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A Comparative Study on the Frequency of Respiratory, Gastrointestinal, and Allergic Disorders between Bottle-Fed and Breast-Fed Infants from Birth to Twelve Weeks of Age

Sylvia C. Souza

Abstract

A COMPARATIVE STUDY ON THE FREQUENCY OF RESPIRATORY, GASTROINTESTINAL, AND ALLERGIC DISORDERS BETWEEN BOTTLE-FED AND BREAST-FED INFANTS FROM BIRTH TO TWELVE WEEKS OF AGE

by Sylvia C. Souza

Questions concerning the advantages of breast-feeding have been debated since the introduction of commercially-prepared formula about 50 years ago. Some recognized benefits of breast milk include less respiratory as well as other infections, less allergy in infancy and later life, and a lower morbidity rate in less-developed countries. From 1955 to 1971 in the United States there was a decline in the incidence of breast-feeding related to several factors which included the introduction of formula, mothers returning to the work force, and strict maternity units' rules and routines. Since 1971 to the present there has been a resurgence in the incidence of breast-feeding. The American Academy of Pediatrics in 1978 issued a statement in support of breast-feeding and recommended intensified promotion and return to breast-feeding. In this comparative study of 50 infants from birth to 12 weeks of age, the data supported some important findings relating to illnesses and feeding methods.

The purpose of this study was to compare the effect of two methods of feeding on infant health. It was hoped that the findings would enable nurses to better assist expectant mothers in making a decision on infant feeding methods.

The null hypotheses were: (1) there will be no significant

difference ($p=0.05$) in the number of respiratory disorders between bottle-fed and breast-fed infants from birth to 12 weeks of age, (2) there will be no significant difference ($p=0.05$) in the number of gastrointestinal disorders between bottle-fed and breast-fed infants from birth to 12 weeks of age, and (3) there will be no significant difference ($p=0.05$) in the number of allergies between bottle-fed and breast-fed infants from birth to 12 weeks of age.

A nonrandom convenience sample of 50 clients was selected for the study. Twenty-five mothers were in the breast-feeding group and 25 were in the bottle-feeding group. A booklet was designed and given to each of the mothers in which she was to record her infant's illnesses. These included: the common cold, otitis media, bronchitis, pneumonia, vomiting, diarrhea, colic, eczema, hives, and asthma. The booklet also included diet record forms on which the mother indicated when the solid foods such as cereals, vegetables, fruits, juices, meats, and eggs were introduced to the infant's diet.

The data were analyzed using the stepwise multiple regression analysis with the frequency of the respiratory, gastrointestinal, and allergic disorders as the dependent variables. The independent variables consisted of the feeding method and the solid foods. The feeding method was forced into the analysis by the remaining variables.

Do breast-fed infants have fewer respiratory disorders than bottle-fed infants? There were more respiratory disorders noted in the bottle-fed group (23) as compared to the breast-fed group (13), but this was not statistically significant; therefore, null hypothesis #1 was retained.

Do breast-fed infants have fewer gastrointestinal disorders than bottle-fed infants? The data analysis indicated that there was a significant difference in the frequency of gastrointestinal disorders noted ($p<.01$) among the breast-fed (29) and bottle-fed (90) groups; thus, null hypothesis #2 was rejected. The gastrointestinal disorders occurred more frequently in the bottle-fed infants. The stepwise multiple regression analysis indicated that there may be an association with increased frequency of vomiting and the early introduction of juices. A direct cause and effect relationship, however, was not established.

Do breast-fed infants have fewer allergic disorders than bottle-fed infants? The data analysis indicated no significant difference in the incidences of allergic disorders among the breast-fed (4) and bottle-fed (2) groups; therefore, null hypothesis #3 was retained.

Some implications for nursing from this study indicate that community health nurses and others who provide information to expectant mothers about the advantages of breast-feeding should include the fact that mothers who breast-feed their babies have fewer episodes of respiratory and gastrointestinal disorders than mothers who bottle-feed.

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by

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Each person whose signature appears below certifies that this thesis in their opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

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THE PROBLEM

Introduction

The subject of breast-feeding has long been a topic of interest to health care professionals, scientists, and parents. The advantages and disadvantages of breast-feeding have been tested, announced, and questioned. The recent trend has been for physicians to encourage all mothers to breast-feed as evidenced in a statement recently issued by the American Academy of Pediatrics (AAP, 1978, p. 597). The advantages of breast-feeding over bottle-feeding of infants include: immunologic protection against infections and gastroenteritis, less food allergy in infancy and later life, increased economy to the parents since lactation can be achieved relatively inexpensively, and the establishment of a positive interaction between mother and child (AAP, 1978, p. 594; Lamm, Delaney and Dwyer, 1977, p. 71; Esterly, Arak, Ginberg, Howell, Kirschner, Miller and Zurburg, 1976, p. 245; Jelliffe and Jelliffe, 1976, p. 153).

At the beginning of the twentieth century breast-feeding was widely accepted as the only source of nutrients for infants. After World War II breast-feeding was replaced by commercially-prepared and evaporated milk formulas (Martinez and Nalezianski, 1979, p. 686). This widespread use of artificial formulas has expanded rapidly in the affluent western societies and has rapidly spread to the third world countries (AAP, 1978, p. 591; Jelliffe and Jelliffe, 1978, p. 10; Hambraeus, 1977, p. 27;

Worthington, 1977, p. 3). Since 1971 there has been a resurgence in the incidence of breast-feeding, and mothers are now continuing to nurse for a longer period of time (Martinez and Nalezienski, 1979, p. 686).

Advances in scientific knowledge and technology have considerably improved medical services in recent years. In spite of these advances, curricula for physicians and nurses have not emphasized nutrition (Jelliffe, E., 1977, p. 49; Hambraeus, 1977, p. 32). Some health professionals have depended on the manufacturers of infant formulas for knowledge of infant nutrition. These manufacturers have done an efficient job in the production of certain products, e.g., infant formulas and semi-solid foods. In many instances their role has been harmful to infant feeding because the ease of formula feeding has led to a decrease in breast-feeding (Jelliffe, E., 1977, p. 49; Farmer, Begg, Birkbeck, Hardy, Hassall, Hindle, Howie, Hunter and King, 1977, p. 144).

The Background and Need for Study

From 1955 to 1971, the trend of breast-feeding had decreased remarkably in the United States as well as around the world. In the countries of the "Third World," mostly located in the tropics and subtropics, the incidence of breast-feeding has noticeably decreased (Jelliffe and Jelliffe, 1978, p. 10). Breast-feeding has been on a decline in Mexico. For example, in 1960, 91 percent of infants were fully breast-fed at the age of six months but only 9 percent were fully breast-fed at the same age in 1970 (Jelliffe and Jelliffe, 1978, p. 213).

Today in the United States there is a resurgence of interest to

adequate education, funding, and reasonable home hygiene such as water supply, fuel, etc.

The current increased rate of breast-feeding in the United States must be viewed as a major public health benefit. Nurses in the community health setting are in a position in which they may teach patients about breast-feeding, including the benefits, techniques, and how to deal with problems that arise so that the current rates and duration for breast-feeding will continue to rise.

Problem Statement

The problem identified from the literature was that infants who are bottle-fed are more susceptible to respiratory, gastrointestinal, and allergic disorders as compared to breast-fed infants.

Purpose of the Study

The purpose of this study was to find out the effect of the two methods of feeding on infant health. It was hoped that the information gained would help nurses to better assist expectant mothers in making a decision on infant feeding methods.

Research Questions

In this study the researcher attempted to answer the following questions: Is there a greater incidence of respiratory disorders among those who are bottle-fed than among those who are breast-fed during the first three months of life? Is there a greater incidence of gastrointestinal disorders among infants who are bottle-fed than among those who are

breast-fed during the first three months of life? Is there a greater incidence of allergies among infants who are bottle-fed than those who are breast-fed during the first three months of life?

Theoretical Basis

The literature reviewed identified reasons why breast-feeding is more advantageous than bottle-feeding. Human milk is nutritionally superior to formula because of its immunologic protection against respiratory infections, otitis media, gastrointestinal disorders and decreased occurrence of allergic reactions in the infant (AAP, 1978, p. 594; Baggott, 1978, p. 30; Downham, Scott, Sims, Webb, and Gardner, 1976, p. 274; Brown, 1975, p. 17). As a result of Cunningham's study on 326 infants in a hospital in New York, he revealed lower morbidity rates for infants who were breast-fed during the first year of life. Life-threatening illnesses did not occur in any breast-fed infant, while five cases of pneumonia and one case of hemophilus influenzae meningitis were seen in bottle-fed infants studied (Cunningham, 1977, p. 727). Vomiting and diarrhea also occurred more frequently in the bottle-fed group (Cunningham, 1977, p. 727).

Formulas cannot be humanized biologically because human milk and formula are much too complex and dissimilar. There have been critical deficiencies and excesses discovered in formula during the past years--for example, too high a level of tyrosine, too low a level of arachidonic acid and the amino acids (Jelliffe and Jelliffe, 1977, p. 1143). The protein of breast milk contains no beta-lactoglobulin. According to

Hambraeus, beta-lactoglobulin is the main component found in formula, and it is the most common allergen in formula responsible for allergies in infancy (Hambraeus, 1977, p. 28).

According to Maslow, "Life is a process of choices--choices toward safety, defensiveness or fear, and choices toward growth." (Maslow, 1967, p. 281). Every expectant mother has the right to make her own decision regarding which infant-feeding method to choose, but to make a sound choice she needs accurate and complete information. Physicians and nurses need to have accurate, current information to give their clients.

Null Hypotheses

1. There will be no significant difference (p=0.05) in the number of respiratory disorders between bottle-fed and breast-fed infants from birth to 12 weeks of age.

2. There will be no significant difference (p=0.05) in the number of gastrointestinal disorders between bottle-fed and breast-fed infants from birth to 12 weeks of age.

3. There will be no significant difference (p=0.05) in the number of allergies between bottle-fed and breast-fed infants from birth to 12 weeks of age.

Definition of Terms

The following terms were defined to the mothers in this study:

Bottle-fed. Infant fed a commercially-prepared formula.

Breast-fed. Infant breast-fed, with no more than one daily supplemental formula feeding.

Respiratory disorders. (1) Common cold--a condition characterized by a runny nose; it may be accompanied by a cough or a temperature of 101 degrees or above, rectally, as reported by the mother (Reynolds, 1978, p. 67); (2) otitis media--an ear infection as diagnosed by a physician or a nurse practitioner; (3) bronchitis--a lower respiratory infection as diagnosed by a physician or a nurse practitioner; (4) pneumonia --a lower respiratory infection as diagnosed by a physician or a nurse practitioner.

Gastrointestinal disorders. (1) Vomiting--the infant throws up a moderate amount of his/her food or milk after a feeding (Christie, 1977, p. 11); (2) diarrhea--a change in character of stool usually involving an incrdase in frequency, fluid content or volume, having more than five watery stools within 24 hours as reported by the mother (Christie, 1977, p. 13); (3) colic--constant crying for several hours, with drawing of the legs onto the abdomen or passage of large amounts of flatus (Christie, 1977, p. 15).

Allergic disorders: (1) Eczema--red skin with pustules, scales or crust. The affected area may be dry or have a watery discharge. A skin irritation as diagnosed by a physician or a nurse practitioner (Hurwitz, Grebin, and Grebin, 1978, p. F); (2) hives--an elevation of the skin that is white in the center with a pale red edging and is accompanied

by itching. It varies in size and can be located on any section of the body. A skin irritation as diagnosed by a physician or a nurse practitioner (Hurwitz, and Others, 1978, p. F); (3) asthma--a respiratory condition as diagnosed by a physician or a nurse practitioner.

Delimitations of the Study

1. Only primiparous mothers were included in this study.
2. The diagnosis of vomiting and diarrhea was dependent on the mother's judgment, thus making the diagnosis subjective.
3. The introduction of allergenic foods such as eggs and wheat products was uncontrolled but recorded.

Summary

The problem identified from the literature reports that bottle-fed infants are more prone to respiratory, gastrointestinal, and allergic disorders as compared to breast-fed infants. This study was, therefore, conducted to find out if there was a relationship between infant feeding patterns and infant health. It was hoped that this information would help nurses in counseling expectant mothers.

The remainder of this study will consist of a review of related literature and research studies, a description of the research methodology and design, a presentation of the findings, and conclusions and nursing recommendations.

Chapter 2

REVIEW OF LITERATURE

Infants are dependent on human milk or commercially prepared formulas for their nutritional needs. Human milk is ideally suited for the infant and it supplies all the nutritional need for optimal growth in an infant for at least the first four months of life (Barness, 1977, p. 3; McLaren and Burman, 1976, p. 57). Despite this fact, the incidence of breast-feeding from 1955 to 1971 was on a decline in North America (Welsh and May, 1979, p. 1; Pipes, 1977, p. 101; Worthington, Vermeersch, and Williams, 1977, p. 157; Fomon, 1974, p. 1). According to Martinez and Nalezienski, there has been a resurgence in breast-feeding incidences since 1971 (1979, p. 687). It is also possible to rear infants on commercially-prepared formulas, but there are some nutritional disadvantages in this method of infant feeding (McLaren and Burman, 1976, p. 57).

Due to the ease and convenience of preparing commercial formulas, after World War II, its popularity increased (Chaney, Ross, and Witschi, 1979, p. 401; Fomon, 1974, p. 14; Bogert, Briggs, and Calloway, 1973, p. 459). A small percentage of infants receive formula prepared with evaporated milk, water and carbohydrate, and a very few consume fresh cow's milk. Occasionally milk-free formulas made from soy products or goat's milk are fed to infants with milk allergy (Chaney, and Others, 1979, p. 401; Fomon, 1974, p. 387).

The topics covered in this review of literature include a brief

history of infant feeding patterns, a discussion regarding health professionals and infant feeding, a comparison between breast milk and formula, and the relationship of feeding method to disease.

History of Infant Feeding Patterns

Infant feeding practice has changed tremendously over the last 50 years because of the development of alternative methods of feeding infants (Jelliffe and Jelliffe, 1976, p. 153). Before this time period, if infants survived, they were fed breast milk either by mothers or by wet nurses (Gerrard and Tan, 1978, p. 20; Worthington, 1977, p. 8). During the early part of the nineteenth century, infant mortality increased for those not breast-fed (Cunningham, 1977, p. 726; Fomon, 1974, p. 1; Worthington, 1977, p. 8).

Trends in Breast-Feeding

During the 1940's, approximately 65 percent of infants in the United States were breast-fed during the newborn period; by 1958, 25 percent of seven-day old infants were breast-fed (Fomon, 1974, p. 7). In 1966, only 18 percent of the mothers breast-fed their babies when they left the hospital (Sjolin, Hofvander, Hillerrisk, 1977, p. 505). In a study done by Martinez in 1973, 10 to 15 percent of infants still breast-fed by age two months, and by age six months, only 5 percent of infants were breast-fed (Martinez, 1973, p. 1). A recent study by Martinez and Nalenzienski (1979, p. 686) reported a resurgence in the incidence of breast-feeding from 1971 through 1978. The authors also indicated that more mothers are now nursing for a longer period of time.

Social class appears to be an important variable in influencing breast-feeding in the United States (Jelliffe and Jelliffe, 1978, p. 300; Fomon, 1974, p. 7). For example, from the beginning of 1930 to the middle of 1940, breast-feeding was more common among the lower social classes. "Since the early 1960's, various studies have suggested that breast-feeding is less common among the lower than among the upper social classes in the United States, in Sweden, and in the United Kingdom." (Fomon, 1974, p. 9) A 1971 study done in New York City revealed that breast-feeding was infrequent among low income families (Riveria, 1971, p. 277). Formerly, the population group most likely to breast-feed their infants were college students, physicians, and health-oriented individuals (Sjolin, and Others, 1977, p. 505; Worthington, Vermeersch, and Williams, 1977, p. 157; Fomon, 1974, p. 11). The current trend indicates that low income families and mothers whose education did not exceed elementary or high school also rank high among those who choose to breast-feed (Martinez and Nalezienski, 1979, p. 686).

Examples of declining breast-feeding rates, however, are also seen in many countries. Both resource poor and resource rich countries have been involved in this decrease in the incidence of breast-feeding. During 1951, approximately 80 percent of the infants in Singapore were still breast-fed at three months of age; in contrast, less than 10 percent were still being breast-fed in 1971 (Jelliffe and Jelliffe, 1978, p. 217). Gerrard and Tan assert that the mortality rate of Indian babies could have been reduced by one-third if these infants were breast-fed rather than bottle-fed (Gerrard and Tan, 1978, p. 21).

During 1974, in less technically developed countries it was estimated that 9.4 million cases of severe protein calorie malnutrition existed annually. Approximately 4.7 million children could have been protected wholly or in part through breast-feeding by adequately-fed mothers (Bengoa, 1974, p. 3).

Trends in Formula Feeding

It was only during the last few decades that large-scale production of alternative sources of nutrition for newborn infants began. The first commercially-prepared formulas in the 1950's were sold in the form of powder. Within 10 years concentrated liquid formula was marketed. The impetus of ready-to-feed formulas increased rapidly in 1967, and by 1970 these canned products were used frequently both in hospitals and in homes.

Available evidence indicates that short-term effects of bottle-feeding in industrialized countries are usually good; however, little is known regarding the long-term effects of bottle-feeding. "It has been said that the introduction of breast milk substitutes represents by far the largest in vivo experiment without a control series." (Hambraeus, 1977, p. 18).

Formula manufacturers have spent a great deal of money advertising their products. Through posters, billboards, mass media, free samples, and brochure distributions to health care and lay people, the manufacturers have made themselves well known. Their advertising emphasizes social class status and convenience (Jelliffe and Jelliffe, 1978, p. 227; Worthington,

and Others, 1977, p. 157). In other words, persuasion and motivation based on prestige are commonly used by these companies. Many feel that these techniques are unethical because in underdeveloped countries and in the rural and urban areas of the resource poor population, bottle-feeding is extremely difficult to undertake due to limited purchasing power, lack of environmental hygiene, and low levels of maternal education. Under such circumstances infants are likely to receive contaminated formula. According to King, and Others, "Bottle-feeding is one of the worst things that has come to Africa from Europe and America." (King, King, Morley, Burgess, and Burgess, 1972, p. 81)

Economics of Infant Feeding

Breast-feeding is an economical method of infant feeding. According to Berg, a nutritional planner with the World Bank, the loss of mother's milk and the rapid spread of formula feedings constitutes a "natural resource" crisis (Berg, 1973, p. 29). The loss in this natural resource is worth hundreds of millions of dollars in many of the world's low-income countries. For example, "In Kenya the estimated $11.5 million annual loss in breast milk is equivalent to two-thirds of the national health budget or one-fifth of the average annual economic aid." (Berg, 1973, p. 30).

The extra calories necessary for lactation can be obtained very cheaply, thus making lactation economical (Lamm, Delaney, and Dwyer, 1977, p. 71; Jelliffe and Jelliffe, 1976, p. 420; Lillington, 1975, p. 512; Arnel, Creery, Lloyd, Oppe, Stroud, Wharton, and Widdowson, 1975, p. 450).

In a survey done by Lamm and others on the cost of formula produced by several companies, commercial milk-based formulas are nearly twice the cost of evaporated milk formulas. "Concentrated formulas are least expensive, followed by powdered, with ready-to-feed products being the most expensive." (Lamm, and Others, 1977, p. 74)

The foods which are selected for lactation will play a role in determining the total cost of breast-feeding. When inexpensive sources or nutrients are chosen, human milk can be produced more inexpensively. Nonetheless, when a rather expensive diet is used, the maximum cost of breast-feeding for milk supply was comparable with the highest-priced ready-to-feed formula. It would "seem that ready-to-feed formulas are . . . caviars of formula so far as prices go." (Lamm, and Others, 1977, p. 76)

Health Professionals and Infant Feeding

There has been a lack of knowledge among many health professionals about the uniqueness of breast-feeding (Magnus, 1978, pp. 134-135; Hambraeus, 1977, p. 32). The curricula in health professional schools devote little or no time to the physiology and advantages of breast-feeding (Davies, 1979, p. 541; Worthington, and Others, 1977, p. 159; Winick, 1975, p. 8). The result is a generation of health professionals who are not knowledgeable enough with the practical aspects of the management of breast-feeding or who are not convinced of the superiority of breast-feeding.

Nurses in hospitals, prenatal, or pediatric clinics have not been

actively involved in discussing breast-feeding advantages, techniques, and problems with mothers (Magnus, 1978, p. 136; Cole, 1977, p. 352). Many obstetricians in the United States are either neutral or negative about breast-feeding, while pediatricians rarely get to talk with an expectant mother before her baby's birth and many would not encourage nursing even if they did (Coffin, 1978, p. 39; Riordan, 1977, p. 95; Scott, 1974, p. 446; Washburn, 1974, p. 141; Winter, 1972, p. 127; Leeson, 1972, p. 942). In a study conducted by Dr. Auerbach, 85 percent of the mother-doctor relationships indicated doctors expressed no preference for the types of infant feeding to suggest to mothers (Auerbach, 1976, p. 316). "Many hospitals manage newborns according to the convenience of the hospital personnel and consideration of maternal (paternal)-infant contact and breast-feeding often is cast aside, depending on how busy and/or sensitive the medical staff are." (Magnus, 1978, p. 134)

Despite some negative attitudes by health professionals regarding counseling mothers on breast-feeding, some physicians have stated support in favor of breast-feeding for "poorer, less developed communities where alternatives are neither economically feasible nor hygienically practicable." (Jelliffe and Jelliffe, 1976, p. 153) In a study done by Ladas, he revealed that the two environmental variables of information and social support led to success in breast-feeding (Ladas, 1970, p. 702). In addition, when pediatricians are in support of breast-feeding a significant number of mothers will choose to breast-feed and be successful at it (Worthington, 1977, p. 3; Cole, 1977, p. 352; Ladas, 1970, p. 703).

The present trend has been to educate health professionals as well

as mothers about breast-feeding. According to Levi, "The more doctors, midwives, health visitors, and mothers know about breast-feeding, the more likely it is that successful breast-feeding will be established." (Levi, 1979, p. 732)

Comparison Between Breast Milk and Formula

Advances in technology and nutrition have led to the development of newer infant formulas which closely resemble human milk. However, there are still known and unknown differences between infant formula and breast milk. A comparison will be made of some of these differences according to what is known at this time.

Protein

"The need for protein, especially its constituent amino acids for synthesis of body proteins, and its nitrogen for the synthesis of many other physiological important compounds, is well known." (Slater and Jelliffe, 1977, p. 5) The concentration of protein in cow's milk is approximately twice that of breast milk and, hence, water dilution is required (Williams, 1978, p. 182; Smith, 1977, p. 91; McLaren and Burman, 1976, p. 58; Fomon, 1974, p. 143). Casein is the main protein in formula, whereas the whey proteins and lactoalbumin are predominant in human milk. In formula the casein/albumin-globulin whey ratio is approximately 76:24; in human milk it is approximately 40:60 (American Academy of Pediatrics, 1978, p. 592). The lower casein content of breast milk allows for a soft, easy-to-digest curd in the infant's stomach

(Pipes, 1977, p. 102). The sulfur amino acids present in both cow's milk and human milk are methionine and cystine. Methionine is present in greater concentrations in cow's milk, relatively more cystine is present in human milk (American Academy of Pediatrics, 1978, p. 592; McLaren and Burman, 1976, p. 61). The low protein content of human milk is ideally suited to the metabolic uses by the newborn infant, especially those of the premature infant whose liver is inefficient in converting methinonine to cystine and in metabolizing tyrosine (Siimes and Hallman, 1979, p. 173; American Academy of Pediatrics, 1978, p. 592; Hambraeus, 1977, p. 22; Raiha, 1974, p. 147). Two other amino acids, phenylalanine and histidine, have been shown to cause hyperaminoacidemia in low-birthweight newborns, thus leading to ill consequences (Jelliffe and Jelliffe, 1976, p. 154).

Breast milk also provides a source of nonprotein nitrogen which plays a role in anabolism and growth. The nonprotein nitrogen in breast milk constitutes approximately 25 percent of the protein concentration, whereas in formula only 5 to 6 percent of the total protein is supplied as nonprote in nitrogen (American Academy of Pediatrics, 1978, p. 592; Hambraeus, 1977, p. 22; Fomon, 1974, p. 142).

Fat and Cholesterol

Dietary fat provides about 50 percent of the calories in human milk. It constitutes the major source of energy for the infant, and it serves as a carrier for fat-soluble vitamins and certain fatty acids such as linoleic and arachidonic acids (Slater and Jelliffe, 1977, p. 5; Hambraeus, 1977, p. 25). Unsaturated fatty acids dominate in breast milk, oleic acid being predominant, whereas saturated fatty acids dominate in

cow's milk (American Academy of Pediatrics, 1978, p. 592; Hambraeus, 1977, p. 25; Widdowson, Southgate and Schultz, 1974, p. 867). The content of linoleic acid, a polyunsaturated fatty acid, is higher in breast milk as compared to cow's milk or formula.

The lipids in human milk are better absorbed than those of earlier marketed formulas using butterfat (American Academy of Pediatrics, 1978, p. 592; McLaren and Burman, 1976, p. 61; Anderson, Dibble, Mitchell, and Rynbergen, 1972, p. 144; Fomon, 1974, p. 162). "Vegetable oils which replace butterfat in newer infant formulas, have significantly improved fat absorption--even in the first month of life--to practically the level achieved with breast milk." (American Academy of Pediatrics, 1978, pp. 591-592). In addition, recent studies have shown that the high levels of arachidonic acid in human milk may be optimal for brain development (Slater and Jelliffe, 1977, p. 6).

Human milk contains cholesterol, which plays a significant role in early feeding of the infant (American Academy of Pediatrics, 1978, p. 592; Pipes, 1977, p. 30; Jackson, 1977, p. 65; Anderson, 1975, p. 19). It has been found that relatively high ingestion of cholesterol during infancy may induce enzymes that can better metabolize cholesterol and thereby control the level of cholesterol in the blood in later life (American Academy of Pediatrics, 1978, p. 592; Jackson, 1977, p. 65; Hahn and Kirby, 1973, p. 690). Some studies have postulated that breast-fed infants have fewer incidences of arterial disease in later life; however, more active research is needed to determine its significance (American Academy of Pediatrics, 1978, p. 592; Jackson, 1977, p. 65).

Carbohydrates

Lactose is the major carbohydrate in all milks (Hambraeus, 1977, p. 25; Jelliffe, 1976, p. 153; Wilson, Fisher and Fugua, 1975, p. 363; Williams, 1973, p. 389). Cow's milk contains approximately 70 percent carbohydrate as compared to 30 percent in human milk. Most commercially prepared formulas provide about 42 percent of the energy value in carbohydrates (Fomon, 1974, p. 187). If the amount of carbohydrate should exceed 50 percent, the intestinal mucosal cells might not be able to hydrolyze and absorb the lactose, thus causing water to enter the intestine; the result is diarrhea (Wilson, and Others, 1975, p. 366). Human milk contains L-bifidus factor, a nitrogen-containing carbohydrate which is required by the bacteria lactobacillus for growth in promoting a healthier nutritional status (Chaney, Ross, and Witschi, 1979, p. 397; Welsh and May, 1979, p. 1; Gyorgy, 1971, p. 970).

Lactose occurs naturally in milk and is the least sweet of all the common sugars. It would be the best sugar to add to formulas, but it is expensive. Traces of other carbohydrates like glucose, galactose, and other nitrogen-containing carbohydrates are also present in both milks. The sugars commonly added to formulas are sucrose, glucose, fructose, and dextromaltose (Hambraeus, 1977, p. 27).

Iron

Iron in human nutrition prevents anemia. The content of iron in breast milk is sufficient to sustain continued growth up to four to six months (Owen, 1978, p. 3; Polner, 1978, p. 42; Slater and Jelliffe, 1977, p. 10; Rozee, 1976, p. 19; Fitzpatrick, Reeder, and Mastroianni, 1971, p. 379).

When milk is saturated with iron it loses its bacteriostatic properties; thus, because of the low iron content in breast milk, the bacteriostatic protein-lactoferrin and transferrin are extremely useful (American Academy of Pediatrics, 1978, p. 593). Lactoferrin is present in much higher quantities in human milk than in cow's milk or formula. Bacteria requires iron for growth, thus lactoferrin inhibits the growth of several pathogens. Lactoferrin has provided marked resistance against infectious gastroenteritis caused by Escherichia coli (Hambraeus, 1977, pp. 23-24; Hanson and Winberg, 1972, p. 845; Bullen, Rogers and Leigh, 1972, p. 69).

Immunological Aspects

"It has long been recognized that breast-fed infants seem to be protected against many infections, especially in surroundings of poor hygiene." (Jelliffe and Jelliffe, 1976, p. 154) At birth, the infant's immune system is immature and his ability to fight off invasive microorganisms is weak. However, his immunological defenses can be enhanced through breast-feeding (Pittard, 1979, p. 85; Ores, 1979, p. 497; Grams, 1978, p. 340). Human milk contains humoral factors such as secretory IgA, lactoferrin, lysozymes, and the bifidus factors which all function as protective agents against infections (Marano, 1979, p. 63; Choi, 1978, p. 852; Baggott, 1978, p. 30; Taylor, 1977, p. 235; Lawton and Shortridge, 1977, p. 253). "Most of the factors contributing to immunologic protection cannot be supplied by heat treated formula." (American Academy of Pediatrics, 1978, p. 592). MacKeith states that even a short period of breast-feeding, for example, one to two months, provides the important anti-infective agents to the neonate (MacKeith, 1969, p. 277).

"Immunity is a physiological response or series of responses of cells of the immune system to a foreign substance." (Grams, 1978, p. 340) The two types of lymphocytes are T-lymphocytes and B-lymphocytes (Dick, 1979, p. 304). The T-lymphocytes are found in the thymus, while the B-lymphocyte's location of origination is as yet unknown to humans (Grams, 1978, p. 340). The T-lymphocyte's function is to provide cellular immunity against a foreign agent; and this immunity cannot be passively transferred. Next, the B-lymphocytes from the antibodies may be passively transferred. Thus, a mother is able to transfer her antibodies either across the placental barrier or via her breast milk to her infant (Marano, 1979, p. 63; Grams, 1978, p. 341).

Immunoglobulin is divided into five classes: IgG, IgM, IgD, IgE, and IgA. Each of these classes serve specific functions. IgE has been known to be associated with allergic diseases, since persons with allergies have an unusually high IgE level. The function of IgD is unknown and it is found in low concentrations in the bloodstream. The serum level of IgG, IgA, and IgM are significantly higher in colostrum-fed infants (American Academy of Pediatrics, 1978, p. 594; Choi, 1978, p. 852).

IgA is the predominant class of immunoglobulin found in colostrum, breast milk, tears, saliva, and secretions of the respiratory, urogenital, and gastrointestinal tracts; it protects the infant from harmful substances passing through the gut wall into the infant's system (Grams, 1978, p. 341; Lackner and Cummingham, 1977, p. 1; Hambraeus, 1977, p. 24). "The mean IgA immunoglobulin concentration in colostrum and milk range

from 158 mg/gm protein on the first day to 113 mg/gm protein two days postpartum, and the concentration 180 days postpartum ranged from 20 to 27 mg/gm protein." (Ogra and Ogra, 1978, p. 548). From Ogra and Ogra's studies, breast-feeding during the first week after onset of lactation is vital in providing the infant with the high concentration of antibodies (1978, p. 549).

The IgG appears early in the immune response and acts to destroy and fight against antigens. The level of IgG in colostrum and milk range from 1.4 to 4.9 mg during the first 180 days postpartum (Ogra and Ogra, 1978, p. 547). In contrast, IgM level of 28 mg/gm protein was highest in colostrum but decreased to 3.5 to 4.1 mg/gm protein during the 120-180 days postpartum period (Ogra and Ogra, 1978, p. 547).

As mentioned earlier, lactoferrin contributes to a large extent to the marked resistance against gastroenteritis. Lysozymes have a direct bactericidal effect by potentiating the activity of immune antibodies (Hambraeus, 1977, p. 24). The bifidus factors are known to be partly responsible for the suppression of Escherichia coli and the other enteric pathogens (Welsh and May, 1979, p. 3; McLaren and Burman, 1976, pp. 62-63).

Relationship of Feeding Method to Disease

Breast-fed babies have fewer infections, especially gastrointestinal and respiratory infections, than bottle-fed babies (Marano, 1979, p. 62; American Academy of Pediatrics, 1978, p. 594; Pullan, Dellagrammatikas and Steiner, 1977, p. 620; Jelliffe and Jelliffe, 1978, p. 12).

The studies of Woodbury and Grulee, carried out before the advent of antibiotics and when breast-feeding was still popular, indicated that infections were more common and mortality rates were higher in the bottle-fed as compared to the breast-fed infants (Grulee, Sanford, and Schwartz, 1935, p. 1986; Grulee, Sanford, and Herron, 1934, p. 735; Woodbury, 1922, p. 668). Allergic disorders occur less often in breast-fed infants because of the low allergenicity of breast milk (Bahna, 1978, p. 5; Jelliffe and Jelliffe, 1977, p. 1143; Taylor, 1977, p. 235; Esterly, and Others, 1976, p. 245).

Respiratory Disorders

Respiratory infections are seen less frequently in breast-fed infants (Ellestad-Sayed, and Others, 1979, p. 295; Lockhart, 1979, p. 2; Esterly, and Others, 1976, p. 245; Brown, 1975, p. 17; Gerrard, 1974, p. 758; Adebonojo, 1972, p. 28). In 1976, Downham and others supported the observation that breast-feeding protects against respiratory diseases. Their results revealed that the incidence of respiratory syncytical virus infections was much less in breast-fed infants (Downham, Scott, Simm, Webb, and Gardner, 1976, p. 274).

The large amounts of lysozymes found in breast milk have been postulated to provide protection against harmful bacteria. "Clinical studies seem to support the idea that breast-fed infants are more resistant to nonenteric infections, and the presence of lactoferrin and lysozymes may be the reason." (Brown, 1975, p. 17)

Respiratory disorders such as the common cold, otitis media, bronchitis, and pneumonia occur more often in bottle-fed babies

(Ellestad-Sayed, and Others, 1979, p. 295; Taylor, 1977, p. 235; Brown, 1975, p. 17; Gerrard, 1974, p. 762; Abedonojo, 1972, p. 28). In a study done by Cunningham on infants in New York State, he discovered that otitis media was twice as common in bottle-fed babies than in breast-fed babies. Also, pneumonia and hospital admissions were ten times more frequent (Cunningham, 1977, p. 726).

Gastrointestinal Disorders

Immunologic protection against gastrointestinal disorders cannot be supplied by heat-treated formulas since they do not contain the anti-infection properties of colostrum (Jelliffe and Jelliffe, 1972, p. 34). Recent studies have shown that breast-fed babies have a much lower morbidity and mortality rate in underdeveloped countries with poor sanitation (Ellestad-Sayed, Cooden, Dilling, and Haworth, 1979, p. 295; Larsen and Homer, 1978, p. 417; Brooke, 1978, p. 314; Kannaaneh, 1972, p. 302; James, 1972, p. 690). Cunningham in his study showed that middle-class breast-fed infants had fewer episodes of vomiting and diarrhea than bottle-fed infants (Cunningham, 1977, p. 726).

Breast-feeding provides the infant with good protection against such organisms as Escherichia coli, salmonella, and shigella, which are found in the intestinal tract and frequently cause diarrhea (Bullen, 1977, p. 220; Lackner and Cunningham, 1977, p. 1). The IgA immunoglobulin present in colostrum provides specific antibodies which suppress the activity of Escherichia coli (Baggott, 1978, p. 30; Bullen, 1978, p. 220; Walker-Smith, 1978, p. 564; Silver, Kempe, and Bryan, 1977, p. 43). A substance known as the bifidus factor is present in breast milk, and this

substance promotes the growth of friendly bacteria in the infant's intestinal tract.

Studies have shown that breast milk might protect the premature infant against necrotizing enterocolitis when predisposing conditions to necrotizing enterocolitis such as anoxia and hypothermia were present at birth (Paxson and Cress, 1979, p. 61; Reisner and Garty, 1977, p. 507; Stein, 1977, p. 199). According to Whorwell and others, there is a decreased incidence of ulcerative colitis noted in breast-fed individuals; however, no correlation was found between breast-feeding and Crohn's disease (Whorwell, Holdstock, Whorwell, and Wright, 1979, p. 382).

Infantile colic is a common gastrointestinal disorder. Its etiologies are many, such as food allergy, disturbances in the mother-child relations or intestinal hyperperistalsis (Rowell, 1978, p. 20). Jakobsson and Lindberg believe that "colic is a well-known symptom of intolerance to cow's milk protein." (1978, p. 437) Breast-fed infants are well believed to have been susceptible to colic as well as bottle-fed infants because cow's milk proteins were transmitted from the mother to her infant via her breast milk. When nursing mothers were put on a diet free of cow's milk, the incidences of colic disappeared promptly (Jakobsson and Lindberg, 1978, p. 437).

Allergic Disorders

Cunningham and others state that human milk is the safest and least allergenic source of animal protein, and it should be the only food for the infant during his first four to six months of life (Lackner and Cunningham, 1977, p. 2). Cow's milk allergy has been on the increase

since breast-feeding was abandoned and replaced by artificial feeding at an early age (Stintzing and Zetterstrom, 1979, p. 383; Lockhart, 1979, p. 2; Bahna, 1978, p. 1; Goldman and Heiner, 1977, p. 133; Jelliffe, 1977, p. 49). Thus, allergies such as eczema, uticaria, and asthma occur more often in bottle-fed infants when untreated cow's milk or solid foods are introduced early into the infant's diet (Brooke, 1978, p. 318; Barness, 1977, p. 3; Matthew, Norman, Taylor, Turner, and Soothill, 1977, p. 321; Taylor, 1977, p. 236; Brown, 1975, p. 17; Gerrard, 1974, p. 762; Goldman, Anderson, Sellars, Saperstein, Kniker, and Halpern, 1963, p. 425). When infants are fed cow's milk or solid foods before four months of age, they do not have the necessary enzymes to digest the larger molecules of intact protein (Rupp, 1977, p. 84).

Infants are more susceptible to developing an allergy if there is a family history of allergies such as asthma or eczema (Morris-Owen, 1978, p. 575; Grams, 1978, p. 344; American Academy of Pediatrics, 1978, p. 595; Rupp, 1977, p. 85). Mothers who have a family history of allergy are encouraged to breast-feed in order to decrease or eliminate exposure of their infant to the allergenic protein in cow's milk (Grams, 1978, p. 344; American Academy of Pediatrics, 1978, p. 595).

Wittig and others stated that breast-fed children have later onset of allergic disorders such as asthma or allergic rhinitis than bottle-fed children (Wittig, McLaughlin, Leifer and Belloit, 1978, p. 87). Foods such as eggs or chocolate may, when taken by nursing mothers, result in their infants developing eczema. Gerrard states that when these foods were eliminated from the mother's diet, in most cases the eczema cleared up (Gerrard, 1979, p. 69).

Summary

This chapter on the review of literature discussed the past and present trends of infant feeding patterns. A section on the role of the health professionals and infant feeding was discussed. The contents of protein, fat, cholesterol, carbohydrates, and immunoglobins found in breast milk were compared to the content found in formula. A section on the relationship of feeding methods to disorders such as respiratory, gastrointestinal, and allergies was presented.

Chapter 3

RESEARCH METHOD AND DESIGN

This study was a descriptive, non-experimental study using the survey-type approach to ascertain the relationship between two feeding methods and infant health.

Variables

Independent Variables

The independent variables were: (1) bottle-fed, and (2) breast-fed.

Dependent Variables

The dependent variables were: (1) respiratory disorders which included the common cold, otitis media, bronchitis, and pneumonia, (2) gastrointestinal disorders which included vomiting, diarrhea, and colic, and (3) allergies which included eczema, hives, and asthma.

Uncontrolled Variables

The uncontrolled variables were: (1) infants who were introduced to solid foods like cereals, vegetables, juices, fruits, meats, and eggs during the study, (2) infant's exposure to crowds and visitors in the home, and (3) mother's inability to accurately recall her infant's past medical history.

Selection of Subjects

The sample was a non-random convenience sample consisting of a total of 50 clients. Twenty-five clients were in the breast-fed group and 25 were in the bottle-fed group.

Criteria for Selection of Subjects

The criteria for selection of the two groups were as follows:

The mothers in the sample (1) were primiparous, (2) were 18-35 years of age, (3) had a minimum education of two years of high school, (4) were free of any physical or mental disabilities that might prevent proper care of their infants, and (5) were nonsmoking, since infants born to smoking mothers are small for gestational age (Meyer, 1979, p. 975; Blake and Sawyer, 1972, p. 619).

The infants in the sample (1) were 38-43 weeks gestation at birth; (2) weighed more than 2500 grams (5 pounds, 8 ounces) at birth, and (3) had no known birth defects or history of admission to a newborn intensive care unit.

The mothers and fathers (1) had no history of allergies like eczema, hives, and asthma, and (2) had no children at home under 10 years of age in order to prevent spreading of common childhood illnesses such as the common cold, etc. (Grams, 1978, p. 343).

Setting

This study was conducted in San Bernardino, California. San Bernardino County covers 42,000 square miles and includes a population of

slightly less than 1.5 million people. The number of live births in this county in 1979 was 11,882. The target population was the number of live births at a private university medical center, and two community hospitals in this county.

Research Tool

The researcher designed a questionnaire with instructions in the form of a booklet for this study. The booklet was entitled, "Your Child's Health Record." One booklet was designed for the mothers of breast-fed infants (see Appendix D), and one for the mothers of bottle-fed infants (see Appendix E).

There were three sections in each booklet. Sections I and II were identical for the two groups studied, while Section III varied somewhat.

Section I of the booklet contained the researcher's name, home telephone number, definition of illnesses and examples of how to record in the booklet. Section II of the booklet allowed for weekly recordings of the number of illnesses the infant had from birth to 12 weeks of age. Here the mothers stated in writing when and for how long their infants had the respiratory, gastrointestinal, or allergic disorders. Section III of the booklet asked for a brief weekly diet record of solid foods eaten by the infant. Also, in this third section nursing mothers stated how often they supplemented their infants' diets with formula, and mothers bottle-feeding stated the brand name of their infant formula. The booklet was designed by the researcher after reviewing the literature on infant feeding (Grams, 1978, pp. 343-344; Adebonjo, 1972, pp. 27-28). The data for the study were collected over a period of 11 to 13 weeks.

Pilot Study

A pilot study was done with two breast-feeding and two bottle-feeding primiparas for two weeks. The pilot study was for the purpose of appraising the research tool and to lessen the possibility of the mothers misunderstanding how to keep a weekly health and diet record.

One change was made in the research tool after the pilot study. The term urticaria was changed to hives, since the mothers were unfamiliar with the former term.

Methods Used to Obtain Consent and Data Collection

The biographical information of sample mothers (see Appendix F) and infants (see Appendix G) was obtained from the mother's hospital chart and from the mother during her first or second day postpartum at the hospital. The researcher explained the purpose of the study and each section of the booklet to her (see Appendixes H and I). A written informed consent was signed by the mothers prior to data collection (see Appendix J). The mothers were assured of the anonymity of their participation in the study and were encouraged to call the researcher if they had any questions regarding the booklet or their participation.

The first day in week number one was the day the mother and her infant were discharged from the hospital. Between two and three weeks postpartum the researcher made a home visit, and the mother's ability to keep the record in the booklet accurately and consistently was ascertained.

A telephone call was made when the infant was about six or seven weeks old to determine if the mother was able to keep the booklet recording up to date. A final home visit was made when the infant was between 11 and 13 weeks of age to collect the booklet for data analysis.

Mother and infant were eliminated from the research study if: (1) the mother stopped breast-feeding before her infant was 11 weeks old, (2) breast-fed infants were receiving more than one supplemental formula feeding per day, (3) the infant in either of the two groups was hospitalized for any reason, and (4) the sample number had been reached.

The privacy of the clients was guarded closely during the study by never using the clients' names in the analysis of data. Permission to conduct the study was granted to the researcher by the Loma Linda University Committee on Human Studies (Appendix A).

Data Analysis

To test hypotheses one, two, and three, the stepwise multiple regression analysis was used, with the frequency of the respiratory, gastrointestinal, and allergic disorders as the dependent variables. The independent variables consisted of the feeding method and the introduction and duration of each of the solid foods. The feeding method was forced into the analysis at the first step, followed stepwise by the remaining variables (Nie, Hull, Jenkins, Steinbrenner, and Brent, 1975, p. 320). The means of the age of the mothers, the infants' gestation and birth weights were obtained. In addition, frequency distribution of ethnic groups, sex of the infants, and the respiratory, gastrointestinal and allergic disorders were analyzed.

Methodological Assumptions

The methodological assumptions for this study were that: (1) bottle-feeding or breast-feeding was the desired method of infant feeding by the mother, (2) prior knowledge of infant feeding for the two groups would be similar, (3) the mother's recollection of her infant's health history was accurate, and (4) the booklet developed for and used in this research was valid and reliable in measuring the subject's incidences of illnesses.

Methodological Limitations

The limitations that may have affected the results of the research included: (1) the small sample size for each of the two groups, (2) the use of a non-random sample may have decreased the representativeness of the population, (3) the uncontrolled extraneous variables may have influenced the results, and (4) the results might have been more conclusive if the study had been continued until the infants were nine to 12 months of age.

Summary

In this chapter the methodology of the research was presented. The independent, dependent, and uncontrolled variables were stated. The criteria for selection of subjects, the research tool, the data collection procedure and analysis, and the methodological assumptions and limitations of the study were discussed.

Chapter 4

DATA ANALYSIS AND DISCUSSION OF FINDINGS

This research was conducted on two groups of infants, breast-fed and bottle-fed. Statistical analysis was done to determine differences in respiratory, gastrointestinal, and allergic disorders among these two groups during the first three months of life.

The original sample size consisted of 60 subjects, with 30 infants in each group. Five infants from the breast-fed group were dropped because their mothers later chose to bottle-feed. In the bottle-fed group, five infants were dropped for various reasons. One infant had to be readmitted to the hospital due to a heart defect. The researcher was unable to locate two of the mothers by telephone, mail, or home visit, and the other two no longer wished to participate in the study.

This chapter begins with a presentation of the biographical data and the statistical analysis of the hypotheses. A subsequent discussion of the findings will follow.

Presentation of Findings

An overview of the biographical data and the frequency of disorders noted in each infant in the breast-fed group is presented in Table 1. The profile for the bottle-fed group is presented in Table 2.

Table 1

Biographical Data and the Frequency of Disorders
Seen in the Breast-Fed Group

Code No.	Age of Mother	Race	Sex	Birth Weight (lbs)	Gest. (wks)	Respiratory Disorders				Gastrointestinal Disorders			Allergic Disorders		
						Cold	Otitis Media	Bron-chitis	Pneu-monia	Vomit-ing	Diar-rhea	Colic	Eczema	Hives	Asthma
1	21	W	M	7.3	40	0	0	0	0	0	0	7	0	0	0
2	27	W	M	8.4	40	0	0	0	0	0	0	0	0	0	0
3	19	W	F	7.5	40	0	0	0	0	0	0	0	0	0	0
4	27	W	F	7.1	41	1	0	0	0	0	0	0	0	0	0
5	25	W	F	7.9	40	0	0	0	0	0	0	0	0	0	0
6	33	W	M	6.9	40	0	0	0	0	0	0	0	0	0	0
7	25	W	M	8.5	41	2	0	0	0	0	0	0	0	0	0
8	31	W	M	7.7	41	1	0	0	0	1	1	0	0	0	0
9	21	W	M	8.7	40	0	0	0	0	1	0	0	0	0	0
10	26	W	F	7.8	40	0	0	0	0	1	0	0	0	0	0
11	33	M	F	6.8	40	0	0	0	0	0	0	1	0	0	0
12	27	W	M	9.9	41	0	0	0	0	2	0	0	0	0	0
13	19	W	M	6.2	41	1	0	0	0	0	0	1	0	0	0
14	16	W	M	6.5	40	0	0	0	0	0	1	1	0	0	0
15	22	W	F	7.1	40	1	0	0	0	0	0	0	0	0	0
16	26	W	F	8.0	40	0	0	0	0	3	1	0	2	0	0
17	29	W	F	8.0	40	1	0	0	0	0	0	0	0	0	0
18	32	W	F	8.7	40	2	0	0	0	2	0	0	0	0	0
19	25	W	F	8.0	40	0	0	0	0	0	0	0	0	0	0
20	19	W	M	8.0	42	0	0	0	0	0	1	0	0	0	0
21	19	W	M	8.0	39	0	0	0	0	0	0	0	0	0	0
22	21	W	M	8.9	40	1	0	0	0	0	0	0	0	0	0
23	27	W	M	8.6	40	1	0	0	0	0	0	0	0	0	0
24	23	B	F	6.3	40	0	0	0	0	0	0	0	0	0	0
25	25	W	M	7.5	40	2	0	0	0	4	1	0	2	0	0
				Total Incidences		13	0	0	0	14	5	10	4	0	0

Table 2

Biographical Data and the Frequency of Disorders
Seen in the Bottle-Fed Group

Code No.	Age of Mother	Race	Sex	Birth Weight (lbs)	Gest. (wks)	Respiratory Disorders				Gastrointestinal Disorders			Allergic Disorders		
						Cold	Otitis Media	Bron-chitis	Pneu-monia	Vomit-ing	Diar-rhea	Colic	Eczema	Hives	Asthma
1	26	W	F	7.0	41	0	0	0	0	0	0	0	0	0	0
2	25	W	F	8.0	40	0	0	0	0	8	1	7	0	0	0
3	20	W	F	7.9	40	4	0	0	0	2	2	2	0	0	0
4	18	W	M	8.4	40	2	0	0	0	0	0	0	0	0	0
5	18	W	M	7.1	40	1	0	0	0	0	0	0	0	0	0
6	25	W	M	8.8	41	1	0	0	0	0	0	0	0	0	0
7	24	W	F	7.4	41	0	0	0	0	0	0	0	0	0	0
8	31	W	M	6.7	41	1	0	0	0	5	0	0	0	0	0
9	21	B	M	7.1	41	0	0	0	0	4	1	2	0	0	0
10	23	M	M	8.2	40	2	0	0	0	0	1	0	0	0	0
11	18	M	M	7.5	40	1	0	0	0	6	0	0	0	0	0
12	20	W	F	6.7	40	1	0	0	0	0	0	0	0	0	0
13	32	M	M	6.3	40	0	0	0	0	0	0	0	0	0	0
14	18	M	M	7.9	40	1	0	0	0	0	0	0	0	0	0
15	26	B	F	7.5	40	2	0	0	0	0	0	2	0	0	0
16	26	M	M	7.7	40	2	0	0	0	6	2	0	0	0	0
17	18	M	F	6.0	40	1	0	0	0	7	2	0	0	0	0
18	27	W	M	7.4	41	0	0	0	0	7	0	3	0	0	0
19	20	M	M	6.3	41	2	0	0	0	0	0	0	0	0	0
20	32	W	M	8.4	40	0	0	0	0	2	2	0	0	0	0
21	19	W	F	8.0	41	0	0	0	0	5	1	0	0	0	0
22	25	W	F	6.3	41	0	0	1	0	0	0	0	0	0	0
23	29	W	M	7.0	40	0	0	0	0	1	0	4	0	0	0
24	32	W	M	7.8	40	1	0	0	0	1	0	0	0	0	0
25	20	W	M	7.9	40	0	0	0	0	1	1	2	2	0	0
				Total Incidences		22	0	1	0	55	13	22	2	0	0

Biographical Data

The biographical data were compiled on the two groups of breast-fed and bottle-fed infants. The data included the age of the infants' mothers, ethnic group, gestation, birth weight, and sex of infants.

The ages of the two groups were similar to each other. The combined mean age for the groups was 23.7 years. Breast-feeding mothers were slightly older than bottle-feeding mothers. The age factor in this study could not be compared to other studies because most studies did not mention the age of mothers or use age as a criteria for selection (see Table 3).

Table 3

Mean and Standard Deviation of Mothers by Feeding Methods

	N	Mean Age	s.d. (s)
Breast-fed	25	24.1	4.6
Bottle-fed	25	23.3	4.5
Total	50	23.7	4.4

The ethnic groups of the mothers are presented in Table 4. Both groups had a higher percent of whites than any other ethnic group. This is most likely due to private pay patients who deliver at community hospitals. A higher percentage of Mexican-Americans were noted to be in the bottle-feeding group. Here, the socioeconomic and geographic area would

have much to do with the ethnic group. The percentage of Blacks in this study was similar in both groups.

Table 4

Distribution of Ethnic Groups by Feeding Methods

	N	% White	% Black	% Mexican American
Breast-fed	25	92.0	4.0	4.0
Bottle-fed	25	64.0	8.0	28.0
Total	50	78.0	6.0	16.0

Table 5 presents the mean gestation and birth weights of the infants. From this baseline, no significant difference was seen in the groups in regards to the infants' age of gestation and birth weight. The similarity may be due in part to limitations of criteria for selection or mothers seeking early prenatal care.

Table 5

Mean Gestation and Birth Weight by Feeding Methods

	N	Gestation (weeks)	Birth Weight (pounds)
Breast-fed	25	40.2	7.8
Bottle-fed	25	40.4	7.4
Total	50	40.3	7.6

The sex distribution was equal and essentially the same in the breast-feeding and the bottle-feeding groups. Males did dominate in both groups as shown in Table 6.

Table 6

Sex Distribution by Feeding Methods

	N	Male	Female
Breast-fed	25	14	11
Bottle-fed	26	16	9
Total	50	30	20

Respiratory Disorders and Types of Feedings: Hypothesis 1

The respiratory disorders consisted of the common cold, otitis media, bronchitis, and pneumonia. Each of the illnesses' frequencies were looked at separately and then analyzed statistically as a collective group, T_1 in Table 7.

There were 13 incidences of the common cold in the breast-fed group; however, the difference was not significant ($p<.05$). One case of bronchitis was noted in the bottle-fed group. There were no incidences of otitis media or pneumonia in either group.

Overall, there was no significant difference in any of the respiratory disorders among the two groups of breast-fed and bottle-fed infants at the 5 percent level of significance. In addition, through the stepwise

Table 7

The Incidences and the Mean Frequencies ± Standard Error of Respiratory Disorders by Feeding Methods

	Breast-fed (N_1=25)		Bottle-fed (N_2=25)		
	Incidences	Mean Frequency	Incidences	Mean Frequency	Significance
Common Cold	13	0.52±0.14	22	0.88±0.20	N.S.
Otitis Media	0	0	0	0	N.S.
Bronchitis	0	0	1	0.04±0.04	N.S.
Pneumonia	0	0	0	0	N.S.
T_1	13	0.52±0.14	23	0.92±0.20	N.S.

regression analysis, the introduction of solid foods and its duration were not significantly related to the respiratory disorders.

Gastrointestinal Disorders and Types of Feedings: Hypothesis 2

The gastrointestinal disorders included vomiting, diarrhea, and colic. The three disorders were analyzed separately and then collectively as T_2. The findings of the three gastrointestinal disorders and their summary are presented in Table 8.

There were 14 incidences of vomiting in the breast-fed groups as compared to 55 incidences in the bottle-fed group, and this was noted to be significant ($p<.01$). The increased frequency of vomiting was associated with early introduction of juices in the infants' diets. The five incidences of diarrhea and the 10 incidences of colic in the breast-fed group were less than the 13 incidences of diarrhea and 22 incidences of colic in the bottle-fed group. There was a significant difference in the overall gastrointestinal disorders among the two groups ($p<.01$).

Allergic Disorders and Types of Feedings: Hypothesis 3

The allergic disorders consisted of eczema, hives, and asthma. The frequency of the three disorders was analyzed separately and collectively as T_3 in Table 9.

There were four incidences of eczema seen in the breast-fed group as compared to two cases in the bottle-fed group. No incidences of hives or asthma were noted in either group. There were no overall significant differences in allergic disorders among the two groups at the 5 percent level of significance.

Table 8

The Incidences and the Mean Frequencies ± Standard Error of Gastrointestinal Disorders by Feeding Methods

	Breast-fed (N_1=25)		Bottle-fed (N_2=25)		
	Incidences	Mean Frequency	Incidences	Mean Frequency	Significance
Vomiting	14	0.56±0.21	55	2.20±0.56	p .01
Diarrhea	5	0.20±0.08	13	0.52±0.15	N.S.
Colic	10	0.40±0.28	22	0.88±0.33	N.S.
T_2	29	1.16±0.36	90	3.60±0.83	p .01

Table 9

The Incidences and the Mean Frequencies ± Standard Error of Allergic Disorders by Feeding Methods

	Breast-fed (N_1=25)		Bottle-fed (N_2=25)		
	Incidences	Mean Frequency	Incidences	Mean Frequency	Significance
Eczema	4	0.16±0.11	2	0.08±0.08	N.S.
Hives	0	0	0	0	N.S.
Asthma	0	0	0	0	N.S.
T_3	4	0.16±0.11	2	0.08±0.08	N.S.

Interpretation of the Findings

The researcher observed no significant differences in the incidences of respiratory and allergic disorders in the two groups. There was a significant difference in the frequency of gastrointestinal disorders noted ($p<.01$) between the breast-fed and bottle-fed groups. There was a total of 90 gastrointestinal incidences in the bottle-fed group as compared to 29 in the breast-fed group (see Tables 1 and 2). Overall the statistical analysis of this research cannot prove a direct cause and effect relationship between feeding method and infant health, except for Hypothesis 2.

Discussion of Findings

The total respiratory disorders noted in the breast-fed group was 13 as compared to 23 seen in the bottle-fed group. The gastrointestinal disorders occurred three times more frequently in the bottle-fed group. There were 90 incidences of gastrointestinal disorders in the bottle-fed group as compared to 29 incidences in the breast-fed group (see Tables 1 and 2). The total incidences of allergic disorders for the breast-fed group were four as compared to two noted in the bottle-fed group. The overall total disorders noted in all three categories was 46 incidences seen in the breast-fed group as compared to 115 incidences in the bottle-fed group; thus, the overall disorders occurred 2.5 times more often in the bottle-fed infants.

In both groups the respiratory, gastrointestinal, and allergic

disorders occurred more frequently among the male infants, 18 in the breast-fed group and 30 in the bottle-fed group as compared to 10 females in the breast-fed group and 16 in the bottle-fed group. White infants in both groups, 23 in the breast-fed group and 16 in the bottle-fed group, had the most disorders as compared to the other two races; however, it was noted that the majority of the infants were white.

There were seven infants in the breast-fed group who did not have any respiratory, gastrointestinal, or allergic disorders as compared to three infants in the bottle-fed group. The majority of the infants who had no disorders in the breast-fed group were white females; one Black female infant had no disorders noted. The bottle-fed group had two white females and one Mexican-American male with no disorders seen (see Tables 1 and 2).

Discussion of Respiratory Disorders

The results of the increased frequency of colds found in bottle-fed infants are similar to observations made by several researchers that breast-feeding protects against the common cold (Lockhart, 1979, p. 2; Downham, and Others, 1976, p. 274; Adebonojo, 1972, p. 28). However, no definite confirmation can be made regarding breast milk providing immunity against the common cold because its noted increased frequency was not statistically significant. Several authors had stated that otitis media, bronchitis, and pneumonia occurred more often in bottle-fed babies (Ellestad-Sayed, and Others, 1979, p. 295; Taylor, 1977, p. 235; Brown, 1975, p. 17). There were no incidences of otitis media or pneumonia in either group in this study. There was one incident of bronchitis in one

bottle-fed infant, but it was not statistically significant. The decrease in the number of respiratory incidences may possibly be due to the milder winters experienced in California as compared to other parts of the United States where these other studies were conducted.

Discussion of Gastrointestinal Disorders

The breast-fed infants had considerable less incidences of vomiting, 14 compared to 55; diarrhea, 5 compared to 13; and colic, 10 compared to 22, in the bottle-fed infants (see Tables 1 and 2). In Cunningham's study, he stated that gastrointestinal disorders occurred less frequently in breast-fed infants (1977, p. 726). The stepwise multiple regression analysis showed that there may be an association with increased frequency of vomiting and the early introduction of juices. A direct cause and effect relationship cannot be proven since this was not an experimental study. The infant may have had a cold and the introduction of juices to cure the cold may have induced the vomiting. In addition, the mother's own interpretation of her child's illness was subjective.

Discussion of Allergic Disorders

The two incidences of eczema noted in the bottle-fed group contradicts Brooke's study, which showed bottle-fed infants being more prone to eczema (1978, p. 318).

Studies by Matthew and others reported that allergies such as eczema, hives, and asthma occurred more often in bottle-fed infants when solid foods were introduced early into the infant's diet (Matthew, and Others, 1977, p. 321). This study showed no significant difference in

allergic disorders among the two groups despite early introduction of solid foods. One explanation for the decrease in allergic disorders may have been the study's short duration and small sample size.

Summary

Chapter 4 presented the findings of the biographical data and the results of the statistical analysis of the three hypotheses proposed in Chapter 1. Some of the results of the respiratory and allergic disorders were not expected. There was no significant difference in the two groups in regards to respiratory and allergic disorders. A significant difference in the gastrointestinal disorders among the two groups ($p<.01$) was noted. Interpretation of the findings was discussed.

Chapter 5

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Chapter 5 will present a summary of the study, the conclusions drawn, the implications for nursing, and the researcher's recommendations for future and/or further study.

Summary

The advantages and disadvantages of breast-feeding have been tested, discussed, and questioned for many years. The goal of the research was to determine the effect of the two methods of feeding, breast-feeding and bottle-feeding, on infant health during the first three months of life.

A review of the literature focused on the history of infant feeding, the health professionals and infant feeding, and a comparison between breast milk and formula. The current literature regarding the relationship of feeding to diseases was presented. There have not been many nursing studies done correlating feeding methods with respiratory, gastrointestinal, and allergic disorders.

A total of 50 subjects was studied. There were 25 infants in the breast-fed group and 25 in the bottle-fed group. The data were collected by use of a booklet entitled, "Your Child's Health Record." The mother recorded the number of respiratory, gastrointestinal, and allergic disorders the infants had from birth to 12 weeks of age and when solid foods

were introduced. Biographical data such as the mother's age, race, gestation of the infants, their birth weights, and sex were obtained and compared.

Three hypotheses were tested:

1. Hypothesis I. There will be no significant difference ($p=0.05$) in the number of respiratory disorders between bottle-fed and breast-fed infants from birth to 12 weeks of age. This hypothesis was accepted.

2. Hypothesis II. There will be no significant difference ($p=0.05$) in the number of gastrointestinal disorders between bottle-fed and breast-fed infants from birth to 12 weeks of age. This hypothesis was rejected ($p<.01$).

3. Hypothesis III. There will be no significant difference ($p=0.05$) in the number of allergic disorders between bottle-fed and breast-fed infants from birth to 12 weeks of age. This hypothesis was accepted.

The biographical data of this study were similar in both groups in regards to mothers' age, the infants' gestation, birth weight, and sex. There was a combined average of 78 percent whites and 6 percent Blacks in both groups, but there were only 4 percent Mexican-Americans in the breast-fed group as compared to 28 percent in the bottle-fed group.

Conclusion

The data in this study indicated that gastrointestinal disorders occurred more frequently in bottle-fed infants (90) than in breast-fed infants (29). There were more respiratory disorders noted in the

bottle-fed group (23) as compared to the breast-fed group (13), but this was not statistically significant. The breast-fed infants (4) did not appear to have less allergic disorders than bottle-fed infants (2). However, the results might have been more conclusive if the study had continued until the infants were nine to 12 months of age, when allergic conditions are more likely to occur. The mothers' ages and ethnic origins were not factors in relation to the study's outcome. The infants' gestational ages, birth weights, and sex were not factors affecting the study's results. There was an association between early introduction of juices in the infants' diets and the increased incidence of vomiting.

Implications for Nursing and Recommendations

Some implications for nursing can be drawn as a result of this study. As professionals promoting preventive health care, community health nurses should provide information to expectant mothers in prenatal clinics about the advantages of breast-feeding. According to Grams, "She should be informed about the differences in rates of infection in breast-fed and formula-fed infants but told that the exact mechanisms for these differences are unknown." (Grams, 1978, p. 344)

The study has supported the evidence reported in the literature that breast-fed infants have fewer gastrointestinal disorders, and there were less respiratory symptoms in the breast-fed group. Therefore, most mothers should be encouraged to breast-feed their babies.

With an association noted between early introduction of juices and the increased incidence of gastrointestinal disorders, nurses should

provide mothers with additional diet counseling regarding delaying the introduction of juices in their infant's diet. Also, mothers who have infants with frequent gastrointestinal disorders should be encouraged to discontinue the juices.

If mothers live in areas where economic, nutritional and hygiene levels are below standard, breast-feeding should be promoted to a greater extent, since breast milk will provide the infant with some protection which results in fewer episodes of respiratory and gastrointestinal disorders.

Recommendations for Further Study

Prior to replication of this study, the definition of terms for each illness should be refined by being more specific and through the use of more lay language.

The following are recommendations for further studies:

1. The replication of this study limiting the sample to a single cultural or socioeconomic group.

2. A similar study following the infants until they reach the age of nine to 12 months, since most allergic disorders usually develop later in the first year of life.

3. A similar study including a third comparison group of nursing mothers who stopped breast-feeding. This would further clarify whether colostrum enhances the infant's immunity system.

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APPENDIX A

LETTER OF CONSENT FROM THE COMMITTEE ON HUMAN STUDIES

LOMA LINDA UNIVERSITY

GRANTS RESOURCES SERVICE

Loma Linda Campus
LOMA LINDA, CALIFORNIA 92350
La Sierra Campus
RIVERSIDE, CALIFORNIA 92515

August 27, 1979

Sylvia Souza
24932 Mound Street
Loma Linda, California 92354

Dear Ms. Souza:

I have reviewed the revised consent form for your study entitled "A comparative study on the frequency of respiratory, gastrointestinal, and allergic disorders between bottle-fed and breast-fed infants from birth to three months of age." I find that it meets the requirements of the Committee on Human Studies as stated in review at the regular meeting held August 8, 1979.

If there are further modifications to the proposed research protocol or consent form, or problems arising from the study, please notify the committee in writing of these changes or problems. If you have questions, please feel free to contact us.

Best wishes in your study.

Sincerely yours,

Linda G. Halstead
Secretary
Committee on Human Studies

LGH:ag
cc Lyn Elwell

APPENDIX B

LETTERS OF REQUEST TO UNDERTAKE THE STUDY

24932 Mound Street
Loma Linda, CA 92354
August 21, 1979

Miss Gertrude Haussler
Assistant Administrator
Loma Linda University Medical Center
Loma Linda, CA 92354

Dear Miss Haussler:

As a graduate student in nursing, I am investigating the effect of feeding patterns on infant health. This study is to meet part of the requirements for a master's degree in nursing at Loma Linda University. I am hereby requesting your permission to involve the mothers who deliver their babies at Loma Linda University Medical Center in the study. My research advisor, Frances Miller, and the Loma Linda University Committee on Human Studies have approved this research study.

The proposed research will be a comparative study between bottle-fed and breast-fed infants. The subjects will be chosen from the first 40 who meet the criteria and consent to participate in the study. A booklet, "Your Child's Health Record" will be given to the mother prior to her discharge which will enable her to keep a record of the frequency of respiratory, gastrointestinal and allergic disorders from birth to 12 weeks of age. The respiratory disorders will include the common cold, otitis media, bronchitis, and pneumonia. The gastrointestinal disorders will include vomiting, diarrhea and colic. The allergic disorders will be eczema, urticaria, and asthma. In addition, a brief feeding record of the infant will be obtained. Between two and three weeks postpartum an appointment will be made for the researcher to make a home visit and when the infant is about six to seven weeks old a telephone call will be made to ascertain the mother's ability to keep the booklet accurate and up to date. A final visit will be made when the infant is between 11 and 13 weeks of age to pick up the booklet for the final data collection. The confidentiality of the subjects will be maintained as the data will be coded and no names will be used. The subjects will have the right to withdraw without prejudice at any time during the study.

With your permission I would like to do a pilot study of four infants in September and begin the study data collection in October. I expect to complete the study by the end of December.

Space has been provided on the enclosed sheet for your reply. Thank you for your assistance.

Sincerely,

Sylvia Souza, R.N., B.S.

xc: F. Miller
C. Woodward

24932 Mound Street
Loma Linda, CA 92354
August 21, 1979

Mrs. Veronica Bender
Head Nurse, OB/Gyn Regular Nursery
Loma Linda University Medical Center
Loma Linda, CA 92354

Dear Mrs. Bender:

As a graduate student in nursing, I am investigating the effect of feeding patterns on infant health. This study is to meet part of the requirements for a master's degree in nursing at Loma Linda University. I am hereby requesting your permission to involve the mothers who deliver their babies at Loma Linda University Medical Center in the study. My research advisor, Frances Miller, and the Loma Linda University Committee on Human Studies have approved this research study.

The proposed research will be a comparative study between bottle-fed and breast-fed infants. The subjects will be chosen from the first 40 who meet the criteria and consent to participate in the study. A booklet, "Your Child's Health Record" will be given to the mother prior to her discharge which will enable her to keep a record of the frequency of respiratory, gastrointestinal and allergic disorders from birth to 12 weeks of age. The respiratory disorders will include the common cold, otitis media, bronchitis, and pneumonia. The gastrointestinal disorders will include vomiting, diarrhea and colic. The allergic disorders will be eczema, urticaria, and asthma. In addition, a brief feeding record of the infant will be obtained. Between two and three weeks postpartum an appointment will be made for the researcher to make a home visit and when the infant is about six to seven weeks old a telephone call will be made to ascertain the mother's ability to keep the booklet accurate and up to date. A final visit will be made when the infant is between 11 and 13 weeks of age to pick up the booklet for the final data collection. The confidentiality of the subjects will be maintained as the data will be coded and no names will be used. The subjects will have the right to withdraw without prejudice at any time during the study.

With your permission I would like to do a pilot study of four infants in September and begin the study data collection in October. I expect to complete the study by the end of December.

Space has been provided on the enclosed sheet for your reply. Thank you for your assistance.

Sincerely,

Sylvia Souza, R.N., B.S.

xc: F. Miller
C. Woodward

24932 Mound Street
Loma Linda, CA 92354
August 21, 1979

Mrs. Marilyn Thunquest
Director of Module I--Parent/Child
Loma Linda University Medical Center
Loma Linda, CA 92354

Dear Mrs. Thunquest:

As a graduate student in nursing, I am investigating the effect of feeding patterns on infant health. This study is to meet part of the requirements for a master's degree in nursing at Loma Linda University. I am hereby requesting your permission to involve the mothers who deliver their babies at Loma Linda University Medical Center in the study. My research advisor, Frances Miller, and the Loma Linda University Committee on Human Studies have approved this research study.

The proposed research will be a comparative study between bottle-fed and breast-fed infants. The subjects will be chosen from the first 40 who meet the criteria and consent to participate in the study. A booklet, "Your Child's Health Record" will be given to the mother prior to her discharge which will enable her to keep a record of the frequency of respiratory, gastrointestinal and allergic disorders from birth to 12 weeks of age. The respiratory disorders will include the common cold, otitis media, bronchitis, and pneumonia. The gastrointestinal disorders will include vomiting, diarrhea and colic. The allergic disorders will be eczema, urticaria, and asthma. In addition, a brief feeding record of the infant will be obtained. Between two and three weeks postpartum an appointment will be made for the researcher to make a home visit and when the infant is about six to seven weeks old a telephone call will be made to ascertain the mother's ability to keep the booklet accurate and up to date. A final visit will be made when the infant is between 11 and 13 weeks of age to pick up the booklet for the final data collection. The confidentiality of the subjects will be maintained as the data will be coded and no names will be used. The subjects will have the right to withdraw without prejudice at any time during the study.

With your permission I would like to do a pilot study of four infants in September and begin the study data collection in October. I expect to complete the study by the end of December.

Space has been provided on the enclosed sheet for your reply. Thank you for your assistance.

Sincerely,

xc: F. Miller
C. Woodward

Sylvia Souza, R.N., B.S.

24932 Mound Street
Loma Linda, CA 92354
August 21, 1979

Mrs. Mary Jane Tilson
Director of Nursing
San Bernardino Community Hospital
San Bernardino, CA 92411

Dear Mrs. Tilson:

As a graduate student in nursing, I am investigating the effect of feeding patterns on infant health. This study is to meet part of the requirements for a master's degree in nursing at Loma Linda University. I am hereby requesting your permission to involve the mothers who deliver their babies at San Bernardino Community Hospital in the study. My advisor, Frances Miller, and the Loma Linda University Committee on Human Studies have approved this research study.

The proposed research will be a comparative study between bottle-fed and breast-fed infants. The subjects will be chosen from the first 40 who meet the criteria and consent to participate in the study. A booklet, "Your Child's Health Record" will be given to the mother prior to her discharge which will enable her to keep a record of the frequency of respiratory, gastrointestinal and allergic disorders from birth to 12 weeks of age. The respiratory disorders will include the common cold, otitis media, bronchitis, and pneumonia. The gastrointestinal disorders will include vomiting, diarrhea and colic. The allergic disorders will be eczema, urticaria, and asthma. In addition, a brief feeding record of the infant will be obtained. Between two and three weeks postpartum an appointment will be made for the researcher to make a home visit and when the infant is about six to seven weeks old a telephone call will be made to ascertain the mother's ability to keep the booklet accurate and up to date. A final visit will be made when the infant is between 11 and 13 weeks of age to pick up the booklet for the final data collection. The confidentiality of the subjects will be maintained as the data will be coded and no names will be used. The subjects will have the right to withdraw without prejudice at any time during the study.

With your permission I would like to do a pilot study of four infants in September and begin the study data collection in October. I expect to complete the study by the end of December.

Space has been provided on the enclosed sheet for your reply. Thank you for your assistance.

Sincerely,

Sylvia Souza, R.N., B.S.

xc: F. Miller
C. Woodward

24932 Mound Street
Loma Linda, CA 92354
August 21, 1979

Dr. Abram Hodes
Chairman, Pediatrics Committee
San Bernardino Community Hospital
San Bernardino, CA 92411

Dear Dr. Hodes:

As a graduate student in nursing, I am investigating the effect of feeding patterns on infant health. This study is to meet part of the requirements for a master's degree in nursing at Loma Linda University. I am hereby requesting your permission to involve the mothers who deliver their babies at San Bernardino Community Hospital in the study. My advisor, Frances Miller, and the Loma Linda University Committee on Human Studies have approved this research study.

The proposed research will be a comparative study between bottle-fed and breast-fed infants. The subjects will be chosen from the first 40 who meet the criteria and consent to participate in the study. A booklet, "Your Child's Health Record" will be given to the mother prior to her discharge which will enable her to keep a record of the frequency of respiratory, gastrointestinal and allergic disorders from birth to 12 weeks of age. The respiratory disorders will include the common cold, otitis media, bronchitis, and pneumonia. The gastrointestinal disorders will include vomiting, diarrhea and colic. The allergic disorders will be eczema, urticaria, and asthma. In addition, a brief feeding record of the infant will be obtained. Between two and three weeks postpartum an appointment will be made for the researcher to make a home visit and when the infant is about six to seven weeks old a telephone call will be made to ascertain the mother's ability to keep the booklet accurate and up to date. A final visit will be made when the infant is between 11 and 13 weeks of age to pick up the booklet for the final data collection. The confidentiality of the subjects will be maintained as the data will be coded and no names will be used. The subjects will have the right to withdraw without prejudice at any time during the study.

With your permission I would like to do a pilot study of four infants in September and begin the study data collection in October. I expect to complete the study by the end of December.

Space has been provided on the enclosed sheet for your reply. Thank you for your assistance.

Sincerely,

Sylvia Souza, R.N., B.S.

xc: F. Miller
C. Woodward

24932 Mound Street
Loma Linda, CA 92354
August 21, 1979

Dr. John Miller
Chairman, OB/Gyn Committee
San Bernardino Community Hospital
San Bernardino, CA 92411

Dear Dr. Miller:

As a graduate student in nursing, I am investigating the effect of feeding patterns on infant health. This study is to meet part of the requirements for a master's degree in nursing at Loma Linda University. I am hereby requesting your permission to involve the mothers who deliver their babies at San Bernardino Community Hospital in the study. My advisor, Frances Miller, and the Loma Linda University Committee on Human Studies have approved this research study.

The proposed research will be a comparative study between bottle-fed and breast-fed infants. The subjects will be chosen from the first 40 who meet the criteria and consent to participate in the study. A booklet, "Your Child's Health Record" will be given to the mother prior to her discharge which will enable her to keep a record of the frequency of respiratory, gastrointestinal and allergic disorders from birth to 12 weeks of age. The respiratory disorders will include the common cold, otitis media, bronchitis, and pneumonia. The gastrointestinal disorders will include vomiting, diarrhea and colic. The allergic disorders will be eczema, urticaria, and asthma. In addition, a brief feeding record of the infant will be obtained. Between two and three weeks postpartum an appointment will be made for the researcher to make a home visit and when the infant is about six to seven weeks old a telephone call will be made to ascertain the mother's ability to keep the booklet accurate and up to date. A final visit will be made when the infant is between 11 and 13 weeks of age to pick up the booklet for the final data collection. The confidentiality of the subjects will be maintained as the data will be coded and no names will be used. The subjects will have the right to withdraw without prejudice at any time during the study.

With your permission I would like to do a pilot study of four infants in September and begin the study data collection in October. I expect to complete the study by the end of December.

Space has been provided on the enclosed sheet for your reply. Thank you for your assistance.

Sincerely,

Sylvia Souza, R.N., B.S.

xc: F. Miller
C. Woodward

24932 Mound Street
Loma Linda, CA 92354
August 21, 1979

Mrs. Alice Raumin
Director of Nursing
Redlands Community Hospital
Redlands, CA 92373

Dear Mrs. Raumin:

As a graduate student in nursing, I am investigating the effect of feeding patterns on infant health. This study is to meet part of the requirements for a master's degree in nursing at Loma Linda University. I am hereby requesting your permission to involve the mothers who deliver their babies at Redlands Community Hospital in the study. My research advisor, Frances Miller, and the Loma Linda University Committee on Human Studies have approved this research study.

The proposed research will be a comparative study between bottle-fed and breast-fed infants. The subjects will be chosen from the first 40 who meet the criteria and consent to participate in the study. A booklet, "Your Child's Health Record" will be given to the mother prior to her discharge which will enable her to keep a record of the frequency of respiratory, gastrointestinal and allergic disorders from birth to 12 weeks of age. The respiratory disorders will include the common cold, otitis media, bronchitis, and pneumonia. The gastrointestinal disorders will include vomiting, diarrhea and colic. The allergic disorders will be eczema, urticaria, and asthma. In addition, a brief feeding record of the infant will be obtained. Between two and three weeks postpartum an appointment will be made for the researcher to make a home visit and when the infant is about six to seven weeks old a telephone call will be made to ascertain the mother's ability to keep the booklet accurate and up to date. A final visit will be made when the infant is between 11 and 13 weeks of age to pick up the booklet for the final data collection. The confidentiality of the subjects will be maintained as the data will be coded and no names will be used. The subjects will have the right to withdraw without prejudice at any time during the study.

With your permission I would like to do a pilot study of four infants in September and begin the study data collection in October. I expect to complete the study by the end of December.

Space has been provided on the enclosed sheet for your reply. Thank you for your assistance.

Sincerely,

Sylvia Souza, R.N., B.S.

xc: F. Miller
C. Woodward

24932 Mound Street
Loma Linda, CA 92354
August 21, 1979

Dr. Harry Wang
Chairman, Pediatrics Committee
Redlands Community Hospital
Redlands, CA 92373

Dear Dr. Wang:

As a graduate student in nursing, I am investigating the effect of feeding patterns on infant health. This study is to meet part of the requirements for a master's degree in nursing at Loma Linda University. I am hereby requesting your permission to involve the mothers who deliver their babies at Redlands Community Hospital in the study. My research advisor, Frances Miller, and the Loma Linda University Committee on Human Studies have approved this research study.

The proposed research will be a comparative study between bottle-fed and breast-fed infants. The subjects will be chosen from the first 40 who meet the criteria and consent to participate in the study. A booklet, "Your Child's Health Record" will be given to the mother prior to her discharge which will enable her to keep a record of the frequency of respiratory, gastrointestinal and allergic disorders from birth to 12 weeks of age. The respiratory disorders will include the common cold, otitis media, bronchitis, and pneumonia. The gastrointestinal disorders will include vomiting, diarrhea and colic. The allergic disorders will be eczema, urticaria, and asthma. In addition, a brief feeding record of the infant will be obtained. Between two and three weeks postpartum an appointment will be made for the researcher to make a home visit and when the infant is about six to seven weeks old a telephone call will be made to ascertain the mother's ability to keep the booklet accurate and up to date. A final visit will be made when the infant is between 11 and 13 weeks of age to pick up the booklet for the final data collection. The confidentiality of the subjects will be maintained as the data will be coded and no names will be used. The subjects will have the right to withdraw without prejudice at any time during the study.

With your permission I would like to do a pilot study of four infants in September and begin the study data collection in October. I expect to complete the study by the end of December.

Space has been provided on the enclosed sheet for your reply. Thank you for your assistance.

Sincerely,

Sylvia Souza, R.N., B.S.

xc: F. Miller
C. Woodward

24932 Mound Street
Loma Linda, CA 92354
August 21, 1979

Dr. Joseph Mayo, II
Chairman, OB/Gyn Committee
Redlands Community Hospital
Redlands, CA 92373

Dear Dr. Mayo:

As a graduate student in nursing, I am investigating the effect of feeding patterns on infant health. This study is to meet part of the requirements for a master's degree in nursing at Loma Linda University. I am hereby requesting your permission to involve the mothers who deliver their babies at Redlands Community Hospital in the study. My research advisor, Frances Miller, and the Loma Linda University Committee on Human Studies have approved this research study.

The proposed research will be a comparative study between bottle-fed and breast-fed infants. The subjects will be chosen from the first 40 who meet the criteria and consent to participate in the study. A booklet, "Your Child's Health Record" will be given to the mother prior to her discharge which will enable her to keep a record of the frequency of respiratory, gastrointestinal and allergic disorders from birth to 12 weeks of age. The respiratory disorders will include the common cold, otitis media, bronchitis, and pneumonia. The gastrointestinal disorders will include vomiting, diarrhea and colic. The allergic disorders will be eczema, urticaria, and asthma. In addition, a brief feeding record of the infant will be obtained. Between two and three weeks postpartum an appointment will be made for the researcher to make a home visit and when the infant is about six to seven weeks old a telephone call will be made to ascertain the mother's ability to keep the booklet accurate and up to date. A final visit will be made when the infant is between 11 and 13 weeks of age to pick up the booklet for the final data collection. The confidentiality of the subjects will be maintained as the data will be coded and no names will be used. The subjects will have the right to withdraw without prejudice at any time during the study.

With your permission I would like to do a pilot study of four infants in September and begin the study data collection in October. I expect to complete the study by the end of December.

Space has been provided on the enclosed sheet for your reply. Thank you for your assistance.

Sincerely,

Sylvia Souza, R.N., B.S.

xc: F. Miller
C. Woodward

APPENDIX C

LETTERS GRANTING PERMISSION FOR THE RESEARCH PROJECT

Date: 9/18/79

Dear: Sylvia Souza

Your request for permission to collect data for your research project at San Bernardino Community Hosp has been received and reviewed. The following action has been taken:

✓ You have my permission to conduct your study in our facility.

___ Your request has been temporarily denied pending provision of additional information.

___ Your request cannot be granted at this time.

Also, it will be necessary for you to:

___ Obtain permission from the attending physician since your study involves patients and/or their records.

___ Obtain additional permission from _____.

___ Notify and/or advise the following persons of your study.

___ Make an appointment with _____ for additional discussion and information provision.

___ Other

If I can be of further help, please let me know.

Sincerely,

John Preston Williams M.D.

Date: 9/25/79

Dear: Sylvia Souza

Your request for permission to collect data for your research project at San Bernardino Comm. Hosp. has been received and reviewed. The following action has been taken:

X You have my permission to conduct your study in our facility.

___ Your request has been temporarily denied pending provision of additional information.

___ Your request cannot be granted at this time.

Also, it will be necessary for you to:

___ Obtain permission from the attending physician since your study involves patients and/or their records.

___ Obtain additional permission from _____.

___ Notify and/or advise the following persons of your study.

___ Make an appointment with _____ for additional discussion and information provision.

___ Other

If I can be of further help, please let me know.

Sincerely,

Abram Hoda M.D

Date: September 17th 1979

Dear: Ms. Souza

Your request for permission to collect data for your research project at San Bernadino Comm. Hospital has been received and reviewed. The following action has been taken:

✓ You have my permission to conduct your study in our facility.

___ Your request has been temporarily denied pending provision of additional information.

___ Your request cannot be granted at this time.

Also, it will be necessary for you to:

✓ Obtain permission from the attending physician since your study involves patients and/or their records.

___ Obtain additional permission from _____.

___ Notify and/or advise the following persons of your study.

___ Make an appointment with _____ for additional discussion and information provision.

___ Other

If I can be of further help, please let me know.

Sincerely,

Mary Jane Lucas R.N.
Director of Nursing Service

Date: 12 Sept 79

Dear: Sylvia Souza

Your request for permission to collect data for your research project at Redlands Com Hospital has been received and reviewed. The following action has been taken:

✓ You have my permission to conduct your study in our facility.

___ Your request has been temporarily denied pending provision of additional information.

___ Your request cannot be granted at this time.

Also, it will be necessary for you to:

___ Obtain permission from the attending physician since your study involves patients and/or their records.

___ Obtain additional permission from _____.

___ Notify and/or advise the following persons of your study.

___ Make an appointment with _____ for additional discussion and information provision.

___ Other

If I can be of further help, please let me know.

Sincerely,

Harry C. Wang MD
Chairman, Pediatrics Dept
Redlands Community Hospital

Date: 8/24/79

Dear: Ms. Souza

Your request for permission to collect data for your research project at Redlands Com. Hosp. has been received and reviewed. The following action has been taken:

____ You have my permission to conduct your study in our facility.

____ Your request has been temporarily denied pending provision of additional information.

____ Your request cannot be granted at this time.

Also, it will be necessary for you to:

✓ Obtain permission from the attending physician since your study involves patients and/or their records.
the proposal will have to be presented to the OB-Gyn department meeting 9/24/79.

____ Obtain additional permission from _____.
Also the Pediatrics department may wish to discuss this. Please contact me by phone 793-3311 just prior to the

____ Notify and/or advise the following persons of your study.

____ Make an appointment with Dept. OB-Gyn meeting to for additional discussion and information provision.

____ Other will gladly present your proposal.

If I can be of further help, please let me know.

Sincerely,

(Ms Souza MS

Date: 9/17/79

Dear: Sylvia Souza RN

Your request for permission to collect data for your research project at Redlands Community Hospital has been received and reviewed. The following action has been taken:

✓ You have my permission to conduct your study in our facility.

___ Your request has been temporarily denied pending provision of additional information.

___ Your request cannot be granted at this time.

Also, it will be necessary for you to:

✓ Obtain permission from the attending physician since your study involves patients and/or their records. Not for each Dr. that there is involved -

___ Obtain additional permission from ____________________.

___ Notify and/or advise the following persons of your study.
The Pediatric Dept has given permission for your study - Also OB-Gyn Comm. has given approval -

___ Make an appointment with ____________________ for additional discussion and information provision.

___ Other

If I can be of further help, please let me know.

Sincerely,

Alice Raumi
Director of Nursing Service
Redlands Community Hospital

Date: 9-4-79

Dear: Sylvia

Your request for permission to collect data for your research project at LLUHC has been received and reviewed. The following action has been taken:

✓ You have my permission to conduct your study in our facility.

___ Your request has been temporarily denied pending provision of additional information.

___ Your request cannot be granted at this time.

Also, it will be necessary for you to:

✓ Obtain permission from the attending physician since your study involves patients and/or their records.

✓ Obtain additional permission from Pediatricians.

___ Notify and/or advise the following persons of your study.

___ Make an appointment with _____ for additional discussion and information provision.

___ Other

If I can be of further help, please let me know.

Sincerely,

Veronica Brady

I will be very interested in the outcome of your study. Do keep me informed!

Date: 8/24/79

Dear: Sylvia

Your request for permission to collect data for your research project at LLUMC has been received and reviewed. The following action has been taken:

✓ You have my permission to conduct your study in our facility.

___ Your request has been temporarily denied pending provision of additional information.

___ Your request cannot be granted at this time.

Also, it will be necessary for you to:

✓ Obtain permission from the attending physician since your study involves patients and/or their records.

___ Obtain additional permission from _____.

✓ Notify and/or advise the following persons of your study.
Veronica Bender, Head Nurse 3200
Julie Sanderson, " " L+D

___ Make an appointment with _____ for additional discussion and information provision.

___ Other

If I can be of further help, please let me know.

Sincerely,

Marilyn Thurgood

LOMA LINDA UNIVERSITY MEDICAL CENTER

Date: 8-24-79

Dear: Lydia Sousa:

Your request for permission to collect data for your research project at Loma Linda University Medical Center has been received and reviewed. The following action has been taken:

✓ You have my permission to conduct your study in our facility.

___ Your request has been temporarily denied pending provision of additional information.

___ Your request cannot be granted at this time.

Also, it will be necessary for you to:

✓ Obtain permission from the attending physician since your study involves patients and/or their records.

___ Obtain additional permission from _____.

✓ Notify and/or advise the following persons of your study.
Marilyn Blanquet, Director
Parent/Child Module

___ Make an appointment with _____
for additional discussion and information provision.

___ Other

If I can be of further help, please let me know.

Sincerely,

Gertrude L. Haussler

Gertrude L. Haussler, M.S.
Assistant Administrator
Nursing

Date: 9-21-79

Dear: Sylvia Shaw

Your request for permission to collect data for your research project at _____ has been received and reviewed. The following action has been taken:

✓ You have my permission to conduct your study in our facility.

____ Your request has been temporarily denied pending provision of additional information.

____ Your request cannot be granted at this time.

Also, it will be necessary for you to:

____ Obtain permission from the attending physician since your study involves patients and/or their records.

____ Obtain additional permission from _____.

____ Notify and/or advise the following persons of your study.

____ Make an appointment with _____ for additional discussion and information provision.

____ Other

If I can be of further help, please let me know.

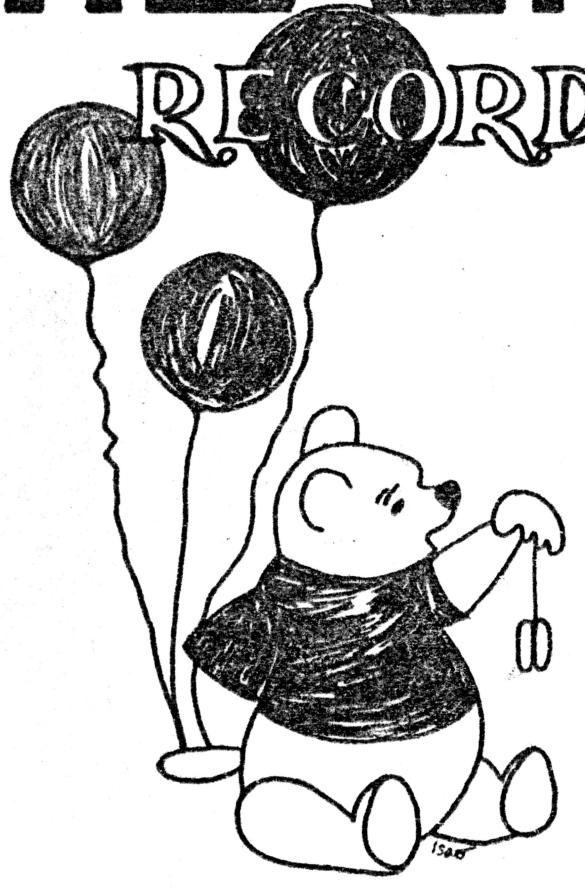
Sincerely,

[signature]

APPENDIX D

HEALTH RECORD BOOKLET FOR BREAST-FED INFANTS

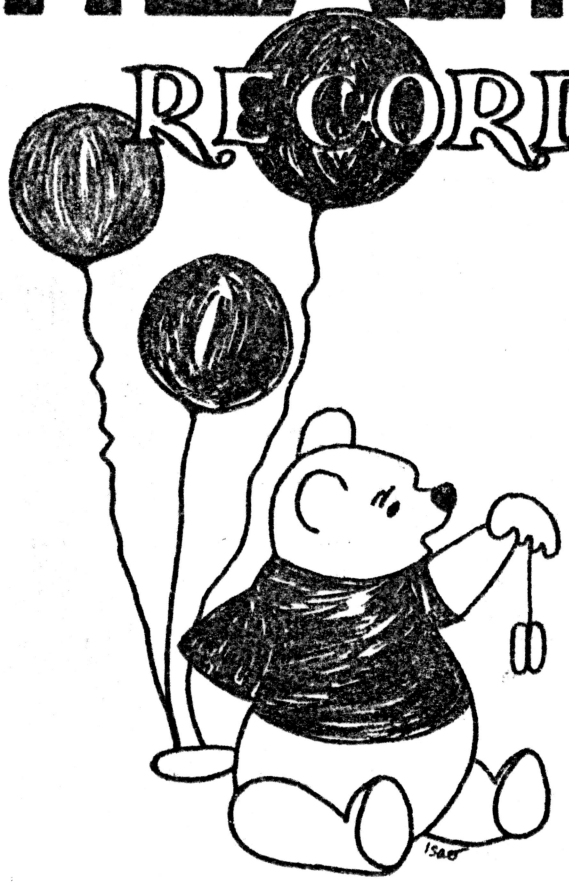
YOUR CHILD'S HEALTH RECORD



APPENDIX E

HEALTH RECORD BOOKLET FOR BOTTLE-FED INFANTS

YOUR CHILD'S HEALTH RECORD



APPENDIX F

BIOGRAPHICAL INFORMATION SHEET FOR SELECTION OF SAMPLE MOTHERS

BIOGRAPHICAL INFORMATION SHEET FOR SELECTION OF SAMPLE MOTHERS

*1. Primapara
   a. acceptable = yes
   b. unacceptable = no

*2. Age of mother: _____
   a. acceptable = 18-35 years old
   b. unacceptable = under 18 or over 35

*3. Race:
   a. Caucasian
   b. Black
   c. Mexican-American
   d. Oriental
   e. Other_____

*4. Education of mother:
   a. acceptable = at least two years of high school education
   b. unacceptable = have not had two years of a high school education

*5. Maternal physical or mental disabilities:
   a. acceptable = no disabilities
   b. unacceptable = disabilities present

*6. History of family allergies: asthma, urticaria, eczema
   a. acceptable = none
   b. unacceptable = allergies present

*7. Mother smokes cigarettes:
   a. acceptable = no
   b. unacceptable = yes

Name_____

Address_____

_____

Telephone number_____

Hospital number_____

Breast-feeding_____ Bottle-feeding_____

*Critical criteria
acceptable = fits criteria
unacceptable = does not fit criteria

APPENDIX G

BIOGRAPHICAL INFORMATION SHEET FOR SELECTION OF SAMPLE INFANTS

BIOGRAPHICAL INFORMATION SHEET FOR SELECTION OF SAMPLE INFANTS

1. Sex:
   a. male
   b. female

2. Infant's date of birth _____

*3. Infant birth weight: _____
   a. acceptable = more than 2500 grams (5 lb. 8 oz.)
   b. unacceptable = less than 2500 grams (5 lb. 8 oz.)

*4. Gestational age: _____
   a. acceptable = 38-42 weeks gestation
   b. unacceptable = less than 38 weeks or more than 42 weeks gestation

*5. Diagnosed a premature or postmature at birth:
   a. acceptable = no
   b. unacceptable = yes

*6. Admission to the Nursery Intensive Care Unit:
   a. acceptable = no
   b. unacceptable = yes

*7. Siblings under 10 years of age at home:
   a. acceptable = no
   b. unacceptable = yes

*Critical criteria
acceptable = fits criteria
unacceptable = does not fit criteria

APPENDIX H

PROCEDURE OF INFORMED CONSENT FOR BREAST-FED INFANTS

PROCEDURE OF INFORMED CONSENT FOR BREAST-FED INFANTS

The researcher will state the following to the parents:

"My name is Sylvia Souza and I am a graduate student in nursing. As part of the requirements for my master's degree, I am trying to find out how many illnesses your baby has in his/her first three months."

"You will be given a booklet entitled 'Your Child's Health Record.' This booklet will be divided into three sections."

"The first section will contain my name and home telephone number. If at any time during the study you have questions please feel free to call me. I will only answer questions concerning how to record in the booklet. I cannot tell you how to manage your baby's illnesses, rather your pediatrician or nurse practitioner should be the one contacted. This section will also have the definition of the illnesses that I will be recording along with some examples on how to write in the booklet."

"The second section will be the section on which you will record your baby's illnesses. Here you will state when and for how long your baby has the following illnesses: vomiting, diarrhea, colic, common cold, otitis media, bronchitis, pneumonia, eczema, hives, and asthma."

"The third section to the booklet will contain a brief diet record of your infant. Please state in the appropriate box what type and amount of solid foods your baby has had for the week. There is another box in which you will be asked if you are still breast-feeding, and also how often you supplement your baby with formula. If you have discontinued breast-feeding please state your reason for doing so and contact me."

"This study will last for about 12 weeks. The first week will begin on the day you and your baby are discharged from the hospital together. I will call you at home in about 2-3 weeks to make an appointment to visit you at home. At this time, I will answer any questions you have about how to record in the booklet. I will then make a telephone call when your baby is 6-7 weeks old once again to see how you are managing with the recording. I will then make a final home visit when your baby is about 12 weeks old to obtain the 'Your Child's Health Record' booklet."

APPENDIX I

PROCEDURE OF INFORMED CONSENT FOR BOTTLE-FED INFANTS

PROCEDURE FOR INFORMED CONSENT FOR BOTTLE-FED INFANTS

The researcher will state the following to the parents:

"My name is Sylvia Souza and I am a graduate student in nursing. As part of the requirements for my master's degree, I am trying to find out how many illnesses your baby has in his/her first three months."

"You will be given a booklet entitled 'Your Child's Health Record.' This booklet will be divided into three sections."

"The first section will contain my name and home telephone number. If at anytime during the study you have questions please feel free to call me. I will only answer questions concerning how to record in the booklet. I cannot tell you how to manage your baby's illnesses, rather your pediatrician or nurse practitioner should be the one contacted. This section will also have the definition of the illnesses that I will be recording along with some examples on how to write in the booklet."

"The second section will be the section in which you will record your baby's illnesses. Here you will state when and for how long your baby has the following illnesses: vomiting, diarrhea, colic, common cold, otitis media, bronchitis, pneumonia, eczema, hives, and asthma."

"The third section to the booklet will contain a brief diet record of your infant. Please state in the appropriate box what type and amount of solid foods your baby has had for the week. State the formula brand that you are using and if you changed formulas write its name under the column, Infant Current Formula, and in the next column give a reason for the change."

"This study will last for about 12 weeks. The first week will begin on the day you and your baby are discharged from the hospital together. I will call you at home in about 2-3 weeks to make an appointment to visit you at home. At this time, I will answer any questions you have about how to record in the booklet. I will then make a telephone call when your baby is 6-7 weeks old once again to see how you are managing with the recording. I will then make a final home visit when your baby is about 12 weeks old to obtain the 'Your Child's Health Record' booklet."

APPENDIX J

CONSENT FORM FOR PARTICIPANTS

CONSENT FORM

I have been told that the purpose of this study is to investigate the effects of feeding patterns and infant health.

It has been explained to me fully and I am aware that as a participant in this study:

1. I will be visited by the nurse when my baby is 2-3 weeks old and again when my baby is 12 weeks old.

2. The nurse will telephone me when my baby is 6-7 weeks old to ask some questions.

3. I will be asked to keep a record of the number of illnesses my baby has had up to the age of three months.

4. I will be asked to keep a record of my baby's diet.

5. I have been given an opportunity to ask questions and they have been satisfactorily answered.

"It has been explained to me and I am aware that participation in this research project is voluntary and that I have the right to withdraw from it at any time without incurring any disadvantages to myself or to my child. Any and all information obtained through this study will be treated in a confidential manner. Reports or publications resulting from this study will not contain any information which might lead to my identification as a participant in the study.

"I have considered all of the above statements and hereby give my free and voluntary consent to participate in A Study of Feeding Patterns and Infant Health, under the supervision of Sylvia Souza, R.N., graduate student in nursing, Loma Linda University, and in witness thereof, I have signed this consent."

_____ _____

Signature Date

_____

Witness

CONSENT FORM

I have been told that the purpose of this study is to investigate the effects of feeding patterns and infant health.

It has been explained to me fully and I am aware that as a participant in this study:

1. I will be visited by the nurse when my baby is 2-3 weeks old and again when my baby is 12 weeks old.
2. The nurse will telephone me when my baby is 6-7 weeks old to ask some questions.
3. I will be asked to keep a record of the number of illnesses my baby has had up to the age of three months.
4. I will be asked to keep a record of my baby's diet.
5. I have been given an opportunity to ask questions and they have been satisfactorily answered.

"It has been explained to me and I am aware that participation in this research project is voluntary and that I have the right to withdraw from it at anytime without incurring any disadvantages to myself or to my child. Any and all information obtained through this study will be treated in a confidental manner. Reports or publications resulting from this study will not contain any information which might lead to my identification as a participant in the study."

"I have considered all of the above statements and hereby give my free and voluntary consent to participate in A Study of Feeding Patterns and Infant Health, under the supervision of Sylvia Souza, R.N., graduate student in nursing, Loma Linda University, and in witness thereof, I have signed this consent."

_____ _____

Signature Witness

_____

Date