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FACTORS RELATED TO THE ESTABLISHMENT OF BREASTFEEDING

By

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ABSTRACT

FACTORS RELATED TO THE ESTABLISHMENT OF BREASTFEEDING

by

Susan Sheaffer Davis

Primiparous women intending to breastfeed, who had pregnancies and births without complications, along with their healthy newborns, comprised the study subjects (n=79 pairs). Demographic, medical, and breastfeeding information was collected from medical records and a scripted telephone interview of the mother two to six weeks following birth. Logistic regression yielded the following model of four predictors of the successful establishment of breastfeeding (as measured by breastfeeding status at day fifteen): successful first breastfeeding latch, breastfeeding attitude score (a composite score of a mother's responses to five questions), attendance at a prenatal breastfeeding class, and first breastfeeding within thirty minutes of birth. Over 30% of mother-baby pairs experienced difficulty establishing breastfeeding. Use of nalbuphine (Nubain) and/or an epidural of fentanyl and bupivacaine for labor pain relief was associated with failure of the infant to latch at the first breastfeeding. However, under the conditions of this study, labor medication status was not significantly related to the successful establishment of breastfeeding.

DEDICATION

To Greg and Jen,
and breastfeeding moms and babies everywhere

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supportive of this effort, but who were the source of its inspiration and meaning.

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LIST OF ABBREVIATIONS

BNBAS: Brazelton Neurobehavioral Assessment Scores

D&C: dilation and curettage

DHA: docosahexaenoic acid

ENNS: Scanlon's Early Neonatal Neurobehavioral Score

IDDM: Insulin-Dependent Diabetes Mellitus

IRRC: Institutional Research and Review Committee

NACS: Neurologic Adaptive Capacity Score

NTS: Newborn Teaching Service

OB: Obstetric

ROGES: Resident Obstetric Gynecologic Education Services

ROM: Rupture of membranes

UCRIHS: University Committee on Research Involving Human Subjects

INTRODUCTION

Humans have been evolving for millions of years. As members of the mammalian family, the young are fed the milk of the mother following birth. Selective pressures have resulted in a species-specific milk that is particularly adapted to the needs of the human infant. Throughout human history failure to breastfeed has resulted in disastrous rates of mortality (Lawrence, 1994, pp. 28-33). It is somewhat surprising, then, to find that in the United States today it is not uncommon for the initiation of breastfeeding to result in failure, and to have many breastfeeding mother-infant pairs stop breastfeeding in the first weeks following birth (Dungy et al., 1992; Feinstein et al., 1986; Frank et al., 1987; Mansbach et al., 1991; Samuels et al., 1985; Saunders & Carroll, 1988). In light of the evolutionary history of our species, it seems peculiarly non-adaptive that breastfeeding should have such a low success rate. The multitude of benefits of breastfeeding are then lost to that mother and infant.

Many who work with new mothers and their infants have expressed concern that exposure to medication given to the mother during labor and passed to the fetus via the placenta may decrease the likelihood of successfully establishing breastfeeding.

I. STATEMENT OF PROBLEM

A number of studies have documented the effect of labor medication on the neonate and the initiation of breastfeeding. In 1961, Brazelton reported that neonates of women who were more heavily sedated with barbiturates during childbirth were delayed 48 hours in attaining effective feedings in comparison to those whose mothers had little or no barbiturates. Infants of the more heavily medicated women also showed a 24 hour lag in the beginning of weight gain. B.R. Kuhnert, Linn, Kennard & P.M. Kuhnert (1985) found that meperidine (British, pethidine; trade name, Demerol) given to women during labor significantly lowered the Brazelton Neurobehavioral Assessment Scores (BNBAS) of the infants in their study when compared to the offspring of unmedicated women; however, the difference may not be meaningful clinically. Rajan and Oakley (1990) reported that women who received pethidine breastfed for a shorter duration than those who did not. In a general article on breastfeeding and anesthesia, Lee and Rubin (1993) recommended avoiding the use of pethidine in women who were breastfeeding. Righard and Alade (1990) showed that both pethidine and mother-infant separation had a negative impact on the first feeding. They found that an infant was much less likely to breastfeed effectively if the mother had been given pethidine during labor. In addition, when contact was disrupted for routine

hospital baby care such as bathing and dressing, breastfeeding success at first feeding was significantly reduced.

In the United States at this time newer forms of obstetric analgesia often replace the use of systemically administered narcotics. A mainstay of labor pain relief today is epidural injection of a combination of an opioid and a local anesthetic (Kotelko, 1995). A study of a large population in England (Rajan, 1994) reported no association between epidural analgesia administered during labor and whether mothers and their babies were breastfeeding at six weeks postpartum. The study, however, did not specify the drug or drugs used.

Some studies have compared different local anesthetics delivered via the epidural route, such as lidocaine, chloroprocaine, and bupivacaine. In 1981 Murray et al. used the BNBAS to assess neonates of women who had received either bupivacaine with or without oxytocin, or little or no medication during labor. They found effects of the drugs to be strongest on the first day of life, and evidence of behavioral recovery by day five. In a series of studies Abboud, working with various other investigators (Abboud et al., 1982; Abboud et al., 1983; Abboud et al., 1984), reported no differences among the neurobehavioral test scores of neonates of women who received either epidural bupivacaine, lidocaine, or chloroprocaine during labor. In some of the Abboud studies

medicated groups were also compared to selected non-medicated control groups and found not to differ.

Recently reported are several studies that looked at epidurals using a combination of fentanyl, an opioid, and bupivacaine, a local anesthetic. In a 1989 study of labor analgesia, Jones et al. compared extradural (epidural) bupivacaine, alone, to bupivacaine and fentanyl combined, in women having either spontaneous vaginal or operative births. They reported no significant differences in the neonates as measured by Apgar-minus-color score at one minute and five minutes, or naloxone (a narcotic antagonist) administration to the infant. There were no non-medicated controls. The measures they used to assess the neonate were relatively crude (Shnider & Levinson, 1993, pp. 674-5); such general tests may not reveal deficits in behavior as subtle and complex as feeding.

Epidural bupivacaine with and without fentanyl were compared by King et al. (1990) in a study of women undergoing elective cesarean operative births. Studies of cesarean births are unable, of course, to include non-medicated controls. They found no differences at birth between the two groups of neonates as measured by mean birth weights, base deficits of umbilical arterial and venous blood, and Apgar scores. No infants in either group required drugs for neonatal resuscitation. Again, these tests are not

designed to measure behaviors such as feeding. In their discussion the authors stated that a much larger study would be needed to assess neonatal outcome fully.

Concentrations of fentanyl and bupivacaine (maternal vein, umbilical vein and maternal vein/umbilical vein ratio) following epidural infusion during labor were measured by Bader et al. (1995). They reported that Apgar score, Scanlon's Early Neonatal Neurobehavioral Score (ENNS, Scanlon et al., 1974), and umbilical artery blood gas values "were within normal limits in all cases" (p. 830). There were no non-medicated controls. Breastfeeding was not specifically addressed. The conclusion states that no significant drug accumulation or adverse neonatal effects, as measured by blood concentrations, umbilical blood gas values and neurobehavioral test scores, were found. Whether these measurements are accurate indicators of fetal tissue uptake of the medication or of feeding behavior is unknown.

In 1995 work done by Kotelko et al. was reported at the Annual Meeting of the American Society of Anesthesiologists and in the journal Anesthesiology. Four groups of parturients who delivered term infants vaginally were studied: two groups received epidural labor analgesia, either bupivacaine alone or bupivacaine and fentanyl; the third group received fentanyl intravenously; the fourth group received no narcotic or anesthesia. Several measures

of neonatal sucking were made during the first ten minutes of the first two feedings, either bottle or breast, following birth. The only significant difference found was a depression of sucking measures in the group of infants whose mothers had received intravenous fentanyl. This research showed that in this case there was no difference between infants of unmedicated mothers and those who had epidurals of either bupivacaine alone or in combination with fentanyl. Whether these sucking measures are predictive of successful establishment of breastfeeding remains a question.

Loftus et al. (1995) compared three epidural regimens: healthy parturients received bupivacaine alone, bupivacaine and fentanyl , or bupivacaine and sufentanil. The Neurologic Adaptive Capacity Score (NACS) (Amiel-Tison et al., 1982) was used for neonatal neurobehavioral assessment. No differences among neonates were found at fifteen minutes and two hours after birth. However, at twenty-four hours the bupivacaine/fentanyl infants scored significantly lower on the NACS than the other two medication groups. No non-medicated controls were included in the study. It is not known whether a lower NACS at twenty-four hours would be associated with a neonate's inability to breastfeed successfully. These findings introduce a concern that deleterious effects of medications may not show up immediately following birth, and that research that looks only at the period immediately

following birth (for example, Bader et al., 1995; Jones et al., 1989; and King et al., 1990) may be missing significant negative effects of epidural analgesia.

From the studies cited one can appreciate the ambiguities that exist in the literature and the resultant uncertainty as to whether labor medication has a deleterious effect on the establishment of breastfeeding. In a 1992 review of epidural labor pain relief Howell and Chalmers concluded that "remarkably little is known about [the] short-term and long-term effects [of epidural blocks]."

A number of measures used to assess the safety of the effect of epidural medication on the neonate, such as Apgar scores or use of resuscitation drugs (e.g., Jones et al., 1989; King et al., 1990), have limitations (Shnider & Levinson, 1993, pp. 674-675, Apgar score assessment) that prevent the detection of a possible negative impact on the establishment of breastfeeding. The more sophisticated neonatal neurobehavioral tests (the ENNS and the NACS) in common use have only a small portion devoted to breastfeeding behaviors, and these behaviors are tested individually, not as the complex of actions that comprise feeding (Shnider & Levinson, 1993). It is not known whether these test scores are predictive of the successful establishment of breastfeeding. Another type of test, analysis of umbilical cord blood

drug concentrations, is used in studies as a more precise indication of medication exposure than, for example, the Apgar score or use of a narcotic antagonist. The drug status of the fetus cannot be measured directly; therefore, cord blood values are used to infer the degree of drug exposure of fetal tissues such as the brain. However, since there are a number of factors that influence drug uptake by tissues, and these factors differ according to the drug and the site of action (Shnider & Levinson, 1993), the blood tests may be inaccurate and/or misleading. In light of the limitations of these evaluative tests, coupled with the ambiguous results of published research, a question remains as to whether epidural fentanyl and bupivacaine for labor analgesia have a deleterious effect on the successful establishment of breastfeeding.

The neonatal assessment tools just mentioned are widely used in studies of the effects of labor medication. In a comparatively small number of studies certain aspects of breastfeeding have served as the outcome. Few studies (Brazelton, 1961; Matthews, 1989; Rajan, 1994; Richards & Bernal, 1971) have looked at the successful establishment of breastfeeding as a whole. Most of these studies involved different drug regimens and hospital routines and are, therefore, not relevant to current birth practices. While it is important to be able to document the disruption of any facet of breastfeeding, it can be argued that such

disruptions are only temporary setbacks that do not have significant long term consequences on the successful establishment of breastfeeding, and, therefore, are more easily dismissed. Thus it was decided that the outcome for the present research would be the successful establishment of breastfeeding as measured by the ability of the mother and her infant to sustain breastfeeding through the first fifteen days of the infant's life.

The purpose of this study is to determine the relationship between the labor medication status of the nulliparous parturient intending to breastfeed, and the status of breastfeeding at day fifteen postpartum.

II. OBJECTIVES AND HYPOTHESES

This research had the following objectives and hypotheses.

OBJECTIVE: To identify characteristics of women intending to breastfeed, their neonates, their labors and deliveries, and their establishment of breastfeeding.

OBJECTIVE: To describe the process of establishing breastfeeding, including problems encountered and help received.

OBJECTIVE: To determine if breastfeeding establishment is affected by labor medication status.

Hypothesis: The establishment of breastfeeding as measured by breastfeeding status at day fifteen is not related to labor medication status.

OBJECTIVE: To determine what factors predict the successful establishment of breastfeeding as measured by breastfeeding status at day fifteen using logistic regression analysis.

Hypothesis: Selected maternal, infant, and breastfeeding characteristics and practices predict breastfeeding status at day fifteen.

III. RESEARCH QUESTION

The research question is as follows:

What is the relationship between the labor medication status of the nulliparous parturient intending to breastfeed and the establishment of breastfeeding at day fifteen?

The labor medication status under consideration is epidural anesthesia using a combination of fentanyl and bupivacaine, or the absence of such medication. Data were collected from the maternal and neonatal medical records and from a postpartum scripted telephone interview.

A REVIEW OF THE LITERATURE

I. INTRODUCTION

Breastfeeding is the best way for a mother to nourish and nurture her infant. The nutritional, immunological, hormonal, psychological and other benefits to both mother and infant have been widely documented (Jensen, 1995; Institute of Medicine, 1991; American Academy of Pediatrics, 1997). However, not every mother who chooses to breastfeed her infant is successful in doing so. The number of breastfeeding mother-infant pairs often declines rapidly in the first days and weeks following birth (Barron et al., 1988; Beaudry & Aucoin-Larade, 1989; Dungy et al., 1992; Serafino-Cross & Donovan, 1992). If breastfeeding is not successful in the first days of life, its multitude of benefits cannot be realized. There are many factors (Kurinij & Shiono, 1991; Perez-Escamilla et al., 1993; Righard & Alade, 1990) that contribute to such a failure.

The question arises as to whether pain relief medications administered to the parturient have a deleterious effect on breastfeeding. The scientific literature on this question is ambiguous (e.g., Amiel Tison et al., 1994; Bader et al., 1995; Jones et al., 1989; King et al., 1990; Kotelko et al., 1995; Loftus et al., 1995; Murphy et al., 1991; Nissen et al., 1995; Sepkoski et al., 1994; Sepkoski et al., 1992). This review of the literature,

therefore, will explore the advantages of breastfeeding and the evidence for effects of labor medications on the neonate, particularly factors affecting the successful establishment of breastfeeding.

II. BREASTFEEDING

Throughout the history of humankind, mothers have nurtured and nourished their infants by breastfeeding. It is only in the very recent past, when alternatives to breastfeeding came into existence that did not carry a very high risk of mortality to infants, that there were compelling reasons to explore the advantages of human milk and breastfeeding.

In the second half of this century, research began to provide information on the composition of human milk and the benefits that come from breastfeeding. Many of the early studies were flawed in design and biased in nature. For example, the term breastfeeding was not precisely defined. Unsubstantiated claims were made for breastfeeding without taking into account the complexity of the issues under scrutiny (e.g. intelligence) and the possibility of confounding factors. Those advantages that were well-documented were spread over a number of disciplines, e.g. nutrition, immunology, and psychology. Often the preponderance of evidence in favor of breastfeeding is less apparent because of the fragmentation of this body of information among the life sciences,

social sciences, and medical educational settings. Today a large body of research holds that breastfeeding is the superior infant feeding mode.

A. NUTRITIONAL BENEFITS

The nutritional benefits of human milk are the result of the evolution over millions of years of a species-specific milk that comprises the spectrum and ranges of nutrients best suited to the optimal development of the human infant. While numerous advantages of breastfeeding have been documented, it is reasonable to assume that others are yet to be discovered. Human milk is composed of carbohydrates, proteins, fats, minerals, vitamins, and water. This list of nutrients only begins to suggest the complexity of human milk, however. More specifically, human milk has humoral components such as hormones, growth factors, and anti-infection agents; and cellular components such as macrophages and lymphocytes (Jensen, 1995). While each of these constituents can be classified as one or more of the five nutrients listed, their special significance lies in their unique functional roles as macromolecules and cells. Babies should consume only one food for at least the first four months of life, according to the recommendation of the American Academy of Pediatrics (1998), the American Dietetic Association and others, at a time of rapid growth and development. The question of the nature of that food assumes

singular importance. Other choices for the diet of infants, human milk substitutes or formulas, are most often based on cow's milk, or, to a lesser extent, the soybean. It follows that the constituents of infant formulas are present both in different forms and in different proportions than in human milk. And almost none of the special cellular and humoral components in human milk are present in commercial infant formulas.

The case of fat in infant diets can be instructive and serve as a model for the kinds of differences that exist between human milk and its substitutes. For many years the role of fat was seen as the means of energy storage in the body, a source of energy when the need arose. The amount of fat in the diet of infants was deemed important, not the source nor the composition of the fat. As research results from the study of cardiovascular disease in adult humans became available and it appeared that diets low in saturated fat and cholesterol protected against heart disease, the trend in the formula industry was to switch from formulations high in saturated fats to those using vegetable oils low in saturated fat, and also devoid of long chain fatty acids. As Crawford (1993, p. 707S) writes, "there was a curious insistence on replacing the animal lipid by a vegetable oil with only linoleic acid in it." Human milk contains detectable amounts of at least six polyunsaturated fatty acids of carbon chain lengths longer than 18, including

docosahexaenoic acid (DHA); no commercial infant formulas manufactured in this country have detectable amounts of any these fatty acids (Clark et al., 1992). Further, formulas often have very high ratios of linoleic acid to α-linolenic acid (Clark et al., 1992), which may limit the formation of DHA. As in all decisions as to the composition of formulas, cost and shelf life are also considerations. Given these constraints, the resultant infant formulas are only an approximation of human milk.

The understanding of the roles of fatty acids in biological systems has expanded dramatically to include, in addition to serving as fuel molecules, such functions as precursors of local hormones and intracellular messengers, building blocks of phospholipids and glycolipids, and the modification of proteins for anchoring in membranes (Stryer, 1995). Researchers became interested in the question of whether or not optimal development of the infant's central nervous system, high in DHA concentration, could be supported by infant diets that did not contain the longer chain polyunsaturated fatty acids (D.G.Birch et al., 1992; E.E. Birch et al., 1992; Hoffman et al., 1993; Makrides et al., 1993; Uauy et al., 1992). Uauy et al. (1992), for example, used measures of visual acuity to test retinal and cortical function, comparing infants on diets of human milk, formula that contained no detectable long-chain polyunsaturated fatty acids (comparable to a commercially

available formula), and a formula that had been supplemented with marine oil, a source of n-3 fatty acids, including DHA. They found that the visual acuity of infants fed human milk or formula supplemented with marine oil is significantly better than that of infants fed the formula corresponding to the commercial infant formula. The absence of the longer chain polyunsaturated fatty acids, possibly DHA, in particular, at the time of rapid central nervous system development in infants, may lead to deficits in brain and retina function that are not reversed by the later inclusion of these fatty acids in the diet. These results were found when both preterm and full term infants were studied.

The discovery of the roles of lipids in development and metabolism is ongoing. It is known that human milk contains certain lipid constituents that are not found in infant formulas, and that some of these may be necessary for optimal human growth and development.

Other nutrients confer other advantages on the breastfed child. A full discussion of each of these benefits is beyond the scope of this thesis.

B. IMMUNOLOGICAL, GROWTH, AND DEVELOPMENTAL BENEFITS

The nature of the evidence for immunological, growth, and developmental benefits for breastfeeding falls into two categories.

The first is the presence in human milk of a complex system of anti-infection agents of a number of different kinds. The second is the growing number of research studies of careful design that find that breastfed infants have fewer illnesses, and that their illnesses are of shorter duration than formula fed infants, both in industrialized as well as developing nations.

Constituents of human milk with nonnutritive functions

The following list is comprised of various substances found in human milk. The functions and benefits of many constituents have been elucidated. For the remaining components, it is reasonable to assume that many of them will be found to contribute to the immune system and to the growth and development of the infant, but their exact function awaits further study.

Anti-infection properties of human milk

Direct protection against pathogens. Many of the cellular and humoral components of human milk have anti-infection properties, providing protection against agents of disease that are bacterial, viral, and protozoan. Humoral anti-infection agents include oligosaccharides and glucoconjugates, immunoglobulins, lactoferrin, lactoperoxidase, lysozyme, fibronectin, complement components, and mucins (Institute of Medicine, 1991; Jensen, 1995; Lawrence, 1994; Newburg, 1997). Partially digested substrates in human milk such as fatty acids, monoglycerides, and

β-casomorphins may also confer protection (Jensen, 1995).

Cellular components that are known to have anti-infection capabilities are macrophages and, possibly, lymphocytes (Institute of Medicine, 1991). Many of these components have multiple functions and interact with each other.

Promoters of protective microorganisms. The bifidus growth-promoter activity favors the growth of bacteria which suppress the proliferation of enteropathogens (Jensen, 1995).

Antiinflammatory agents. Human milk contains "a host of antiinflammatory agents including agents that double as direct protective agents, antioxidants, enzymes that degrade inflammatory mediators, antienzymes, cytoprotective agents, and modulators of leukocyte activation" (Institute of Medicine, 1991, p. 138).

Immunostimulating agents. Evidence for immunostimulating agents in human milk includes: higher than expected levels of secretory IgA in the urinary tract of breastfed infants; an increase in certain immune factors (for example, the cytokine interferon- α, and fibronectin) in the blood of infants exposed to disease; and immunomodulators such as α-tocopherol, cytokines (several interleukins, tumor necrosis factor- α, transforming growth factor-β, and other factors) and prolactin found in human milk. This evidence is taken as an indication of the stimulation of the

breastfed infant's immune system resulting in increased protection against disease (Ellis et al., 1997; Jensen, 1995).

Enzymes in human milk

Enzymes found in human milk have been reviewed by Hamosh (1986, chap. 4). One group of enzymes has digestive functions in the neonate, for example, amylase, bile salt stimulated lipase, and possibly proteases. Another group of milk enzymes has anti-infection properties, such as lysozyme, peroxidase and possibly bile salt stimulated lipase. A third group of enzymes is important in stimulating neonatal development. Included in this group are antiproteases. The function for a number of other enzymes found in human milk has not yet been determined.

Other constituents of human milk with nonnutrient functions

Growth factors and hormones. Over twenty hormones and hormone-like substances have been identified in human milk at this time. Their significance in the infant, for the most part, has not been determined (Jensen, 1995). Epidermal growth factor is known to stimulate the growth of certain cells. It is believed to be of significance in the maturation of the gut (Morriss, 1986, chap. 5). A more precise description of the roles of epidermal growth factor and other factors found in human milk awaits further study.

Nucleotides. In his report on nucleotides, Barness (1994) states that nucleotides are "present in human milk in larger

quantities than in ...infant formulas". Jensen concludes that recent studies suggest that dietary nucleotides may be semi-essential for newborn animals (Jensen, 1995). Hamosh (1997), in introductory remarks for a symposium on milk and development of the neonate, states that there is good agreement in the scientific literature for a role for nucleotides in immune function and intestinal repair after injury. Further study as to their functions is needed.

Evidence of immunological protection

Breastfed infants are sick less often, and illness episodes are less severe when they do occur, in comparison to formula fed infants. Recent research (Beaudry et al., 1995; Dewey et al., 1995), has been carried out in carefully designed and controlled studies in developed countries; in the case of the Dewey study, in an affluent population. Breastfeeding also appears to be protective against atopic disease. In a group of preterm infants with a family history of atopy, at age 18 months after term, those babies who had early exposure to cow's milk were at significantly greater risk of having one or more allergic reactions (Lucas et al., 1990). A prospective follow-up study done in Finland of normal, term infants documented protection against allergies to age seventeen years (Saarinen & Kajosaari, 1995).

The thymus, a lymphoid organ necessary in early life for the normal development of immunological function (McDonough, 1994),

was shown by Hasselbalch and colleagues (Hasselbalch et al., 1996), by age four months, to be considerably larger in breastfed infants than in formula fed infants. The significance of this finding is unknown, but it would be consistent with a more developed immune system in breastfed infants.

The U.S. Preventive Services Task Force (1996) reports that "epidemiologic evidence and randomized prospective studies suggest that infant consumption of breast milk for at least 6 months may reduce the risk of otitis media, lower respiratory tract illness, meningitis, allergic illness, diarrhea, hospital admissions, and abnormal cognitive development in the child."

Summary of benefits of human milk

Breastfeeding provides the human infant with a fresh, nutritious diet of both high quality and variability, as well as an armamentarium against disease. In addition, it is readily available, is at body temperature, has a low renal solute load compared with human milk substitutes, requires no equipment, sterilization, or clean water supply and is convenient and economical. Given the present state of our understanding of nutrition and the composition of human milk, breastfeeding is the infant feeding practice which best meets the needs for optimal human health, growth and development.

C. PSYCHOLOGICAL BENEFITS

Cognitive development

In *The Child in the Family*, (Belsky et al., 1984, p. 41-42) the authors cite several key dimensions of maternal functioning that "emerge from the vast literature on parental influence during infancy as consistent predictors of individual differences in infant cognitive functioning." They are: attentiveness, physical contact, verbal and material stimulation, and responsiveness. Breastfeeding supplies the optimum environment for the expression of each of these important dimensions of maternal behavior (Alberts et al., 1983). The act of breastfeeding is almost indistinguishable from them. Breastfeeding virtually ensures the maternal functioning best for infant cognitive development.

Morrow-Tlucak et al., (1988) reported that breastfed infants at the age of 1 and 2 years had significantly higher Bayley scores, an indication of developmental status (Osofsky, 1987), than formula fed infants. The difference was small, but remained after using "rigorous covariate control" (Morrow-Tlucak et al., 1988).

A number of studies have reported that breastfed infants, or infants fed human milk, have greater cognitive abilities at later stages of development than infants fed formulas (Bauer et al., 1991; Lucas et al., 1992; Rodgers, 1978; Taylor & Wadsworth, 1984). Lucas and colleagues studied 300 premature infants fed by

intragastric tube, either their own mother's milk or formula. At age 7.5-8 years the children who received human milk scored over 8 points higher on an IQ test, after controlling for maternal education, socio-economic status, and other factors. Only further research will provide a more definite answer as to whether human milk or breastfeeding is responsible for the higher cognition scores achieved by breastfed children. Due to the nature of cognitive abilities and the complexity of the environment in which these abilities develop, and the myriad possibilities for confounding, such a relationship will be difficult to demonstrate conclusively.

Continuity of care

Breastfeeding fills the baby's need for long-term maternal contact and touch. It ensures that the mother and infant will have frequent contact every day. The mother's body has provided a safe and nourishing environment for the developing fetus for nine months. In the immediate newborn period the infant already recognizes the sound of the mother's voice, and shows a preference to it over other female voices (Klaus & Klaus, 1985). Breastfeeding provides a continuation of the care and nurturing that starts before birth and proceeds throughout the neonatal period and beyond (Gaull et al., 1985).

Constancy of care

Following birth, the practice that has evolved over millions of years, is for one person, the mother, to breastfeed the infant frequently, throughout the first months of life into early childhood. Lawrence (1994), the author of one of the most important reference books on breastfeeding for the medical profession, and a physician and mother, notes that during breastfeeding the mother and infant "are alone together during breastfeeding, and the mother gives her full attention to the baby with stroking and fondling. Social interaction with the baby is less frequent when [the baby] is bottle fed, and the mother is often in a distracting social situation or someone else feeds the infant" (p. 195).

Psychophysiology of breastfeeding women

Wiesenfeld and colleagues (1985) write, the "manner in which a mother responds to her infant's signals has been accorded a central role in the formation of attachment, and has also been associated with patterns of cognitive growth....Ethological theorists specify that sensitive caregiving requires prompt and contingent caregiver response to the infant's signals;...contingent responding is believed to promote the development of a sense of competence, trust, and confidence." In one of the few studies to explore whether breastfeeding women differ psychophysiologically from bottle feeders, Wiesenfeld et al. (1985) found "strikingly different

response patterns characterizing breast- and bottle-feeding mothers across response measures." On subjective measures of emotional response breastfeeders expressed greater satisfaction with the feeding experience, e.g., it was good for the baby's health, good for the mother's health, and a pleasant physical experience. Further, breastfeeders felt more strongly that feeding was relaxing for the baby and for the mother. This is consistent with the finding of Leifer (1977), that bottle-feeding women found infant feeding emotionally neutral or boring, versus breastfeeding mothers, who felt feedings were emotionally gratifying. Wiesenfeld et al. (1985) also found that breastfeeding mothers "were more inclined to want interaction with [their] infant and they also expressed greater satisfaction with the feeding experience." Using measures of maternal cardiac rate and electrodermal data, they reported response patterns that differed by feeding mode. This led to the interpretation of their findings as suggesting a "differential physiology in the lactating mother, as well as different prior personality factors operating on choice of feeding mode."

The relationship between maternal role adjustment and infant feeding method was researched by Virden (1988). She reported less maternal anxiety and more mother-infant mutuality in mothers who were breastfeeding at one month past birth in contrast to mothers who were bottle feeding. In addition, as Lawrence (1994)

notes, the mother's response to unrestricted nursing is "a more even mood cycle than the mood swings associated with ovulation and menstruation"

Attachment and bonding

Attachment is a vital aspect of the maternal/infant relationship. Breastfeeding, with its physical closeness, frequency of contact, and physiological involvement of mother and baby, is the infant feeding mode that is most likely to enhance bonding or attachment. Countless women have attested to the warmth and closeness of breastfeeding as strengthening the mother-infant bond.

Pleasure of breastfeeding

Newton (1971) reported several physical phenomena associated with breastfeeding. She noted the tactile stimulation of the maternal areolar area during a feeding session. "In addition [to receiving the pleasurable sensations of sucking,] the mother experiences a generalized body response. The temperature of the mammary skin rises, and the uterus contracts rhythmically." Riordan and Rapp (1980) proposed that "breastfeeding/lactation...is a sexually pleasurable process for the mother in addition to providing nourishment for her infant." They further suggested "that the very survival of *Homo sapiens* has been dependent on [the] sensual reinforcements of breastfeeding."

Researchers are now documenting what many women have experienced throughout the history of the human species; that breastfeeding brings to the mother-infant dyad a unique closeness that is the result of the physical and psychological nature of breastfeeding. This is frequently interpreted in subjective, often emotional terms, what some mothers have described as "the tranquil and peaceful sensual feelings" of breastfeeding (Riordan & Rapp, 1980).

Summary of psychological benefits of breastfeeding

Breastfeeding fosters the maternal-infant relationship both in that the behaviors of breastfeeding are so interwoven with nurturing as to be almost inseparable from them, and in that the mother is a physiologically unique person who is linked to her infant in an interdependent and mutually pleasurable way.

D. OTHER ADVANTAGES OF BREASTFEEDING

Convenience

Breastfeeding is convenient, economical and ecological. It is convenient because the supply of milk is always present, ready, and at the correct temperature; needs no sterilization, reconstitution, or other preparation; requires no supply of formulas, no bottles, no nipples, or other paraphernalia; requires no refrigeration or safe water supply, and is easily portable.

Economy

Estimates of the economy of breastfeeding will vary due to the inexactitude of the present level of our understanding of the nutritional requirements of lactating women, the various ways in which additional dietary needs may be met by nursing women, and the different costs of commercial formulas. In spite of the lack of complete information in these areas it is possible to choose foods that are both economical and appropriate, and to realize a very considerable savings by breastfeeding.

Health expenses are another area of cost savings for parents as well as taxpayers, whose tax dollars support such governmental agencies as WIC (Special Supplemental Nutrition Program for Women, Infants and Children). Studies have begun to appear, such as Montgomery & Splett (1997), documenting that breastfed babies have lower medical expenses than infants fed artificial human milks.

Environmental advantages

Although there is no specific research supporting it, breastfeeding is sound environmental policy. There are no requirements for containers of formula, feeding bottles, nipples, and sterilizing equipment. Utilization of breastfeeding places less demand on the dairy industry and its use of fertilizers, pesticides,

disinfectants, dairy equipment, transportation, energy, and water. It decreases the need for the manufacture of formulas.

III. LABOR MEDICATION

A. LIMITATIONS OF LABOR MEDICATION RESEARCH

Human research and changing labor medication practices

The issue of labor medication is complex. Research on the effect of labor medication on the pregnant woman and her fetus or neonate is limited by ethical concerns, often preventing random assignment to treatment group, or manipulation of medication dose and timing, for example. Further, the medical literature is difficult to interpret because of changing drugs, drug doses, and routes of administration; different total dosages per patient; different intervals from the time of the first and last dose to delivery; the idiosyncratic response of the individual patient; and the individual nature of each labor. Moreover, studies are also difficult to interpret and compare due to the use in some cases of a number of different medications in addition to the drugs under study, such as labor medications given early in labor (Murphy et al., 1991); other pain relief medications given during the epidural (King et al., 1990); local anesthetics used just before birth (Chestnut et al., 1988; Kuhnert et al., 1985; Murphy et al. 1991; Murray et al., 1981); inhalation medication (Belsey et al., 1981; King et al., 1990; Murphy et al., 1991; Murray et al., 1981), and possible drug

exposure through postpartum medications and breast milk (these latter two exposures are almost never reported, according to Kuhnert, 1985). Not all studies include non-medicated controls. Some are, rather, either a comparison of different doses of the same drug (Cohen et al., 1987); a comparison of the effects of two or more drugs, either alone or in combination with another drug (Kuhnert et al., 1984; Loftus et al., 1995); or the effect of one drug alone or combined with another drug (Bader et al., 1995; Chestnut et al., 1988; Cohen et al., 1987; Jones et al., 1989; Murphy et al., 1991). In some studies vaginal and cesarean births are considered together (Abboud et al., 1984; Chestnut et al., 1988; Murphy et al., 1991). However, anesthesia for the two types of birth can be different, not necessarily in type of medication or route of administration, but rather in terms of dosage, number, and timing of doses. There may also be other factors associated with operative births and not vaginal births, or vice versa. The consideration of these two different types of birth together further complicates the interpretation of results.

Another factor that may complicate the detection of the effects of labor medication, is the drug-delivery interval. It is often assumed that drug exposure to the fetus is highest shortly after the anesthetic is delivered to the mother and that levels subsequently subside from these early higher levels. Research has shown that

some drugs administered to the mother during the last hour preceding birth do not have a detectable effect on the neonate, whereas the same drugs with a longer drug-delivery interval have a deleterious effect (Kuhnert et al., 1985; Matthews, 1989; Righard & Alade, 1990). Few research articles address this issue, and its omission may prevent the accurate assessment of the effects of labor medications.

Neonatal assessment

Do the tools presently used in research to determine the safety of labor medication adequately assess neonatal outcome, particularly in respect to the successful establishment of breastfeeding?

Apgar scores

Apgar scores (Abboud et al., 1983; Chestnut et al., 1988; Cohen, et al., 1987; Jones et al., 1989; King et al., 1990; Kuhnert et al., 1984) are measures that have been used for assessing neonatal outcome in the study of maternal medication administered during labor. Apgar scores consist of the sum of ratings for five traits: color, heart rate, reflex irritability, muscle tone, and respiratory effort of the newborn. Examinations are made at one and five minutes. In Anesthesia for Obstetrics (Shnider and Levinson, 1993) the Apgar score is characterized as a relatively crude measure, made by personnel who may not be objective,

covering a very short period of time, often before many serious problems have presented, and measuring only those vital functions necessary to sustain life. The text continues:

> Because the infant has to be considerably affected to significantly lower the score, subtle effects of perinatal asphyxia or maternal medication may be missed entirely. Newer and more sophisticated techniques of examining the neurologic and behavioral aspects of the newborn have repeatedly demonstrated profound and sometimes prolonged depression in infants who have perfectly normal Apgar scores. Thus studies using this index as an outcome measure that have judged drug regimens as 'safe' must be reinterpreted in the light of more recent data. (p. 675)

Neonatal neurobehavioral assessment tools

The Brazelton Neonatal Behavioral Assessment Scale (BNBAS) is a more sophisticated tool. It looks specifically at the mother-infant interaction. Training for administrators of the test is extensive, and the test itself takes 30-45 minutes (Norris, 1993). The results are not easily quantifiable for statistical analysis (B.R. Kuhnert, Linn & P.M. Kuhnert, 1985). In recent anesthesiology research the BNBAS has often been replaced by two newer tests, the Early Neonatal Neurobehavioral Scale (ENNS) and the Neurologic and Adaptive Capacity Score (NACS).

Scanlon et al. (1974) devised the Early Neonatal Neurobehavioral Scale (ENNS) to examine the effect of anesthetic drugs by assessing neonatal muscle tone and habituation to repeated stimuli. Testing, done from 2 to 8 hours post birth, is timed to coincide with the postulated period of maximum drug effect

(Norris, 1993). The test takes from 6 to 10 minutes to perform (Shnider & Levinson, 1993). Of the fifteen observations made, two relate directly to breastfeeding: rooting is assessed, as is sucking (Norris, 1993).

One of the most widely used tests in anesthesiology research at this time, the Neurologic and Adaptive Capacity Score (NACS), attempts to distinguish between the effects of birth trauma and of maternal drugs by examining differences in muscle tone among various muscle groups (Amiel-Tison et al., 1982). This test takes under 5 minutes. Twenty parameters are assessed: one, sucking, relates directly to breastfeeding behavior; rooting is not tested. Bramwell, writing in the Norris text (1993), states:

> In an attempt to simplify the complexities of the Brazelton and ENNS examinations, the NACS fails to understand the capabilities of the neonate and the process of early development adequately. So, the NACS may not detect drug and other effects in neonatal performance. (p. 284).

Weaknesses in the ENNS and the NACS exist. Each relies on the subjective judgments of personnel regarding the neonate (Norris, 1993). A relatively small percentage of each test measures behavior that has a direct impact on breastfeeding. Perhaps more importantly, no measure is made of feeding behavior as a whole, as the coordinated complex of activities that comprises successful breastfeeding. Further, it is not just the act of feeding which must be achieved early in life, but the initiation of what is partially a

learned behavior. These measures, widely used to assess neonatal outcome in studies of maternal labor medications, may not accurately predict whether breastfeeding has been adversely affected.

Tissue drug levels

The most accurate and direct measures of neonatal exposure to medication, analysis of tissues for drug levels, are unavailable for the study of the effects of labor medication on the neonate. One of the best indicators that is available, blood levels of medications, may not give an accurate measure of drug accumulation due to fetal tissue uptake parameters that cannot be assessed accurately (Shnider & Levinson, 1993). One particular complication is "ion trapping", where the amount of a basic drug (such as local anesthetics and opiates) taken up by a given tissue varies with pH; as pH decreases, as it would in a stressed fetus, tissue drug uptake increases (Norris, 1993) for a given level of drug in the maternal circulation. The result would be a significantly higher concentration of drug in the fetus than in the mother.

In summary, complete information regarding drug exposure is all but impossible to obtain for humans. In Norris's book on obstetric anesthesia (1993) Douglas concludes,

> Effects [of drugs] on the fetus...can only be measured indirectly. Current methods of testing the newborn...may not detect subtle changes. When drug effects are detected, it is difficult to assess their overall impact. (p. 141)

Other factors that may disrupt the establishment of breastfeeding

There are a number of factors other than drugs that may play a role in the disruption of the establishment of breastfeeding. These include the interruption of mother-infant contact in the period immediately following birth, documented by Righard and Alade (1990), as having a deleterious effect on the success of the first breastfeeding. In their study the interruption of mother-infant contact was occasioned by routine hospital care. Further investigation in this area could prove fruitful in the quest to avoid disrupting the initiation of breastfeeding.

Delay in the timing of the first breastfeeding has been shown by a number of studies to be associated with a decrease in duration of breastfeeding (Beaudry & Aucoin-Larade, 1989; Feinstein et al., 1986; Wright & Walker, 1983).

Some health professionals have hypothesized that the often aggressive treatment of the oral area of the newborn with suctioning, endoscopic viewing of the larynx, and in some cases gastric suctioning (Widstrom et al., 1987), tends to obtund feeding reflexes and behaviors in the immediate postpartum period.

Recent research by Chen et al. (1998) has documented the role of stress during labor and delivery and its detrimental effect on lactogenesis.

The common thread in each of these factors is the setting in which initiation of breastfeeding takes place, and the attendant routines and practices. In the United States that is most often the hospital. The question must be raised as to how protective and supportive this environment is for the breastfeeding new mother and her infant.

B. EFFECTS OF LABOR MEDICATIONS

A number of studies have documented the effect of labor medication on the neonate and the initiation of breastfeeding. In 1961, Brazelton reported that neonates of women who were more heavily sedated with barbiturates during childbirth were delayed 48 hours in attaining effective feedings in comparison to those whose mothers had little or no barbiturates. Infants of the more heavily medicated women also showed a 24 hour lag in the beginning of weight gain. Kuhnert et al. (1985) found that meperidine (British, pethidine; trade name, Demerol) given to women during labor significantly lowered the Brazelton Neurobehavioral Assessment Scores (BNBAS) of the infants in their study when compared to the offspring of unmedicated women; however, the difference may not be meaningful clinically. Rajan and Oakley (1990) reported that women who received pethidine breastfed for a shorter duration than those who did not. In a general article on breastfeeding and anesthesia, Lee and Rubin (1993) recommended avoiding the use

of pethidine in women who were breastfeeding. Righard and Alade (1990) showed that both pethidine and mother-infant separation had a negative impact on the first feeding. They found that an infant was much less likely to breastfeed effectively if the mother had been given pethidine during labor. In addition, when contact was disrupted for routine hospital baby care such as bathing and dressing, breastfeeding success at first feeding was significantly reduced.

In the United States at this time newer forms of obstetric analgesia often replace the use of systemically administered narcotics. A mainstay of labor pain relief today is epidural injection of a combination of an opioid and a local anesthetic (Kotelko, 1995). A study of a very large population in England (Rajan, 1994) reported no association between epidural analgesia administered during labor and breastfeeding ongoing at six weeks postpartum. The study, however, did not specify the drug or drugs used.

Some studies have compared different local anesthetics delivered via the epidural route, such as lidocaine, chloroprocaine, and bupivacaine. In 1981 Murray et al. used the BNBAS to assess neonates of women who had received either bupivacaine with or without oxytocin, or little or no medication during labor. They found effects of the drugs to be strongest on the first day of life and evidence of behavioral recovery by day five. In a series of studies

Abboud, working with various other investigators (Abboud et al., 1982; Abboud et al., 1983; Abboud et al., 1984), reported no differences among the neurobehavioral test scores of neonates of women who received either epidural bupivacaine, lidocaine, or chloroprocaine during labor. In some of the Abboud studies medicated groups were also compared to selected non-medicated control groups and found not to differ.

Recently reported are several studies that looked at epidurals using a combination of fentanyl, an opioid, and bupivacaine, a local anesthetic. In a 1989 study of labor analgesia, Jones et al. compared extradural (epidural) bupivacaine, alone, to bupivacaine and fentanyl combined, in women having either spontaneous vaginal or operative births. They reported no significant differences in the neonates as measured by Apgar-minus-color score at one minute and five minutes, or naloxone (a narcotic antagonist) administration to the infant. There were no non-medicated controls. The measures they used to assess the neonate were relatively crude (Shnider & Levinson, 1993, pp. 674-5); such general tests may not reveal deficits in behavior as subtle and complex as feeding.

Epidural bupivacaine with and without fentanyl were compared by King et al. (1990) in a study of women undergoing elective cesarean operative births. Studies of cesarean births are

unable, of course, to include non-medicated controls. They found no differences at birth between the two groups of neonates as measured by mean birth weights, base deficits of umbilical arterial and venous blood, and Apgar scores. No infants in either group required drugs for neonatal resuscitation. Again, these tests are not designed to measure behaviors such as feeding. In their discussion the authors stated that a much larger study would be needed to assess neonatal outcome fully.

Levels of concentrations of fentanyl and bupivacaine following epidural infusion during labor were measured by Bader et al. (1995). They reported that Apgar score, Scanlon's Early Neonatal Neurobehavioral Score (ENNS, Scanlon et al., 1974), and umbilical artery blood gas values "were within normal limits in all cases" (p. 830). There were no non-medicated controls. Breastfeeding was not specifically addressed. The conclusion states that no significant drug accumulation or adverse neonatal effects, as measured by umbilical blood gas values and neurobehavioral test scores, respectively, were found. Whether these measurements are accurate indicators of fetal tissue uptake of the medication or of feeding behavior is unknown.

In 1995 work done by Kotelko et al. was reported at the Annual Meeting of the American Society of Anesthesiologists and in the journal Anesthesiology. Four groups of parturients who

delivered term infants vaginally were studied: two groups received epidural labor analgesia, either bupivacaine alone or bupivacaine and fentanyl; the third group received fentanyl intravenously; the fourth group received no narcotic or anesthesia. Several measures of neonatal sucking were made during the first ten minutes of the first two feedings, either bottle or breast, following birth. The only significant difference found was a depression of sucking measures in the group of infants whose mothers had received intravenous fentanyl. This research showed that in this case there was no difference between infants of unmedicated mothers and those who had epidurals of either bupivacaine alone or in combination with fentanyl. Whether these sucking measures are predictive of successful establishment of breastfeeding remains a question.

Loftus et al. (1995) compared three epidural regimens: healthy parturients received bupivacaine alone, bupivacaine and fentanyl , or bupivacaine and sufentanil. The Neurologic Adaptive Capacity Score (NACS) (Amiel-Tison et al., 1982) was used for neonatal neurobehavioral assessment. No differences among neonates were found at fifteen minutes and two hours after birth. However, at twenty-four hours the bupivacaine/fentanyl infants scored significantly lower on the NACS than the other two medication groups. No non-medicated controls were included in the study. It is not known whether a lower NACS at twenty-four hours

would be associated with a neonate's inability to breastfeed successfully. These findings do introduce a concern that deleterious effects of medications may not show up immediately following birth, and that research that looks only at the period immediately following birth (for example, Bader et al., 1995; Jones et al., 1989; and King et al., 1990) may be missing significant negative effects of epidural analgesia.

From the studies cited one can appreciate the ambiguities that exist in the literature and the resultant uncertainty as to whether labor medication has a deleterious effect on the establishment of breastfeeding. In a 1992 review of epidural labor pain relief Howell and Chalmers concluded that "remarkably little is known about [the] short-term and long-term effects [of epidural blocks]."

C. MEDICAL TEXTBOOKS

Treatment of effects of labor medication and breastfeeding

Four medical textbooks were reviewed for their content regarding neonatal effects of labor medications, especially whether the initiation and establishment of breastfeeding were affected (Table 1). Two textbooks in general obstetrics considered were Danforth's Obstetrics and Gynecology, Scott et al., 7th edition, 1994; and Maternal-Fetal Medicine, Creasy and Resnik, 3rd edition, 1994. Two obstetrical anesthesiology texts used were

Table 1: Information on Labor Medication and Breastfeeding in Selected Medical Textbooks

TEXTBOOK	EPIDURAL BENEFITS	EPIDURAL NEGATIVES	NEONATAL EFFECTS	INDEX	EFFECTS ON BREAST-FEEDING
Scott, DiSaia, Hammond and Spellacy Danforth's Obstetrics and Gynecology 1994 (1121 pages)	Pain relief Parturient remains awake and cooperative (139) Low incidence of complications when technique is correctly used (139) Can be used for vaginal and/or cesarean delivery (139)	Regional local anesthetics: Distribution to fetus "depends on maternal tissue uptake, maternal blood concentration, uterine blood flow, and maternal and fetal metabolism and excretion" and is affected by asphyxia, which results in increased brain and myocardial toxicity and ion trapping (134) Disadvantages of lumbar epidural analgesia: possibility of poor perineal analgesia, uneven analgesia, delayed onset of action, technical difficulty, intravascular injection, accidental dural puncture, hypotension (139) Major complications of local anesthetic use: high blood levels of the drug ->toxicity toxicity -> "drowsiness, lightheadedness, tinnitus, circumoral paresthesias, metallic taste, slurred speech, blurred vision, unconsciousness, convulsions, and cardiac dysrythmias and arrest" Epinephrine, psychomotor, and allergic reactions (135)	Neonatal outcomes unaffected by local anesthetic drugs after FHR changes (136) If newborn respiratory depression occurs due to labor opiates and related compounds, can be reversed by naloxone hydrochloride (155) Not found in index: Brazelton, ENNS, NACS	Lactation: yes Breastfeed-ing: yes Pages 168-172 on breastfeed-ing and related topics	No link between labor pain medications and breastfeeding found in text

Table 1 (con'd)

TEXTBOOK	EPIDURAL BENEFITS	EPIDURAL NEGATIVES	NEONATAL EFFECTS	INDEX	EFFECTS ON BREAST-FEEDING
Creasy and Resnik Maternal-Fetal Medicine, Principles and Practice 1994 (1237 pages)	Pain relief: excellent (552) Consciousness of mother unaltered (552) Excellent safety record (552) Requires less drug than caudal (552) Suggestion that drugs lower catecholamine release due to maternal pain and anxiety, which may benefit fetus (the "decrease in central nervous system metabolism resulting from the drug therapy reduces oxygen requirements, lactate formation, edema, and tissue damage.") (550)	"Most difficult form of anesthesia to administer" (552) Associated with late decelerations in fetal heart rate (552) Appears to lengthen second stage of labor; is associated with increased need for oxytocin and instrument delivery (552) Serious respiratory depression is rare (1/1200) (552) Transient nausea (552) Urinary retention (552) Pruritis (552)	Paragraph on meperidine and drug-depressed infants in chapter on problems in the neonate (1139)	Lactation: yes Breastfeeding: yes Chapter on the breast and the physiology of lactation (144-161)	No link between labor pain medications and breastfeeding found in text

Table 1 (con'd)

TEXTBOOK	EPIDURAL BENEFITS	EPIDURAL NEGATIVES	NEONATAL EFFECTS	INDEX	EFFECTS ON BREAST-FEEDING
Norris Obstetric Anesthesia 1993 (910 pages)	Epidural fentanyl: excellent labor analgesia (139) Adding fentanyl to bupivacaine improves and prolongs labor analgesia (139) Epidural fentanyl during cesarean section produces "no changes in neonatal respiratory rate, minute ventilation, or pulmonary compliance immediately after delivery" (139) Patient remains awake (319) Avoids "the potential risks associated with...systemic analgesics" (319) Can be continuous (319) Can be flexible (319) Potential problems "are often overestimated in frequency and severity" (319) A "more rapid onset of more profound analgesia with little motor blockade" (328) Combination "significantly lowers the risk of systemic local anesthetic toxicity" (328)	"Fetal hypoxia and acidosis accentuate the transfer of [local anesthetics]" (137) "Acidosis...appears to intensify the toxic effects of local anesthetics on the fetus and newborn" (137) "Neurobehavioral studies show varying results depending on the test used. Any effects found are subtle and must be sought diligently." (137) Bupivacaine half-life of elimination is increased in pregnancy (138) Bupivacaine metabolite, 2,6-pipecolylxylidine, is inactive (138) Both mother and fetus may be adversely affected, such as effects on labor and changes in maternal hemodynamics (319) Possibility of adverse maternal and fetal effects, most seriously, maternal and fetal respiratory depression (328) Bupivacaine: "a potent cardioelectrophysiologic poison" (626)	Both bupivacaine and 2,6-pipecolylxylidine can be detected in the urine of the neonate for at least 36 hours (138) "Current methods of testing the newborn...may not detect subtle changes. When drug effects are detected, it is difficult to assess their overall impact." (141) "No adverse effects on...the neonate have been attributed to this [epidural bup/fent] technique" (331) "Infants of hypotensive mothers [having epidural anesthesia for ces sect] had ...weak rooting and sucking reflexes for 2 days (615)	Lactation: no Breastfeeding: no	No mention of breastfeeding found in text

Table 1 (con'd)

TEXTBOOK	EPIDURAL BENEFITS	EPIDURAL NEGATIVES	NEONATAL EFFECTS	INDEX	EFFECTS ON BREAST-FEEDING
Shnider and Levinson Anesthesia for Obstetrics, Third Edition 1993 (744 pages)	Effective pain relief Quality "of analgesia is high in relation to the degree of motor block" (90) [Bupivacaine: "Duration is long, especially when epinephrine is added" (87)] "The only technique [continuous epidural analgesia]...[offering] quiet and gentle progress through all the painful stages of labor and delivery without undue risk and without the need for systemic analgesics" (97) [Bupivacaine: "the most reliable and least offensive amide local anesthetic for epidural analgesia in labor and delivery" (98)] Regional anesthesia: allows parturient to be "awake and able to participate in labor and delivery" (135) Continuous epidural anesthesia allows more "mobility in bed" and pelvic muscle tone "is maintained, possibly decreasing the incidence of malpositions" and the parturient "is better able to make expulsive efforts" (145)	Cardiotoxic (88) Bupivacaine-fentanyl, one of "the most popular epidural infusions"...carries "a higher toxicity potential than the lidocaine-fentanyl mixture..." (99) Local anesthetic toxicity -> "restlessness, incoherent speech, metallic taste, dizziness, blurred vision, tremors, and convulsions" CNS stimulation or depression Cardiovascular symptoms; blood vessel vasodilation and hypotension Uterine vasoconstriction and uterine hypertonus resulting in fetal distress (142) Short duration, which may be related to systemic absorption (167) Narcotics: "risk of neurotoxicity" (172) Chief side effects of intraspinal narcotics: "pruritis, nausea, vomiting, somnolence, urinary retention, and late respiratory depression" (178) Respiratory depression,	No mention of bupivacaine effects on neonate in chapter on perinatal pharmacology (77) It "seems extremely unlikely that [epidural bupivacaine has] any immediate or long-term adverse effects on the infant" (98) Studies of epidural bupivacaine alone or with fentanyl show no adverse effects on NACS (687) "There is as yet no evidence that prolonged adverse effects are associated with neurobehavioral	Lactation: no Breastfeed -ing: no	"Successful establish-ment of breastfeeding may be threatened by undue drowsiness in the infant" (689) Breastfeeding and anesthetic drugs, one page in chapter on anesthesia for postpartum sterilization surgery: most references appear to be to postpartum maternally-administered drugs resulting in infant exposure via drugs excreted in breast milk, (although it is not always stated) (255-6); Recent investigations have suggested that even small doses of maternal labor narcotics can delay effective breast-feeding hours or even days (255) Fentanyl administered during labor showed a lack of excretion in breast milk (255) There is "a lack of

Table 1 (con'd)

TEXTBOOK	EPIDURAL BENEFITS	EPIDURAL NEGATIVES	NEONATAL EFFECTS	INDEX	EFFECTS ON BREAST-FEEDING
(Shnider and Levinson Anesthesia for Obstetrics, Third Edition 1993 744 pages con'd)	Decreases "the likelihood of fetal drug depression and maternal aspiration pneumonitis" with other forms of anesthesia The "only proven benefits [of fentanyl added to bupivacaine]...is the finding of less motor blockade" (168-9) Epidural fentanyl has been widely used, appears safe within dose limits (172)	"when ...peak plasma level" is reached, or "6 or more hours after the initial administration of narcotic" (178) Naloxone may cause serious problems (181) Fentanyl: placental transfer occurs "Neurobehavioral changes (short term) can be seen with all narcotics" (183) Umbilical plasma narcotic levels may not be as important as brain tissue levels (183)	depression caused by maternal medication." (689) Early bonding may be impaired (689)		detailed information on the excretion of maternally administered drugs in milk"; most drugs given to the mother will be excreted in her milk (255)

Obstetric Anesthesia, Norris, 1993; and Anesthesia for Obstetrics, Shnider and Levinson, 1993.

The major concern in each of these texts in regard to the advantages and adverse effects of labor medication are those that occur during parturition. The occurrence of maternal and fetal effects are treated extensively. Neonatal effects are presented to a much lesser degree. Respiratory depression is the consequence considered to be the most serious. As can be seen in the table, in the case of epidural bupivacaine and fentanyl, adverse effects are presented as being rare and readily reversible by use of a narcotic antagonist when they do occur. The topic of breastfeeding is addressed in the obstetrics texts as a separate entity. It is not related to possible negative effects of labor medication. In the textbooks on obstetrical anesthesiology neither breastfeeding nor lactation is listed in the index, and neither appears to be considered to a significant extent in either book. Shnider and Levinson (1993, p. 689) have one sentence acknowledging that the establishment of breastfeeding may be threatened by "undue drowsiness in the infant," a statement that is open to interpretation (is this a temporary setback, a minor inconvenience, or is breastfeeding success or failure in the balance?). The concern expressed is, in the next sentence, diminished by the following: that it is "perhaps of greater prognostic significance when

neurobehavioral depression occurs that cannot be attributed to medication..."

IV. SUMMARY

Breastfeeding has a powerful, positive impact on the newborn, nutritionally, immunologically, and psychologically; on the mother; and on the mother-infant relationship. While many women and their infants establish breastfeeding successfully, many do not. The causes for this failure are many. The scientific literature regarding labor medication as having a deleterious impact on breastfeeding is ambiguous. Some studies show no effect of medication on the neonate, others show some effect on behaviors unrelated to breastfeeding, or they show a disruption of breastfeeding that could be considered minor or temporary. Do the medications currently used for epidural labor medication have a significant negative impact on the establishment of breastfeeding?

MATERIALS AND METHODS

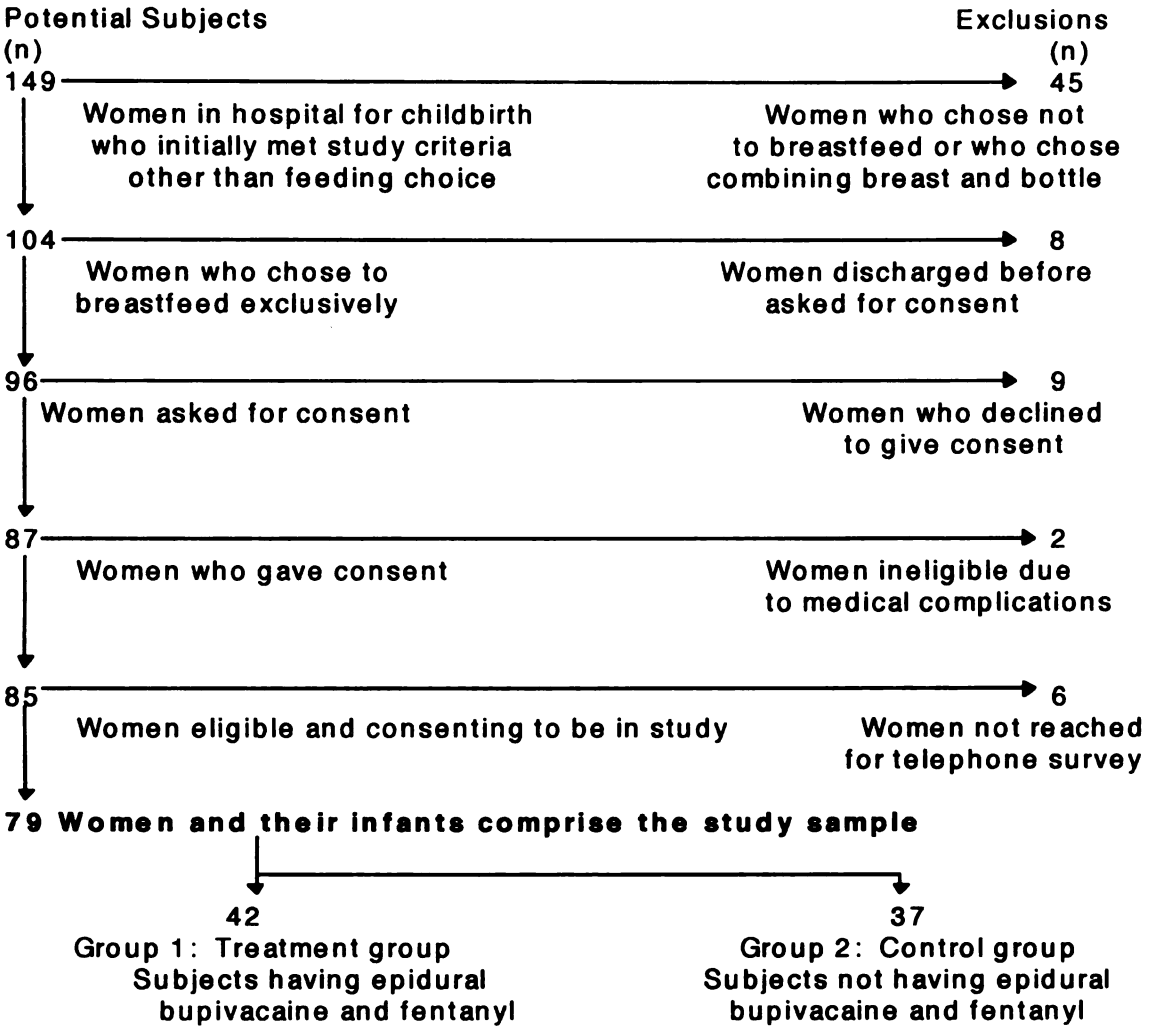
I. RESEARCH APPROVAL

Application was made to the Michigan State University Committee on Research Involving Human Subjects (UCRIHS), and to the Institutional Research and Review Committee of Sparrow Hospital for approval of the proposed research. Approval was granted in June and July, 1997, respectively (Appendices A and B).

II. RESEARCH DESIGN

The purpose of this research was to investigate the relationship of selected factors, including labor medication, to the establishment of breastfeeding (Figure 1). For this prospective study women in the hospital for childbirth were asked for their consent to participate in the research. Only women who had indicated that they intended to breastfeed and who met certain other criteria were considered. Women who had received an epidural and those who had not were enrolled in the study. If they gave consent, they were interviewed by telephone two to six weeks following the birth of their baby. Demographic, breastfeeding, and related information was collected from the maternal and infant medical records as well as from the telephone survey. Upon completion of the survey the subject was sent a letter of thanks from the investigators (JTB and SD), a five dollar gift certificate to a local store, and an addressed, stamped postcard for her to sign and

Phase I: RECRUITMENT, CONSENT, ENROLLMENT OF SUBJECTS



Phase II: DATA COLLECTION

MEDICAL RECORDS: demographic, breastfeeding and related information
Maternal Medical Record
Infant Medical Record

TELEPHONE SURVEY: demographic, breastfeeding and related information
Took place from two to six weeks following birth

Phase III: LETTER TO SUBJECTS

Thank you letter, Gift Certificate, and Postcard to be returned upon receipt of gift certificate
Sent upon completion of telephone survey

Figure 1: Research Design

mail indicating that she had received the letter. Confidentiality was maintained throughout the investigation.

III. SUBJECTS

A. CRITERIA FOR INCLUSION IN THE STUDY

Research articles on labor medication were used to compile a comprehensive list of criteria for both parturient and neonatal subjects (Abboud et al., 1984; Bader et al., 1995; Crowell et al., 1994; King et al., 1990; Kuhnert et al., 1985; Kuhnert et al., 1988; Loftus et al., 1995; Matthews, 1989; Murray et al., 1981; Vinson et al., 1993; Wiener et al., 1979. Also, D.R. Gambling & J.D. Wiley, personal communication, October 17, 1995; A. Rosen & R. Lawrence, personal communication, 1994). Criteria that were obviously irrelevant for this study were deleted from the list. An expert review by eight physicians (seven obstetricians and one family practice resident) and two nurses was conducted (Appendix C). Four physicians and two nurses responded. Using their responses the subject criteria list was further refined by the investigators (JTB and SD). Anesthesiologist Kenneth Rudman, MD, in a meeting with one of the investigators (SD) and using the Expert Review Instrument, further defined the inclusion and exclusion criteria.

Parturients met the following criteria:

- intent to breastfeed as recorded prior to childbirth in the Vaginal Delivery Labor and Delivery Clinical Pathway

- no previous live births
- a pregnancy without abnormalities or complications
- a vaginal, singleton birth, including low forceps and vacuum extraction births, without abnormalities or complications
- no communicable disease, clinical manifestation of infection, nor known substance abuse
- no positive history of clinical psychological abnormalities that may interfere with ability to participate in the study
- able to communicate in English

Neonates met the following criteria:

- 37-42 weeks gestation
- birth weight: ≥ 2500g
- well newborn, without abnormalities or complications
- not in Neonatal Intensive Care Unit over 8 hours

The design of the research was directed not only to answering the research question but also to minimizing the intrusion into the lives of the new mother and newborn so as not to add to their burden.

See Appendix D, Definitions, for more detailed explanation of terminology used in Materials and Methods.

B. ELIGIBILITY, CONSENT, ENROLLMENT IN THE STUDY

Subjects who met the study criteria were enrolled during their postpartum stay for childbirth at Sparrow Hospital, a community hospital in a medium-sized Midwestern city, from July to November, 1997. Due to the greater proportion of laboring women who receive epidural medication at the hospital where the research took place, enrollment was carried out in three phases in order to minimize historical bias. At the beginning of each phase both women who

received epidural labor pain medication and those who did not were enrolled. This was followed by a period when only women who did not receive epidural labor medication were enrolled. During periods of enrollment the delivery record of the Department of Labor and Delivery, the daily record of all hospital births, was checked by the investigator (SD) to determine whether any of the newly delivered mothers and their infants met the study criteria. The postpartum hospital stay is approximately 48 hours at this hospital; therefore the record was usually checked at least once a day during enrollment periods. Every eligible woman was asked to consider being a subject in the study. The Consent Form (Appendix E) was explained to her in full by the investigator (SD), in the presence of a witness. If the woman agreed to participate, the Consent Form was then signed by the study subject, the investigator, and the witness. One signed copy was placed in the maternal medical record and one was kept by the researcher. The subject received an unsigned copy for her records. Enrollment took place on 93 of the 129 days of the enrollment period (42 days of enrolling both types of subjects, 51 days enrolling only women who received no epidural pain medication); there were 36 days on which no one was enrolled. A total of 149 women qualified to be in the study before taking into account feeding choice. Of the 149, 104 (69.8%) planned to breastfeed their infants, 35 (23.5%) planned to

bottle feed, and 10 (6.7%) planned to combine the two feeding modes. Therefore, 104 initially met all criteria. An effort was made to avoid disturbing the mother in the hours immediately following birth. Consequently eight of the 104 women left the hospital before they were asked to participate and were therefore unavailable for inclusion in the study. Nine women declined to give consent. In two cases complications developed postpartum that made these women ineligible for the study. Six women could not be reached for the telephone survey despite numerous attempts to contact them. Seventy-nine breastfeeding women and their infants met the study criteria, completed all aspects of the study, and comprised the study population (Figure 1).

IV. REVIEW AND DEVELOPMENT OF INSTRUMENTS

A. THE RESEARCH QUESTION

Research question:

What is the relationship between the labor medication status of the nulliparous parturient intending to breastfeed and the status of breastfeeding at day fifteen?

The labor medication status under consideration was either epidural anesthesia using a combination of fentanyl and bupivacaine, or no such epidural anesthesia.

Breastfeeding status at day fifteen was chosen as a measure of the successful establishment of breastfeeding. Failure to establish breastfeeding can occur over a period of time, including a number of days. Similarly, lack of successful breastfeeding for the first feeds does not necessarily mean that the mother-baby dyad will not go on to establish breastfeeding, as will be seen later in the discussion. No woman in the study planned to breastfeed for as short a period of time as two weeks, so it was assumed that stopping breastfeeding during the first fifteen days was an unplanned occurrence.

Data were collected from the maternal and neonatal medical records and from a postpartum scripted telephone interview.

Dependent variable: breastfeeding status at day 15 postpartum

Independent variable: epidural combination of bupivacaine and fentanyl versus no epidural bupivacaine and fentanyl

B. ADDITIONAL VARIABLES

In order to determine what other variables, in addition to those of the research question, should be considered in this study as possibly influencing the early cessation of breastfeeding, a list of variables from articles from the scientific literature on breastfeeding duration was compiled (Beaudry & Aucoin-Larade, 1989; Bloom et al., 1982; Dungy et al., 1992; Feinstein et al., 1986; Frank et al., 1987; Mansbach et al., 1991; Perez-Escamilla et al.,

1994; Ryan et al., 1990; Samuels et al., 1985; Saunders & Carroll, 1988; Serafino-Cross & Donovan, 1992; Slaven & Harvey, 1981; Taylor et al., 1986; Woodward, 1988; Wright and Walker, 1983). Estimations were made as to the effect of a number of variables on the duration of breastfeeding from graphs, charts and other reports of results, sometimes inferring duration at two weeks when only longer periods of time were reported. The reported decrease in percentage of women breastfeeding at day fifteen estimated from these studies ranged from approximately 2.5%-45%.

An expert review was then sought from eight physicians and two nurses. Questions included in the expert review addressed whether certain factors were likely to have an effect on breastfeeding and whether it would be reasonable to include them in this study. Information from the six respondents (four physicians and two nurses) was then used to refine the list of variables about which information would be collected. An expert review was conducted by SD by telephone with Thomas Hale, Ph.D., Director of Clinical Laboratories, Associate Professor of Pediatrics, Associate Professor of Pharmacology, Texas Tech University School of Medicine, and author of Medications and Mothers' Milk (1996), on those aspects of the research relating to medication issues (Appendix C).

A request for information on factors that may have a negative impact on the establishment of breastfeeding was made of lactation consultants via the internet listserve Lactnet and of other practicing lactation consultants. Approximately eight lactation consultants responded. A summary of this information was compiled and several of the suggestions led to the inclusion of additional variables in the study.

C. DESCRIPTION OF INDEPENDENT VARIABLES

The breastfeeding attitude/commitment score

The breastfeeding attitude variable is a composite score measuring the strength of the mother's attitude toward and commitment to breastfeeding. It is comprised of the mean of five equally weighted individual scores obtained from the answers to five telephone survey questions. The questions solicited information in five areas that research has shown are related to breastfeeding duration:

1. The mother's assessment of her own commitment to breastfeeding just before the baby was born, on a scale of 1 to 5 (Beaudry et al., 1989; Coreil & Murphy, 1988; Janke, 1988).

2. The timing of the decision to choose breastfeeding as the feeding mode for her baby, before pregnancy or during pregnancy (Kurinij & Shiono, 1991).

3. The mother's planned duration of breastfeeding in months, just before the baby was born (Coreil & Murphy, 1988; Loughlin et al., 1985).

4. The mother's perception of whether a baby could do as well when formula fed versus when breastfed. (This question was asked so that agreeing with the statement meant that the mother equated formula feeding with breastfeeding. If the mother chose to disagree it meant she considered that formula feeding was not as good for the baby. This wording was chosen to increase the likelihood of the mother answering candidly when asked a sensitive question.)

5. The mother's assessment of her breastfeeding environment as supportive, mixed, or not supportive (Janke, 1988).

Factor analysis showed that questions 1-4 were the measure of an attitude construct. Since the second factor involved only the fifth question and was not significant, it was decided to use the mean score of the five responses as the variable for analysis. Ten cases had a single missing value. For these the composite score was calculated by using the mean of the four existing scores. The possible range of mean scores is 1-5; the range observed in this study was 1.60-5.00.

Medication variables

The research question addresses the issue of epidural bupivacaine and fentanyl used for labor analgesia/anesthesia. However, the non-epidural group for the epidural status variable was comprised of many women (20 of 36 non-epidurals) who had received the narcotic nalbuphine (Nubain) systemically. This led to the consideration of several different types of medication variables. The first medication variable had four categories of drug exposure:

1. labor epidural bupivacaine and fentanyl
2. systemic Nubain (nalbuphine) during labor
3. both Nubain and epidural bupivacaine and fentanyl
4. no Nubain, no epidural bupivacaine and fentanyl

The second medication variable consisted of two categories, and was a collapsed version of the first medication variable:

1. Nubain and/or labor epidural bupivacaine and fentanyl
2. no Nubain, no labor epidural bupivacaine and fentanyl

The third medication variable consisted of two categories:

1. epidural bupivacaine and fentanyl
2. no epidural bupivacaine and fentanyl

The fourth medication variable consisted of two categories:

1. both labor Nubain and epidural bupivacaine and fentanyl

2. no combination of Nubain and epidural bupivacaine and fentanyl (Nubain only; or epidural bupivacaine and fentanyl only; or neither)

Other variables

For a description of the other variables, see Results and Discussion, Table 6: Associations between the Establishment of Breastfeeding and Maternal, Infant, Birth, and Breastfeeding Characteristics

D. THE INSTRUMENT FOR MEDICAL RECORD DATA COLLECTION

The list of variables formed the basis of two instruments, the Data Collection Document (Appendix F) and the Telephone Interview Script (Appendix G). A draft instrument of the Data Collection Document, comprising the subject criteria and information to be collected from the medical records, was created by SD and JTB. It included all variables that could be found in the medical records of the mother and her infant. This instrument was reviewed by the hospital's Director of Women's Services, the Department Manager of OB Special Care, and, as directed by the hospital institutional review board, a Perinatal Clinical Nurse Specialist. Their suggestions, where appropriate, were incorporated into the instrument. Each section of the Data Collection Document corresponded to the section of the medical record where that information was located. The order of the data

within each section followed that of the medical record. The hospital Perinatal Clinical Nurse Specialist provided information on the location in the medical record of certain data, and when data were recorded in several different places, which recording was most appropriate for the present research. The instrument was revised after access to actual medical records dictated certain changes. In addition, some parts of the medical record were undergoing format changes by the hospital during the study, and the research instrument was modified to reflect those changes.

E. THE INSTRUMENT FOR THE TELEPHONE SURVEY

The research called for certain information that was not to be found in the medical records, such as the history of breastfeeding once the mother and baby had left the hospital. For the collection of these data a scripted telephone survey (Appendix G) was created following the survey principles described in Dillman (1978). The interview script underwent a series of reviews and revisions. The first review was by a group of registered dietitians and nutrition experts, some of whom had experience working in the public health sector, some with breastfeeding expertise, and some who were knowledgeable about survey design. The revised script was then tested by actual telephone interviews of women, all of whom had had babies, several of whom were new mothers, and among whom there were nutrition experts, those familiar with public health, and

those experienced in survey construction. More revisions followed. The Perinatal Clinical Nurse Specialist also reviewed the script and made suggestions regarding the telephone survey. The appropriate changes were made. When approximately fifteen surveys of study subjects were completed, the survey was once again assessed and a few minor changes were made.

F. COLLECTING DATA FROM THE MATERNAL MEDICAL RECORD

Maternal and infant medical records of study subjects were requested from the Medical Record Department of Sparrow Hospital. No records were allowed out of the Department for purposes of this research; therefore, all data were collected at that site. Information related to demographics, pain medications, and issues related to breastfeeding was recorded in the Data Collection Document by the investigator (SD). These data were entered into the statistical program StatView 4.5. A research assistant did an independent review of a selection of hospital medical records of the study subjects, mothers and infants, and then checked her results against a printout of the dataset. Following this every Data Collection Document was checked against the dataset printout for accuracy and completeness.

G. COLLECTING DATA FROM THE TELEPHONE SURVEY

Each subject was interviewed in the period from approximately two to six weeks following birth using the scripted

telephone survey. The interview took approximately one half hour. Calls were repeated as necessary to reach the respondent and to conduct the interview at a time convenient to her. No women who were contacted by telephone refused the interview, but several women could not be reached, even after numerous attempts. Responses were recorded on the interview form (see Appendix G) and from that form were entered into the statistical program. Each scripted telephone survey was checked by a research assistant against the dataset printout for accuracy and completeness.

V. COMPENSATION OF THE STUDY SUBJECTS

At the completion of the telephone interview the respondent was thanked for her participation in the study. Her current address was ascertained. A letter of thanks signed by the two Michigan State University researchers (JTB, SD), the $5.00 gift certificate for a local store, and a typed postage-paid postcard addressed to the researcher (SD) were mailed to the subject. The letter requested that she sign and mail the card. The postcard bore a statement that she had received the gift certificate for her participation in the study.

VII. STATISTICAL ANALYSIS

Data were entered into the statistical program StatView 4.5. The initial statistical analyses were done to determine the relationship of the independent variables to the outcome variable,

the status of breastfeeding at day fifteen. Chi-square tests were used for categorical variables and *t* tests were used for continuous variables. The variables chosen, as suggested by the scientific literature, were maternal age, maternal education, maternal ethnicity, insurance status (as an indicator substitute of socio-economic status), prenatal class on breastfeeding, smoking, birth control, jaundice status of the baby, gestational age of the infant, time interval following birth to the first breastfeeding, and a breastfeeding attitude score. In addition, demographic information and other factors considered to possibly have an effect on the outcome were also examined. The level of significance for these analyses was set at the $\alpha < 0.05$ level. Chi-square p values are reported unless the number of expected subjects in one or more of the cells of the chi-square analysis had fewer than 5.0 cases, in which case Fisher's Exact p value is given.

The outcome, whether or not the mother and infant are still breastfeeding at a given time, is a binary dependent variable; therefore logistic regression was chosen for further statistical analysis of the data.

RESULTS and DISCUSSION

The successful establishment of breastfeeding is the *sine qua non* of the mother-baby breastfeeding relationship. Once breastfeeding has been established its duration may be influenced by many factors, but if breastfeeding is not successfully established, there is no breastfeeding.

I. DESCRIPTION OF SUBJECTS, BIRTH, BREASTFEEDING

Characteristics of the mothers, infants, delivery, and breastfeeding are given in Tables 2-5.

A. CHARACTERISTICS OF THE MOTHERS

Women in this study were parturients at a community hospital in a medium-sized Midwestern city. All women, upon admission to the hospital for childbirth, had expressed the intention to breastfeed their infants. The baby born at the time of enrollment in the study was the first live birth for the woman, although not necessarily her first pregnancy, and therefore all study subjects were experiencing feeding their own infant for the first time. Gravidity ranged from 1-6, with a mean of 1.4 pregnancies. Women ranged in age from 18 to 44 years, with a mean age of 26.5 years. Maternal education level completed ranged from 10 to 19 years, with a mean of 14.7 years. Married women were in the majority, 72.2%. Sixty-five (82.3%) were listed as Caucasian; six African-American; three Hispanic; two Native American; and three Other.

Table 2: Characteristics of the Mothers

		Number of Subjects	Percent of Subjects	Range	Mean	Standard Deviation
Maternal Age (Years)		79	(100.0)	18 to 44	26.52	5.55
Maternal Education (Years)		78	(98.7)	10 to 19	14.69	2.19
Marital Status	Married	57	(72.2)			
	Single	22	(27.8)			
Maternal Ethnicity	Caucasian	65	(82.3)			
	Black	6	(7.6)			
	Hispanic	3	(3.8)			
	Native American	2	(2.5)			
	Other	3	(3.8)			
Insurance Status	Private	68	(86.1)			
	Government	11	(13.9)			
Type of Medical Service: Birth	ROGES*	11	(13.9)			
	Private Physician	64	(81.0)			
	Midwife	2	(2.5)			
Type of Medical Service: Postpartum	NTS**	21	(26.6)			
	Private Physician	57	(72.2)			
Smoking	Smoker	4	(5.1)			
Contraception	Contraception	5	(6.3)			

* ROGES: Residents Obstetric Gynecologic Education Services

** NTS: Newborn Teaching Service

Table 3: Characteristics of Birth

		Number of Subjects	Percent of Subjects	Range	Mean	Standard Deviation
Gravidity		78	(98.7)	1.0-6.0	1.38	0.85
Type of Labor	Spontaneous	44	(55.7)			
	Augmented	14	(17.7)			
	Induced	21	(26.6)			
Rupture of Membranes, Spontaneous	SROM	42	(53.2)			
Artificial	AROM	37	(46.8)			
Type of Delivery	Spontaneous	74	(93.7)			
	Vacuum	5	(6.3)			
	Forceps	0	(0.0)			
Labor, First Stage (Hours)		79	(100.0)	0.17-22.67	7.39	4.73
Labor, Second Stage (Hours)		79	(100.0)	0.15-3.52	1.15	0.71
Labor, Third Stage (Hours)		78	(98.7)	0.03-2.08	0.17	0.26
Total Length of Labor (Hours)		78	(98.7)	0.90-23.77	8.64	4.69

Table 4: Characteristics of the Infants

		Number of Subjects	Percent of Subjects	Range	Mean	Standard Deviation
Gender	Female	41	(51.9)			
	Male	38	(48.1)			
Apgar Score, 1 minute		79	(100.0)	4.0-9.0	7.73	0.96
Apgar Score, 5 minutes		79	(100.0)	7.0-10.0	8.91	0.37
Rooting Absent		9	(11.4)			
Sucking Absent		1	(1.3)			
Number of Voids First 24 Hours		77	(97.5)	0-6	2.13	1.38
Number of Stools First 24 Hours		78	(98.7)	0-6	2.92	1.46
Jaundice, Bilirubin* Over 16 mg/dL		7	(8.9)			
Gestational Age		76	(96.2)	37-41	39.77	0.75
Birth Weight		79	(100.0)	5.94-10.88	7.62	0.92

*Bilirubin: Serum bilirubin levels, mg/dL

Table 5: Characteristics of Breastfeeding

		Number of Subjects	Percent of Subjects	Range	Mean	Standard Deviation
Breastfeeding Status, Day Fifteen	Breastfeeding	64	(81.0)			
	Not Breastfeeding	15	(19.0)			
First Breastfeeding Evaluation, No Latch-on		17	(21.5)			
Second Breastfeeding Evaluation, No Latch-on		16	(20.3)			
Attended Prenatal Class on Breastfeeding		56	(70.9)			
Attended Hospital Breastfeeding Class		34	(43.0)			
Breastfeeding within Thirty Minutes		29	(36.7)			
Breastfeeding within Two Hours		59	(74.7)			
Lactation Consult		18	(22.8)			

Eleven women (13.9%) had some form of government insurance, sixty-eight (86.1%) did not. Four women (5.1%) smoked and five (6.3%) received chemical contraception in the first two weeks following birth.

B. CHARACTERISTICS OF BIRTHS

Most labors were categorized as spontaneous, 44 or 55.7%. Fourteen (17.7%) were augmented with pitocin and 21 (26.6%) were induced with or without augmentation. Rupture of membranes was spontaneous in 42 (53.2%) cases and artificial in 37 (46.8%) cases. The length of the first stage of labor ranged from ten minutes to twenty-two hours, forty minutes, mean of 7.39 hours. The second stage of labor ranged from nine minutes to three hours thirty-one minutes, mean of one hour, nine minutes. The third stage of labor ranged from two minutes to two hours, five minutes; mean, ten minutes. The total length of labor varied from fifty-four minutes to twenty-three hours, forty-six minutes, averaging eight hours, thirty-eight minutes.

C. CHARACTERISTICS OF THE INFANTS

Of the seventy-nine infants, 41 (51.9%) were females, 38 (48.1%) males. Birth weights ranged from 5.94-10.88 lbs., with a mean of 7.62 lbs. Apgar scores at one minute ranged from 4 to 9, with a mean of 7.7. Apgar score at five minutes ranged from 7-10, with a mean of 8.9. At the initial neonatal physical assessment

rooting was absent in 9 (11.4%) infants; sucking was absent in one infant. Gestational age by physical examination ranged from 37-41 weeks, with a mean of 39.8 weeks. Number of voids recorded in the first 24 hours ranged from 0-6, mean of 2.1; number of stools recorded in the first 24 hours ranged from 0-6, with a mean of 2.9. Bilirubin levels reported by mothers during the survey exceeded 16 mg/dL in seven cases; no mothers reported bilirubin levels in excess of 20 mg/dL.

D. CHARACTERISTICS OF BREASTFEEDING

Breastfeeding began within thirty minutes of birth, by mother's report, for 29 (36.7%) mother-baby pairs, and within two hours for 59 (74.7%) pairs. Seventeen mother-baby dyads (21.5%) experienced no latch on during the first breastfeeding; sixteen pairs (20.3%) had no latch on for the second breastfeeding. Fifty-six (70.9%) women attended a prenatal class on breastfeeding. Thirty-four (43.0%) attended the hospital breastfeeding class. Eighteen women (22.8%) had a consult with the hospital Lactation Consultant.

II. SUBJECTS COMPLETING THE STUDY

During the enrollment period 104 women who initially met the study criteria indicated that they planned to breastfeed their infants. When enrolling potential subjects an effort was made to avoid approaching the newly delivered woman when she was in the

immediate postpartum period. Hospital stays for childbirth are brief, however, and eight women who appeared to have been eligible for the study left the hospital before they could be asked to participate and were, therefore, unavailable for inclusion in the study. Nine women refused consent and six women could not be reached for the telephone survey. In two cases complications developed postpartum that made these women and their infants ineligible for the study. Seventy-nine breastfeeding women and their infants met the study criteria in full and comprise the study population.

III. STATISTICAL ANALYSIS: CHI-SQUARE AND *t* TESTS

In this study population 64 mother-baby pairs (81%) were breastfeeding at day fifteen and 15 (19%) were no longer breastfeeding. Factors that influence the success of breastfeeding as measured by its duration have been reported in the scientific literature. Other factors have been proposed by health care professionals. A summary of chi-square and *t* tests of these factors and the outcome variable, breastfeeding status at day fifteen, is presented in Table 6. In addition, several versions of medication status were also examined for a possible relationship to breastfeeding status at day fifteen.

Table 6: Associations between the Establishment of Breastfeeding and Maternal, Infant, Birth, and Breastfeeding Factors

Chi-Square Tests, Established Bf* v.:	χ^2 p value	Fisher's Exact p value**	Description of Variable
Epidural Status	p=.2443		Epidural*** with bupivacaine and fentanyl: yes v. no
Medication Status		p=.2847	Epidural +/or Nubain****: yes v. no
Nubain Status	p=.9646		Nubain: yes v. no
Both EpNub Category		p=.6774	Epidural + Nubain: yes v. no
Newmed Status (4 levels)	p=.5789		Epidural only, Nubain only, Epidural + Nubain, neither
Gender	p=.6523		Infant gender
Labor Categories (3 levels)	p=.4218		Spontaneous, augmented, induced
Rupture of Membranes (ROM)	p=.5753		Spontaneous ROM, artificial ROM
Delivery Type		p>.9999	Spontaneous v. vacuum
Marital Status		p> 9999	Married v. single
Insurance Category	p=.3724		Government, government + other, other
Newinsurance Category		p>.9999	Government v. private
Resident Obstetric Gynecologic Education Services (ROGES)		p=.4398	Resident Obstetric Gynecologic Education Services (ROGES) v. private physician
Baby's Doctor		p=.1012	Newborn Teaching Service v. private physician
Breast Pump (3 levels)	p=.7161		Breast pump: yes, no, not checked
Maternal Ethnicity	p=.1330		Maternal Ethnicity (Caucasian, African American, Hispanic, Native American, Other
Midwife		p>.9999	Midwife v. physician
Resuscitation Status (4 levels)	p=.4587		No resuscitation, oxygen, intubation, bag
Bf in 2 hrs (hospital)	p=.1285		First breastfeeding within first 2 hrs: yes v. no (medical record, 64 subjects)
Hospital Bf Class (Med Record, 40)		p=.4761	Attended hospital breastfeeding class: yes v. no (from Medical Record, 40 subjects)
Lactation Consultant (LC) consultation	p=.5183		No consult, one consult, two consults
Rooting		p=.6759	Rooting present: yes v. no
Sucking		p>.9999	Sucking present: yes v. no
Stop bf	p=.4019		Advised to stop breastfeeding: yes v. no
First Bf Evaluation: Latch (3 levels)	p=.0038		First breastfeeding good latch, fair latch, no latch
First Bf Evaluation: Latch, Y/N (2 levels)		p=.0025	First breastfeeding latch: yes v. no

Table 6 (con'd)

Chi-Square Tests:	χ^2 p value	Fisher's Exact p value*	Description of Variable
Skin to Skin		p>.9999	First breastfeeding, skin-to-skin: yes v. no
Second Bf Success (3 levels)	p=.0024		Second breastfeeding success: yes, fair, no success
Second Bf Success, Y/N (2 levels)		p=.0097	Second breastfeeding latch: yes v. no
Success of First and Second Bfs		p=.0052	First or second breastfeed latch: yes v. no
Formula in Hospital	p=.0001		Formula : yes v. no
Prenatal Class, Y/N		p=.0299	Prenatal class on breastfeeding: yes v. no
Hospital Bf Class	p=.1414		Attended hospital breastfeeding class: yes v. no (from Survey, 78 subjects)
Help needed		p=.4447	Needed breastfeeding help: yes v. no
Medication plan	p=.3597		Labor plan: no medication, no epidural, options open, epidural, undecided
Meds at Home		p=.6921	Medications taken at home: yes v. no
Birth Control		p=.0447	Contraceptive shot or pill, first 15 days: yes v. no
Smoker		p=.1612	Smoking during first 15 days: yes v. no
Jaundice Category		p=.0218	Bilirubin over 16 mg/dL v. under 16 mg/dL
Circumcision	p=.9121		Negative effect, none, positive, unsure
Pacifier Use (4 levels)	p=.2491		Important to baby, used some, used little, not used
Discharge Formula		p=.2075	Received formula at discharge: yes v. no
Suction Category (3 levels)	p=.7895		No suctioning, oro-naso suctioning, gastric suctioning, both types of suctioning
Latch-no-suck Category		p=.0183	Latch, no suck: yes v. no
Sleep Category	p=.3700		Sleepiness, mom or baby: yes v. no
Drugged Category		p=.1885	Drugged, mom or baby: yes v. no
Nipplesore Category	p=.8771		Mom (or Medical Record) reported nipples sore: yes v. no
Mastitis Category		p>.9999	Mom reported mastitis: yes v. no
Mom Concerned Category	p=.0119		Mom had breastfeeding concerns: yes v. no
Maternal Age Groups (6 levels)	p=.6050		Age groups: <20, 20-24, 24-29, 30-34, 35-39, 40-44
Maternal Age Final (3 levels)	p=.1812		Age groups: <20, 20-29, 30 and above
Maternal Education Category (5 levels)	p=.2621		Years of schooling: 10-11, 12-13, 14-15, 16-17, 18-19
Maternal Education Final (3 levels)	p=.1388		Years of schooling: 10-11, 12-15, 16-19 yrs
Maternal Ethnicity (5 categories)	p=.1330		Caucasian, Black, Native American, Hispanic, Other
Newage Category (7 levels)	p=.2425		Time of first breastfeeding following birth

Table 6 (con'd)

Chi-Square Tests:	χ^2 p value	Fisher's Exact p value*	Description of Variable
Bf by 2 hrs (Survey)		p=.1885	Time of first breastfeeding within first 2 hours following birth v. after 2 hours (survey, 79 subjects)
Bf by 30 min (Survey)	p=.0369		Time of first breastfeeding within first 30 min following birth v. after 30 minutes (survey, 79 subjects)

t tests, Established Bf v.:	*t* test p value	Description of Variable
Category Birth Weight	p=.3540	Birth weight
Category Gravidity	p=.8307	Gravidity
Category Apgar-1 minute	p=.5497	Apgar-1 minute
Category Apgar-5 minutes	p=.7977	Apgar-5 minutes
Category Labor Stage 1, Hours	p=.8858	Labor, Stage 1, hours
Category Labor Stage 2, Hours	p=.5211	Labor, Stage 2, hours
Category Labor Stage 3, Hours	p=.5267	Labor, Stage 3, hours
Category Labor, Total Hours	p=.7817	Labor, total hours
Category Maternal Age	p=.1523	Maternal Age, years
Category Paternal Age	p=.2482	Paternal Age, years
Category Maternal Education	p=.1359	Maternal Education, years
Category Paternal Education	p=.1219	Paternal Education, years
Category Voids, Day 1	p=.1457	Number of voids, first 24 hours
Category Stools, Day 1	p=.0104	Number of stools, first 24 hours
Category Gestational Age, Exam	p=.0070	Gestational age by examination
Category Temperature	p=.3237	First temperature of infant
Category Bf Minutes Postpartum	p=.1244	Time interval following birth of first breastfeeding, minutes
Category First Successful Bf	p=.2638	Number of feed that was the first successful breastfeeding
Category Milk Came In	p=.8647	Mom's report: timing of milk coming in
Category Proportion No/Poor Bfs	p=.0535	Number of poor or no breastfeeding feeds to total number of feeds
Category ATT	p=.0416	Mom's assessment of her commitment to breastfeeding (scale of 1-5)

Table 6 (con'd)

t tests, Established Bf v.:	*t* test p value	Description of Variable
Category BFDEC	p=.0450	Decision to breastfeed made before pregnancy v. during pregnancy (scale of 1-5)
Category MOSPL	p=.0025	Months mother planned to breastfeed (scale of 1-5)
Category FORM	p=.0006	Mom's opinion that formula equals breastfeeding: agree, unsure, disagree (scale of 1-5)
Category SUPP	p=.4414	Mom's evaluation of level of support of her environment (scale of 1-5)
Category Attavg	p=.0002	Average of 5 equally weighted attitude scores, averages taken ignoring missing values (scale of 1-5)

*Bf=breastfeeding
**Fisher's Exact p value is reported when the number of subjects expected in one or more cells of the chi-square analysis is below 5.0.
***Epidural in this study refers to those women who received epidural bupivacaine and fentanyl during labor. One subject received Xylocaine and Nesacaine epidurally. The epidural administration of anesthetic medication began 1:19 hours before birth with doses of 3 cc and 10 cc of Xylocaine; at 0:09 hours before birth the subject received 10 cc of 3% Nesacaine. A second subject received 15 cc of Xylocaine at 2:05 hours before birth. Because of the absence of bupivacaine and the narcotic fentanyl, given the nature, doses, and timing of the administration of these drugs, and given the IV fluid volume of 2000 ml or less, these subjects were not included in the epidural group.
****Epidural and Nubain in this variable refer to pain medications given during labor.

A. FACTORS ASSOCIATED WITH BREASTFEEDING STATUS AT DAY FIFTEEN

Chi-square tests or *t* tests were used to determine the relationship between the outcome variable of breastfeeding status at day fifteen and each of the independent variables. Table 6 lists the p-values for these tests. Results of the analyses for the main independent variables are given in Table 7. The variables found to be significantly related to breastfeeding status at day fifteen at this stage of the analysis were:

- Breastfeeding Attitude Score
- Prenatal Class Including Breastfeeding
- Gestational Age
- Breastfeeding by Thirty Minutes
- Success of the First Breastfeeding: Latch, Yes/No
- Success of the Second Breastfeeding: Latch, Yes/No
- Stooling First 24 Hours
- Use Of Formula in the Hospital
- Use Of Chemical Contraception
- Jaundice

A high Breastfeeding Attitude Score is one of the strongest predictors of breastfeeding status at day fifteen. This is in agreement with a number of articles in the scientific literature that find that duration of breastfeeding is related to the attitude of the mother (for references, see Materials and Methods, Description of Independent Variables). Education is one of the keys to maintaining and improving the strength of the commitment to and attitude toward breastfeeding of childbearing women. The more

Table 7 Establishment of Breastfeeding and Variables from Scientific Literature and Statistical Analyses

	Subjects		Breastfeeding Status, Day Fifteen				p Values
			Breastfeeding		Not Breastfeeding		
Variable	n	%	n	%	n	%	
Epidural Status							
Epidural	42	(53)	32	(76)	10	(24)	
No Epidural	37	(47)	32	(86)	5	(14)	0.2443* NS
Medication Status (4 levels)							
Epidural Bupivacaine & Fentanyl	33	(42)	25	(76)	8	(24)	
Nubain	23	(29)	19	(83)	4	(17)	
Both Epidural & Nubain	9	(11)	7	(78)	2	(22)	
No Epidural, No Nubain	14	(18)	13	(93)	1	(7)	0.5789* NS
Epidural and/or Nubain							
Epidural and/or Nubain	65	(82)	51	(78)	14	(22)	
No Epidural, No Nubain	14	(18)	13	(93)	1	(7)	0.2847** NS
Epidural and Nubain							
Epidural and Nubain	9	(11)	7	(78)	2	(22)	
No Combination Ep/Nub	70	(89)	57	(81)	13	(19)	0.6774** NS

Table 7 (con'd)

			Breastfeeding		Not Breastfeeding		
Variable	n	%	n	%	n	%	
Maternal Age (yr)							
<20	8	(10)	6	(75)	2	(25)	
20-29	51	(65)	39	(76)	12	(24)	
30 and over	20	(25)	19	(95)	1	(5)	0.1812* NS
Maternal Education (yr)							
10-11	4	(5)	4	(100)	0	(0)	
12-15	35	(44)	25	(71)	10	(29)	
16 and above	39	(49)	34	(87)	5	(13)	0.1388* NS
Insurance Status							
Government Insurance	11	(14)	9	(82)	2	(18)	
Private Insurance	68	(86)	55	(81)	13	(19)	>.9999** NS
Maternal Ethnicity							
Caucasian	65	(82)	52	(80)	13	(20)	
Black	6	(8)	6	(100)	0	(0)	
Hispanic	3	(4)	1	(33)	2	(67)	
Native American	2	(3)	2	(100)	0	(0)	
Other	3	(4)	3	(100)	0	(0)	0.1330* NS

Table 7 (con'd)

Variable	Breastfeeding n	Breastfeeding %	Not Breastfeeding n	Not Breastfeeding %	
Time of First Breastfeeding (min following birth)					
≤30	29	(37)	27	(93)	2 (7)
>30	50	(63)	37	(74)	13 (26) 0.0369*
Prenatal Breastfeeding Class					
Yes	56	(71)	49	(88)	7 (13)
No	23	(29)	15	(65)	8 (35) 0.0299**
First Breastfeeding Latch					
Yes	62	(78)	55	(89)	7 (11)
No	17	(22)	9	(53)	8 (47) 0.0025**
Jaundice					
≤16 mg/dL	72	(91)	61	(85)	11 (15)
>16 mg/dL	7	(9)	3	(43)	4 (57) 0.0218**
Birth Control					
Birth Control	5	(6)	2	(40)	3 (60)
No Birth Control	74	(94)	62	(84)	12 (16) 0.0447**
Discharge formula					
Yes	67	(85)	56	(84)	11 (16)
No	11	(14)	7	(64)	4 (36) 0.2075** NS

Table 7 (con'd)

			Breastfeeding		Not Breastfeeding		
Variable	Mean	StDev	Mean	StDev	Mean	StDev	**p Values**
Breastfeeding Attitude Score							
Mean Score (79)	3.90	0.84	4.06	0.76	3.20	0.86	0.0002***
Gestational Age							
Mean gestational age (76)	39.77	0.75	39.9	0.644	39.8	0.750	0.0070***

* Chi square p value
** Fisher's Exact p value
*** Unpaired t-test, p value

clearly the benefits of breastfeeding are understood by the woman, her health professionals, and those in her cultural environment, and the more breastfeeding is the accepted norm in society at large, the higher this measure will be, and the more women will succeed at breastfeeding.

Two variables that also showed a significant relationship to breastfeeding establishment were the success of the first and second breastfeedings following birth. Failure of the infant to latch onto the breast during the first attempt to breastfeed was related to failure to establish breastfeeding. No latch-on at the second breastfeeding was also associated with cessation of breastfeeding by day fifteen. These early disruptions were predictors for failure to establish breastfeeding. (See further discussion under Description of Problems Establishing Breastfeeding and Logistic Regression, below .)

Gestational age also showed significance: breastfeeders' infants had slightly longer gestations than non-breastfeeders. This was somewhat surprising given the limited range of gestational ages in the study. The criterion for inclusion was 37-42 weeks. Due to the absence of 42 week gestations in our sample the actual range was only 37-41 weeks. The only two 37 week gestation neonates were not being breastfed at day fifteen. Further analysis showed that when these two cases were deleted from the sample,

the results of the *t* test showed no significant difference in gestational age between the breastfeeders and the non-breastfeeders. Those neonates having gestations of 37 weeks or shorter may be at greater risk for failure to establish breastfeeding, and therefore in greater need of breastfeeding support and protection.

Jaundice of the infant, with mothers reporting bilirubin numbers over 16 mg/dL in 7 of 79 cases, also showed significance for an association with unsuccessful establishment of breastfeeding. No mothers reported levels of 20 mg/dL or higher in this study population. The bilirubin cutoff point of 16 mg/dL was chosen because bilirubin levels below that point seemed to have no negative effects on breastfeeding, while levels above 16 mg/dL raised concern by health professionals and/or mothers in some cases. Possible agents for jaundice-related disruption of breastfeeding could be one or more of the following: the process of repeated testing, i.e. the attendant stress of getting a new baby to the testing site, of repeated heel pricks, and of therapy, if given (which one mother described as "horrid"); the possible lethargy associated with higher bilirubin levels; and the difficulties for breastfeeding that accompany these factors. Several cases were found where maternal concern for the baby's welfare and the mother's attributing the elevated bilirubin levels to breastfeeding

were negative influences on establishing breastfeeding. One pediatrician's office nurse told the mother that breastfeeding was possibly the cause of the high bilirubin (peaking at 16.5 mg/dL, by mother's report), as opposed to the more likely cause of lack of breastfeeding, and that breastfeeding would have to be discontinued for about three days if bilirubin levels did not decrease. While the definition and treatment of hyperbilirubinemia is somewhat controversial (Worthington-Roberts & Williams, 1997), treatment would be considered either unnecessary at this level, or at most the recommendation would be 24-48 hours (Riordan & Auerbach, 1993). This mother, having some other difficulty in addition to the threat of having to stop breastfeeding for three days, chose to take the matter into her own hands, as she saw it, and discontinued breastfeeding. The different ways in which these situations are handled by the physician and other health care workers can make or break breastfeeding.

Women who had taken a prenatal class that included information on breastfeeding tended to establish breastfeeding more often than those who did not have such a class (Fisher's Exact Test, $p=0.0299$). This relationship could be due to the increase in breastfeeding knowledge of the mother, or it could serve as a marker for women who are committed to breastfeeding, or both.

When the first breastfeed took place within the first thirty minutes following birth, breastfeeding was more likely to be established successfully than when initiation of breastfeeding took place more than thirty minutes post birth. The variable Breastfeeding Initiation by 30 Minutes bears some elaboration. A number of articles can be found in the scientific literature that have shown that breastfeeding is of significantly longer duration when the first breastfeeding is sooner after birth, as opposed to later (Beaudry & Aucoin-Larade, 1989; Feinstein et al., 1986; Rajan and Oakley, 1990; Wright & Walker 1983). A wide variety of intervals of time are used to distinguish early from late first feeds. Times range from an early time of within a half hour of birth, to intermediate times, to a division of subjects into before and after sixteen hours. In the hospital where the present research took place the first breastfeeding is recorded as having taken place during the first two hours following birth or not. This information was missing in 15 of 79 records. No statistical significance was found between breastfeeding status in the two feeding groups using a chi-square analysis of this data from the hospital records ($p=0.1285$). Mothers were also asked the timing of the first breastfeeding during the telephone interview. Using the latter results, subjects were divided into two groups using two different cutoff points for the timing of the first breastfeeding, thirty minutes and two hours. For these

analyses, data were complete for 77 subjects. When breastfeeding began within the first two hours, versus beginning after two hours, a chi-square test showed no significant difference for breastfeeding status on day fifteen between the two groups (Fisher's Exact p value, 0.1885). When the groups were divided into those who breastfed within the first thirty minutes, and those who began breastfeeding after thirty minutes following birth, the chi-square p value was 0.0369. The variable using the thirty minute cutoff point was the one of these two that showed greater significance in logistic regression, where it seems to show some importance in the understanding of what factors differentiate the successful breastfeeder from the unsuccessful breastfeeder. It is appropriate that the hospital medical records emphasize the importance of beginning breastfeeding soon after birth by having a blank to be filled in for timing of the first breastfeeding. However, the use of the two hour demarcation point may be missing the essence of the optimal conditions under which to begin breastfeeding.

Those women who began the use of contraceptive drugs during the first two weeks postpartum, 5 of 79 subjects, established breastfeeding successfully less often than women not on contraceptives. It is possible that exposure to agents in contraceptives would have a physiological effect strong enough and rapid enough to disrupt lactation in the first two weeks

following birth. Or the use of early contraception may be associated with other traits predictive of breastfeeding failure. Giving a contraceptive drug within two weeks of birth would not be recommended by physicians for the majority of patients, so this subset of subjects may be unique in other ways.

A number of studies have considered the influence of formula use in the early postpartum period on the successful establishment of breastfeeding. In this study formula use in the hospital was associated with failure to successfully establish breastfeeding. This relationship bears further scrutiny. Thirty-four of seventy-nine infants received formula during their hospital stay. Of the thirty-four, twenty-one established breastfeeding and thirteen did not. For six of these thirteen breastfeeding dyads formula was not given in the beginning breastfeedings, but later, usually after breastfeeding problems had developed. Formula use in some cases is a marker for breastfeeding problems. In general the use of formula may be viewed as having one of three possible roles: it may contribute to problems, it may be a neutral factor, or it may actually help in the resolution of problems by buying time while remedies are sought. In light of the different possible reasons for formula use and the different possible effects of such usage, interpreting the association between formula use in hospital and failure to establish breastfeeding must be done with caution. In this study there were

cases where formula use was neutral or possibly an aid to establishment of breastfeeding. Whether it disrupted establishment of breastfeeding in some instances is not clear from these results, but it is a distinct possibility. It should be noted, however, apart from the possible negative effects on the establishment of breastfeeding, that these considerations do not address any long-term deleterious effects of early exposure to formula.

Number of stools recorded during the first 24 hours of life was related to successfully establishing breastfeeding; the greater the number of stools, the more likely that breastfeeding would succeed. It is probable that frequent stooling is a marker for a strong beginning to breastfeeding.

B. FACTORS NOT ASSOCIATED WITH BREASTFEEDING STATUS AT DAY FIFTEEN

In addition, a number of other variables that have been identified as being related to breastfeeding duration in some scientific literature, were considered:

- Maternal Age
- Maternal Education
- Maternal Ethnicity
- Insurance Status: government or private, as an indication of socioeconomic status.

These variables did not show a statistically significant relationship to breastfeeding status at day fifteen.

There are a number of possible explanations for the findings that certain variables traditionally shown to be predictive of breastfeeding duration were not associated with successful establishment of breastfeeding in this study (Table 7). First, the outcome of breastfeeding status at day fifteen as a measure of the successful establishment of breastfeeding is a special case of the duration of breastfeeding. Most research on breastfeeding duration does not address cessation of breastfeeding in the first two weeks following birth directly, but rather looks at duration over a period of months or years. The factors associated with the end of breastfeeding for longer periods of time may well be different from those that are in play at the beginning of breastfeeding. Second, the study sample may be too homogeneous and/or too small to reveal differences in patterns of establishing breastfeeding among women who vary on these traits.

Other variables suggested by other studies and health care professionals with a reportedly weaker, inconsistent, or unknown relationship to breastfeeding duration were also examined:

- Marital status
- Epidural status
- Medication status
- Spontaneous versus artificial rupture of membranes
- Private physician care for obstetrics versus Resident Obstetric Gynecologic Education Services (ROGES)
- Birth under the care of a midwife
- Length of the stages of labor and total length of labor
- Type of labor (spontaneous, augmented, induced)

- Type of delivery (spontaneous, vacuum, forceps)
- Private physician care for the infant versus Newborn Teaching Service (NTS)
- Breastfeeding within the first two hours
- Suctioning
- Resuscitation
- Infant gender
- Birth weight
- Rooting
- Sucking
- Skin-to-skin contact (first breastfeeding)
- Circumcision
- Pacifier use
- Apgars at one and five minutes
- Receipt by the mother of free formula (upon discharge from the hospital)

None of the initial analyses showed that any of these variables were related to the breastfeeding outcome in this study, including the variable epidural status, the subject of the research question of this thesis.

The scientific literature examining the effect of the practice of dispensing free formula to the breastfeeding new mother upon her discharge from the hospital is ambiguous, with some studies reporting a relationship between receiving formula and breastfeeding failure and other studies finding no relationship. The present research did not show a relationship between receipt of formula and the establishment of breastfeeding. This result should in no way be construed as support for the unethical practice of dispensing formula practiced by many hospitals (Margolis, 1991).

For further statistical analysis of the relationship of certain variables to the successful establishment of breastfeeding see Logistic Regression below.

IV. STATISTICAL ANALYSIS: LOGISTIC REGRESSION

A. THE BASE MODEL

For further analysis of the factors that may be related to the successful establishment of breastfeeding, logistic regression was used to build a model that would predict breastfeeding status at day fifteen. The statistical packages StatView 5.0 and SPSS were used. A pool of variables was chosen based on the scientific literature, preliminary analyses, and logistic regression. The likelihood-ratio test was used for determining variables to be removed from the model. The entry criterion was $p < 0.05$ for the score statistic; the removal criterion for the likelihood ratio was $p \geq 0.10$.

Two pairs of variables that measure similar traits were considered for the regression analysis. The first trait was timing of the first breastfeeding. The second trait was success of the first and second breastfeeding, latch or no latch. One variable from each pair was used for the pool of variables for analysis. Preliminary logistic regression analyses had shown consistently that one variable of each pair had shown greater significance for the logistic likelihood ratio test and the Wald statistic. For the first trait, timing of the first breastfeeding, breastfeeding beginning on or before thirty minutes postpartum versus after thirty minutes, was the variable that showed greater significance over the variable that

used two hours as the cutoff point. For evaluation of the success of the first and second breastfeedings, success of the first breastfeeding showed greater significance for the tests mentioned above. Breastfeeding Initiation by 30 minutes and Success of the First Breastfeeding were then used as two of the variables for logistic regression analysis.

These two variables along with ten other relevant variables comprised the pool of twelve variables used for logistic regression:

- Maternal Age
- Maternal Education
- Insurance Status
- Maternal Ethnicity
- Gestational Age
- Breastfeeding Initiation by 30 minutes
- Success of the First Breastfeeding Latch
- Prenatal Class
- Attitude Score
- Jaundice Status
- Contraception
- Smoking

Forward selection of variables resulted in a base model of four predictor variables (Success of First Breastfeeding, Attitude Score, Prenatal Class, Breastfeeding Initiation by 30 minutes). The final model of the four predictor variables correctly classified 90.7% of cases.

Table 8: Logistic Regression Model of Predictors for the Establishment of Breastfeeding

Variable	β	S.E.	Wald	df	Sig	R	Exp (β)
Bf by 30	1.9953	1.0958	3.3152	1	.0696	.1350	7.3540
First bf latch	-3.3276	1.0617	9.8229	1	.0017	-.3292	.0359
Attitude Score	1.7673	.5735	9.4969	1	.0021	.3222	5.8552
Prenatal bf class	-1.8866	.9032	4.3528	1	.0367	.1809	.1516
Constant	-3.7563	1.8268	4.2282	1	.0398		

Bf by 30: breastfeeding initiation in thirty minutes or less
First bf latch: success of first breastfeeding, latch or no latch
Attitude Score: breastfeeding attitude/commitment score
Prenatal bf class: attendance at a prenatal class on breastfeeding

The four variables in the logistic regression base model were significantly related to breastfeeding establishment and have been discussed in the reporting of the initial statistical analyses. Further discussion of the variable Success of the First Breastfeeding may be found in Description of Problems Establishing Breastfeeding below.

B. LOGISTIC REGRESSION: MEDICATION VARIABLES

The original intent of this research was to determine whether epidural status was associated with a decrease in the establishment of breastfeeding. From chi-square and logistic regression analyses epidural status did not appear to be related to the breastfeeding outcome. However, the non-epidural group for the epidural status variable was comprised of a large proportion of women (20 of 36 non-epidurals) who had received the narcotic

nalbuphine (Nubain) systemically. There were a number of indications in the medical records and the surveys of newborns having had signs of being affected by drugs such as Nubain. Several mothers also stated that they were too drugged to hold and/or to breastfeed their newborn. The possibility of a disruption of the establishment of breastfeeding under these circumstances suggested examining the difference between the medicated group described above (women who had either epidural bupivacaine/fentanyl or Nubain), versus their non-medicated counterparts. In light of these findings, a series of medication variables was created for statistical analysis (see Materials and Methods).

Each of four medication variables was added to the base model of four variables, and logistic regression was used to determine if any of these variables helped predict establishing breastfeeding successfully while controlling for the other variables in the model. None of the medication variables, Epidural Status, Newmed Status (4 levels), Medication Status (2 levels), and Epidural/Nubain Status, when added to the logistic regression model, resulted in a significant change in the Log Likelihood Function. Therefore, in the interest of parsimony, none was included in the model.

V. ESTABLISHING BREASTFEEDING

A. ESTABLISHING BREASTFEEDING WITHOUT PROBLEMS

Before delving into the nature and extent of problems that the mothers and their infants in this study experienced establishing breastfeeding, it is important to note that many subjects began and established breastfeeding with relative ease. Some of the evaluations in the medical records include the following:

- breastfeeding very well
- vigorous breastfeeding
- feeding well at breast
- good latch

These positive evaluations occurred numerous times. They were sometimes intermixed with negative notes for the same case.

One evaluation of the beginning of breastfeeding in this study consisted of a score based on the feeding record in the infant's medical record. It was arrived at by employing a ratio of unsuccessful feeds to total number of feeds. For fourteen cases the scores were zero, that is to say, all feeds listed were successful breastfeeds, indicating a smooth and unremarkable successful beginning to breastfeeding.

Comments from a number of mothers in the study included the following:

- At the first breastfeeding, mom remarked on how well the baby breastfed.
- Beginning breastfeeding went "very, very well", and "It was so natural."
- "I was so excited she was doing it", and "I was really nervous, too"

- Mom was surprised at first breastfeeding, saying, "He went to town!"
- "He knew what to do from the first get-go."
- Mom was "so excited she's taken to it so well" and "the bonding is there!"

B. PROBLEMS ESTABLISHING BREASTFEEDING

It became clear during the conduct of this research that a considerable proportion of mother-infant pairs experienced serious difficulties as they attempted to establish breastfeeding. For the first attempt to breastfeed, 17 of 79 breastfeeding dyads (21.5%) experienced no latch-on and 15 had limited success latching onto the breast (19%), for a total of 32 (40.5%). For the second breastfeeding, 16 experienced no latch-on (20.3%), and an additional 12 (15.2%) had limited success. Twenty-five dyads (31.6%) had no latch-on for one of the first two breastfeedings and eight additional breastfeeding pairs (10.1%) experienced no latch-on for either one of the first two attempts to breastfeed. An even greater number of women reported latch-on difficulties for more than one feeding, but not necessarily the first two feedings. As the statistical analyses have shown, failure to latch-on during the first or second breastfeeding attempt is significantly related to failure to establish breastfeeding at day fifteen.

Other problems encountered were sore nipples and mastitis. Although no questions were asked specifically about these conditions, it was found that at least 33 women had sore nipples.

This was usually reported during the telephone survey; occasionally it was found in the medical chart. Three women reported cases of mastitis.

Sleepiness of the infant during the first days of life was a common concern, along with the attendant worries of inadequate intake and apprehension regarding establishing breastfeeding.

Examples of problems

The following are comments regarding establishing breastfeeding made by mothers in our study during the telephone interview; some are from written notes in the medical record. Thirty-one different dyads are represented:

- "it's [breastfeeding] so hard"
- baby "didn't come out knowing what to do".... "He knows now"
- very difficult in beginning
- baby "crying uncontrollably"
- baby crying, pushing away, mom frustrated
- baby latches, then screams
- poor infant feeding
- baby frantic at breast
- baby not latching well
- baby not eating well, not sleeping well, losing weight
- never latched
- very hungry
- very painful
- sore, bruised nipples
- cracked, bleeding nipples
- baby too sleepy to breastfeed
- mom concerned (at least 11 instances)
- mom frustrated (at least 9 instances)

These remarks will give some idea of the difficulties experienced by the women in our study. There is a common thread that may run through many of these problems experienced while establishing breastfeeding: a faulty latch. Newborns who have difficulty latching on to their mothers' breasts or who latch on but

cause trauma to the breast as evidenced by nipple pain and possibly by mastitis, may be exhibiting a disruption of the complex of behaviors that constitute effective breastfeeding.

C. OVERCOMING PROBLEMS

Recognizing problems: fragmentation of health care

It is important that health professionals appreciate the extent to which problems are encountered during the establishment of breastfeeding. It is possible, due to the fragmentation of care in our health system that few are aware of the overall picture. The obstetrician is involved through the birth, is responsible for the mother, and may or may not, but should, be instrumental in promoting, supporting, and protecting breastfeeding. The pediatrician is responsible for the baby, but not for one of the major players in the breastfeeding dyad, the mother. The hospital nurses in Labor and Delivery may see breastfeeding start, but their role includes no prenatal interaction and ends abruptly after a few hours. The nursery nurses and the hospital Lactation Consultant may play an important role, and yet their influence is usually limited to 24 to 48 hours. Private Lactation Consultants see women with breastfeeding problems but are unsure what proportion of mothers need and seek their help. It is difficult to escape the conclusion that there are far too many problems and that they are much more difficult than need be. Establishing breastfeeding

should not be traumatic, painful, stressful. Mothers and babies should not be put through an obstacle course in order to establish breastfeeding. The nature and extent of problems must be recognized in order for them to be remedied and, perhaps more importantly, prevented.

Inadequate training of health care professionals

Freed and others have documented that health care professionals, from dietitians to nurses to family practice residents, to pediatricians, and others, do not receive adequate training in breastfeeding (Anderson & Geden, 1991; Bagwell et al., 1993; Freed et al., 1992; Freed et al., 1995; Goldstein & Freed, 1993; Lowe, 1990; Michelman et al., 1990; Reames, 1985; Strembel et al., 1991; Winikoff et al., 1986). Consequently the breastfeeding mothers and infants in their care do not receive the proper breastfeeding support and protection.

Examples of help subjects received

That a fairly large proportion of women who intended to breastfeed were able to establish breastfeeding as indicated by their breastfeeding status at day fifteen in spite of the obstacles they had to overcome is somewhat surprising. What are some of the ways that these women were helped? Women in our study sample had some knowledge of the importance of breastfeeding and also of some helpful breastfeeding practices. For example, a number of

subjects knew to begin breastfeeding shortly after birth, in the delivery room, if possible. Some mothers knew to avoid giving formula in the beginning and to avoid bottles if other fluid was given. Many subjects (n=55) had taken prenatal classes on breastfeeding. At least fourteen mothers mentioned that they had read on the subject, with some of the latter saying that they had read extensively. Other mothers had watched video tapes on breastfeeding. Fifty-seven women credited hospital nurses with helping them with some aspect of breastfeeding. Not all received help from that corner, however. Comments about hospital nurses ranged from "great," "wonderful," "helpful," to the mother saying she "didn't want help," to the nurse was "more detrimental than helpful," the nurse was "rude," the nurse was a "drill sergeant," she (the RN) "was getting angry with me." One subject, about to leave the hospital, was encouraged by a nurse to attend the breastfeeding class. The nurse told the mother, "I'll sleep better tonight" knowing that she had attended class. The mother gave credit both to the nurse and to the helpful information that she learned in the class for her subsequent success. Another mother, on the verge of quitting in the middle of a trying night, was prompted by the nurse to give it one more try. The baby latched and from there on things improved. One mother mentioned the support she felt from the pictures of nursing women and babies that were hung in the

hospital mother-baby center. Two women who were discouraged and overwhelmed by new motherhood (I was "frazzled," "fried") were rescued by their own mothers, one who moved in with her daughter and one who came and picked up the new mother, baby and all, and brought them to her home. These grandmothers took over everything but the feeding of the baby. Their grateful daughters credited them with having saved breastfeeding.

Clearly some of the subjects succeeded through their own perseverance. I "toughed it out," or I "was determined."

Some women did not get the help they needed. In most of the cases where women were no longer breastfeeding at day fifteen there were instances where an intervention might have preserved breastfeeding if it had come, and come at the right moment.

Twenty-four mothers mentioned being helped by the hospital Lactation Consultant. One mother said she received lots of help and that the services offered by the hospital were "invaluable." Eighteen subjects received at least one lactation consult, several received two. A number of subjects conferred with the Lactation Consultant by phone. Other helpers mentioned were the mother's mother (8 times), husband (5 times), other family members (at least 7 times), friends (14 times), private Lactation Consultants (approximately 8 times), a physician, a midwife, Public Health

Department workers, a Nutritionist, a Lactation Specialist, and La Leche League.

D. PREVENTION OF PROBLEMS

A premise of this research is that the ability of a newborn to latch on to the mother's breast and breastfeed effectively, thereby initiating breastfeeding successfully, is a behavior that, having been subjected to rigorous pressures of natural selection throughout evolutionary history, must be strongly ingrained in the newborn infant. Further, that when this behavior fails to take place, the likelihood is that something has intervened to prevent its expression.

Does the present study yield any evidence for factors that may be negatively influencing the successful initiation and establishment of breastfeeding?

E. THE ROLE OF LABOR MEDICATION

The original intent of this research was to determine whether epidural status was associated with a decrease in the establishment of breastfeeding. From chi-square and logistic regression analyses epidural status was not significantly related to breastfeeding outcome.

There were a number of observations in the medical records or by mother's report that some newborns and some mothers were too drugged to be able to function well (Table 9). Five women

reported variously that they were too tired to breastfeed, "out of it," or groggy. One of these women said she was groggy from the episiotomy pain medication. Another said she was not ready to begin breastfeeding due to pain medication given the last hour before birth; formula was given. All five women had Nubain and local anesthesia. One of the five women had a pudendal block in addition to Nubain and local anesthesia. Six neonates were "floppy," "groggy," "flaccid," or "sluggish." One of the mothers of these six had only an epidural; one had only Nubain; and one had both Nubain and an epidural; two had Nubain, a local and a pudendal block; and one had Nubain and a local. Two of these infants, one whose mother had an epidural, the other whose mother had Nubain, required treatment with a narcotic antagonist (see discussion below). Both mother and baby were affected in two cases. Thus a total of nine breastfeeding dyads were affected by medication in the way described.

Two other woman had Demerol following birth, after epidurals during labor. One described herself as "out of it," and one said she was not ready to breastfeed due to Demerol (given 40 minutes following birth). Why were these women given Demerol when the scientific literature contraindicates its use in breastfeeding women (Hale, 1996; Lee & Rubin, 1993; Wittels et al., 1990)?

Table 9: Reports of Effects of Pain Medication and Pain Medication Status

Case	Epid	Nubain	Local	Pud Blk	Comments
17		X	X		mom "groggy" from episiotomy pain (Mother's report)
22		X	X		mom too tired to start breastfeeding due to pain medication last hour (Mother's report)
30		X	X	X	mom groggy (Mother's report) baby groggy (Mother's report)
41	X	X			baby decreased tone initially, "mom had Nubain" (Med Rec)
43	X				mom not ready to breastfeed "due to Demerol" post birth (Mother's report)
48	X				baby required naloxone (Med Rec)
59		X			baby required naloxone (Med Rec)
62		X	X		mom groggy from drugs (Mother's report)
89	X		X		mom "out of it", had Demerol post birth (Mother's report)
91		X	X		baby "really groggy", mom groggy parents attributed to Nubain (Mother's report)
93		X	X	X	baby sluggish, bluish, due to Nubian 1 hour before birth (Med Rec)

There may be an under-representation of attributing deleterious effects to drugs. For example, there were other reports of respiratory distress and decreased muscle tone not linked in the notes to drugs. In one case the nursing staff discussed a newborn trying to breastfeed and attributed the failure of the infant to initiate breastfeeding as the result of the epidural. This was not reported in the medical record. The initiation of breastfeeding cannot be smooth when one or both of the partners is in a drugged condition.

It will be recalled that the success of the first breastfeed as well as the success of the second breastfeed were found to be related to the successful establishment of breastfeeding (at chi-square p values of .0025 and .0024, respectively). Furthermore, certain labor medication categories were shown to be negatively related to the success of the first breastfeed (Table 10). These labor medication variables included the following:

Newmed Status (4 levels): Epidural only, Epidural/Nubain, Nubain only, Neither (chi-square p value, 0.0147)

Med Status (2 levels): Epidural and/or Nubain: yes v. no (Fisher's exact p value, 0.0324)

Nubain Status: Nubain: yes v. no (chi-square p value, 0.0218)

Epidural/Nubain Status: Epidural and Nubain versus Epidural only, Nubain only, Neither (Fisher's exact p value, 0.0192)

In fact, the mothers of all the infants who failed to latch on during the first breastfeeding had received either an epidural and/or Nubain: there were no infants of non-medicated women in the group of babies that did not latch on at the first feed. In this study there was not a relationship between labor medication status and breastfeeding status at day fifteen.

The cases of two newborns who received the narcotic antagonist naloxone following birth may be instructive. When depression of the neonate due to the narcotic given the mother

Table 10: Associations between First Breastfeeding Latch versus Medication Status and Other Selected Variables

Variable	χ^2 p value	Fisher's Exact p value*	Description of Variable
Epidural Status	p=.2817		Epidural with bupivacaine and fentanyl : yes v. no
Medication Status		p=.0324	Epidural +/or Nubain: yes v. no
Narcotic Status		p=.1926	Narcotic during hospitalization: yes v. no
Hospital Narcotic Status Postpartum	p=.3402		Postpartum narcotic during hospitalization: yes v. no
Nubain Status	p=.0218		Nubain: yes v. no
Both EpNub Category		p=.0192	Epidural + Nubain: yes v. no
Newmed Status (4 levels)	p=.0147		Newmed Status (Epidural only, Nubain only, Epidural + Nubain, neither)
Second Breastfeeding Latch		p=.0044	Second breastfeeding latch: yes v. no
Drugged Category		p=.0090	Mother or infant drugged: yes v. no
Nipplesore Category	p=.0046		Mother had sore nipples: yes v. no
Apgar-1	p=.0314		Apgar score at one minute
Labor Stage 1	p=.4267		Length of Stage 1 of labor in hours
Labor Stage 2	p=.9274		Length of Stage 2 of labor in hours
Labor Stage 3	p=.2862		Length of Stage 3 of labor in hours
Labor Total Hours	p=.4041		Total length of labor in hours

* Fisher's Exact p value is used when the number of subjects expected in one or more cells of the chi-square analysis is below 5.0.

during labor reaches a certain level, naloxone is administered to the newborn. It reverses the effect of the narcotic for one to two hours (Shnider & Levinson, 1993). One mother had received epidural bupivacaine and fentanyl, the other had received Nubain 25 minutes preceding birth. One newborn (epidural) latched well for the first breastfeed but was then too sleepy to breastfeed or did not latch on for a minimum of 6 of the next 9 feeds. This very patient and determined mother pumped and cup-fed for about one week before switching to breastfeeding and going on to establish a successful breastfeeding relationship. The second baby (Nubain), by mother's report, latched with help for the first breastfeed, latched the second breastfeed, but had a very difficult time latching at 24 hours. The medical record shows that other than the first feed, for the six feeds of the first 24 hours there was one breastfeed, four feeds marked "slept," and one marked "a few sucks." Once home the mother resorted to bottle feeding for a day and half; this mother and breastfeeding were subsequently "saved" by her own mother's help and support. This raises the following question: Do these represent cases of narcotized neonates who are revived by naloxone, who breastfeed effectively in the very beginning, but when the narcotic antagonist wears off, are ineffective breastfeeders who have difficulty establishing breastfeeding? Only future research can answer this question definitively.

To summarize the findings regarding medication, having labor medication is associated with failure of the newborn to latch on to the mother's breast at the first feeding. Failure of the newborn to latch on the first feeding and the second feeding is related to failure to establish breastfeeding.

There are a number of factors that limit the power of this study. The size of the study population, and, especially, the size of the group who no longer breastfed at day fifteen, and the size of the group who received neither an epidural or Nubain, are small. The scientific literature included a wide range of breastfeeding cessation rates, and there was no way to accurately predict the rate of breastfeeding success in this particular sample. Medication doses and time intervals between drug administration and delivery were not considered in these analyses, which also may prevent the clarification of relationships between medication and breastfeeding success. In addition, other pain medications were given, including pudendal blocks and local anesthetics. For the purposes of this study these medications were included in the non-medicated group, although there is at least one study, Murray et al., 1981, that found high lidocaine levels in neonates resulted in poorer scores on the Brazelton Neonatal Behavioral Scale. Still other possible candidates for obscuring the picture are the pain medications sometimes used before labor and in the postpartum period. The

further elucidation of the role that labor pain medication may play in the establishment of breastfeeding awaits future studies of greater complexity and larger samples with greater statistical power.

F. SUCCESSFUL ESTABLISHMENT OF BREASTFEEDING

In spite of frequent and serious difficulties establishing breastfeeding 81% of the couples, mothers and babies, were able to overcome the obstacles they met and to breastfeed to day fifteen and beyond. From one point of view this is an encouraging finding. However, in terms of our national goals, of the stated policy of such organizations as the American Academy of Pediatrics (1998) and the American Dietetic Association (1997), of the expressed intent of every woman in the study, and of the loss of the breastfeeding relationship for these mothers and babies, a decrease of 19% of breastfeeding in a two week period leaves much room for improvement. Add to this the physical and emotional trauma of many of those who succeeded and one finds that the toll being exacted from these mothers and their babies is great.

BENEFITS, STRENGTHS, AND LIMITATIONS OF THE STUDY

I. BENEFITS OF THE STUDY

The scientific community recognizes that breastfeeding is superior to all other means of nourishing and nurturing an infant. Cessation of breastfeeding during the days immediately following birth is a common occurrence. It is important to understand the factors that influence the successful establishment of breastfeeding in order that the infants and their mothers who have chosen to breastfeed are able to realize the benefits of breastfeeding. This research is intended to shed light on the nature of the establishment of breastfeeding and how it might be accomplished more often and with fewer problems.

This study identifies factors in a preliminary analysis of the data that are related to the successful establishment of breastfeeding. Further, it uses regression analysis to determine more precisely which factors are significant predictors of the successful establishment of breastfeeding while controlling for other factors in the analysis. Previous research has focused on one factor at a time. The outcome chosen most often has been duration over a period of several months or longer. Many of the factors under consideration have been variables that cannot be changed, such as maternal age, maternal education, socioeconomic status. This study was directed at identifying those factors that are

influential in the initial stages of the establishment of breastfeeding. In addition, several of the variables that appear to be predictors of the successful establishment of breastfeeding represent factors over which the new mother can have some control, for example, her attitude and commitment to breastfeeding, smoking, the timing of the first breastfeeding, and her labor medication. Such information may be used to help women make informed choices.

II. STRENGTHS OF THE STUDY

The rate of breastfeeding failures can be high in the first days following childbirth. It is important to discover which factors in the perinatal environment might be responsible for decreasing the rate of successful initiation and establishment of breastfeeding. In order to be informed when making choices about childbirth, a woman needs to have information regarding any factors that may pose an obstacle to her successful establishment of infant feeding.

The hospital childbirth environment was chosen as the setting for this study to most closely approximate the actual experience of many parturients in the United States today. While the study sample was not large, the subjects represented a wide range of maternal ages, maternal educational levels, various levels of socio-economic status, and different ethnicities.

Through the use of a telephone survey two to six weeks postpartum the study design allowed the examination of the establishment of breastfeeding, or lack thereof, over a period of the first two weeks, and the documentation of the number and nature of some of the difficulties experienced by the breastfeeding dyads and some of the solutions that were found. The in-person interview allowed for the establishment of a rapport between the investigator and the subject, promoting candor and completeness in answering questions; the opportunity to clarify the meaning of questions and to probe for answers; and the collection of information unavailable in the medical record. Data from the medical records were used to provide additional information on factors that may have had an effect on the breastfeeding outcome.

Another strength of the study was its non-intrusive approach. Contact with the subjects in the beginning hours and days of life of the newborn was limited and thus the mother-baby relationship was protected. Contrast the approach used in this study, for example, with a study in which an apparatus was applied to the newborn during early feeds for the purpose of measuring chin movements as an indication of breastfeeding.

A global measure of the success of the establishment of breastfeeding was used. This contrasts with the use of a neonatal neurobehavioral assessment tool, which is limited as to the period

of time in which it is administered and, while much broader in scope as to the behaviors being tested, includes very few behaviors directly related to breastfeeding. In addition, those few feeding-related behaviors being tested are only facets of the larger whole that comprise breastfeeding. Other research has used tests of a gross nature, such as the Apgar score, as the assessment of neonatal status. Still other research has looked at only the first or the first and second feedings.

III. LIMITATIONS OF THE STUDY

Treatments, labor medication in this study, could not be randomly assigned. Any effect of medication found may in fact be attributable to factors other than medication that were not being considered.

The sample size is small. When it was discovered that the majority of patients who did not have an epidural had a potent narcotic administered systemically, new medication variables were created to take this into account. In the process the size of the treatment groups was further reduced. In addition, the group that was no longer breastfeeding at day fifteen, in terms of the statistical analysis, was relatively small.

Labor medication is complex. For purposes of this study some simplifications and assumptions were made which may exaggerate or obscure results. Varying doses and timing of epidural and other

drugs were not taken into account. Local anesthetics and pudendal blocks were categorized as no medication, although in one case the mother described herself as being groggy from a local anesthetic. There also is at least one study, Murray et al., 1981, that found high lidocaine (a local anesthetic) levels in neonates resulted in poorer scores on the Brazelton Neonatal Behavioral Scale. Still other possible candidates for obscuring the picture are the pain medications sometimes used before labor, in early labor, or in the postpartum period.

The use of breastfeeding status at day fifteen is problematical in that cessation of breastfeeding may be due to reasons other than those under consideration, or a combination of factors may be at work. It is, therefore, more difficult to determine which factors are instrumental in the failure to establish breastfeeding.

The rate of enrolling eligible women in the study was fairly high, as was the rate of survey completion. However it is possible that the nature of those women who were not in the study differed from those women who were subjects. Women who were having difficulties with feeding or any other aspect of the hospital postpartum period may have been less likely to give consent and therefore breastfeeding problems may be under-estimated. For example, the baby of one mother, who was clearly overwhelmed, was re-hospitalized with a feeding difficulty as the suspected

cause. This woman did not agree to be in the study. The number of women not giving consent was not large (9), so it is presumed any bias present would be small. Women who could not be reached for the telephone survey were probably more likely to be lower in socio-economic status as the problems in contacting them were, for example, no telephone, uncertainty of future residence, or unplanned change of residence. Consequently, this group would be under-represented in the study sample.

IV. FUTURE RESEARCH

Future research could address the limitations mentioned above, including considerations of doses of drugs, timing of drug administration, and poly-drug therapy. The further elucidation of the role that labor pain medication may play in the establishment of breastfeeding awaits future studies of greater complexity and larger samples with greater statistical power.

The role of intravenous fluid loading during labor is another area of possible study. It has been hypothesized that the extra fluids may have an inhibitory effect on the secretion of oxytocin, possibly negatively affecting lactation. This issue was not addressed in the present study due to the inability to collect from the medical record accurate measures of fluids administered.

A third and potentially important area for further research is the role of continuous mother-baby contact in the immediate

postpartum period. The research of Righard and Alade (1990) implicated the traditional post birth hospital routine in the disruption of the initiation of breastfeeding. If their results should be corroborated, it would be very useful in determining the direction of restructuring that routine so as to minimize negative effects and maximize the successful establishment of breastfeeding.

SUMMARY AND CONCLUSIONS

Approximately 70% of women who met other study criteria planned to breastfeed exclusively. After two weeks, 81% of the women who had initiated breastfeeding continued to breastfeed. Predictors of breastfeeding status at day fifteen were:

- Successful latch at the first breastfeeding
- Mother's attitude to breastfeeding
- Mother's attendance at a prenatal class on breastfeeding
- Thirty minutes or less between birth and first breastfeed

Labor medication was associated with failure of the newborn to latch onto the breast at the first breastfeeding. Labor pain medication status was not shown to be related under the conditions of this study to breastfeeding status at day fifteen. Because of study limitations it is not possible to rule out disruption of the establishment of breastfeeding by labor pain medication, especially in light of the association between pain medication and latch at the first breastfeeding. Limiting the use of labor pain medication may improve latching, and breastfeeding in general.

Mothers, health professionals, and educators should be knowledgeable about both the benefits and practice of breastfeeding. Further, the results of this research direct attention to the importance of *prevention* of problems experienced by women and their infants establishing breastfeeding.

Eighty-one percent of breastfeeding mothers and babies breastfed to day fifteen and beyond. Some of these dyads had serious difficulties but were able to overcome the obstacles they met and go on to establish breastfeeding. From one point of view this is an encouraging finding. However, in terms of our national goals, in terms of the stated policy of such organizations as the American Academy of Pediatrics (1998) and the American Dietetic Association (1997), in terms of the expressed intent of every woman in the study, and in terms of the loss of the breastfeeding relationship for these mothers and babies, a decrease of 19% in the number of breastfeeding mothers and babies in a two week period is unsatisfactory. Add to this the physical and emotional trauma of many of those who succeeded and one finds that the toll being exacted from these mothers and their babies is great. This research provides some guidance as to how the breastfeeding environment may be improved.

Appendix A

UCRIHS Approval

MICHIGAN STATE
UNIVERSITY

June 3, 1997

TO: Jenny Bond
236 Food Science & Hum. Nut.

RE: IRB#: 97-277
TITLE: EFFECTS OF SELECTED PERINATAL FACTORS ON THE INITIATION OF INFANT FEEDING
REVISION REQUESTED: N/A
CATEGORY: FULL REVIEW
APPROVAL DATE: 06/02/97

The University Committee on Research Involving Human Subjects'(UCRIHS) review of this project is complete. I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the UCRIHS approved this project and any revisions listed above.

RENEWAL: UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Investigators planning to continue a project beyond one year must use the green renewal form (enclosed with the original approval letter or when a project is renewed) to seek updated certification. There is a maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please use the green renewal form. To revise an approved protocol at any other time during the year, send your written request to the UCRIHS Chair, requesting revised approval and referencing the project's IRB # and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

PROBLEMS/ CHANGES: Should either of the following arise during the course of the work, investigators must notify UCRIHS promptly: (1) problems (unexpected side effects, complaints, etc.) involving human subjects or (2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

If we can be of any future help, please do not hesitate to contact us at (517)355-2180 or FAX (517)432-1171.

Sincerely,

David E. Wright, Ph.D.
UCRIHS Chair

DEW:bed

cc: Susan Davis

OFFICE OF
RESEARCH
AND
GRADUATE
STUDIES

University Committee on Research Involving Human Subjects (UCRIHS)

Michigan State University
246 Administration Building
East Lansing Michigan
48824-1046

517/355-2180
FAX 517/432-1171

Appendix B

Sparrow Hospital IRRC Approval

SPARROW
HEALTH SYSTEM

July 1, 1997

Jenny T. Bond, PhD, RD
Dept of Food Science & Human Nutrition
Food Science and Human Nutrition Building
Michigan State University
East Lansing MI 48824-1224

RE: **Effects of Selected Perinatal Factors on the Initiation of Infant Feeding (#0196)**

Dear Dr. Bond:

On behalf of the Sparrow Hospital Institutional Research Review Committee, I am in receipt of the revised short consent form and the letter of confirmation from Sandy Metzger, RNC, BSN. I also noted that per Sandy Metzger's suggestions, the wording in the telephone survey has been modified slightly and poses no additional risk factors to the subjects.

At the May 12, 1997, IRRC meeting, the Committee approved this study pending receipt of the information listed above. After careful review, I find that you have complied with the wishes of the Committee and made the modifications requested. Therefore, effective immediately, formal approval is granted for this protocol. Approval is valid for one year and will end July 1, 1998.

Please be reminded that you are required to inform the Committee promptly, per Federal Regulations and Committee Policies, of any changes in the study (for example, protocol reviews, safety reports, etc.). As principal investigator, you also agree to maintain the confidentiality of all subjects. One month prior to the approval expiration date, you will be required to provide the Committee with an Application for Renewal. Forms are available upon request by calling 483-2164. If no update is received, the protocol will automatically be closed at Sparrow Hospital at the end of twelve months.

Sincerely,

George S. Abela MD/81.

George S. Abela, MD, Chairperson
Institutional Research Review Committee
Sparrow Hospital

sl

1215 E. Michigan, P.O. Box 30480, Lansing, MI 48909-7980 • (517) 483-2700

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Appendix C

Expert Review Instrument:
Physician and Nurse
Kenneth Rudman, MD
Thomas Hale, PhD

Physician Review of Proposed Research

Susan Davis, August, 1996
Dr. Jenny Bond
Michigan State University

I. Research question:

What is the relationship between the labor medication status of the nulliparous parturient intending to breastfeed and the duration of breastfeeding at one and two weeks?

The labor medication status under consideration is either non-medication or epidural anesthesia using a combination of fentanyl and bupivacaine. Data will be collected from the maternal and neonatal medical records and from a postpartum scripted telephone interview.

II. The inclusion criteria for the subjects for the proposed study are as follows:

Maternal inclusion criteria:

- ≥ 18 years of age
- intended to breastfeed at admission to hospital for childbirth
- nulliparity
- a normal, uncomplicated pregnancy
- a normal, vaginal, singleton birth, including low forceps and vacuum extraction births
- no communicable disease or clinical manifestation of infection
- not known to be positive for substance abuse or HIV
- no positive history of clinical psychological abnormalities that may interfere with ability to participate in the study
- able to communicate in English

Neonatal inclusion criteria:

- 37-42 weeks gestation
- birth weight: 2500 g and above
- Apgar ≥8-10 at 5 minutes
- healthy, normal

Comments and suggestions (related to inclusion criteria): _____

_____

_____

_____

III. The following data will be collected for all subjects from the maternal and neonatal charts:

- Maternal age
- Maternal weight
- Maternal ethnicity
- Maternal education in years
- Maternal smoking
- Marital or cohabitation status
- Insurance and aid status: private insurance, HMO, WIC, Medicaid
- Data on birth
  - Delivery date
  - Delivery time
  - Sex of infant
  - Gestation
  - Birth Weight
  - Apgar at 1 minute, at 5 minutes

- Labor
  - Spontaneous delivery
  - Augmented delivery
- Membranes
  - Spontaneous (SROM)
  - Artificial rupture of membranes (AROM)
- Delivery
  - Spontaneous
  - Forceps (low only)
- Duration of Labor
  - Length of 1st stage
  - Length of 2nd stage
  - Total length of labor
- Anesthesia: choice expressed during the prenatal period
- Anesthesia during labor
  - None
  - Local
  - Epidural (fentanyl and bupivacaine)
  - Nitrous oxide
- Hydration:
  - Lactated Ringer's: total volume, timing of first and last administrations, total time, time from first and last doses to delivery
  - Lactated Ringer's with pitocin: total dose of pitocin, timing of first and last administrations
  - Catheterization: urinary void: total volume during labor
- Urinary frequency and volume, if recorded
  - during labor
  - postpartum during hospitalization
- Breastfeeding information, if recorded
  - Initiation of breastfeeding: time; evaluation
  - Maternal/infant interaction
  - Formula discharge packet
- Cord blood values, if available: pCO_2, pH, pO_2 (if available)
- Gastric suctioning: Y/N
- Circumcision: Y/N; birth to circumcision interval; anesthesia type
- Reflexes: suck strength; rooting reflex present: Y/N
- Supplementation: time, type (water, dextrose water, formula), amount
- Mother-infant separation
- Rooming-in
- Pacifier use in the hospital (if recorded)
- Data on all inclusion criteria not listed above

Comments and suggestions (relating to the above data): _____

_____

_____

_____

_____

_____

_____

IV. Should the following information be collected for possible inclusion in the study; that is, **are these data likely to affect the outcome of breastfeeding at one and/or two weeks?** Or, does other information that is being collected make the collection of these data unnecessary?

A. Data on parturient:
Gravidity
Comment:_____

B. Labor
Induced, indicated
Induced, elected, or one category for induced?

Comment: _____

_____

C. Membranes
Fluid: clear
meconium-stained

Comment: _____

D. Presentation:
Vertex
Anterior
Posterior
Transverse
Compound
Breech
Face
Brow
Transverse lie

Comment:_____

_____

E. Delivery:
Rotation _____ to _____
Forceps _____ Manual _____

Comment:_____

_____

F. Placenta/Cord:
Date
Time

Comment: _____

G. Episiotomy/Lacerations:
Midline
Mediolateral
Sphincter
Perineum _____ degree _____
Vagina
Periurethral
Cervix

Comment: _____

_____

_____

H. Completely dilated at _____
Length of 3rd stage

Comment:_____

I. Postpartum blood loss

<250 ml	>500 ml
<500 ml	transfusion

Comment:_____

_____

J. Jaundice: phototherapy , Y/N, type (bili lights, bili blanket); other

Comment:_____

_____

_____

_____

V. Questions follow that are related to variables for which we plan to collect data:

A. Maternal inclusion criteria

1. Are there specific criteria that should be enumerated for "a normal, uncomplicated pregnancy" or will abnormal, complicated pregnancies be ruled out by the other criteria listed?

_____

_____

_____

2. Are there specific criteria that should be enumerated for "a normal vaginal, singleton birth" or will abnormal or compromised births be ruled out by the other criteria listed?

_____

_____

_____

3. Are there specific criteria that should be enumerated for "a normal, healthy newborn" or will abnormality or morbidity be ruled out by the other criteria listed?

_____

_____

_____

_____

B. Length of labor

1. Do you think that the length of any of the stages of labor, or the total length of labor, has an effect on the initiation of breastfeeding?

C. Artificial rupture of membranes (AROM)

1. Do you think that AROM has an effect on the initiation of breastfeeding?

D. Induction of labor

1. Do you think that induction has an effect on the initiation of breastfeeding?

E. Augmentation of labor

1. Do you think that augmentation has an effect on the initiation of breastfeeding?

What measurement for augmentation would you recommend: total dose of pitocin, length of time of oxytocin delivery, other?

F. Forceps (low only)

1. Do you think that low forceps delivery has an effect on the initiation of breastfeeding?

2. Do you think it is reasonable to include low forceps deliveries in this study?

G. Vacuum extraction

1. In your experience, approximately what percentage of deliveries would involve vacuum extraction?

2. Do you think that vacuum extraction has an effect on the initiation of breastfeeding?

3. Do you think it is reasonable to include vacuum extraction deliveries in this study?

H. Oral contraception: time, type

1. In your experience, are oral contraceptives prescribed to be used in the first two weeks following birth?

I. Other labor medications

1. Should women who receive labor medications other than epidurals, e.g. meperidine early in labor, local anesthetics, and/or inhalation nitrous oxide, be included in the non-medicated group?

J. Labor anesthesia

total dose, timing of first and last doses, or every dose; number of doses; length of time receiving medication; drug to delivery interval

fentanyl, bupivacaine

chloroprocaine

1. Which of these measures of epidural medication do you think would give the truest representation of neonatal drug exposure?

2. If a woman receives labor epidural medication including chloroprocaine, as well as bupivacaine and fentanyl, should she be included in the study?

3. Is there any other measure of neonatal drug exposure that could be taken from the medical records that you would recommend?

K. Tubal ligation

1. In your experience, is this procedure performed in combination with childbirth?

2. If it is, do you think that tubal ligation has an effect on the initiation of breastfeeding?

3. Do you think it is reasonable to include information on tubal ligation in this study?

L. Postpartum medication: dose, time, route of administration, including pitocin and prostaglandins; Darvocet; meperidine; Phenergan; Inapsine; Seconal; acetaminophen with codeine; Vicodin-ES; ibuprofen; Benadryl

1. Are there any other drugs that should be included in this list? Omitted?

M. Gastric suctioning

1. Approximately how often in your setting is this procedure performed?

2. Do you think it has an effect on the initiation of breastfeeding?

3. Do you think it is reasonable to include information on gastric suctioning in this study?

N. Circumcision

1. Do you think that circumcision has an effect on the initiation of breastfeeding?

O. NICU: admission, length of time under 24 hours (over 24 hours will be excluded from the study)
Only infants admitted to the NICU for less than 24 hours will be included in the study.

1. Does this seem like a reasonable cutoff point?

P. Hydration: the intravenous fluid administration associated with epidural medications

1. Is lactated Ringer's the only solution used for the prehydration associated with epidurals? _____

2. Do you think hydration might make a difference in the initiation of breastfeeding?

3. Are there other measures of hydration that might be considered?

4. What measure would you consider most likely to reveal an effect of hydration on the initiation of breastfeeding, if one exists?

5. Are there any other considerations related to hydration that you think it might be useful to look at?

Early-onset jaundice

1. Does early-onset jaundice have an impact on the initiation of breastfeeding?

2. If so, what measure would you suggest for dividing the neonates into two groups, one which would be affected and one which would not, regarding initiation of breastfeeding?

K. Is there any measure that you could suggest that would differentiate between the effect that epidural medication might have on the initiation of breastfeeding and the effect that a difficult labor might have on breastfeeding initiation?

Comments:

Name and title of person completing this survey:

Thank You!

Appendix D

Definition of Terms, Materials and Methods

DEFINITIONS

Intent to breastfeed: The intent of a woman to breastfeed her infant as recorded on the Vaginal Delivery Labor and Delivery Clinical Pathway upon admission to hospital to give birth

Establishment of breastfeeding: The successful establishment of breastfeeding, for purposes of this research, is considered to be a process that takes place over a number of feeds, possibly over a number of days, until breastfeeding is the method of infant feeding that survives at day fifteen.

Parturient subject: A subject in this study will be a parturient who will not have given birth to a living offspring previously and, therefore, will not have fed any biological child of her own; a subject may be a multigravida.

Pregnancy without abnormalities or complications:
Maternal IDDM is excluded.

A vaginal singleton birth, without abnormalities or complications:

including:

- spontaneous births, induced births, augmented labor, low forceps or vacuum extraction
- dysfunctional uterus
- precipitous delivery
- postpartum bleeding < approximately 1000 cc
- shoulder dystocia
- atony

excluding:

- cesarean births (cesarean birth for previa, abruption, prematurity, pre-eclampsia, other)
- postpartum bleeding > approximately 1000 cc
- D&C
- sepsis
- $MgSO_4$ treatment.

No communicable disease or clinical manifestation of infection, or known to be positive for substance abuse: as recorded in the Admission Record 1.

No positive history of clinical psychological abnormalities that may interfere with ability to participate in the study: as recorded in the Prenatal Record and Admissions Assessment. **Ability to communicate in English:** as recorded in the maternal Clinical Pathway, or determined by the person obtaining consent.

Normal, healthy newborn, without abnormalities or complications:

37-42 weeks gestation
birth weight ≥ 2500 g
not admitted to the neonatal intensive care unit for over 24 hours.

Labor epidural medication: The administration during labor epidurally of the combination of bupivacaine and fentanyl. These subjects may or may not have received other labor pain medication (pudendal block, local anesthesia, and/or droperidol).

No labor epidural medication: This group received no epidural bupivacaine and fentanyl. One patient received epidural lidocaine (13 cc approximately 1 hour before birth) and 3% chloroprocaine (10 cc 9 minutes before birth) epidurally. A second subject received 15 cc of lidocaine at 2:05 hours before birth. Because of the absence of bupivacaine and the narcotic fentanyl, given the nature, doses, and timing of the administration of these drugs, and given the IV fluid volume of 2000 ml or less, these subjects were included in the non-epidural bupivacaine/fentanyl category. Any women in the study may have received a pudendal block, local anesthesia, and/or droperidol during labor.

Nubain: The systemic administration during labor of the drug nalbuphine.

Breastfeeding: mother and infant breastfeeding exclusively, or breastfeeding with supplementation no more than one feeding per day of non-breast milk product.

Appendix E

Patient Consent Form

PATIENT CONSENT FORM

TO: _____
Patient's Name

Participating in Research

Sparrow Hospital permits physicians and other qualified persons to engage in research studies about methods of treatment and care. You have been chosen to participate in an important study that is being undertaken by Sparrow Hospital and Michigan State University. You have the right to consent or refuse participation in this project. If you choose not to participate it will have no bearing on any aspect of your health care. You may withdraw from the research study at any time without penalty or loss of benefits to which you are otherwise entitled. Participation in this research will not involve any extra costs to you or your health care insurer.

This Research Project

The purpose of the study, entitled "Effects of Selected Perinatal Factors on the Initiation of Infant Feeding," is to discover whether certain factors in the childbirth environment have an effect on infant feeding.

The procedure for this project is to collect information from the hospital medical records of you and your baby for your hospital stay for childbirth . You will be called for a telephone interview between two to four weeks following birth.

Your participation in this research study will take place within a period of six weeks or less. The amount of time required will be approximately one half hour or less for the telephone interview. All information will remain confidential.

You will have the satisfaction of participating in an important study regarding mother and infant health and the mother-baby relationship in order to help mothers and babies in the future. To show our appreciation for your participation in the study, you will receive a $5.00 gift certificate for Meijer Stores upon completion of the phone interview.

If you have any question regarding this research, your rights as a research subject, or any other related concerns about your participation, you may contact:

Susan Davis, Michigan State University, Research Investigator: (517) 351-7598
Dr. Jenny T. Bond, Michigan State University, Research Investigator: (517) 355-1756
Michigan State University, Risk Management and Insurance Office: (517) 355-5022
Sparrow Hospital Office of Risk Management: (517) 483-2343

Your signature below constitutes your acknowledgment that:

1. the consent form has been verbally explained to you, and that you have had the opportunity to read it;
2. you understand and agree to the above;
3. you desire to participate in the project described;
4. all information will remain confidential; and
5. you have received a full copy of this consent form.

_____ _____
Participant's Name Date

_____
Signature of Patient (18 years or older)

_____
Witness

INVESTIGATOR'S STATEMENT

I acknowledge that the nature and purpose of the study were fully explained to the patient by me before the patient consented.

_____ _____
Designated Research Study Enroller Date

Appendix F

Data Collection Document

DATA COLLECTION DOCUMENT

MATERNAL MEDICAL RECORD Column 1, ID number:

DELIVERY RECORD

Data on birth

C. 2 Delivery date _____
C. 3 Delivery time _____

C. 4 Sex of infant female = 0, male = 1

C. 5 Estimated Gestation (weeks) _____

C. 6 Birth weight (lbs and ozs) _____

Data on parturient

C. 7 Gravida _____
C. 8 Para _____

Data on neonate

C. 9 Apgar * 1 minute _____
C. 10 5 minutes _____

Labor

C. 11 Spontaneous S = 0, Augmented A = 1, Induced I = 2

Membranes

C. 12 Spontaneous rupture of membranes SROM = 0
Artificial rupture of membranes AROM = 1

C. 13 Date and Time of rupture _____

C. 14 Meconium Clear = 0, Light = 1, Stain = 2

Delivery

C. 15 Spontaneous S = 0, Forceps F = 1, Vacuum extractor V = 2

Duration of Labor

C. 16 1st stage _____
C. 17 2nd stage _____
C. 18 3rd stage _____
C. 19 Total labor _____

Anesthesia

C. 20 Unmedicated = 0, Epidural = 1, Local = 2

Blood loss: _____

Less than 1000 cc = 0
Equal to or over 1000 cc = 1

ORANGE ADMISSION RECORD

C. 38 Maternal age (years) _____

DATA COLLECTION DOCUMENT

C. 78 Marital status or cohabitation — single = 0, cohabiting = 1, married = 2, divorced = 3

Insurance status: C. 39 — Medicaid = 0, WIC = 1, HMO = 2, Private insurance = 3

C. 40 ROGES (Resident OB/Gyn Educational Service) — Y = 1, N = 0

C. xx Financial Class 02 16

ADMISSION RECORD 1: PATIENT HISTORY

C. 45 Smoking — Y = 1, N = 0

C. 46 # packs /day x years _____

C. xx IDDM — N = 1

C. xx Anesthesia Plan — local = 0, epidural = 1, other = 2

PREGNANCY RECORD 1

C. 75 Maternal age (years) _____

Occupation: father _____ mother _____

C. 76 Maternal education (years): _____

C. 77 Maternal smoking: non-smoker = 0, smoker = 1

PREGNANCY RECORD 2

C. 79 Maternal height: _____

C. 80 Maternal prepregnant weight _____

Physical exam: breast/nipples exception: _____

24 HOUR FLUID RECORD

Lactated Ringer's

C. 32 L. R. volume (ml) _____
C. 33 first infusion, time _____
C. 34 last infusion, time _____
C. 35 time to delivery _____

D-5-Lactated Ringer's with Pitocin

C. xx Pitocin dose before delivery _____
C. xx D-5-L.R. volume (ml) _____

DATA COLLECTION DOCUMENT

Urinary output

C. 36 Urinary output without catheter: total volume during labor (cc) _____
C. 37 Catheterization: urinary void: total volume during labor (cc) _____

LABOR AND DELIVERY RECORD

C. 57 Station at admission _____
C. 59 Time _____
C. 60 Dilation at admission _____
C. 61 Time _____
C. 62 Dilation (last before intervention) _____
C. 63 Time _____

C. xx $MgSO_4$ treatment N = 0

MEDICATION ADMINISTRATION RECORD Labor and Delivery or Postpatum

Lactated Ringer's
C. xx times _____
C. 32 L. R. volume (ml) _____

D-5-Lactated Ringer's with Pitocin
C. xx Pitocin dose before delivery _____
C. xx D-5-L.R. volume (ml) _____
C. xx times _____

Pitocin added to L.R.: dose _____

Postpartum medications
C. xx type _____
C. xx dose _____
C. xx times _____

C. xx type _____
C. xx dose _____
C. xx times _____

COMBINED 24 HOUR FLUID, LABOR AND DELIVERY, MEDICATION ADMINISTRATION RECORDS

Medication:
Non-epidural
C. xx Perinatal, non-epidural type _____
C. xx dose _____
C. xx time _____

Pitocin (before delivery)
C. xx total dose of Pitocin _____
C. 55 first dose, time _____
C. 56 last dose, time _____

Pitocin following delivery _____

Lactated Ringer's: Volume
C. xx L.R. total volume _____
C. 33 first infusion, time _____
C. 34 last infusion, time _____

Volume
C. xx D-5-L. R. total volume _____
Combined volumes
C. xx L.R. and D-5-L. R. total volume _____

Urinary output
C. 36 Urinary output without catheter: volume during labor (cc) _____
C. 37 Catheterization: urinary void: volume during labor (cc) _____
total volume during labor (cc) _____

Postpartum medications

C. xx	type	_____	C. xx	type	_____
C. xx	dose	_____	C. xx	dose	_____
C. xx	times	_____	C. xx	times	_____

OBSTETRIC ANESTHESIA RECORD

Anesthetics

C. 31	1.5% Lidocaine (Xylocaine)	total dose	_____
C. 21	cc of 0.25% bupivacaine	total dose	_____
C. 22		timing of first dose	_____
C. 23		timing of last dose	_____
C. 24	0.125% bupivacaine with 2 μg/ml fentanyl	total dose	_____
C. 25		timing of first dose	_____
C. 26		timing of last dose	_____
C. 27	fentanyl: 100 μg/ml	total dose	_____
C. 28		timing of first dose	_____
C. 29		timing of last dose	_____
C. 30	2% Nesacaine	total dose	_____

other _____

other _____

VAGINAL DELIVERY LABOR AND DELIVERY CLINICAL PATHWAY

Page 1, top of page: C. 70 Infant feeding: breast = 1, bottle = 0

C. xx Baby's physician: NTS = 0, Pt. request = 1

Page 2, column 1: Active Labor — C. 71 2nd stage/delivery: Infant to: Mother Baby Nursery = 0, RNICU= 1

Page 2, column 2: Recovery — C. 72 Maternal/infant interaction: normal = 0, exception = 1

Exception: _____

VAGINAL DELIVERY POST PARTUM CLINICAL PATHWAY

Page 1, top of page: C. 70 Infant Feeding: breast = 1, bottle = 0

Page 1, column 1: 1st 24 hours postpartum

Problems: _____

0-24 hrs: C. xx Consults: Lactation Consultant: Y = 1, N = 0

Breasts _____

Assessment _____

Page 1, column 2: 24-48 hours Postpartum

DATA COLLECTION DOCUMENT

Problems: _____

24-48 hours C. xx Consults: Lactation Consultant Y = 1 N = 0

Breasts _____
Assessment _____

Breast pump Y = 1 N = 0

Notes _____

NEONATAL MEDICAL RECORD

NORMAL NEWBORN CLINICAL PATHWAY and IDENTIFICATION RECORD

Top of page 1

Ethnic information: C. 81 mother Caucasian = 0, Black = 1, Hispanic = 2, Asian = 3, Native American = 4, Other = 5, Unknown = 6

C. 82 father Caucasian = 0, Black = 1, Hispanic = 2, Asian = 3, Native American = 4, Other = 5, Unknown = 6

C. 41 Nurse Midwife patient Y = 1 N = 0
(Health Central or Blue Fare Network only: Sameerah Shareef and Myra Bayes)

C. xx Baby's physician NTS = 0 Pt. request = 1

Page 1, column 1, 1st 24 hours Resuscitation:

C. xx Oxygen Y = 1 N = 0
C. xx Free Flow Y = 1 N = 0
C. xx Bag Y = 1 N = 0
C. xx Intubation Y = 1 N = 0
C. xx ET suction Y = 1 N = 0

Circumcision C. xx Circumcision Y = 1 N = 0
C. xx Time of circumcision _____

DATA COLLECTION DOCUMENT

Breastfeeding	C. xx	Breastfed within 2 hours of delivery	Y = 1 N = 0
Breastfeeding information	time _____	amount _____	
	time _____	amount _____	
	time _____	amount _____	
	time _____	amount _____	
	time _____	amount _____	
	time _____	amount _____	
	time _____	amount _____	
	time _____	amount _____	
	time _____	amount _____	
Feedings: Breastfeeding:		C. xx number of times _____ C. xx number of minutes _____	
Elimination		C. xx Void, number of times _____ C. xx Stool, number of times _____	

Page 1, column 2

Predelivery medications: cross check, do not record: Epidural, Pitocin Induction/ Augmentation

Feeding Education		4-6 hours	Y = 1 N = 0
		6-24 hours	Y = 1 N = 0
		Attended breastfeeding class	Y = 1 N = 0
Potential Problems	C. xx	Feeding appropriately exception	Y = 1 N = 0
	C. xx	Adequate elimination exception	Y = 1 N = 0

Page 2, column 1: 24 - 48 hours

Problems: _____

Breastfeeding:	C. xx	Latch on and adequate suck	Y = 1 N = 0
Consults	C. xx	Lactation Consultant checked	Y = 1 N = 0
	C. xx	LC consult	Y = 1 N = 0
		number of consults (from reports in record) _____	
Circumcision	C. xx	Circumcision	Y = 1 N = 0
	C. xx	Time of circumcision _____	
Nursing Assessment: Elimination	C. xx	Void, number of times _____	

DATA COLLECTION DOCUMENT

C. xx Stool, number of times _____

Breastfeeding information

time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____

Feedings: Breastfeeding:

C. 99 number of times _____
C. 100 number of minutes _____

Page 2, column 2: 48-72 hours

Problems: _____

Consults C. xx Lactation Consultant checked Y = 1 N = 0

Circumcision C. xx Circumcision Y = 1 N = 0

C. xx Time of circumcision _____

Nursing Assessment: Elimination

C. xx Void _____
C. xx Stool _____

Breastfeeding information

time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____
time _____ amount _____

NEWBORN INFORMATION SHEET

cross check for: nicotine drugs do not record

Infant weights

Birth weight _____
Day, weight _____
Day, weight _____

NEWBORN RECORD

Infant temperature _____

Gestational age (by exam) _____

Rooting reflex Y = 1 N = 0

Suck reflex Y = 1 N = 0

Appendix G

Telephone Interview Script

TELEPHONE INTERVIEW SCRIPT
for the SPARROW HOSPITAL and MICHIGAN STATE UNIVERSITY
JOINT RESEARCH PROJECT

*Hello. May I please speak to_____?
(RESPONDENT'S NAME)
*Is this _____? This is Sue Davis, and I am calling for the mother and
(RESPONDENT'S NAME)
baby research project that you were contacted about when you were in the hospital. [It's sponsored by Sparrow Hospital and Michigan State University.] Thank you so much for agreeing to take part. Your participation is very important to the success of this study. As you may remember we have a reward for all the women who answer the survey. I'll be getting back to that at the end.

The interview usually takes about 20 minutes? Is this a convenient time?
(IF YES; IF NO, CONTINUE.)
I can call back at another time. Would _____ be OK?
(DAY, TIME)
Good.
I believe your baby is about _____days old, now. Is that right?
*You had a little _____, (GIRL, BOY)? What's her/his name? _____ Congratulations!
*And how's she he doing?

I'd like to explain that because this is research, I have to ask the questions in a certain order, so please bear with me. If something comes up that we want to discuss we can talk at the end.

*Remember, _____, there are no right or wrong answers. I'm just interested
(RESPONDENT'S NAME)
in your careful, honest responses. As I go along, please stop me if there is anything that you don't understand.

The first few questions are about breastfeeding.

When you went to the hospital to have your baby, you indicated that you planned to breastfeed. Is that correct?

Y N Undecided

(IF NO, END INTERVIEW WITH LAST PARAGRAPH; IF YES, CONTINUE)

Did you ever breastfeed your baby? Y N

Are you still breastfeeding? Y N

So you never attempted breastfeeding, is that right? NEVER

What was the reason you never started breastfeeding? _____

_____

(GO TO QUESTIONS WITH DIAMONDS)

Y When was the last day you breastfed? (DAYS AFTER BIRTH) _____

And why did you stop breastfeeding? _____

Are there other reasons for your stopping? _____

What's the main reason you stopped? _____

♦ Has anyone advised you at any time since the baby was born to stop breastfeeding? Y N

(IF NO; IF YES, CONTINUE)

♦ Who advised you to stop breastfeeding? _____
(RELATIONSHIP OF PERSON)

♦ And what reason did they give for telling you to stop breastfeeding?

_____

*Going back to when you were in the hospital, _____: when was the very first time you tried to breastfeed your baby, how long after the baby was born? _____ (HOURS AFTER BIRTH)
(RESPONDENT'S NAME)

At that time,

was your baby awake?	Y	N
Was your baby alert?	Y	N
Did the baby latch-on or attach well to the breast?	Y	N
Did the baby suck well?	Y	N

(IF NOs; IF YES)

About how many minutes total time did the baby feed that first time? ____ (MINUTES) (SKIP NEXT QUESTION AND CONTINUE)

When was the first breastfeeding, with a good latch-on and good, strong sucking? _____
(HOURS AFTER BIRTH)

Was your baby taken away for bathing, dressing, or for any reason, before your first attempt at breastfeeding, or after? BEFORE AFTER

Where was the first breastfeeding? DELIVERY RECOVERY ROOM

Thinking back to that first time, how was it decided when you would start your very first breastfeeding? ___

_____

Was your baby wrapped in a blanket for that first breastfeeding?
BLANKET WRAP SKIN-TO-SKIN

How did your second breastfeeding go? Awake Alert Good Latch Good Suck

Timing (hours after birth) _____

*Were there any times during (BABY'S NAME) first four days of life when latching on and sucking weren't good and strong, or when s/he was too sleepy to nurse? Y N

DAY 1	too sleepy to nurse	poor latch	poor suck
DAY 2	too sleepy to nurse	poor latch	poor suck
DAY 3	too sleepy to nurse	poor latch	poor suck
DAY 4	too sleepy to nurse	poor latch	poor suck

Did this (SLEEPINESS, POOR LATCH, POOR SUCK) have any effect on breastfeeding?

_____

- When did you notice your milk coming in, that is, a noticeable increase in the amount of milk you had, that made your breasts feel full? _____ (HOURS OR DAYS AFTER BIRTH)

- Did you become engorged? Y N
- How would you describe your engorgement? MILD MODERATE SEVERE
- How many times were you engorged? _____ (NUMBER OF TIMES)

*Do you know when your baby regained her/his birthweight? (HOURS OR DAYS AFTER BIRTH) _____

*The next questions are about what _____ was fed in the hospital.
(BABY'S NAME)

Did your baby have anything besides breast milk during the time you were in the hospital, such as water, sugar water, or formula? Y N

Your baby had only breast milk in the hospital, right? Y N

[Was your baby given water or sugar water in the hospital? Y N

(IF NO; IF YES)

Why was water given? _____

Did your baby have any formula in the hospital? Y N

(IF NO; IF YES)

Why was formula given to your baby? _____

_____

In the hospital, what was used to feed water or formula to your baby: a lactation device, a cup, a bottle, something else?
LACTATION DEVICE CUP BOTTLE OTHER _____

After you came home from the hospital did your baby have any formula, during the first 2 weeks? Y N

(IF NO; IF YES)

From the time you came home from the hospital until the baby was (TWO WEEKS OLD OR BEFORE QUITTING), how much formula a day did your baby get, on average?

_____
(NUMBER OF TIMES/DAY - OR - AMOUNT/DAY)

Was the amount of formula your baby took more each day, less each day, or about the same?
MORE SAME LESS
How did you decide whether to breastfeed or give formula when your baby was hungry? _____

_____

Do you feel giving formula, either in the hospital or at home, had an effect on your breastfeeding?
Y N

What effect did it have? _____

• _____ , the next questions are about any help with breastfeeding that you have had.
(RESPONDENT'S NAME)

◆ Did you attend any classes where breastfeeding was discussed? Y N
(NO; YES)

◆ How many classes were there? _____ (NUMBER)

◆ Who offered this class? _____ PRENATAL HOSPITAL

Once you started breastfeeding, did you find you needed help? Y N
(IF NO; IF YES)

Did you get the help you needed? Y N

(IF NO; IF YES)

Who helped you? HOSPITAL NURSE LACTATION CONSULTANT FRIEND

YOUR MOTHER OTHER _____ (RELATIONSHIP OF PERSON)

What help did you get (INCLUDING TIME IN HOURS)? _____

_____

◆ Now I'd like to ask how the people in your life are responding to your breastfeeding. There are three choices; please choose one:

First: people are not supportive of your breastfeeding your baby.
Second: people around you do not care one way or another about your breastfeeding
Third: they're supportive of your breastfeeding

First Second Third

◆ How would you describe how strongly you felt about breastfeeding just before your baby was born?
On a scale of one to five, with one being the lowest and five being the highest, where would you rank yourself on how strongly you felt about wanting to breastfeed this baby, just before the baby was born?
1 2 3 4 5

- When did you decide how you were going to feed your baby? Please choose one: Was it before you became pregnant, or after?

  BEFORE PREGNANCY (2) DURING PREGNANCY (0)

- Did you plan to breastfeed exclusively, or to introduce a bottle? EXCLUSIVE BOTTLE COMB
- When did you plan to introduce a bottle? _____
- Just before your baby was born, how long did you plan to breastfeed your baby? ____ (MONTHS)

- Here is a statement; do you agree or disagree with it: As a rule, babies fed formula do just as well as babies who are breastfed. Do you agree, disagree, or are not sure?

  AGREE (0) NOT SURE (1) DISAGREE (2)

- Next, I'm going to ask you about labor medication.

Before you went to the hospital to have your baby, had you decided whether or not you were going to have any medication for pain relief during childbirth? Y N

(IF NO; IF YES)

- What kind of pain medication had you decided to have? Epidural Local Other
- And what did you end up having? _____

Next are some questions about medicines that you may have taken after you came home from the hospital.

I will list some pain medicines that women are often given after delivery. Please tell me if you took any of these during the first week following the birth of your baby, when you were at home:

Darvocet N or Darvon (propoxyphene)	Phenergan (promethazine)	Vicodin ES (hydrocodone)	Codeine
Inapsine (droperidol)	Seconal (secobarbital)	Tylenol #3 (acetaminophen)	Compazine (prochlorperazine)
Nubain (nalbuphine)	Demerol (meperidine)	Morphine	Benadryl, Cheracol (diphenhydramine)

How much (OF EACH MED) did you take? _____

Are there any other medicines that you took in the first week after birth? _____

(NO; YES)

(MED, WHEN, HOW MUCH) _____

- The next questions are about birth control medicines.

Some women start birth control medication soon after birth.

Are you taking any birth control pills? Y N

Have you had a birth control shot, or Depo-Provera? Y N

The next 2 questions are about smoking. Are you a smoker? Y N

(IF DOESN'T SMOKE; IF YES)

About how many cigarettes a day do you smoke? _____ (NUMBER OF CIGARETTES)

Back to the baby. Now, about jaundice.

Did your baby have high bilirubin or jaundice? Y N
(NO; YES, CONTINUE)

What was your baby's highest level of bilirubin? _____

Were you told to change the way you were feeding because of jaundice or jaundice treatment?
Y N

Who told you to change? _____ (RELATIONSHIP OF PERSON)

What advice did they give? _____

Did the jaundice interfere with your breastfeeding? Y N

How did jaundice interfere with breastfeeding? lethargy bili blanket bili lights
other _____

◆ Now, a few questions about work.

*Are you working outside the home now, _____ ? Y N
(RESPONDENT'S NAME)

◆ (IF STILL EXCLUSIVELY BREASTFEEDING *IF SUPPLEMENTING OR STOPPED BREASTFEEDING)

Did your plans to work outside the home have an effect on your decision to:
not breastfeed? quit breastfeeding? supplement with formula?
Y N

What effect did work have on your breastfeeding? _____

*We're almost done _____ , just a few more questions.
(RESPONDENT'S NAME)

*(FOR MOTHER'S OF GIRLS; FOR MOTHER'S OF BOYS)

Was your baby circumcised? Y N

(IF NO; IF YES)

Was there any difference between breastfeeding before the circumcision and breastfeeding after the circumcision? Y N
(NO; YES)

And how was breastfeeding different after the circumcision: _____

_____

S Davis Thesis: T doc surv 8/22/87

Now, about pacifier use.

Please pick the sentence that best describes your baby:

* One, the pacifier is an important part of her/his life?
Two, my baby takes a pacifier but isn't crazy about it
Three, my baby does not use a pacifier

About free formula.
When you left the hospital, were you given any free samples of formula, for example, in a package of materials? Y N

Did you use the formula? Y N

This is the last question:
Is there anything else that you can think of that has had an effect on your breastfeeding your baby? _____

_____

_____

On behalf of Michigan State University and Sparrow Hospital, I would like to thank you for your help and participation in this research project. We will be sending your reward in the next week. Where would you like it sent? _____ (ADDRESS) Thank you so much!

* Indicates line where information regarding respondant or her baby is to be inserted; for example, respondant's name, infant's name, etc.

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