otitis media compared to infants whose mothers do not smoke tobacco.

A non-experimental, observational study was chosen allowing participant mothers to naturally choose to smoke or not to smoke tobacco. While natural differences existed between these two groups of mothers, which may influence the dependent variable, this design allowed a means to explore the possible difference between independent and dependent variables without violating professional ethics (Polit & Beck, 2012). The study design likewise is a combined retrospective and prospective cohort study which utilized existing retrospective data from clinical chart information as well as prospective data collected through a study survey tool.

In an effort to help facilitate the collection of data relevant to this study, clinics which participated in the study were provided a brief patient survey tool which was to be used during routine history taking procedures. This survey tool addressed primary variables, confounding variables and moderating variables thus enabling a more thorough perspective. However, the survey was not so intrusive as to disrupt normal clinical procedures for staff or pediatricians. This survey simply provided a means to collect primary data relevant to the study.

The availability of time and resources were also a factor in selecting the research design. By choosing a prospective cohort design, the opportunity to collect data during a single patient visit to pediatric clinics reduced the time involvement of researchers and the intrusion on sites of recurrent data collection. In addition, this design allowed collection of pertinent data without interrupting

natural choices between mothers and infants, health providers and patients, and normal operational workflows. Each of these reduced the amount of financial investments and time demands required in collecting study information by both researchers and pediatric clinic staff (Polit & Beck, 2012).

A retrospective analysis is helpful when a particular phenomenon is linked to a past phenomenon or set of phenomena (Polit & Beck, 2012). In this case, otitis media has been shown in the literature to be linked to past maternal smoking (Yilmaz et al., 2012). Despite the study design being prospective in nature, retrospective data concerning past infant and maternal histories by way of survey information will be included in the study. For example, maternal smoking as well as breastfeeding have been shown to affect the later development of otitis media negatively and positively respectively (Ladomenou et al., 2012; Yilmaz et al., 2012). Participants will therefore be screened retrospectively to determine whether or not mothers breastfed the first 6 months of life and whether they smoked tobacco. Selection of participants was based on the presence of breastfeeding since this is inclusion criteria; however, other information served as data collection resources only and not criteria for inclusion.

The prospective aspect of the study involved primary data collection from mother-infant dyads who received a diagnosis of otitis media. This aspect of the study ensured specific information could be obtained efficiently to enhance the quality of the study. Finally, a cohort study was relevant due to the comparison

between groups of breastfed infants whose mothers did and did not smoke. Because of these considerations, the mixed retrospective-prospective cohort research design chosen was felt to be ideal given the demands of the study as well as the resources available.

The study proposed to access infant and maternal health data in participating pediatric clinics in Tallahassee, Florida, to determine the occurrence of otitis media among infants during their first six months of life in relation to maternal smoking and exclusive breastfeeding. A prospective six month period of time was identified in which all infant visits (age six months or less) to the pediatric office coded as acute otitis media by International Classification of Disease (ICD) and/or Diagnostic Related Group (DRG) codes were selected for study screening. These identified patients were obtained through different clinics in Tallahassee, Florida, that agreed to provide data for the study through a formal consent and authorization process.

Participants were then screened for inclusion and exclusion criteria for sample selection by the researcher. An inclusion and exclusion checklist was provided to participants to facilitate identification process (See Appendix A). Of those who met study criteria for participation, the researcher then administered a brief study survey tool (See Appendix B) for additional information collection.

At the end of the 6 month period of data collection, total numbers of participants were tallied for both maternal smoking and non-smoking groups. An

assessment of adequate participation was then made to determine if statistical power relevance was met for both cohorts. If statistical power relevance had not been met, the time period was expanded to achieve adequate participant volumes. Once accomplished, data was then collected and analyzed for interpretation.

While the current research design has some limitations in absolutely delineating cause and effect between maternal smoking and breastfeeding on the one hand and otitis media occurrence on the other, ethical and resource limitations support this design as optimal in pursuing the study's intended purpose. Threats to validity were discussed in a subsequent section, but the ability to best define a causal difference between the variables in a meaningful, quantitative way can be readily accomplished within the constraints present. In doing so, the knowledge and information regarding the effects maternal smoking and breastfeeding have on the occurrence of otitis media will be expanded.

Methodology

In the subsequent sections, methodology involving population definitions, sampling procedures and procedures for recruitment, participation and data collection were described.

Population

For purposes of this study, the target population to which the data interpretation was applied included all infants less than 5 years of age who were exclusively breastfed during the first 6 months of life. The study sought to define

the relative risk maternal smoking imposes on this target population by comparing infants of mothers who do and do not smoke tobacco. The target population was narrowed further to reflect infants and mothers within the United States since social and public health policies which may be influenced by this study particularly affect the population within this culture and region. Since this target population is vast in scope in terms of size and characteristics, a sample population was sought to best represent this target population. An attempt to generalize the results to the target population was considered as part of the study's results and interpretations.

Sampling and Sampling Procedures

Having defined the target population, it was evident probability sampling is beyond the capacity of resources available for this study. As a result, a nonprobability sampling strategy was employed using a nonrandom means by which to recruit and select sample participants (Polit & Beck, 2012). While every potential element of the sample population did not have the opportunity for inclusion in the study, an effort was made to reduce sampling bias and to obtain a representative sample of the target population as best as possible. With this in mind, the sampling strategy used involved components of consecutive, convenience and purposive sampling strategies (See Figure 6).

In relation to selection of potential participants within pediatric clinics, a consecutive sampling strategy was utilized. Consecutive sampling allows

inclusion of all participants meeting sampling frame requirements during a particular time period. Thus any member of the target population suffering otitis media and meeting inclusion criteria was asked to participate in the study (Polit & Beck, 2012). Consecutive sampling can be used in both prospective and retrospective study designs. In this study, all infants with otitis media during their first six months of life were screened within the time frame considered in a prospective manner. Those that met inclusion and exclusion criteria were then be administered an additional survey tool for additional data collection. By choosing a six month window for prospective, consecutive sampling, seasonal variations of otitis media will be reduced as will population variations in characteristics. Among nonprobability sampling strategies, consecutive sampling in a prospective manner offers the best chance to reduce sample bias (Polit & Beck, 2012).

In addition to this sampling strategy, convenience sampling was also being used regarding geographic regions of sample consideration. Resource limitation prevented consecutive sampling throughout the nation or state, and therefore convenience sampling was limited to pediatric clinics within the city of Tallahassee, Florida. The convenience of these clinics in proximity allowed more efficient use of time and other resources (Polit & Beck, 2012). While regional bias may be present and affect generalizability of results to the target population, this sampling strategy was necessary in order to complete the task at hand.

While convenience sampling within local pediatric clinics was necessary, an attempt to attain a representative sample of the target population was pursued through purposive sampling techniques (Polit & Beck, 2012). Within convenient regions, pediatric clinics with socio-demographic profiles of patients reflective of state and national patterns were chosen. Large pediatric clinics as well as pediatric clinics in varying socioeconomic regions helped include potential participant's representative of the target population. This strategy was employed also to reduce sampling bias as possible (Polit & Beck, 2012).

Pediatric clinics in Tallahassee, Florida were selected based on the above sampling strategies described. Once these clinics were identified and agreed to provide patient records for the study, a six month time period was defined from which a sample was drawn. This reflected the convenience and purposive sampling strategies already described. All infants from birth to 6 months with a diagnosis of otitis media were included for initial screening. If these infants and their mothers met inclusion and exclusion criteria, they were enrolled into the study and given the data collection survey. This reflected the consecutive sampling strategy aspect of the study.

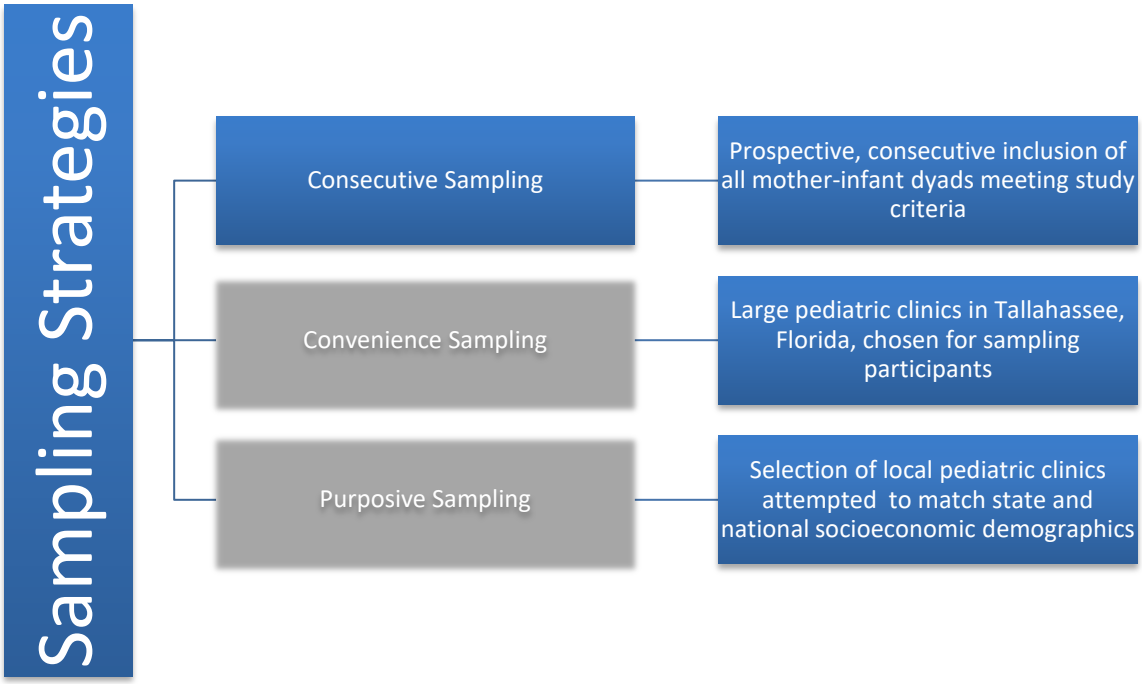

Figure 6: Components of sampling strategy

The sampling frame will be consisted of all infants diagnosed with acute otitis media who were less than 5 years of age and present to participating clinics during a defined six months period of time. The six month time period provided a large enough duration to avoid seasonal and sampling variations in the sample selected, and it allowed enough time for adequate numbers of participants to be included (Polit & Beck, 2012). Once these criteria were met, additional inclusion and exclusion criteria were considered.

Inclusion criteria required exclusive breastfeeding for the first 6 months of life. This permitted the allowance of solid food supplements after 4 months of

age. In addition, all participants had a chart available for review within the clinic chosen for the study. Exclusion criteria included part-time breastfeeding during the first six months of infancy or periodic supplementation of formula to breastfeeding. The resultant group of infants and their mothers comprised the sample selected for preliminary study. Infants with twins or multiples were not excluded from the study since neither the quantity of maternal smoking exposure nor the total quantity of breastfeeding volumes were being measured in this study. These participants were then administered the study survey tool which inquired about more detailed historical information relevant to the study (See Appendix B).

Figure 7: Screening and sampling process

Questions determined whether or not maternal smoking was present or absent; the number of prior otitis media occurrences; relevant past medical history concerning respiratory and ear-related problems; family history relevant to respiratory and ear-related problems; birth and delivery history; presence of other smokers in the household; the use of e-cigarettes; the presence of siblings, twins

or multiples; and socio-demographic information including maternal age, maternal education, maternal marital status, socioeconomic class, ethnicity, and gender. Each of these served as additional independent, covariate, modifying variables which were examined statistically during data interpretation.

The initial sample of participants was $N = 430$. A requirement of the mothers, the primary study participants, was that they consistently breastfed their infants for at least six months. A review of the data showed that 28 mothers reported not breastfeeding or inconsistently breastfeeding for six months. The 28 participants were removed from the data set. The final sample size was $N = 402$ mothers, 93.5% of the original sample. A *post hoc* power using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) for a logistic regression was conducted to determine the level of power achieved with a sample size of $N = 402$. The number of independent variables was set at eight. Power was set at .80. Significance was set at $p < .05$. Cohen's f^2 was set at .085 for a small to moderate effect. An expected odds ratio difference was set at a 1.50 representing a .60/.40 probability level and the mean and standard deviation of the distribution of scores for the predictor variables, set at M = 0 and SD = 1. Based on these parameters, the power achieved for this study was .94.

Based on epidemiological study, approximately two-thirds of all infants have at least one bout of otitis media by 12 months of age (Teele et al., 1989). Given this information, a minimum of 600 surveys would be required to identify 400 potential participants which equates to 100 surveys per month during the time

period allotted. Assuming some logistical shortcomings in clinic procedures, uneven distribution between maternal smokers and non-smokers, and other limitations of records and diagnosis coding, a target of 200 surveys per month among the different clinics chosen should provide adequate numbers for statistical significance and interpretation. The total sample considered was 402 infants, who were all breastfed for at least six months.

Procedures for Recruitment, Participation and Data Collection

The procedures involved in the recruitment process involved a series of steps. The initial recruitment procedure involved identification and selection of pediatric clinics within Tallahassee, Florida. Clinics were selected based on previously described sampling strategies, and then each was approached for recruitment. The purpose of the research study will be explained in detailed so that authorization from each clinic to utilize participant's health data may be gained.

The requirements of participation from each of the clinics included participation from clinical and possibly administrative staff in screening potential samples and administering the study survey tool to select mother-infant dyads. Therefore, some clinic resources were expanded in the process of their participation. Given this situation, non-monetary compensation in the way of unrelated clinic volunteer activities by the researcher was used to encourage clinic participation based on the expenditure of clinic resources required.

Given the information that was accessed from participating pediatric clinics involved private health information of infants and mothers, the authorization form for participation clarified the need to ensure anonymity of patient information (also known as individually identifiable health information, IIHI) (U.S. DHHS, 2013). The actual procedure by which this was achieved was managed by designated clinic staff. After all patient data had been obtained based on the sampling frame described, a clinic staff made a copy the summary chart data and study survey tool for the researchers omitting and/or eliminating all IIHI. This ensured HIPAA compliance in adhering to the Privacy Rule since none of the data being reviewed was linked to an actual participant identifier (U.S. DHHS, 2013).

In addition, clinic staff ensured a Health Insurance Portability and Accountability Act (HIPAA) consent form was signed in the charts provided by the mother of the infants enrolled. Only those aspects of the chart relevant to the noted variables of this study needed to be provided which may have eased the burden on pediatric clinic staff. Alternatively, clinic staff may have also chosen to transfer chart information to an anonymous data collection sheet if this is less burdensome.

The data collection required the following information to be provided anonymously to the researcher concerning mother-infant dyads screened for the study: total number of infants less than age 5 years with acute otitis media during

prospective data collection; all completed inclusion and exclusion criteria checklist sheets; and all study survey tools for those meeting study criteria. This served as the primary research data for the study.

The actual recruitment procedure involved a signed authorization and informed consent form administered to the participating clinic and provided to the researcher acknowledging the purpose of the study. This also identified the researchers participating receiving clinic data, the specific information being sought within the data provided, and the anticipated responsibilities of both the clinic and the researchers (Polit & Beck, 2012). In addition, the detail of the time period for data collection was defined. Once the authorization form was signed by the clinic, data collection began at the designated time period through study completion. Any difficulties experienced in complying with the participation agreement and data collection procedures were communicated with an attempt to resolve issues so the completion of study may proceed.

Exit strategies for the participating pediatric clinics to terminate their participation in the study occurred after all data has been collected for the defined time period of the study, researcher examined the data and determined that adequate infant-mother dyads meeting sampling frame requirements are present to achieve statistical power of analysis.

Upon conclusion of the data collection process, a formal conclusion letter was provided to each participating clinic thanking them for their role in the study.

Feedback was elicited at that time so that any unidentified shortcomings, difficulties or opportunities for improvement may be appreciated. This information was useful in relation to data analysis and interpretation, results interpretation, conclusions and in future studies.

Upon completion of data collection, statistical analysis was performed between the two groups of participants relative to their number of diagnoses of otitis media. Statistical analysis included adjustments for the other variables listed as well. Using the sampling method described, 402 participants were expected to be enrolled. The initial sample of participants was $N = 430$. A requirement of the mothers, the primary study participants, was that they consistently breastfed their infants for at least six months. A review of the data showed that 28 mothers reported not breastfeeding or inconsistently breastfeeding for six months. The 28 participants were removed from the data set. The final sample size was $N = 402$ mothers, 93.5% of the original sample.

A *post hoc* power using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) for a logistic regression was conducted to determine the level of power achieved with a sample size of $N = 402$. The number of independent variables was set at eight. Power was set at .80. Significance was set at $p < .05$. Cohen's f^2 was set at .085 for a small to moderate effect. An expected odds ratio difference was set at a 1.50 representing a .60/.40 probability level and the mean and standard deviation of the distribution of scores for the predictor variables, set at M = 0 and SD = 1. Based on these parameters, the power achieved for this study was .94.

Data Analysis

One binary logistic regression was conducted to answer the eight research questions posited in the study. The overall model results are first presented, followed by results for each research question. Each dichotomous variable was coded where 0 = no and 1 = yes, and the dependent variable was coded as 0 = no, no incidence of otitis media and 1 = yes, at least one incidence of otitis media. It should be noted that an odds ratio of 1.00 indicates that the respective independent variable did not significantly affect the odds of the outcome of otitis media incidence (Szumilas, 2010). Therefore, if the 95% confidence interval (CI) for the odds ratio contains 1.00, the results are considered non-significant even if the Wald χ^2 value is significant at $p < .05$ (Szumilas, 2010).

Threats to Validity

The current study inferred a causal relationship between the negative effects maternal smoking on developing otitis media, despite breastfeeding protection. The degree of validity with which this inference can be made was maximized through considering potential threats to validity which could undermine the study's results and generalizability (Polit & Beck, 2012). These potential threats will be reviewed here.

External Validity

External validity pertains to the ability to generalize the results found in this study to the target population. Through purposive and consecutive sampling strategies, accurate representation of the target population was attempted in the

study sample. Likewise, through the use of multiple clinic sites for data collection, replication of results can be demonstrated adding further to external validity and the ability to expand the application of the study's findings to the target population (Polit & Beck, 2012). Despite these efforts, some persistent threats to external validity persisted.

The most notable external threat involved the interaction between the causal relationship of the variables and the individual participants (Polit & Beck, 2012). By comparing maternal smokers to maternal non-smokers, the primary relationship between smoking and otitis media occurrence is assumed, but other variables have been noted as being potentially involved. These variables will be reviewed and statistically controlled to help define the primary causal relationship. However other unknown differences between maternal smokers and non-smokers may exist which influence the development of otitis media and are not available for analysis.

The study only included mothers who exclusively breastfeed their infants for the first six months of life. The ability to generalize this information to all mothers is limited since inherent differences between mothers who choose to breastfeed and those who do not may exist and affect otitis media occurrence as well. Therefore, the study sought to limit its application to mothers exclusively breastfeeding. While this narrows the overall target population to which the study results apply, inferences may still be considered regarding the effects on maternal

smoking and otitis media occurrence on all infants which may result in additional study in the future.

Individual characteristics not reviewed in the data evaluation which also may have affected external validity may involve the failure to adequately select participants who lack health insurance. Similarly, individuals who are non-compliant with pediatrician visits and who prefer to self-diagnose and treat would be preferentially omitted from the study. These aspects could affect the degree of generalizability of the study results to the target population (Polit & Beck, 2012). Unfortunately, the ability to identify this population is difficult, and resources are too limited to pursue efforts in this direction. This specific population is believed to be a small percentage of the target population since infant health coverage has been shown to cover 93% of children (Bloom et al., 2011). However this remains a noteworthy consideration for other future studies.

Other external influences may include geographic factors since all participants will reside within Tallahassee, Florida. While socio-demographic features of participants will be included in data analysis, this geographic restriction could limit generalizability of results to other regions of the state or nation (Polit & Beck, 2012). Resource restriction however limits the ability to expand recruitment to other regions.

The other consideration affecting external validity involves treatment variations which may occur among pediatricians and clinics in treating otitis

media (Polit & Beck, 2012). For example, different medications and treatment regimens utilized could affect otitis media recurrence rates. As a result, this could arbitrarily affect occurrence rates among participants outside the causal relationship being studied between maternal smoking, breastfeeding and otitis media. Standards among professional pediatric organizations in the treatment of otitis media have resulted in the majority of infants being treated similarly with minor variations (Hoberman et al., 2011). The usefulness of examining this variance is therefore deemed unnecessary.

Internal Validity

The primary threat to internal validity involves the selection of participants and their characteristics. By allowing the selection of participants to occur naturally between maternal smoking and non-smoking groups, inherent characteristics may exist that could affect the ability to infer a clear relationship between maternal smoking, breastfeeding and the occurrence of otitis media (Polit & Beck, 2012). Inherent differences among mothers and infants could affect the development of otitis media in each of these groups separately beyond the causal relationship inferred with maternal smoking. While this remains a threat to internal validity, an attempt to control several of these potential covariate and moderating variables as defined in the literature will be attempted. In turn, this should minimize these internal validity threats. Other common internal validity threats such as temporal ambiguity, history, maturation, mortality and

instrumentation issues are not relative to this natural selection and prospective study design (Polit & Beck, 2012).

Construct Validity

Construct validity pertains to the ability of constructs developed within the study to represent concepts and specifics accurately and with precision (Polit & Beck, 2012). Threats to construct validity in the current study are relatively few, but they deserve mentioning because of the methodology adopted. The dependent variable of otitis media as a construct has been represented in this study as a physician/pediatrician diagnosis of acute otitis media as defined by medical coding (ICD or DRG coding). Issues could interfere with the ability of this construct to accurately identify participants with otitis media for a couple of reasons. First, a medical code of acute otitis media could be assigned to a patient visit due to the lack of another more precise diagnostic code. Secondly, an omission of a medical code for acute otitis media could occur even when present if other more acute or serious conditions are coded only. In the first instance, an over-representation of otitis media occurrences would result while the opposite would occur in the second scenario.

Another threat to construct validity may occur due to documentation errors or omissions. In completing the inclusion and exclusion checklist and the study survey tool, clinical and administrative staff errors may be made. While actual definitions of these infant-mother characteristics are well accepted, the construct

representing these definitions is subject to documentation limitations at times. Misinterpretation of the study instrument questions could thus reflect another opportunity for interpretation and documentation errors. Therefore this represents a second threat to construct validity.

Both of these threats to construct validity will be assessed and managed by document review by researchers. One purpose of the study survey tool is to aid in the identification of other variables influencing the cause and effect relationship between the independent and dependent variables. However the study survey tool also allows greater clarification of participant characteristics which reduce errors related to omissions and documentation errors otherwise.

Patients with otitis media whose charts lack medical coding will notably be absent for review. However in all probability, the omission likely reflects other more serious health problems which would potentially reflect covariate variables. This belief in addition to the presumed small number of situations reflective of this validity threat renders this concern small.

Instrument Validity

The Study Survey Tool (Appendix B) utilized for this study was self constructed based on literature review concerning risk factors associated with the development of otitis media within infants as well as in relation to the dependent, independent, moderating and confounding variables identified as part of this study. The instrument therefore does not have prior use in other studies, and the

ability to compare this instrument to other measures is difficult offering an inability to explore criterion-related validity. However the validity of the instrument can be supported based on face validity, content validity, and to a lesser extent constructs validity (Polit & Beck, 2012).

In regards to face validity, the study survey tool was constructed based on expert statements and opinions in the literature regarding target constructs related to infant development of otitis media. This also relates to content validity since efforts were made to include only relevant items within the instrument which were appropriate to the construct of otitis media (Polit & Beck, 2012). Likewise an effort was made to include all dimensions of the construct within the survey itself. Noted dimensions of otitis media include infant characteristics, maternal characteristics and environmental characteristics (Donaldson, 2014; Landomenou et al., 2010; Yilmaz et al., 2012). Infant characteristics include prior respiratory infections, ear infections, allergies, cranial anomalies, birth difficulties, and reflux disease as well as family history of ear pathologies and infections. Maternal characteristics associated with otitis media in an infant are tobacco use, level of education, age, and socioeconomic status. Lastly environmental characteristics associated with otitis media in infants include household occupancy number, volume of tobacco smoke, and secondhand smoke exposure (Donaldson, 2014; Landomenou et al., 2010; Yilmaz et al., 2012). By identifying these dimensions of otitis media development in infants, and by including survey questions identifying

these dimensions, the face and content validity of the instrument is well supported.

In considering construct validity, the concern exists that the instrument is measuring the exact concept it is intended to measure (Polit & Beck, 2012). In the current situation, the concept of otitis media on a spectrum of abstract to concrete exists more on the concrete side. Logical analysis involves a factor analysis of the different dimensions of this concept, and like content analysis, the literature and expert opinions support a defined set of risk factors related to these dimensions (Donaldson, 2014; Landomenou et al., 2010; Yilmaz et al., 2012). Again these components are all represented in the survey tool, and the lack of abstractness did not require further conceptual analysis. Known group administration of the survey tool would have been performed if available participants were present; however this opportunity was not present. Regardless, the relatively well-defined concept of otitis media, and the alignment of the study survey tool questions with all the dimensions of this concept, support adequate construct validity for use of this instrument (Polit & Beck, 2012).

Statistical Conclusion Validity

Based on the extensive literature review, existing statistical conclusion validity has been well established between maternal smoking and the development of otitis media. Several studies have noted a higher relative risk among infants whose mother smoke tobacco postpartum compared to those who

do not smoke (Haberg et al., 2010; Yilmaz et al., 2010; Yilmaz et al., 2012). Likewise the literature supports a reduced risk of upper respiratory infections in infants who breastfeed exclusively for the first 6 months of life (Ladomenou et al. 2010; Yilmaz et al., 2010). In the current study, the same statistical conclusion validity exists between maternal smoking, breastfeeding and the occurrence of otitis media in infants. This does not assume other variables do not influence this relationship; however efforts to identify known risks factors related to otitis media development in infants will be pursued through primary survey instruments. Likewise these variables will be assessed statistically in relation to the study participants in order to control their influence on results and interpretations.

Based on other existing studies, known variables accepted as influential in the occurrence of otitis media other than maternal smoking and breastfeeding include male gender, cranial deformities, congenital ear deformities, family history of otitis media, increased number of siblings, other respiratory problems, and allergies (Hafren et al., 2012; Ladomenou et al., 2010; Yilmaz et al., 2012). The study design has been developed so that these variables can be assessed statistically in relation to the primary independent variables. As a result, this will enhance the statistical conclusion validity of the study's results.

Ethical Procedures

In accordance with ethical standards and legal policies, the patient and clinic data and information will be accessed and handled with the utmost respect

and care. In an effort to avoid any potential violations of the Privacy Rule under the Health Insurance Portability and Accountability Act (HIPAA), all patient information and data will be received in a completely anonymous manner (U.S. DHHS, 2013). Clinic staff will either eliminate all patient identifiers in copied materials meeting initial inclusion criteria to prevent any links to actual participants, or a transfer of non-identifying data from participants will be recorded on an anonymous data sheet.

In either case, individually identifiable health information will be absent thus avoiding the need for direct patient consent under HIPAA rules (U.S. DHHS, 2013). Should any violation of anonymity occur, the specific patient data in question will not be included in analysis and review, and the information will be handled with professional confidentiality in accordance with HIPAA policies and the pediatric clinic policies. In addition, a notation in the results section of the study will be made to highlight any potential effects this may have on the validity of the results.

Despite these precautions in relation to participant privacy, an authorization informed consent form will be provided and signed by all participating clinics detailing the purpose of the study, the researchers involved, participant data requested, and other details of methodology. During the course of the study, all data received will be handled and maintained in a locked environment preventing unauthorized access. Only researchers will be allowed to

access the information during this time. Once the data has been collected, analyzed and interpreted, the data will be discarded to prevent unauthorized access unless legal requirements demand otherwise.

Summary and Conclusion

In summary, the current study will be performed using a combined prospective-retrospective, non-experimental cohort design to examine the effect maternal smoking has on the occurrence of otitis media among infants exclusively breastfed during their first six months of life. Sampling measures will include convenience sampling to recruit pediatric clinics in Tallahassee, Florida, while purposive sampling will narrow down clinic choices in these regions to best approximate a representative sample of the target population of breastfed infants in the U.S. Likewise consecutive sampling will be allowed to reduce sampling bias by collecting all participants meeting inclusion and exclusion criteria with a given time period.

Based on literature review and statistical power analysis, a six month period will be chosen in which all infants less than 5 years of age diagnosed with otitis media will be considered. This time period should provide adequate numbers for study even after inclusion and exclusion criteria are met. In addition to the independent and dependent variables of maternal smoking, breastfeeding and otitis media, other covariate and moderating variables will be examined through survey instruments so a more accurate causal relationship can be

determined among the primary relationships. These other variables will involve socio-demographic information, number of siblings, past medical history, family history, birth history, maternal characteristics and exposure to other secondhand smoke. Statistical analysis will allow these other variables to be controlled thus enabling the primary study end relationships to be better assessed.

A variety of validity threats exist and will be reduced as best as possible to allow a clear assessment of the cause and effect relationships between maternal smoking, exclusive breastfeeding and otitis media occurrence to be realized. Research design and sampling strategies seek to allow optimal generalizability given the resources available. Likewise constructs will be monitored as well as potential biases to ensure greater precision of definitions, quantitative measurements and data interpretations. While all threats to validity cannot be eliminated, the degree of validity of the study will be maximized within the constraints present. In addition, the research design will utilize existing resources within pediatric clinics to collect data from the sample in an anonymous fashion so privacy rule violations will not be an issue. While authorization and informed consent forms regarding the study's purpose and details will be obtained from each participating clinic, anonymity of data and a lack of intervention avoid the need to obtain individual patient, parental or guardian consent.

Based on this methodology and design, the subsequent chapter will discuss data collection, statistical analysis and interpretation of results. Specific

details of quantitative data obtained from each of the participant clinics will be reported highlighting the important results associated with the primary research questions presented. Likewise a description of statistical measures used and their results will be presented with a concomitant summary of the study's findings.

Chapter 4: Results

Introduction

Maternal tobacco smoking is a significant risk factor for infants during the first six months of life in terms of negative health effects, with disorders of the respiratory system being the most common (Karmaus et al., 2008). Otitis media, a respiratory disorder which frequently occurs in infants, is more prevalent among infants whose mothers smoke tobacco (Yilmaz et al., 2012). Breastfeeding during the first six months of infants' life may impart protective factors for infants of mothers who smoke tobacco (Karmaus et al., 2008). The primary purpose of this study, in which all mothers breastfed their infants for at least six months, was to examine if the incidence of otitis media was more common among infants of mothers who smoked cigarettes in comparison to mothers who did not. The study furthermore examined otitis media incidence among infants who differed with regard to (a) exposure to second-hand smoke, (b) maternal factors of education, marital status, and age, and (c) maternal, family, and infant medical conditions.

The purpose of this chapter is to provide the results of the study. The chapter opens with a summary of the data collection process and continues with a description of the study sample. The assumptions of logistic regression, the statistical analysis used in hypothesis testing, are presented. The results of the logistic regression are then discussed. The chapter ends with a summary.

Data Collection

This quantitative study, which utilized a causal comparative research design, was conducted between March 2015 and September 2015. Data were collected from mothers attending large pediatric clinics in Tallahassee, Florida. A combination of sampling strategies were utilized, including consecutive sampling of participants based on inclusion and exclusion criteria, convenience sampling in selecting larger clinics within Tallahassee, and purposive sampling in the selection of representative clinics within this city. Data collection included past medical history and family history in addition to other information needed based on the survey questionnaire of the mother and infant.

Descriptive Statistics: Study Participants

The initial sample of participants was $N = 430$. A requirement of the mothers, the primary study participants, was that they consistently breastfed their infants for at least six months. A review of the data showed that 28 mothers reported not breastfeeding or inconsistently breastfeeding for six months. The 28 participants were removed from the data set. The final sample size was $N = 402$ mothers, 93.5% of the original sample. A

post hoc power using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) for a logistic regression was conducted to determine the level of power achieved with a sample size of $N = 402$. The number of independent variables was set at eight. Power was set at .80. Significance was set at $p < .05$. Cohen's f^2 was set at .085 for a small to moderate effect. An expected odds ratio difference was set at a 1.50 representing a .60/.40 probability level and the mean and standard deviation of the distribution of scores for the predictor variables, set at M = 0 and SD = 1. Based on these parameters, the power achieved for this study was .94.

The mean age of the participants was 28.56 years ($SD = 6.74$), with ages ranging from 18 to 43 years. Mothers were asked the number of persons in the household. The mean number of household members was 4.18 ($SD = 1.78$), with the number of household members ranging from 2 to 11. Information on categorical descriptive information for the study participants is presented in Table 1. The majority of participants ($n = 233$, 58.0%) were single whereas almost a third ($n = 112$, 27.8%) were married; substantially fewer participants were separated or divorced ($n = 57$, 14.2%). Almost one-half ($n = 182$, 45.3%) of participants had a four-year college degree, while almost a third ($n = 110$, 27.4%) of participants were high school graduates. Additional information on the education level of participants is presented in Table 1. Almost one-half ($n = 196$, 48.8%) of the study participants did not provide information on their annual household income. Of the remaining participants, the largest number ($n = 64$,

15.9%) reported an annual household income of less than $15,000. Additional information on annual household income is presented in Table 1.

Table 1

Descriptive Statistics: Study Participants (N = 402)

	Frequency	*Percentage*
Marital Status		
Single	233	58.0
Separated/Divorced	57	14.2
Married	112	27.8
Highest Level of Education		
Less than a high school degree	18	4.5
High school degree	110	27.4
4-year college degree	182	45.3
More than a 4-year college degree	92	22.9
Annual Household Income		
Less than $15,000	64	15.9
$15,000-$25,000	57	14.2
$25,001-$40,000	48	11.9
$40,001-$100,000	24	6.0
Greater than $100,000	13	3.2
Missing	196	48.8

Participants were asked questions about their cigarette smoking, with results presented in Table 2. Of the 402 participants, 205 (51.0%) did not smoke and 197 (49.0%) did smoke cigarettes. Of the participants who did smoke cigarettes, the number of cigarettes smoked per day was relatively low (see Table 2). The majority of

participants (*n* = 296, 73.6%) reported residing in a smoke-free household. Please see Table 2 for additional information about household smoking.

Table 2

Descriptive Statistics: Cigarette Smoking Variables

	Frequency	*Percentage*
Smoke Cigarettes		
No	205	51.0
Yes	197	49.0
Number of Cigarettes Smoked per Day		
None (Non-smoker)	205	51.0
Not Daily	37	9.2
Less than 5	45	11.2
5-10	74	18.4
11-20	30	7.5
More than 20	11	2.7
Number of Other Smokers in Household		
0	296	73.6
1	81	20.1
2	18	4.5
3	6	1.5
4	1	0.3
Exposure to Second Hand Smoke		
No	296	73.6
Yes	106	26.4

The last set of variables concerned mother, family, and infant medical conditions, with results presented in Table 3. Mothers were asked if their infants had cranio-auditory medical conditions, and 180 (44.8% of) mothers reported that their infants did not while 222 (55.2% of) mothers reported that their infants did have these medical conditions. With regard to family history of medical conditions, 284 (70.6% of) mothers reported having while 118 (29.4% of) mothers reported not having a family history of medical conditions. Finally, two hundred and thirty (57.2% of) mothers reported having while 172 (42.8% of) mothers reported not having birth difficulties.

Table 3

Descriptive Statistics: Mother, Family, and Infant Medical Conditions Variables

	Frequency	*Percentage*
Infant had Cranio-Auditory Medical Conditions		
No	180	44.8
Yes	222	55.2
Family History of Medical Conditions		
No	284	70.6
Yes	118	29.4
Mother had Birth Difficulties		
No	230	57.2
Yes	172	42.8

Testing of Assumptions for Logistic Regression

As with any inferential statistics, logistic regression has assumptions that must be met (Hosmer, Lemeshow, & Sturdivant, 2013). One assumption is that any interval or ratio-coded independent variables show normality in the distribution of scores (Hosmer et

al., 2013). Normality can be determined by the $z_{skewness}$ value, which is the skewness value divided by the skewness standard error (Ghasemi & Zahediasl, 2012). With sample sizes of over 300, a $z_{skewness}$ value that is less than 3.28 indicates that the variable shows relative normality (Ghasemi & Zahediasl, 2012). Age was the only ratio variable that was an independent variable. The $z_{skewness}$ value of the age variable was 2.55, lower than the critical value of 3.28, thus indicating that the assumption of normality was met.

Another assumption is that the independent variables do not show multicollinearity (Hosmer et al., 2013). Lack of multicollinearity can be determined by correlation coefficients less than $r = .90$, $p < .001$ (Garg & Tai, 2013). Spearman's rho correlations were conducted with all of the independent variables and are presented in Table 4. The Spearman's rho correlation analysis is the non-parametric equivalent to Pearson bivariate correlation analysis and is conducted when the variables to be correlated are a combination of categorical (dichotomous), ordinal, linear, or ratio variables (Neuhäuser, 2011). As seen in Table 4, some significant correlations did emerge, but not at the level of multicollinearity. As such, the assumption of lack of multicollinearity was met.

Table 4

Spearman's Rho Correlations: Study Independent Variables

	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*
Maternal Cigarette Smoking	1.00							
2. Infant Second Hand Smoke	`.11*	1.00						
3. Maternal Education	-.08	-.00	1.00					
4. Maternal Marital Status	.00	-.06	.27***	1.00				
5. Maternal Age	-.12*	-.20***	.32***	.65***	1.00			

6. Maternal Birth Difficulties	.18***	.02	.02	.03	.03	1.00		
7. Infant Cranio-Auditory Cond.	.22***	.18***	.13*	.04	.06	.04	1.00	
8. Family Medical History	.09	.02	.18***	.04	.12*	.07	.27***	1.00

Note. Maternal cigarette smoking coded as 0 = no, 1 = yes; infant exposure to second-hand smoke coded as 0 = no, 1 = yes; maternal education status coded as 0 = high school degree, 1 = four-year degree or higher; maternal marital status coded as 0 = single, 1 = not single; maternal birth conditions coded as 0 = no, 1 = yes; infant cranio-auditory conditions coded as 0 = no, 1 = yes; and family medical history coded as 0 = no, 1 = yes

Hypothesis Testing: Results from Logistic Regression

One binary logistic regression was conducted to answer the eight research questions posited in the study. The overall model results are first presented, followed by results for each research question. Each dichotomous variable was coded where 0 = no and 1 = yes, and the dependent variable was coded as 0 = no, no incidence of otitis media and 1 = yes, at least one incidence of otitis media. It should be noted that an odds ratio of 1.00 indicates that the respective independent variable did not significantly affect the odds of the outcome of otitis media incidence (Szumilas, 2010). Therefore, if the 95% confidence interval (CI) for the odds ratio contains 1.00, the results are considered non-significant even if the Wald χ^2 value is significant at $p < .05$ (Szumilas, 2010).

Results from the logistic regression are presented in Table 5. The omnibus chi-square was significant, $\chi^2(8) = 55.57$, $p < 0.001$. The non-significance of the Hosmer and Lemeshow chi-square test confirmed that the model was a good fit to the data, $\chi^2(8) = 6.08$, $p = .638$. Results from the classification table showed that 72.6% of the infant otitis media incidence was correctly classified into its respective category based on the predictor variables. The Cox and Snell R^2 was .13 and the Nagelkerke R^2 for this model was .19, which indicated a medium size.

Table 5

Binary Logistic Regression: Predictors of Otitis Media Incidence (N = 402)

Predictors	*B*	*SE*	*Wald* χ^2	*Df*	*P*	*Odds Ratio*	*95% CI for Odds Ratio*	
							Lower	*Upper*
Maternal Smoking	-.42	.25	2.78	1	.095	0.66	0.40	1.08
Infant Exposure SH Smoke	.05	.28	0.03	1	.875	1.05	0.60	1.82
Maternal Education	*.65*	*.28*	*5.54*	*1*	*.019*	*1.92*	*1.12*	*3.31*
Maternal Marital Status	.21	.31	0.43	1	.513	1.23	0.66	2.27
Maternal Age	.05	.02	4.34	1	.037	1.05	1.00	1.10
Maternal Birth Difficulties	-.32	.25	1.58	1	.209	0.73	0.45	1.19
Infant Cranio-Auditory Conditions	-1.18	.26	20.99	1	<.001	0.31	0.19	0.51
Family History of Conditions	-.74	.31	5.86	1	.015	0.48	0.26	0.87

Research Question 1: The first research question inquired as to whether there was a significant difference in otitis media incidence in breastfed infants during the first six months of life whose mothers are or are not tobacco smokers. Results from the logistic regression showed that maternal tobacco smoking did not significantly predict otitis media incidence in breastfed infants, Wald $\chi^2(1) = 2.78$, $p = .095$. Based on the lack of significant results, the null hypothesis was retained for the first research question.

Research Question 2: The second research question asked whether infants who were breastfed and exposed to secondhand smoke were at significantly higher risk for developing otitis media. Results from the logistic regression showed that infant exposure to second-hand smoke did not significantly predict otitis media incidence in breastfed infants, Wald $\chi^2(1) = 0.03$, $p = .875$. Based on the lack of significant results, the null hypothesis was retained for the second research question.

Research Question 3: The third research question inquired as to whether infants who were breastfed from mothers with lower education were at significantly higher risk for developing otitis media. Results from the logistic regression lower education of mothers did significantly predict otitis media incidence in breastfed infants, Wald $\chi^2(1) = 5.54$, $p = .019$. Mothers with a high school degree were almost two times (odds ratio = 1.92, 95% CI = 1.12 to 3.31) more likely to have infants with otitis media than were mothers with a four-year college degree or higher. Based on the significant results, the null hypothesis was rejected for the third research question.

Research Question 4: The fourth research question asked if infants who were breastfed and had single mothers were at a significantly higher risk for developing otitis media. Results from the logistic regression showed that single motherhood did not significantly predict otitis media incidence in breastfed

infants, Wald $\chi^2(1) = 0.43$, $p = .513$. Based on the lack of significant results, the null hypothesis was retained for the fourth research question.

Research Question 5: The fifth research question concerned whether infants who were breastfed and who had younger mothers were at a significantly higher risk for developing otitis media compared to older mothers. While the Wald χ^2 was significant, Wald $\chi^2(1) = 4.34$, $p = .037$, the 95% odds ratio contained 1.00, thereby negating the significance of this predictor. Based on the lack of significant results, the null hypothesis was retained for the fifth research question.

Research Question 6: The sixth research question inquired as to whether breastfed infants whose mothers had difficulties during delivery were at a significantly higher risk for developing otitis media. Results from the logistic regression showed that maternal difficulties during delivery did not significantly predict otitis media incidence in breastfed infants, Wald $\chi^2(1) = 1.58$, $p = .209$. Based on the lack of significant results, the null hypothesis was retained for the sixth research question.

Research Question 7: The seventh research question asked if breastfed infants who had pre-existing cranio-auditory medical conditions were at a significantly higher risk for developing otitis media. Results from the logistic regression showed that pre-existing cranio-auditory medical conditions did significantly predict increased otitis media incidence in breastfed infants, Wald

$\chi^2(1) = 20.99$, $p < .001$. Infants who *did not* have pre-existing cranio-auditory medical conditions were 69% (odds ratio = 0.31, 95% CI = 0.19 to 0.51) *less likely* to have otitis media than were infants with pre-existing cranio-auditory medical conditions.

Research Question 8: The eighth and last research question queried if breastfed infants who had a family history of auditory, immunologic, and/or cranial disorders were at a significantly higher risk for developing otitis media. Results from the logistic regression showed that family history of auditory, immunologic, and/or cranial disorders did significantly predict otitis media incidence in breastfed infants, Wald $\chi^2(1) = 5.86$ $p = .015$. Infants who *did not* have a family history of auditory, immunologic, and/or cranial disorders were 52% (odds ratio = 0.31, 95% CI = 0.19 to 0.51) *less likely* to have otitis media than were infants who did have such a family history.

Summary

The primary purpose of this study, conducted with 402 mothers who had breastfed their infants for at least six months, was to examine if the incidence of otitis media significantly differed between breastfed infants of mothers who smoked cigarettes and mothers who did not smoke cigarettes. Results from the logistic regression showed that the incidence of otitis media did not significantly differ between mothers who did and did not smoke cigarettes. The lack of

significance suggests that breastfeeding may have protected the infants against the harmful effects of maternal cigarette smoking.

Other factors did however emerge as significant, influencing the incidence rate of otitis media in infants. Mothers with a high school degree were almost two times more likely to have infants with otitis media than were mothers with a four-year college degree or higher. Infants with pre-existing cranio-auditory medical conditions were more likely to have otitis media than were infants that did not have these conditions. Moreover, a family history of auditory, immunologic, and/or cranial disorders placed infants at risk for otitis media. These results and the study overall are discussed in chapter 5.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

Breastfeeding for infants age 6 months and younger is generally accepted as a recommended practice among mothers and is advocated by the American Association of Pediatrics (AAP) (Chantry et al., 2006). In addition, research has also supported a relationship between maternal tobacco use and an increased risk of developing otitis media among infants (Csakanyi et al., 2012; Jensen et al., 2013). Even exposure to secondhand smoke has been positively linked to higher rates of otitis media among infants (Alpert et al., 2011; Brooks et al., 2011). Given these literature findings, the question naturally arises as to whether breastfeeding may offer protections to infants exposed to maternal or secondhand tobacco use. Some researchers have demonstrated

breastfeeding does offer such protections in infants in relation to lower respiratory tract infections (Karmaus et al., 2008). Also, research supports breastfeeding as reducing overall risk for developing upper respiratory infection in general for infants (Yilmaz et al., 2012). But what remains unclear is the degree of risk tobacco exposure presents for the development of otitis media in infants and the degree of protection breastfeeding offers in this setting.

With these questions in mind, the purpose of the current study was to evaluate the incidence of otitis media among exclusively breastfed infants who were either exposed or not exposed to maternal tobacco use during their first 6 months of life. Primary outcome measures thus evaluated the occurrence of otitis media during infants' first 6 months in both groups. In addition, because other variables have been associated with heightened risk of otitis media among infants, secondary outcomes were examined in relation to otitis media risk and secondhand smoke, maternal education, maternal age, maternal marital status, maternal birth problems, preexisting infant cranial-auditory-immunologic problems, and family history of cranial-auditory-immunologic problems. These secondary measures were important in providing additional data sources as well as allowing better isolated assessments of breastfeeding benefits and maternal smoking risks. As a result, the study sought to help fill current literature gaps regarding these areas of interest.

With these goals in mind, retrospective and prospective assessments were collected in an observational cohort study using self-reporting survey tools to obtain

primary and secondary measures. Likewise, sample enrollment utilized a combination of consecutive, convenience and purposive sampling techniques due to resource limitations while still trying to minimize bias and select a representative sample of the study population. Socio-demographic data and otitis media diagnostic data were then collected and analyzed through logistic regression statistical analysis with subsequent reporting and tabulations. Overall, a total of 402 maternal-infant dyads were enrolled who met inclusion and exclusion criteria and successfully completed the study.

As a summation of these analysis results, no statistically significant difference was noted in the occurrence of otitis media among exclusively breastfed infants who were or were not exposed to maternal smoking. In addition, no statistically significant difference was noted in most secondary measures between the two dyad cohorts as it pertained to secondhand smoke, marital status, marital age, or maternal birth problems. Interestingly, however, higher rates of otitis media among breastfed infants were associated with lower maternal education levels, the presence of preexisting infant cranial-auditory-immunologic conditions, and the presence of a family history of these same conditions. In an effort to better understand these results, an interpretive discussion will follow as well as a discussion concerning the limitations, implications and future research recommendations related to this study.

Interpretation of Findings

In summarizing the results of this study, the key finding failed to demonstrate an association between maternal smoking and increased otitis media occurrence among

exclusively breastfed infants in the first 6 months of life when compared to exclusively breastfed infants who were not exposed to maternal smoking. In comparing this finding to the literature, several comments are worth making. As noted, breastfeeding has been identified as a protective factor in deterring the development of both upper and lower respiratory tract infections in infants (Karmaus et al., 2008; Kull et al., 2002; Yilmaz et al., 2012). At the same time, maternal tobacco use has been found to be associated with higher otitis media rates among infants (Csakanyi et al., 2012; Jensen et al., 2013; Yilmaz et al., 2012). With this in mind, the current study sought to try and clarify the degree with which breastfeeding might protect infants against otitis media development in the setting of maternal smoking.

The failure of the current study to show any difference among the two cohort groups could thus suggest a number of possibilities. First, the degree of protection breastfeeding provides infants against otitis may far outweigh the risks imposed by maternal tobacco use. Some authors have suggested breastfeeding could offer such profound protections through maternal antibody transfer, direct antimicrobial effects, and positive immune-modulatory effects (Chantry et al., 2006). Alternatively, another possibility exists where the degree of maternal tobacco exposure was not significant enough to yield negative effects. Indeed, approximately 79 percent of the women who identified themselves as tobacco users used a half-pack of cigarettes per day or less. If higher amounts of tobacco use are required to pose a significant risk for otitis media

development, then the results may have failed to show an accurate depiction of overall risk.

Given these considerations, research has suggested maternal tobacco use increases the risk of infant upper respiratory infection by 23-fold, yet breastfeeding only provides a 5-fold level of protection (Yilmaz et al., 2012). Given the fact 197 women were included in the tobacco use cohort in this study; an increase risk for otitis media among this cohort's infants would have been expected based on prior research. This leads to the consideration that the risk for other upper respiratory infections (other than otitis media) for infants with exposure to maternal smoking is even more significant than previously thought. However, since other types of upper respiratory infections were not assessed in this study, this conclusion cannot be made at this time.

In regards to secondary measures evaluated, secondhand smoke deserves notable commentary. Prior research has supported than reductions in secondhand smoke exposure among infants has been associated with reductions in otitis media occurrence (Alpert et al., 2011). Likewise, otitis media has been found more frequently when secondhand smoke is present (Brooks et al., 2011). In this study, differences between the two cohorts were not seen in otitis media occurrence and secondhand smoke exposure. Again, this may suggest breastfeeding offers significant protection against otitis media for infants exposed to secondhand smoke. Alternatively, the degree of exposure to secondhand smoke in the cohorts examined may have been inadequate to demonstrate a positive correlation effect. Indeed, only 26.4 percent of the sample described any degree of

secondhand smoke exposure, and three-quarters of these dyads stated only one person in the household used tobacco. Therefore, it remains difficult to determine definitively the extent with which breastfeeding may be protective in this setting and the amount of secondhand smoke exposure which may be needed to increase otitis media risk.

The other secondary measures reported in this study were not inconsistent with prior literature findings. Notably, research has shown that otitis media occurs more frequently among infants whose mothers have lower educational levels, younger maternal age and lower socioeconomic conditions (Yilmaz et al., 2012). Likewise, literature has supported associations between higher otitis media rates and preexisting craniofacial conditions, a family history of otitis media, and a history of birth complications (Hafren et al., 2012). Therefore, the findings in this study which show heightened risk of otitis media in mothers with lower education levels, infants with cranial-auditory-immunologic disorders, and infants with family histories of these conditions is not surprising. It is noteworthy however the degree of risk imparted to these variables. Specifically, infants of mothers with high school education or less were twice as likely to suffer otitis media when compared to infants of college education mothers or higher. Likewise, preexisting histories or family histories of cranial-auditory-immunologic conditions increased risk of otitis media by 69 percent and 52 percent respectively. As a result, this study does help quantify the risk of these variables in the sample selected.

In contrast to the literature, no significant correlation was noted between otitis media risk and maternal age or prior infant birth difficulties. These findings occurred

despite having adequate numbers of participant mothers who described prior birth difficulties (42.8 percent), and despite having a good age range among maternal participant demographics (ages 18 to 43 years). In considering these findings, the variability and complex nature of birth difficulties may account for this study's results since specifics regarding the types of birth difficulties were not explored. And maternal age may represent a relatively weak risk factor when considered separate from other factors (like maternal education) which may not have been revealed in the current study and sample size.

In alignment with the theoretical framework of this study, issues surrounding breastfeeding, maternal tobacco use, and the other secondary variables described with the occurrence of infant otitis media deserve holistic considerations. Pender's Health Promotion Model embraces such complex interactions in an effort to better understand causation and risk. Through identifying such interactions, knowledge can then be used to affect behaviors and environments in promoting better health and preventing illness (Pender, 2012). As it pertains to this study specifically, findings continue to support a protective effect of breastfeeding on infant health which should be encouraged. Likewise, encouragement of higher educational attainment by mothers and heightened awareness of otitis media risk in the setting of preexisting conditions and family histories are also supported by this study. And while the results fail to clearly identify the degree of risk from maternal tobacco use and secondhand smoke exposure, advice against these

behaviors should continued to be advocated based in existing research evidence until future research offers greater clarification.

Limitations of the Study

In evaluating this study, limitations do exist which need to be considered. Despite large cohort groups evaluated, external validity threats may exist in relation to sampling techniques and inclusion criteria. First, while consecutive sampling was utilized, convenience sampling as well as purposeful sampling reflects a nonrandom approach to participant selection. These methodologies, despite efforts to enroll a sample representative of the national population, could affect the ability to generalize the findings of this study. In addition, by choosing only mothers who exclusively breastfeed, biases may be interjected related to infant care beliefs in general. These likewise could affect occurrence of otitis media among infants and hinder generalizability. Regardless, the large sample size and statistical power indices still support serious considerations of the findings.

Other limitations could also involve internal and construct validity of the results. Research has demonstrated that the risk of otitis media is higher among mothers of low socioeconomic status (Yilmaz et al., 2012). While this data was collected, it was not included in the statistical analysis. Therefore, income levels of maternal participants could have affected the presence (or absence) of statistical significance of the results. Other potential problems may have been the presence of normal variance in anatomical structures which might lead to more frequent otitis media occurrences. Since formal

examinations were not conducted, this could have affected results as well. By relying on diagnostic codes and diagnoses through chart review and self-reports, these variations could have accounted for higher otitis media rates in either group. While each of these are worthy considerations in regards to study limitations, the sample size and power index of the study, however, makes it less likely such factors would have affected the overall results and analysis.

The final limitation of the study relates to the low amount of tobacco use per day among the maternal tobacco use cohort. This as well as the low percentage of secondhand smoke exposure households could have potentially masked a significant effect on otitis media occurrence. This would be particularly true if higher exposure amounts are required to affect otitis media risk, which could be the case among an exclusively breastfed infant population receiving protective health effects. These considerations are noteworthy when planning future research studies and evaluations.

Recommendations for Future Study

Given literature review findings, and given the results of this current study, future research could build further on existing findings related to otitis media risks and protections among infants. The association with both maternal tobacco use and secondhand smoke exposure with otitis media in infants has been established (Alpert et al., 2011; Brooks et al., 2011; Jensen et al., 2013). Likewise, protection from developing otitis media through breastfeeding has similarly been supported in prior studies (Chantry et al., 2006). However, what remains to be defined is the degree with which these

variables affect otitis media occurrence. In the present study, no differences were found between maternal tobacco use and non-tobacco use cohort in relation to otitis media occurrence, and limitations have been noted which could account for these findings, or lack thereof. Therefore, future research considerations should attempt to expand on this research effort to define these persistent research questions.

Specifically, future research should examine the quantity of maternal tobacco use and secondhand smoke exposure when assessing the risk of developing otitis media risk among infants who are exclusively breastfed. This would help provide a spectrum of exposure which would allow better quantification of risk as well as levels of protection breastfeeding offers. Unfortunately, the current study did not permit enrollment of such participants, and therefore, even larger sample sizes may be needed to examine these questions further.

In addition, it was also noted that sample selection of mothers who breastfeed could bias results as well. Because of this, an observational study involving four cohort groups (breastfeeding mothers who do and do not smoke as well as non-breastfeeding mothers who do and do not smoke along with their infants) could be devised to better clarify the actual degree of protection breastfeeding provides as well as the actual risk tobacco exposure poses to infants in relation to otitis media. Such a study design would allow less bias while also permitting greater consecutive participant enrollment in the sample to be study. Both would be advantageous in clarifying the current research questions.

Finally, while examining the array of other variables related to otitis media risk in infants is beneficial, a detailed analysis of these variables is not necessary. The association of otitis media among infants with low maternal education, preexisting related medical conditions, and family history of related medical conditions is supported by the present study. Likewise, maternal birth problems have already been identified in other research work (Hafren et al., 2012). However, demographic data collection should be collected in all of these areas to allow comparison among cohort groups to ensure each group is comparable to one another socio-demographically and historically. Controlling for variances in these areas is recommended, but detailed analysis of these specific risks for otitis media among infants is not required.

Implications of Findings

Based on the findings of this study, and based on the theoretical framework guiding this research, individual, community, and societal level implications exist for positive social change. Specifically, the results support individual behavioral change to be encouraged in regards to educational attainment among mothers of infants as this is associated with lower risk of otitis media. Likewise, community outreach programs and educational policies at local, state and federal levels would favor better infant health in this specific area of wellness.

In addition, the presence of preexisting cranial-auditory-immunologic conditions among infants should provoke greater awareness of the risk for otitis media among parents, healthcare providers and other healthcare workers. The same can be said for

infants with family histories of such conditions. With knowledge of this association, efforts can be better utilized to target disease prevention in this population.

While the study failed to provide details of the degree of risk maternal tobacco use and/or secondhand tobacco exposure in relation to otitis media occurrence, the literature reviews within this study support continued health promotion and disease prevention efforts through tobacco abstinence (Jensen et al., 2013). This naturally affects individuals, and particularly parents, but likewise, it also has implications in terms of policy formation and advocacy at community, organizational, and societal levels.

Lastly, the protective effect of breastfeeding in deterring the occurrence of otitis media among infants is neither validated nor disproven. Literature continues to support a positive association between breastfeeding and better infant health as well as reduced otitis media incidence (Chantry et al., 2006). In an effort to encourage breastfeeding, organizations and government agencies have eliminated tobacco as a banned agent during pregnancy (Pulley & Flanders-Stepans, 2002). However, other research shows that tobacco use reduces both the incidence and duration of breastfeeding among women with their children (Ever-Hadani et al., 1994; Liu et al., 2006; Weiser et al., 2009). Unfortunately, this study fails to guide these policies effectively at this time, and future research should specifically address these issues since results have the potential for significant implications in policy and advocacy stances.

Conclusions

Evidenced-based research has consistently supported the protective benefits of breastfeeding in relation to respiratory infections, and likewise, maternal smoking and secondhand smoke exposures have been noted to heighten the risk of such conditions. Despite this evidence, however, the degree that breastfeeding protects infants and that maternal tobacco use increases risk has yet to be determined. As a result, health organizations have adopted policies which have removed tobacco as a banned substance for women who are breastfeeding in order to encourage breastfeeding behaviors overall. Unfortunately, evidence also supports that maternal tobacco use reduces both the likelihood and the duration with which breastfeeding will occur. In an effort to clarify these issues, and thus better guide health policies and individual behaviors, this study sought to assess the degree with which breastfeeding protects infants from otitis media when exposed to maternal smoking in comparison to infants not exposed.

The results of this study failed to show any significant difference between the two cohorts described, and an additional variable of secondhand smoke exposure similarly failed to show significant differences between the groups as well. These findings could indicate a powerful protective effect of breastfeeding against otitis media since all infants of both cohorts were exclusively breastfed, or the results could reflect a lack of adequate tobacco-related exposure to demonstrate risk. Likewise, potential sampling errors and selection biases may have influenced results as well. With this in mind, additional studies to further clarify these issues are needed. Specifically, assessment of higher tobacco-

related exposures during infancy in relation to otitis media occurrence, and an evaluation of tobacco-related otitis media risk in both breastfed and non-breastfed infants, may be considered.

While the study did not show significance in relation to tobacco-related exposures among infants in association with otitis media, the study did confirm, as indicated in the literature, an association between low maternal education, preexisting infant cranial-auditory-immunologic disorders, and family history of such disorders as risks for otitis media in this group. Therefore, continued advocacy and policies encouraging higher maternal education attainment and a heightened level of concern or infants with such histories are supported. Likewise, literature review highlights the need to advocate tobacco abstinence among mothers and breastfeeding as disease preventing and health promoting activities. Until additional studies clarify these issues further, these recommendations should remain in place.

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Appendix A

Inclusion-Exclusion Checklist for Maternal Smoking/Breastfeeding/Otitis Media Study

(All responses must be circled for study participation)

Patient Identifier #

_____

Clinic Identifier #

_____

Inclusion Criteria

1. Is infant less than 5 years of age? No/ Yes
2. Does infant have diagnosis of acute otitis media? No/ Yes
3. Has infant been exclusively breastfed through first 6 months of life? No/ Yes (solid foods permitted after 4 months of age)

Exclusion Criteria

1. Does infant receive formula supplementation? No/ Yes
2. Does infant receive cow's milk or goat's milk supplementation? No/ Yes
3. Does infant receive any other nutrition besides vitamins, minerals, water? No/ Yes

Study Participation Eligibility

__ If all answers above are circled, the inclusion criteria are met. Please continue to Page2.

__ If all answers above are not circled, please Stop Here, as not all inclusion criteria are met.

Appendix B

Study Survey Tool for Maternal Smoking/Breastfeeding/Otitis Media Study

Patient Identifier # _____

Clinic Identifier # _____

Questions concerning mother:

1. Mother's current age:
   _____
2. Mother's highest level of education

☐ <high school ☐ high school ☐ college ☐>college

3. Mother's marital status

☐ single ☐ separated ☐ divorced ☐married

4. No. of people living in household
   _____
5. Average annual household income
   _____
6. Does the mother smoke tobacco? ☐ yes ☐no
7. If yes, how many cigarettes a day does the mother smoke?

☐ <5 cigarettes ☐ 5-10 ☐ 10-20 ☐>20 ☐Not daily

8. How many other people in household smoke tobacco?
   _____
9. Did the mother exclusively breastfeed the infants for up to 6 months ☐ yes ☐no
10. Other information:
    _____

Questions concerning infant:

1. How many times has the infant had otitis media prior?
   _____
2. Please mark all the following medical illnesses/conditions the infant has experienced since birth:

☐ respiratory infection ☐ head injury ☐ ear surgery ☐allergies

☐ reflux disease ☐ colic ☐ cranial anomaly ☐pharyngitis

3. Did the infant experience any of the following birth difficulties?

☐ premature delivery ☐ C-section ☐ failure to thrive ☐birth trauma

4. Is there a family history of the following conditions?

☐ ear infections ☐ early hearing loss ☐immune d/o ☐cranial anomalies

5. Other information: _____