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Evaluation of an Early Discharge Policy For Infants With Apnea of Prematurity

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EVALUATION OF AN EARLY DISCHARGE POLICY FOR INFANTS WITH
APNEA OF PREMATURITY

By

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A dissertation submitted in partial fulfillment of the requirements for the degree of
Doctor of Philosophy at Virginia Commonwealth University

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Acknowledgment and Dedication

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This paper is dedicated to my mother who inspired me by her love and devotion not only to her children but also as a dedicated nurse who cared for premature babies. It was there in the Neonatal Intensive Care Unit working with her that I realized what I wanted to do in my life. I would also like to dedicate this paper to my beautiful daughter, whose love and support through many nights of studying and dining together kept me moving forward on the path to success. I wish her that same great success in her life. To my Dad, whose brilliant mind and great expectations just keep you striving for more; and finally to my husband, whom I love with all of my heart.
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Abstract

This research examines the safety and cost effectiveness of an institutional policy on discharge of preterm infants with Apnea of Prematurity (AOP) from the Virginia Commonwealth University Medical Center Newborn Intensive Care Unit (VCUNC NICU) with caffeine therapy and a cardiorespiratory monitor. This practice policy was developed over a decade ago as a cost containment measure in neonatal care and continues to be implemented today despite the lack of a formal evaluation. The secondary objective was to examine through a review of the literature the psychosocial impact of premature birth on the family and the potential effect on the infant’s hospital discharge. The evaluation of this policy is based on the conceptual framework of effectiveness, efficiency, and equity in health care. Results were used to generate policy recommendations.

This is a retrospective case study of 933 infants admitted to the VCU Medical Center and the community hospital NICU between 1993 and 2002 diagnosed with Apnea of Prematurity. Data was obtained from the Neonatal Information System database at Virginia Commonwealth University Health System (VCUHS), the Virginia Department of Health, and the VCUHS hospital information system. In this mixed methods study, the infants were divided into two groups: 1) those discharged from the hospital on caffeine citrate therapy, and a cardiorespiratory monitor for continued management of apnea; and 2) those that were hospitalized until resolution of apnea. Data was analyzed for differences in mortality and morbidity, hospital readmissions and cost of hospital care from birth to 1 year of age. Interviews were conducted with NICU clinicians to obtain a qualitative perspective on this policy.

No significant differences were found in the mortality rate between the two groups (p=.65), and the causes of the four deaths were unrelated to Apnea of Prematurity. Mean hospital costs were approximately $58,000 in both groups. Bronchiolitis was the leading cause for hospital readmission and there was no difference in the rate of hospital readmissions. Based on interviews with NICU clinicians, the policy works well and early discharge is advantageous to the infant and family. Therefore, we find no reason to not continue this policy. Study results support the importance and direction for further research on early discharge of infants with AOP and enhanced epidemiologic surveillance of this population.
Chapter 1

Introduction

The immense financial cost of neonatal intensive care for infants born prematurely continues to rise as the number of low birthweight infants (LBW; birthweight less than 2500 grams) born each year increases. In 2004, 8.1% of all births in the U.S. were less than 2500 grams (5 ½ lbs), 3.4% were less than 1500 grams, and 12.5% were born prematurely, prior to 37 completed weeks of gestation (March of Dimes Peristats 2007). Between 1994 and 2004, the proportion of all infants born at LBW increased by 14%. At the same time, survival rates have improved dramatically for infants of extremely low birthweight (VLBW, less than 1500 grams), 80% of infants born after 26 weeks of gestation will now survive to be discharged from the hospital (MOD Quick Reference, 2006). Low birthweight infants are often admitted to the newborn intensive care unit (NICU) after birth. The average length of a hospital stay in the NICU is highly dependant on birthweight and gestational age and ranges from 60 +/- 30 days for very low birthweight infants. Recent technological advances in neonatal intensive care have contributed greatly to the increased survival rates of premature infants but have also increased the costs of treatment of prematurely born infants. Estimated annual direct care costs of infants requiring NICU hospitalization in the first year of life are over four million dollars annually in the United States, accounting for 35% of the total health care costs of the estimated 4.5 million U.S. births annually (Lewit 1995).
Cost containment efforts by managed care insurance plans have focused primarily on transfer of neonates to lower levels of hospital care and on reduction on length of hospitalization through early discharge programs. Health services research has examined the use of health services for premature infants and the associated costs but with little attention to the impact of clinical practice policies in neonatal intensive care. Health policy research to support practice and rigorously evaluate policies is needed as medicine and public health move towards evidence based practice.

*Apnea of Prematurity*

Apnea of Prematurity (AOP) is a common complication of prematurity and affects about 90% of VLBW infants and 25% of LBW infants. Though several definitions are used for AOP, the most commonly used definition is the sudden cessation of air flow that lasts for at least 20 seconds or, if lasting less than 20 seconds, is accompanied by changes in vital signs such as an abnormally slow heart rate or a marked decrease in blood oxygen levels (Finer et al., 2006). There is no agreement, however, on the duration or severity of apnea that is pathologic in preterm infants (Finer 2006). AOP typically presents in the first few days of life and usually resolves by 37 weeks post-menstrual age but it may persist until 43 weeks post-menstrual age in the more immature infant. Apnea of Prematurity is a diagnosis of exclusion; other complications including infections, diseases of the pulmonary system, and neurologic complications may also cause apnea. This condition is attributed to an immature central nervous system as well as an imbalance in peripheral input that modulates the control of breathing by the central nervous system. Infants with AOP demonstrate a decreased respiratory response to carbon dioxide
levels; this response which may be mechanical or chemoreceptor based. Current medical treatment of AOP in the NICU is supported by evidence compiled from the Cochrane Collaboration on Neonatal Care (NICHD CRNG, 2003). Pharmacologic treatment with methylxanthines, such as caffeine citrate or theophylline, stimulates the respiratory neural centers and enhances diaphragmatic tone. Continuous positive airway pressure (CPAP), a type of mechanical ventilatory support, is also efficacious as a general non-specific stimulant. Both interventions typically decrease the frequency and severity of AOP, occasionally eliminating AOP upon initiation of therapy. Practice by U.S. neonatologists regarding the duration of cardiorespiratory monitoring in the NICU for AOP varies widely (Merritt 2003). In most NICUs, preterm infants are not discharged until AOP has resolved for seven to ten days after the discontinuation of methylxanthine therapy, as evidenced by a subtherapeutic plasma caffeine concentration.

To decrease length of hospitalization, management of AOP at the Virginia Commonwealth University Medical Center (VCUMC) changed in the late 1990’s (Appendix A. Policy on Apnea of Prematurity). In the VCUMC Newborn Intensive Care Unit (NICU), if a premature infant is apnea-free while receiving caffeine and is otherwise stable for hospital discharge, caffeine administration is discontinued and a plasma caffeine concentration is measured seven days later. If an infant’s AOP does not recur between the time of medication discontinuation and 48 hours after a subtherapeutic plasma caffeine concentration (<4 mg/dl) is documented, the patient is discharged from the hospital. If apnea does recur after discontinuation of caffeine administration and is otherwise the sole reason for continued hospitalization, then caffeine therapy is resumed. If the patient’s apnea does not require more than minimal
intervention, the infant is discharged from the hospital on continued treatment with caffeine citrate and on home cardiorespiratory monitoring. Usually, both are discontinued by a pediatrician within several months.

This practice has not been formally evaluated and clinical trials on early discharge of the preterm infant to home with both caffeine citrate and cardiorespiratory monitoring for management of their AOP were not found when conducting a review of the medical literature. Recently published recommendations from the Apnea of Prematurity Group stress the importance of future research on AOP and outline the framework specifically for the conduct of randomized clinical trials (Finer 2006).

Background

The VCU Medical Center (VCUMC) is an urban university hospital located in the City of Richmond, Virginia. The hospital is a regional perinatal center, providing specialty care for high risk pregnant women and infants. The primary population it serves lives in a city with high rates of poverty and crime. The teenage pregnancy rate is 68.8, more than twice the state rate, and 62 percent of births are to unmarried women. African American infants account for slightly more than half of the 3,032 live births and are two times more likely to be born at low birth weight than white infants; 15% are born at less than 2500 grams. The rate of infant mortality among blacks is extremely high at 18.3, two and a half times that of white infants. The primary causes of infant mortality are prematurity, and Sudden Infant Death Syndrome (SIDS). These mothers and infants primarily seek care at VCUMC and when their infants are born prematurely at a low
birthweight, they are cared for in this NICU. Thus, the policy being studied affects many of these infants.

On a national level, this study has relevance to several important health policy initiatives. Healthy People 2010 present a health policy agenda for the nation that addresses the widening gap in health disparities, specifically in relation to the increasing rates of premature birth and infant mortality. The second initiative is the recent federal legislation focused on the prevention of prematurity known as the PREEMIE Act. The third important initiative is Evidence Based Practice (EBP), a paradigm for gathering evidence to support decision making in medicine and in health care to achieve improved health outcomes (Robey 2004).

Healthy People 2010

One of the goals of Healthy People 2010 is to eliminate health disparities in certain populations. Within the focus area on Maternal, Infant, and Child health, Objective 16 specifically targets reduction in the rate of infant mortality to 4.5, reduction of low birthweight to a rate of 5.0, very low birthweight to a rate of 0.9, and a reduction in the rate of preterm birth to 7.6 (rates are per 1,000 live births) (Healthy People 2010). Most of the increase observed in these rates from 1998-2002 was attributed to non-Hispanic black women and infants. No progress toward achievement of these indicators was reported at midcourse review by the Centers for Disease and Prevention (CDC) (Healthy People 2005). African American women are still three times more likely to give birth prematurely, and their infants are 2 ½ times more likely to die than white infants. Major health and environmental factors contributing to the risk of prematurity have been identified including previous preterm birth, infection, tobacco use, low
socioeconomic class, and low education. Even after adjusting for these confounders, Black women continue to have a higher incidence of premature births. Recent research on premature labor identified another possible explanation for this disparity, a genetic variant among African American women that results in a collagen deficiency associated with preterm premature rupture of the membranes (PPROM), a major cause of premature birth (Wang et al. 2006).

Federal Legislation

Despite the advances in obstetric and neonatal medicine, we still do not know the cause of preterm labor, and thus we do we know how to prevent a premature birth. Until recently, there has been a paucity of research specifically targeting the mechanisms of preterm labor. This deficiency is mainly due to the lack of research funding allocated for this effort. The agenda is changing however, as the rising rates of preterm birth and their contribution to infant mortality has created a crisis in public health. In response to this problem, a number of organizations and agencies from both the private and public sectors have targeted their focus on prevention of prematurity and infant mortality. In 2004, the National March of Dimes began a prematurity awareness campaign to support research and program funding at the national, state, and local levels. Their “call to action” is now being supported by federal legislation, S707, “Prematurity Research Expansion and Education for Mothers who Deliver Infants Early Act” or the “PREEMIE Act” passed by Congress in December 2006 and signed by the president. This bill became Public Law No: 109-450 and authorizes approximately $65 million over 5 years for research and education initiatives (THOMAS Library of Congress, 2007).
“The purpose of the PREEMIE Act is to (1) reduce rates of preterm labor and delivery; (2) work toward an evidence–based standard of care for pregnant women at risk of preterm labor or other serious complications, and for infants born preterm and at a low birthweight; and (3) reduce infant mortality and disabilities caused by prematurity”. The PREEMIE Act specifically outlines a plan to carry out its purpose. The content of the sections is stated as follows: Section 3 addresses research relating to preterm labor and delivery and the care, treatment, and outcomes of preterm and low birthweight infants. It includes general expansion of CDC research, including studies on the relationship between prematurity and birth defects, and support for the Pregnancy Risk Assessment Monitoring Survey (PRAMS). Section 4 addresses public and health care provider education and support services. Section 5 calls for the establishment of an Interagency Coordinating Council on Prematurity and Low Birthweight. Section 6 calls for a Surgeon General’s Conference on Premature Birth, and Section 7 address specific Head Start regulations (THOMAS Library of Congress, 2007).

Another important and long standing policy driven initiative is the federally funded Healthy Start Program of Health Resources and Services Administration (HRSA) Maternal Child Health Bureau. Healthy Start is focused on reducing health disparities with community based prevention programs to reduce premature birth and infant mortality in this population (Howell, 1998). Healthy Start programs consist of community based projects that provide a spectrum of services to childbearing women and their children. These programs may consist of case management, clinical and outreach services for pregnancy, parenting, substance use and nutrition from the preconception period through pregnancy and birth, and up to age 2 for the child. Fetal Infant Mortality Review (FIMR) is another component of Healthy Start and is a public health
surveillance activity that examines the causes and circumstances of fetal and infant deaths. FIMR identifies issues and gaps in services and makes recommendations for improvements in health care and also plays a role in policy development for maternal and infant health (Koontz et al. 2004).

Evidence- Based Practice

Funding future research initiatives on prevention of prematurity will allow the scientific community to contribute evidence for influencing the formation of policies to support clinical practice. In a quest to improve the quality of medical care, the concept of evidence-based practice has recently gained momentum. The synthesis of evidence, which can range from expert opinion to a meta-analysis of well designed controlled studies, is the core activity of evidence-based practice, and several authors have developed rigorous methods for achieving this (Robey 2004). The well known National Institute of Child Health and Human Development (NICHD) Cochrane Neonatal Collaborative Review Group conducts systematic reviews of randomized clinical trials of human data. Other researchers (Sandelowski and Barroso, 2003) have also developed methods to synthesize qualitative data, but there remains a lack of rigorous methods to examine quantitative evidence provided by randomized clinical trials compared to studies that use different methods. The process begins with the identification of a problem or intervention and the statement of a hypothesis followed by a search for any evidence using different search engines. The evidence is then evaluated for quality and classified as either supporting or opposing the issue. Finally, the data are summarized and a recommendation is made with an explanation regarding the level of evidence. The “levels of evidence” is a classification mechanism to evaluate the hierarchy of scientific rigor and quality. The Agency for Healthcare
Research and Quality has five levels, other systems that exist are comprised of three to more than eight levels (AHRQ 2001). From a health policy standpoint, clinical practice guidelines should specify the level of scientific evidence used to support their development.

Evidence based decision making was recently put forth as a recommendation by the Institute of Medicine (IOM) in “Crossing the Quality Chasm”, a blueprint for improving the quality of healthcare in the United States (IOM 2001). Health care professionals who utilize evidence-based practice (EBP) have reported greater satisfaction than those who do not (Dawes 1996). Despite the support, this approach to healthcare has progressed slowly and is being impeded due to a multitude of barriers. These barriers stem from three major areas: 1) healthcare providers, 2) healthcare organizations, and 3) available evidence (Melynk 2005). Issues with lack of training in EBP and the time required for use, the lack of funding and research, inadequate support from institutions and professional organizations, lack of leadership personnel for this initiative, and the need for national coordination and resources for marketing are some of the contributing factors that have been cited as impeding evidence based practice (Melynk 2005).

These larger health policy agendas provide justification for the focus of this research. Although this research is focused on one NICU in an urban hospital, the results may have implications for policy development on a larger scale as it provides additional support for an alternative strategy for early discharge of infants in the NICU.
Conceptual Framework

In clinical medicine, when health care providers are presented with a health problem, they gather information from the client, rule out differential diagnoses, weigh alternative treatments, and finally decide on the most appropriate treatment. The health outcomes of the patient are evaluated, and if the treatment is not successful it may be revised. Often a specific course of treatment may be utilized frequently, and if found to be successful it may evolve into a guideline or policy in that specific area of health care. Such a course of treatment may or may not be supported sufficiently by prior research. These clinical based guidelines are an example of health policy at the institutional level.

The process of policy making in healthcare is not always based on evidence or even on informed decisions, but rather on pressure by external parties that exert their influence in order to achieve particular objectives or desired outcomes. These objectives may be focused on improving health, but can also be focused on achieving an economic advantage. In the past decade, pressure from managed care organizations to reduce the rising cost of health care has driven hospitals to develop cost containment policies. These policies can range from monitoring the medical necessity of hospital care to initiatives focused on “disease management”. For example, the economic burden of preterm birth has been discussed as a national concern. Ten percent of infants are born preterm, and they consume over fifty percent of the 10 billion dollars spent on newborn care annually (Morrison, 2001). Furthermore, the majority of these infants are on Medicaid, requiring third party payers in Medicaid managed care to develop cost containment strategies for this population.
This study focuses on a clinical based guideline that was developed by clinicians over 10 years ago to decrease the length of hospital stay for infants in the NICU in order to reduce the cost of hospital care. Just like other types of health policy, clinical based guidelines are often proposed, developed, and implemented without sufficient evidence to support them. Furthermore, there is also a lack of systematic and well designed evaluations to review the effectiveness and efficiency of the interventions. Even when those criteria are addressed, “it rarely includes a focus on equity, are the recommendations fair?” (Dans et al. 2007).

The process of policy analysis is often expensive and time consuming, which results in many proposed policies being only partially completed or not done at all. Up to this point there has been no formal evaluation of this policy. In practice, infants treated according to these guidelines were initially followed by a physician in a neonatal specialty clinic after discharge. No adverse events were identified related to their early discharge. Therefore, the practice of early discharge was continued, and infants were followed by their pediatricians. Since this method of evaluation did not provide sufficient data on which to base any further recommendations, the need to examine this population was identified. Policy evaluation is the basis for modification of any policy, and should ideally occur as part of a continuum of analytic activities throughout the policy making process, not simply after implementation (Longest 1998).

Using a combination of health services and health policy research approaches, this study provides an evaluation of an institution-based health care policy through the application of all three criteria, effectiveness, efficiency, and equity (Aday 2006). This framework for evaluation was applied at both the institutional and the individual levels, as shown in Figure 1. At the top tier level of the diagram is the institutional policy developed by the key stakeholders. The second
tier level represents the application of the policy to the individual/patient. The lower tier level contains the three measurement criteria, and each criterion was defined in the following manner. Effectiveness was measured by examining specific health indicators for these infants - mortality or death prior to one year of age, and morbidity, the number and type of hospital readmissions in that same time period. Efficiency was measured by examining the health care hospital costs incurred by these infants through one year of age. Equity was evaluated by examining the health disparities in this population and whether they were fairly and effectively addressed. This was considered by examining the application of this policy to a cohort of infants treated at the VCUMC NICU.

Figure 1. Framework for evaluation of health policy. Adapted from Aday, 2006.

A method of evaluation which further addresses the issue of equity was developed by The Knowledge Plus Project of the International Clinical Epidemiology Network. This method uses five criteria defined by the authors as an “equity lens” (Dans et al. 2007). Four of the five
criteria were found to be applicable to this study, addressing the effects of the intervention, how it is valued, barriers to it, and the impact of the intervention on disadvantaged and privileged populations. These criteria are discussed in relation to this policy in the results section. The remaining criterion was not used, as it applies to guidelines that contain public health recommendations and are not directly applicable.

According to this model, the results of the evaluation of each of the criteria of effectiveness, efficiency, and equity feed back up to the key stakeholders at the institutional level for policy modification. The recommendations from this study will be provided to key stakeholders, including the medical director and clinicians in the VCUMC NICU, for possible policy modification and to guide future research on infants with AOP.
Chapter 2

Literature Review

Discharge of the Premature Infant

The average length of hospital stay for a very low birth weight infant (500-1500 grams) is approximately 60 +/- 30 days (Vermont Oxford Network Center Data, 2000). It is well known that prolonged hospitalization of these infants increases the risk of medical and psychosocial complications (Casiro 1993). Exposure to the NICU environment results in an increased risk of nosocomial or hospital acquired infections such as methacillin resistant staphylococcus aureaus (MRSA). Potentially adverse effects on the infants’ later physiologic development have also been demonstrated as a result of excessive noise, bright light, the lack of day night cycles, and lack of bonding with the mother. Recent developments in neonatal care are addressing these environmental issues through alteration of the environment, physical redesign of new neonatal units, and programs that foster parental involvement in the care of their infant.

The timing of discharge for premature infants from the NICU is complex and is based primarily on the stability of the infant, readiness of the parents to care for their infant, and variations in practice patterns by neonatologists. Prior to pressure from managed care programs, discharge of these infants was based on a set of specified criteria, including achievement of a set weight of 4.5 to 5.0 pounds. Early discharge of the premature infant in the NICU has been driven mainly by third party payers, managed care, and hospitals as a cost containment measure. Over the past decade the length of hospitalization for infants weighing greater than 750 grams at birth has not significantly changed (Merritt 2003). The continual increase in the percentage of
low birthweight infants presents an opportunity for improvement in early discharge practices which may lead to decreased length of stay for infants in the NICU.

In an attempt to provide a standard set of discharge criteria, the American Academy of Pediatrics Committee on Fetus and Newborn (1998) proposed guidelines for discharge of the high risk neonate based on a review of available evidence. Four categories of recommendations are included that focus on the types of high risk problems encountered - the preterm infant, the infant who is dependent on medical technology, the infant whose family places him at risk, and the infant who is facing an early death. The committee attempted to provide a broad set of recommendations that are based on the status of the infant, planning for home care needs, environmental issues related to the family and the home, community capacity, and the system of health care (Committee on Fetus and Newborn 1998). Attention to all of these criteria ensures that a comprehensive assessment is completed and is important to a successful discharge. Emphasis should be placed on tailoring the plan to the individual infant and family and the decisions of the physicians. Preterm infants should demonstrate three essential physiologic abilities prior to consideration of their discharge- maintenance of normal temperature in an open crib; coordination of sucking, swallowing, and breathing while consuming full feedings; and an acceptable rate of growth. The achievement of mature cardiorespiratory function is also important for these infants (Committee on Fetus and Newborn 1998).

Several prospective randomized clinical trials have examined the feasibility of earlier discharge of premature infants from the NICU. All of these studies were dependent on the availability of home health care nursing care and follow up by neonatologists. Casiro found that
a significant reduction in the average length of a hospital stay could be achieved with
community based nursing support for infants who weighed 1501 - 2000 grams at birth (Casiro et
al. 1993).

In another study, early discharge of very low birthweight infants prior to achieving a
weight of 2200 grams with the use of home nursing support was also found to be both safe and
cost-effective. In addition, there was no difference in the number of hospital readmissions or
acute care visits for this group (Brooten 1986). Discharge of a group of infants from the NICU
weighing only 1300 grams versus those weighing 1800 grams was also shown to be safe and cost
effective when appropriate selection criteria were followed (Cruz 1997). The major limitation in
these studies was the small sample size of the intervention groups (n= 27 to 50). A larger study
reviewed the effects of a NICU early discharge program on a group of 257 premature infants.
Compared to the 477 control infants, they found a significant decrease in mean discharge weight
and length of stay along with a reduction in cost of care without excessive morbidity (Kotegal et
al. 1995).

Premature infants born at 30-34 weeks gestation enrolled in the Kaiser Permanente
Medical Care Program in California were discharged earlier from the NICU than those cared for
in hospitals in Massachusetts and in the United Kingdom. For the total cohort of 4359 infants,
the mean postmenstrual age at discharge was 35.9, 36.3, and 36.3 weeks respectively (p=0.001).
These differences were partly attributed to the integrated approach to care by this health
maintenance organization (Profit et al. 2006). It is important to note however that none of these
studies included infants discharged home on an apnea monitor or on medication for apnea,
caffeine citrate.
**Discharge of the Infant with Apnea of Prematurity**

Apnea of Prematurity often lasts beyond the time when infants are otherwise stable and meet the criteria set forth by the AAP committee for discharge. Studies have shown that smaller premature infants with a gestational age of 24-27 weeks at birth continued to experience significant apnea and bradycardia beyond 37 weeks and as long as 38 – 39 weeks postconceptional age (Donohue 1997, Eichenwald 1997). The length of hospitalization was longer in these infants compared to infants born at 28 weeks or older who usually are discharged at 37 weeks postconceptional age. Variation in medical practice exists on the timing of discharge for infants with AOP from the NICU to the home. Most neonatologists require observation for 5-7 days beyond the last apneic episode before discharge to home (Merritt 2003). Darnell et al. (1997) conducted a study to determine a margin of safety for discharge to home after the last apnea period. They examined the occurrence of apnea, bradycardia, and oxygen desaturation in otherwise healthy preterm infants with AOP and found that the apnea episodes were separated by as many as eight days prior to the last episode before discharge. Therefore, it was determined that their discharge criteria of a 7 – 10 day period free of clinically significant apnea was reasonable clinical practice (Darnell et al. 1997).

Other medical complications of prematurity can influence the occurrence of apnea, the medical stability of the infant, and the timing of discharge independent from the resolution of AOP. Respiratory distress syndrome (RDS) is a deficiency in the production of surfactant by the lungs; often, ventilatory support and oxygen are needed to sustain adequate respiratory function for these infants. With Bronchopulmonary Dysplasia (BPD) or chronic lung disease which
results from severe RDS, the lungs become scarred due to the long term respiratory support and oxygen therapy is needed for longer periods of time after discharge. Intraventricular hemorrhage (IVH) occurs due to the rupture of fragile blood vessels in the brain from instability of the blood pressure, and Periventricular Leukomalacia (PVL) or calcification of the vessels in the brain results from lack of oxygen. Other problems include Necrotizing Enterocolitis (NEC) a toxic condition causing death of the intestines, gastroesophageal reflux, and bacterial or viral infections. These complications have been identified as the most frequent confounding conditions in studies of AOP.

Much controversy remains surrounding the discharge of infants with AOP prior to the resolution of apnea. When reviewing the literature, there is a major lack of evidence to support this practice. Two groups, the National Institutes of Health Consensus Development Conference on Infantile Apnea and Home Monitoring and the Canadian Paediatric Society Fetus and Newborn Committee, have developed policies for the use of home apnea monitoring for infants discharged with unresolved apnea (NIH 1987, Canadian Paediatric Society 1992). In the discharge guidelines discussed above, the AAP committee states that consideration of home cardiorespiratory monitoring and studies of cardiorespiratory function prior to discharge for infants with unresolved apnea is stated as a “matter of individual clinical judgment”. A survey of 252 neonatologists found that 66% occasionally discharged infants on Xanthines but 27% said they never did. In addition, 80% said they occasionally to frequently discharged infants on apnea monitors (AAP conference 1996), supported by evidence that the use of home monitoring by parents has been shown to be successful. Data from the Pediatrix Medical Group on 1588 NICU infants discharged with home apnea monitors did not result in earlier discharge and was more
dependent on physician preference than medical indication. The most important factors
associated with monitor use in a stepwise evaluation were site of birth, diagnosis of apnea,
previous treatment with methylxanthines, being outborn, birthweight and gestational age. No
significant difference was found in length of stay, postmenstrual age and weight at discharge for
this group compared to the infants sent home without monitors (Perfect-Sychowski 2001). Only
one published study was found in which preterm infants were discharged home on caffeine
citrate; no mention was made of the use of home apnea monitors. This retrospective study was
conducted in France to examine factors related to apnea that persisted after 37 weeks post
conceptual age. Forty-one infants who were discharged home from the NICU on caffeine citrate
were compared with 123 infants discharged without caffeine (Ducrocq et al. 2006). At 42 weeks
PCA, those infants on caffeine were readmitted to the hospital for monitoring and
discontinuation of caffeine. Several factors were found to be significantly associated with
persistent apnea; birthweight <1500 grams, hypotension, treatment with CPAP, gastroesophageal
reflux, and multiparity. No deaths or negative effects were reported by the parents in this cohort.
This practice may be an alternative to continued hospitalization for infants receiving caffeine that
are otherwise stable for discharge and have persistent apnea (Ducrocq et al. 2006).
Problems after Discharge

Preterm infants have significantly more health problems in the first year of life than their term counterparts and lower gestational age is thought to be an important contributor to excess morbidity. Higher incidences of respiratory infections, vomiting, diarrhea, and otitis media have been documented (Emond 1997). Rehospitalization is recognized as an index of morbidity in the extremely low birthweight infant. In a review by Doyle, as many as fifteen studies have reported the rates of readmission for these infants to meet or exceed 50% when compared to term newborns (Doyle 2003). Significantly more respiratory illness was diagnosed in very preterm infants after discharge, especially among those infants with Bronchopulmonary Dysplasia (Doyle 2003). A recent study from Massachusetts examined the impact of early discharge among late preterm infants that were admitted to a newborn nursery using policies for term infants. The results showed a two-fold increase in hospital readmission rates compared to term infants among those late preterm infants that were breastfeeding (Tomashek 2006). The most common diagnoses included feeding problems and jaundice. This study provided further support that appropriate discharge policies for preterm infants be developed and supported by evidence based recommendations in order to prevent morbidity. Premature infants require closer follow up after discharge due to their multiple medical problems.

The Psychosocial Impact of Premature Birth on the Family

Many studies have examined the adverse health effects of preterm birth on the parents, especially on the mother. Mothers who give birth to premature infants grieve the loss of the expected “normal baby”, and hospitalization in the NICU creates additional barriers in parenting
a newborn. Parents have been found to experience high levels of stress, anxiety, and depression (Carter 2005, Miles 1999, Pinelli 2002, Singer 1999, Melnyk 2006). Loss of the parental role due to separation and the lack of knowledge of how to interact with their infant contribute to parents’ inability to adequately bond with their infants. The early interactions between a mother and her premature infant may be influenced by a mother’s perceptions and expectations of her infant (Olexa and Stern 1999). This “premature stereotyping” has been examined by Stern and colleagues, and is thought to be related to negative perceptions and less desirable behavior as observed in mothers’ interactions with premature infants compared to term infants (Stern, Karraker, Meldrum-Sopko, & Norman, 2000). Negative behavior exhibited by the mothers of premature infants is thought to affect not only care giving behavior but to also compromise the later development of the premature infant. The researchers explain this phenomenon as a “self-fulfilling prophecy process” (Stern et al. 2000). The mother treats her premature infant according to the way she perceives and expects him to behave, over time resulting in an infant that has developed these expected behaviors (Stern et al. 2000).

Premature infants are often identified as being medically vulnerable and this vulnerability influences the manner in which adults, especially parents, respond to premature infants. Perceptions of vulnerability may be negative in their nature, leading to worse developmental outcomes of premature infants at one year corrected age and have been associated with increased use of health care services (Allen et al. 2004). Maternal anxiety at the time of NICU discharge was also significantly associated with a higher perception of child vulnerability after discharge (Allen et al. 2004). In another study of African American preterm infants at 3 to 4 months corrected age, two types of maternal perceptions, an infant that was unresponsive to the
mother’s cues and the mother’s belief that she had lacked the ability to feed her infant were also predictive of infant vulnerability (Teti, Hess, and O’Connell 2005). The relationship between prematurity stereotyping and perceptions of infant vulnerability is not well understood. However, an association has been suggested between “early maternal cognitions and both contemporaneous maternal behavior and later childhood developmental outcomes” (Stern et al. 2005).

The quality of maternal adaptation to the parental role prior to discharge of the preterm infant is extremely important and is predictive of the perceptions of infant vulnerability in the first year of life (Teti et al. 2005). In order to identify mothers at highest risk for this problem, it is recommended that clinicians give special attention to maternal adaptation behaviors before discharge from the NICU (Ibid 2005). Interventions to prevent or decrease these perceptions of vulnerability should be incorporated into the plan of care during the NICU stay. An example of a successful intervention for parental psychological trauma prevention in the NICU was parents receiving early crisis intervention and psychological support (Jotzo and Poets 2005).

Early discharge of the infant from the NICU to home facilitates parents’ ability to care for and bond with their infant in addition to removing stress created by the NICU environment. Parents also have more of a feeling of control over their infants when they are the primary caregivers. Successful discharge planning consists of intensive teaching, encouragement, and support from the NICU staff as well as adequate home health services to prepare the parent to care for their infant. This process should begin early in the NICU stay, after the prognosis of survival is relatively assured. Infants with multiple medical needs will need more intensive discharge planning, and multidisciplinary care coordination will assist in an improved transition
process from the hospital to home (Scherf and Reid 2006). Recent studies by Kaarelsen and Melnyk found that an early intervention program to improve parent infant interactions conducted by nurses in the NICU was successful in reducing parenting stress after preterm birth that continued after discharge. Kang et al. (1995) conducted a follow-up project for preterm infants consisting of both hospital State Modulation (SM) and nursing home intervention NSTEP-P behavioral intervention programs. They found the greatest improvement in positive social infant interaction among mothers with limited formal education when using both programs and improved social interaction for all educational levels with the SM program alone (Kang et al. 1995).

It appears that behavioral intervention programs focused on improving the quality of maternal infant relationship as well as early discharge planning with follow-up after discharge will better assist the family to care for their preterm infants. Although standard guidelines exist for discharge planning, it is important that discharge programs individually assess both the needs of the infant and the family to achieve the most success.

The psychosocial impact of premature birth and early discharge on the family is an important additional factor to consider when evaluating effectiveness of this early discharge policy. If neonatal clinicians recognize that a family is unable or not ready to care for the infant they are able to take this into consideration when planning the discharge. It was outside the scope of the current study to interview the parents of these infants, and there are no variables in the datasets being utilized that pertain to psychosocial measurements. To address this gap, a series of qualitative interviews were conducted with VCUMC NICU clinicians.
The Cost of Prematurity

Although many studies have looked at the cost and use of health services for preterm infants; few have evaluated the cost effectiveness of specific practice policies for preterm infants in the NICU especially related to early discharge. The eight studies reviewed all attempted to quantify the costs of preterm birth and low birth weight using various methodologies. Two studies were limited in scope as they included only the costs associated with the initial NICU admissions after birth (Adams 2003, Gilbert et al. 2003). Other studies went further to examine the costs of medical care received in the first year of life (Rowgowski 1998, Rowgowski 2003, Cuevas 2005). Only one study assessed the long term impact of preterm birth on medical costs for the first five years of life (Petrou 2003). Other researchers have also examined the economic impact on health care, education, social services and the family related to long term care of these infants (Petrou 2001). All of the studies reviewed were retrospective in nature and stratified hospital costs by birth weight and/or gestational age, used different study designs, data collection methods, and analysis. One study examined the costs of preterm infants within a randomized clinical trail (Cuevas 2005) while three studies were done on population based cohorts in specific geographic areas – California and the UK (Gilbert 2003, Petrou 2003, Rowgowski 1998). Others used convenience samples, a cohort of preterm infants from 29 hospitals in the Vermont Oxford Network that participated in the NICU Quality Improvement Collaborative (Rowgowski 2003) and private sector claims on maternal infant pairs from 200 payers nationwide (Adams 2003).

In a systematic review of other long term economic studies on preterm and low birth weight from 1980-1999, the authors found that few studies used a sound economic analysis to examine the cost of preterm birth (Petrou 2001). The issue of how to measure the costs of
neonatal care is indeed problematic. Most of the data available is based on hospital charges. These charges are not accurate measures of costs as they include mark up rates for a specific service or unit. Charges should be converted to costs using Medicare cost to charge ratios to obtain a truer estimate of the cost.

Much of the cost data is presented in means or averages as in the studies by Adams 2003, Cuevas 2005, Gilbert 2003, Petrou 2003, Rowgowski 1998. Subsequently, Rowgowski found that the average charge for the NICU hospitalization may have overestimated the cost by as much as 53% and used median costs in her study with the NICU Quality Improvement Collaborative. Using the median treatment costs provides a more accurate measure even though in very low birth weight infants they are skewed by outliers on the highest end of the cost curve. Total inpatient hospital costs consist of both accommodation costs and ancillary costs. Further detailed analysis includes patient mix, birthweight, gestational age, survival, and type of unit. All of these factors are important when benchmarking economic performance and they are difficult to obtain because most hospital information systems do not link specific indicators to billing information. The median NICU treatment cost for a cohort of 6797 very low birthweight infants (VLBW <1500 gm) in 1998 was $53,316 for a 47 day stay or a cost per day of $1,249 dollars. A further breakdown by birthweight as seen in Figure 2 and Table 1 resulted in a total cost of $103,637 or $1,643 per day for infants in the 501-750 gram weight range with an 81 day length of stay. In contrast, infants in the larger weight group 1251-1500 grams had a total cost of $31,226 or $1,051 per day for a 32 day stay. (Rowgowski 2003).
Mean hospital costs were reported as higher and calculated to be as high as $224,000 for infants in the 500 – 700 gram group (Gilbert 2003), $273,900 in another group <750 grams (Rowgowski 1998), $205,204 in the group weighing <1250 grams at birth (Cuevas 2005) and $93,800 in the <1500 gram group (Rowgowski 1998). In a more complex analysis of the impact of preterm birth on hospital costs for the first 5 years of life, preterm infants were compared to normal newborns. The mean adjusted cost difference was $22,798 for infants < 28 weeks gestation and $18,654 for infants 28-31 weeks (Petrou 2003).
Table 1. Costs of Hospital Care for Premature Infants by Birthweight

<table>
<thead>
<tr>
<th>Study</th>
<th>Birthweight</th>
<th>Median costs: total / daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003 Rowgowski</td>
<td>501-750</td>
<td>$103,637 / $1643</td>
</tr>
<tr>
<td></td>
<td>1251-1500</td>
<td>$31,226 / $1051</td>
</tr>
<tr>
<td></td>
<td>&lt;1500 gm</td>
<td>$53,516 / $1249</td>
</tr>
<tr>
<td>1998 Rowgowski</td>
<td>&lt;750 gm</td>
<td>$273,900</td>
</tr>
<tr>
<td></td>
<td>&lt;1500 gm</td>
<td>$93,800</td>
</tr>
<tr>
<td>2005 Cuevas</td>
<td>&lt;1250 gm</td>
<td>$205,204</td>
</tr>
<tr>
<td>2003 Gilbert</td>
<td>500-700 gm</td>
<td>$202,700 – $224,000</td>
</tr>
</tbody>
</table>

In order to obtain information about the cost of neonatal care in Virginia, hospital cost data was obtained from VCUMC on all 2259 infants discharged from the NICU for the time period of January 1997 – November 2003 from the hospital information system. Data elements in Table 2 include the number of infants discharged, total in patient hospital days, average length of stay, case mix, total costs, average total charges and costs, and daily charges and costs in the NICU. Median costs per year were unable to be calculated as the data is in aggregate format. The advantage of obtaining matched data to our study sample enables detailed cost breakdowns by a number of different variables in the dataset.
Table 2. NICU Costs, VCUHS Hospital Information System, 1997-2003

<table>
<thead>
<tr>
<th>Years</th>
<th>Total Discharges</th>
<th>Days Total</th>
<th>Average # Days</th>
<th>Case Mix Index</th>
<th>Total Charges</th>
<th>Avg.Total Charge</th>
<th>Total Costs</th>
<th>Av. Total Costs</th>
<th>Daily Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>320</td>
<td>9,861</td>
<td>30.82</td>
<td>3.146</td>
<td>$23,331,779</td>
<td>$72,912</td>
<td>$6,232,194</td>
<td>$19,476</td>
<td>$632</td>
</tr>
<tr>
<td>1998</td>
<td>306</td>
<td>9,133</td>
<td>29.85</td>
<td>3.006</td>
<td>$22,544,309</td>
<td>$73,674</td>
<td>$7,466,482</td>
<td>$24,400</td>
<td>$818</td>
</tr>
<tr>
<td>1999</td>
<td>333</td>
<td>9,561</td>
<td>28.71</td>
<td>3.021</td>
<td>$24,320,513</td>
<td>$73,035</td>
<td>$8,955,237</td>
<td>$26,893</td>
<td>$937</td>
</tr>
<tr>
<td>2000</td>
<td>317</td>
<td>8,533</td>
<td>26.92</td>
<td>2.945</td>
<td>$22,502,997</td>
<td>$70,987</td>
<td>$10,500,043</td>
<td>$33,123</td>
<td>$1,231</td>
</tr>
<tr>
<td>2001</td>
<td>306</td>
<td>9,025</td>
<td>29.49</td>
<td>2.888</td>
<td>$26,179,373</td>
<td>$85,554</td>
<td>$11,300,282</td>
<td>$36,929</td>
<td>$1,252</td>
</tr>
<tr>
<td>2002</td>
<td>349</td>
<td>9,978</td>
<td>28.59</td>
<td>3.262</td>
<td>$30,604,617</td>
<td>$87,692</td>
<td>$13,976,747</td>
<td>$40,048</td>
<td>$1,401</td>
</tr>
<tr>
<td>2003</td>
<td>328</td>
<td>8,826</td>
<td>26.91</td>
<td>3.314</td>
<td>$30,437,032</td>
<td>$92,796</td>
<td>$12,939,593</td>
<td>$39,450</td>
<td>$1,466</td>
</tr>
<tr>
<td>Total</td>
<td>2259</td>
<td>64,917</td>
<td>28.77</td>
<td>3.041</td>
<td>$179,920,620</td>
<td>$69,581</td>
<td>$71,370,578</td>
<td>$27,540</td>
<td>$967</td>
</tr>
</tbody>
</table>

The case mix index is defined as the weight assigned to each Diagnosis Related Group (DRG) by the Health Care Financing Agency (HCFA), the average score was 2.9 – 3.3 and increased slightly over the 7 year period. Although this cost data was not stratified by birthweight and gestational age, the vast majority of infants had diagnoses of extreme immaturity, RDS, or prematurity with major problems. Average total costs doubled from $19,476 in 1997 to $39,450 in 2003 for an average length of stay of 29-30 days. Daily costs started at $632 in 1997 and increased 63% to $1466 by 2003. These costs may appear low when looking at the other data presented but are inclusive of infants in all birthweight categories that were admitted to the NICU. When examining a more serious and expensive diagnosis of extreme immaturity (birthweight < 1000 grams), the total average cost was $62,000 for a 50 day length of stay. This particular hospital information database was the only one found in our local area that could extract cost data for neonates.
Virginia Health Information (VHI) is the sole agency that collects hospital discharge data in the state of Virginia and publishes an industry report which contains hospital service line data for neonatology. Table 3 depicts this data for VCUHS and for the area Richmond hospitals with NICUs for the year 2003. There are several components included in this report. The resource index measures resource consumption; higher values indicate greater complexity and higher cost of hospital care. Also included is the average length of hospital stay in days per patient and the total average charges for hospital care per infant. These figures reflect hospital charges only, not the actual costs of patient care. Of note is that VCUHS MCV Hospitals has a lower resource index, length of stay, and total actual charges despite being the regional perinatal center with the highest level and complexity of neonatal services. The average daily charge for the VCUMC NICU amounts to $3,531, 2.5 times greater than the average daily cost discussed above.

Table 3. Virginia Hospital Service Line Data: Neonatology

<table>
<thead>
<tr>
<th>Facility</th>
<th>Resource Index</th>
<th>Average Length of Stay</th>
<th>Average Total Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCUHS</td>
<td>3.10</td>
<td>12.68</td>
<td>$44,776</td>
</tr>
<tr>
<td>Henrico Doctors Hospital</td>
<td>2.54</td>
<td>14.68</td>
<td>$66,739</td>
</tr>
<tr>
<td>CJW Medical Center</td>
<td>3.86</td>
<td>14.16</td>
<td>$65,109</td>
</tr>
<tr>
<td>Bon Secours St. Mary’s Hospital</td>
<td>1.99</td>
<td>7.93</td>
<td>$19,732</td>
</tr>
<tr>
<td>Bon Secours Memorial Regional</td>
<td>2.63</td>
<td>7.95</td>
<td>$16,474</td>
</tr>
</tbody>
</table>

Source: Virginia Health Information, 2003

One study was found that specifically examined the cost effectiveness of caring for infants with the specific diagnosis of apnea of prematurity. Researchers from Harvard University used computer modeling to examine the economic impact of varying durations of pre-discharge
monitoring of infants with AOP admitted to their NICU. Hospital costs were obtained from itemized billing records on the infants and converted to costs using Medicare charge to cost ratios. They found that as the duration of monitoring in the NICU increased, the cost effectiveness declined. In fact, cost effectiveness was poorer for infants over 30 weeks gestation. It was recommended that neonatal discharge guidelines for these infants be written with consideration of alternative uses of resources (Zupanic 2003).

In summary, it is difficult to obtain accurate and consistent cost data on preterm infants due to the range of differences across these types of studies. However, there are several common findings that are important. First there is an inverse relationship between hospital costs for preterm infants and gestational age/birth weight. As gestational age and birth weight decreases, hospital costs increase. Even small increases in gestational age and birth weight could result in significant cost savings in hospital costs and other long term costs of care for preterm infants.

Second, preterm births are extremely expensive and account for a large proportion of health care costs. These findings are important for clinical and policy implications and the planning of health services. Additional research needs to be done looking at specific ways to reduce costs related to the system of care delivery, including alternative options for discharge and coordination of services for these infants. The difficulty lies in evaluating the cost savings of specific strategies for reducing the risk or delaying a premature birth.

*Approaches to Disease Management in Neonatal and Perinatal Care*

Interventions targeted at high risk mothers that will improve the birth outcomes of their infants are necessary to prevent neonatal morbidity and mortality and reduce the costs associated
with preterm birth. Managed care organizations have been the primary driving force in the development of cost containment programs focused on disease management in perinatal care. These programs are focused on the optimal management of high risk conditions during pregnancy and on neonatal care to prevent or reduce complications and shorten the length of hospital stay. Different types of programs have been developed with a focus on nursing care management of the patient, this allows for improved coordination of health and human services and the provision of additional education for patients about their illness. Not all strategies have proven successful however in terms of quality improvement and cost savings (Carman et al. 2004). In a review of nine perinatal care management programs the main deficiency among them was a lack of specific program goals and objectives and a prospectively designed evaluation plan (Carman et al. 2004). Quality comprehensive prenatal care is believed to be one of the most effective means to reducing the risk of preterm birth. One example of a case management program not included in the above review was able to demonstrate successful results.

The “Partners With Mom” program began in 1999 by Johns Hopkins Healthcare LLC (JHHC) a managed care provider (Hawkins 2005). The target population is pregnant women with Medicaid Insurance as they tend to be the highest risk for preterm birth and neonatal mortality. The focus of the program is a case management approach for women with high risk conditions including prior preterm birth, preterm labor, preexisting and gestational diabetes, hypertension, substance abuse, HIV, adolescent pregnancy, asthma, cardiovascular disease, sickle cell, and seizure disorders along with other identified medical conditions (Hawkins 2005). Women are admitted into the program in the 2nd trimester of pregnancy (mean gestational age of 25 weeks) but prior to 34 weeks to maximize the impact of the interventions on the pregnancy outcome.
Referrals are encouraged from all health care providers; a phone and written consent is obtained from the patient, a risk assessment is completed, and educational interventions are targeted to the specific disease that determined her eligibility. Program services include phone contacts and home visits, referrals, counseling, ongoing assessments, medical equipment and coordination of transportation. A database is maintained on all clients and is linked to the neonatal database.

Infants in the NICU are also enrolled in the program and a number of cost reduction strategies are employed to contain costs and reduce the length of stay. Infants are transferred to the appropriate level of neonatal care based on the acuity of their condition either between or within the hospital network. Levels of care range from Level I (lowest) to level III (highest) through review of their medical status by neonatal nurse practitioners and consulting physicians. Several other policy options exist in this program to enhance revenue for the care of premature and sick neonates which include coordination of insurance benefits, social security for infants born at less than 1200 grams, and a fee for service Medicaid program for identified high cost neonatal conditions. For those infants discharged early or those requiring additional health care services and support, a Special Needs Child Disease Management Program was established. Reported total cost savings for the NICU portion of the program in 2002 amounted to 2.9 million dollars. In addition, a 7.8% decrease in NICU admissions occurred from 2001 to 2002 among the “Partners With Mom” participants, and transfers to a lower level of neonatal care resulted in a cost savings of 17% in average daily hospital cost (Diehl-Svrjcek 2005).

Further evaluation of the program (1999-2002) revealed that among the 735 maternity participants, 84% were Medicaid recipients. Preterm labor, diabetes, and substance abuse were
identified as the most common problems in pregnancy among these women. Preterm birth decreased from 40.7% to 25% in the group overall but the largest impact was seen in the preterm labor prevention group. Preterm births less than 37 weeks gestation decreased from 66.7% to 28.2%, with a 30% reduction in NICU births. Average total claims increased by $3,000 related to increased use of prenatal services but decreased from $22,718 to $10,410 among the preterm labor group. The percent of births born at low, very low, and extremely low weight decreased except in the substance using group. The mean length of stay also decreased the most for mothers in the preterm labor group from 3.96 to 2.65 days (Hawkins 2005).

Similar programs implemented by other Medicaid managed care organizations have also had positive results in terms of reducing neonatal intensive care unit admission rates. In a review of birth outcomes from the Monroe Plan for Medical Care in New York from 1997-2003, NICU admission rates decreased to 56.7 per 100 births from a rate of 107.6 with a cost savings of 2 dollars for every dollar spent (Stankaitis, Brill & Walker 2005). In a 20 year neonatal study from Stockholm Sweden, there was a decrease in the length of stay for moderately preterm infants as a result of interventions in the NICU which emphasized individualized care, comprehensive discharge planning and supportive home care (Altman 2006).

Other recent interventions in the Medicaid managed care population have also shown beneficial results in reducing preterm births. One such study found a 14.3% decrease in NICU admission rates among women receiving 17 alpha- hydroxyprogesterone caproate (17P) for previous history of preterm delivery (Mason et al. 2005). In addition, there was a significant decrease in NICU length of stay and hospital costs compared to the control group. This study was a longitudinal review of 2004-2005 data and contained only a small study group (n=24);
however, the authors concluded that treatment with 17P was beneficial to this high risk population. A multicenter, randomized controlled trial conducted by NICHD demonstrated a 33% reduction in preterm birth among women who had a prior spontaneous preterm birth that received 17P in the prenatal period. The use of 17P in this population has been supported by the American College of Obstetrics and Gynecology since 2003 (ACOG Committee Opinion 2003). In an attempt to assess the impact of 17P on the national preterm birth rate, Petrini et al used 2002 birth certificate data. Based on a 22.5% preterm birth recurrence rate the resulting effect was a 2% reduction in the preterm birth rate thus preventing 10,000 preterm births (Petrini et al. 2005).

An evaluation of over 59,000 women enrolled in national managed care programs was conducted by telephone interviews to identify maternal risk factors associated with NICU admissions. Women with preterm labor, preterm premature rupture of the membranes, multiple gestation, diabetes, pregnancy induced hypertension, and placental abruption were independently associated with a three times greater risk of a NICU admission (Ross et al. 1999). It was concluded that multiple gestation was also a leading risk factor and that screening may be valuable to identify all of these women for targeted interventions during pregnancy to reduce the risk of NICU admissions.

Another approach to cost containment in neonatal care entails examination of the actual system of care in the newborn intensive care unit. A study of 850 moderately preterm infants 30-34 weeks gestation from California and Massachusetts NICUs demonstrated that discharge of these infants is highly correlated with unit census (Profit et al. 2007). The physician’s decision to discharge was based not only on clinical readiness of the infant but on the unit workload. The
probability of discharge was 32% greater when the census was high (p<.001), but 20% less likely when the census was low (p<.01) (Profit et al. 2007).

Examples of the various disease management strategies and programs in both perinatal and neonatal care discussed here have been shown to be effective in reducing the cost of neonatal intensive care. However, these programs all contain a variety of different components and this makes it difficult to draw comparisons between them. The development and evaluation of additional programs is still needed for this high risk population.

The real life application problems that are presented provide a basis for deciding how best to apply this information to drive health policy and reduce the costs associated with preterm births. Additional opportunities for research include determining the cost savings on specific clinical policies to shorten length of stay in the NICU as in this dissertation study. This information will assist in determining the safety and cost effectiveness of early discharge from the VCU Medical Center NICU for infants with apnea of prematurity.
Chapter 3
Methods and Study Design

Although many studies have looked at the cost and use of health services for preterm infants, few have evaluated the impact of early discharge policies for preterm infants with Apnea of Prematurity in terms of safety and cost effectiveness. In addition, the question of how these types of policies are applied in practice and the impact on the infant and family are important considerations. Qualitative data gained from interviews with both the clinicians caring for these infants and the families can assist us in evaluating how well the policy is working, the impact on the family, and provide us with information to improve or modify a policy. This study is able to provide a perspective on this from one NICU experience with the assistance of the clinicians. Due to the retrospective design, interviews with these families are outside the scope of this study and therefore that information is drawn from the literature. The formulation of this research question stemmed from the need to understand more about the outcomes of the infants who qualified for discharge under the guidelines of this unique clinical policy.

Research Questions, Objectives and Hypotheses

Among patients with active but controlled Apnea of Prematurity (AOP) who are discharged from a Newborn Intensive Care Unit before complete resolution of the AOP, is there an increased incidence of life threatening episodes or death, and is the policy cost effective? In addition, what is the perceived psychosocial impact of this policy on the infant and family?
Criteria for Evaluation and Objectives for the Study

Effectiveness:

Objective 1. Examine the mortality up to one year after discharge for this cohort of infants with Apnea of Prematurity

Efficiency:

Objective 2. Determine the number and type of hospital readmissions and ER visits to VCUMC for these infants (also has an effectiveness component as type of readmission addresses morbidity)

Objective 3. Determine the hospital costs from birth up to one year for preterm infants admitted to the VCUMC NICU over the ten year time period with the diagnosis of Apnea of Prematurity

Objective 4. Compare the differences in readmissions and hospital costs between infants with AOP who are discharged home early on caffeine and an apnea monitor to those who remain in the NICU until resolution of their AOP

Equity:

Objective 5. Describe the subjective reaction of the providers about the implementation, utility, adherence, and recommended changes to the policy

Objective 6. Develop policy recommendations on early discharge for infants with AOP based on the evaluation of the evidence and knowledge acquired through this study.
The following hypotheses were developed and tested:

**Hypothesis 1.** There was no difference in mortality between the infants discharged home early on caffeine and a monitor and those who remained in the NICU until resolution of their AOP.

**Hypothesis 2.** Hospital costs for preterm infants with AOP at VCU MC increased significantly over the ten year study period.

**Hypothesis 3.** There is a significant difference in readmissions and cost of care between the infants discharged home early on caffeine and a monitor and those who remained in the VCUMC NICU.

   H3a. Hospital readmissions are lower in the early discharge group.

   H3b. Hospital costs are lower in the early discharge group.

**Hypothesis 4.** Evidence gathered in this study will support the continuation of the policy on AOP.

**Methods**

This is a retrospective case study which compares infants with AOP discharged home from the NICU on caffeine and apnea monitor with a comparison group consisting of infants who stayed in the NICU until resolution of their AOP. The initial study population that was identified included all preterm infants n=1213 admitted and discharged home from the regional center VCUMC NICU n=840 and from their community hospital NICU n=375 affiliate in Richmond over a ten year period from 1993-2002 with a diagnosis of Apnea of Prematurity. Hospital readmission and cost data was only available on the infants from VCUMC (n=675) up to one year of age. The collection of data was obtained from two existing sources, (1) VCUMC
Neonatal Information System database, a PC based system used for over 15 years, and (2) VCUMC health information system billing data on costs and charges. An analysis data file was created by combining this data which was in Microsoft Excel. Microsoft Access was used to match the variables from each data set. A database was then created in SPSS 13.0, cases were matched on the infants first and last name and medical record number.

To provide a qualitative perspective for the study, an interview questionnaire was developed by the candidate to collect data on the provider’s assessment of the VCUMC NICU policy on apnea of prematurity (Appendix B). A pilot interview was conducted with a neonatal nurse clinician who was familiar with a similar policy but was not working in this NICU. Face to face interviews were conducted by the candidate with each of the eight clinicians from the VCUMC NICU to determine their opinions about the policy. A letter of introduction was mailed to the faculty with a copy of the questionnaire one week prior to the interview so that the clinician would be familiar with the information being asked. An appointment was set up for the interview in a private office. The subject was asked to give verbal consent to the tape recording. During the tape recording, the interviewer made notes on the form to guide analysis of the tapes. A random number was assigned to match the tape to the questionnaire and the tapes were transcribed and analyzed by the candidate.

This study was approved for an expedited review by the VCU Institutional Review Board of the VCU Office of Research Subjects Protection due to the confidential nature of health information. For the quantitative data, identifiers on the subjects were needed initially to match the databases being queried. A waiver of informed consent was approved. The study posed no risk to human subjects (infants) as they are not directly involved in this research, only their
medical information was used. Reports were de-identified and contained only aggregate data. An amendment to the study was submitted and approved to conduct face to face interviews with the faculty physicians and nurse practitioners in the NICU in order to gain their opinions on this policy. Verbal consent was obtained from these subjects. The letter of introduction and interview questionnaire are included as Appendix B.

Analysis Database

The quantitative portion of this study includes variables from the NICU database: medical record number, first and last name of infant, sex, race, gestational age, birth weight, date of admission, length of stay, diagnosis at discharge (five most prevalent neonatal diagnoses in addition to AOP), and whether infant was sent home on caffeine and apnea monitor. Variables from hospital billing database include: medical record number, first and last name of infant, sex, date and cost of NICU admission, dates and costs of hospital readmissions to VCUHS and primary diagnosis at discharge (ICD 9 & ICD 10 codes with applicable diagnoses). All variables were coded and labeled in SPSS. (Table 4).

Infants who died in Virginia within the first year of birth were identified by a computerized search of the 1994-2003 linked birth/infant death certificates; this was completed by the Virginia Department of Health, Division of Health Statistics. For those infants, a summary of each death which includes a description of the variables related to the date of death, age at death, and underlying cause from the infants medical record was completed.

A descriptive analysis of the data includes frequencies and percentiles for the categorical variables of race, gender, and diagnoses. Means and medians were computed for birthweight,
gestational age, diagnoses, length of stay, postconceptual age at discharge, hospital readmissions, hospital costs and charges for each group. Odds ratios, T–tests, and Chi square analyses were used for comparisons between groups. The data was analyzed for mean differences in readmissions, gestational age, birth weight, LOS in the NICU and hospital costs between the study group and the control group. Since the distribution of these variables did not violate assumptions of normality, a LOG transformation of costs and charges did not need to be performed for statistical comparisons between groups. Data on readmissions and cost comparisons was stratified by birth weight and gestational age to examine potential differences in initial illness severity between the two discharge groups. Significance testing was set at .05.

**Provider Interviews**

From a qualitative perspective, the interview questionnaire provides data to elucidate the clinicians’ perspective on this policy. Policy evaluation by the users of the policy provides important information unable to be gathered quantitatively from outcome data which assists in the process of policy modification. This questionnaire consists of seven questions, both closed and open ended in nature about the application, usefulness, and recommended changes in the policy. The answer choices were based on a 3 point scale, a number value was assigned to code responses for these questions and simple frequencies were calculated. The numbered results from the interview questionnaires were entered into SPSS for analysis and responses for open ended questions were summarized in a written format.
Table 4. Study Variables

<table>
<thead>
<tr>
<th>Variable [ID]</th>
<th>Operational Definition</th>
<th>Level of Measurement</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Gender: male or female</td>
<td>Nominal</td>
<td>1 = male</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 = female</td>
</tr>
<tr>
<td>Race</td>
<td>Three category race</td>
<td>Nominal</td>
<td>1 = white</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 = black</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 = Asian</td>
</tr>
<tr>
<td>Gestational Age</td>
<td>Number of completed weeks gestation in a pregnancy up to 37 weeks</td>
<td>Scale</td>
<td>1 – 37 weeks as numbered</td>
</tr>
<tr>
<td></td>
<td>(definition of premature birth is less than 37 completed weeks)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birth weight</td>
<td>Weight of infant at birth in grams</td>
<td>Scale</td>
<td>0 – 2500 grams as numbered</td>
</tr>
<tr>
<td></td>
<td>(definition of low birthweight is less than 2500 grams)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of stay</td>
<td>Number of days spent in the hospital</td>
<td>Scale</td>
<td>Days as numbered</td>
</tr>
<tr>
<td>Date of Admission</td>
<td>Date admitted to hospital</td>
<td>Scale</td>
<td>1-10 corresponds to years 1993-2003</td>
</tr>
<tr>
<td>Date of Discharge</td>
<td>Date discharged from hospital</td>
<td>Scale</td>
<td>1-10 corresponds to years 1993-2003</td>
</tr>
<tr>
<td>Diagnosis at discharge</td>
<td>Medical diagnosis</td>
<td>Nominal</td>
<td>Description of condition</td>
</tr>
<tr>
<td>Pregroup</td>
<td>Discharged from hospital on caffeine</td>
<td>Nominal</td>
<td>1 = yes caffeine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 = no caffeine</td>
</tr>
<tr>
<td>Post conceptional age at discharge</td>
<td>Age in number of weeks since conception</td>
<td>Scale</td>
<td>Weeks as numbered</td>
</tr>
<tr>
<td>Apnea monitor</td>
<td>Discharged home on an apnea monitor</td>
<td>Nominal</td>
<td>1 = yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 = no</td>
</tr>
<tr>
<td>Type of admission to hospital</td>
<td>Inpatient or Emergency Room</td>
<td>Nominal</td>
<td>1 = inpatient</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 = emergency room</td>
</tr>
<tr>
<td>Diagnosis related group / DRG</td>
<td>Grouping of medical diagnosis</td>
<td>Scale</td>
<td>As numbered</td>
</tr>
<tr>
<td>ICD 9 or 10</td>
<td>International Classification of Disease</td>
<td>Scale</td>
<td>Number assigned to the specific diagnosis</td>
</tr>
<tr>
<td>Date of death</td>
<td>Date infant died</td>
<td>Date</td>
<td>Month/ day/year</td>
</tr>
<tr>
<td>Underlying cause of death</td>
<td>Primary cause of death</td>
<td>Scale</td>
<td>Description of cause of death</td>
</tr>
<tr>
<td>Age at death</td>
<td>Age in weeks</td>
<td>Scale</td>
<td>Weeks as numbered</td>
</tr>
</tbody>
</table>
Chapter 4
Data Analysis and Discussion

Results of the data analysis are organized by the evaluation criteria of effectiveness, efficiency and equity with the corresponding objectives and hypotheses.

<table>
<thead>
<tr>
<th>Evaluation Criterion #1: Effectiveness “safety”</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective 1</strong>: Determine the incidence of mortality in the study population.</td>
</tr>
</tbody>
</table>

| Hypothesis 1: There was no difference in mortality between the infants discharged home early on caffeine and a monitor and those who remained in the NICU until resolution of their AOP. |

After cleaning the data, the total data set consisted of 933 infants; 38.9 percent (363) were discharged home with caffeine and a monitor (study group) and 61 percent (570) were discharged home from the NICU without caffeine and a monitor (control group).

The driving force behind this study was to determine if the practice of discharging infants home on caffeine and a monitor from the VCUMC NICU was a safe practice. After discharge, no significant difference was found in the mortality between the two groups (p=.65) prior to one year of age. Mortality was a rare event; there were two infant deaths in each group (.55% in the study group and .35% in the control group). The specific causes of mortality were not related to apnea of prematurity. In the study group, both babies died of Sudden Infant Death Syndrome (SIDS); in the control group, one baby died of SIDS and one died from bronchopneumonia. Three infants were autopsied by a forensic pathologist at the Office of the Chief Medical
Examiner (OCME) in Richmond Virginia who certified the cause of those deaths as SIDS. The other infant was autopsied by a hospital pathologist who certified the cause of death as Bronchopneumonia. Medical records were reviewed on each infant, including autopsy reports for the deaths to verify the information.

**Infant Deaths in the Study Group**

**Case #1.** The infant was born at 27 weeks gestation with a birthweight of 980 grams. The length of hospital stay in the NICU was 66 days. At discharge, this infant was 36 weeks post conceptional age on caffeine and a monitor. At 4 months of age, this infant was found unresponsive face down in a crib. The infant was still on an apnea monitor and caffeine. The cause of death was ruled as SIDS and the manner of death was natural.

**Case #2.** The infant was born at 27 weeks gestation with a birthweight of 1070 grams. The length of stay in the NICU was 54 days. At discharge, this infant was 35 weeks post conceptional age on caffeine and a monitor. At 3 months of age, this infant was found unresponsive face down in a crib with blankets. The cause of death was ruled as SIDS and the manner of death was natural.

**Infant Deaths in the Control Group**

**Case #3.** Infant was born at 26 weeks gestational age at a birthweight of 700 grams. The length of stay in the NICU was 89 days. Apnea of Prematurity was resolved. The postconceptional age at discharge was 38 weeks. At 4 months of age, this infant was found
unresponsive in a crib. He was reported to be healthy until that time with mild congestion but no fever. The cause of death was determined to be respiratory failure and acute bronchopneumonia.

**Case #4.** Infant was born at 30 weeks gestation at a birthweight of 1470 grams. The length of stay in the NICU was 39 days. Apnea of prematurity was resolved. The infant was discharged at 34 weeks postconceptional age. This infant died suddenly and unexpectedly at one month of age. The cause of death was ruled as SIDS, the manner of death is natural.

Hypothesis 1 is supported by the data; there was no significant difference in the mortality between the infants discharged home early on caffeine and a monitor and those who remained in the NICU until resolution of their AOP. The causes of death were not related to AOP.

**Demographics of the Study Population**

Demographic findings are detailed in Table 5 showing percentages and odds ratios with corresponding p values and confidence intervals, T tests were also calculated on the mean birthweight. Significant differences were found in the racial composition between the groups (p=.000). The majority of black infants, 70% (371) were in the control group, compared to 30% (161) in the study group. White infants were almost equally distributed between the two groups 49% (182) versus 51% (187). Asians, Hispanics and other races comprised less than 4% of the infants in each group and were also equally distributed. The odds of being sent home on caffeine and a monitor were 2.37 greater for white infants than for black infants (p=.000, CI 1.78-3.15). Males have 1.5 times increased odds over females for being discharged early (p=.003, CI 1.17-1.91).
There was no significant difference in the mean birthweight between the study 1289gms and the control 1247gms (p=.187) groups. A significant difference was found when the data was analyzed by two birthweight specific categories. A higher percent (63%) of very low birthweight infants (less than 1500 gms) were in the control versus 37% in the study group. Moderately low birthweight infants (1500 - 2500gms) were more evenly distributed, 45% in the study group and 55% in the control group. The odds of being sent home on a monitor were 1.42 times higher for moderately low birthweight babies (p=.022, CI 1.03-1.97). The mean estimated gestational age by dates did not differ significantly, 28.7 weeks in the study group and 29.2 weeks in the control group (p=.82).

Table 5. Demographic Data on Infants with Apnea of Prematurity

<table>
<thead>
<tr>
<th></th>
<th>Caffeine / Monitor</th>
<th>No Caffeine / No Monitor</th>
<th>P value</th>
<th>OR</th>
<th>CI .05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of infants admitted to NICU</td>
<td>N = 363 (38.9%)</td>
<td>n = 570 (61.1%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated gestational age (wk)</td>
<td>28.74 + 2.92</td>
<td>29.20 + 2.75</td>
<td>.082</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22-27</td>
<td>130 (46)</td>
<td>154 (54)</td>
<td>.15</td>
<td>1.56</td>
<td>.82-2.98</td>
</tr>
<tr>
<td>28-33</td>
<td>214 (36)</td>
<td>381 (64)</td>
<td>1.03</td>
<td>.56-1.93</td>
<td></td>
</tr>
<tr>
<td>34-37</td>
<td>19 (35)</td>
<td>35 (65)</td>
<td>Referent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birthweight (kg)</td>
<td>1288.59 + 482.73</td>
<td>1247.22 + 455.13</td>
<td>0.187</td>
<td>t test</td>
<td></td>
</tr>
<tr>
<td>500- 999</td>
<td>121 (40)</td>
<td>180 (60)</td>
<td></td>
<td>0.63</td>
<td>.34-1.14</td>
</tr>
<tr>
<td>1000-1499</td>
<td>137 (34)</td>
<td>263 (66)</td>
<td></td>
<td>0.49</td>
<td>.27-.88</td>
</tr>
<tr>
<td>1500-1999</td>
<td>75 (59)</td>
<td>99 (41)</td>
<td></td>
<td>0.68</td>
<td>.36-1.29</td>
</tr>
<tr>
<td>2000-2499</td>
<td>22 (38)</td>
<td>15 (62)</td>
<td>Referent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;2500</td>
<td>8 (45)</td>
<td>13 (55)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low weight births (1500 - 2499 gms)</td>
<td>105 (45)</td>
<td>127 (55)</td>
<td>*.022</td>
<td>1.42</td>
<td>1.03-1.97</td>
</tr>
<tr>
<td>Very low weight births (&lt;1500 gms)</td>
<td>258 (37)</td>
<td>443 (63)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>161 (30)</td>
<td>371 (70)</td>
<td>*.000</td>
<td>Referent</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>187 (51)</td>
<td>182 (49)</td>
<td>2.37</td>
<td>1.78-3.15</td>
<td></td>
</tr>
<tr>
<td>Other = Asian, Hispanic</td>
<td>15 (47)</td>
<td>17 (53)</td>
<td>2.03</td>
<td>.94-4.4</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>156 (34)</td>
<td>302 (66)</td>
<td>*.008</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>207 (44)</td>
<td>267 (56)</td>
<td>1.5</td>
<td>1.17-1.91</td>
<td></td>
</tr>
</tbody>
</table>
Seven primary discharge diagnoses from the NICU hospitalization were examined, Respiratory Distress Syndrome (RDS), Bronchopulmonary Dysplasia (BPD), Intraventricular Hemorrhage (IVH), GE Reflux, Periventricular Leukomalacia, Sepsis, and Necrotizing Enterocolitis (NEC). A significant difference was found in the occurrence of BPD 27.3% in the study group and 18% in the control group, infants in the study group had a 1.72 times increased risk of BPD (p=.001, CI 1.24-2.39). These infants also had a 4.87 times increased risk of GE Reflux (p=.000, CI 2.82-8.47). The odds of having NEC however were only .58 in the study group (p=.035, CI .34-.99). There were no other significant differences in these primary diagnoses between the two groups.

The mean length of hospital stay in the NICU was 52.1 days in the study group and 53.1 days in the control group, also not a significant difference. When stratified by birthweight categories, there were no significant differences in the length of stay between the two groups for either the very low or moderately low weight infants. In addition, no significant difference was found in the mean postconceptional age at discharge between the two groups (p=.82), 36.4 weeks in the study group and 36.8 weeks in the control group.
<table>
<thead>
<tr>
<th>Number of infants in NICU</th>
<th>Caffeine / Monitor</th>
<th>No Caffeine / No Monitor</th>
<th>P value</th>
<th>OR</th>
<th>CI .05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary diagnoses NICU admission:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory Distress Syndrome</td>
<td>195 (53.7)</td>
<td>293 (51.4)</td>
<td>0.49</td>
<td>1.1</td>
<td>.84-1.44</td>
</tr>
<tr>
<td>Bronchopulmonary Dysplasia</td>
<td>99 (27.3)</td>
<td>102 (17.9)</td>
<td>0.001</td>
<td>1.72</td>
<td>1.24-2.39</td>
</tr>
<tr>
<td>Intraventricular hemorrhage</td>
<td></td>
<td></td>
<td>0.604</td>
<td>0.92</td>
<td>.67-1.27</td>
</tr>
<tr>
<td>Grade I</td>
<td>47 (12.9)</td>
<td>74 (13.0)</td>
<td>0.386</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>9 (2.5)</td>
<td>24 (4.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 3</td>
<td>23 (6.3)</td>
<td>32 (5.6)</td>
<td>0.881</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 4</td>
<td>6 (1.7)</td>
<td>12 (2.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GER Reflux</td>
<td>57 (15.7)</td>
<td>21 (3.7)</td>
<td>0</td>
<td>4.87</td>
<td>2.82-8.47</td>
</tr>
<tr>
<td>Periventricular Leukomalacia</td>
<td>22 (6.1)</td>
<td>26 (4.6)</td>
<td>0.312</td>
<td>1.35</td>
<td>.72-2.51</td>
</tr>
<tr>
<td>Sepsis</td>
<td>188 (51.8)</td>
<td>282 (49.5)</td>
<td>0.49</td>
<td>1.1</td>
<td>.84-1.44</td>
</tr>
<tr>
<td>Necrotizing Enterocolitis</td>
<td>22 (6.1)</td>
<td>57 (10%)</td>
<td>0.035</td>
<td>0.58</td>
<td>.34-99</td>
</tr>
<tr>
<td>Postconceptional age at discharge</td>
<td>36.42 + 3.45</td>
<td>36.76 + 3.44</td>
<td>0.82</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of Stay in NICU (days)</td>
<td>52.14 + 27.7</td>
<td>53.13 + 29.81</td>
<td>0.61</td>
<td></td>
<td>t test</td>
</tr>
<tr>
<td>VLBW (&lt;1500 grams) n=701</td>
<td>63.91</td>
<td>60.32</td>
<td>0.529</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LBW (1500&gt;) n=232</td>
<td>23.20</td>
<td>28.04</td>
<td>0.826</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Evaluation Criterion #2: Efficiency

<table>
<thead>
<tr>
<th>Objectives 2-4: Determine the hospital costs from birth up to one year.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examine the number and type of hospital readmissions.</td>
</tr>
<tr>
<td>Compare the differences in readmissions and hospital costs between the two groups.</td>
</tr>
</tbody>
</table>

**Hypothesis 2.** Hospital costs for preterm infants with AOP at VCU MC increased significantly over the ten year study period.

**Hypothesis 3.** There is a significant difference in readmissions and cost of care between the infants discharged home early on caffeine and a monitor and those who remained in the VCUMC NICU.

- **H3a.** Hospital readmissions are lower in the early discharge group.
- **H3b.** Hospital costs are lower in the early discharge group.

As with other health care costs cited in the literature review, the cost of hospital care for all of these infants increased significantly over the 10 year period. There was actually a 43% increase in mean hospital charges from $108,375 in 1993 (N=103) to $155,291 in 2002 (n=53). In terms of actual costs, there was only an 8.5% increase in the mean hospital costs from $68,308 in 1993 to $74,102 in 2002. Within the ten year period, the mean range of costs varied from a low of $34,331 in 1997 to a high of $82,781 in 2001. The sum total hospital costs for infants in the study group were equal to $13,922,365 and the NICU costs amounted to $12,931,431 (n=241, mean NICU cost $53,657). For the control group, the sum total hospital costs equaled $25,194,589 and the NICU costs accounted for $22,893,423 (n=434, mean NICU cost $52,750). The total NICU costs for these infants over the ten year period was $35,824,854. The data supports Hypothesis 2 that the cost of hospital care increased significantly over the ten year period due primarily to the increased markup of hospital charges.
**Morbidity**

The primary indicator of morbidity after discharge examined in this study was the number and type of visits to the emergency department and inpatient hospital admissions to VCUHS. Table 7 depicts readmission data for the subset of infants who stayed in the MCVH NICU, n= 675, of whom 241 were in the study group and 434 in the control group. There were no significant differences in the number of inpatient readmissions or in Emergency Department (ED) visits between the study group and the control group within one year after discharge from the NICU (Table 7). In both groups, over half of the infants had more than one readmission to the hospital and two thirds had visited the ED more than once. A further breakdown revealed that infants in the study group accounted for 257 admissions, 106 being inpatient. Of those, 38 % had one inpatient admission, 24% had 2 admissions and 38% had greater than two admissions. There were 151 total visits to the ED with 68% having more than one visit. The control group had 542 admissions, 219 of whom were inpatient. Like the study group, 38 % had one inpatient admission, 24 % had 2 admissions and 38% had greater than two admissions. This group had 323 ED visits with 68% having more than one visit. This data does not support Hypothesis 3a that hospital readmissions are lower in the early discharge group.

<table>
<thead>
<tr>
<th>Table 7. Emergency Department Visits And Hospital Admissions To VCUMC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caffeine / Monitor</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>Emergency Dept (ED) admissions</td>
</tr>
<tr>
<td>Inpatient readmissions</td>
</tr>
</tbody>
</table>
In addition to the number of readmissions, the reasons for readmission to the hospital after discharge were also examined to determine whether infants were returning to the hospital with apnea of prematurity. The eleven most frequent discharge diagnoses for readmissions are detailed in Table 8 which shows the percentage of admissions for each diagnosis within each group. The most commonly occurring diagnosis in both groups of infants was bronchiolitis followed by upper respiratory infections (URI) and otitis media. These diagnoses were not related to Apnea of Prematurity.

Table 8. Readmission Data for MCVH with Eleven Most Common Discharge Diagnoses

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Caffeine/monitor</th>
<th>No caffeine/ monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral enteritis</td>
<td>1 (.4)</td>
<td>9 (1.6)</td>
</tr>
<tr>
<td>Hypovolemia</td>
<td>5 (1.9)</td>
<td>8 (1.5)</td>
</tr>
<tr>
<td>Otitis Media</td>
<td>18 (6.9)</td>
<td>27 (4.9)</td>
</tr>
<tr>
<td>Acute URI</td>
<td>23 (8.8)</td>
<td>54 (9.9)</td>
</tr>
<tr>
<td>Acute bronchiolitis</td>
<td>42 (16.1)</td>
<td>82 (15)</td>
</tr>
<tr>
<td>Asthma unspecified</td>
<td>5 (1.9)</td>
<td>11 (2.0)</td>
</tr>
<tr>
<td>Esophageal reflux</td>
<td>14 (5.4)</td>
<td>19 (3.5)</td>
</tr>
<tr>
<td>Constipation</td>
<td>2 (.8)</td>
<td>9 (1.6)</td>
</tr>
<tr>
<td>Fever</td>
<td>9 (3.5)</td>
<td>20 (3.7)</td>
</tr>
<tr>
<td>Respiratory Abnormalities</td>
<td>10 (3.9)</td>
<td>13 (2.4)</td>
</tr>
<tr>
<td>Vomiting alone</td>
<td>3 (1.2)</td>
<td>9 (1.6)</td>
</tr>
</tbody>
</table>

Costs and charges for both emergency department visits and inpatient admissions which include the NICU stay and hospital readmissions to VCUHS are detailed in Table 9. There were no significant differences found in the mean ED costs, $694 for the study group versus $621 for the control group. Mean inpatient costs did not differ significantly between the groups; $58,276 in the study group and $57,985 in the controls.
A further breakdown of mean cost data stratified by birthweight categories of VLBW and LBW was examined between the study group and the control group. Within each birthweight category, the mean costs between the two groups were not significantly different. For VLBW infants, the ED costs were $742 in the study group versus $634 in the controls and the inpatient costs were $68,058 versus $64,234. For the LBW infants, ED costs were $511 in the study group versus $521 in the controls and the inpatient costs were $20,543 versus $26,652. As expected, the cost of the very low birthweight infants in both groups was more than double for those born at a larger birthweight. The mean cost of hospital care was not significantly lower in the group who were discharged early; therefore, Hypothesis 3b is not supported from this data.

Table 9. Cost of Emergency Department and Hospital Admissions, VCUMC

<table>
<thead>
<tr>
<th></th>
<th>Caffeine / Monitor</th>
<th>No Caffeine / No Monitor</th>
<th>Chi Square</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ED and Inpatient charges &amp; costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean charges ED</td>
<td>737.</td>
<td>697.</td>
<td>not sig</td>
<td>.448</td>
</tr>
<tr>
<td>Mean costs ED</td>
<td>694.</td>
<td>621.</td>
<td>not sig</td>
<td>.461</td>
</tr>
<tr>
<td>Mean charges Inpatient</td>
<td>135,704.</td>
<td>124,513.</td>
<td>not sig</td>
<td>.482</td>
</tr>
<tr>
<td>Mean costs Inpatient</td>
<td>58,276.</td>
<td>57,985.</td>
<td>not sig</td>
<td>.482</td>
</tr>
<tr>
<td>Median costs ED</td>
<td>487.</td>
<td>394.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median costs Inpatient</td>
<td>48,745.</td>
<td>47,005.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VLBW &lt;1500gms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ED costs</td>
<td>742.</td>
<td>634.</td>
<td>not sig</td>
<td>.536</td>
</tr>
<tr>
<td>Median ED costs</td>
<td>496.</td>
<td>405.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Inpatient costs</td>
<td>68,058.</td>
<td>64,234.</td>
<td>not sig</td>
<td>.480</td>
</tr>
<tr>
<td>Median Inpatient costs</td>
<td>61,884.</td>
<td>51,034.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LBW &gt;1500gms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ED costs</td>
<td>511.</td>
<td>521.</td>
<td>not sig</td>
<td>.320</td>
</tr>
<tr>
<td>Median ED costs</td>
<td>$478.</td>
<td>304.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Inpatient costs</td>
<td>20,543.</td>
<td>26,652.</td>
<td>Not sig</td>
<td>.457</td>
</tr>
<tr>
<td>Median Inpatient costs</td>
<td>14,677.</td>
<td>19,264.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Cost data includes admissions up to 1 year of age
<table>
<thead>
<tr>
<th>Evaluation Criterion #3: Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective 5.</strong> Describe the subjective reaction of the providers about the implementation, utility, adherance, and recommended changes to the policy</td>
</tr>
<tr>
<td><strong>Objective 6.</strong> Develop policy recommendations on early discharge for infants with AOP based on the evaluation of the evidence and knowledge acquired through this study</td>
</tr>
<tr>
<td><strong>Hypothesis 4.</strong> Evidence gathered in this study will support the continuation of the policy on AOP.</td>
</tr>
</tbody>
</table>

Since the findings revealed a significant racial difference in the composition of the groups, the data on black race were stratified to better understand the relationship of race to other variables between the two groups. Analysis of the data by race and birthweight revealed a higher percentage of extremely low weight (<1000 gm) black infants in the control group, 80% versus 63% in the study group. In addition, significantly more moderately low weight (1500-2500 gm) white infants were in the study group, 71% versus 47% in the control group. Both of these findings would in part explain this discrepancy. Additional analysis on black infants between the two groups found that the mean birthweight, gestational age, length of stay, and hospital costs (Table 10) did not explain why more there were significantly more white infants than black infants being discharged on caffeine and a monitor.
Table 10. Data on Black Infants with Apnea of Prematurity

<table>
<thead>
<tr>
<th></th>
<th>Birthweight (grams)</th>
<th>GA by dates</th>
<th>LOS NICU</th>
<th>ED Costs</th>
<th>Inpatient Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Caffeine/Monitor</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>161</td>
<td>161</td>
<td>161</td>
<td>52</td>
<td>115</td>
</tr>
<tr>
<td>Mean</td>
<td>1118.78</td>
<td>27.77</td>
<td>59.85</td>
<td>$769</td>
<td>$68,507</td>
</tr>
<tr>
<td>Median</td>
<td>1030</td>
<td>28</td>
<td>57</td>
<td>$519</td>
<td>$56,193</td>
</tr>
<tr>
<td><strong>No Caffeine/No Monitor</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>371</td>
<td>371</td>
<td>371</td>
<td>118</td>
<td>325</td>
</tr>
<tr>
<td>Mean</td>
<td>1155.08</td>
<td>28.63</td>
<td>59.85</td>
<td>$603</td>
<td>$60,064</td>
</tr>
<tr>
<td>Median</td>
<td>1110</td>
<td>28</td>
<td>57</td>
<td>$415</td>
<td>$48,504</td>
</tr>
</tbody>
</table>

*Interview Data*

As previously discussed, the qualitative portion of the study consisted of interviews with the clinicians in the VCUMC NICU. After the questionnaire was distributed to the clinicians, face to face interviews were completed individually within a private office by the researcher. All interviews were audio taped and transcribed, numerical results were entered into an Excel spreadsheet and the comments summarized. Eight of ten clinicians completed the interviews, one person did not participate due to moving out of town, and one was not available due to their schedule. All participants reviewed the policy and agreed that the purpose of the policy is to provide a guideline for the diagnosis and treatment of AOP. Specifically, it provides an outline of the drug management for AOP in terms of caffeine dosing including the initiation,
continuation, and discontinuation of treatment. Additionally, it defines which babies being discharged from the NICU can be done so safely on caffeine and a monitor. Seven of eight clinicians thought that it was clearly written. One person rated it as somewhat clear because it is a bit vague in terms of caffeine dosing. That dosage they believed should be adjusted based on the patient. Five clinicians had a lot of experience as they had cared for greater than 55 infants with apnea of prematurity in the last year. Of the remaining 3, one cared for 15-25 infants, one cared for 25-40 infants, and one cared for 40-55 of these infants. The clinicians all agreed that the policy was very useful in providing appropriate evaluation and treatment for infants experiencing AOP. All of them said they used it with almost every case and it helped them to decide which infants with AOP qualify for early discharge and which ones do not. It was seen as especially helpful for new clinicians as it is a different practice from other NICU’s. Seven of eight stated that they always follow the policy when caring or these infants, only one said sometimes. The policy was not thought to be helpful when there is a possible differential diagnosis such as reflux or sepsis, or where a diagnostic controversy may exist. It was also thought to be lacking in guidance on when to stop caffeine. In terms of checking a caffeine level one week after discontinuation, this is not as helpful because it takes a different amount of time to reach a subtherapeutic level depending on the maintenance dose.

All but one clinician had observed that parent infant interactions and care giving behaviors were affected by the notion of vulnerability especially among young and first time parents. These parents are very nervous about their baby and perceive them as very fragile. They are less likely to engage in the care of their infant and are scared they may harm their child. Even seasoned parents are worried however, the notion of vulnerability is not as strong as society has a
changing perception of prematurity, and it is thought to be more accepted. In terms of how it should affect early discharge, some thought that we should not discharge them early on a monitor if there are questions about the capacity of the parent to care for the infant. These parents may need more time and more education. Teaching them to focus on the infant and their behaviors rather than on the monitor helps the attachment behaviors improve. Reassurance and support from the staff assists these parents to understand and better care for their infant, it was observed that the more they participate in their care, the more comfortable they become. In other words, the more involved parents are with their infant, the lesser their perception of vulnerability.

In answer to the last question, changes were recommended to the policy by five of the clinicians and for the most part they were similar changes. They included: change the maintenance dose of caffeine to 5mg/kg/day, discontinue the caffeine based on the infant’s maturity (33-34 weeks) and the absence of central apnea (5-7 days, or >7 days), not on weight. Finally, when adjusting dose of caffeine, add an extra dose to get the level up faster.

The interview results from the clinicians positively support the policy along with the quantitative data. In terms of the fourth hypothesis, we find no reason to not continue this policy.
Discussion of Results

This study on infants with Apnea of Prematurity has some notable strengths. It is an evaluation of a long standing clinical policy which has enabled us to examine the outcomes of these infants who were discharged home early. Often, clinical practice exists without the benefit of an evaluation and until recently, clinical trials to evaluate the long term safety of caffeine administration for apnea of prematurity had not even been conducted. Over ten years of data that included all of the infants admitted to the regional center NICU, a reasonably large number of infants, allowed us to have enough power to have statistically significant findings. The qualitative portion of the survey enabled us to see if the policy was being utilized for its intended purpose and to obtain feedback for any recommended changes. Experienced clinicians are caring for these infants, and the majority of them follow this policy for diagnosis, treatment, and early discharge of infants with AOP. The interview participants were very open and were willing to discuss changes that they thought should be made to the policy which consisted of adding more details regarding caffeine dosing and using gestational age as a criteria for discontinuation of caffeine. The vulnerability of these infants was recognized especially with new parents as well as the strong nursing support and assists all families. The readiness and ability of the parents to care for the infant was factored into the decision to discharge. Comments from the clinicians included “we have gotten no feedback from families of negative effects from sending them home early” and “taking the child out of the hospital and putting them in a loving environment is generally beneficial”.

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Overall, there were very few significant differences between the group of infants discharged home on caffeine and a monitor and those who stayed in the NICU until resolution of their apnea of prematurity. These differences were found when comparing racial composition, birthweight categories of VLBW and LBW, and certain NICU diagnosis.

In terms of the risk of mortality, it is known that black infants are two and a half times more likely to die in the first year of life as white infants. All four of the infants in this study who died were black. In examining cause specific mortality, SIDS is the leading cause of postnatal death (>28 days of age) in the nation as well as in Virginia accounting for a rate of 82 deaths per 100,000 live births in 2005. The racial disparity is evident, African American infants have the highest rate of SIDS. In fact, SIDS accounts for 25% of infant deaths in Richmond City, and is second only to prematurity.

“SIDS is defined as the sudden death of an apparently healthy infant under one year of age and is diagnosed after a complete case investigation consisting of an autopsy, a death scene investigation, and review of the infants medical history” (Willinger, 1991). It is a diagnosis of exclusion, the etiology still remains unknown and it is considered to be a natural death. Premature infants in particular are known to be at a higher risk for SIDS than term babies. The remaining infant death was due to bronchopneumonia which is the third most common cause of sudden unexpected infant deaths in Virginia. This diagnosis is made by microscopic examination of lung tissue postmortem and is considered a natural death.

Although there was no difference in the mean birthweight or gestational age between the two groups, the control group had a higher percentage of very low birthweight (<1500 grams) infants which would likely increase their risk of morbidity over the study group. This may have
been the underlying reason why they were not sent home from the NICU early, they may have had more medical complications and did not meet the criteria for discharge.

**NICU Diagnoses**

Differences in the primary diagnosis from the NICU admission were significant for BPD, GE reflux, and NEC. Infants who were discharged on caffeine and a monitor were 1.7 times more likely to have BPD, and 4.9 times more likely to have GE reflux but were almost half as likely to have NEC. These findings should be interpreted with consideration of the following. Infants with BPD often have prolonged stays due to the chronic need for oxygen, which when physiologically stable, can also be managed at home. The diagnosis of GE reflux is not always made in a consistent manner making it difficult to do comparisons. If a premature infant is taking full feedings and gaining weight however then GE reflux would not likely delay the discharge. The complications from NEC especially the more advanced stages of the disease would likely prolong the stay of the infant, thus not allowing them to be eligible for discharge under this policy.

**Costs**

The mean length of stay in the NICU between the two groups differed by only one day. The study group stayed an average of 52 days and the mean inpatient cost was $58,000. This amounts to about $1120 per day. Usually, these infants would remain in the unit at least another 5 – 7 days until resolution of their apnea. Under this discharge policy, the predicted hospital cost savings from our data can be estimated to be $5600 to $7800 per infant. We then examined if the
costs for this group after discharge were shifted disproportionately to other services. Again, no significant differences were found in the number of readmissions to the emergency department or inpatient hospital admissions when compared to the control group. When we discharged these infants home early on a monitor and caffeine, the costs shifted to other types of outpatient services which include physician and other home health care services, medical equipment such as apnea monitors, and prescription drugs. Detailed costs related to home care were not available for this cohort of infants, so phone calls were made by the candidate to local companies to obtain approximate retail charges for the Richmond area (Table 11). The average daily charges are usually higher in the first month after discharge due to the increased frequency of nursing home visits; this varies depending on the health of the infant and the capacity of the family to care for the infant. The approximate retail cost amounted to $132 per day which is a significant savings over a hospital day in the NICU. Other early discharge programs for NICU infants have also determined them to be cost effective. An evaluation of one cost containment program showed a significant savings in hospital charges of $10,609 per infant, which was 30 times greater than program expenses of $500 per infant (Kotegal, 1995).

Table 11. Retail costs for neonatal follow up care in Richmond, 2007

<table>
<thead>
<tr>
<th>Service</th>
<th>Frequency</th>
<th>Retail cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home health care: skilled nursing visits</td>
<td>Once daily x 2 weeks, 3x week x 2 weeks</td>
<td>160. per visit</td>
</tr>
<tr>
<td>Medical equipment: apnea monitor (includes supplies)</td>
<td>Monthly rental</td>
<td>350.</td>
</tr>
<tr>
<td>Medication: caffeine citrate (compounded)</td>
<td>Monthly supply</td>
<td>250.</td>
</tr>
<tr>
<td>Pediatrician visits</td>
<td>Once a week x 4 weeks</td>
<td>165. per visit</td>
</tr>
</tbody>
</table>
Readmissions

The fact that there were no significant differences in rates of emergency room visits or inpatient admissions between the two groups of VCU/ MCV patients further supports the safety and efficacy of the policy. Although this data is not inclusive of all readmissions, we know that most parents return to the hospital of birth when the infant is ill as they have previously established a medical home there. This hospital is the regional medical center and has provided most of the pediatric care in the area for many years until the proliferation of Neonatal/ Pediatric services in the community in the early 1990’s. The most common reasons for readmission in both groups included bronchiolitis, upper respiratory infections, and otitis media, and not for reasons related to apnea of prematurity. These diseases are the most common reasons for hospital readmissions in premature infants as supported by others conducting follow up studies after discharge from the NICU (Emond, 1997). An interesting question was raised in regards to readmissions of the infants who went home on caffeine and an apnea monitor when looking at the diagnoses which are respiratory in nature. “Is it possible that the illness in question may have masked the symptoms of Apnea of Prematurity?” Although this may have been possible, it could only be verified at the time of admission with a thorough medical history. This may be an area for future inquiry and would necessitate a medical record review to see if that information is available.

Race

The significant racial disparity seen between the two groups was an unanticipated finding. The odds of a white infant being discharged home on caffeine and a monitor were 2.4
times greater than for a black infant. There are a number of reasons that may account for this difference that may either be attributed to the infant’s physiologic state or possibly to the parents’ readiness and ability to care for their infants. In terms of the infant, a more severe disease status, being extremely premature and very low birth weight, a higher complication rate, or not attaining other physiologic indicators of maturity would delay the discharge. Additional analysis on black infants between the two groups found that the mean birthweight, gestational age, length of stay, hospital costs (Table 12) and NICU diagnosis did not explain why there were significantly more white infants than black infants being discharged on caffeine and a monitor.

This finding may however be explained through a psychosocial perspective which lies outside the scope of this study. Factors such as parental involvement with the infant in the nursery, educational attainment influencing the ability to learn to care for these infants, financial resources, and the amount of family support to assist with care of the infant may influence the decision of the providers to discharge an infant early. Data has shown that African American women are more likely to deliver prematurely and are often single mothers with a lower education who live in poverty. Alternatively, a mother may want the infant to be “well” before going home as the added responsibility of caring for a premature infant that is on medication and an apnea monitor can be a stressful and overwhelming experience. If there is a bias on the part of the providers, it cannot be explained by this data and we need better data collection instruments that would include objective measures of the decision to discharge.
Conclusions

From the evidence gathered in this study, we find no reason to not support the continuation of this policy. The lack of significant differences in the mortality and morbidity of the infants in the two groups are positive findings in support of the safety and effectiveness of this policy. In terms of efficiency, there were no significant differences in the hospital readmission rates or in the cost of hospital care. If the infants in the study group had remained in the NICU a week longer, until resolution of their Apnea of Prematurity, the NICU costs would have been higher. Thus, it appears to be cost effective to send them home on caffeine and a monitor. The fact that this is a retrospective study is a limitation to verifying this with certainty as there is no randomization component.

Equity was the final criterion used for evaluation of this policy. The consideration of the component of equity is largely gleaned from the interviews with the clinicians as well as with informal discussions regarding discharge planning of these infants with the nurse clinicians from the NICU. Earlier in Chapter 1, a method to examine equity from The Knowledge Plus Project of the International Clinical Epidemiology Network was discussed. The authors proposed an “equity lens to evaluate how well clinical practice guidelines address issues of equity” (Dans et al. 2007). This study has enabled us to use that lens to examine the following four issues related to equity.

First, are the “effects of the intervention different in disadvantaged and privileged populations?” In this intervention, an important consideration is the adherence of the family to the use of an apnea monitor and the administration of the medication caffeine citrate. Differences in socioeconomic status, educational level and health beliefs may influence their adherence. The
guidelines consider “practical strategies” for adherence in disadvantaged populations. Examples of these include consideration of ability to pay for care; discharge teaching on care of the infant, and home nursing support are included in the plan for discharge.

Second, is consideration given to “differing values regarding the effects of the intervention by disadvantaged compared with privileged populations?” Often the values of health providers differ from their patients and this may lead to disparities in health care (Dans et al. 2007). Involving all parents in the decision making and eliciting their concerns and preferences regarding discharge and care of their infant is an integral part of the care of these infants. Careful consideration is given by the clinicians to the willingness and ability of the parent to care for the infant prior to discharge. This was especially evidenced by the references to the support and teaching of the parents by the nursing staff.

Third, are there strategies to “minimize barriers to implementation in disadvantaged populations?” Access to care is a key component of the discharge plan for these infants. The lack of insurance, inability to pay for care, and transportation issues are reviewed in the discharge planning process. Where a family is unable to afford the home care or medication, costs are discounted by the providers. Physician and nurse practitioner adherence to the policy does not appear to be a barrier to discharging these infants home on an apnea monitor and caffeine.

Lastly, does the “assessment of the impact of the recommendation include disadvantaged populations?” The added benefits of early discharge home rather than staying in an intensive care unit are unequivocal for all infants and have been previously discussed; these include improved parent infant bonding, increased family interaction in a less stressful environment, and
finally a reduced risk of nosocomial infections for the infant. Further studies to explore these parent’s experiences would assist in understanding the impact of the policy from their perspective.

**Limitations**

There are several limitations of this study that should be mentioned. First, this study is limited to one regional NICU, although it is the largest and oldest in the region, and one small community hospital NICU. Because this is not a population based study, these findings may not be able to be generalized to other populations of premature infants.

The medical data on the neonates was drawn from a nationally developed neonatal information system hospital discharge database which is in the VCUMC NICU. As with all databases, the information may not be 100% complete; however, the same nurse with specialty training has entered this data since the inception of the database lending to the reliability of this data.

Some difficulty was encountered with merging datasets due to the lack of a unique identifier; several variables were used in the matching process to overcome this. Matching these infants with death certificate information from the State Vital Statistics yielded incomplete results on the first attempt. One of the well known limitations in matching infant birth and death data is that infants do not have unique identifiers such as a social security number at birth. In this cohort, the name of the infant as given by the birth mother was not always available in the NIS database. Some of those infants who were unable to be matched were then identified by the birth mothers name matched with the infant’s date of birth. Others were identified through the billing
information and the follow up clinic database within the hospital system, after which a second match at the Office of Vital Statistics was attempted and yielded much improved results. 

Data on number and cost of readmissions may also be incomplete as the number and cost of hospital readmissions outside of VCUHS were unable to be accessed. The VHI Virginia hospital discharge database contains admissions for patients hospitalized in Virginia but they could not perform data matching at the patient level because their data is stripped of identifiers. As infants do not have social security numbers at birth, any attempt to obtain matching data was unreliable. Furthermore, VHI data is based on hospital charges, which as previously discussed are reportedly inflated, and was not available prior to 1997.

Both charges and actual costs on the MCVH NICU infants were obtained through the general hospital information billing system. All of this information is limited to in patient hospital costs only and does not include any physician or home health nursing, respiratory services, durable medical equipment or drug costs. Although the total long term costs of these infants can not be determined from this study, an estimate of the costs associated with ambulatory health care for the infants going home on an apnea monitor and caffeine is presented based on information acquired from local companies in Richmond, Virginia.

Other possible confounders that may impact readmissions not considered in this study include parents’ ability to care for the infant at home; however, parent experiences with their premature infants after discharge are derived from the literature. 

The implications of this study are important for both the clinical neonatal and health policy arenas, despite the limitations. The incidence of preterm birth and low birthweight continues to increase in this country and requires immediate priority. The consequences to the
individual, the family, and to society are immense. Furthermore, the economic impact from this limited population is substantial. This study provides further support for alternate use of resources to care for infants with Apnea of Prematurity. With the acquisition of additional resources for practice, research, and policy, improvement in the care of these infants may be realized.
Chapter 5

Summary and Recommendations

Using epidemiologic methods to influence health policy allows us to gather evidence to not only support policy development but to evaluate existing policies and gain insight into other opportunities for future research (Scott, Mason and Chapman, 1999). This study was focused on policy evaluation, an important and often neglected step in the policymaking process which should lead us to modification and improvement of a policy.

The evidence examined in this study was used to evaluate the safety and efficacy of a unit based clinical policy for early discharge of infants with AOP. The safety of the policy was supported by the data. No increased mortality or morbidity was observed in the infants who were discharged home early. Although the findings did not support a significant cost savings attributed to an early discharge, we were able to project the estimated cost savings from the data that was obtained. As previously mentioned, these figures should be confirmed with additional studies. The equity of this policy was evaluated with results from interviews completed with the clinicians. The majority agreed that the policy is being used for its intended purpose. Consideration of minor modifications which include drug dosage and gestational age changes are recommended by clinicians. A review of the existing literature supports these suggested changes. We found no reason to not continue this policy.

Early discharge of infants from NICU has potential for cost savings and additional research is needed. The reduction of health care expenditures is important to neonatologists and pediatricians, hospitals, home health providers, health insurance plans, health policy makers, and
families. Finally, early discharge is especially beneficial to the infant and family from a psychosocial perspective.

The following policy recommendations are presented as a result of the information collected through this research. The Institute for Health Economics recent consensus statement on Healthy Mothers- Healthy Babies yields recommendations that support changes in public policy and health care delivery systems, and encourages future research (IHE 2007). In keeping with their approach, these recommendations encompass policy development at both the institutional and state levels and involve multidisciplinary partnerships in order to successfully accomplish them.

Recommendations for Practice:

1. Institute a discharge follow up program at VCUMC for all infants going home on caffeine and a monitor. Guidelines for early discharge of the high risk neonate and neonatal follow up care from specific health care associations (NANN 1997, AAP 1998) have been established with the benefit of research and clinical practice experience to support them. These policies are designed to be broad in nature in order to meet the specialized needs of the premature infant (NANN 1997) and should be used a basis for this program. One method to help ensure timely pediatric follow up is through a high risk infant tracking program. This program could be facilitated through a partnership between Virginia Commonwealth University and the Virginia Department of Health. Follow up care has been linked to improvement in outcomes for both the infant and the family (NANN 1997). Consideration of the development of a prospective web based data collection system which contains medical information on patient
history, pediatric visits, hospital readmissions and discharge diagnoses as well as when
the monitor and caffeine are discontinued. Physicians would be notified of follow up visits
and have the ability to enter data on the infant. An evaluation component would allow for the
opportunity to have feedback from the families not only on the impact of early discharge but
on other experiences encountered with caring for a preterm infant.

Recommendations for Research:

1. Epidemiologic surveillance is needed to track annual mortality data on all infants with
   Apnea of Prematurity using matched study data from VDH Office of Health Statistics.
2. Further research is needed to ascertain a more accurate cost savings on infants with AOP.
3. Expand the databases in which the data on infants hospitalized in a NICU is stored and create
   a unique identifier to enable merging of datasets from various data sources including
   discharge data from Virginia Health Information VHI. This will allow further research to be
done in a more efficient and comprehensive manner.
4. The VCUMC NICU should consider joining the Vermont Oxford Network for the collection
   of data and research on infants admitted to the NICU. Recommend that other NICUs in
   Virginia providing services at the higher acuity level (levels 3 and 4) also join the network.

Recommendations for Policy:

1. The Virginia Department of Health, Office of Licensure considers the collection and
dissemination of outcome data on premature infants from all NICUs in the state for providers
and insurers. Currently, this office has regulatory authority for designation of hospital service
levels for NICUs although the process is self declared by the hospital. Availability of this data would allow providers and researchers the opportunity to review and identify issues with this population that may need to be examined in further detail.

5. In working toward the prevention of infant deaths, specifically due to Sudden Unexpected Infant Deaths, recommend that the General Assembly consider legislation with allocated funding for VDH to institute a statewide campaign on SIDS risk reduction. In the 2008 General Assembly session, the house bill on infant mortality which contained this mandate was defeated.

6. Recommend that Medicaid and third party payers provide funding for high risk neonatal follow up programs that include a data collection and evaluation component for NICUs in Virginia. This would help to contain health care costs related to neonatal care in the state.
References


Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st


Stern M, Karraker K, McIntosh B, Moritzen S, Olexa M. Prematurity stereotyping and mother’s interactions with their premature and full term infants during the first year. J Pediatric Psychology. 2006;31(6):597-607.


Appendices

Appendix A.  VCUHS Policy on Apnea of Prematurity

Appendix B.  Provider Interviews
Appendix A.

**SUBJECT:** Apnea of Prematurity

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**PURPOSE:** To provide appropriate evaluation and treatment for infants experiencing apnea of prematurity.

**DEFINITION:**
- **Apnea** is complete cessation of respiration twenty seconds or longer and may be associated with cyanosis and decrease oxygen saturation.
- **Apnea of Prematurity** is a self-limited, maturational dysfunction of respiration that usually resolves by 40-44 weeks post conceptional age.

**POLICY:**
- The NNP may identify and evaluate the infant with apnea. The NNP may initiate treatment following the guidelines of this protocol and in consultation with the physician.

**PROCEDURE:**
1. Apnea of prematurity is a diagnosis of exclusion. In consultation with the physician, establish prematurity as the etiology of the apneic episodes. (i.e. Ruling out CNS, sepsis and reflux as etiologies).
2. After consultation with the physician, may start caffeine citrate, loading dose 20 mg/kg, then 10 mg/kg QD.
3. If apnea persists, caffeine dose will be adjusted by 5 mg/kg to a maximum of 20 mg/kg. Caffeine dose will be adjusted for weight gain to maintain symptom-free state.
4. If apneic episodes persist with increased frequency, decreased oxygen saturation, and need for intervention, then continuous positive airway pressure (CPAP) will be initiated. CPAP will be continued until adequate weight gain is achieved and/or symptoms have subsided.
5. Caffeine levels: Due to the minimal toxicity with caffeine, levels will not need to be followed. If symptoms develop that could be attributed to caffeine (i.e., tachycardia, emesis, irritability), then a level may be checked.
6. In anticipation of discharge and after consulting with physician, may discontinue caffeine when infant’s weight is 1550-1650 gm. A caffeine level will be checked one week after caffeine was discontinued.
7. After achieving a subtherapeutic caffeine level (<4mg/dl), infant will be observed utilizing trend monitor for 48 hours to verify no occurrence of apnea.
8. Pending trend monitor results, decisions for further evaluation and treatment will be made in collaboration with the attending physician.
9. The NNP in collaboration with the primary nurse will arrange for appropriate discharge teaching (i.e., medication administration, CPR, use of home apnea...
10. After consulting with physician, NNP may order caffeine for discharge administration.


Edited by: Barbara Reyna, MS, CRNP
1/2000

Approved by:

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Medical Director, NICU

Sharon A. Cone, MS, RNC, NNP Date
Nurse Manager, NICU
Appendix B. Provider Interviews

Letter of Introduction

I am conducting a study on infants with apnea of prematurity as part of my doctoral dissertation work in health policy at VCU. The specific focus of this questionnaire is to evaluate the policy on apnea of prematurity from the MCV hospital NICU. You were selected to participate because of your experience working in the NICU treating infants with apnea of prematurity.

I will be asking you several questions about the policy in a private interview, it will take about 15-20 minutes. Your responses will be kept confidential. The interview will be audiotaped but your name will not be recorded. A unique identifier will be assigned to your responses. The tapes and notes will be stored in a locked cabinet. After the information from the tapes is typed up, the tapes will be destroyed. Your responses will be summarized along with other participants’ responses in the publication of the study. You do not have to participate in this study and you may also choose not to answer particular questions that are asked in the study. There is no foreseeable risk to participating. You may not get any direct benefit from this study, but the information that I learn from you may assist us in making improvements to this policy. There are no costs for participating in this study other than the time you will spend answering the questions below. There is also no compensation for participating in this study.

Please review the attached policy and questionnaire prior to our interview. If you have questions, complaints, or concerns about the research please contact Cheryl Bodamer at 828-5949. Thank you in advance for your participation.
Questionnaire

Evaluation of the MCVH NICU Policy on Apnea of Prematurity

Q1 Have you reviewed this policy on apnea of prematurity?
1 YES
2 NO

Can you briefly describe the content and purpose of the policy?

Q2 On a scale of 1-3 how clearly is this policy written?
1 VERY CLEAR
2 SOMEWHAT CLEAR
3 NOT AT ALL CLEAR

Q3 How many infants with apnea of prematurity have you cared for in the last year?
1 1-15
2 15-25
3 25-40
4 40-55
5 >55

Q4 How useful have you found this policy to be in providing appropriate evaluation and treatment for infants experiencing apnea of prematurity?
1 VERY USEFUL
2 SOMEWHAT USEFUL
3 NOT AT ALL USEFUL

Can you think of a situation where use of the policy helped you handle a case?

Q5 When caring for infants with apnea of prematurity, how often do you follow this policy?
1 NEVER
2 SOMETIMES
3 ALWAYS

In what situations is the policy not helpful?

Q6 Some literature suggests that parents’ perception of vulnerability of a preterm infant may affect parent-infant interactions and caregiving behaviors. Have you
observed anything of this kind from your experience in the NICU? What are your thoughts about how this information should affect early discharge of preterm infants?

Q7 What specific changes would you recommend to be made to this policy?