Pediatric bronchiolitis is an acute, highly-communicable, viral-mediated lower respiratory tract illness of early childhood. As the most common lower respiratory illness in infants, bronchiolitis represents the leading cause of infant hospitalizations worldwide (McNaughten, Hart, & Shields, 2017). Considerable controversies persist for clinicians who care for these children resulting in practice variation. Bronchiolitis places a considerable demand on healthcare resources, including $1.73 billion dollars for US hospitalizations from 2000-2009 (Hasegawa, Tsugawa, Brown, Mansbach, & Camargo, 2013), 238 outpatient visits, 71 hospitalizations, and 77 emergency department (ED) visits per 1000 infant years (Carroll et al., 2008). In 2014, the American Academy of Pediatrics published a clinical practice guideline (Ralston et al. 2014) which proposed substantial changes, including recommendations against routine use of inhaled bronchodilators or oral steroids. Following publication, there has been limited research examining the clinical and financial outcomes for children treated for bronchiolitis in the outpatient setting.

A descriptive, retrospective cohort analysis was done to indirectly examine the effects of clinician adherence to the 2014 AAP Guideline by examining the comparative effectiveness of the use of albuterol, oral steroids, symptomatic home management, and/or complementary therapies for children who had clinically diagnosed bronchiolitis and who were treated in the outpatient setting. Comparative effectiveness was ascertained by the analysis of relevant clinical
outcomes data from the year prior to the publication of the 2014 *Guideline* and for four years after. Outcome variables in the outpatient setting were compared to determine clinical effectiveness of the use of albuterol, oral steroids, symptomatic home management, and complementary therapies for the treatment of pediatric bronchiolitis. There was no statistically significant difference in ED, urgent care visits, or numbers of hospitalizations for children treated with albuterol. There was a statistically significant increase in outpatient visits in the group who had been treated with albuterol, which may be reflective of either the severity of the bronchiolitis illness or the increased vigilance of the clinician following the prescribing of albuterol. The use of an oral steroid was associated with higher hospitalization rate in this study but this data is likely confounded by the small sample size.
Dedication

This scholarly paper is dedicated to my husband Vinnie. Your unwavering and steadfast love, support, and encouragement were my lighthouse when I needed comfort, guidance, and direction on this journey. Luke, Holly, Brianne, Mike, Bailey, Tommy, Evan, and Lisa; I cannot thank you enough for your constant cheerleading and encouragement. Many times you had to wait for me, postpone things for me, and change plans for me and I am so blessed by your immense love and support. Thank you Fiona and Maura. Your unconditional love and hugs kept me smiling when I wanted to cry and strong when I needed strength. I am also eternally grateful to my siblings who never once doubted that I would complete this journey and their love was instrumental in my efforts to keep going! To my family at FPA, especially Tricia, I owe you a debt of gratitude for your support, encouragement, and your willingness to make this project a success. To my cohort at Georgetown University; you are my strong, brilliant, determined inspirations! Finally, and most importantly, I dedicate this work to my parents who sparked my passion for lifelong learning and endless curiosity. Mom and Dad, although your journey on this Earth ended, your legacy for learning continues and I am forever thankful for you.
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Chapter I - Introduction

Pediatric bronchiolitis is an acute, highly-communicable, viral-mediated lower respiratory tract illness of early childhood. Diagnosed clinically, bronchiolitis is the most common lower respiratory tract illness in infants and represents the leading cause of hospitalization of infants worldwide (McNaughten, Hart, & Shields, 2017). Infants and children with bronchiolitis may experience a range of symptoms, however the classic initial presentation of pediatric bronchiolitis includes symptoms of upper respiratory tract infection such as nasal congestion and fever which then progresses to lower respiratory tract involvement characterized by cough, wheezing, rales, tachypnea, or increased work of breathing (Florin, Plint, & Zorc, 2017; Ralston et al., 2014). Dehydration often occurs in infants with bronchiolitis as a result of paroxysms of coughing, post-tussive emesis, and poor oral intake due to the child’s respiratory distress and lethargy (Bower & McBride, 2015). For some infants and children, early mild clinical symptoms may advance to worsening respiratory distress, apnea, and death from lower airway obstruction (Ralston et al., 2014). Clinically, the hallmark of pediatric bronchiolitis is the rapid variability of the child’s signs, which can confound the clinician’s assessment and management of this common viral illness.

Representing a significant public health burden, bronchiolitis has been the target of much clinical interest and research efforts. Described in the literature as acute catarrhal bronchitis, wheezy bronchitis, asthmatic bronchiolitis, and interstitial bronchopneumonia, bronchiolitis as an illness entity continues to confuse clinicians and cause controversy regarding management. Although several viruses cause bronchiolitis, respiratory syncytial virus (RSV) is the most common viral organism accounting for more than 60% of all acute respiratory tract infections in children and for more than 80% of lower respiratory tract infections in infants younger than one
year of age (Piedimonte & Perez, 2014). Utilizing data culled from the 2002 Health Care Utilization Project-National Inpatient sample, it was estimated that annually, 149,000 children are hospitalized for bronchiolitis (Pelletier, Mansbach, & Camargo, 2006). Additionally, for children less than two years of age, bronchiolitis hospitalization accounted for 18.8% of all hospital admissions in this age group (Hasegawa, Tsugawa, Brown, Mansbach, & Camargo, 2013). These hospitalizations are associated with significant financial burden. From 2000-2009, the total hospital charges for bronchiolitis hospitalizations were estimated to be $1.73 billion dollars in the US (Hasegawa, Tsugawa, Brown, Mansbach, & Camargo, 2013).

Worldwide, there are numerous clinical guidelines for the management of infants with bronchiolitis, regardless of the viral etiology (Baraldi et al., 2014; Friedman, Rieder, & Walton, 2014; "NICE guideline," 2015). However, the numerous definitions of bronchiolitis varies among these international clinical guidelines which only adds to clinician diagnostic and treatment variability regarding guideline recommendations (Drysdale, Green, & Sande, 2016). Consequently, many bronchiolitis management decisions are made subjectively by clinicians and it is this subjectivity which leads to significant practice variation among hospitals and clinicians who care for children with bronchiolitis (Luo, Nkoy, Gesteland, & Glasgow, 2014). This variability of the definition, diagnosis, and management of pediatric bronchiolitis may be affecting the clinical outcomes of the children affected by this common viral illness.

This chapter will explore the phenomenon of pediatric bronchiolitis, as well as the extensive financial, clinical, and social burdens of this childhood illness. The concept of clinician adherence to the 2014 Clinical Practice Guideline on the Diagnosis, Management and Prevention of Bronchiolitis (Ralston et al. 2014) (hereafter referred to in this paper as the "Guideline") will be presented. This concept of clinician adherence and its potential effects on
the clinical outcomes and quality of care for infants and children ages one through 23 months of age will be posited. Finally, an organizational needs assessment and evidence-based theoretical framework will be utilized to clarify and highlight the challenges faced by clinicians experiencing the variance in clinical practice following the issuance of the 2014 Guideline. This clinical variance in practice and the subsequent clinical outcomes in infants and children forms the foundation for this research.

**Background**

In 2014, the American Academy of Pediatrics, a large well-respected organization of over 64,000 pediatricians, published the *Clinical Practice Guideline on the Diagnosis, Management and Prevention of Bronchiolitis* (Ralston et al. 2014). Founded in 1935 by 35 pediatricians, the American Academy of Pediatrics (AAP) maintains an important national and international role in guiding the clinical decision-making of pediatric providers. Dedicated to health quality improvement efforts, the AAP cites its quality mission as ensuring “every child gets the right care every time” (American Academy of Pediatrics, 2017, para. 3). Reflecting a “less is more” approach to medical interventions, the 2014 Guideline offered 14 key action statements (KAS) which provided clinical guidance on a breadth of topics including the diagnosis, management, and prevention of bronchiolitis. These KAS were “premised on an underlying belief that because bronchiolitis is a short-lived generally non-fatal disease, treatment cannot offer long-term benefit, and that most treatment should therefore be avoided” (Walsh & Rothenberg, 2015, p. 5). However, the 2014 Guideline advocated several clinical recommendations for which there is evidence of inconsistent adherence in both the primary care setting and the emergency department setting (Levine, 2015; Walsh & Rothenberg, 2015).
Key Action Statements

Of the 14 KAS recommended in the 2014 clinical practice Guideline, 10 of the 14 recommendations focused on tests or treatments to avoid (Quinonez & Schroeder, 2015). The use of bronchodilator medications such as albuterol or salmeterol was included in the “to be avoided” category and was explicated in KAS #2 (Ralston et al., 2014). Ralston and colleagues (2014) acknowledged that although some studies had evaluated the use of bronchodilator medications for viral bronchiolitis, several randomized controlled studies had failed to demonstrate consistent benefit from such agents (Gadomski & Scribani, 2014). Indeed, a 2014 Cochrane Collaboration systematic review examined 30 studies that assessed bronchodilator use in pediatric bronchiolitis (Gadomski & Scribani, 2014). According to the Cochrane review, the use of bronchodilators did not change the outcomes for infants admitted to the hospital. Additionally, for those children who were managed in the outpatient setting, bronchodilators did not significantly improve oxygen saturation, hospital admission rates, or the time to resolution of symptoms (Flores & Horwitz, 1997; Kellner, Ohlsson, Gadomski, & Wang, 1996).

While Ralston and his colleagues acknowledged that several meta-analyses and systematic reviews have shown that bronchodilators may improve clinical symptom scores for children with bronchiolitis, the authors cautioned the reader that such symptom scores may vary from one observer to another and for this reason, clinical scores were not considered valid measures of clinical efficacy of bronchodilators. Moreover, Ralston et al. asserted that there was no well-established way to truly determine an objective method of response to bronchodilators and the evidence did not support the benefit of such use.

In the 2014 Guideline, KAS #5 was aimed at the clinician’s use of systemic corticosteroids in infants and children with bronchiolitis. This KAS specifically stated that
clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting (Ralston et al., 2014). Citing a comprehensive systematic review and large multicenter randomized trials (Alansari et al., 2013; Schuh et al., 2002), the authors maintained that corticosteroids alone do not provide significant benefit to children with bronchiolitis. Additionally, Ralston et al. (2014) maintained that the most recent Cochrane systematic review (Fernandes et al., 2013) suggested that corticosteroids do not reduce outpatient admissions when they are compared to placebo. The authors clarified that although there is no evidence of short term adverse effects from corticosteroid therapy other than prolonged viral shedding, there was inadequate evidence to be certain of safety in infants and children with bronchiolitis (Ralston et al., 2014).

In spite of the abundance of evidence used to support the 2014 bronchiolitis Guideline, it is evident that as a collective entity, many pediatric clinicians are choosing to adhere to only some of the fourteen action key action statements while directly eschewing others. Quinonez and Schroeder (2015) examined the medical community’s response to the 2014 Clinical Practice Guideline on the Diagnosis, Management, and Prevention of Bronchiolitis and hinted that the “identification and correction of physiologic abnormalities is ingrained in medical culture and has been pervasive in the management of bronchiolitis” (p. 794). Gadomski and Scribani (2014) summarized the current widespread use of bronchodilators for bronchiolitis succinctly. They assert that the clinician’s use of bronchodilators in spite of lack of supporting evidence is likely due to the similarity of symptoms and signs of bronchiolitis and asthma. Bronchodilators are indeed effective in the treatment of asthma; but, according to Gadomski and Scribani, the use of bronchodilators for bronchiolitis is not physiologically indicated. The pathophysiology of wheezing in bronchiolitis is actually different from that of wheezing with asthma. Bronchiolitis
causes wheezing due to airway obstruction and plugging of the small airways rendering it unresponsive to traditional bronchodilator therapy. However, the pediatric clinician is challenged by attempts to ascertain if the wheezing infant has asthma and bronchiolitis or merely bronchiolitis with subsequent mucus plugging. The authors cited this confusion among clinicians as a likely reason why albuterol continues to be used for infants and children with bronchiolitis in spite of current recommendations to avoid bronchodilators.

There is growing evidence of diagnostic and treatment variability regarding the 2014 Guideline statements and resultant dissention among the medical community. Walsh and Rothenberg (2015) vehemently disagreed with the AAP committee’s recommendation to avoid the use of bronchodilators in children with bronchiolitis. Regarding the AAP’s rationale for the avoidance of bronchodilators in the management of bronchiolitis, Walsh and Rothenberg offered counterpoint analyses directed at the research studies that formed the basis for some of the rationales. The authors scrutinized the findings of the meta-analysis contained in the Cochrane review by Gadomski et al. (Gadomski & Scribani, 2014). Specifically, the authors disagreed with the committee’s interpretation of the study results and asserted that concluding results from an “inadequately powered study is no basis for concluding a drug has no effect” (Walsh & Rothenberg, 2015, p. 3). Furthermore, Walsh and his colleague argued that attaching weight to placebo-controlled studies, as done by the AAP when justifying their KAS recommendations, effectively excluded any other studies that compared bronchodilators by type. Moreover, Walsh and Rothenberg asserted that the use of a placebo is not the standard of care for children in respiratory distress due to bronchiolitis and thus cannot be considered a correct comparator (Walsh & Rothenberg, 2015). Finally, Walsh and Rothenberg cited a dissenting viewpoint regarding the physiologic response to albuterol in children. While the AAP 2014 Guideline
posited that albuterol non-responders could not be distinguished from responders, Walsh and Rothenberg stated “a therapeutic trial distinguishes them handily” (Walsh & Rothenberg, 2015, p. 3). Furthermore, a therapeutic trial of albuterol can distinguish responders from non-responders and albuterol is a cost-effective strategy in preventing direct hospital admissions from the ED in many children.

Other pediatric clinicians cite treatment variability and skepticism regarding the AAP’s 2014 Guideline. Brian Kuzik (Kuzik, 2016) declared that for the clinician attempting to adhere to both the Canadian Paediatric Society and the American Academy of Pediatrics bronchiolitis guidelines, the “number of recommended options for active treatment is officially zero” (Kuzik, 2016, p. 351). Citing a fundamental flaw in the pediatric bronchiolitis studies, Kuzik reminded the reader that the AAP guideline’s definition of bronchiolitis excludes children who have wheezed more than once in their lives. Contributing to the variability regarding the bronchiolitis definition, the UK bronchiolitis guideline defines bronchiolitis by the predominance of crackles rather than wheezes in an effort to distinguish it from asthma ("NICE guideline," 2015). Dissention in the medical community regarding the 2014 Guideline and its KAS leads to clinical practice variation and warrants further examination.

Specifically, KAS2 advises “clinicians should not administer albuterol (or salbutamol) to infants and children with a diagnosis of bronchiolitis” (Ralston et al., 2014, p. 1474). Albuterol and Salbutamol are two bronchodilator medications that, when inhaled, cause relaxation of the airway smooth muscle and improve overall aeration of the lungs and lessen the work of breathing (Davids & Schapira, 2017). Additionally, KAS 5 states “clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting” (Ralston et al., 2014, p. 1475). Indeed, even a brief review of the current national literature (Luo,
Nkoy, Gesteland, & Glasgow, 2014; Walsh & Rothenberg, 2015; Zamora-Flores, Busen, Smout, & Velasquez, 2015) and international literature (Johnson et al., 2013; Plint, Grenon, Klassen, & Johnson, 2015; Walsh & Rothenberg, 2015) illuminated the dissenting views among pediatric clinicians regarding some of these clinical guideline recommendations. Although the authors of the 2014 Guideline cautioned the reader to use his/her clinical judgement and that the document was not intended to be the sole source of guidance, variation in clinical practice has resulted (Ralston et al., 2014). This practice variation among pediatric clinicians who manage bronchiolitis may be impacting the clinical outcomes of children with bronchiolitis.

**Significance of the Problem**

**Clinical and Financial Burdens**

Representing a significant public health burden, bronchiolitis is the most common cause of hospitalization among infants during the first 12 months of life (Ralston et al., 2014). These hospitalizations consume considerable health care resources and are also associated with substantial financial burden. Estimates of this financial burden elucidate the growing problem of bronchiolitis management. Bronchiolitis contributes to approximately 238 outpatient visits, 71 hospitalizations, and 77 emergency department (ED) visits per 1000 infant years (Carroll et al., 2008).

From 2000-2009, the total hospital charges for bronchiolitis hospitalizations were estimated to be $1.73 billion dollars in the US (Hasegawa, Tsugawa, Brown, Mansbach, & Camargo, 2013) making bronchiolitis one of the most expensive diseases among hospitalized children (Pelletier, Mansbach, & Camargo, 2006). For all-cause bronchiolitis, it is estimated that 149,000 children are hospitalized annually (Pelletier, Mansbach, & Camargo, 2006). Other researchers (Hall et al., 2013) specifically examined respiratory syncytial virus (RSV)-caused
bronchiolitis. One sobering finding presented by Hall et al. (2013) estimated that the average RSV hospitalization rate is 5.2 per 1000 children under 24 months old in the US and is even higher in infants under two months of age, approaching 17.9 per 1000 children.

Hall et al. (2013) further estimated that more than 57,000 hospitalizations and 2.1 million outpatient visits are associated with RSV infections in the US each year for children less than five years old. Between 2000-2009, the total US hospital charges for bronchiolitis hospitalization were estimated to have increased from $1.3 billion in 2000 to $1.7 billion in 2009, representing a 30% increase nationally, adjusted for inflation (Hasegawa, Tsugawa, Brown, Mansbach, & Camargo, 2013). However, this trend was not isolated to pediatric bronchiolitis hospitalizations. From 2000-2010, healthcare spending in the US increased at a rate faster than any other industry, averaging a 2.9% increase annually during that decade (Moses et al., 2013). Only total government spending (at 3.3% per year) exceeded the annual growth of healthcare spending during the 2000-2010 period (Moses et al., 2013).

Paradoxically, from 2000-2009 the annual proportion of hospitalizations for bronchiolitis remained relatively constant for children less than two years and actually decreased for children less than one month of age. Only children aged 12-23 months experienced increased hospitalizations during that time period which could not account for the 30% increase in hospitalization costs. One possible explanation behind this dramatic increase in costs associated with hospitalizations is that this estimate is reflective of an overall increase in the average hospital charge per case-day because the actual volume of hospitalizations declined and the average length of stay (los) remained constant or slightly declined. Additionally, although the population of bronchiolitis may be similar in severity, the use of inpatient services may be increasing because of the acuity of the children who contract bronchiolitis. Researchers posited
that the prevalence of children with chronic medical conditions in the US population may, in fact, be increasing which thereby leads to increased hospitalization rates with illnesses such as bronchiolitis and increased intensive resources used such as mechanical ventilation during respiratory illnesses (Hasegawa, Tsugawa, Brown, Mansbach, & Camargo, 2013).

Globally, respiratory syncytial virus (RSV) is the predominant viral pathogen for pediatric bronchiolitis while human rhinovirus (HRV) is the second most common pathogen, accounting for 60-80% of pediatric cases and 25.6% of pediatric cases respectively (Mansbach et al., 2012). Additionally, co-infections can occur and may be present in approximately 30% of children with bronchiolitis (Mansbach et al., 2012). Other causative pathogens in pediatric bronchiolitis include influenza virus and human metapneumovirus. Regardless of the underlying viral etiology, bronchiolitis results in significant morbidity and mortality not only in the U.S. but worldwide (Nair et al., 2010). In addition to the economic burden of multiple outpatient visits and hospitalizations, there is a “growing body of evidence to suggest that RSV bronchiolitis, regardless of hospitalization status, is a significant risk factor for on-going respiratory morbidity characterized by transient early wheezing and recurrent wheezing within the first decade of life and possibly into adulthood” (Fauroux et al., 2017, p. 192). This increased respiratory morbidity not only increases health care costs but can also decrease the overall quality of life for the child and influence the parental perception of the child’s health several months’ post-bronchiolitis diagnosis (Rolfsjord et al., 2016).

Social Burden

In addition to the clinical and economic burdens resulting from pediatric bronchiolitis, there are significant social burdens following this diagnosis. Carroll et al. (2008) conducted a retrospective cohort study of over 100,000 term infants enrolled in Tennessee Medicaid
programs. After extracting data from non-low birth weight infants from the years 1995-2003, the authors reported the rates of bronchiolitis visits (including non-RSV type), were “238 outpatient visits per 1000 infant-years, 77 emergency department visits per 1000 infant-years, and 71 hospitalizations per 1000 infant-years” (Carroll et al., 2008, p. 58).

RSV-related bronchiolitis also poses a significant threat to premature infants. Lanari and colleagues found that the risk estimates for hospitalization for infants increased by two-fold for infants born at 33-34 weeks gestation and by 1.5 fold for infants between 35-37 weeks gestation at birth. Additionally, for premature infants with bronchiolitis who are hospitalized, there exists a greater risk for re-hospitalization and the possibility of developing subsequent reactive airway disease (Lanari et al., 2015).

Heikkinen, Ojala, and Waris (2017) also explored the substantial social impact of bronchiolitis on families. Utilizing data from children diagnosed with RSV-associated bronchiolitis, the researchers examined the social burden of bronchiolitis for working parents and their children. Employing a symptoms diary collection tool, the researchers found that the mean duration of RSV bronchiolitis was 13.0 +/- 7.8 days for children less than three years of age (p=0.005)(Heikkinen, Ojala, & Waris, 2017). Moreover, the extended longevity of most bronchiolitis illnesses in younger children leads to subsequent parental work absenteeism. Heikkinen et al. (2017) found that for parents of younger children with bronchiolitis, the rate of missed work days was ≥1 day of work with a mean duration of absenteeism of 2.6 days (Heikkinen et al., 2017, p. 20). In addition, among 110 children less than three years of age, the mean duration of absenteeism from school or daycare were high. According to Heikkinen et al. (2017), the rate of absenteeism per 100 children less than three years of age who were diagnosed with RSV bronchiolitis was 195 days (p<.001)(p. 21).
To underscore the immense burden bronchiolitis places on society, researchers have implicated this common illness in the development of pediatric asthma. In a prospective cohort study of over 3000 children, researchers examined the role severe bronchiolitis played on the development of asthma. In a multivariable logistic regression which adjusted for several risk factors, “severe bronchiolitis remained a strong risk factor for developing asthma by age 5 years (odds ratio 2.57; 95% confidence interval 1.61-4.09)” (Balekian, Linnemann, Hasegawa, Thadhani, & Camargo, 2017, p. 92).

Although bronchiolitis is a ubiquitous illness of infancy and early childhood, its highly variable clinical presentation contributes to substantial challenges in predicting patient outcomes on the initial presentation. Furthermore, the heterogeneity of bronchiolitis definitions and clinical practice guidelines presents the clinician with no effective targeted therapies or methods of identifying infants at the highest risk of developing severe disease (Hancock, Charles-Britton, Dixon, & Forsyth, 2017). Finally, the bronchiolitis management strategies are confusing for pediatric clinicians because the outpatient studies targeting effective management of bronchiolitis were heterogeneous utilizing oxygen saturation, admission to hospital, or time to resolution of symptoms as outcome variables (Gadomski & Scribani, 2014).

**Bronchiolitis Management**

**Bronchodilator Use**

In an effort to tackle this significant burden of disease, the American Academy of Pediatrics published a clinical practice guideline entitled the *2014 Clinical Practice Guideline: The Diagnosis, Management, and Prevention of Bronchiolitis* (Ralston et al., 2014). This *Guideline* included 14 Key Action Statements (KAS) which emphasized overall supportive care for children with bronchiolitis and recommended against the use of bronchodilators such as
albuterol or salbutamol, epinephrine, systemic corticosteroids, chest physiotherapy, and antibiotics for children with bronchiolitis ages one through 23 months. It is interesting to note that of the 14 KAS, 10 of them included tests or treatments to avoid (Quinonez & Schroeder, 2015).

The use of bronchodilators (inhaled medications that enhance relaxation of the smooth muscles around the bronchioles thereby increasing the luminal space of the airways), is now included in the “to be avoided” category. Ralston and colleagues (2014) cited that although “several studies and reviews have evaluated the use of bronchodilator medications for viral bronchiolitis, most randomized controlled trials have failed to demonstrate a consistent benefit from alpha or beta adrenergic agents” (p. 1480). Additionally, Ralston et al. (2014) posited that although administration of inhaled bronchodilators resulted in child/parental brief improvement in clinical symptom scores, the time to disease resolution, the need for hospitalization, and length of stay of hospitalization were not significantly improved through the use of inhaled bronchodilators. Finally, in alignment with the Guideline’s “Primum non nocere” (“first do no harm”) philosophy, Ralston et al. (2014) cautioned the clinician that the use of inhaled bronchodilators such as albuterol and salbutamol may cause harm in some children including tachycardia and tremors.

**Systemic Corticosteroid Use**

Emphasizing the avoidance of interventions that lack a favorable risk-benefit ratio, Ralston et al. (2014) recommended in the Guideline that clinicians should not administer systemic corticosteroids such as methylprednisolone or dexamethasone to infants and children with a diagnosis of bronchiolitis in any setting. Corticosteroids are pharmacologic agents that, when taken orally or via intravenous routes, have a potent anti-inflammatory effect and may
potentially decrease bronchial airway inflammation and relieve symptoms of cough and wheeze ("United States National Library of Medicine," 2017). Ralston et al. (2014) maintained that the most recent Cochrane systematic review (Fernandes et al., 2013) supported the avoidance of corticosteroids for children with bronchiolitis. In their meta-analysis, Fernandes and colleagues (2013) reported that although bronchiolitis does indeed involve acute inflammation of the bronchiolar airways with necrosis and mucus plugging, there is likely a heterogeneity in the anti-inflammatory pathways for children with bronchiolitis and the use of corticosteroids have limited anti-inflammatory use in this condition. Moreover, Fernandes et al. (2013) stated that although there is no evidence of short-term adverse effects from corticosteroid therapy, there was inadequate evidence to be certain of safety in infants and children with bronchiolitis.

**Guideline Adherence**

In spite of the volume of evidence used to create the 2014 *Guideline*, variations in provider treatment preference seems to be common (Mittal et al., 2014). The American Academy of Pediatrics published the 2014 *Guideline* in an effort to provide evidence-based medicine to guide the clinician’s management of children with bronchiolitis and reduce variation in clinical practice. Nevertheless, nationally there is marked variation in practice and dissention among clinicians regarding some of the KAS (Walsh & Rothenberg, 2015).

Furthermore, it is evident that from both a national and international perspective, the pediatric bronchiolitis *Guideline* does not reflect the actual medical management in primary, emergent, or hospital settings. Some authors argue that this lack of guideline “effect” probably results from the difficulties involved in achieving a consensus for the clinical diagnosis of acute bronchiolitis (Everard, 2009). However, it is also possible that the supporting studies used to formulate the 2014 *Guideline* included a mixed population of children and may thus have missed
valuable pharmacologic treatment effects in some children. Everard (2009) reminded the reader that for infants and children with bronchiolitis, there are likely two groups of children. The first group includes those children who have obstructive disease resulting from the viral bronchiolitis infection. The second group includes those children who are pre-disposed to asthma who also develop obstruction from both mucus, cellular debris, and bronchospasm. The second group would respond favorably to bronchodilator and/or corticosteroid therapy while the first group would not.

**International Variability in Treatment**

Variability and lack of consensus in clinical management of bronchiolitis exists internationally as well. One study from France concurred with the US observation that among medical practices, “drug prescription is nevertheless the pattern that least complies with the guidelines” (Touzet et al., 2007, p. 654). Cahill, Finan, and Loftus (2002) cited that among physicians surveyed about their clinical management of bronchiolitis, bronchodilator therapy use was widespread in Ireland and the use of salbutamol was reported by 24% of physicians. This diversity in management is mirrored in the South African bronchiolitis guidelines which state that inhaled bronchodilators offer modest benefit and may produce short term improvements in clinical signs although they have not been shown to affect “any important clinical outcomes” (Green, Zar, Jeena, Madhi, & Lewis, 2010, p. 323). Joseph summarized the clinical management variation well stating “the definition of bronchiolitis, the clinical scoring systems, and the outcome measures used in the bronchiolitis literature vary significantly, complicating interpretation of the data” (Joseph, 2011, p. 2).

**Ethical and Legal Considerations**

Ethically, it is conceivable that such variance in practice and management could lead to
an asymmetry of care as clinician non-adherence to the bronchiolitis guidelines may impact the quality of care delivered to some children while other children whose clinicians abide by the guidelines receive a different standard of care. From a legal perspective, it is clear that performing a medical service, writing prescriptions for bronchodilators and corticosteroids for bronchiolitis, and billing a patient or third party payer is fraught with legal ramifications since those interventions have not been advised in the 2014 *Guideline* for this diagnosis. The unfortunate national trend in medicine to “do more” is most certainly affecting clinician adherence to the bronchiolitis *Guideline* and likely plays a role in our nation’s skyrocketing per capita healthcare costs.

**The Problem**

Following a review of the literature, it is evident that variability in clinician adherence to the 2014 *Guideline* exists both nationally and internationally. This practice variation poses a challenge at the individual, population, and institutional level. The repercussions of practice variation and the lack of longitudinal evaluation of the resultant clinical outcomes affects infant or children aged 1-23 months. However, it is reasonable to assert that the entire population of children with bronchiolitis are affected since many clinical guidelines are extrapolated to the general pediatric population. Each organization or health care system is also affected by these guidelines as they attempt to implement them with consistency and medical accuracy. Unfortunately, even with this plethora of evidence, an organization can resist examining its own practices and be resistant to change. This resistance to change and clinician non-adherence to the 2014 *Guideline* may contribute to deleterious outcomes in the pediatric population affected by bronchiolitis.
Purpose of the Study

Acute bronchiolitis in infants and children is a viral infection of the lower respiratory tract that contributes to significant health burden worldwide. Additionally, “the clinical management remains challenging despite the frequency, global reach, economic cost, and morbidity and mortality associated with bronchiolitis” (Florin et al., 2017, p. 211). Although several studies have assessed the role of bronchodilators and/or corticosteroids for the treatment of bronchiolitis, systematic reviews have found no significant benefit (Fernandes et al., 2013) (Gadomski & Scribani, 2014). Considerable knowledge gaps, controversies, and diagnostic and treatment variability persist for clinicians who care for children with bronchiolitis. The 2014 Guideline proposed substantial changes to its prior guideline statements and to date, there is a paucity of research examining the clinical and financial outcomes for infants and children treated for bronchiolitis in the outpatient setting.

In an attempt to explore the clinical outcome effects of clinician adherence or non-adherence to the 2014 Guideline, this clinician will investigate KAS #2, “Clinicians should not administer albuterol (or salbutamol) to infants and children with a diagnosis of bronchiolitis” and KAS #5, “Clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting” (Ralston et al. 2014, p.1483).

Organizational Needs Assessment

In a primary care setting of 10 pediatricians and four nurse practitioners, there is variation in the operationalization of the 2014 Guideline. This large private practice encompasses two physical offices in a suburban community approximately 15 miles outside a large metropolitan center in the mid-Atlantic region of the US. The patient population includes infants and children from birth through age 21 and of these children, almost all have health insurance and adequate
prescription coverage. The practice accepts most major insurances and provides multiple visit options including walk-in appointments for sick children, scheduled appointments, wellness visits, and after-hours appointments. As described by Schein (Schein, 2010), this pediatric organization holds an “unwritten mission”, or espoused belief, that the clinical providers will see all sick children the same day the parent or guardian request an appointment. Additionally, the organization has been recognized by the National Committee for Quality Assurance (NCQA) as a Patient Centered Medical Home and was the first pediatric practice in its state to achieve that certification.

The pediatric providers at this site meet weekly to discuss current pediatric trends in medicine and to review common practices among the group regarding frequent pediatric diagnoses such as management of pediatric bronchiolitis, urinary tract infections, asthma, childhood obesity, and adolescent mood disorders. AAP guidelines and news releases are frequently reviewed and discussed in a collegial, non-confrontational environment and a culture of learning is highly encouraged. All medical management decisions are created by, and voted upon, by the physicians and nurse practitioners after thoughtful discussions and review of current “best practices” and the most recent evidence in the literature.

Before undertaking any exploration of a clinical question or attempting to change behaviors among providers, it is imperative to assess the organizational culture, including that culture’s assets and deficits. Utilizing Schein’s (Schein, 2010) cultural theory as a framework for discussion, this organization’s assets are highlighted. As Schein (2010) observed, the first level of any organizational culture is “artifacts”.

This pediatric clinic site was the first in its state to achieve pediatric certified medical home designation (PCMH). The practice includes two large well-equipped offices, a state-of-the-
art electronic medical record documentation system, a largely insured population, and a motivated staff who embody the concept of team-based care as described by the National Committee for Quality Assurance (NCQA)’s Patient-Centered Medical Home (PCMH)(NCQA PCMH Recognition: Concepts, 2018). In addition to team-based care, the practice embraces same day appointments, team huddles, care coordination, and extensive quality improvement projects that focus on quality metrics. These organizational behaviors are all critical to maintaining its PCMH designation and are also foundational to helping the practice achieve the triple aim of healthcare.

The second level of this organization, as described by Schein (2010), is the espoused values. As discussed earlier, a core value of this organization is its “kids first” belief and the willingness to see all sick patients the same day the caregiver calls for an appointment. Similarly, the organization espouses a patient-centered medical home model in which team-based care, communication, and coordination has been shown to improve the quality of care. The NCQA PCMH designation is acknowledged by many payers as a hallmark of high-quality care (NCQA PCMH Recognition: Concepts, 2018). Additionally, this organization espouses a close adherence to the AAP guidelines and emphatically embraces process improvement measures in the management of common pediatric diagnoses. Finally, there is a spirit, or culture, of learning and sharing knowledge among the team members including nursing assistants, licensed practical nurses, medical assistants, registered nurses, medical and nurse practitioner students, nurse practitioners, and physicians.

However, as Schein (2010) astutely observed, there is a cyclical nature of organization and culture. Individuals create organizations that develop cultures and, consequently, these organizations then acculturate individuals who join the organization. What does this type of
As champions of evidence-based medicine, this organization attempted to adhere to the 2014 *Guideline* recommendations. However, as children returned for repeat visits to the clinic due to wheezing, respiratory distress, or parental concerns, marked clinician variation in practice was observed which included the use of inhaled bronchodilators for infants with stable pulse oximetry and vital signs, but persistent wheezing. The prescribing of oral steroids was also implemented on a trial basis for these patients as an adjunctive therapy on a case-by-case basis when the child’s respiratory status was not improving with more conservative therapies. This deviation from the 2014 *Guideline* represented an uncharacteristic trend away from the consensus-based practice strategies the organization embraced. In the following RSV seasons (2015-2017), and after careful consideration of the 2014 RSV season, the clinicians again attempted to adopt a “less is more” approach for pediatric bronchiolitis. However, as Luo and colleagues found, “due to an insufficient level of detail and limited amounts of evidence, existing clinical practice guidelines provide guidance for a limited number of patients and still rely heavily on individualized clinical judgment” (Luo et al., 2014, p. 693).

In keeping with this trend, infants and children with bronchiolitis who presented to this clinic post-2014 *Guideline* publication received medical management decisions that varied in adherence to the KAS presented in the *Guideline*. These children were sometimes treated with supportive care such as nasal suctioning and the use of a humidifier in the home. Others were given inhaled bronchodilators such as albuterol or levalbuterol and, if indicated, were given a prescription for oral corticosteroids. As these infants and children improved, it is possible that for these 10 pediatricians and four nurse practitioners, this prescribing behavior was reinforced. Parental endorsement of these pharmacotherapies was also likely reinforced as they watched
their children improve over the course of the illness. Contrary to the AAP’s Guideline, clinicians in this organization were utilizing interventions such as bronchodilators and corticosteroids and perhaps creating a culture of “doing more” which was reinforced by perceived clinical improvement and perceived parental satisfaction. Thus, over the course of three bronchiolitis seasons, a new “culture” was adopted by this organization which, as literature suggests (Mittal et al., 2014) leads to a wide variation in the use of treatments for children with bronchiolitis; a phenomenon that was mirrored both nationally and internationally.

Quinonez and Schroeder (2015) cautioned the clinician who care for children with bronchiolitis that no intervention was benign and all clinicians should consider the evidence before advising interventions that are not evidence-based. Taking a counterpoint stance, Walsh and Rothenberg (2015) argued that the AAP Guideline did not enlist key stakeholders when it was written and was built on the false premise that because bronchiolitis was a short-lived usually non-fatal disease, treatment cannot offer long term benefits and should thus be avoided. Moreover, Walsh and Rothenberg (2015) challenged the reader that relieving acute respiratory distress through such interventions such as albuterol is, in fact, supported by available evidence (Walsh et al., 2008). Which “culture” is correct or reflects best evidence-based practice? Schein (2010) emphasized that when faced with a problem, an organization will find a solution that works and over time, it is likely that the new “solution” will become taken for granted and treated as a reality. For the pediatric organization discussed, the new “solution” was adopt a more individualized approach in the care of infants and children with bronchiolitis, which essentially represented variability in adherence to the KAS #2 and #5 as clinicians prescribed bronchodilators and steroids for some children who were not improving with more conservative treatment modalities.
After review of this practice setting, it was clear that variation in the organization’s practice had evolved and a brief review of the literature revealed other organizations experienced practice variation as well. At a weekly meeting, the practice variation was verbalized and other providers in the organization voiced similar quality concerns, cited unsatisfactory parental opinions, and observed marked practice variability in the primary care setting, the emergency department setting, and the acute care patient setting. Additionally, clinicians at the site observed that children who were treated according to the 2014 Guideline, regardless of the treatment site, accrued more follow-up visits to primary care and clinically seemed worse at those visits. This, coupled with their anecdotal mistrust of the evidence used to generate the recommendations, prompted the clinicians to reconsider the 2014 Guideline and current best practices.

**Research Question**

**Background**

Melnyk and Fineout-Overholt (2015) stated that the first step of evidence based practice (EBP) is the formulation of a clinical question. This clinical question is asked in the PICOT format and is defined as a “process in which clinical questions are phrased in a manner that yields the most relevant information from a search” (Melnyk & Fineout-Overholt, 2015, p. 609). The PICOT format identifies the P (population), I (intervention or issue of interest), C (comparison intervention or status), O (outcome), and T (time frame). The PICOT format will be utilized as a framework for this scholarly inquiry into the clinical management of pediatric bronchiolitis.

When attempting to follow the 2014 Guideline, anecdotal increased utilization of “follow up appointments” was noted in the primary care clinic as were increased emergency department visits for infants and children with bronchiolitis. Overall parental dissatisfaction with the length
of illness in their child with bronchiolitis was also observed. Anecdotal (S. L., Pediatric Medical Director, personal communication, July 12, 2017) and empirical evidence among pediatric clinicians and scholarly literature (Joseph, 2011; Luo et al., 2014; Walsh & Rothenberg, 2015) noted that “a variety of therapies, such as bronchodilators, are used in bronchiolitis with little supporting evidence and minimal consensus on their use other than recommending that clinicians individualize care based on course and severity” (Luo et al., 2014, p. 693).

**PICOT Question**

In an effort to examine the effect of clinician guideline adherence or non-adherence for pediatric patients with bronchiolitis, the following question was formulated:

For infants and children (ages 1-23 months) with clinically diagnosed bronchiolitis, how does clinician adherence or non-adherence to the 2014 *AAP Guideline for Diagnosis, Management, and Prevention of Bronchiolitis* affect the children’s clinical outcomes from 2013-2018?

The (P) population includes children with clinically diagnosed bronchiolitis from one month through 23 months of age, which is consistent with the Pediatric Bronchiolitis *Guideline* definition. Bronchiolitis is clinically diagnosed and defined by observation of signs and symptoms including cough, rhinorrhea, tachypnea, wheezing, rales, and for some children, increased respiratory effort manifested as grunting, nasal flaring, or retractions (Ralston et al., 2014). The (I) intervention or variable of interest is clinician adherence to the 2014 *Guideline*. Specifically, adherence for this project is defined as no use of albuterol or levalbuterol in the office and no prescriptions written for home use of bronchodilators. The (C) comparison is clinician non-adherence to the 2014 *Guideline* as defined by use of, or prescriptions written for, bronchodilators and/or oral corticosteroids. The (O) outcomes as described by Florin et al.,
(2014) used to evaluate the clinical outcomes following clinician adherence or non-adherence are described below in “outcome measures”. The (T) or time-frame will include the RSV seasons beginning in 2013 and ending after RSV season 2018. Due to the seasonal nature of bronchiolitis infections, the RSV season is defined as October through March in this clinician’s geographic region.

**Outcome Measures**

Outcomes to be measured include hospitalization within 14 days of bronchiolitis diagnosis for either bronchiolitis or bronchiolitis sequelae, duration or length of stay (LOS) if hospitalized, number of primary care visits per episode within a 14 day time from day of diagnosis, use of bronchodilators both in the office setting and/or the outpatient setting, and use of oral corticosteroids either in the office setting or outpatient setting. The number of subsequent visits to a primary care provider within 14 days of the bronchiolitis diagnosis will also be measured. Additionally, the number of emergency department or urgent care visits within a 14 day period from onset of bronchiolitis illness will be measured and the use of antibiotics or chest x-rays will also be measured to align with the current literature outcome measures.

**Evidence-Based Practice Model**

Evidence-based practice (EBP) is a comprehensive strategy that combines research evidence with clinical expertise in an effort to change clinical practice. This change effort can be viewed through the concept of a theoretical framework. Although several EBP models or frameworks exist, they share commonalities. These commonalities include the identification of a problem that needs addressed, inclusion of stakeholders or change agents, identification of a practice change shown to be effective through research, identification of barriers to a practice change, an evaluation of the impact of the practice change on outcomes measures, and the
identification of activities that will help sustain the change in the practice setting (Melnyk & Fineout-Overholt, 2015). The evidence of wide practice variation and clinician non-adherence to the 2014 *Guideline* illuminate the need for close examination of those guideline statements to determine what barriers exist in the translation from research to bedside. The evidence based practice model well-suited for this scholarly project is the Steven’s Star Model (School of Nursing: UT Health Science Center: Star Model Website, 2015).

The Steven’s Star Model depicts various forms of knowledge and knowledge acquisition as a sequence through points of the star. As new knowledge is transformed through the five points of the star, or stages, the final outcome is evidence-based quality improvement of healthcare through knowledge acquisition. The first point of the star, or step one, is the stage where new knowledge is generated through traditional research methodologies and scientific inquiries. This step is a process of discovery and, used as a framework for this scholarly project, provides the framework for studying the phenomenon of pediatric bronchiolitis, conducting an initial literature review to determine the significance and burden of this disease, generating a PICOT question based upon those findings, and collecting baseline data both before and after the implementation of the 2014 *Guideline*.

The second point of the star, or step two, is the stage where the body of research knowledge is amassed and summarized. This is the stage where systematic reviews and meta-analyses take place. Known as the evidence summary stage, this point is also knowledge generating and provides the framework utilized by researchers during the review and appraisal of the current pertinent literature. The review of pediatric bronchiolitis literature was conducted using key terms from the PICOT question, which was generated in the initial discovery phase, or the first star point.
The third point of the star, or step three, explicates the process whereby the transformation of these systematic reviews and Meta analyses are then translated into practice recommendations, such as clinical practice guidelines. These clinical practice guidelines (CPGs) are then integrated into practice in step four. It can be argued (School of Nursing: UT Health Science Center: Star Model Website, 2015) that Ralston et al. (2014) illustrated this step in knowledge transformation when they synthesized the literature and published the 2014 *Guideline*.

The fourth point of the star, or step four, is often the most familiar to clinicians because this stage highlights where the integration of clinical practice guidelines and recommendations occur. It is at this very point in the model where the source of clinical controversy exists in the pediatric bronchiolitis literature. After the 2014 *Guideline* was published, there was wide variation in adoption of this *Guideline* into clinical practice and this phenomenon forms the basis of this clinician’s scientific inquiry.

Finally, the fifth point of the star, or step five, is where endpoints and outcomes are evaluated. Examples of this in the pediatric bronchiolitis literature include metrics such as the number of days hospitalized for a patient with bronchiolitis, pulse oximetry measurements, the number of patients admitted for bronchiolitis, and the number of parental days of missed work due to pediatric bronchiolitis. It is at this stage of the EBP model where the literature demonstrates a marked paucity of data regarding clinical outcomes of children with bronchiolitis managed in the outpatient settings. The Steven’s STAR EBP model (School of Nursing: UT Health Science Center: Star Model Website, 2015) provides guidance for clinicians and researchers during all five stages and facilitates the adoption of findings into clinical practice. Furthermore, as an anchor for new sciences of improvement, the Steven’s STAR model can
facilitate the openness to new discoveries as the DNP scholarly project unfolds.

**Definition of Terms**

For the purposes of this scholarly work, the following terms and definitions will be utilized.

**Infants and children**: Operationally defined as any child aged one-23 months of age.

**Clinically diagnosed bronchiolitis**: A “constellation of clinical signs and symptoms occurring in children younger than two years, including a viral upper respiratory tract prodrome followed by increased respiratory effort and wheezing. Clinical signs and symptoms of bronchiolitis consist of rhinorrhea, cough, tachypnea, wheezing, rales, and increased respiratory effort manifested as grunting, nasal flaring, and intercostal and/or subcostal retractions” (Ralston et al., 2014, p. 1479). Acceptable International Classification of Diseases (ICD) 9 codes include 466.19 and 499.0 (bronchiolitis/bronchiolitis unspecified). Acceptable ICD 10 codes include J 21.0 (acute bronchiolitis due to respiratory syncytial virus), J 21.1 (acute infective bronchiolitis due to human metapneumovirus), J 21.8 (acute bronchiolitis due to unspecified organism), and J 21.9 (acute bronchiolitis with influenza).

**Clinician**: A licensed physician or licensed nurse practitioner

**Clinician adherence**: “Steady or faithful attachment” (Merriam-Webster Dictionary website, n.d., para.1). For this study, clinician adherence was conceptually and operationally defined (Ament et al., 2015) as the proportion of patients receiving treatment according to the clinical practice guideline recommendations. Extracted directly from the 2014 Guideline, the researcher identified two performance measures which reflected clinician adherence to the Guideline for bronchiolitis management. The two performance measures included KAS #2 (“clinicians should not administer albuterol (or salbutamol) top infants and children with a diagnosis of
bronchiolitis”) and KAS #5 (“clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting”) (Ralston et al., 2014).

Clinician non-adherence: “A lack of adherence” (Merriam-Webster Dictionary website, n.d., para. 1). In this work, clinician non-adherence is conceptually and operationally defined (Ament et al., 2015) as the proportion of patients not receiving treatment according to the clinical practice Guideline recommendations (specifically KAS #2 and KAS #5)(Ralston et al., 2014). Again, the use of a bronchodilator or corticosteroid was reflective of clinician non-adherence.

Hospitalization: Any admission to a hospital within 14 days of the bronchiolitis diagnosis related to the diagnosis of bronchiolitis but not including an “observation period” in the emergency department or outpatient urgent care setting.

Bronchodilator: A beta-2 agonist pharmacologic agent that expands the lumina of the bronchi by relaxing the bronchial smooth muscle ("NIH Daily Med," 2006). Operationally defined as inhaled albuterol OR levalbuterol OR salbutamol. Although epinephrine can be utilized as a bronchodilator, its usage was not included for this study.

Corticosteroid: A pharmacologic synthetic equivalent of glucocorticoid hormone produced by the adrenal cortex with potent anti-inflammatory and immunosuppressive properties ("United States National Library of Medicine," 2017) operationally defined as oral methylprednisolone or oral dexamethasone.

Conclusion

This chapter examined the phenomenon of pediatric bronchiolitis as well as the extensive financial, clinical, and social burdens of this common childhood illness. The important concept of clinician adherence to the 2014 Guideline was explored and the effects of adherence on the clinical outcomes of infants and children with bronchiolitis was posited as one method of
determining the efficacy and translation of those guidelines. Finally, an organizational needs assessment and theoretical framework were reviewed. This information will provide a valuable framework in the process of discovery for the DNP scholarly project. Practice variation is evident in the current literature and current clinical practice. This clinical variance in practice and the resulting clinical outcomes in infants and children form the foundation for the Doctor of Nursing Practice (DNP) scholarly project.
Chapter II- Review of the Literature

Introduction

This chapter will address the methodology utilized when conducting the review of the literature for this scholarly project. The conduction of the search strategy including the databases used, the search terms, and limiting search criteria will also be explained. Finally this chapter will provide a synthesis of the information found in the relevant research articles. Thematic commonalities, as well as gaps in the literature will be identified and discussed.

Literature Review

Utilizing the evidence-based approach as a framework, the PICOT question was utilized to initiate a review of the available literature. The PICOT question is:

For infants and children (ages 1-23 months) with clinically diagnosed bronchiolitis, how does clinician adherence or non-adherence to the 2014 AAP Guideline for Diagnosis, Management, and Prevention of Bronchiolitis affect the children’s clinical outcomes from 2013-2018?

A review of the literature was then undertaken. Search terms from the PICOT question were used to generate an electronic search of the medical literature. Databases used in this search included the National Library of Medicine’s bibliographic database/article index (Ovid Medline), the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Cochrane Database of Systematic Reviews. Initial medical subject headings (MeSH) search terms for Ovid Medline included “bronchiolitis+”, OR “respiratory syncytial viruses” AND “risk factors”. This search yielded 141 hits and was limited to humans, 2012-2017, English, all infants birth to 23 months and infants 1-23 months. These articles were screened by their titles and abstracts for application to the PICOT question. Only one article (Heikkinen et al., 2017) (a quasi-
experimental prospective follow up study of two large cohorts of children with RSV) was selected and the search strategy was modified to MeSH terms “respiratory viruses OR “infant” AND “practice guideline” OR “guideline adherence” AND “bronchiolitis”. No limits were placed on this search and out of 35 articles, two were selected based on their abstracts and availability of full text, as well as their alignment with the PICOT question. The first article included in this new search was a quasi-experimental, quantitative retrospective chart review which examined clinical outcome measures in children before and after a clinical practice guideline (CPG) was adopted (Zamora-Flores et al., 2015). The second article yielded through this search was a French study which utilized a quasi-experimental non-randomized design exploring the impact of national bronchiolitis clinical practice guideline on practice patterns of primary care pediatricians (Touzet et al., 2007).

A further search of Ovid Medline was done using MeSH terms “albuterol” AND “bronchiolitis” and was limited to articles published in the last seven years and those where the subjects were humans. A prior search for articles in the previous five years had shown that there is a paucity of research related to the newer bronchiolitis guidelines and the age of the articles was expanded to accommodate this finding. With this new limit, 30 articles were found and one (Gadomski & Scribani, 2014) was selected based upon its relation to the PICOT question. Gadomski and Scribani’s article (2014) was a systematic review examining the use of albuterol for children with bronchiolitis. The authors (Gadomski & Scribani, 2014) included randomized controlled trials (RCTs) comparing bronchodilators with placebo for bronchiolitis. Thirty trials were included with 35 data sets representing 1992 infants with bronchiolitis in 11 inpatient and 10 outpatient settings.
Expanding on the prior search, an additional search of Ovid Medline was performed using MeSH terms “bronchiolitis” AND “albuterol” AND “infancy”. Again, no limits were set on the year of publication or subject type. Numerous authors have asserted that the 2014 Guideline’s meta-analysis was limited by significant heterogeneity and for this reason, studies were considered for use regardless of the clinical setting of the patient population if they aligned with the PICOT question. Utilizing this search strategy, 89 articles were found, of which four were selected; Condella et al., 2018; Plint et al., 2016&Walsh et al., 2008). A decision was made to include the Walsh (Walsh et al., 2008) study regardless of the publication date due to the scarcity of similar, but more contemporary studies.

MeSH terms “bronchiolitis” AND “outpatients”, without any limits, yielded no results. One final Ovid search was done using the MeSH terms “prednisolone” AND “wheezing” AND “efficacy”. No limits were placed upon that search and five articles resulted of which three were found acceptable based upon their quality of research and the application to the PICOT question (Jartti et al., 2006;Jartti et al., 2015,&Lehtinen et al., 2007).

A search of CINAHL was done using the medical subject headings (MeSH) “bronchiolitis” AND “steroids” without limits. Again, the limits were omitted because of the lack of recent research after the 2014 bronchiolitis Guideline was published. This search yielded 45 articles which were reviewed first via the abstracts and then via the body of work in full text. Research studies were included if they were in English and aligned with the PICOT question. Only one article met the criteria and was a systematic review and meta-analysis of steroid and bronchodilator use for acute bronchiolitis in the first two years of life (Hartling et al., 2011).

The Cochrane Database of Systematic Reviews was searched using the terms “bronchiolitis” AND “bronchodilator” AND “pediatric”. This search was limited to full
systematic reviews and only those articles published in the last seven years. This search yielded 45 results of which one was selected based upon its applicability to the PICOT question and the full text availability (Fernandes et al., 2013). An additional search was done in the Cochrane Database using “bronchiolitis” AND “hypertonic saline” with limits set for studies published between 2005 and 2017. Hypertonic saline was included in the search strategy MeSH terms because of its use as a comparison modality in the 2014 *Guideline* (Ralston et al., 2014). Only systematic reviews or meta-analyses were considered. Eight studies were found using this strategy and one was accepted (Umoren, 2011).

Finally, the 2014 *Clinical Practice Guideline for the diagnosis, management, and prevention of bronchiolitis* (Ralston et al., 2014) was utilized for an ancestry search through the published references. From this search method, two articles were selected (Hall et al., 2013; Petruzella & Gorelick, 2010) based upon their alignment with the PICOT terms and the ability to obtain the articles in full text. Articles older than 10 years were omitted from this ancestry search. In an effort to obtain additional research other than systematic reviews, hand searching through the existing references was done. Through an ancestry search of one study (Zamora-Flores et al., 2015) two studies (Johnson et al., 2013; Plint et al., 2015) were found which met the inclusion criteria.

**Appraisal of the Literature: SORT Rating**

All articles were examined in full-text format before being included for consideration and any duplicate articles were omitted as they were found. Articles that were “reviews” or “editorials” or “commentaries” were excluded, as were articles older than 10 years. Each study was appraised individually for both the quality and level of evidence utilizing the Strength of Recommendation Taxonomy (SORT) tool (Ebell et al., 2004).
Ebell et al. (2004) elucidated the importance of utilizing quality research to drive evidence-based medicine practices. They also acknowledged that any tool for rating research should be straightforward enough that the primary care clinician could integrate the research and recommendations into his/her daily practice. Ebell et al. (2004) thus developed the SORT tool in an effort to examine and rate research studies based on three key elements: quality, quantity, and consistency of evidence. The SORT is a “comprehensive taxonomy for evaluating the strength of a recommendation based on a body of evidence and the quality of an individual study” (Ebell et al., 2004, p. 555). The SORT tool also addresses issues of patient-oriented evidence which makes this particular tool well-suited to examine research related to patient outcomes such as pediatric bronchiolitis research. The taxonomy rates the quality of individual studies as SORT levels:

1: Good- quality patient-oriented evidence,

2: Limited –quality patient-oriented evidence or,

3: Other evidence

Additionally, the taxonomy includes ratings for strength of the overall body of evidence:

A (recommendation is based on consistent and good-quality patient-oriented evidence),

B (recommendation based on inconsistent or limited-quality patient-oriented evidence),

C (recommendation based on consensus, usual practice, opinion or disease-oriented evidence) (Ebell et al., 2004, p.551).

**Critique and Synthesis of Previous Evidence**

From the 403 articles retrieved from the electronic data base search, all were individually reviewed and a total of 14 were selected. From these 14 studies, ten primary sources and four secondary sources were identified as meeting possible criteria for inclusion. Of the four
Of the 13 primary sources, 10 were quasi-experimental and used a quantitative design. Four of the 13 (nine) primary sources utilized a prospective study design (Hall et al., 2013; Heikkinen et al., 2017; Lehtinen et al., 2007, &Petruzella & Gorelick, 2010). Lehtinen et al. (2007) also utilized a randomized double-blind design to assign children to oral prednisolone or placebo groups. Three of the 13 primary sources utilized a retrospective chart review methodological approach (Condella et al., 2018; Plint et al., 2016; &Zamora-Flores et al., 2015).

Additionally, of the original 13 primary sources, one of them (Touzet et al., 2007) employed both a retrospective and prospective method of data collection and analysis. One study (Walsh et al., 2008), represented an experimental, double-blinded controlled trial of patients who received either three doses of racemic albuterol or one dose of racemic epinephrine plus two saline nebulizers. No placebo arm was included by the researchers but the study was included based upon its close association with the PICOT question and its focus on clinical outcomes for children who received bronchodilator therapy. Finally, three of the 13 primary sources utilized a
double-blinded, randomized placebo-control trial design (Alansari et al., 2013; Jartti et al., 2006; &Jartti et al., 2015). One secondary source (Gadomski & Scribani, 2014) was included because of its application to the PICOT question.

The 14 sources were then graded using the SORT (Ebell et al., 2004) taxonomy. Seven sources (Condella et al., 2018; Hall et al., 2013; Heikkinen et al., 2017; Petruzella & Gorelick, 2010; Plint et al., 2016; Touzet et al., 2007, & Zamora-Flores et al., 2015) were given a SORT level 2 rating. One source (Gadomski & Scribani, 2014) was originally given a SORT level 2 rating, but upon closer inspection the rating was changed to a SORT level 1 rating. Five additional sources were given SORT Level 1 ratings (Alansari et al., 2013; Jartti et al., 2006; Jartti et al., 2015; Lehtinen et al., 2007, & Walsh et al., 2008). Based upon the SORT ratings for overall body of evidence, these studies collectively are given a SORT Level A rating.

Themes in the Literature Related to Bronchiolitis

Several themes emerged as the literature review was conducted. Most of the more recent bronchiolitis research underscored the growing consensus that when treating pediatric bronchiolitis, supportive care is advised as the mainstay of therapy for both outpatient and inpatient children (Bower & McBride, 2015 & Kyler & McCulloh, 2018). In addition to themes related to therapies to be used or avoided, recent literature seeks to predict which infants will require hospitalization or escalation of care versus those who can successfully be managed in the outpatient setting (Freire et al., 2018). Several newer studies examine the growing evidence that RSV-associated bronchiolitis is associated with long-term wheezing and asthma and much research is being done to clarify this relationship (Fauroux et al., 2017 & Mansbach et al., 2016)). Finally, much of the recent research is either emergency-department or hospital-based which creates the knowledge gap regarding the clinical management of bronchiolitis in the primary care
pediatric setting. Because of the inherent vulnerability of this population (children), many of the research articles represented chart reviews or retrospective studies while randomized placebo controlled trials were scarce.

**Avoidance of Bronchodilators**

For the last few decades, a multitude of studies have been conducted to evaluate various therapeutic strategies for bronchiolitis. The body of evidence regarding pediatric bronchiolitis has focused on issues of clinician avoidance for most interventions, including pharmacotherapy such as bronchodilating agents (Parikh, Hall, & Teach, 2014). Pediatric bronchiolitis has caused escalation in health care costs related to hospitalizations and primary care visits, as well as over-utilization of emergency department services (Pelletier et al., 2006). Quinonez and Schroeder (2015) challenged the interventional line of thinking for management of pediatric bronchiolitis and asserted that perhaps “doing something” instead of “watchful waiting” has, in fact, led to poorer outcomes in infants and children with bronchiolitis. Ralston et al. (2014) concluded that although several studies have attempted to evaluate the use of bronchodilator medications for viral bronchiolitis, “most randomized controlled trials have failed to demonstrate a consistent benefit from alpha or beta adrenergic agents” (Ralston et al., 2014, p. 1480).

However, Ralston and his colleagues (2014) clarified that the term “benefit” has historically been defined as an improvement in provider-evaluated symptom scores, which can be subjective and lead to variation in interpretation. Destino et al. (2012) concurred, stating “among the many varying respiratory scores for bronchiolitis, reliability and validity have not been adequately established (Destino et al., 2012, p. 203). Ralston (2014) also added that these scores may vary from observer to observer and do not correlate with more objective measures such as spirometry. However, the majority of children in the outpatient setting are incapable of
performing spirometry and the preponderance of studies found in this literature review did not use spirometry as an outcome measure. Thus, according to the body of evidence, some clinicians believe that the AAP Guideline does not appear to reflect routine practice and therefore implementation of these KAS remains variable (Johnson et al., 2013; Mittal et al., 2014 and Zamora-Flores et al., 2015). Some researchers have explored the clinical outcomes of children who have been treated with nebulized albuterol versus nebulized racemic epinephrine (Walsh et al., 2008) and concluded that for patients who received albuterol, successful discharge from the emergency department was more likely. Finally, although Ralston et al. (2014) recommended avoidance of the use of all bronchodilators, some studies are demonstrating a synergistic effect of nebulized bronchodilators and systemic corticosteroids with subsequent improvement in clinical outcomes (Plint et al., 2015).

**Disease Resolution and Length of Stay**

The course of illness for bronchiolitis varies and can last as long as two to three weeks (Ralston et al., 2014). The longevity of this viral illness prompts some researchers to use length of stay in the hospital or days of illness as variables of measurement when assessing bronchiolitis treatments. Indeed, Ralston and his colleagues found that the time to disease resolution, need for hospitalization, and length of stay for children hospitalized were not significantly improved through the use of bronchodilators. Petruzella (2010) also examined duration of illness in infants with first time bronchiolitis who presented to the emergency department. In this prospective cohort study of infants less than 12 months of age (n=95), the researcher measured the time from the onset of symptoms of illness to the resolution of the illness. Petruzella (2010) considered the illness resolved when the patient was free from cough for a 24 hour period. This researcher demonstrated that the median time to resolution of symptoms was 15 days, and 25% of the
infants continued to be symptomatic at day 20 of illness.

Condella and colleagues (Condella et al., 2018) conducted a multicenter study of albuterol use among infants hospitalized with bronchiolitis. The authors posited that the AAP’s 2014 Guideline recommendation to avoid albuterol lead to wide-sweeping variation in clinician practice. Condella et al. argued that the analyses used by the AAP were limited by significant heterogeneity, small sample sizes, and lacked standardized outcomes. According to Condella and colleagues, their results showed that there are subgroups of children who clinicians will preferentially treat with albuterol (children ≥2 months of age and children who were wheezing). While the authors acknowledged that the AAP based their recommendation against albuterol use on the lack of an appropriate objective measure to assess a response of bronchiolitis to a bronchodilator, they argued that the use of such tools to measure clinical scores post-bronchodilator are yet to be widely adopted. Condella et al. concluded by stating that “our inability to measure a benefit does not mean it is insignificant” (Condella et al., 2018, p. 482).

Other researchers (Heikkinen et al., 2017) have explored the duration of bronchiolitis illness and the resultant clinical, social, and financial burden. In a prospective cohort study of children ≤13 years of age during two respiratory seasons in Finland, they measured 2231 child-seasons of follow up for bronchiolitis. Using symptom diaries, the researchers calculated the mean duration of illness for children less than three years of age as 13.0 +/- 7.8 days. For children ages 3-6 years, the duration dropped slightly to 10.5 +/- 6.5 days. Heikkinen and colleagues (2017) also measured parental work absenteeism, a novel metric that had not appeared in the earlier literature review. Their data showed that for parents of children less than three years of age, an average of at least one or more days of work was missed with a mean rate of 2.6 days.
Other than Heikkinen (2017), few studies focused on the outpatient child with bronchiolitis and the impact on the health care utilization and parental days missed from work. This likely represents a gap in the literature. Luo et al., (2014) agreed and stated that there is a lack of published data regarding predicting, in the primary care setting, whether a bronchiolitis patient will need hospitalization, urgent care, or emergency department services for the bronchiolitis within the near future.

Hospitalizations

As stated earlier, bronchiolitis is a common cause of pediatric hospitalization and for this reason, this measurement appears frequently in the research literature. Although several organisms play a role in pediatric bronchiolitis, RSV is the most common and is well-represented in the literature as a leading cause of hospitalization. Hall et al. (2013) analyzed data from a five-year prospective population based surveillance for children who were hospitalized with laboratory confirmed RSV from October 2000-2005. Hall and colleagues found that of the 2149 children enrolled, 26% were infected with RSV and therefore eligible for inclusion. The average rate of RSV hospitalization in this group was 5.2 per 1000 children < 24 months of age. However, in the younger group (infants ≤1 month of age), the hospitalization rate was 17.9 per 1000 children. Hall et al. (2013) added to the general body of knowledge about RSV hospitalizations with an even more sobering statistic. Most of the children hospitalized (79%) were previously healthy and only 3% of those hospitalized were very preterm infants (< 30 weeks gestation).

Use of Corticosteroids

Bronchiolitis involves acute inflammatory changes of the bronchioles regardless of the causative agent (Fernandes et al., 2013). Although it is reasonable to assume the use of
corticosteroids (ant-inflammatory medications) would help with this pathophysiologic process, Ralston et al. (2014) stated clinicians should not administer systemic corticosteroids for children with bronchiolitis in any setting. Citing a Cochrane systematic review (Fernandes et al., 2013), Ralston and colleagues (2014) maintained that corticosteroids do not significantly reduce outpatient admissions when compared to placebo. However, some researchers (Lehtinen et al., 2007) investigated the effects of prednisolone, an oral steroid, for children with a first wheezing episode following a rhinovirus infection or eczema. Recall that rhinovirus is one of several etiologic agents responsible for pediatric bronchiolitis. Lehtinen and colleagues (2007) investigated the rates of recurrent wheezing following a rhinovirus-induced bronchiolitis. Citing a gap in the literature, the authors recognized that while RSV is the most common virus responsible for bronchiolitis, rhinovirus is the second most common virus associated with the illness and can trigger wheezing in as many as 45% of cases. Lehtinen (2007) and his team conducted a prospective 1-year follow up of a cohort of children age three to 35 months who had experienced a first time wheezing episode. In a randomized double-blinded study, the researchers measured 118 children’s symptoms prospectively and found that prednisolone decreased the probability of recurrent wheezing in children with exam but not in those without eczema. Also, prednisolone was associated with less recurrent wheezing in the rhinovirus group but not in the RSV group.

Other researchers (Jartti et al., 2006 and Jartti et al., 2015) examined the role of systemic corticosteroids in the treatment of early childhood wheezing. In his 2006 research, Jartti and colleagues sought to determine whether prednisolone was effective in rhinovirus-induced early wheezing. In a randomized, double-blinded placebo-controlled study, hospitalized children (n=78) with bronchiolitis received either oral prednisone or placebo. Children were included if
they were experiencing their first or second episode of wheezing induced by rhinovirus or RSV. The researchers found that prednisolone did not influence the time until ready for discharge, but it did decrease relapses during the subsequent two month period in rhinovirus affected children.

In a 2013 randomized, placebo-controlled study of 200 healthy infants diagnosed with bronchiolitis, Alansari (Alansari et al., 2013) and colleagues compared the efficacy and safety of dexamethasone (an oral steroid) with placebo for acute bronchiolitis who were identified as being at risk for asthma based upon a family history of asthma in a first-degree relative. In this study, all participants were treated with inhaled salbutamol (a bronchodilator). Alansari et al. found that the use of an oral steroid (Dexamethasone) was associated with a shortened time to discharge in children with eczema or a family history of asthma in a first – degree relative. However, it is important to note that all of the patients enrolled in this study received inhaled bronchodilator therapy (Salbutamol) (Alansari et al., 2013).

In 2015, Jartti et al. published another study examining the short and long-term efficacy of prednisolone for first acute rhinovirus induced wheezing. In this randomized, double-blinded placebo-controlled study, children (n=74) there was no statistically significant difference between the two groups for occurrence of new episode of wheezing within two months, number of physician confirmed wheezing episodes within 12 months, or initiation of a regular controller medication for asthma symptoms within 12 months. However, the group who received prednisolone had less cough, rhinitis, noisy breathing, severe breathing difficulties, and nocturnal respiratory symptoms at home within two weeks of treatment.

Adherence to Clinical Practice Guidelines

Given the high burden of disease from bronchiolitis and the controversy and variance associated with medical management of children with this illness, it is important to consider how
clinical practice guidelines are utilized and represented in the literature. Touzet et al., (2007) conducted a quasi-experimental quantitative survey of physicians in France that employed a pre/post design with the first survey one year before the consensus development conference and the second survey one year after the consensus development. The researchers measured use of bronchodilators in the office setting, decisions to hospitalize or transfer the child to the emergency department, prescriptions for antibiotics, and laboratory or radiology studies ordered. In Touzet’s study, there was a significant decrease in the number of prescriptions written for bronchodilators, corticosteroids, and antibiotics. The aim of Touzet’s 2007 study was to measure the impact of a national consensus guideline on the clinical practices of primary care pediatricians and general practitioners and thus clinical outcomes data for the children enrolled in the study were not presented. However, Touzet reminded the reader that “non-adherence to guidelines does not necessarily imply inappropriate medical decisions” (Touzet et al., 2007, p. 655). Additionally, Touzet stressed that the aim of the clinical practice guideline (CPG) was not to reduce medical practices to a strict adherence but “rather help practitioners evolve in their approach to bronchiolitis care” (Touzet et al., 2007, p. 655).

Zamora-Flores and colleagues (2015) also examined the effect of adherence to a CPG for the treatment of bronchiolitis in their high risk Hispanic pediatric population. In an effort to decrease costs and the number of diagnostic evaluations performed as well as medications used, the authors implemented a teaching program for clinicians which incorporated the 2006 AAP Bronchiolitis Guideline. Utilizing a retrospective chart review of 322 patients admitted to a rural community hospital, the researchers found statistically significant decreases in cost per day and decreases in both the use of antibiotics and chest x-rays in the post –CPG cohort. However, the authors admit that because of the retrospective chart review design, some data was lacking such
as family and environmental factors that may have put their population at a higher risk. Furthermore, consistency was lacking in their data regarding issues of prematurity, exposure to tobacco smoke, parental age, or family history of asthma.

**Rationale for the Project**

Bronchiolitis represents a significant health burden in the US and abroad. The multitude of hospitalizations related to bronchiolitis stress the health care resources of the US and contribute to rising healthcare costs. However, it is not only hospitalizations for bronchiolitis that are increasing health care spending. With an estimated 2.1 million outpatient visits associated with bronchiolitis in the US each year for children less than five years of age (Hall et al., 2013), bronchiolitis is an expensive pediatric illness. It is evident that from a national and international perspective, the pediatric bronchiolitis clinical practice guidelines do not reflect the actual medical management in primary, emergent, or hospital settings. This variation in practice may be the result of a lack of agreement on the definition of bronchiolitis, the use of multiple clinical scoring systems, and the use of outcome measures that are not easily extrapolated to the outpatient setting.

However, it is also possible that in the supporting studies used to formulate the 2014 AAP Guideline, the inclusion of a heterogeneous population of children (Condella et al., 2018) may have resulted in inconsistent results that are lacking applicability to the outpatient setting. Everard (2009) reminded the reader that for infants and children with bronchiolitis, there are likely two groups. As discussed earlier, some children with bronchiolitis have simple mucus plugging and obstruction. Others, however, are likely phenotypically different, are pre-disposed to asthma, and may develop obstruction from bronchospasm. The second group would respond favorably to bronchodilator and/or corticosteroid therapy while the first group would not
(Everard, 2009). In an effort to increase knowledge related to the clinical outcomes of infants and children with bronchiolitis whose treatment plan adhered or did not adhere to the 2014 Guideline, it is this clinician’s aim to quantify these clinical outcomes both before and after the issuance of the Guideline and compare the two cohorts by examining the clinical outcomes and calculating the comparative effectiveness of treatment modalities.

**Conclusion**

This chapter addressed the methodology utilized in the review of the literature for this scholarly project. Criteria for a detailed search were presented, including the search databases used and the relevant search terms and criteria. The 10 articles chosen for inclusion met the search criteria and were relevant to the PICOT question. Synthesis of the information found in these studies was provided and thematic trends were noted. The issues of bronchodilator and corticosteroid avoidance, reducing days of illness or length of stay in the hospitalized child, and clinician adherence to the Guideline represented trends appearing in the current literature. Other trends noted included the avoidance of corticosteroids and clinician adherence to clinical practice guidelines. These thematic trends were discussed and provided the background and rationale for the DNP scholarly project.
Chapter III - Methods

Background

After a review of the literature for the management of pediatric bronchiolitis, it was observed that most outcome metrics for this phenomenon are measured in emergency department or hospital settings. For these reasons, this study focused on outcome measures more applicable to the children with bronchiolitis in an outpatient setting.

For comparative purposes, identical outcome metrics were identified for eligible children in 2013 treated in the primary outpatient clinic (one year prior to the publication of the 2014 Guideline). In 2013, clinicians who cared for children with bronchiolitis utilized the clinical recommendations suggested by the American Academy of Pediatrics 2006 Diagnosis and Management of Bronchiolitis, hereafter referred to in this paper as the 2006 Guideline ("2006 Diagnosis and Management," 2006). Subtle differences existed in the medical management recommendations for children with bronchiolitis prior to the publication of the 2014 Guideline and, for the purposes of clarification of describing the cohorts, these differences are explained below in Table 1. These subtle differences were acknowledged, discussed with a statistician, and will be accounted for in the analysis of data.

Table 1

Guideline Differences from 2006-2014

<table>
<thead>
<tr>
<th>KAS #2</th>
<th>KAS #5</th>
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</thead>
<tbody>
<tr>
<td>2006 Guideline</td>
<td>Avoid routine use of bronchodilators (albuterol or salbutamol)</td>
</tr>
<tr>
<td>2014 Guideline</td>
<td>Avoid any use of bronchodilators (albuterol)</td>
</tr>
</tbody>
</table>
Although 14 Key Action Statements were included in the 2014 *Guideline*, clinician adherence to two of these statements (KAS #2: “clinicians should not administer albuterol or salbutamol to infants and children with a diagnosis of bronchiolitis”, and KAS #5: “clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting” (Ralston et al., 2014)) were identified as the independent variables for this retrospective cohort analysis. The multiple clinical outcomes (identified in chapter I) experienced by each cohort member were thus identified as the dependent variables.

**Design and Implementation Plan**

This study is a descriptive, retrospective cohort analysis which explores the impact of variation in clinician guideline adherence on the clinical outcomes of infants and children, aged 1-23 months, who have been diagnosed with bronchiolitis. To ascertain the effects of variation in guideline adherence, the researcher examined the comparative effectiveness of the use of albuterol, salbutamol, oral steroids, symptomatic home management, and/or complementary therapies for children who were clinically diagnosed bronchiolitis and who were treated in the outpatient setting. Comparative effectiveness was ascertained by the collection and analysis of relevant outcomes data from the year prior to the publication of the 2014 *Guideline* and for the four years following the *Guideline*’s release. The use of Electronic Health Records (EHR) was utilized to extract the outcome variables for this population. Then, the outcome variables relevant to children with bronchiolitis in the outpatient setting were compared statistically to determine the clinical effectiveness of the use of albuterol, oral steroids, symptomatic home management, and/or complementary therapies for the treatment of pediatric bronchiolitis.
Sample and Sampling Plan

Determination of Sample Size

A preliminary power analysis was conducted by the researcher and statistician using G* Power. An acceptable power level of 0.80 was agreed upon. Based upon the power analysis, a sample size of 196 patients in each cohort was recommended and this goal was communicated with the data extractor. The two cohorts were categorized as children treated for bronchiolitis during the pre-2014 Guideline period and children treated for bronchiolitis during the post-2014 Guideline period.

Project Instruments

Extraction Tool

An investigator-created clinical extraction tool was developed to capture the clinical outcome metrics of interest and all data on this tool was extracted from the electronic health record (EHR) by one Registered Nurse extractor who was trained in the usage of this tool. Following the review of the literature, pertinent clinical outcomes variables were identified for children with bronchiolitis treated in the outpatient setting. These variables were then added to an Excel document to form the clinical extraction tool. Data entries were added in numerical or text format and all text formats were assigned corresponding numerical values for the purposes of statistical analyses. The strengths of using EHR data have been explicated in current literature as being relatively inexpensive and an efficient source of collecting secondary data which can prove to be invaluable in healthcare research (Bailey et al., 2013).

However, due to the inherent difficulties posed by retrospective chart analyses and the probability of some clinical information being entered in a narrative format in the patient’s chart, a Registered Nurse who is familiar with both the EHR software and pediatric clinical
terminology functioned as the honest broker in data extraction. Prior to implementation of the
data extraction, a short educational meeting was conducted with the data extractor to explain the
primary and secondary aims of the project. The use of the extraction tool was clarified and
eligibility criteria for inclusion were reinforced.

**Procedures**

**Pilot Study**

The data extractor pulled a sample of 10 charts and the outcomes metrics gleaned from
those 10 charts were entered into the data extraction tool for the researcher’s review. This pilot
sample was conducted to determine the success of the novel investigator-created data extraction
tool as a feasible means of collecting relevant retrospective clinical outcome metrics data.

Finally, prior to review of the data, the data extractor removed all identifying pieces of
information for each patient and the completed data extraction tool was then presented to the
principal investigator (PI). Aggregate data for each metric in the extraction tool was noted and
each metric was delineated by the year the outcome occurred.

**Project Sponsors and Resources**

The pediatric practice chosen for this analysis both supported and encouraged this
educational effort and the clinicians were receptive to the purpose of the study. Additionally, the
practice endorsed the participation of their Registered Nurse/data extractor as an “honest broker”
for this study.

**Human Subject Review**

The researcher completed the Collaborative Institutional Training Initiative (CITI)
Program for social and behavioral research prior to the implementation of this DNP project. The
benefits of this project were reviewed with the medical director of the study site and were cited
as adding to the body of knowledge related to the clinical outcomes for children with bronchiolitis preceding and following the issuance of the 2014 Guideline. Written approval was then obtained from the medical director of the study site.

This project has inherent value in that it can glean important outcomes data that can be used to determine the comparative effectiveness of bronchodilator, oral steroid, or complementary therapy use in children with bronchiolitis in the outpatient primary care setting. There is a paucity of randomized, controlled trials for pediatric bronchiolitis patients in the outpatient setting specifically regarding medical management. This knowledge gap can be addressed through the use of well-designed cohort descriptive studies.

Anonymity of the patients was maintained by having all data de-identified by the honest broker prior to presenting it to the researcher. The Georgetown Institutional Review Board (IRB) determined that the study did not meet criteria for human subject research. Although no formal IRB approval was required at the practice site, a formal site approval letter was signed by the medical director and submitted to the faculty mentor at Georgetown University prior to implementation of the project.

**Population**

The convenience sample included pediatric patients enrolled in a large primary care practice in the Mid-Atlantic region of the United States.

Inclusion criteria:

- Infants and children, ages 1-23 months, clinically diagnosed with bronchiolitis prior to October 2015, as evidenced by the *International Classification of Diseases 9th Revision* (ICD 9) codes 466.19 (acute bronchiolitis due to other infectious organisms), 466.11 (acute bronchiolitis due to RSV), and 079.6 (respiratory syncytial virus)(Centers for Disease

- For the time period after October 2015, infants and children, ages 1-23 months, clinically diagnosed with bronchiolitis as evidenced by the *International Classification of Diseases 10th Revision* (ICD 10) codes J21.9 (acute bronchiolitis, unspecified), J21.0 (acute bronchiolitis due to respiratory syncytial virus), and J21.8 (acute bronchiolitis due to other specified organisms) (Centers for Disease Control and Prevention: International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Website, 2018).

  Exclusion criteria:

- Any child not meeting the age criteria or ICD 9 or ICD 10 diagnostic criteria. Additionally, exclusion criteria include children with immunodeficiencies, underlying respiratory illnesses such as recurrent wheezing, chronic neonatal lung disease, neuromuscular disease, cystic fibrosis (CF), or hemodynamically significant congenital heart disease (CHD).

**Procedures and Timeline**

The research proposal was submitted for IRB consideration to Georgetown University in December, 2017. Additionally, a one hour training session was held with the data extractor in December 2017 in preparation for the proposed pilot sample of 10 patients. Following review of the pilot data, the data extraction tool was deemed reflective of the desired content by the researcher. After IRB approval was obtained in April, 2018, the medical director and office administrator were reminded in writing of the DNP scholarly project and the impending use of EHR data as discussed in the project site agreement document. The Georgetown IRB approval number was included in the letter’s content.
Data extraction was initiated in May 2018 and completed in September 2018 and targeted eligible patient records from 1 October 2013 through 1 April 2018 for analysis. Although bronchiolitis has a seasonal predilection in the site’s Mid-Atlantic region, with an increased incidence in October through March, sporadic cases do occur in the remaining months and a decision was made to include all months in the retrospective cohort analysis in an effort to capture more data. Based upon the pilot study’s time analysis, it was estimated that a total of two hours was needed to extract data for each month and consequently, a total of six hours per week was allotted for data extraction for a total of approximately 16 weeks.

Following the data extraction, the data was de-identified by the honest broker and presented to the researcher for review and analysis via electronic password-protected email with the data extraction tool as an attachment.

**Instruments and Tools**

The data extraction tool was developed in Microsoft Excel and included both demographic metrics and pertinent outcome metrics for the pediatric population with bronchiolitis.

**Outcome Measurements**

Several outcome measures or metrics were included in this analysis with the principal aim of identifying what effect(s), if any, adherence or non-adherence to the 2014 Guideline statements had upon the health outcomes of children with bronchiolitis in the outpatient setting. In addition to the demographic measures (age at time of diagnosis), other metrics were added and can be grouped thematically. These themes include pharmacotherapies, health care resources, and family history.
Pharmacotherapies
Pharmacotherapy metrics measured included whether or not inhaled albuterol, inhaled salbutamol, or oral steroids were used during the course of the bronchiolitis illness. If any of these pharmacotherapies were used, the number of days of use was then measured.

Health Care Resources

Another emerging theme included the use or over-use of health care resources and for this reason, the number of outpatient visits, urgent care visits, emergency department visits, and hospitalization episodes was measured in this population as a simple tally of any episodes of use of these resources within 14 days of the bronchiolitis diagnosis. Additionally, the use of imaging modalities such as chest x-rays was added to the metrics measured. Due to the population included in this research project, the metric “complementary/other therapies” was added in an effort to capture other potential treatment modalities and again tallied on the data extraction tool and assigned a corresponding numerical value for the purposes of statistical analyses.

Family History

Finally, because the literature suggests that a family history of atopy may be predictive in identifying children for whom bronchiolitis can become a severe, life-threatening illness, this metric was added under the “family history” theme.

Data Analysis Plan

In order to address the primary and secondary aims of this study, descriptive statistics including frequency distributions, means, and standard deviations were calculated. Additionally, inferential statistics were used to examine what effect, if any, the use of albuterol and/or prednisone had on the rate of hospitalization and the use of emergency department or urgent care services.
The initial data analysis included the use of descriptive statistics to describe the group of children included in the retrospective analysis. Specifically, descriptive statistics were utilized to capture sample characteristic metrics including the age of the child at the time of the bronchiolitis diagnosis, the month and year at the time of the diagnosis, and the use or non-use of pharmacotherapy at the time of the diagnosis of bronchiolitis or within 14 days of the diagnosis. The clinician’s use of pharmacotherapies such as albuterol or oral steroids, in alignment with the PICOT question, was measured as was the parental use of complementary measures such as nasal saline, humidifiers, and over-the-counter (OTC) or herbal remedies. Family history of atopic illnesses were also elucidated via the use of descriptive statistics. Finally, outcome metrics aimed at capturing healthcare utilization were measured to include the use of chest x-rays and visits made to a healthcare provider within 14 days of the bronchiolitis diagnosis. These visits included urgent care visits, emergency department visits, and hospitalization episodes and were analyzed through the use of descriptive statistics. Following the analysis of data using descriptive statistical measures, chi square tests of independence and independent sample t tests were used to examine differences in outcomes by treatment modalities. Finally, a regression analysis was performed to determine what variables, if any, had the largest impact on the utilization of healthcare for children with bronchiolitis who met the inclusion criteria.
Chapter IV - Results

The results of this retrospective chart analysis will be described in this chapter. The characteristics of the sample, both pre and post-2014 cohort, will be described and evaluated utilizing both descriptive and inferential statistical analyses. Additionally, the intervention and outcomes metrics will be analyzed and compared.

Primary and Secondary Aims

The DNP scholarly project had one primary aim and one secondary aim. The primary aim was to indirectly examine clinician adherence to the 2014 AAP Guideline by measuring outcomes metrics to scrutinize the comparative effectiveness of the use of albuterol, oral steroids, symptomatic home management, and/or complementary therapies for children who had clinically diagnosed bronchiolitis and were treated in the outpatient setting. The secondary aim of this DNP scholarly project was to determine the treatment modality that had the greatest impact on the clinical outcomes for infants and children with bronchiolitis.

Population Metrics

Characteristics of the Sample

For the time period one year prior to the publication of the 2014 Guideline and for the four years subsequent to the publication, a total of 245 electronic medical records met the inclusion criteria and their data were analyzed for this study. This sample (N = 245) was comprised of infants and children ages 1-23 months of age who were seen in one primary care outpatient setting. Of these 245 children, the mean age at time of the bronchiolitis diagnosis was 7.4 months (SD 4.6). Additionally, 131 (53.5%) were male and 114 (46.5%) were female. Finally, the sample was divided into the pre-2014 Guideline publication cohort and the post-2014 Guideline cohort.
**Pre-2014 cohort.** The mean age of children at the time of the bronchiolitis diagnosis in the pre-2014 group was 6.0 months (SD 3.6). Of this group, 31 (51.7%) were male and 29 (48.3%) were female. Family history of atopic illness was collected and was found in 26 (43.3%) of the pre-2014 cohort. Ethnicity was specifically not collected in order to eliminate possible identifiers from the sample set.

**Post-2014 cohort.** Of the 245 records meeting inclusion criteria, 185 were from the 2014-2018 period. The mean age of children at the time of the bronchiolitis diagnosis in the post-2014 group was older, at 7.8 months (SD 4.7). Of this post-2014 group, 100 (54.1%) were male and 85 (45.9%) were female. A family history of atopic illness was found in 96 (51.9%) of the post-2014 cohort.

**Comparison.** There was no significant difference in the gender mix from the pre-2014 cohort and the post-2014 cohort ($\chi^2 (1) = 0.104, p = .747$). Similarly, there was no difference between the pre-2014 and post-2014 groups in family history of atopic illness ($\chi^2 (1) = 1.327, p=.249$). There was, however, a statistically significant difference in the age of children between the two groups. Children in the post-2014 *Guideline* group were significantly older (7.8 months) than those from the pre-2014 group (6.0 months), $t (243) = 2.799, p = .006$. (Table 2).
Table 2

Characteristics of the Sample. (N = 245)

<table>
<thead>
<tr>
<th></th>
<th>Pre-2014 Guideline (n=60)</th>
<th>Post-2014 Guideline (n=185)</th>
<th>Total (N=245)</th>
</tr>
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<td></td>
<td>n</td>
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<td>n</td>
</tr>
<tr>
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<table>
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<td>4.6</td>
</tr>
</tbody>
</table>

**Intervention Metrics**

**Use of Albuterol Metric**

Of the 245 patient records included in the study, 128 children (52.2%) ages 1-23 months were identified as having either used inhaled albuterol at their office visit or had a prescription for inhaled albuterol given to their caregiver for home use. If albuterol was used, the total number of days in this group was 17.3. (SD = 12.0). Additionally, there was no difference in the prescription of albuterol by gender of the child in either the pre-2014 cohort ($\chi^2 (1) = 1.993; p = .158$) or the post-2014 cohort ($\chi^2 (1) = 0.159; p = .690$). Similarly, the age of the child, regardless of the cohort, was not found to be a statistically significant factor in whether or not albuterol was used. For the total sample, the mean age of those prescribed albuterol was 7.6 months (SD = 4.7) compared to 7.12 months (SD = 4.3) for those not prescribed albuterol ($t (243) = 0.787, p =$
A family history of atopic illnesses such as eczema, allergic rhinitis, or asthma, was also not found to be associated with increased use of albuterol. For the total sample, 49.6% of children with no family history of atopy and 54.9% of those with a family history of atopy were prescribed albuterol, $\chi^2 (1) = 0.696; p = .404$.

**Pre-2014 cohort.** In the year prior to the 2014 *Guideline* publication, 63.3% of children who met inclusion criteria and were diagnosed with bronchiolitis in the study site received an inhaled bronchodilator (albuterol) either during their office visit or as a prescription for home use following the diagnosis. If albuterol was prescribed in this group, the mean number of days prescribed was 15.6 (SD = 12.8).

**Post-2014 cohort.** Following the publication of the 2014 *Guideline*, 90 of the 185 children (48.6%) who met inclusion criteria and were diagnosed with bronchiolitis in the study site received an inhaled bronchodilator (albuterol) either during their office visit or as a prescription for home use following the diagnosis. If albuterol was prescribed in this group, the mean number of days prescribed was 18.1 (SD = 11.6).

**Comparison.** There was a statistically significant decrease in prescriptions for albuterol (63.3% under the pre-2014 *Guideline* group) versus 48.6% under the post-2014 *Guideline* group, $\chi^2 (1) = 3.913, p = .048$. However, among those prescribed albuterol, there was no difference in the number of the days of the prescription from the pre to post 2014 groups (15.6 days vs 18.1 days, $t (124) = 1.069, p = .287$). Additionally, there was no difference in the prescription of albuterol by gender of the child in either the pre-2014 cohort ($\chi^2 (1) = 1.993; p = .158$) or the post-2014 cohort ($\chi^2 (1) = 0.159; p = .690$). Similarly, the age of the child, regardless of the cohort, was not found to be a statistically significant factor in whether or not albuterol was used. For the total sample, the mean age of those prescribed albuterol was 7.6 months (SD = 4.7)
compared to 7.12 months (SD = 4.3) for those not prescribed albuterol ($t (243) = 0.787, p = .432$). A family history of atopic illnesses such as eczema, allergic rhinitis, or asthma, was also not found to be associated with increased use of albuterol. For the total sample, 49.6% of children with no family history of atopy and 54.9% of those with a family history of atopy were prescribed albuterol, $\chi^2 (1) = 0.696; p = .404$.

**Use of Oral Steroid Metric**

Of the 245 patient records included in the study, eight children (3.3%) who met inclusion criteria were identified as having used an oral steroid (prednisolone or dexamethasone) at their office visit or received a prescription for an oral steroid for home use. If an oral steroid was used, the mean number of days in this group was 5.1 (SD = 10.2). Of those prescribed prednisone, 12.5% were hospitalized compared to only 1.7% of those who were not prescribed prednisone, a statistically significant difference, $\chi^2(1) = 4.525, p = .033$.

**Pre-2014 cohort.** In the year prior to the 2014 Guideline publication, none of the 60 children who met inclusion criteria and were diagnosed with bronchiolitis in the study site received an oral steroid.

**Post-2014 cohort.** In the years following the 2014 Guideline, 8 of the 185 children (4.3%) met inclusion criteria and were diagnosed with bronchiolitis in the study site and received an oral steroid either during their office visit or as a prescription for home use following the diagnosis. If an oral steroid was prescribed, the mean number of days prescribed was 5.1 (SD = 10.2). It should be noted that four of the children received the oral steroid exclusively at the office visit and prescriptions for home use ranged from 3-5 days with only one child receiving a 30 day prescription for oral steroids.

**Comparison.** There was no statistically significant change in the use of prednisone
between the pre vs post 2014 *Guideline* groups; however, there were no prescriptions written for prednisone in the pre-2014 group ($\chi^2(1)= 2.682, p = .205$). Of note, however, 87.5% of those prescribed an oral steroid (prednisolone) were also prescribed albuterol.

**Home Management (CAM/OTC/Humidity or Saline) Metric**

Of the 245 patient records included in the study, 57 (23.3%) of children had documentation of reported use of an over-the-counter remedy. Additionally, 182 children (74.3%) had caregivers who used nasal saline and/or humidity for relief of their bronchiolitis symptoms. There were no reported use of herbal supplements or therapies in either cohort.

**Pre-2014 cohort.** In the year prior to the 2014 *Guideline* publication, 19 of the 60 included patients (31.7%) reported OTC preparations as complementary therapy. Fifty-four of the 60 patients (90%) utilized nasal saline and/or humidity measures.

**Post-2014 cohort.** In the years following the 2014 *Guideline*, 57 of the 245 children (23.3%) who met inclusion criteria and were diagnosed with bronchiolitis in the study site utilized OTC remedies and 182 (74.3%) utilized nasal saline and or humidity therapy.

**Comparison.** There was no statistically significant change in the percentage of children who used OTCs (31.7% under the pre-2014 *Guideline* group to 69.2% under the post-2014 *Guideline* group), $\chi^2 (1) = 3.142, p = .076$. However, there was a statistically significant drop in the percentage of children who used humidity from 90% pre-2014 to 69.2% post-2014, $\chi^2 (1) = 10.272, p=001$). (Table 3)
Table 3

**Characteristics of the Interventions**

<table>
<thead>
<tr>
<th></th>
<th>Pre-2014 Guideline (n=60)</th>
<th>Post-2014 Guideline (n=185)</th>
<th>Total (N=245)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Albuterol</td>
<td>38</td>
<td>63.3</td>
<td>90</td>
</tr>
<tr>
<td>Prednisone</td>
<td>0</td>
<td>0.0</td>
<td>8</td>
</tr>
<tr>
<td>OTC tx</td>
<td>19</td>
<td>31.7</td>
<td>38</td>
</tr>
<tr>
<td>Humidifier/Saline</td>
<td>54</td>
<td>90.0</td>
<td>128</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>M</th>
<th>SD</th>
<th>M</th>
<th>SD</th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days of albuterola</td>
<td>15.6</td>
<td>12.8</td>
<td>18.1</td>
<td>11.6</td>
<td>17.3</td>
<td>12.0</td>
</tr>
<tr>
<td>Days of prednisone</td>
<td>0</td>
<td>0.0</td>
<td>5.1</td>
<td>10.2</td>
<td>0.2</td>
<td>2.0</td>
</tr>
</tbody>
</table>

*If prescribed*

**Outcomes Metrics**

Outcome variables in the outpatient setting were compared to determine the clinical effectiveness of the use of albuterol, oral steroids, symptomatic home management, and complementary therapies for the treatment of pediatric bronchiolitis. Following the analysis of the data using descriptive statistical measures, a regression analysis was used to determine what variables, if any, had the largest impact on the utilization of healthcare for children with bronchiolitis who met the inclusion criteria.

For the time period one year prior to the publication of the 2014 *Guideline* and for the four years subsequent to the publication, a total of 245 electronic medical records were reviewed and outcomes metrics were compiled. Outcome metrics included the use of chest x-rays, the
number of outpatient visits within 14 days of the bronchiolitis diagnosis, the number of urgent care or emergency department visits within 14 days of the diagnosis, and the total number of hospitalizations for the child within 14 days of the bronchiolitis diagnosis. Additionally, if hospitalized, the length of stay (LOS) was calculated.

**Chest X-rays Metric**

There were no chest x-rays ordered in the 245 records sampled for this study. Although it is possible that the children included in both cohorts received chest x-rays as part of their bronchiolitis evaluations in the emergency department or urgent care settings, these records were not able to be obtained in this analysis.

**Number of Outpatient Visits Metric**

The number of outpatient visits ranged from zero to four visits within 14 days of the bronchiolitis diagnosis. Of the total number of patients (N = 245), the mean number of outpatient visits was 1.2 visits (SD = 0.9) within 14 days of the bronchiolitis diagnosis. Those children who were prescribed albuterol had a statistically higher average number of outpatient visits (M = 1.34, SD = .91) than those not prescribed albuterol (M = 0.99, SD = .89), t (243) = 3.068, p = .002. Of those prescribed albuterol, 84.4% had at least one outpatient visit while 68.4% of those not prescribed albuterol had at least one outpatient visit within 14 days of the bronchiolitis diagnosis.

**Pre-2014 cohort.** In the year prior to the 2014 *Guideline* publication, the mean number of outpatient visits was 1.4 visits (SD = 0.9) for the 60 included patients. This metric included any outpatient visits occurring within 14 days of the bronchiolitis diagnosis.

**Post-2014 cohort.** In the years following the 2014 *Guideline* publication, the mean number of outpatient visits was 1.1 visits (SD = 0.9%) for the 185 included patients.
Number of ED or Urgent Care Visits Metric

Of the total number of patients (N = 245), the mean number of Emergency Department (ED) or Urgent Care visits was 0.03 (SD = 0.17) visits within 14 days of the bronchiolitis diagnosis. Using chi squared test of independence, no statistically significant difference was found in the likelihood of having an ED visit within 14 days of a bronchiolitis diagnosis, $\chi^2 (1) = 1.063, p = .303$. Of the children who were prescribed albuterol, 3.9% had one ED visit within 14 days of the bronchiolitis diagnosis as did 1.7% of those who were not prescribed albuterol.

Pre-2014 cohort. In the year prior to the 2014 Guideline publication, the mean number of ED or Urgent Care visits was 0.05 (SD = 0.22).

Post-2014 cohort. In the years following the 2014 Guideline, the mean number of ED or Urgent Care visits for the 185 included patients was 0.02 (SD = 0.15).

Number of Hospitalizations Metric

For the total number of patients (N = 245), the total number of patients hospitalized within 14 days of the bronchiolitis diagnosis was 5 (2.0%).

Pre-2014 cohort. In the year prior to the 2014 Guideline publication, none of the 60 patients who met inclusion criteria were hospitalized for bronchiolitis.

Post-2014 cohort. In the years following the 2014 Guideline, five of the 185 children (2.7%) who met inclusion criteria and were diagnosed with bronchiolitis in the study were hospitalized. The total number of days of hospitalization was 2.4 (SD = 0.5).
Table 4

*Characteristics of Outcomes Metrics*

<table>
<thead>
<tr>
<th>Metric</th>
<th>Pre-2014 Guidelines (n = 60)</th>
<th>Post-2014 Guidelines (n = 185)</th>
<th>Total (N= 245)</th>
</tr>
</thead>
<tbody>
<tr>
<td>hospitalized</td>
<td>n %</td>
<td>n %</td>
<td>N %</td>
</tr>
<tr>
<td>0</td>
<td>0.0</td>
<td>5</td>
<td>2.0</td>
</tr>
<tr>
<td><em>M</em> SD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>number outpatient visits</td>
<td>1.4</td>
<td>1.1</td>
<td>1.2</td>
</tr>
<tr>
<td>number ED visits</td>
<td>0.05</td>
<td>0.02</td>
<td>0.03</td>
</tr>
<tr>
<td>number of days hospitalizedb</td>
<td>0</td>
<td>2.4</td>
<td>2.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There was no statistically significant difference in hospitalization from the pre-2014 to post-2014 Guideline, $\chi^2 (1) = 1.655$, $p = .198$. However, it should be noted that the number of hospitalizations were so small that the cell size assumption for chi squared was not met so the test results should be viewed with caution. The metrics “number of outpatient visits, number of ED visits, and number of days hospitalized” are all highly skewed, therefore the nonparametric Mann Whitney test was used for comparisons. The number of ED visits and number of days hospitalized did not differ significantly from pre- to post-2014 Guideline, Mann Whitney $U = 5392.5, Z = 1.44$, $p = .253$ and Mann Whitney $U = 5400.0, Z = 1.285, p = .199$, respectively.

bIf hospitalized
Additionally, there were significantly more outpatient visits pre-2014 *Guideline* than post, Mann Whitney $U = 4617, Z = 2.086, p = .037$.

**Albuterol Use and Hospitalization**

Of those who were prescribed albuterol, 2.3% were hospitalized within 14 days of being seen in the outpatient clinic compared to 1.7% of those who had not been prescribed albuterol. Using the chi square test of independence, there was no statistically significant difference in the likelihood of being hospitalized by use of albuterol, $\chi^2 (1) = 0.123, p = .726$. Using a chi square test of independence, there was no statistically significant difference in the likelihood of being hospitalized by use of albuterol, $\chi^2 (1) = 0.123, p = .726$.

**Albuterol Use and Emergency Department Visits**

Of those children who were prescribed albuterol, 3.9% had one ED visit within 14 days as did 1.7% of those who were not prescribed albuterol. Using a chi square test of independence, no statistically significant difference was found in the likelihood of having an ED visit within 14 days of being seen for those who used albuterol, $\chi^2(1) = 1.063, p = .303$.

**Albuterol Use and Outpatient Visits**

The number of outpatient visits ranged from zero to four within 14 days of being diagnosed with bronchiolitis in the outpatient clinic. Those who were prescribed albuterol had a statistically higher average number of outpatient visits ($M = 1.34, SD = .91$) than those not prescribed albuterol ($M = 0.99, SD = .89$), $t (243) = 3.068, p = .002$. Of those children who were prescribed albuterol, 84.4% had at least one outpatient visit while 68.4% of those not prescribed albuterol had at least one outpatient visit.
**Prednisone Use and Hospitalizations**

Only eight children were prescribed prednisone in the total sample. Of those prescribed prednisone, 12.5% were hospitalized compared to only 1.7% of those who were not prescribed prednisone, a statistically significant difference, $x^2(1) = 4.525, p = .033$. It should be noted that the child prescribed prednisone who was hospitalized had also been prescribed albuterol.

**Predicting the Number of Outpatient Visits**

The single outcome that differed by the use of an albuterol prescription was the number of subsequent outpatient visits. To further explore factors related to number of outpatient visits, a linear regression model with the total number of outpatient visits as the dependent variable was examined. The independent variables in the model included albuterol prescription, gender of child, and age of child. The model was statistically significant, $F(3, 241) = 4.159, p = .007$, indicating that the independent variables explain a statistically significant amount of variation in the outcome. Nevertheless, the amount of variation explained was small, $R^2 = .049$, just under 5%. Only the use of an albuterol prescription was a statistically significant predictor of the number of subsequent outpatient visits. Controlling for gender and age, having an albuterol prescription increased the number of outpatient visits by 0.36. Table 5 shows the regression results.
Table 5

*Predicting the Number of Outpatient Visits*

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>p</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuterol prescribed</td>
<td>0.363</td>
<td>.002</td>
<td>[0.137, 0.589]</td>
</tr>
<tr>
<td>Child is male</td>
<td>0.031</td>
<td>.791</td>
<td>[-0.196, 0.257]</td>
</tr>
<tr>
<td>Child age in months</td>
<td>-0.022</td>
<td>.090</td>
<td>[-0.046, 0.003]</td>
</tr>
<tr>
<td>Constant</td>
<td>1.128</td>
<td>.000</td>
<td>[0.853, 1.403]</td>
</tr>
</tbody>
</table>
Chapter V - Discussion of Findings

Overview

Prior to discussing the findings of this retrospective chart review, it is important to recall the clinical burden of bronchiolitis and the diagnostic challenges facing clinicians worldwide. Annually in the United States, 149,000 children are hospitalized for bronchiolitis and for the children less than two years of age, such as the group represented in this study, bronchiolitis hospitalization accounts for 18.8% of all hospitalizations (Pelletier, Mansbach, & Camargo, 2006). These hospitalizations are coupled with staggering financial burdens. From 2000-2009, the total charges for bronchiolitis hospitalizations were estimated to be $1.74 billion dollars in the US. (Hasegawa, Tsugawa, Brown, Mansbach, & Camargo, 2013). The ubiquitous nature of pediatric bronchiolitis coupled with the mounting financial drain on our healthcare system has contributed to bronchiolitis being the target of much clinical interest and research efforts, many of which have taken place in hospitalized children.

Worldwide, numerous clinical guidelines exist for the management of children with bronchiolitis (Australasian Bronchiolitis Guideline website, 2016; Baraldi et al., 2014; Friedman, Rieder, & Walton, 2014, &"NICE guideline," 2015) yet bronchiolitis as an illness entity continues to confound clinicians and cause controversy regarding management. It is likely that the heterogeneous definitions of bronchiolitis among these international clinical guidelines adds to clinician treatment variations regarding guideline recommendations (Drysdale, Green, & Sande, 2016). In 2014, in an effort to reduce practice variation, the American Academy of Pediatrics published the Clinical Practice Guideline: The Diagnosis, Management, and Prevention of Bronchiolitis (Ralston et al., 2014). Following its publication, there has been limited research examining the clinical and financial outcomes for children treated for bronchiolitis in the
outpatient setting.

Consequently, many bronchiolitis management decisions are made subjectively by clinicians and it is this subjectivity which leads to significant practice variation among hospitals and clinicians who care for children with bronchiolitis (Luo, Nkoy, Gesteland, & Glasgow, 2014). This descriptive, retrospective cohort analysis was done to indirectly examine clinician adherence to the 2014 AAP *Guideline* by examining the comparative effectiveness of the use of albuterol, oral steroids, symptomatic home management, and/or complementary therapies for children who had clinically diagnosed bronchiolitis and were treated in the outpatient setting. Comparative effectiveness was ascertained by the collection and analysis of relevant clinical outcomes data from the year prior to the publication of the 2014 *Guideline* and for four years after.

**The Sample**

This study found no difference in the gender mix between the pre and post 2014 *Guideline* cohorts. However, children in the post-2014 *Guideline* cohort were significantly older (7.8 months) than the pre-2014 cohort (6.0 months). Additionally, there were no differences in the history of family atopy between the two cohorts. Current literature regarding pediatric bronchiolitis frequently explores the younger age of the child at diagnosis and family history of atopy as possible predictors for a more severe course of illness. The statistically significant older post-2014 cohort may have future implications for research.

Age is not the only variable examined in current literature. Some researchers compare viral etiologies of bronchiolitis as predictors of illness severity. Compared with RSV-associated bronchiolitis, children with rhinovirus-associated bronchiolitis tend to be older (Mansbach et al., 2016). Although the 2014 *Guideline* advises against testing children with bronchiolitis for
viruses, there is emerging evidence that suggests that bronchiolitis is a heterogeneous condition with differing short and long-term outcomes, including pediatric asthma. In a secondary analysis of the 30th Multicenter Airway Research Collaboration prospective observational study of children hospitalized with bronchiolitis, Mansbach and colleagues posited that the different treatment modalities by clinicians at academic medical centers across the US is an “implicit acknowledgement by these treating clinicians that they consider bronchiolitis to be a heterogeneous respiratory illness” (Mansbach et al., 2016, p. 204). Noting that the viral etiology, specifically related to rhinovirus, likely contributes to bronchiolitis severity and long-term complications including asthma, Mansbach et al. suggested that the large-scale studies used to support the “no albuterol” recommendation were primarily in RSV-related bronchiolitis patient and should be replicated with children who have rhinovirus-related bronchiolitis. These repeat treatment trials may prove to be important in the management of children with bronchiolitis, because at this time, it is estimated that 40-50% of infants with severe bronchiolitis will later be diagnosed with asthma and for children with rhinovirus related bronchiolitis, this risk is exceptionally high.

This study also discovered that family history of atopic illnesses did not change prescribing habits for albuterol. In the pre-2014 cohort, 64.7% of children with no family history and 61.5% with a family history of atopy were prescribed albuterol ($p = .801$). In the post-2014 cohort, 43.8% with no family history and 53.1% with a family history of atopy were prescribed albuterol ($p = .206$). This finding concurs with that of Condella et al. who reported parental history of asthma did not significantly change the likelihood a child would receive albuterol for bronchiolitis (Condella et al., 2018).
Interventions: The Use of Albuterol

The results of this retrospective analysis indicated that there were some prescribing habit changes following the publication of the 2014 Guideline specifically related to the use of inhaled bronchodilators (albuterol). The data collection tool specifically measured the use of albuterol and, if used, the number of days prescribed. In this study group, there was a statistically significant decrease in the number of prescriptions written for albuterol ($\chi^2 (1) = 3.913, p = .048$) following the 2014 Guideline publication. However, among the pre and post-2014 cohorts, when albuterol was used, there was no statistically significant difference in the number of days the albuterol was prescribed (15.6 days vs 18.1 days, $p = 2.87$). It must be noted that the total number of albuterol prescriptions may not have been an accurate reflection of the actual total number of albuterol prescriptions. For children who returned to the clinic following the bronchiolitis diagnosis, it was not uncommon for a prescriber to then use albuterol in the subsequent days or weeks following the initial bronchiolitis visit but the data collection tool failed to capture these events.

The widespread use of albuterol or salbutamol for pediatric bronchiolitis remains common as evidenced by this study and the current literature (Caballero, Polack, & Stein, 2017; Condella et al., 2018, &Plint et al., 2015). Although the results of this study showed a decrease in overall albuterol use in the post-2014 cohort, albuterol use still was documented in 48.5% of infants and children included in the study. Similarly, in a large 17-center observational study of 1,016 infants less than a year of age who were hospitalized with bronchiolitis between 2011-2014, pre-admission albuterol use ranged from 23-84 % (Condella et al., 2018). In spite of the AAP’s 2014 Guideline publication, albuterol use in outpatient or emergency department settings remains high. Although the etiology behind the continued use of albuterol in children with
bronchiolitis is likely multifactorial, the evidence cited by the 2014 AAP for eliminating even a trial of albuterol in bronchiolitis is “limited to small studies with no standardized outcomes and no clear focus on albuterol or infants less than one year of age” (Condella et al., 2018, p. 480). Moreover, although the AAP Guideline did acknowledge that a subgroup of children may have some clinical benefits from the use of albuterol, this subgroup was not defined in the 2014 publication and attempts to define these “responders” to albuterol have tended to focus on the clinical setting at the time of bronchiolitis diagnosis or treatment.

Condella et al. argued that this subgroup has characteristics (age ≥ two months or ≥ 6-11.9 months, presence of wheezing at time of diagnosis, and prior use of a bronchodilator) and any guidelines that restrict the use of bronchodilators for all bronchiolitis patients without “specifically addressing these patient characteristics are not targeting a significant source of the variation they aim to reduce” (Condella et al., 2018, p. 481).

**Interventions: The Use of Oral Steroids**

The results of this analysis indicated that of the total sample (N = 245), oral steroids were used in eight children (3.3%) and that there was no statistically significant change in the use of prednisone between the pre-2014 and post-2014 cohorts. However, of note, there were no oral steroids prescribed in the pre-2014 cohort. Although the 2014 AAP Guideline recommended against the use of oral steroids for bronchiolitis, the use of such steroids persists. Utilizing a physician-survey, Plint and colleagues examined the prescribing practices for steroids in children who presented to Canadian pediatric emergency departments (Plint et al., 2015). For physicians caring for children with bronchiolitis, the survey revealed few respondents (2.6%) reported “always” using oral steroids while 62.8% reported they “sometimes” use steroids for pediatric bronchiolitis. Interestingly, Plint et al. found that corticosteroid use was influenced primarily by
the severity of the illness and, in 87% of steroid use, tended to be used as a combined therapy with epinephrine (a bronchodilator) (Plint et al., 2015).

This consideration of oral steroid as an adjunct to a bronchodilator to treat bronchiolitis is emerging in the current literature. Although the meta-analysis by Gadomski and Scribani (2014) did not support the use of oral steroids for pediatric bronchiolitis, the relationship between bronchiolitis and atopic asthma leads some researchers to explore the potential effects of oral steroids in bronchiolitis. Alansari and colleagues compared the efficacy and safety of an oral steroid (dexamethasone) with placebo for acute bronchiolitis in children who had eczema or who were at risk of asthma (Alansari et al., 2013). Asthma risk was defined as the child having eczema or having a first degree relative with asthma. Their findings supported the hypothesis that an oral steroid course (dexamethasone) reduced the time to discharge for patients with eczema or a family history of asthma \( (p = .015) \). The Alansari study reminded the clinician that for infants who present with bronchiolitis symptoms, a history of atopic illness may be predictive of a favorable response to an oral steroid and/or a bronchodilator course of treatment. Furthermore, the consideration that there may be a subgroup of children for whom either bronchodilator and/or steroid therapies may be effective reinforces the premise of Condella et al. who stressed that further trials would allow this subgroup to be more precisely defined (Condella et al., 2018).

**Interventions: The Use of Complementary Therapies**

The results of this retrospective analysis revealed that in the pre-2014 cohort, the use of a humidifier or nasal saline was reported in 54 of the 60 patients (90%). There was a statistically significant drop \( (p = .001) \) in the percentage who used humidifiers in the post-2014 cohort with 69.2% of patients reporting the use of these same modalities. However, there was no statistically
significant change in the percentage of patients who used OTCs or herbal remedies (31.7% in the pre-2014 cohort versus 20.5% in the post-2014 cohort, \( p = .076 \)).

Although the use of cool mist humidity is widely used for infants and children with bronchiolitis, the evidence to support this modality is lacking. It is posited that the use of humidified air helps children with bronchiolitis by decreasing their respiratory tract secretions and alleviating the symptoms of respiratory distress (Umoren, 2011). However, Umoren and colleagues concluded that due to the lack of studies comparing the effectiveness of humidity, there is insufficient evidence to make a practice recommendation for mist therapy in children with bronchiolitis.

The use of complementary and alternative medicine (CAM) such as herbal supplements was also explored in this study. Of the total population included in the study, there were no reported uses of herbal treatments or CAM. However, as stated before, effective pharmacotherapy for bronchiolitis is being closely scrutinized by clinicians and the use of bronchodilators and/or oral steroids is controversial and in opposition to the 2014 AAP Guideline. The use of CAM is gaining popularity and was examined in a 2017 systematic review by Kua and Huey Lee (Kua & Huey Lee, 2017). Of the 11 studies identified by the authors, eight were randomized controlled trials and three were cohort studies. The primary outcome examined was length of stay for children hospitalized for bronchiolitis. Only two CAM modalities reported significant benefit and those studies examined children treated with Chinese herbal medicine or Vitamin D. However, the authors reported that “systematic assessment of treatment efficacy is often complicated by the wide range of outcome measures used by investigators” (Kua & Huey Lee, 2017, p. 13).
Comparison of the Outcomes Metrics

Albuterol and Health Care Utilization Trends

A 2014 Cochrane Review of the use of bronchodilators including albuterol concluded that although there was limited and transient improvement following the use of such pharmacotherapies, the use of bronchodilators were of questionable clinical benefit (Gadomski & Scribani, 2014). However, in contrast to this study, Gadomski and Scribani utilized outcomes metrics that were more applicable to the hospitalized population, although some outpatient studies were included in their analysis. Unlike the studies utilized for Gadomski and Scribani’s meta-analysis, this study did not include pulse oximetry, length of illness, or length of hospital stay as outcome metrics.

However, similar to Gadomski and Scribani’s (Gadomski & Scribani, 2014) assertions, this study found that there was no statistically significant difference in the likelihood of a child being hospitalized whether or not they had used albuterol, $\chi^2 (1) = 0.123, p = .726$. Similarly, there was no statistically significant difference in the likelihood of a child having an emergency department visit within 14 days of being seen for bronchiolitis. The use of albuterol as a bronchodilator was, however, associated with an increased utilization of outpatient visits for children who received albuterol.

In their meta-analysis, Gadomski and Scribani also examined the utilization of healthcare resources related to albuterol use (Gadomski & Scribani, 2014). However, unlike this study, Gadomski and Scribani explored the use of bronchodilators such as albuterol or salbutamol and what effect, if any, they had on hospital admission rates, duration of hospitalization stay, the time to resolution of illness, and the effect on pulmonary function testing.

In their analysis, 11 inpatient and 10 outpatient studies were utilized. The authors
reported that for those groups, oxygen saturation did not improve with bronchodilators (MD -0.43, 95% confidence interval (CI) -0.92 to 0.06, n = 1242). Additionally, outpatient bronchodilator treatment did not reduce the rate of hospitalization (11.9% in bronchodilator group versus 15.9% in the placebo group, odds ratio (OR) 0.75, 95% CI 0.46 to 1.21, n = 710). Finally, inpatient bronchodilator treatment did not reduce the duration of hospitalization (MD 0.06, 95% CI -0.27 to 0.39, n = 349).

However, the effect estimates for inpatients (MD -0.62, 95% CI -1.40 to 0.16) were slightly larger than for outpatients (MD -0.25, 95% CI -0.61 to 0.11) for oximetry. A sub-analyses limited to nebulized albuterol or salbutamol among outpatients (nine studies) showed no effect on oxygen saturation (MD -0.19, 95% CI -0.59 to 0.21, n = 572), average clinical score (SMD -0.36, 95% CI -0.83 to 0.11, n = 532) or hospital admission after treatment (OR 0.77, 95% CI 0.44 to 1.33, n = 404) and adverse effects reported in those children who received bronchodilators included tachycardia, oxygen desaturation and tremors.

The authors of the meta-analysis, however, were clear that the analysis was limited by the small sample sizes and the lack of standardized study design and validated outcomes across the studies.

**Oral Steroid and Health Care Utilization Trends**

Of the eight children who were prescribed prednisone in this retrospective chart analysis, one (12.5%) was hospitalized. For the remaining 244 children who did not receive prednisolone or other oral steroid pharmacotherapies, only 1.7% were hospitalized which was a statistically significant difference, \( \chi^2 (1) = 4.525, p = .033 \). However, for the one child was received oral steroids who was also hospitalized, the use of albuterol as an adjunctive pharmacotherapy was utilized. Although these findings may lead one to conclude that the use of prednisone made it
more likely for the child to be hospitalized, this isolated finding may be confounded by the increased severity of the child’s bronchiolitis illness.

In contrast to these findings, Jartti et al. (Jartti et al., 2015) found no statistically significant difference in the number of outpatient clinic visits or hospitalizations within two months of discharge for infants with bronchiolitis. Jartti and colleagues (Jartti et al., 2015) also studied the use of oral prednisolone for infants with bronchiolitis for children with rhino-virus mediated bronchiolitis. The authors concluded that although prednisolone treatment cannot be routinely recommended for children with bronchiolitis, its use may be beneficial to a subgroup of children with high viral load (rhinovirus) at presentation. The 2015 Jartti et al. study also suggested that for children with bronchiolitis, the use of oral steroids was associated with a statistically significant decrease in cough (p = .002) and rhinitis (p = .008) two weeks after discharge. Ansari et al. (Alansari et al., 2013) examined the family history of atopic illnesses in relation to the use of oral steroids for infants and children with bronchiolitis. Ansari et al. found that, for infants with bronchiolitis who were at an increased risk of asthma, the use of systemic steroids decreased the time to readiness for discharge. However, that outcome metric was not explored in this study.

**Key Findings**

Following the statistical analysis of this retrospective chart review, some key observations were noted. The use of albuterol in children with bronchiolitis had no statistically significant impact on whether or not the child was hospitalized or went to an urgent care or emergency department. The outcome metric “number of outpatient visits” was the only metric influenced by the use of albuterol according to the analysis. In fact, the use of albuterol contributed to increased outpatient visits for this population according to the analysis. However,
it must be noted that these children quite possibly were more severely affected by bronchiolitis and thus warranted increased outpatient visits. Of the children who received oral steroids, the incidence of hospitalization increased significantly. However, this finding was more likely related to the small sample size versus a true relationship between these two variables. Finally, in spite of anecdotal reports of clinicians continuing to use albuterol in spite of the 2014 Guideline statement, the use of albuterol in this clinical setting actually significantly decreased in the years following that publication.

Limitations

Several limitations were acknowledged in this study. The sample size, the use of electronic health records (EHR) which lack uniformity of patient management terms, the use of the ICD 9 and ICD 10 codes for “bronchiolitis”, and the constraints of the data collection tool are all limitations of this retrospective analysis. The study results were derived from a small sample (N = 245) of infants and children, 1-23 months of age, who were diagnosed and treated for bronchiolitis in an outpatient primary care practice from 2013-2018. Therefore, the results of this study are not generalizable to all infants and children with bronchiolitis.

Although the preliminary power analysis conducted by the researcher and a statistician using G* Power recommended a sample size of 196 patients in each cohort, the sample size was limited by the use of the selected ICD 9 and ICD 10 codes. Specifically, the inclusion of only the ICD 9 codes 466.19 (acute bronchiolitis due to other infectious organisms), 466.11 (acute bronchiolitis due to RSV), and 079.6 (respiratory syncytial virus) and ICD 10 codes J21.9 (acute bronchiolitis, unspecified), J21.0 (acute bronchiolitis due to respiratory syncytial virus), and J21.8 (acute bronchiolitis due to other specified organisms) served to exclude infants and children who were diagnosed with cough, upper respiratory tract infection, or wheezing.
In the study site, the use of an electronic medical record program had been customized to suit the needs of physicians and nurse practitioners. This customization included the addition of a “short list” of the ten most frequently diagnosed medical conditions to facilitate faster documentation. The ICD 10 code for “cough” (R05) appears fourth on this list while upper respiratory tract infection, acute (J06.9) appears fifth. “Bronchiolitis” (J21.9) and “bronchiolitis with RSV” (J21.0) appears 10th on the shortcut list. Furthermore, the “cough” diagnosis also has an easily accessed drop-down treatment plan which includes such strategies as albuterol via nebulizer and oral steroid administration. Although “wheezing” occurs further down the common diagnoses list at this facility, it was reported by the honest broker to be far more common in the retrospective chart review than the bronchiolitis diagnosis codes. Finally, the lack of a uniform pick-list that included CAM or herbal supplements likely limited the number of these modalities being reported.

The investigator-designed data collection tool also contributed to this study’s limitations. The metrics “use of albuterol” and “number of days of albuterol prescribed” did not adequately address those children who were either prescribed albuterol at a later visit by another provider or by a provider in another setting such as the urgent care, emergency room, or while hospitalized. Similarly, due to the limitations of the retrospective chart analysis design, the data captured in the emergency department, urgent care, or while hospitalized was unable to be reliably captured.

Finally, although children in this study who received an albuterol prescription at the time of the bronchiolitis diagnosis had a statistically higher average number of outpatient visits (M = 1.34), the reason for the outpatient visits was not explicitly explored. Their outpatient visits could have been due to increased provider vigilance once starting the albuterol, worsening clinical course, or parental concerns. Additionally, the severity of the bronchiolitis illness was
not reported for this study group. This lack of severity index may lead to misrepresentation of the sample and contribute to heterogeneity of the outcomes.

**Strengths**

Much uncertainty about the optimal management of bronchiolitis exists, which leads to substantial variation in practice. Moreover, studies aimed at exploring the comparative effectiveness of albuterol in children with bronchiolitis are often fraught with heterogeneity both in the outcome metrics chosen and in the sampling of included children. This study represented a relatively homogeneous sample of infants and children 1-23 months of age who were treated by the providers at one pediatric primary care practice. Furthermore, the use of such metrics which the 2014 *Guideline* specifically advised to avoid such as continuous pulse oximetry (KAS 6b), analysis of RSV status (KAS 1c) and respiratory assessment scores (KAS 2) were not included in this study in order to improve the homogeneity of the sample and to facilitate comparison to the 2014 *Guideline* statements.

This study also served to address the paucity of research directed at the management of pediatric bronchiolitis in the outpatient setting. If one examines RSV alone, approximately 20% of the birth cohort requires outpatient medical evaluation during the first year of life due to RSV-mediated bronchiolitis (Hall et al., 2009). This study attempted to address the clinical and financial burden from bronchiolitis.

**Implications for Practice**

It is evident that the recommendation to not give albuterol and/or oral steroids for bronchiolitis has generated practice variation among pediatric clinicians worldwide. While the 2014 *Guideline* acknowledges that a subset of patients who present with clinically diagnosed bronchiolitis may have reversible bronchospasm, the AAP concluded that attempts to define this
subset or ascertain measurable improvement metrics have not been successful. Guidelines that restrict the use of bronchodilators in all patients with bronchiolitis are likely overlooking a subgroup who may actually respond favorably to these pharmacotherapies (Condella et al., 2018). Given that the most recent Guideline does not account for these children, it is imperative to attempt to identify this possible subgroup of responders in the clinical setting. Finally, the use of outcomes metrics that are uniform, precise, and valid to patients in the outpatient setting can help with retrospective chart analyses such as this study.

Implications for Research

Bronchiolitis in infants and children, especially due to RSV or rhinovirus, has been strongly associated with childhood asthma (Feldman, He, Moore, Hershenson, & Hartert, 2015). At this time, it is unclear what factors predispose infants to developing asthma and what role recurrent wheezing plays such as the wheezing following acute bronchiolitis. Luo and colleagues (Luo et al., 2014) argued that many bronchiolitis management decisions are made subjectively and the use of predictive modeling for bronchiolitis may help determine the optimal care and reduce variation. Research directed at the characteristics of children who develop recurrent wheezing may help guide the current bronchiolitis management strategies. Luo’s systematic review looked at methods of predicting several outcomes for children with bronchiolitis, some of which included hospitalization admission from the ED or the observation unit, predicting ICU admissions, predicting optimal disposition in the primary care setting, and predicting which infants would develop apnea and require respiratory support. Luo et al. stated that there is no published work to predict whether a bronchiolitis patient will be hospitalized, use urgent care, or need ED services within three days of diagnosis. Identifying this as an “open problem”, the authors advised further research to identify bronchiolitis patients at high risk for requiring acute
care services in the future (Luo et al., 2014). Similarly, more prospective controlled studies which address the comparative effectiveness of albuterol and/or oral steroids are needed.

**Conclusion**

The clinical, social, and financial burdens of pediatric bronchiolitis were explored through this study. With an annual hospitalization rate of 149,000 children per year in the US, bronchiolitis hospitalizations are accompanied by significant financial burden. Although bronchiolitis is a common and pervasive illness of infancy and early childhood, the diagnosis, management, and prevention of bronchiolitis creates substantial challenges for pediatric clinicians worldwide. Outpatient studies that target effective management of bronchiolitis are heterogeneous and use outcome metrics such as oxygen saturation, pulmonary function tests, or time to resolution of symptoms. These metrics are not always clinically relevant to the clinician who is managing infants and children in the outpatient setting over the course of the bronchiolitis illness. The publication of the 2014 AAP Guideline advised against the use of albuterol and/or oral steroids for the treatment of children with bronchiolitis. This study attempted to examine relevant outpatient metrics in children with bronchiolitis who were treated with or without albuterol and/or oral steroids. Although the study had a smaller than expected sample size, the use of albuterol was not found to have significant impact on emergency room or urgent care usage. Similarly, the use of albuterol did not predict increased hospitalizations. Outpatient visits were increased in the group who had been treated with albuterol which may be reflective of either the severity of the bronchiolitis illness or the increased vigilance of the clinician following the prescribing of albuterol. Finally, the use of an oral steroid was associated with higher hospitalization rate in this study but this data is likely confounded by the small sample size. It would be beneficial to replicate this study in the outpatient setting and include severity of illness.
and other diagnoses such as “wheezing” to more accurately represent the multitude of infants and children treated for bronchiolitis in the outpatient setting.
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Abstract


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