

THE EFFECTS OF A NUTRITION INTERVENTION
PROGRAM DURING PREGNANCY:
PHASE TWO

by
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A dual thesis submitted to the faculty of
The University of Utah
in partial fulfillment of the requirements for the degree of

Master of Science

College of Nursing
The University of Utah

June 1984

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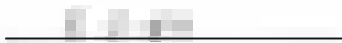
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ABSTRACT

This study sought to identify the effects of an individual prescription for protein and kilocalorie requirements during pregnancy on subsequent maternal and infant outcomes using an experimental control group with 29 subjects in phase one and 18 subjects in phase two. The method of nutritional counseling was not found to have a significant impact on increasing the amounts of protein and kilocalories consumed by the experimental group in phase two; findings indicate that those subjects who ate an adequate amount of both protein and kilocalories did not have significantly larger birthweight infants than those who had inadequate nutritional intake ($p=.10$, two-tailed test, twin births excluded). However, those women who had an adequate early weight gain in addition to adequate prescription ingestion as compared to those with inadequate early weight gain and inadequate prescription ingestion, gained significantly more weight ($p=.00072$) and showed a trend toward higher birthweight infants ($p=.09$, two-tailed test, twin births excluded).

CONTENTS

| | |
|---------------------------|-----|
| ABSTRACT. | iv |
| LIST OF TABLES. | vii |
| LIST OF FIGURES | x |
| ACKNOWLEDGMENTS | xi |

Chapter

| | |
|---|----|
| I. INTRODUCTION | 1 |
| Problem Statement. | 4 |
| Purpose. | 5 |
| Conceptual Framework | 5 |
| II. REVIEW OF THE LITERATURE | 10 |
| Montreal Diet Dispensary | 22 |
| Hypotheses | 24 |
| Assumptions. | 26 |
| Limitations. | 27 |
| III. METHODOLOGY. | 28 |
| Design | 28 |
| Sample | 29 |
| Instrumentation. | 31 |
| Procedure. | 35 |
| IV. RESULTS AND DISCUSSION | 42 |
| Sample | 42 |
| Characteristics of the Study Group | 44 |
| Nutrition Prescription | 56 |
| Reliability and Compliance of the Subjects | 63 |
| Hypotheses | 69 |
| Comparison of Protein and Kilocalorie Ingestion After Twenty Weeks | 83 |
| Outcome Data | 85 |
| Significant Correlations Between Variables | 95 |
| V. SUMMARY AND RECOMMENDATIONS. | 97 |

Appendices

| | |
|---|-----|
| A. NUTRITIONAL FORMS. | 101 |
| B. STUDY FORMS. | 117 |
| C. NUTRITIONAL ASSESSMENT AND COUNSELING APPROACHES . . . | 130 |
| D. COMPARISONS BETWEEN GROUPS WITH TWIN BIRTHS INCLUDED . | 136 |
| SELECTED BIBLIOGRAPHY | 138 |

LIST OF TABLES

| | |
|---|----|
| 1. Comparison of Demographic Data Between the Experimental and Control Groups. | 46 |
| 2. Comparison of Previous Obstetrical History Between the Experimental and Control Groups. | 48 |
| 3. Comparison of Anthropometric Measures Between Experimental and Control Groups. | 51 |
| 4. Comparison of Personal Health Hazards Between the Experimental and Control Groups. | 52 |
| 5. Comparison of Study Contacts Between the Experimental and Control Groups. | 54 |
| 6. Comparison of WIC Participation Between the Experimental and Control Groups. | 55 |
| 7. Comparison of Medications Used in Pregnancy Between the Experimental and Control Groups. | 57 |
| 8. Comparison of Estimated Protein and Kilocalorie Ingestion Prior to the Initial Assessment Between the Experimental and Control Groups. | 58 |
| 9. Comparison of Protein and Kilocalorie Ingestion at Initial Assessment Between the Experimental and Control Groups | 60 |
| 10. Comparison of the Components in the Nutritional Prescription Between the Experimental and Control Groups | 61 |
| 11. Comparisons of Additions for Corrective Allowances Between the Experimental and Control Groups. | 62 |
| 12. Comparison of the Categories for Nutritional Stress Between the Experimental and Control Groups. | 64 |
| 13. Comparison of the Reliability of Nutritional Information Given by Subjects in the Experimental and Control Groups. | 65 |

| | | |
|-----|---|-----|
| 14. | Compliance with the Nutritional Prescription by the Subjects in the Experimental Group. | 68 |
| 15. | Birthweights and Maternal Complications in Women with Low Pregravid Weight | 71 |
| 16. | Birthweights and Maternal Complications in Women With Inadequate Early Pregnancy Weight Gain and Failure to Meet Their Nutritional Prescription Thereafter. | 74 |
| 17. | Comparison of Maternal Weight Gain, Maternal Complications and Their Infants' Birth- weights with Nutrition Prescription Ingestion After 20 Weeks | 78 |
| 18. | Early Pregnancy Weight Gain and Prescription Ingestion After 20 Weeks Compared with Maternal Weight Gain, Maternal Complications and Their Infants' Birthweights. | 81 |
| 19. | Comparison of Prescription Ingestion for Entire Study Period Between the Experimental and Control Groups | 84 |
| 20. | Comparison of Maternal Weights Between the Experimental and Control Groups. | 86 |
| 21. | Comparison of Labor and Delivery Procedures Between the Experimental and Control Groups. | 88 |
| 22. | Comparison of Infant Sex Between the Experimental and Control Groups. | 89 |
| 23. | Comparison of Antepartal Complications Between the Experimental and Control Groups. | 90 |
| 24. | Comparison of Intrapartal Complications Between the Experimental and Control Groups. | 92 |
| 25. | Comparison of Postpartal Complications Between Experimental and Control Groups. | 93 |
| 26. | Comparison of Infant Outcomes Between the Experimental and Control Groups. | 94 |
| 27. | Significant Correlations Between Variables | 96 |
| 28. | Frame Size--Female | 107 |
| 29. | Table of Desirable Weights for Women | 108 |

| | |
|--|-----|
| 30. Canadian Dietary Standards for Adults, 1948. | 109 |
| 31. Group Comparisons with Twin Birthweights Included | 137 |

LIST OF FIGURES

| | |
|--|----|
| 1. Hypothesized relationships of effects of nutrition on baby outcome. | 7 |
| 2. An initial model for a participative process of nutritional counseling in pregnancy | 8 |
| 3. Distribution of subjects into subgroups. | 38 |
| 4. Final sample breakdown | 98 |

ACKNOWLEDGMENTS

I wish to thank several people for their support and encouragement throughout this project. First, to my husband, Chuck, who helped me through graduate school by his constant patience and loving encouragement. Second, to our committee members whose guidance and knowledge made it possible to benefit from this research experience. Third, a special thanks to Carol Sweeney for her expert counsel. Fourth, to my classmates whose sense of humor and continual support made it all worthwhile.

-Janet Chandler Place

This thesis would not have been possible without the support and encouragement of many persons. Appreciation is extended to the members of my Supervisory Committee, Joyce Foster, Chairman, Neil Kochenour, and Barbara Prater for their continued interest, guidance, and support during the preparation of the second phase of this study. Appreciation is extended to Clinic III, to labor and delivery, postpartum and newborn nursery nurses at the University of Utah Medical Center for their cooperation and assistance.

My classmates each deserve a sincere note of thanks for they have meant more to me than they could possibly know.

A special thank you to my friends, especially Janet Place, my thesis partner, and Frenchie Burnett, both of whom have served as a steadfast source of comfort, endless encouragement, support

and love throughout the formation and writing of this manuscript.

Deepest appreciation and gratitude is given to my parents, Lloyd and Tillie Specht, and brother Darren for their love and encouragement through times of trial and triumph and to Jim, Cheryl and Hannah Joy Specht for reminding me about the miracle of birth.

Finally, I sincerely thank all of the mothers and babies who participated in this study and for whom I have had the honor to care for in years past.

-Jean Marie Specht

CHAPTER I

INTRODUCTION

It is widely accepted that maternal nutrition affects infant outcome. To what extent, and by what means these effects occur have remained an area of controversy. The diets of pregnant women have been subject to numerous encouragements and restrictions over the past several decades, some of which proved ultimately harmful. There is currently no general consensus on what to specifically advise the pregnant woman to eat during her pregnancy, or even what is optimal weight gain. The recommended balance of protein, carbohydrates, fats, and kilocalories has varied widely among practitioners. Questions on how maternal nutrition affects fetal mortality and morbidity, and the effects of a nutritionally-balanced diet throughout pregnancy on labor, delivery, and the postpartum remain unanswered.

The emphasis has shifted toward having quality pregnancies and outcomes, rather than quantity. The "perfect" baby is expected, especially by those couples who are having fewer children. We, as health care providers, cannot guarantee a perfect outcome to any couple. Hopefully, what we can provide is sound advice on how to maximize the chances of an optimal outcome of pregnancy.

In addition to the hardship on the family of a less-than-perfect infant, the impact on society is significant. With any handicapped

infant comes the cost of rehabilitation and treatment until recovery, long-term stabilization, or death ensues. It has been estimated that the cost of maintaining a defective child throughout life is more than \$100,000 (Higgins, Crampton & Moxley, 1972). In addition to this cost is the cost to society in the loss of a productive citizen. It is known that infants who are growth retarded at birth often have an increased rate of long-term mental and motor impairment (Naeye, 1981). Because it is considerably less expensive to prevent maternal and infant morbidity than to cure it, the factors important in reducing morbidity become a great concern to both health care providers giving the care and society and individuals paying for the care. The cost of perinatal morbidity and mortality is not a hardship which the family concerned should bear alone, but also should become the concern of health personnel and politicians.

Nutrition is one area that is known to affect birth outcome. What the mother eats, as reflected by diet recall and weight gain, has a significant bearing on the health of her infant. The Collaborative Study of Cerebral Palsy (Singer, Westphal & Niswander, 1968) found that a greater maternal weight gain in pregnancy was related to both increased infant birthweight and growth and performance during the infant's first year of life. Low birthweight infants have a higher mortality rate as well as an increased incidence of mental retardation, cerebral palsy, learning problems and disabilities, visual and hearing defects, neurological defects and poor infant growth and development (Singer et al., 1968). Traditionally,

low birthweight has been defined as less than 2500 grams; however, those infants who weigh between 2500 and 3000 grams at birth have a three times greater mortality rate than the 3000 to 3500 gram birthweight infants. The 2500 to 3000 gram birthweight infants are at higher risk for the morbidity factors, which affect the less than 2500 gram birthweight infants (Ontario Department of Health, 1967; State of California Department of Health, 1976; Rooth, 1976). With the higher mortality and morbidity rates of the under 3000 gram birthweight infants, it is significant that in 1980 at the time of the last census, 23% of all live births in the United States weighed less than 3000 grams (Public Health Service, 1982).

As little as 120 grams in mean birthweight of two groups may make a significant difference in pregnancy outcome. In two studies (Higgins, 1975; Susser & Rush, 1973) a mean difference of 120 grams between private and public patients in Montreal, and between white and black patients in New York was found. The 120 gram mean difference was in favor of the private patients in Montreal and in the white patients in New York. This may have contributed to the 50% increase in perinatal mortality and a 60% increase in low birthweight infants in public patients (Higgins, 1975), and twice the infant mortality among the black patients (Susser & Rush, 1973).

Low prepregnant weight also affects pregnancy outcome. It is found that when women start out pregnancy underweight, they deliver infants at a younger gestational age and of lower birthweights and lengths (Brown, Jacobson, Askue & Peick, 1981; Tompkins & Wiehl, 1954). A low maternal weight before pregnancy was cited

by Leader, Wong, and Deitel (1981) as the second leading determinant of low birthweight and contributes to a disproportionate amount of neonatal mortality. Rosso (1981) found that mean weight of infants increased as prepregnancy weight in relation to ideal weight of the mothers increased. The data suggested that mothers who had a postpartum weight at least ten percent higher than their ideal body weight had provided the fetus with a maternal environment that was optimum for fetal development.

Maternal nutrition also affects prepregnancy outcome in terms of maternal morbidity. Pregnant women who are of low weight starting into the pregnancy are at greater risk for complications such as pregnancy induced hypertension, antepartum hemorrhage, and premature labor (Leader et al., 1981; Pitkin, 1981). An adequate weight gain during pregnancy is necessary to lay down maternal stores sufficient enough to stay the mother through fetal demands, lactation, and an unexpected period of deprivation.

The certified nurse-midwife (CNM) is intimately involved with the assessment and counseling of the pregnant client. The CNM is concerned with providing individualized care to the maternal/fetal unit and nutrition counseling is an important aspect of this care. Determining the client's requirements according to her height, ideal weight, body frame, activity level, and stress factors may be an important part of health care for the prevention of maternal and infant morbidity and mortality.

Problem Statement

The problem of this study was to identify the effects of an

individual prescription for protein and kilocalorie requirements during pregnancy on subsequent maternal and infant outcomes.

Purpose

The purpose of this work was to compare the effects of the Higgins Method for Nutritional Intervention in Pregnancy in a randomized, experimental control group design, viewing maternal weight, complications, and infant birthweights. The effects were also compared in relation to maternal pregravid weight. The researchers were involved in serial dietary intake analysis in the second half of pregnancy with a group of essentially normal pregnant women. Comparisons were then made on pregravid weight, pregnancy weight gain and protein/kilocalorie ingestion between the intervention and nonintervention groups.

Due to the large sample size needed to allow for adequate data analysis of eight subgroups, this study was the second phase of an ongoing project. Data collected from this study are reported in combination with data collected in phase one from researchers Carol Sweeney and Helen Smith. Phase one data collection was done from August 1 to October 15, 1982 (Smith & Sweeney, 1983).

Conceptual Framework

The conceptual framework consists of two parts: a) a hypothesized model for physiologic action between maternal nutritional intake before and during pregnancy and maternal fetal relationships leading to optimal fetal growth and development, and b) an initial model of a participative process of nutritional counseling in which

the client is made aware of her nutritional needs, current intake, and required food additions for optimal outcome as a basis for client action (Smith & Sweeney, 1983).

The first conceptual model (Figure 1) was originally developed by Dr. Joyce Foster (1981) and shows the hypothesized relationship of the effects of nutrition on fetal outcome. This model emphasized that adequate food intake and absorption will lead to an adequate pregravid weight as well as adequate weight gain during pregnancy. This, in turn, will lead to an increase in maternal body mass, plasma volume and nutrient load available to the placenta. These factors lead to a healthy placenta, and optimal neonatal weight and health.

The second conceptual model (Figure 2), also developed by Dr. Foster (1981), shows the hypothesized effect of a participative process of nutritional counseling in pregnancy. This model describes the interaction which takes place between the client and health care provider. The client initially provides the demographic data necessary for the provider to develop the individual nutrition prescription. The provider uses that information, and develops an individual plan based on height, ideal weight, body frame, activity level, and stress factors. The provider assesses what motivational factors would be effective in getting the client to accept the dietary prescription and in implementing it. These factors are shared and the client, with appropriate counseling, intakes the required food additions. Serial evaluation of nutritional intake is done by the provider, with modifications of the prescription done as appropriate. The client implements the required

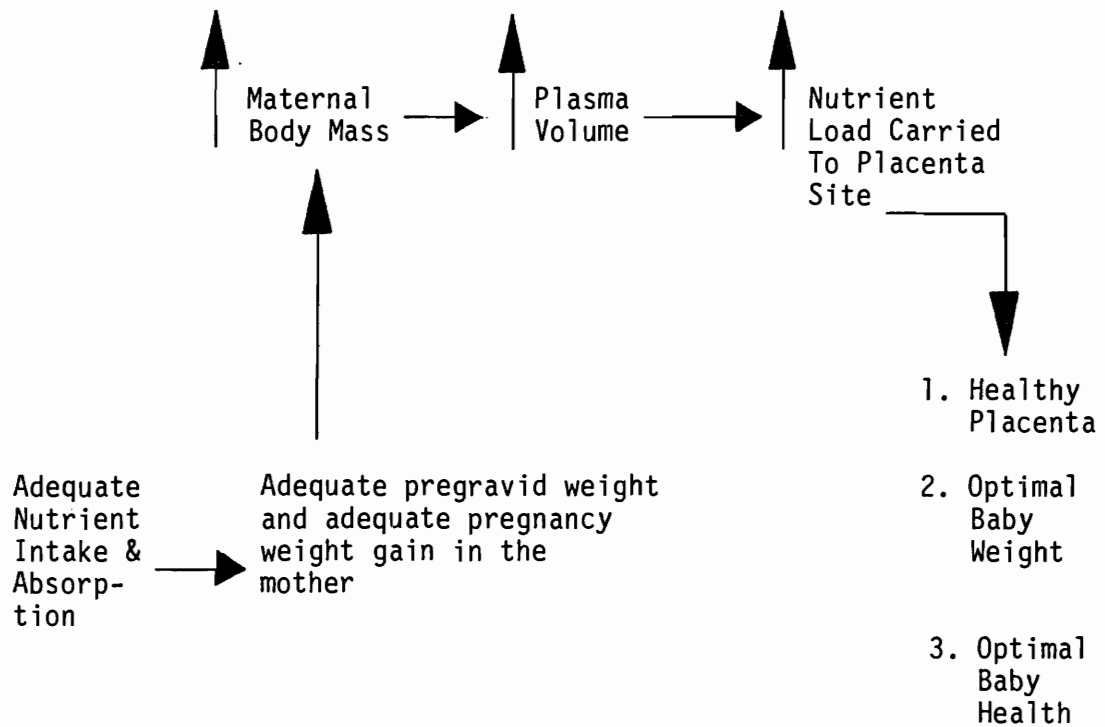


Figure 1. Hypothesized relationships of effects of nutrition on baby outcome (Foster, 1981).

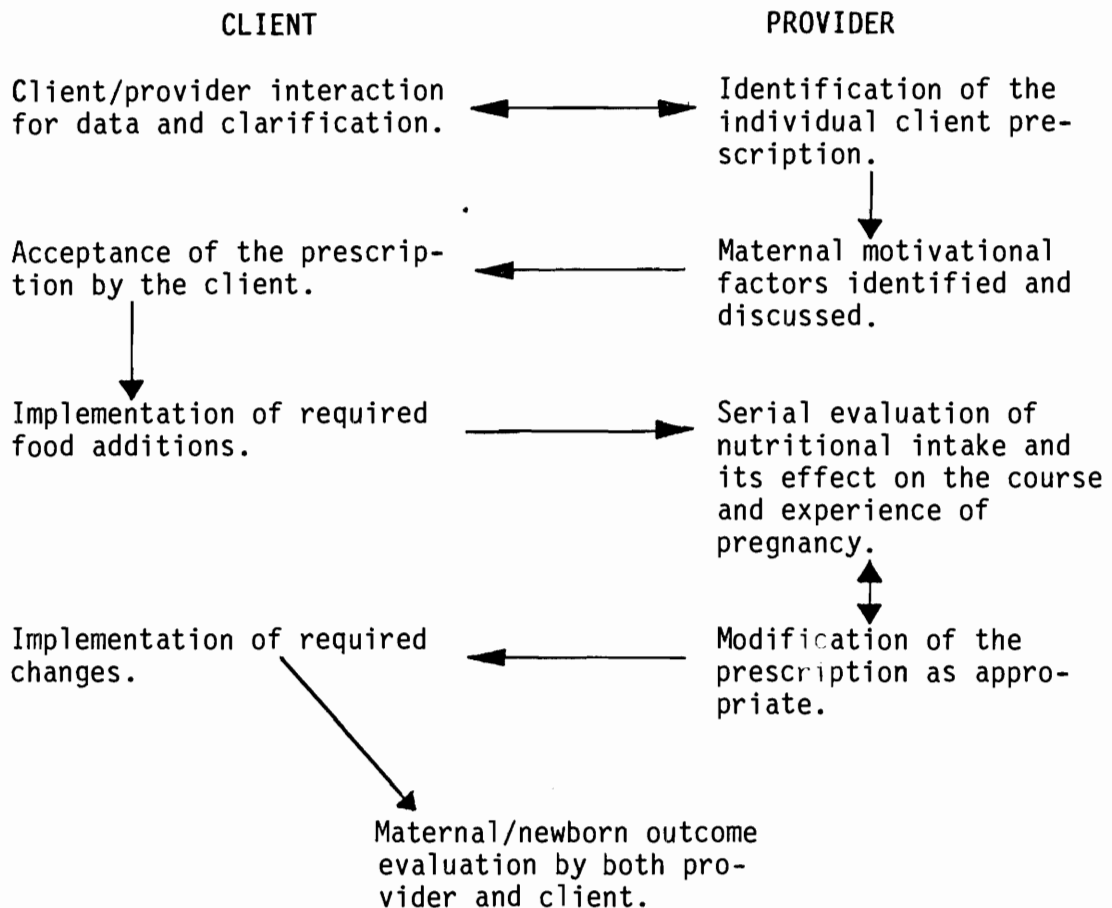


Figure 2. An initial model for a participative process of nutritional counseling in pregnancy (Foster, 1981).

changes to her diet as counseled by the provider. Maternal and newborn outcomes are evaluated by the provider and the client in the form of maternal and newborn variables.

CHAPTER II

REVIEW OF THE LITERATURE

The review of literature covered the period between 1940 and 1983. World War II provided a unique set of situations in which the effects of maternal nutrition on infant outcomes could be studied. The seige of Leningrad lasted for 18 months during which time food was scarce and maternal nutrition poor. There was a resulting increase in low birthweight infants, stillbirths, prematurity and infant mortality rates (Antonov, 1947). The famine in Holland during the winter of 1944-45 placed maternal nutrition at starvation levels. Infants affected by the starvation diets in the last trimester of pregnancy had a substantial reduction in birthweights compared with the more normal birthweights of infants whose last trimester of pregnancy occurred after the famine was over (Smith, 1947). In Britain, extra food was rationed to all pregnant women whenever possible during the war. Overall, the diet of low-income pregnant women was greatly improved, whereas all conditions other than nutrition were reported to have deteriorated. With the improved diet there was an increased reduction in the stillbirth, prematurity and neonatal death rates (Jameson, 1947).

Burke (1948) studied 216 pregnant women serially throughout pregnancy to determine the effect of diet on maternal and infant outcomes. The women's diets during pregnancy were assessed and

the women categorized as having either excellent, good, fair, or poor diets. The study found a strong relationship between good and excellent diets of the mother during pregnancy and their infants having a good physical condition at birth. Mothers with a poor maternal diet had infants with poor physical conditions at birth, including low birthweight, major congenital defects, stillbirths or neonatal deaths. Good and excellent diets also corresponded with a lower incidence of complications during pregnancy, than in the women who had poor diets in pregnancy.

More recent studies have dealt with specific factors and their relationship to maternal and infant outcome. Factors such as pre-gravid weight, maternal weight gain in pregnancy and supplementation to maternal diets are identified as having a significant relationship with maternal and infant outcomes.

The woman's nutritional state prior to pregnancy reflects the amount of reserve stores the mother has available to draw upon during pregnancy to meet the increased energy needs for her and the fetus. Several studies (Eastman & Jackson, 1968; Gormican, Valentine & Satter, 1980; Peckham & Christianson, 1971; Simpson, Lawless & Mitchell, 1975) have shown that there is a positive relationship between the mother's pregravid weight and the infant's birthweight. Tompkins and Wiehl (1954) found that mothers who are greater than 5% underweight have the highest percentage of low birthweight infants. Underweight women also run a high risk of antepartum bleeding (Peckham & Christianson, 1971), toxemia and premature infants (Tompkins & Wiehl, 1954) and a higher incidence of fetal

and neonatal deaths (Naeye, 1979).

Maternal weight gain during pregnancy indicates the increased amount of energy utilized for fetal growth and maternal stores. Studies (Gormican et al., 1980; Love & Kinch, 1965; Singer et al., 1968; Weiss & Jackson, 1969) have shown that as maternal weight increased during pregnancy there is a corresponding increase in infant birthweight. This correlation holds even when gestational age and maternal height are controlled. Researchers found in the Collaborative Study of Cerebral Palsy (Singer et al., 1968) that an increase in maternal weight gain resulted in a decrease of premature deliveries, and an improved growth rate and performance in the infant's first year of life. Tompkins and Wiehl (1954) found that a weight loss or a gain of less than five pounds in the first trimester is associated with an increased risk of premature labor. Van den Berg (1981) found that a weight gain of less than 0.5 pounds per week in the last half of pregnancy more than doubled the incidence of infants with birthweights less than 2500 grams.

Eastman and Jackson (1968) have studied over 25,000 pregnant women and observed that pregravid weight and maternal weight gain act independently of each other and are additive in their effects. When both pregravid weight and maternal weight gain are high, large infants resulted. When both are low, infants had low birthweights. When one variable was high and the other low, infants were born with birthweights between the two extremes. Another study (Simpson et al., 1975) showed a significant increase in infants with birthweights less than 2500 grams occurring in the low pregravid weight

and low weight gain group. Tompkins and Wiehl (1954) found that low pregravid weight combined with low weight gain in pregnancy was associated with an increased risk of premature labor.

Several studies have reported the relationship between supplementing maternal diets in pregnancy and maternal and/or infant outcome. An early study (Ebbs, Tisdall & Scott, 1941) compared a group of pregnant women on poor diets, the majority consuming less than 60 grams of protein a day and 1700 kilocalories a day, with those pregnant women who were on supplemented diets or already had a good diet and were given nutritional advice. The majority of these women consumed more than 80 grams of protein and 2400 kilocalories a day. No significant difference in infant birthweights between groups was noted, but the poor diet group had an increased incidence of miscarriages, stillbirths and premature births. Mothers in the supplemented and good diet groups were reported to be better obstetrical risks with less complications than in the poor diet group.

The investigators observed a difference in maternal complications and infant outcome between the poor diet group and the supplemented diet group. However, being an early study, factors that are known today to affect infant outcome were not utilized in the analysis of data in the Ebbs study. Pregravid weight, maternal weight gain during pregnancy, consumption of alcohol and tobacco, and the presence of preexisting medical complications were not assessed. Further methodological problems were identified. Dietary assessments were only done twice during the study. The initial

assessment was done during the fifth month of pregnancy. Women were classified as those with poor diets, 40% of which became the supplemented group and received additional milk, eggs, and oranges throughout the remainder of pregnancy and others who had good diets and were then given nutritional advice to maintain good diets. The second assessment was done approximately four to six weeks before confinement, and showed a significant improvement in the diets of the supplemented and good diet groups in the amounts of kilocalories and protein consumed. However, 44% of the poor diet group improved their consumption of protein, and an analysis of improved caloric consumption was not given. Even with improved diets, these women were still considered to be in the poor diet group and their data analyzed with this group. The assessment of maternal risk throughout pregnancy and the first two weeks postpartum was done by asking the clinic obstetrician in charge of patient care to rate the women. In the obstetrician's opinion, those women with satisfactory progress or only minor complications were placed in the good/fair category, and those with many or major complications into the poor/bad category.

More recently, a medical evaluation on the current Women, Infants, and Children (WIC) program was done to try to determine if the program was effective. This program provided supplements in the form of rations of milk, cheese, eggs, and juice to low income women. The results of this three-year study were that pregnant, low-income women who participated in the study gained more weight than the women who were initially seen but did not participate.

Also, it was concluded that those women who participated in the WIC program had an associated increase in the mean birthweight of babies, and, of those women who participated for more than six months, duration of gestation was five to six days longer (Edozien, Switzer & Bryan, 1979).

One group at particular risk for low birthweight infants is the teenage population. One study done in Baltimore by Paige, Cardano, Mellits, Baerth, and Davis (1981) studied the effects of a nutritional supplement on a group of pregnant, black teenagers. Eighty girls were provided with a 14.5 gram protein/240 kilocalorie liquid supplement on each day of school attendance during their pregnancies. Another 80 girls, simultaneously enrolled in the same school, served as the reference group. In this study, the mean supplement intake of 530 grams of protein and 8691 kilocalories over the course of the study was associated with a decrease in the proportion of low birthweight infants and a statistically significant increase in mean birthweight. The nutritional intake of food other than the supplement was not considered in either group, and it is not known whether the supplement served as a replacement. Prenatal visits, absenteeism, holidays and a schoolteachers' strike influenced the level of supplement consumed.

Recent nutritional supplemental studies have included work done in India, Guatemala, Bogota, New York, Taiwan, and Montreal. These investigations have conflicting results in their outcomes of nutritionally-supplemented pregnant women. They have used different methods in assessing the women, and the types, amount,

duration and timing of supplements varied with each study.

In India, Iyenger (1967) studied pregnant women in two groups, a supplemented group which was hospitalized, and a nonsupplemented group which remained at home. The supplemented group was hospitalized during the last four weeks of pregnancy and fed 60 grams of protein and 2100 kilocalories a day and was placed on enforced bed-rest. This group was split in half. One half received an additional 35 grams of protein and 350 kilocalories in skim milk a day. The other half received an additional 350 kilocalories of nonprotein food supplement a day. The nonsupplemented group remained at home until delivery and had a diet similar to the hospitalized group prior to treatment of 40 grams of protein and 1400 kilocalories a day. The hospitalized group had a significant increase in infant birthweight and an increase in maternal weight gain in the last four weeks of pregnancy in comparison to the home group. There was, however, no significant difference in birthweight or maternal weight gain between the 60 gram protein/day group and the 95 gram protein/day group.

Although the hospitalized group showed a significant increase in maternal weight gain and infant birthweight with dietary supplementation, it is difficult to interpret whether this activity was due to the improved diet alone. Bedrest reduces physical activity and the amount of kilocalories burned for energy and also improves uterine placental blood flow. Hospitalization could have prevented infections or other complications which could have interfered with maternal weight gain and infant birthweight. The lack of difference in

outcome between the 60 grams of protein a day group and the 95 grams of protein a day group is difficult to interpret. The women were not assessed according to their pregravid weight, previous maternal weight gain or individual needs for protein and kilocalories.

In Guatemala, research by Lechtig, Habicht, Delgado, Klein, Yarbrough, and Martorell (1975) compared four villages. Pregnant women in two of the villages received an 11 gram protein and 163 kilocalorie supplement. Women in the other two villages received a 59 kilocalorie supplement. Attendance for partaking the supplement was completely voluntary and there was a wide range of supplement intake reported. The amounts of supplement ingested were recorded for each woman who participated. No significant difference in infant birthweight was found between the two groups. When they regrouped the women into those who received more than 20,000 additional kilocalories during pregnancy, and those who received less than 20,000 additional kilocalories during pregnancy, the incidence of low birthweight infants was seen to be 19% in the less than 20,000 additional kilocalorie group, compared to 9% in the greater than 20,000 additional kilocalorie group.

The researchers reported a significant difference in infant birthweight between groups of women in high calorie supplementation and low calorie supplementation. A significant difference in infant birthweight could not be shown between the protein and kilocalorie-supplemented group and the low kilocalorie-supplemented group, which was the original intent of the study. The authors (Lechtig et al., 1975) postulated that protein was not shown to be a significant

factor because kilocalories were the main limiting factor in the women's diets in their study. They felt the protein-to-kilocalorie ratio of their population was similar to well-nourished populations. By providing a high calorie supplementation, the additional kilocalories could spare protein from energy utilization and a sufficient nitrogen balance could be obtained to produce an associated increase in infant birthweight. In assessing the protein and kilocalorie supplement group with the low kilocalorie supplement group, no analysis of pregravid weight, maternal weight gain in pregnancy or the presence of maternal medical and/or obstetrical complications was made. The amount of supplement actually ingested in both groups was reported to be widely varied, yet no comparison was made of the actual intake of supplement in the protein and kilocalorie group and the low kilocalorie group, nor was an assessment made of the impact of each supplement in the women's total diet.

Mora, de Paredes, Wagner, de Navarro, Suescun, Christiansen and Herrera (1979) investigated pregnant women in Bogota where at least 50% of their children below five years old were malnourished. A protein and kilocalorie supplement was given to one group of pregnant women in the last trimester of pregnancy and compared to a similar group of pregnant women who were not supplemented in pregnancy. The families of the supplemented group received sufficient food to meet a substantial proportion of the recommended dietary allowances for the pregnant women and all members of her family. The supplementation program was assessed and reported to increase protein intake from a mean of 34.9 grams a day to 55.4 grams a day,

and a mean kilocalorie intake of 1611 kilocalories a day to 1766 kilocalories a day in the pregnant women. Only males born in the supplemented group had a significant increase in birthweight, which was associated with the duration of supplementation.

The Bogota study was an attempt to prevent women in the supplemented group from giving their food supplements to other members in the family by counseling the women to eat the supplements in addition to their normal dietary intake, and by increasing the food supply to all members of the women's families. The accuracy of the amount of protein and kilocalories ingested may be questioned. Dietary intake was measured using a 24-hour dietary recall. This was done upon initiation to the study and then repeated once, two months later. No assessment was made of pregravid weight, pre-existing or current maternal medical and/or obstetrical complications, or individual needs for protein and kilocalories. As a whole, the women sampled were deficient in both protein and kilocalories. Although protein was increased by an average of 20 grams per day, kilocalories were only increased by 155 kilocalories per day. It is questioned whether the amount of kilocalories ingested was enough to spare the supplemental protein from energy utilization.

Rush, Stein and Susser (1980) worked among pregnant black women in New York City, who were thought to be at risk of having low birthweight infants. The women were divided into three groups, those who received a canned dietary supplement of 40 grams of protein and 470 kilocalories a day, those who received a canned dietary "complement" of 6 grams of protein and 322 kilocalories a day, and

a control group. The researchers found no significant difference in mean birthweights among the groups. The authors reported that the supplemented group had an increased rate of growth retarded infants who delivered prematurely, with a corresponding increase of neonatal deaths. The authors, therefore, suggested that high protein supplements may cause adverse effects and their usage should be restrained.

There have been several criticisms of the New York City study (Hegsted, 1980; Jacobsen, 1980; Lechtig, 1982; Pencharz, 1981). First, the accuracy of the assessment of dietary intake and supplement is questioned. The riboflavin, to be used as a urinary marker, was inadvertently left out of the canned supplements. Instead, the women were assessed by 24 hour-recall and by asking how much of the supplement they ingested. Second, that the increased protein in the canned supplement was responsible for the adverse outcomes is questioned by Hegsted (1980). Not only did the canned supplement contain more protein than the canned "complement," but also substantially higher amounts of calcium, magnesium, zinc and copper. To single out one substance for blame without controlling the other additional nutrients, is poor analysis. Third, general dietary intake was not monitored and the beverage may have displaced other food intake and produced a toxic effect (Jacobsen, 1980; Pencharz, 1981). Fourth, and the most significant criticism of the New York work, was why women who were not significantly deficit in protein or kilocalories, were given nutritional supplements (Wynn & Wynn, 1982). Lechtig (1982) suggested that the factors of smoking, short birth

intervals, high parity, and young maternal age were the factors responsible for the low birthweight/high prematurity rate of this population.

McDonald, Pollitt, Mueller, Hsueh, and Sherwin (1981) reported on the Bacon Chow Study in Taiwan which compared two groups of pregnant women. One group received a supplement of 40 grams of protein and 300 kilocalories a day, and the other group received a supplement of about 80 kilocalories a day. Supplementation began after three weeks of the delivery of the first study infant, continued through lactation, and through the pregnancy and lactation of a second study infant. Between group comparisons on the birthweight, number of low birthweight infants, or incidence of fetal deaths showed no statistically significant findings. However, the birthweight of the second study infant was statistically different and higher than that of the first study infant in the high supplement group (McDonald et al., 1981).

In the Taiwan research, it was questioned if the estimation of protein and kilocalorie ingestion was really accurate. A preliminary diet survey estimated the average daily intake to be 40 grams of protein and 1200 kilocalories. However, the dietary information was restricted to mealtime consumption, and probably resulted in an underestimation of the total intake. The women in the minimal supplementation group gave births to male and female infants with mean weights of 3160 and 2980 grams respectively, which would be hard to interpret with that amount of protein and kilocalorie intake (McDonald et al., 1981).

All of the previously mentioned nutritional supplementation investigations have some difficulties in methodology. Questions concerning the use of canned supplementation, not meeting enough caloric demands to spare protein from energy utilization, or not incorporating both of the other factors identified as having a significant relationship with maternal and infant outcomes, pregravid weight and maternal weight gain during pregnancy have been raised. Not one of the above mentioned studies took into account each woman's individual needs for protein and kilocalories in providing nutritional supplementation.

There was one study done at a nutritional counseling and supplementation service which provides pregnant women with supplementation based on each woman's individual needs for protein and kilocalories. The outcome data in this study analyzed various factors including pregravid weight, maternal weight gain in pregnancy, individual needs and the amount of total dietary intake, including supplementation. This service is the Montreal Diet Dispensary in Canada.

Montreal Diet Dispensary

At the Montreal Diet Dispensary, individual nutritional counseling, and if necessary, supplemental foods are provided to low-income pregnant women throughout their pregnancies. The amount of protein and kilocalories that is prescribed for the pregnant women is individualized according to their normal requirements, based on their age, ideal body weight and physical activity level, and the additional amounts recommended for pregnancy. Additional

amounts of protein and kilocalories are calculated for pregnant women who are underweight, undernourished and/or under stress conditions. The nutritionists at the Montreal Diet Dispensary suggested additions to women's diet, necessary to meet their individual prescription for protein and kilocalories. At each visit, done at two week intervals, a dietary history was performed to check compliance and to reinforce and readjust the prescription as necessary. The reported noncompliance rate was 19%.

Higgins et al. (1972) reported on the Montreal Diet Dispensary from 1962-73. Pregnant women seen at the dispensary were compared with similar public patients without dispensary counseling who delivered at the same hospital, during the same period of time. The Montreal Diet Dispensary group had a decreased incidence of under 2500 gram birthweight infants, stillbirths, and perinatal deaths, and an overall increase in infant birthweights. The control group's actual intake of protein and kilocalories was not assessed.

Higgins (1975) also compared siblings whose mothers received Montreal Diet Dispensary counseling during pregnancy, and their siblings whose pregnancy did not receive this counseling. The Montreal Diet Dispensary counseled group had a significant increase in infant birthweights and in length of gestation.

In comparing all patients who received Montreal Diet Dispensary counseling, the amount of protein and kilocalorie intake was positively correlated with infant birthweight. The duration of treatment had the greatest effect on infant birthweight and on the increased amount of protein and kilocalories consumed during pregnancy. A

longer length of service was associated with a decrease in mortality and in low birthweight infants.

The Montreal Diet Dispensary research has shown a positive correlation between pregravid weight and infant birthweight, maternal weight gain in pregnancy and infant birthweight, and in amount of protein and kilocalories consumed and infant birthweight. In their comparison investigation with public patients, they were unable to show the amount of protein and kilocalories consumed by the control group, and therefore, were unable to make a comparison of the actual amount of protein and kilocalories consumed between the two groups. However, the maternal and infant outcomes in the treated group were superior to those in the control group.

The present study utilized the Montreal Diet Dispensary approach, but with a randomized prospective clinical trial in which eight subgroups were identified. The following are the hypotheses for this design.

Hypotheses

1. Women whose pregravid weight is less than 95% of their ideal weight will have infants with significantly lower birthweights than women whose pregravid weight is 95% or above their ideal weight.
2. Women whose pregravid weight is less than 95% of their ideal weight will have more maternal complications than women whose pregravid weight is 95% or above their ideal weight.
3. Women whose pregravid weight is less than 95% of their ideal weight and who fail to gain ten pounds in the first 20 weeks of pregnancy will have infants with significantly lower birthweights

than normal or overweight women who fail to gain ten pounds in the first 20 weeks of pregnancy.

4. Women whose pregravid weight is less than 95% of their ideal weight, and who fail to gain ten pounds in the first 20 weeks of pregnancy will have more maternal complications than normal or overweight women who fail to gain ten pounds in the first 20 weeks of pregnancy.

5. Women with a failure to gain ten pounds in the first 20 weeks of pregnancy, who thereafter meet their individual protein and kilocalorie prescriptions, will have infants with significantly greater birthweights, than those who fail to gain ten pounds in the first 20 weeks of pregnancy and do not meet their individual protein and kilocalorie prescriptions thereafter.

6. Women with a failure to gain ten pounds in the first 20 weeks of pregnancy, who thereafter meet their individual protein and kilocalorie prescriptions, will have fewer maternal complications than those women who fail to gain ten pounds in the first 20 weeks of pregnancy and do not meet their individual protein and kilocalorie prescriptions thereafter.

7. Women who have met their individual protein and kilocalorie prescriptions will have significantly greater maternal weight gain during pregnancy than those who have not met their individual protein and kilocalorie prescriptions.

8. Women who have met their individual protein and kilocalorie prescriptions will have significantly fewer maternal complications than those who have not met their individual protein and kilocalorie

prescriptions.

9. Women who have met their individual protein and kilocalorie prescriptions will have infants with significantly greater birthweights than those who have not met their individual protein and kilocalorie prescriptions.

10. Women with a weight gain of ten pounds or more in the first 20 weeks of pregnancy who have met their individual protein and kilocalorie prescriptions will have infants with significantly greater birthweights than those who have both failed to gain ten pounds in the first 20 weeks of pregnancy and have not met their individual protein and kilocalorie prescriptions.

11. Women with a weight gain of ten pounds or more in the first 20 weeks of pregnancy who have met their individual protein and kilocalorie prescriptions will have fewer maternal complications than those who have both failed to gain ten pounds in the first 20 weeks of pregnancy and have not met their individual protein and kilocalorie prescriptions.

12. Women with a weight gain of ten pounds or more in the first 20 weeks of pregnancy who have met their individual protein and kilocalorie prescriptions will have a greater maternal weight gain than those who have both failed to gain ten pounds in the first 20 weeks of pregnancy and have not met their individual protein and kilocalorie prescriptions.

Assumptions

The following assumptions were made in this investigation:

1. The necessary food to allow adequate protein and kilocalorie

requirements to be met will be available to all the women.

2. Most pregnant women desire a healthy baby and a healthy outcome of pregnancy and will take positive action to ensure a positive outcome and a healthy baby whenever circumstances allow.

3. The number of subjects who give false or inaccurate information will be evenly distributed among the groups.

Limitations

The following limitations affected the research:

1. It was not possible to ensure that the women in the study were eating exactly what they stated they were eating, but every effort was made to obtain the most accurate information in the food record.

2. It was not possible to control intervening variables such as smoking, alcohol consumption, and stress but the presence of these intervening variables was recorded.

CHAPTER III

METHODOLOGY

Design

A posttest control group design was used. The subjects were categorized by their pregravid weights into two general groups: a) those women who were less than 95% of their ideal weight and b) those who were 95% or greater than their ideal weight. These groups were divided again according to their weight gain at 20 weeks gestation: a) those who gained less than ten pounds and b) those who gained ten pounds or more. This divided the sample into four groups. Next, the subjects were each assigned to the experimental or control group using a biased coin design. The biased coin design developed by Efron (1971) was used successfully in randomized clinical trials of cancer research, and was adapted for this research by Dr. Marlene Egger, University of Utah. The biased coin design was developed to overcome a frequent objection raised regarding reported studies with systematic allocation of patients to treatment groups--that the researcher knows the schedule of treatment assignments and may consciously or unconsciously schedule researchers to provide certain treatments to certain patients.

The goal of the biased coin selection was to obtain equal numbers of women in the experimental and control groups with a) low pregravid weight and b) failure to gain at least ten pounds by the

twentieth week of gestation. The directions, forms, and format for using the biased coin design are contained in Appendix B.

Sample

The University of Utah Medical Center was the site used for the sample selection. The University Medical Center is a large, tertiary care center which serves the Intermountain West Region. Clients seeking obstetrical care at the Medical Center include private patients of staff physicians, indigent patients, many with borderline health, and referrals of high risk patients from other facilities and physicians. Approximately 1500 deliveries were done in 1983.

Due to the large sample size needed to allow for an eight group design, this study was the second phase of an ongoing project. Data collected from this study are reported in combination with data collected in phase one from researchers Helen Smith and Carol Sweeney. Phase one data collection was conducted from August 1 to October 15, 1982 (Smith & Sweeney, 1983).

Interrater reliability was established at greater than 90%. Comparison of the results of diet interviews was made between the phase one researchers and phase two researchers and reliability proved to be greater than 90%. Then, six diet interviews were obtained with the oral interview being alternated between the phase two researchers. Results were calculated by both researchers and were evaluated by Ms. Sweeney. Comparisons of the results showed greater than 90% reliability.

The study was designed to include all healthy, pregnant women

receiving care at the University Medical Center during the specified study time periods. Study subjects were chosen from the Medical Center clinics, mainly Clinic III and Murray Clinic. Teenage patients being seen in the Teen Clinic were not included because of the special nutritional services provided to them which would have negated the study protocol.

During the time period of March 1 to May 30, 1982 for phase one, and January 1, 1983 to April 15, 1983 for phase two, University of Utah Medical Center obstetrical charts were reviewed on a weekly basis to identify potential study subjects. The specified time period for delivery in phase one was August 1 to October 15, 1982, and was originally June 15 to August 31, 1983 for phase two. This period for phase two was extended to September 15, 1983 in an effort to increase the sample size.

The criteria established to include a woman into the sample were: a) the woman must be able to communicate in English, b) she must be free of existing medical conditions including heart disease, renal disease, essential hypertension, history of gestational diabetes, diabetes or other metabolic disorders, c) she must smoke no more than two packages of cigarettes a day, and d) she must consume less than two ounces of alcohol a day. If the woman's chart revealed that she was due to deliver in the specified time period and met these criteria, she was noted by the researchers to be a potential study subject.

Instrumentation

Demographic Data

The following demographic data were collected: maternal age, ethnicity, marital status, level of education, occupation, family income, parity, complications of prior pregnancies and/or deliveries if applicable, presence of severe nausea and vomiting, smoking, alcohol and drug consumption, current ages and birthweights of other children, the number of people in the household, their ages and relationships, who did the family shopping, who did the family cooking, and participation in the Women, Infants, and Children (WIC) program. The information regarding household activities was to aid in the counseling segment involved with the experimental group.

Individual Prescription for Protein and Kilocalorie Requirements in Pregnancy

The method for determining an individual prescription for protein and kilocalorie requirements during pregnancy was developed by Higgins of the Montreal Diet Dispensary. Some forms for recording the Higgins method were designed by Foster at the University of Utah, utilizing the information from the Montreal Diet Dispensary (Appendix A, Forms B, C, D). Other forms included contain standard tables for ideal weight (Table of Desirable Weights for Women, Appendix A, Table 30), the women's stated activity level, the Canadian Dietary Standards (Appendix A, Table 31) and other forms, food values and equivalents as determined by the Montreal Diet Dispensary (Appendix A, Form A, Chart 1). Formulas for determining corrective allowances for underweight, undernutrition and nutritional

stress are found in Appendix A.

Maternal variables used to measure outcomes in this study were defined as follows:

Protein and Kilocalorie Prescription

The protein and kilocalorie prescriptions are the total amounts of protein and kilocalories to be ingested during each 24-hour period throughout pregnancy, based on each individual woman's body build, weight, activity level and current nutritional status. The protein and kilocalorie prescriptions were calculated using a formula designed by Higgins at the Montreal Diet Dispensary, utilizing the female frame size table (Appendix A, Table 30), the Canadian Dietary Standard for Adults, 1978 (Appendix A, Table 31), the Initial Dietary Intake (Form A), the Personal Pregnancy Nutrition Prescription (Form D) and the Montreal Diet Dispensary Food Values and Equivalents (Appendix A). All these forms and tables are located in Appendix A.

Protein and Kilocalorie Intake

Protein and kilocalorie intake at each encounter was obtained and a mean intake was determined for the total pregnancy. This also facilitated computation of the percent of the prescription ingested versus what was recommended for ingestion.

Compliance versus Noncompliance

Compliance versus noncompliance was measured by progress notes recorded by the researchers at each client contact regarding compliance with the individual prescription. These data were recorded

for the subjects in the experimental group only.

Pregravid Weight

Pregravid weight is the amount of body mass a woman possesses prior to conception. Pregravid weight was measured as the woman's weight in pounds, prior to conception as stated by the woman, or if this was not known, the woman's weight in pounds at the first prenatal visit during the first trimester of pregnancy was used.

Maternal Weight Gain

Maternal weight gain is the amount of fetal tissue, placenta, amniotic fluid, additional maternal uterine muscle, breast tissue, blood, interstitial fluid, protein stores, and fat added to the mother's body mass during the course of pregnancy. Maternal weight gain was measured in pounds as the weight taken at each nutrition assessment encounter throughout pregnancy on the same clinic scale, upon admission to the hospital for labor on the labor admittance scale, and within 24-48 hours postpartum. The scale in Clinic III at the University of Utah Medical Center is a traditional type of scale, Health-O-Meter model with a gross capacity of 350 pounds.

Maternal weight gain during pregnancy was determined as the weight of the woman obtained upon admission to labor and delivery minus the pregravid weight. The scale used in Labor and Delivery at the University of Utah Medical Center, located in Intake Room #2, is a Detecto digital scale, gross capacity 199.9 kgs x 0.1 kg. The measurement was in kilograms. For accuracy and reliability in the weights obtained, correlation was made between the two scales

used to weigh the women.

Infant Birthweight

Infant birthweight is the amount of body mass an infant possesses at the time of birth. Infant birthweight was measured as the number of grams of the nude infant, weighed on the hospital's infant scale within two hours of birth. This weight was obtained in the Transition Nursery at the University of Utah Medical Center on a Detecto Digital Scale, gross capacity 20 kgs. The weight was reported in grams.

Placental Weight

Placental weight is the amount of weight of the placenta, ruptured amniotic sac and umbilical cord as determined after delivery, in grams. This weight was measured on the scale in the Labor and Delivery Suite, University of Utah Medical Center. The scale is a conventional model, a Health-O-Meter by the Continental Company. Gross capacity is 16 kilograms.

Placental Abnormalities

Gross placental abnormalities were determined according to visual inspection, using Williams Obstetrics (Pritchard & McDonald, [16th ed.], New York: Appleton-Century-Crofts, 1980, Chapter 23). Inspection of the placentas was carried out by the resident on call at the University of Utah Medical Center, Labor and Delivery.

Fetal/Placental Weight Ratio

Fetal/placental weight ratio was mathematically computed by

dividing the infant birthweight by the placental weight.

Postpartum Weight

Postpartum weight is the amount of body mass a woman possesses within the first 24-48 hours of delivery. The postpartum weights of the subjects were obtained within the first 24 hours, whenever possible.

Maternal Complications

Maternal complications are secondary diseases or conditions developing in the course of a pregnancy, which often appear unexpectedly and may alter the outcome of an otherwise normal pregnancy. Maternal complications were measured by the presence of such conditions as infections, premature rupture of the membranes, pregnancy induced hypertension, miscarriage, premature labor, anemia and/or hemorrhage, as recognized by the woman's primary care giver, either in the antepartum period, intrapartum period, or the first 24 hour postpartum period. This information was ascertained by the researchers during chart review. Procedures performed in labor and delivery including induction of labor, augmentation of labor, forceps delivery and cesarean section were also recorded.

Procedure

The women identified as potential study subjects were approached at their next clinic visit by one of the researchers. During this interview, the explanation was given to the woman that a study was being conducted about mothers' weight and nutrition and the effect

on the pregnancy, labor and delivery, and the baby. It was explained to her that the initial interview would take about an hour, and then about 30 minutes each time she came to the clinic in the second half of pregnancy. The woman was then asked if she would be interested in being a part of this study. If the woman agreed to be in the study, she was then asked to sign Consent Form 1 (Appendix B).

At this first contact, specific information was obtained. The demographic data sheet was completed by the researcher (Appendix B). The woman's height, prepregnant weight, number of weeks of gestation at time of initial contact and at onset of prenatal care, frame size, and ideal weight were determined. The woman was asked if and how much she smoked or drank. More than two packages of cigarettes and/or more than two oz. of alcohol per day was a disqualification from the study. The woman's frame size was determined by measuring her wrist size in inches and comparing it to her height (Appendix A, Table 28). Ideal weight was determined by height and frame size (Appendix A, Table 29). For each height and frame size, there are three weights given. The woman was asked at which of these three weights she was more comfortable. That weight was determined to be her ideal weight.

With these data available to the researcher, the woman's percent of ideal weight was determined. The woman's prepregnant weight divided by her ideal weight gave the percentage of prepregnant weight. The women were then placed into two groups: a) those women 95% or more of their ideal weight and b) those women less than

95% of their ideal weight.

At 20 weeks gestation, each woman's chart was reviewed for her pregnancy weight gain. Each of the two groups of women were further divided into a) those that gained less than ten pounds by 20 weeks, and b) those that gained ten or more pounds by 20 weeks. The subjects were now in four subgroups. The biased coin design was now applied to further divide the groups into experimental and control groups (Figure 3). The group distributions were known only to the researchers.

An appointment was made with the woman to coincide with her next clinic visit. At the second contact, during the 20 to 24th week of gestation, the women were seen for their initial assessment. The women in the experimental group were asked to sign Consent Form 2 (Appendix B) since nutritional intervention was to be introduced. Both the experimental and control groups saw a slide/sound presentation. Those in the experimental group saw "Building a Healthy Baby: Nutrition for Pregnancy," designed by Foster at the University of Utah as a motivational trigger for compliance with the nutritional prescription. Those in the control group saw "Inside My Mom," a general nutritional motivational film for pregnancy distributed by the March of Dimes.

Nutrition interviews were completed on each woman using Forms A, C, and D (Appendix A). The woman was asked to recall by food group everything she had to eat and drink for the previous seven days. As an aid for increasing accuracy in obtaining the diet histories, the researcher provided various sized cups, glasses,

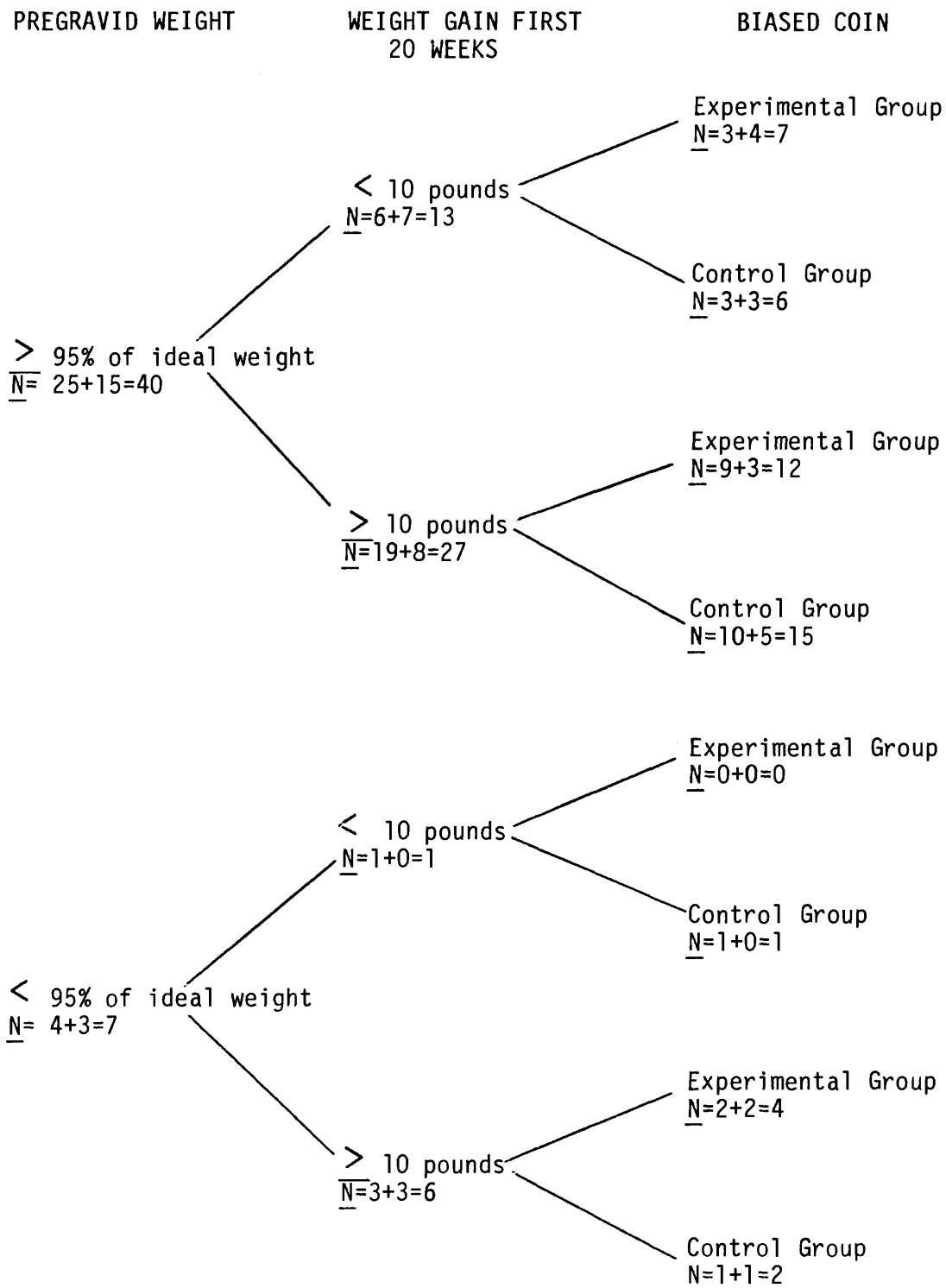


Figure 3. Distribution of subjects into subgroups.
 $\underline{N} = \text{phase 1 } \underline{n} + \text{phase 2 } \underline{n} = \text{Total } \underline{N}.$

cans, bowls, and spoons with the appropriate measurement printed on each.

An individual prescription for protein and kilocalorie requirements during pregnancy was computed. This prescription was based on the woman's requirements for pregnancy, plus any corrective allowances that needed to be added (Form C). The pregnancy requirement was determined by the woman's ideal weight and activity level (Appendix A, Tables 29-30).

There were three corrective allowances that were added into a woman's prescription, if applicable. The first, a corrective allowance for underweight, was added if the woman was less than 95% of her ideal weight (Instruction I, Appendix A). The second, a corrective allowance for undernutrition, was added if the woman had a protein deficit in her initial diet history as compared to her normal plus pregnancy protein requirements (Instruction II, Appendix A). The third, a corrective allowance for nutritional stress was included if the woman had pernicious vomiting, closely spaced pregnancies, poor previous obstetrical outcome, failure to gain at least ten pounds by 20 weeks gestation, or severe emotional stress (Instruction III, Appendix A).

Nutrition interviews were conducted for both experimental and control groups. For the experimental group, however, the comparison of their prescription to their intake was shared with the women. Necessary additions to their diets, if any, were discussed. The nutritional assessment approach and counseling techniques as developed by Higgins were applied by the researcher (Appendix C). For

the control group women, specific questions were answered at any time during the study, but all other requests for more nutrition information were referred to their health care provider.

The woman's weight was recorded on the pregnancy flow sheet (Appendix B) and the next appointment was made coinciding with her health care provider visit.

From 20 to 40 weeks gestation, all women in the sample were seen, whenever possible, every two to four weeks. Frequency of visits was determined by client availability and the clinical protocols for return prenatal visits. During these interviews, all women gave a verbal or combined verbal and written nutrition intake history. The researcher calculated the food intake on Form A (Appendix A) for the intake of the previous seven days. The women were asked about their health, any medical problems, consumption of prenatal vitamins and iron, if prescribed. Questions from the women were answered. The woman's chart was periodically reviewed for medical information and the woman's weight was measured and recorded.

As the time of the first expected delivery approached in each study phase, the researchers involved posted a list of study patients in the Labor and Delivery Suite at the University of Utah Medical Center. The researchers contacted the labor and delivery unit personnel once or twice daily to determine if any subjects had delivered. When a delivery had taken place, one of the researchers visited the Medical Center and reviewed the maternal chart for pertinent information. This information was recorded on the Outcome Data Sheet (Appendix B). Each study subject was visited by the

researcher, weighed, and thanked for being a part of the study. Questions about the study were answered.

A parallel study on the evaluation of the newborn infant was carried out concurrently with phases one and two of the maternal study. The researchers for the infant studies were Ann Peterson for phase one, and Toni LaMalfa and Barbara Ryan for phase two. These researchers were unaware of which subjects were in the experimental and which were in the control group.

CHAPTER IV

RESULTS AND DISCUSSION

A randomized clinical trial of nutrition intake during the last half of pregnancy was conducted at the University of Utah Medical Center. The Stat80 statistical program and the Univac 1100/61 computer were used for statistical data analysis at the University of Utah Computer Center. All group comparisons were done using Fisher's exact test or chi-square test on nominal/ordinal data and two-tailed t-test on interval data. Statistical analysis was done on the combined results of phase one and phase two.

Sample

Chart review was conducted by the two sets of researchers for their respective phases. In phase one, chart review for eligible subjects disclosed 55 women who met the criteria in the designated time period. The 55 clients were contacted and asked to participate. Fifteen women declined to participate: six of them would be moving out of the area to delivery at another site and nine clients' negative response was due to time constraint at clinic visits. Nine (18%) of the total eligible sample of 49 subjects in phase one declined to participate. Forty women agreed to participate in the study, however, eight of this group either moved from the area or sought their care from other providers in the community prior to

the initial nutritional assessment. Twenty-nine women completed the study, as two subjects dropped out by not returning to the clinic for prenatal care thereafter, and one subject was dropped by the researchers after discovery of an unrecorded preexisting medical condition which would have eliminated her initially.

In phase two, 34 women were identified on chart review as being possible subjects. These 34 women were contacted and asked to participate in the study. Eleven women declined to participate: nine due to time constraints at the clinic visits, and two because they were going to seek care at other sites. Therefore, nine (26%) of the total eligible sample of 32 women declined to participate in the study. Of the remaining 23 women who agreed to participate, 18 actually completed the study. The remaining five women did not complete the study for the following reasons: one woman delivered a stillborn at 22 weeks gestation prior to her initial interview, one woman desired to terminate her participation in the study, and three women moved to other locations.

Using the biased coin design method of randomization, the division of the sample resulted in 14 subjects in the experimental group and 15 subjects in the control group in phase one. In phase two, the randomization procedure resulted in the final distribution of nine women in the experimental group and nine women in the control group. Combined phase one and phase two subjects resulted, then, in 23 subjects in the experimental group, and 24 subjects in the control group. Statistical testing was done on the combined data of phase one and phase two subjects for a total n of 47 women.

One woman in the control group of phase one was not included in the analysis of total amounts of protein and kilocalories consumed due to missing data from her nutritional assessment visits. The majority of women who entered the experiment were not underweight and had gained at least ten pounds in the first 20 weeks of pregnancy (27 or 57%, Figure 3). The biased coin design was adequate in placing the study subjects into subgroups. However, the numbers in the initially deficient subgroups were inadequate, even with the combined totals of phase one and phase two. Further phases of this study are planned to remedy this shortcoming.

Characteristics of the Study Group

The 23 experimental and 24 control group subjects were well-matched using the biased coin design. An approximately equal number of subjects, who were initially deficient in weight, were placed in each group. There was no significant difference between groups in demographic data, previous obstetrical history, anthropometric measures, presence of personal health hazards, gestation at initial contact, initial nutritional data or nutrition prescription. There was, however, one slight difference that was not controlled for in the randomization scheme. The week of enrollment in the WIC program was slightly earlier in the control group. A more detailed description of these variables is presented in the following test.

Demographic Data

There was no significant difference between the experimental

and control groups in age, education, marital status, race or income (Table 1). The ages ranged from 17-34 years (\bar{x} =23.1 years). The years of education ranged from 9-18 years (\bar{x} =12.7 years). Eighty-five percent of the subjects were married by time of delivery. Ninety-two percent were Caucasian, 6% were Hispanic, and 2% were Polynesian. Sixty-two percent had an annual income of less than \$10,000, and 70% of the women stated their occupation as homemaker.

Previous Obstetrical History

There was no significant difference in parity or previous obstetrical history between the experimental and control groups (Table 2). There were 18 nulliparas (38%) and 29 (62%) multigravidas. Fourteen (48%) of the multigravidas had two or more previous children. Sixteen (34%) of the women reported previous abortions. There were no previous stillbirths. Previous maternal complications such as pregnancy induced hypertension (PIH) and postpartum hemorrhage was reported by nine multigravidas (31%). Four (14%) of the multigravidas reported previous newborn complications including prematurity and birth defects. The most recent infants' birthweights ranged from 2495 grams to 4394 grams (\bar{x} =3337.4 grams). One multigravida had an infant weighing less than 2500 grams, and ten others had infants weighing less than 3000 grams. The 37% with the most recent baby weighing less than 3000 grams is greater than the 23% reported in the U.S. Vital Statistics, indicating a less than optimally healthy population.

Table 1
Comparison of Demographic Data Between the Experimental and Control Groups

| | Experimental | | | Control | | | Total N=47 | p value |
|--------------------|-----------------|----------------|---------------|-----------------|----------------|---------------|---------------|-----------------|
| | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | Phase 1 n=15 | Phase 2 n=9 | Total n=24 | | |
| Age in years | | | | | | | | |
| \bar{X} | 23.5 | 24.1 | 23.7 | 22.2 | 22.9 | 22.5 | 23.1 | NS ^a |
| SD | 3.6 | 4.5 | 3.9 | 4.6 | 2.5 | 3.9 | 3.9 | |
| Range | 19-32 | 17-32 | 17-32 | 17-34 | 20-26 | 17-34 | 17-34 | |
| Education in Years | | | | | | | | |
| \bar{X} | 13.2 | 12.1 | 12.8 | 12.9 | 12.2 | 12.7 | 12.7 | NS |
| SD | 1.5 | 2.0 | 1.8 | 2.4 | 2.0 | 2.2 | 2.0 | |
| Range | 12-16 | 10-16 | 10-16 | 9-18 | 10-15 | 9-18 | 9-18 | |

Table 1 (Continued)

| | Experimental | | | | | | Control | | | | | | p Value | | |
|-----------------------|-----------------|---------|----------------|---------|---------------|---------|-----------------|---------|----------------|---------|---------------|---------|---------|---------------|---|
| | Phase 1 n=14 | | Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Phase 2 n=9 | | Total n=24 | | | Total N=47 | |
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | |
| Marital Status | | | | | | | | | | | | | | | |
| Single | 2 | 14 | 1 | 11 | 3 | 13 | 3 | 20 | 1 | 11 | 4 | 17 | 7 | 15 | b |
| Married | 12 | 86 | 8 | 89 | 20 | 87 | 12 | 80 | 8 | 89 | 20 | 83 | 40 | 85 | |
| Totals | 14 | 100 | 9 | 100 | 23 | 100 | 15 | 100 | 9 | 100 | 24 | 100 | 47 | 100 | |
| Race - White | 14 | 100 | 8 | 89 | 22 | 96 | 15 | 100 | 6 | 67 | 21 | 88 | 43 | 92 | — |
| Hispanic | 0 | 0 | 1 | 11 | 1 | 4 | 0 | 0 | 2 | 22 | 2 | 8 | 3 | 6 | |
| Polynesian | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 11 | 1 | 4 | 1 | 2 | |
| Totals | 14 | 100 | 9 | 100 | 23 | 100 | 15 | 100 | 9 | 100 | 24 | 100 | 47 | 100 | |
| Income | | | | | | | | | | | | | | | |
| <\$5,000/year | 3 | 22 | 2 | 22 | 5 | 22 | 6 | 40 | 3 | 34 | 9 | 39 | 14 | 30 | |
| \$5,000-9,999/year | 5 | 36 | 2 | 22 | 7 | 31 | 6 | 40 | 2 | 22 | 8 | 35 | 15 | 32 | |
| \$10,000-14,999/year | 2 | 14 | 2 | 23 | 4 | 17 | 1 | 7 | 1 | 11 | 2 | 9 | 6 | 13 | |
| \$15,000-19,999/year | 1 | 7 | 1 | 11 | 2 | 9 | 1 | 7 | 1 | 11 | 2 | 9 | 4 | 8 | |
| \$20,000-24,999/year | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 11 | 1 | 4 | 1 | 2 | |
| > \$25,000/year | 3 | 21 | 1 | 11 | 4 | 17 | 1 | 6 | 0 | 0 | 1 | 4 | 5 | 11 | |
| Missing data | 0 | 0 | 1 | 11 | 1 | 4 | 0 | 0 | 1 | 11 | 0 | 0 | 2 | 4 | |
| Totals | 14 | 100 | 9 | 100 | 23 | 100 | 15 | 100 | 9 | 100 | 24 | 100 | 47 | 100 | |
| Occupation | | | | | | | | | | | | | | | |
| Operator | 1 | 7 | 0 | 0 | 1 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | |
| Craftsman | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 7 | 1 | 11 | 2 | 8 | 2 | 4 | |
| Salesman | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 13 | 0 | 0 | 2 | 8 | 2 | 4 | |
| Clerical | 3 | 21 | 1 | 11 | 4 | 18 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 9 | |
| Prof/Mgr/Bus | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 11 | 1 | 4 | 1 | 2 | |
| Professional | 0 | 0 | 1 | 11 | 1 | 4 | 1 | 7 | 2 | 22 | 3 | 13 | 4 | 9 | |
| Homemaker | 10 | 72 | 7 | 78 | 17 | 74 | 11 | 73 | 5 | 56 | 16 | 67 | 33 | 70 | |
| Totals | 14 | 100 | 9 | 100 | 23 | 100 | 15 | 100 | 9 | 100 | 24 | 100 | 47 | 100 | |

Note. ^aNS = not significant; ^bSample size too small for statistical testing.

Table 2

Comparison of Previous Obstetrical History Between the Experimental and Control Groups

| | Experimental | | | | | | Control | | | | | | p Value | | |
|---------------------------------|-----------------|---------|----------------|---------|---------------|---------|-----------------|---------|----------------|---------|---------------|---------|------------|---------------|-----------------|
| | Phase 1 n=14 | | Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Phase 2 n=9 | | Total n=24 | | | Total N=47 | |
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | | Number | Percent |
| Parity | | | | | | | | | | | | | | | |
| Nullipara | 4 | 29 | 4 | 44 | 8 | 35 | 6 | 40 | 4 | 44 | 10 | 42 | 18 | 38 | NS ^a |
| Multipara | 10 | 71 | 5 | 56 | 15 | 65 | 9 | 60 | 5 | 56 | 14 | 58 | 29 | 62 | |
| Totals | 14 | 100 | 9 | 100 | 23 | 100 | 15 | 100 | 9 | 100 | 24 | 100 | 47 | 100 | |
| Previous abortions | | | | | | | | | | | | | | | |
| Yes | 5 | 50 | 4 | 57 | 9 | 53 | 3 | 33 | 4 | 67 | 7 | 47 | 16 | 45 | NS |
| No | 5 | 50 | 3 | 43 | 8 | 47 | 6 | 67 | 2 | 33 | 8 | 53 | 16 | 55 | |
| Totals | 10 | 100 | 7 | 100 | 17 | 100 | 9 | 100 | 6 | 100 | 15 | 100 | 32 | 100 | |
| Previous stillbirths | | | | | | | | | | | | | | | |
| Yes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | — ^b |
| No | 10 | 100 | 5 | 100 | 15 | 100 | 9 | 100 | 5 | 100 | 14 | 100 | 29 | 100 | |
| Totals | 10 | 100 | 5 | 100 | 15 | 100 | 9 | 100 | 5 | 100 | 14 | 100 | 29 | 100 | |
| Previous maternal complications | | | | | | | | | | | | | | | |
| Yes | 2 | 20 | 2 | 40 | 4 | 27 | 2 | 22 | 3 | 60 | 5 | 36 | 9 | 31 | NS |
| No | 8 | 80 | 3 | 60 | 11 | 73 | 7 | 78 | 2 | 40 | 9 | 64 | 20 | 69 | |
| Totals | 10 | 100 | 5 | 100 | 15 | 100 | 9 | 100 | 5 | 100 | 14 | 100 | 29 | 100 | |
| Previous newborn complications | | | | | | | | | | | | | | | |
| Yes | 3 | 30 | 0 | 0 | 3 | 20 | 0 | 0 | 1 | 20 | 1 | 7 | 4 | 14 | NS |
| No | 7 | 70 | 5 | 100 | 12 | 80 | 9 | 100 | 4 | 80 | 13 | 93 | 25 | 86 | |
| Totals | 10 | 100 | 5 | 100 | 15 | 100 | 9 | 100 | 5 | 100 | 14 | 100 | 29 | 100 | |

Table 2 (Continued)

| | Experimental | | | | | | Control | | | | | | p Value | | |
|--|-----------------|---------|----------------|---------|---------------|---------|-----------------|---------|----------------|---------|---------------|---------|---------------|---------------|------------|
| | Phase 1 n=14 | | Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Phase 2 n=9 | | Total n=24 | | | Total N=47 | |
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | | Number | Percent |
| Previous low infant birthweights | | | | | | | | | | | | | | | |
| <2500 grams | 1 | 10 | 0 | 0 | 1 | 7 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 3 | NS |
| 2500-3000 grams | 2 | 20 | 3 | 60 | 5 | 33 | 3 | 33 | 2 | 40 | 5 | 36 | 10 | 34 | |
| Totals | 3 | 30 | 3 | 60 | 6 | 40 | 3 | 33 | 2 | 40 | 5 | 36 | 11 | 37 | |
| Previous decreasing birthweights (\geq para 2) | | | | | | | | | | | | | | | |
| Yes | 2 | 29 | 0 | 0 | 2 | 25 | 2 | 67 | 3 | 100 | 5 | 83 | 7 | 50 | NS |
| No | 5 | 71 | 1 | 100 | 6 | 75 | 1 | 33 | 0 | 0 | 1 | 17 | 7 | 50 | |
| Totals | 7 | 100 | 1 | 100 | 8 | 100 | 3 | 100 | 3 | 100 | 6 | 100 | 14 | 100 | |
| | Phase 1 n=10 | | Phase 2 n=5 | | Total n=15 | | Phase 1 n=9 | | Phase 2 n=5 | | Total n=14 | | Total n=29 | | p Value |
| Birthweight of last pregnancy in grams | | | | | | | | | | | | | | | |
| \bar{x} | 3353.8 | | 3022.2 | | 3243.3 | | 3550 | | 3237.2 | | 3438.3 | | 3337.4 | | NS |
| SD | 480.5 | | 370.4 | | 462.4 | | 440.6 | | 768.3 | | 570.3 | | 517.5 | | |
| Range | 2495-4139 | | 2608-3515 | | 2495-4139 | | 2948-4082 | | 2551-4394 | | 2551-4394 | | 2495-4394 | | |

Note. ^aNS= not significant; ^bSample size too small for statistical testing.

Anthropometric Measures

There were no significant differences between the experimental and control groups in anthropometric data (Table 3). Maternal height ranged from 152-180 cms (60-71 inches) (\bar{x} =163.3 cms). Pre-pregnant weight ranged from 41-113 kg (90-250 pounds) (\bar{x} =61.8 kg). The ideal weight of the subjects ranged from 46-74 kg (101-163 pounds) (\bar{x} =57.9 kg). Seven women (15%) were less than 95% of their ideal weight at the onset of pregnancy. The ponderal index ranged from 17.6-38.1 (\bar{x} =23.3). Seventeen (36%) of the subjects had a ponderal index of less than 20.8. This level has been associated with an increase in infertility and amenorrhea (Frisch, 1977). Nine of the subjects with low ponderal indexes were in the experimental group; the other eight were in the control group.

Personal Health Hazards

There were no significant differences between the experimental and control groups in personal health hazard data. None of the subjects were regular users of alcohol. Forty women (85%) reported abstaining from alcohol use during pregnancy. The remaining seven women (15%) reported an alcohol intake of less than two ounces of absolute alcohol per month. Thirty-seven (79%) of the subjects were nonsmokers. The other ten women (21%) smoked a range of 3-30 cigarettes per day (\bar{x} =14.3) (Table 4).

Contacts

The subjects began their prenatal care at 6-19 weeks gestation (\bar{x} =13.3 weeks). The researchers made their initial study contacts

Table 3
Comparison of Anthropometric Measures Between Experimental and Control Groups

| | Experimental | | | | | | | | | Control | | | | | | | | | p Value | | | |
|--|-----------------|------------------|------------------|----------------|------------------|------------------|---------------|------------------|------------------|-----------------|------------------|------------------|----------------|------------------|-------------------|---------------|------------------|------------------|---------------|------------------|------------------|-----------------|
| | Phase 1 n=14 | | | Phase 2 n=9 | | | Total n=23 | | | Phase 1 n=15 | | | Phase 2 n=9 | | | Total n=24 | | | | Total N=47 | | |
| | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | |
| Height in cms/ inches | 162.8 64.1 | 7.1 2.8 | 153-175 60-69 | 164.6 64.8 | 9.4 3.7 | 155-180 61-71 | 163.5 64.4 | 7.9 3.1 | 153-180 60-71 | 161.6 63.6 | 4.9 1.9 | 153-173 60-68 | 165.7 65.2 | 6.5 2.6 | 152-173 60-68 | 163.1 64.2 | 5.8 2.3 | 152-173 60-68 | 163.3 64.3 | 6.8 2.7 | 152-180 60-71 | NS ^a |
| Prepregnant weight in kilograms/ pounds | 59.5 131.1 | 16.3 35.9 | 44-108 97-237 | 61.2 135.0 | 11.0 24.3 | 51-89 113-196 | 60.2 132.7 | 14.2 31.3 | 44-108 97-237 | 63.0 138.9 | 16.8 37.1 | 41-100 90-220 | 63.9 140.8 | 20.2 44.6 | 47-113 104-250 | 63.3 139.6 | 17.7 39.1 | 41-113 90-250 | 61.8 136.2 | 16.0 35.3 | 41-113 90-250 | NS |
| Ideal weight in kilograms/ pounds | 57.0 125.6 | 7.6 16.7 | 48-72 105-159 | 58.9 129.9 | 5.9 13.1 | 53-72 116-158 | 57.7 127.3 | 6.9 15.2 | 48-72 105-159 | 57.2 126.1 | 6.6 14.5 | 46-74 101-163 | 59.4 131.0 | 7.0 15.5 | 52-73 114-162 | 58.0 127.9 | 6.7 14.8 | 46-74 101-163 | 57.9 127.6 | 6.7 14.8 | 46-74 101-163 | NS |
| Ponderal Index (kg/ cm ²) | 22.3 | 4.6 | 17.8-35.2 | 22.6 | 3.1 | 17.8-27.5 | 22.5 | 4.0 | 17.8-35.2 | 24.6 | 5.9 | 17.6-36.1 | 23.3 | 6.2 | 17.7-38.1 | 24.1 | 5.9 | 17.6-38.1 | 23.3 | 5.1 | 17.6-38.1 | NS |

Note. ^aNS = not significant.

Table 4

Comparison of Personal Health Hazards Between the Experimental and Control Groups

| | Phase 1 n=14 | | Experimental Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Control Phase 2 n=9 | | Total n=24 | | Total N=47 | | p Value | | | | | | | |
|--|-----------------|-----------------|--------------------------------|--------------------------------------|---------------|---------|-----------------|---------|---------------------------|---------------------------------|---------------|---------|---------------|---------|-----------------|-----------|-----|-------|------------|-----|------|----|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | | | | | | | | |
| Alcohol consumption | | | | | | | | | | | | | | | | | | | | | | |
| None | 12 | 86 | 6 | 67 | 18 | 78 | 14 | 93 | 8 | 89 | 22 | 92 | 40 | 85 | NS ^a | | | | | | | |
| Rarely | 2 | 14 | 3 | 33 | 5 | 22 | 1 | 7 | 1 | 11 | 2 | 8 | 7 | 15 | | | | | | | | |
| Totals | 14 | 100 | 9 | 100 | 23 | 100 | 15 | 100 | 9 | 100 | 24 | 100 | 47 | 100 | | | | | | | | |
| Cigarette usage | | | | | | | | | | | | | | | | | | | | | | |
| None | 13 | 93 | 8 | 89 | 21 | 91 | 10 | 65 | 6 | 67 | 16 | 67 | 37 | 79 | NS | | | | | | | |
| Yes | 1 | 7 | 1 | 11 | 2 | 9 | 5 | 35 | 3 | 33 | 8 | 33 | 10 | 21 | | | | | | | | |
| Totals | 14 | 100 | 9 | 100 | 23 | 100 | 15 | 100 | 9 | 100 | 24 | 100 | 47 | 100 | | | | | | | | |
| | \bar{X} | Phase 1 SD | Range | Experimental Phase 2 \bar{X} | SD | Range | \bar{X} | SD | Range | Control Phase 2 \bar{X} | SD | Range | \bar{X} | SD | Range | \bar{X} | SD | Range | p Value | | | |
| Of smokers, number of cigarettes/ day | 10.0 | NA ^b | - | 20.0 | NA | - | 15.0 | 7.1 | 10-20 | 13.6 | 9.0 | 3-30 | 15.0 | 8.7 | 5-20 | 14.1 | 9.7 | 3-30 | 14.3 | 8.9 | 3-30 | NS |

Note. ^aNS = not significant; ^bnot applicable, n=1.

between 15-24 weeks gestation (\bar{x} =19.3 weeks). A total of one to nine nutritional contacts were made (\bar{x} =6.5 contacts). On the average, each client was seen six to seven times over a period of 15.5 weeks (Table 5). Approximately one hour was spent at the first visit, which included showing a sound/slide presentation and explaining how dietary assessments are done. Each revisit was conducted within 20-45 minutes.

WIC Program

Sixteen (34%) of the subjects were on the Women, Infants, and Children Program (WIC). This is a federally-funded, nutritional supplementation program. There were eight women (17%) in the experimental group and eight (17%) in the control group participating in the program. Of those who participated in the WIC program, the range of onset was 8-34 weeks (\bar{x} =17.4 weeks). Interestingly, there was a slight difference (p =.08; two-tailed test) in the time of onset between the experimental and control groups. The control group mean onset was 14.9 weeks, whereas the experimental mean onset was 19.9 weeks (Table 6). This effect was not controlled for in the study design, and may have muted the differences between the two groups in nutritional intake, as nutrition counseling is provided as part of the WIC program.

Medication During Pregnancy

Inquiry was made by the researchers concerning medications taken by the pregnant woman. Included were both prescribed and over-the-counter medications, and social drug use. General cate-

Table 5
Comparison of Study Contacts Between the Experimental and Control Groups

| | Phase 1 n=14 | | | Experimental Phase 2 n=9 | | | Total n=23 | | | Phase 1 n=15 | | | Control Phase 2 n=9 | | | Total n=24 | | | Total N=47 | | | p Value |
|--|-----------------|------------------|-------|--------------------------------|------------------|-------|---------------|------------------|-------|-----------------|------------------|-------|---------------------------|------------------|-------|---------------|------------------|-------|---------------|------------------|-------|-----------------|
| | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | |
| Onset of prenatal care in weeks gestation | 13.1 | 2.2 | 10-17 | 12.8 | 2.8 | 6-16 | 13.0 | 2.4 | 6-17 | 13.9 | 2.9 | 8-19 | 13.4 | 2.0 | 12-18 | 13.7 | 2.6 | 8-19 | 13.3 | 2.5 | 6-19 | NS ^a |
| Initial contact for study in weeks gestation | 19.8 | 1.8 | 17-24 | 18.1 | 2.4 | 15-22 | 19.1 | 2.2 | 15-24 | 19.9 | 1.7 | 16-22 | 18.9 | 2.6 | 16-22 | 19.5 | 2.1 | 16-22 | 19.3 | 2.1 | 15-24 | NS |
| Initial assessment in weeks gestation | 23.0 | 1.2 | 21-25 | 19.9 | 1.2 | 18-22 | 21.8 | 1.9 | 18-25 | 22.9 | 1.8 | 22-26 | 20.8 | 1.0 | 20-22 | 22.1 | 1.9 | 20-26 | 22.0 | 1.9 | 18-26 | NS |
| Number of nutritional visits | 6.1 | 0.8 | 4-7 | 6.6 | 2.4 | 1-9 | 6.3 | 1.6 | 1-9 | 6.3 | 1.0 | 5-8 | 6.0 | 1.9 | 3-9 | 6.3 | 1.4 | 3-9 | 6.5 | 1.6 | 1-9 | NS |
| Number of weeks in study | 15.1 | 2.9 | 8-21 | 16.6 | 5.9 | 1-19 | 15.7 | 4.3 | 1-21 | 15.3 | 2.4 | 11-18 | 15.3 | 4.7 | 6-22 | 15.3 | 3.3 | 6-22 | 15.5 | 3.8 | 1-22 | NS |

Note. ^aNS = not significant.

Table 6
Comparison of WIC Participation Between the Experimental and Control Groups

| | Phase 1 n=2 | | | Experimental Phase 2 n=6 | | | Total n=8 | | | Phase 1 n=5 | | | Control Phase 2 n=3 | | | Total n=8 | | | Total n=16 | | | p Value |
|--|----------------|------------------|-------|--------------------------------|------------------|-------|--------------|------------------|-------|----------------|------------------|-------|---------------------------|------------------|-------|--------------|------------------|-------|---------------|------------------|-------|--------------------|
| | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | |
| Onset of participation in weeks gestation | 19.5 | 3.5 | 17-22 | 20 | 7.1 | 14-34 | 19.9 | 6.2 | 14-34 | 15.6 | 5.0 | 8-22 | 13.7 | 2.5 | 11-16 | 14.9 | 4.2 | 8-22 | 17.4 | 5.7 | 8-34 | p=.08 ^a |

Note. ^aTwo-tailed t-test.

gories of medications used included prenatal vitamins, iron preparation, antibiotics, analgesics, antiemetics, sedatives and Rhogam given to nonsensitized Rh negative gravidas. There was no significant difference between groups in either types or amounts of medications used during the study. Table 7 provides a breakdown of the medications ingested in both groups.

Initial Nutritional Data

Information at the initial nutritional assessment revealed that during the first 20 weeks, the protein intake ranged from approximately 23-192 grams per day (\bar{x} =79.2 grams). Kilocalorie intake ranged from approximately 935-3833 kilocalories per day (\bar{x} =2224.5 kilocalories). This ranged from 43-349% (\bar{x} =133.4%) of the subject's nonpregnant protein requirements. The range for percent of nonpregnant requirements for kilocalories was 40-183% (\bar{x} =100.7%). This intake was an estimated average based on the woman's recall of her nutritional intake during the first 20 weeks of pregnancy as it varied from her current intake. These nonpregnant requirements apply during the first 20 weeks of pregnancy according to the Higgins Method and Canadian Dietary Standards. Pregnancy additions are not given until the twentieth week. There was no significant difference between experimental and control groups (Table 8).

Nutrition Prescription

At the time of the initial nutritional assessment, a dietary history was also taken from each subject of food intake for the

Table 7

Comparison of Medications Used in Pregnancy Between the Experimental and Control Groups

| | Phase 1 n=14 | | Experimental Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Control Phase 2 n=9 | | Total n=24 | | Total N=47 | | p Value |
|--------------------------------|-----------------|---------|--------------------------------|---------|---------------|---------|-----------------|---------|---------------------------|---------|---------------|---------|---------------|---------|-----------------|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | |
| Prenatal vitamins ^a | 14 | 100 | 9 | 100 | 23 | 100 | 13 | 87 | 9 | 100 | 22 | 92 | 45 | 96 | NS ^b |
| Iron ^c | 4 | 29 | 6 | 67 | 10 | 43 | 2 | 13 | 4 | 44 | 6 | 25 | 16 | 34 | NS |
| Antibiotics ^d | 3 | 21 | 1 | 11 | 4 | 17 | 3 | 20 | 2 | 22 | 5 | 21 | 9 | 19 | NS |
| Vaginal meds ^e | 0 | 0 | 3 | 33 | 3 | 13 | 2 | 13 | 2 | 22 | 4 | 17 | 7 | 15 | NS |
| Analgesics ^f | 4 | 29 | 0 | 0 | 4 | 19 | 4 | 27 | 2 | 22 | 6 | 25 | 10 | 21 | NS |
| Bendectin ^R | 2 | 14 | 1 | 11 | 3 | 13 | 3 | 20 | 2 | 22 | 5 | 21 | 8 | 17 | NS |
| Rhogam ^R | 1 | 7 | 2 | 22 | 3 | 13 | 1 | 7 | 2 | 22 | 3 | 13 | 6 | 13 | NS |
| Sedatives ^g | 1 | 7 | 0 | 0 | 1 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | NS |
| Other ^h | 1 | 7 | 2 | 22 | 3 | 13 | 1 | 7 | 2 | 22 | 3 | 13 | 6 | 13 | NS |

Note. ^aVitamins prescribed but not taken in two cases; ^bNS=not significant; ^cIron not prescribed in 30 cases, iron prescribed but not taken in one case; ^dMedications included Erythromycin, Ampicillin, Septra^R, Macrochantin^R; ^eMedications included Monistat^R; ^fMedications included Tylenol^R, Tylenol with codeine^R, Fiorinal^R, Aspirin; ^gMedications included Seconal^R; ^hMedications included Hycodan^R, Betadine Douche^R, Colace^R, Benadryl^R, Chlor-Trimeton^R, Mylanta^R.

Table 8

Comparison of Estimated Protein and Kilocalorie Ingestion Prior to the Initial Assessment
Between the Experimental and Control Groups

| | Protein | | | | | | | p Value | Kilocalories | | | | | | | p Value |
|---|-----------------|----------------|---------------|-----------------|----------------|---------------|---------------|-----------------|-----------------|----------------|---------------|-----------------|----------------|---------------|---------------|------------|
| | Experimental | | | Control | | | | | Experimental | | | Control | | | | |
| | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | Phase 1 n=15 | Phase 2 n=9 | Total n=24 | Total N=47 | | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | Phase 1 n=15 | Phase 2 n=9 | Total n=24 | Total N=47 | |
| Average daily actual amount | | | | | | | | | | | | | | | | |
| \bar{X} | 76.3 | 86.8 | 80.4 | 77.0 | 79.8 | 78.0 | 79.2 | NS ^a | 2245.7 | 2346.3 | 2285.1 | 2173.8 | 2154.1 | 2166.4 | 2224.5 | NS |
| <u>SD</u> | 16.1 | 39.8 | 27.5 | 22.3 | 46.7 | 32.7 | 30.0 | | 568.7 | 943.5 | 692.2 | 581.5 | 819.1 | 662.8 | 672.6 | |
| Range | 49-113 | 44-145 | 44-145 | 36-133 | 23-192 | 23-192 | 23-192 | | 1406- 3225 | 1005- 3781 | 1005- 3781 | 935- 3204 | 1128- 3833 | 935- 3833 | 935- 3833 | |
| Percent of non- pregnant requirements | | | | | | | | | | | | | | | | |
| \bar{X} | 129.4 | 140.7 | 133.9 | 130.3 | 137.4 | 133.0 | 133.4 | NS | 103.0 | 103.3 | 103.1 | 100.0 | 95.5 | 98.4 | 100.7 | NS |
| <u>SD</u> | 37.5 | 55.7 | 44.6 | 48.0 | 86.7 | 63.5 | 54.5 | | 29.7 | 38.6 | 32.6 | 30.0 | 38.7 | 32.8 | 32.4 | |
| Range | 84-213 | 76-224 | 76-224 | 53-251 | 43-349 | 43-349 | 43-349 | | 64-165 | 40-168 | 40-168 | 41-164 | 56-183 | 41-183 | 40-183 | |

Note. ^aNS = not significant.

previous seven days, using the previously described methodology of Higgins. This history formed the basis for the nutritional prescription. The seven-day diet recalls revealed a range of average daily protein of 23-192 grams (\bar{x} =83.9 grams) and an average daily kilocalorie intake of 1005-4520 (\bar{x} =2366.2 kilocalories). This average daily nutritional intake consumed in the seven-day period ranged from 16-240% (\bar{x} =83.7%) of the protein requirement and 30-147% (\bar{x} =80.6%) of the kilocalorie requirement according to their individual prescriptions. There was no significant difference between experimental and control groups for either the actual food intake or the percent of the prescription in those seven days (Table 9).

There was no significant difference in protein and kilocalorie prescription at 20 weeks between experimental and control groups in pregnancy requirements, corrective allowances, or total nutritional prescription. The basic prescriptions for pregnancy based on ideal weight excluding the correctional additions ranged from 75-113 grams of protein (\bar{x} =85.8 grams) and 2300-3650 kilocalories (\bar{x} =2741.0 kilocalories) (Table 10).

Seven (15%) of the subjects were given a corrective allowance for underweight, 28 (60%) were given a corrective allowance for undernutrition, and 19 (40%) were given a corrective allowance for nutritional stress (Table 11).

The nutritional stress correction included four women (9%) who had two pregnancies within a 12 month period, seven women (15%) who had a previous poor obstetrical outcome and 14 women (30%) who

Table 9
 Comparison of Protein and Kilocalorie Ingestion at Initial Assessment
 Between the Experimental and Control Groups

| | Protein | | | | | | | p Value | Kilocalories | | | | | | | p Value |
|-----------------------------|-----------------|----------------|---------------|-----------------|----------------|---------------|---------------|-----------------|-----------------|----------------|---------------|-----------------|----------------|---------------|---------------|---------|
| | Experimental | | | Control | | | | | Experimental | | | Control | | | | |
| | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | Phase 1 n=15 | Phase 2 n=9 | Total n=24 | Total N=47 | | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | Phase 1 n=15 | Phase 2 n=9 | Total n=24 | Total N=47 | |
| Average daily actual amount | | | | | | | | | | | | | | | | |
| \bar{X} | 81.9 | 86.8 | 83.8 | 86.5 | 79.8 | 84.0 | 83.9 | NS ^a | 2408.9 | 2346.4 | 2384.4 | 2465.5 | 2154.1 | 2348.8 | 2366.2 | NS |
| SD | 18.7 | 39.8 | 28.1 | 26.2 | 46.9 | 34.6 | 31.2 | | 597.0 | 943.4 | 731.6 | 794.2 | 819.1 | 800.6 | 759.5 | |
| Range | 49-113 | 44-145 | 44-145 | 41-137 | 23-192 | 23-192 | 23-192 | | 1406-3425 | 1005-3781 | 1005-3781 | 1090-4520 | 1128-3833 | 1090-4520 | 1005-4520 | |
| Percent of prescription | | | | | | | | | | | | | | | | |
| \bar{X} | 85 | 80.9 | 83.5 | 86.5 | 79.4 | 83.9 | 83.7 | NS | 85 | 77.3 | 81.9 | 85 | 69.7 | 79.4 | 80.6 | NS |
| SD | 27.6 | 41.0 | 32.6 | 29.6 | 68.6 | 46.8 | 40.0 | | 23.7 | 31.9 | 26.8 | 26.5 | 34.7 | 30.1 | 28.3 | |
| Range | 31-145 | 33-127 | 31-145 | 28-126 | 16-240 | 16-240 | 16-240 | | 41-132 | 30-128 | 30-132 | 32-146 | 34-147 | 32-147 | 30-147 | |

Note. ^aNS = not significant.

Table 10
Comparison of the Components in the Nutritional Prescription Between the
Experimental and Control Groups

| | Protein in Grams | | | | | | | p Value | Kilocalories | | | | | | | p Value | |
|-------------------------------------|------------------|----------------|---------------|-----------------|----------------|---------------|---------------|-----------------|-----------------|----------------|---------------|-----------------|----------------|---------------|---------------|---------|----|
| | Experimental | | | Control | | | Total N=47 | | Experimental | | | Control | | | Total N=47 | | |
| | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | Phase 1 n=15 | Phase 2 n=9 | Total n=24 | | | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | Phase 1 n=15 | Phase 2 n=9 | Total n=24 | | | |
| Pregnancy requirements ^a | | | | | | | | | | | | | | | | | |
| \bar{X} | 85.4 | 85.4 | 85.4 | 86.0 | 86.4 | 86.2 | 85.8 | NS ^b | 2717.9 | 2763.9 | 2735.9 | 2700.0 | 2822.2 | 2745.8 | 2741.0 | | NS |
| SD | 7.9 | 7.2 | 7.5 | 8.5 | 11.1 | 9.3 | 8.4 | 216.5 | 175.5 | 198.5 | 194.6 | 339.0 | 258.2 | 228.5 | | | |
| Range | 77-100 | 79-100 | 77-100 | 75-100 | 79-113 | 75-113 | 75-113 | 2375-3050 | 2525-3000 | 2375-3050 | 2300-3000 | 2525-3650 | 2300-3650 | 2300-3650 | | | |
| Total requirements for prescription | | | | | | | | | | | | | | | | | |
| \bar{X} | 101.9 | 111.9 | 105.8 | 104.7 | 124.3 | 112.1 | 109.0 | NS | 2884.3 | 3072.8 | 2958.0 | 2912.7 | 3245.6 | 3037.5 | 2998.6 | | NS |
| SD | 23.6 | 14.7 | 20.8 | 22.3 | 42.1 | 31.8 | 26.9 | 329.3 | 237.4 | 305.6 | 269.4 | 593.2 | 440.1 | 378.3 | | | |
| Range | 78-157 | 92-136 | 78-157 | 78-144 | 79-187 | 79-187 | 78-187 | 2450-3440 | 2720-3455 | 2450-3455 | 2450-3390 | 2600-4390 | 2450-4390 | 2450-4390 | | | |

Note. ^aPregnancy requirements are based on Agnes Higgins Formula, Form C, Appendix A. ^bNS = not significant.

Table 11

Comparisons of Additions for Corrective Allowances Between the Experimental and Control Groups

| | Protein | | | | | | | p Value | Kilocalories | | | | | | | p Value |
|--------------------|--------------|-------------|--------------|-------------|-----------------|--------------|--------------|-----------------|--------------|-------------|--------------|-------------|-------------|--------------|--------------|---------|
| | Experimental | | | Control | | | Total | | Experimental | | | Control | | | Total | |
| | Phase 1 | Phase 2 | Total | Phase 1 | Phase 2 | Total | | | Phase 1 | Phase 2 | Total | Phase 1 | Phase 2 | Total | | |
| Underweight | <u>n</u> =2 | <u>n</u> =2 | <u>n</u> =4 | <u>n</u> =2 | <u>n</u> =1 | <u>n</u> =3 | <u>n</u> =7 | NS ^a | <u>n</u> =2 | <u>n</u> =2 | <u>n</u> =4 | <u>n</u> =2 | <u>n</u> =1 | <u>n</u> =3 | <u>n</u> =7 | NS |
| \bar{X} | 14.5 | 13.0 | 13.8 | 13.0 | 10.0 | 12.0 | 13.0 | | 360.0 | 330.0 | 345.0 | 320.0 | 250.0 | 296.7 | 324.3 | |
| <u>SD</u> | 2.1 | 2.8 | 2.2 | 1.4 | NA ^b | 2.0 | 2.2 | | 42.4 | 63.6 | 47.4 | 35.4 | NA | 47.5 | 50.5 | |
| Range | 13-16 | 11-15 | 11-16 | 12-14 | - | 10-14 | 10-16 | | 330-390 | 285-375 | 285-390 | 295-345 | - | 250-345 | 250-390 | |
| Undernutrition | <u>n</u> =9 | <u>n</u> =5 | <u>n</u> =14 | <u>n</u> =8 | <u>n</u> =6 | <u>n</u> =14 | <u>n</u> =28 | NS | <u>n</u> =9 | <u>n</u> =5 | <u>n</u> =14 | <u>n</u> =8 | <u>n</u> =6 | <u>n</u> =14 | <u>n</u> =28 | NS |
| \bar{X} | 14.8 | 26.4 | 18.9 | 16.1 | 31.0 | 22.5 | 20.7 | | 147.8 | 264.0 | 189.3 | 161.3 | 310.0 | 225.0 | 207.1 | |
| <u>SD</u> | 12.3 | 11.8 | 13.0 | 12.0 | 21.2 | 17.6 | 15.3 | | 122.7 | 118.5 | 130.1 | 119.7 | 211.9 | 175.6 | 152.7 | |
| Range | 2-34 | 12-39 | 2-39 | 2-42 | 4-56 | 2-56 | 2-56 | | 20-340 | 120-390 | 20-390 | 20-240 | 40-560 | 20-560 | 20-560 | |
| Nutritional stress | <u>n</u> =6 | <u>n</u> =4 | <u>n</u> =10 | <u>n</u> =5 | <u>n</u> =4 | <u>n</u> =9 | <u>n</u> =19 | NS | <u>n</u> =6 | <u>n</u> =4 | <u>n</u> =10 | <u>n</u> =5 | <u>n</u> =4 | <u>n</u> =9 | <u>n</u> =19 | NS |
| \bar{X} | 26.7 | 20.0 | 24.0 | 28.0 | 30.0 | 28.9 | 26.3 | | 266.7 | 200.0 | 240.0 | 280.0 | 300.0 | 288.9 | 263.2 | |
| <u>SD</u> | 10.3 | NA | 8.4 | 11.0 | 11.5 | 10.5 | 9.6 | | 103.3 | NA | 84.3 | 109.5 | 115.5 | 105.4 | 95.5 | |
| Range | 20-40 | - | 20-40 | 20-40 | 20-40 | 20-40 | 20-40 | | 200-400 | - | 200-400 | 200-400 | 200-400 | 200-400 | 200-400 | |

Note. ^aNS = not significant; ^bNA = not applicable.

had failed to gain ten pounds by the twentieth week of pregnancy (Table 12).

Reliability and Compliance of the Subjects

A subjective evaluation was made by the researchers at the end of the data collection process regarding the reliability of the subjects. This evaluation was based on the verbal and nonverbal behaviors of the subjects over the course of the nutritional visits. This evaluation was quantified on a Likert-type scale of one to five, with one being the least reliable, and five being the most reliable. The researchers in phase one rated their subjects, with the majority of subjects (83%) ranking four or five on this scale. The researchers in phase two rated their subjects, with 44% ranking four or five on this scale. The combined total rated 68% of the subjects either four or five (Table 13).

Following the approach utilized by Higgins, the researchers attempted to document compliance versus resistance of the prescription given to the experimental group. This was based on the subjects' willingness to eat to prescription and evidence of reasonable effort to do so. The compliance evaluation was quantified again on a scale of one to five, with one being least compliant and five being most compliant. In phase one, ten (71%) of the 14 women in the experimental group were ranked four or five. In phase two, four (50%) of the eight women in the experimental group were ranked four or five. In the total group, 14 (64%) ranked four or five. Of these 14 subjects, eight did, in fact, ingest greater than or equal to 85% of both their protein and kilocalorie prescriptions.

Table 12

Comparison of the Categories for Nutritional Stress Between the Experimental and Control Groups

| | Phase 1 n=14 | | Experimental Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Control Phase 2 n=9 | | Total n=24 | | Total n=47 | | p Value |
|---|-----------------|---------|--------------------------------|---------|---------------|---------|-----------------|---------|---------------------------|---------|---------------|---------|---------------|---------|-----------------|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | |
| Recent pregnancy | 1 | 7 | 0 | 0 | 1 | 4 | 1 | 7 | 2 | 22 | 3 | 13 | 4 | 9 | NS ^a |
| Previous poor obstetrical outcome | 3 | 21 | 0 | 0 | 3 | 13 | 2 | 13 | 2 | 22 | 4 | 17 | 7 | 15 | NS |
| Failure to gain 10 pounds by the 20th week of gestation | 3 | 21 | 4 | 44 | 7 | 30 | 4 | 27 | 3 | 33 | 7 | 29 | 14 | 30 | NS |

Note. ^aNS = not significant.

Table 13

Comparison of the Reliability of Nutritional Information Given by Subjects in the
Experimental and Control Groups

| | Phase 1 n=14 | | Experimental Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Control Phase 2 n=9 | | Total n=24 | | Total N=47 | | p Value |
|-----------------------|-----------------|---------|--------------------------------|---------|---------------|---------|-----------------|---------|---------------------------|---------|---------------|---------|---------------|---------|-----------------|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | |
| Least reliable - 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 11 | 1 | 4 | 1 | 2 | NS ^a |
| ↓ | 2 | 0 | 1 | 11 | 1 | 4 | 1 | 7 | 4 | 45 | 5 | 21 | 6 | 13 | NS |
| | 3 | 1 | 2 | 22 | 3 | 13 | 3 | 20 | 2 | 22 | 5 | 21 | 8 | 17 | NS |
| ↓ | 4 | 4 | 6 | 67 | 10 | 43 | 2 | 13 | 1 | 11 | 3 | 13 | 13 | 28 | NS |
| Most reliable - 5 | 9 | 64 | 0 | 0 | 9 | 39 | 9 | 60 | 1 | 11 | 10 | 42 | 19 | 40 | NS |

Note. ^aNS = not significant.

However, three women stated they understood the diet prescription and felt they could make the appropriate additions, but their compliance never actually materialized into increased intake. These three women ingested 90% protein, 84% kilocalories; 87% protein, 84% kilocalories; and 73% protein, 83% kilocalories, respectively.

One woman was very willing but had many socioeconomic problems and at times inadequate funds to purchase foods. She ingested 71% of her protein prescription and 97% of her kilocalorie prescription.

Another woman ingested 82% of her protein prescription and 87% of her kilocalorie prescription. In her first pregnancy, she had gained an excessive amount of weight and had developed pregnancy-induced hypertension. During nutritional intervention, the woman's mother would object to her increasing her diet for fear of repeating her first pregnancy course. The mother seemed to have a significant influence on what this woman ate.

The last woman ate 70% of her protein and 76% of her kilocalorie prescription. She was ill several times during her pregnancy. She had a "cold" at one time; nausea, vomiting, and diarrhea at another, both which decreased her appetite and affected her intake. She also passed a kidney stone early in her third trimester which affected her appetite.

There were four women (29%) in phase one and four women (50%) in phase two who were ranked one, two, or three on the five point scale as less compliant, for a combined total of eight women (40%). In phase one, there were four women (29%) who were ranked one, two, or three on the five point scale as less compliant. The subject

ranked three ate 85% of her protein prescription and 96% of her kilocalories. At times, she was not willing to eat additions because of fear of gaining too much weight in pregnancy. Two women were ranked two. One of these women ingested 59% of her protein prescription and 66% of her kilocalorie prescription. Although she expressed a willingness to eat, she stated that the heat and lack of appetite kept her from eating. She would substitute the additions suggested for her individual diet rather than adding them to it. The second woman ate 93% of her protein prescription and 78% of her kilocalorie prescription and protested at each visit about the nutritional additions but would reluctantly agree to comply. The woman ranked lowest in compliance ate 69% of her protein prescription and 78% of her kilocalorie prescription, refused in spite of vigorous counseling to increase her intake and also blamed the heat for her diet of watermelon and Coca-Cola (Table 14).

In phase two, there were two women who ranked a three. One woman was agreeable to increasing her intake but also admitted that she did not often have enough money to eat more. She had five small children already in the family. She ate 86% of her protein and 85% of her kilocalorie prescription. The other woman who rated a three was concerned with excessive weight gain during her pregnancy. She had an early diagnosis of polyhydramnios, which resolved by delivery, but this seemed to make her feel bloated early in pregnancy, and not as interested in increasing her nutrient intake. She ingested 80% of protein and 81% of her kilocalorie prescription.

Also in phase two were two women who ranked a two. One woman

Table 14
Compliance with the Nutritional Prescription by the
Subjects in the Experimental Group

| | <u>n</u> =14 | Phase 1 Percent | <u>n</u> =8 | Phase 2 Percent | <u>n</u> =22 | Total Percent |
|---------------------|--------------|--------------------|-------------|--------------------|--------------|------------------|
| Least compliant - 1 | 1 | 7 | 0 | 0 | 1 | 4 |
| 2 | 2 | 14 | 2 | 25 | 4 | 18 |
| 3 | 1 | 7 | 2 | 25 | 3 | 14 |
| 4 | 6 | 43 | 3 | 37 | 9 | 41 |
| Most compliant - 5 | 4 | 29 | 1 | 13 | 5 | 23 |



ate 108% of her protein and 85% of her kilocalorie prescription. Her physician and her husband (also a physician) recommended that she limit her intake because of her early weight gain of 20 pounds by 23 weeks gestation. The last woman, also ranked a two, ingested 36% of her protein prescription and 45% of her kilocalorie prescription. This woman seemed to have some emotional difficulties and lost weight during her pregnancy when her husband was away. She developed significant edema and was hospitalized for pregnancy-induced hypertension for three days at about 33 weeks gestation. She seemed not to be able to make the connection that an increase in milk and a decrease in cola consumption might improve her condition (Table 14).

One woman, in the experimental group of phase two, was not considered in the reliability or compliance data. She delivered at 22 weeks gestation after only one nutritional assessment and therefore could not be evaluated in comparison with later assessments. Her one assessment revealed an intake of 74% of protein and 77% of kilocalorie prescriptions.

Hypotheses

Although all available women at the research site during both data collection periods were included, some of the subgroups failed to contain adequate subjects with the designated characteristics at the completion of phase two. Therefore, only eight of the original 12 hypotheses were able to be tested. The sample size will be increased as other phases of the study are completed. Where numbers were sufficient, appropriate statistics have been applied.

Statistical calculations were done using only singleton births. There were, however, two sets of twin births in the sample. Both of the women with twins were in the control group, were greater than 95% of their ideal weights at the onset of pregnancy, gained less than ten pounds by their twentieth week gestation, and ingested less than 85% of their nutritional prescriptions. Statistical comparisons between groups including the two sets of twin births are presented in Appendix D (Table 31). In the following, each of the 12 hypotheses will be presented.

Hypothesis One

Women whose pregravid weight is less than 95% of their ideal weight will have infants with significantly lower birthweights than women whose pregravid weight is 95% or above their ideal weight.

Hypothesis Two

Women whose pregravid weight is less than 95% of their ideal weight will have more maternal complications than women whose pregravid weight is 95% or above their ideal weight.

Data for hypotheses one and two are presented in Table 15. The mean birthweight in the group with inadequate pregravid weight was 2968.6 grams, while in the group with adequate pregravid weight, the mean was 3303.4 grams, with twin births excluded. This difference of 334.8 grams did not reach the .05 level of significance.

The number of maternal complications was approximately the same for both groups.

Table 15

Birthweights and Maternal Complications in Women with Low Pregravid Weight

| | Pregravid Weight < 95% of Ideal Weight | | | Pregravid Weight ≥ 95% of Ideal Weight | | | p Value |
|-----------------------------------|---|----------------|--------------|---|---------------------|---------------------|-----------------|
| | Phase 1 n=4 | Phase 2 n=3 | Total n=7 | Phase 1 n=25 | Phase 2 n=15 | Total n=40 | |
| Birthweight in grams ^a | | | | | | | |
| \bar{X} | 3142.5 | 2736.7 | 2968.6 | 3297.3 | 3316.0 ^b | 3303.4 ^b | NS ^c |
| <u>SD</u> | 237.5 | 1473.0 | 893.6 | 381.6 | 579.1 | 446.8 | |
| Range | 2890-3400 | 1050-3770 | 1050-3770 | 2500-4020 | 2460-4520 | 2460-4520 | |
| Number of maternal complications: | | | | | | | |
| Antepartal | | | | | | | |
| \bar{X} | .08 | 1.0 | 0.9 | 1.0 | 1.4 | 1.1 | NS |
| <u>SD</u> | 1.0 | 1.0 | 0.9 | 0.9 | 0.9 | 0.9 | |
| Intrapartal | | | | | | | |
| \bar{X} | 0 | 1.3 | 0.6 | 0.6 | 0.5 | 0.6 | NS |
| <u>SD</u> | 0 | 1.5 | 1.1 | .7 | 0.6 | 0.7 | |
| Postpartal | | | | | | | |
| \bar{X} | 1.0 | 0.7 | 0.9 | 0.6 | .73 | 0.6 | NS |
| <u>SD</u> | 0.8 | 1.2 | 0.9 | 0.7 | .70 | 0.6 | |
| Total | | | | | | | |
| \bar{X} | 1.8 | 3.0 | 2.3 | 2.2 | 2.6 | 2.3 | NS |
| <u>SD</u> | 1.7 | 3.0 | 2.2 | 1.7 | 1.5 | 1.6 | |
| Range | 0-4 | 0-6 | 0-6 | 0-6 | 1-6 | 0-6 | |

Note. ^aOf all live births, one 21 week stillborn excluded; ^btwin births excluded; ^cnot significant.

Hypothesis Three

Women whose pregravid weight is less than 95% of their ideal weight and who fail to gain ten pounds in the first 20 weeks of pregnancy will have infants with significantly lower birthweights than normal or overweight women who gain ten pounds in the first 20 weeks of pregnancy.

Hypothesis Four

Women whose pregravid weight is less than 95% of their ideal weight, and who fail to gain ten pounds in the first 20 weeks of pregnancy will have more maternal complications than normal or overweight women who gain ten pounds in the first 20 weeks of pregnancy.

Hypotheses three and four are not yet tested. Only one woman in the sample, in the control group of phase one, had both inadequate pregravid weight (89% of ideal weight) and failed to gain ten pounds in the first 20 weeks (nine pounds). Her infant weighed 3000 grams and she had one complication of a low hematocrit (34%) in the postpartum period.

Hypothesis Five

Women with a failure to gain ten pounds in the first 20 weeks of pregnancy, who thereafter meet their individual protein and kilocalorie prescriptions, will have infants with significantly greater birthweights, than those who fail to gain ten pounds in the first 20 weeks of pregnancy and do not meet their individual protein and kilocalorie prescriptions thereafter.

Hypothesis Six

Women with a failure to gain ten pounds in the first 20 weeks of pregnancy, who thereafter meet their individual protein and kilocalorie prescriptions, will have fewer maternal complications than those women who fail to gain ten pounds in the first 20 weeks of pregnancy and do not meet their individual protein and kilocalorie prescriptions thereafter.

There was an inadequate sample size to test hypotheses five and six. Only one woman, in phase one, failed to gain ten pounds in the first 20 weeks of pregnancy (four pounds) and then went on to meet her protein and kilocalorie prescription (110% of protein and 93% of kilocalories). Her infant weighed 3480 grams, and she had complications of a low hematocrit (35%) in the antepartum and a low hematocrit (35%) in the postpartum period. There were 13 women (in both phases combined) who failed to gain ten pounds in the first 20 weeks of pregnancy and then did not meet their protein and kilocalorie prescriptions thereafter. Their data are presented in Table 16. The total mean birthweight of the infants of these 13 women was 3127.4 grams, with twin births excluded, which was 353 grams less than the woman who met her protein and kilocalorie prescriptions in the second half of her pregnancy. Maternal complications in this group ranged from zero to six.

Hypothesis Seven

Women who have met their individual protein and kilocalorie prescriptions will have significantly greater maternal weight gain during pregnancy than those who have not met their individual protein

Table 16

Birthweights and Maternal Complications in Women With Inadequate Early Pregnancy Weight Gain and Failure to Meet Their Nutritional Prescription Thereafter, n=13

| Subjects ID No. & Group | Weight Gain at 20 weeks Gestation | Total Weight Gain | Percent of Protein Prescription After 20 Weeks | Percent of kcal Prescription After 20 Weeks | Birthweight of Infant | Number and Type of Maternal Complication |
|-------------------------|-----------------------------------|-------------------|--|---|-----------------------|---|
| Phase 1 (<u>n</u> =6) | | | | | | |
| 38-C ^a | -3 lbs. | 9 lbs. | 54 | 81 | 3090 grams | Anemia - AP ^a Anemia - PPa |
| 42-E ^a | 4 lbs. | 15.8 | 71 | 97 | 2550 grams | UTI ^a - AP Gestational diabetes - AP Premature labor - IP ^a |
| 44-E | 9 lbs. | 23 lbs. | 69 | 78 | 3480 grams | ∅ |
| 25-E | 6 lbs. | 13 lbs. | 59 | 66 | 3941 grams | PIH ^a - AP PIH - IP Anemia - PP |
| 30-C | 3 lbs. | 23 lbs. | 64 | 73 | 2948 grams | ∅ |
| 33-C ^b | 9 lbs. | 28 lbs. | 69 | 78 | 3000 grams | Anemia - PP |
| Phase 1 | | | | | | |
| \bar{X} | 4.7 lbs. | 18.6 lbs. | 63 | 78.9 | 3168.2 grams | 1.5 |
| <u>SD</u> | 4.5 | 7.2 | 64 | 10.3 | 481.6 | 1.4 |
| Range | -3 - 9 lbs. | 9-28 lbs. | 54-71 | 66-97 | 2550-3941 grams | 0-3 |

Table 16 (Continued)

| Subjects ID No. & Group | Weight Gain at 20 weeks Gestation | Total Weight Gain | Percent of Protein Prescription After 20 Weeks | Percent of kcal Prescription After 20 Weeks | Birthweight of Infant | Number and Type of Maternal Complication |
|-------------------------|-----------------------------------|-------------------|--|---|--|--|
| Phase 2 (n=7) | | | | | | |
| 11-C | 6 lbs. | 37 lbs. | 33 | 46 | 2460 grams | PIH - AP PIH - IP |
| 15-C | 6 lbs. | 28 lbs. | 59 | 66 | 2770 ^c , 1700 ^d grams | PIH - IP Platelet dysfunction - IP |
| 2-C | 5 lbs. | 31.5 lbs. | 48 | 72 | 2290 ^c , 2630 ^d grams | Pneumonia - AP Hemorrhage - PP |
| 4-E | -6 lbs. | 15.5 lbs. | 70 | 76 | 3200 grams | Kidney stones - AP Anemia - PP |
| 5-E | 1 lb. | 18 lbs. | 82 | 87 | 3010 grams | Herpes - AP Vaginal infection - AP |
| 7-E | 6 lbs. | 36 lbs. | 73 | 83 | 2722 grams | Anemia - PP |
| 9-E | 3 lbs. | 29.5 lbs. | 87 | 84 | 4000 grams | Vaginal infection - AP UTI - AP Anemia - AP PIH - IP UTI - PP Anemia - PP |

Table 16 (Continued)

| Subjects ID No. | Weight Gain at 20 Weeks Gestation | Total Weight Gain | Percent of Protein Prescription After 20 Weeks | Percent of Kcal Prescription After 20 Weeks | Birthweight of Infant | Number and Type of Maternal Complication |
|-------------------|-----------------------------------|-------------------|--|---|-----------------------|--|
| Phase 2 | | | | | | |
| \bar{x} | 3.0 lbs. | 27.9 lbs. | 64.6 | 73.4 | 3078.4 ^e | 2.4 |
| <u>SD</u> | 4.4 | 8.3 | 19.2 | 14.2 | 587.0 | 1.6 |
| Range | -6 - 6 lbs. | 15.5-37 lbs. | 33-87 | 46-87 | 2460-4000 | 1-6 |
| Total n=13 | | | | | | |
| \bar{x} | 3.8 lbs. | 23.6 lbs. | 64.5 | 75.9 | 3127.4 ^e | 2.0 |
| <u>SD</u> | 4.3 | 8.9 | 14.2 | 12.4 | 505.9 | 1.5 |
| Range | -6 - 9 lbs. | 9-37 lbs. | 33-87 | 46-97 | 2290-4000 | 0-6 |

Note. ^aC=Control Group, E=Experimental Group, AP=Antepartum, IP=Intrapartum, PP=Postpartum, PIH=Pregnancy induced hypertension, UTI=Urinary tract infection;
^b11% Under ideal weight at start of pregnancy; ^cTwin A; ^dTwin B; ^eWith twin births excluded.

and kilocalorie prescriptions.

Hypothesis Eight

Women who have met their individual protein and kilocalorie prescriptions will have significantly fewer maternal complications than those who have not met their individual protein and kilocalorie prescriptions.

Hypothesis Nine

Women who have met their individual protein and kilocalorie prescriptions will have infants with a significantly greater birthweight than those who have not met their individual protein and kilocalorie prescriptions.

There were 18 women whose average daily intake of both protein and kilocalories after 20 weeks was greater than or equal to 85% of their prescriptions. There were 28 women whose average daily intake was less than 85%. Their weight gain, complications, and their infants' birthweights are presented in Table 17.

Hypothesis seven was not supported. There was found to be no significant difference in the total maternal weight gain between the two groups. Both groups had an acceptable mean weight gain. The range varied greatly between the groups, however. One woman in the adequate group gained 19.5 pounds (8.86 kg), with the remainder gaining greater than or equal to 23 pounds (10.45 kg). In the inadequate group, five women (18% of the inadequate group) gained less than 16.5 pounds (7.5 kg) during their pregnancies. Three women had excessive weight gains of greater than 50 pounds (22.7 kg).

Table 17

Comparison of Maternal Weight Gain, Maternal Complications and Their Infants' Birthweights
With Nutrition Prescription Ingestion After 20 Weeks

| | Average Daily Prescription ≥ 85% | | | Average Daily Prescription < 85% | | | p Value |
|---|-------------------------------------|----------------|---------------|-------------------------------------|---------------------|---------------------|-----------------|
| | Phase 1 n=13 | Phase 2 n=5 | Total n=18 | Phase 1 n=15 | Phase 2 n=13 | Total n=28 | |
| Maternal weight gain in pounds | | | | | | | |
| \bar{X} | 35.1 | 33.9 | 34.8 | 32.1 | 30.0 | 31.2 | NS ^a |
| <u>SD</u> | 8.0 | 10.2 | 8.3 | 15.8 | 11.0 | 13.6 | |
| Range | 23.0-48.5 | 19.5-45.0 | 19.5-48.5 | 9-66 | 15.5-51 | 9-66 | |
| Number of maternal complications | | | | | | | |
| Antepartum \bar{X} | .9 | 1.2 | 1.0 | .87 | 1.4 | 1.1 | NS |
| Intrapartum \bar{X} | .4 | 0.4 | 0.4 | .60 | 0.7 | 0.7 | NS |
| Postpartum \bar{X} | .6 | 0.0 | 0.0 | .73 | 0.9 | 0.8 | NS |
| Total \bar{X} | 1.9 | 1.6 | 1.8 | 2.2 | 2.9 | 2.6 | NS |
| <u>SD</u> | 1.4 | 1.1 | 1.3 | 1.97 | 1.8 | 1.9 | |
| Range | 0-4 | 0-3 | 0-4 | 0-6 | 1-6 | 0-6 | |
| Birthweight in grams^b | | | | | | | |
| \bar{X} | 3419.2 | 3416.0 | 3418.3 | 3173.6 | 3092.2 ^c | 3141.0 ^c | NS |
| <u>SD</u> | 395.1 | 251.6 | 353.7 | 309.7 | 956.4 | 632.9 | |
| Range | 2500-4020 | 3060-3770 | 2500-4020 | 2550-3941 | 1050-4520 | 1050-4520 | |

Note. ^aNS=not significant; ^bOf all live births, one 21 week stillborn excluded; ^cTwin births excluded.

They gained 51 pounds (23.2 kg), 61 pounds (27.7 kg), and 66 pounds (30.0 kg). By the twentieth week of pregnancy, they had gained 17 pounds (7.7 kg), 21 pounds (9.6 kg), and 48 pounds (21.8 kg), respectively.

Hypothesis eight was not supported. There was no significant difference in the number of maternal complications between those who had an adequate intake and those who did not. The number of complications ranged from zero to six. However, all seven of the subjects with prenatal pregnancy induced hypertension and all three subjects with premature labor were in the inadequate group.

Hypothesis nine was not supported. There was no significant difference between the mean birthweights of those who had an adequate intake and those who did not at the $p=.05$ level (twin births excluded) (two-tailed test). Both birthweight group means were above 3000 grams. There was a 277.3 gram difference between the two means in favor of those with an adequate intake. One woman, who had only an initial nutritional assessment, delivered a stillborn at 21 weeks gestation weighing 360 grams. This fetus was not included in the mean birthweight calculations. Another woman delivered a liveborn infant at 27 weeks that weighed 1050 grams. This infant subsequently expired six hours after birth. This birthweight is included in the calculations.

Hypothesis Ten

Women with a weight gain of ten pounds or more in the first 20 weeks of pregnancy who have met their individual protein and kilocalorie prescriptions will have infants with significantly

greater birthweights than those who have both failed to gain ten pounds in the first 20 weeks of pregnancy and have not met their individual protein and kilocalorie prescriptions.

Hypothesis Eleven

Women with a weight gain of ten pounds or more in the first 20 weeks of pregnancy who have met their individual protein and kilocalorie prescriptions will have fewer maternal complications than those who have both failed to gain ten pounds in the first 20 weeks of pregnancy and have not met their individual protein and kilocalorie prescriptions.

Hypothesis Twelve

Women with a weight gain of ten pounds or more in the first 20 weeks of pregnancy who have met their individual protein and kilocalorie prescriptions will have a greater maternal weight gain than those who have both failed to gain ten pounds in the first 20 weeks of pregnancy and have not met their individual protein and kilocalorie prescriptions.

There were 17 women who had both an adequate weight gain during the first 20 weeks of pregnancy and whose average daily intake of both protein and kilocalories after 20 weeks was greater than or equal to 85% of their individual prescriptions. Thirteen women had an inadequate weight gain and failed to ingest at least 85% of their prescriptions. Table 18 compares maternal weight gain, maternal complications, and their infants' birthweights in these two groups of women. The two sets of twins occurred in the inade-

Table 18

Early Pregnancy Weight Gain and Prescription Ingestion After 20 Weeks Compared With Maternal Weight Gain, Maternal Complications and Their Infants' Birthweights

| | Adequate Early Weight Gain and Adequate Prescription Ingestion Phase 1 n=12 | Adequate Early Weight Gain and Adequate Prescription Ingestion Phase 2 n=5 | Adequate Early Weight Gain and Adequate Prescription Ingestion Total n=17 | Inadequate Early Weight Gain and Inadequate Prescription Ingestion Phase 1 n=6 | Inadequate Early Weight Gain and Inadequate Prescription Ingestion Phase 2 n=7 | Inadequate Early Weight Gain and Inadequate Prescription Ingestion Total n=13 | p Value |
|-----------------------------------|---|--|---|--|--|---|-----------------------|
| Maternal weight gain in pounds | | | | | | | |
| \bar{X} | 36.1 | 33.9 | 35.5 | 18.6 | 27.9 | 23.6 | p=.00072 ^a |
| SD | 7.1 | 10.2 | 8.1 | 7.2 | 8.3 | 8.9 | |
| Range | 23-48.5 | 19.5-45 | 19.5-48.5 | 9-28 | 15.5-37 | 9-37 | |
| Number of maternal complications | | | | | | | |
| Antepartum \bar{X} | .92 | 1.2 | 1.0 | .67 | 1.3 | 0.9 | NS |
| Intrapartum \bar{X} | .42 | 0.4 | 0.4 | .33 | 0.6 | 0.5 | NS |
| Postpartum \bar{X} | .58 | 0.0 | 0.4 | .50 | 0.7 | 0.6 | NS |
| Total \bar{X} | 1.92 | 1.6 | 1.8 | 1.50 | 2.4 | 2.0 | NS |
| SD | 1.5 | 1.1 | 1.4 | 1.4 | 1.6 | 1.5 | |
| Range | 0-4 | 0-3 | 0-4 | 0-3 | 1-6 | 0-6 | |
| Birthweight in grams ^b | | | | | | | |
| \bar{X} | 3412.4 | 3416.0 | 3413.5 | 3168.2 | 3078.4 ^c | 3127.4 ^c | p=.09 ^d |
| SD | 411.9 | 251.6 | 363.9 | 481.6 | 587.0 | 505.9 | |
| Range | 2500-4020 | 3060-3770 | 2500-4020 | 2550-3941 | 2460-4000 | 2460-4000 | |

Note. ^aSignificant at a two-tailed t-test; ^bOf all live births, one 21 week stillborn excluded; ^cTwin births excluded; ^dtwo-tailed t-test.

quate group but their birthweights are not included.

Hypothesis ten was not supported. There was found to be only a trend toward significantly higher birthweight infants ($p=.09$) (two-tailed test) (twin births excluded) between those who had both an adequate weight gain during the first 20 weeks of pregnancy and who ate greater than or equal to 85% of their total individual prescriptions and those who did not. The adequate group had a mean birthweight of 3413.5 grams, 286.1 grams heavier than the mean of 3127.4 in the inadequate group. There were two birthweights less than 3000 grams in the adequate group as compared to eight birthweights less than 3000 grams in the inadequate group. The two sets of twins were in the inadequate group and all had birthweights below 3000 grams (2290, 2630, 2770, 1700 grams) but were not included in the birthweight statistics. (For birthweight comparisons with twin births included, see Appendix D). The one stillborn fetus delivered at 21 weeks gestation was not included in the birthweight calculations since that mother delivered before her initial nutritional intervention.

Hypothesis 11 was not supported. There was no significant difference in the number of maternal complications between those who gained adequately in early pregnancy and ate greater than 85% of their total prescription and those who did not. The number of complications ranged from zero to four in the adequate group and zero to six in the inadequate group.

Hypothesis 12 was supported. There was found to be a significant difference at the $p=.00072$ level (two-tailed test) in the maternal

weight gain between those who had both adequate weight gain and ate greater than or equal to 85% of their total individual prescriptions and those who did not. The adequate group had a mean weight gain of 35.5 pounds (16.1 kg) as compared to the 23.6 pounds (10.7 kg) in the inadequate group.

Comparison of Protein and Kilocalorie Ingestion After Twenty Weeks

Protein

The average daily grams of protein consumed by each subject in the experimental group from the period of the initial nutritional assessment through delivery ranged from 44-120 grams with a group mean of 91 grams. The control group, in the same time period, ranged from 29-136 grams, with a group mean of 82 grams. The difference between these two means did not reach a level of significance.

The average percent of protein prescription ingested daily by each subject in the experimental group ranged from 36-154%, with a group mean of 88%. The control group ingested an average daily amount which ranged from 20-170%, with a group mean of 81%. This difference did not reach a level of significance. Results are shown in Table 19.

Kilocalories

The average daily kilocalories consumed by each subject in the experimental group from the period of the initial nutritional assessment through delivery ranged from 1463-3341 kilocalories, with a group mean of 2542 kilocalories. The control group, in the

Table 19
 Comparison of Prescription Ingestion for Entire Study Period
 Between the Experimental and Control Groups

| | Protein | | | | | | | p Value | Kilocalories | | | | | | | p Value | | |
|-----------------------------|-----------------|----------------|---------------|-----------------|----------------|---------------|---------------|-----------------|-----------------|----------------|---------------|-----------------|----------------|---------------|---------------|---------|----|--|
| | Experimental | | | Control | | | Total N=46 | | Experimental | | | Control | | | Total N=46 | | | |
| | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | | | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | Phase 1 n=14 | Phase 2 n=9 | Total n=23 | | | | |
| Actual average daily amount | | | | | | | | | | | | | | | | | | |
| \bar{X} | 93.7 | 85.9 | 90.6 | 82.8 | 80.9 | 82.1 | 86.3 | NS ^a | 2642.1 | 2385.7 | 2541.8 | 2406.3 | 2414.2 | 2409.4 | 2475.6 | | NS | |
| SD | 16.8 | 21.3 | 18.6 | 10.5 | 33.6 | 21.8 | 20.5 | | 408.8 | 425.7 | 425.4 | 353.0 | 751.8 | 528.4 | 479.0 | | | |
| Range | 66.8-120.0 | 44.2-117.3 | 44.2-120.0 | 65.3-102.1 | 29.2-135.8 | 29.2-135.8 | 29.2-135.8 | | 2018.6-3340.6 | 1463.1-2942.11 | 1463.1-3340.6 | 2085.9-3327.3 | 1249.5-3416.1 | 1249.5-3416.1 | 1249.5-3416.1 | | | |
| Percent of prescription | | | | | | | | | | | | | | | | | | |
| \bar{X} | 95.0 | 77.5 | 88.2 | 83.0 | 76.8 | 80.9 | 84.5 | NS | 92.0 | 78.0 | 86.5 | 83.0 | 77.1 | 80.8 | 83.7 | | NS | |
| SD | 23.3 | 19.1 | 23.0 | 21.1 | 50.3 | 34.5 | 29.3 | | 13.8 | 13.6 | 15.2 | 11.2 | 30.7 | 20.7 | 18.2 | | | |
| Range | 59.0-153.8 | 36.2-107.6 | 36.2-153.8 | 54.0-116.0 | 20.1-169.8 | 20.1-169.8 | 20.1-169.8 | | 66.0-124.0 | 43.2-87.2 | 43.2-124.0 | 68.0-108.0 | 37.5-131.4 | 37.5-131.4 | 37.5-131.4 | | | |

Note. ^aNS = not significant.

same time period ranged from 1250-3416 kilocalories, with a group mean of 2409. This difference between the two groups was not significant.

The percent of kilocalorie prescription ingested daily by each subject in the experimental group ranged from 43-124%, with a group mean of 87%. The control group ingested a range of 38-131%, with a group mean of 81%. The ingested percent of kilocalorie prescription between the two groups did not reach a level of significance (Table 19).

Outcome Data

Maternal Weight

At the time of admission to labor and delivery, the subjects weights ranged from 118 pounds (53.6 kgs) to 281 pounds (127.7 kgs), with a mean of 169 pounds (76.8 kgs). Total maternal weight gain ranged from nine pounds (4.9 kg) to 66 pounds (30.0 kg) with a group mean of 33 pounds (15.0 kg). The postpartum weights were measured within 24 hours of delivery, when possible. Those ten subjects confined to bedrest due to pregnancy induced hypertension were weighed within 48 hours of delivery. The total range of postpartum weights was 107 (48.6 kg) to 269 pounds (122.3 kg) with a mean of 157 pounds (71.1 kg). The total range of postpartum weight loss was 0 to 17 pounds (7.7 kg) with a mean of 11 pounds (5.1 kg). There was no significant difference for any of the weights between the experimental and control groups (Table 20).

Table 20

Comparison of Maternal Weights Between the Experimental and Control Groups

| | Phase 1 n=14 | | | Experimental Phase 2 n=9 | | | Total n=23 | | | Phase 1 n=15 | | | Control Phase 2 n=9 | | | Total n=24 | | | Total N=47 | | | p Value |
|--|-----------------|-----------|---------|--------------------------------|-----------|---------|---------------|-----------|---------|-----------------|-----------|---------|---------------------------|-----------|-----------------------|---------------|-----------|-----------------------|---------------|-----------|-----------------------|-----------------|
| | \bar{X} | <u>SD</u> | Range | \bar{X} | <u>SD</u> | Range | \bar{X} | <u>SD</u> | Range | \bar{X} | <u>SD</u> | Range | \bar{X} | <u>SD</u> | Range | \bar{X} | <u>SD</u> | Range | \bar{X} | <u>SD</u> | Range | |
| Admission weight to hospital in pounds | | n=14 | | n=8 ^a | | n=22 | | n=15 | | n=9 | | n=24 | | n=46 | | | | | | | | NS ^b |
| | 162.6 | 32.8 | 128-250 | 168.5 | 26.2 | 146-226 | 164.8 | 30.0 | 128-250 | 173.5 | 40.3 | 118-281 | 170.9 | 43.6 | 121-272 | 172.5 | 40.6 | 118-281 | 168.8 | 35.8 | 118-281 | |
| Total weight gain in pounds | | n=14 | | n=8 | | n=22 | | n=15 | | n=9 | | n=24 | | n=46 | | | | | | | | NS |
| | 32.2 | 10.1 | 13-49 | 32.3 | 11.7 | 16-51 | 32.2 | 10.4 | 13-51 | 34.9 | 14.5 | 9-66 | 30.2 | 10.1 | 17-45 | 33.1 | 13.0 | 9-66 | 32.7 | 11.7 | 9-66 | |
| Placental weight in grams | | n=14 | | n=6 | | n=20 | | n=12 | | n=4 | | n=16 | | n=36 | | | | | | | | NS |
| | 599.3 | 53.7 | 520-700 | 681.7 | 191.6 | 450-900 | 624.0 | 114.6 | 450-900 | 614.6 | 136.1 | 470-900 | 575.0 | 183.6 | 300-1320 ^c | 604.7 | 143.7 | 300-1320 ^c | 615.4 | 126.8 | 300-1320 ^c | |
| Postpartum weight in pounds | | n=13 | | n=9 | | n=22 | | n=15 | | n=8 | | n=23 | | n=45 | | | | | | | | NS |
| | 150.9 | 35.5 | 119-241 | 154.4 | 24.4 | 132-211 | 152.3 | 30.8 | 119-242 | 161.4 | 41.3 | 107-269 | 160.8 | 47.0 | 114-264 | 161.2 | 42.3 | 107-269 | 156.8 | 37.0 | 107-269 | |
| Postpartum weight loss in pounds | | n=13 | | n=9 | | n=22 | | n=15 | | n=8 | | n=23 | | n=45 | | | | | | | | NS |
| | 11.2 | 2.9 | 5-14 | 10.9 | 4.7 | 0-15 | 11.1 | 3.6 | 0-15 | 12.0 | 3.4 | 4-17 | 9.8 | 3.6 | 6-17 | 11.3 | 3.6 | 4-17 | 11.2 | 3.6 | 0-17 | |

Note. ^aAll decreased n due to missing data; ^bNS = not significant; ^cTwin placenta weighed 1320 grams; weight divided between babies for \bar{X} and SD.

Type of Delivery

Seventy-two percent of the women in the study had normal spontaneous deliveries. Eight (17%) had low forceps deliveries. Five (11%) women had Cesarean section deliveries. Two were repeat, scheduled sections, one was for breech delivery of twins, one was a nulliparous woman with a frank breech delivery of twins, one was a nulliparous woman with a frank breech infant following a trial of labor, and the last was for persistent transverse lie. Ten women (21%) had pitocin inductions, and five women (11%) had pitocin augmentation. There was no significant difference in the type of labor and delivery between the experimental and control groups (Table 21).

There were a total of 18 (37%) female and 31 (63%) male infants delivered. However, there was no significant difference between the experimental and control groups with regard to sex of the infants (Table 22).

Maternal Complications

Complications of the antepartal period included vaginal infections, urinary tract infections, pneumonia, viral upper respiratory infection, varicella, herpes simplex, pregnancy induced hypertension, anemia, gestational diabetes, kidney stones, polyhydramnios, and a back problem treated with narcotics. Thirty-two (70%) of the subjects had at least one antepartal complication. There was no significant difference between the experimental and control groups in either the types or number of antepartal complications (Table 23).

Table 21

Comparison of Labor and Delivery Procedures Between the Experimental and Control Groups

| | Phase 1 n=14 | | Experimental Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Control Phase 2 n=9 | | Total n=24 | | Total N=47 | | p Value |
|----------------------|-----------------|---------|--------------------------------|---------|---------------|---------|-----------------|---------|---------------------------|---------|---------------|---------|---------------|---------|-----------------|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | |
| NSVD ^a | 10 | 71 | 6 | 67 | 16 | 70 | 12 | 80 | 6 | 67 | 18 | 75 | 34 | 72 | NS ^b |
| Forceps | 2 | 14 | 3 | 33 | 5 | 22 | 2 | 13 | 1 | 11 | 3 | 13 | 8 | 17 | NS |
| C-Section | 2 | 14 | 0 | 0 | 2 | 9 | 1 | 7 | 2 | 22 | 3 | 13 | 5 | 11 | NS |
| Pitocin induction | 1 | 7 | 3 | 33 | 4 | 17 | 4 | 27 | 2 | 22 | 6 | 25 | 10 | 21 | NS |
| Pitocin augmentation | 3 | 21 | 1 | 11 | 4 | 17 | 0 | 0 | 1 | 11 | 1 | 4 | 5 | 11 | NS |

Note. ^aNormal spontaneous vaginal delivery; ^bNS = not significant.

Table 22

Comparison of Infant Sex Between the Experimental and Control Groups

| | Phase 1 n=14 | | Experimental Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Control Phase 2 n=11 | | Total n=26 | | Total n=49 | | p Value |
|---------|-----------------|---------|--------------------------------|---------|---------------|---------|-----------------|---------|----------------------------|---------|---------------|---------|---------------|---------|-----------------|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | |
| Females | 3 | 21 | 5 ^a | 56 | 8 | 35 | 6 | 40 | 4 | 36 | 10 | 38 | 18 | 37 | NS ^b |
| Males | 11 | 79 | 4 | 44 | 15 | 65 | 9 | 60 | 7 | 64 | 16 | 62 | 31 | 63 | NS |

Note. ^aIncluded 1 stillborn at 21 weeks gestation; ^bNS = not significant.

Table 23

Comparison of Antepartal Complications Between the Experimental and Control Groups

| | Phase 1 n=14 | | Experimental Phase 2 n=8 | | Total n=22 | | Phase 1 n=15 | | Control Phase 2 n=9 | | Total n=24 | | Total N=46 | | p Value |
|--------------------------------------|-----------------|---------|--------------------------------|---------|---------------|---------|-----------------|---------|---------------------------|---------|---------------|---------|---------------|---------|-----------------|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | |
| All | 7 | 50 | 6 | 75 | 13 | 59 | 11 | 73 | 8 | 89 | 19 | 79 | 32 | 70 | NS ^a |
| Vaginal infections | 0 | 0 | 3 | 38 | 3 | 14 | 3 | 20 | 2 | 22 | 5 | 21 | 8 | 17 | NS |
| Urinary tract infections | 3 | 21 | 1 | 13 | 4 | 18 | 2 | 13 | 1 | 11 | 3 | 4 | 7 | 15 | NS |
| Other infections ^b | 0 | 0 | 1 | 13 | 1 | 5 | 0 | 0 | 3 | 33 | 3 | 13 | 4 | 9 | NS |
| Pregnancy induced hypertension | 1 | 7 | 1 | 13 | 2 | 9 | 4 | 27 | 2 | 22 | 6 | 25 | 8 | 17 | NS |
| Anemia | 4 | 29 | 1 | 13 | 5 | 23 | 6 | 40 | 1 | 11 | 7 | 29 | 12 | 26 | NS |
| Gestational diabetes | 1 | 7 | 1 | 13 | 2 | 9 | 1 | 7 | 0 | 0 | 1 | 4 | 3 | 7 | NS |
| Other ^c | 0 | 0 | 2 | 25 | 2 | 23 | 0 | 0 | 1 | 11 | 1 | 4 | 3 | 7 | NS |

Note. ^aNS = not significant; ^bIncludes pneumonia, viral upper respiratory infection, varicella, herpes simplex; ^cIncludes kidney stone, polyhydramnios, back problem.

Intrapartal complications included pregnancy induced hypertension, premature labor, premature rupture of membranes, and hemorrhage requiring blood transfusion. Twenty (43%) of the subjects had at least one intrapartal complication. There was no significant difference between the experimental and control groups in either the type or number of intrapartal complications (Table 24).

Postpartal complications included pregnancy induced hypertension 24 hours after delivery, hemorrhage requiring blood transfusion, anemia and postpartal infections. Twenty-five (53%) of the subjects had at least one postpartum complication. There was no significant difference between the experimental and control groups in either the number or type of postpartal complications (Table 25).

Baby Outcomes

The range for infant birthweights was 1050-4520 grams (\bar{x} =3250.1, twin births excluded). At the time of delivery, the subjects' weeks gestation was reported to range from 21-43 weeks (\bar{x} =39.0). There was no significant difference between the experimental and control groups in either infant birthweights or weeks gestation at the time of delivery (Table 26). Further information on the infants' gestational, physical, neurological, and behavioral information is currently being analyzed in two companion studies, The Effects of an Individualized Prescription During Pregnancy on Infant Outcome (Peterson, 1984) and The Effects of an Individualized Prescription During Pregnancy on Infant Outcome, Phase two (LaMalfa & Ryan, 1984).

Table 24

Comparison of Intrapartal Complications Between the Experimental and Control Groups

| | Phase 1 n=14 | | Experimental Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Control Phase 2 n=9 | | Total n=24 | | Total N=47 | | p Value |
|--------------------------------------|-----------------|---------|--------------------------------|---------|---------------|---------|-----------------|---------|---------------------------|---------|---------------|---------|---------------|---------|-----------------|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | |
| All | 8 | 57 | 4 | 44 | 12 | 52 | 4 | 21 | 4 | 44 | 8 | 33 | 20 | 43 | NS ^a |
| Pregnancy induced hypertension | 1 | 7 | 3 | 33 | 4 | 17 | 4 | 27 | 2 | 22 | 6 | 25 | 10 | 21 | NS |
| Premature labor | 2 | 14 | 0 | 0 | 2 | 9 | 0 | 0 | 1 | 11 | 1 | 4 | 3 | 6 | NS |
| Premature ROM ^b | 2 | 14 | 1 | 11 | 3 | 13 | 0 | 0 | 2 | 22 | 2 | 8 | 5 | 11 | NS |
| Prolonged ROM | 1 | 7 | 0 | 0 | 1 | 4 | 0 | 0 | 1 | 11 | 1 | 4 | 2 | 4 | NS |
| Hemorrhage | 3 | 21 | 0 | 0 | 3 | 13 | 1 | 7 | 0 | 0 | 1 | 4 | 4 | 9 | NS |
| Platelet dysfunction | 1 | 7 | 0 | 0 | 1 | 4 | 0 | 0 | 1 | 11 | 1 | 4 | 2 | 4 | NS |

Note. ^aNS = not significant; ^bROM = rupture of membranes.

Table 25

Comparison of Postpartal Complications Between the Experimental and Control Groups

| | Phase 1 n=14 | | Experimental Phase 2 n=9 | | Total n=23 | | Phase 1 n=15 | | Control Phase 2 n=9 | | Total n=24 | | Total N=47 | | p Value |
|--------------------------------------|-----------------|---------|--------------------------------|---------|---------------|---------|-----------------|---------|---------------------------|---------|---------------|---------|---------------|---------|-----------------|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | |
| All | 8 | 57 | 5 | 56 | 13 | 57 | 8 | 53 | 4 | 44 | 12 | 50 | 25 | 53 | NS ^a |
| Pregnancy induced hypertension | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 13 | 0 | 0 | 2 | 8 | 2 | 4 | NS |
| Hemorrhage | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 7 | 1 | 11 | 2 | 8 | 2 | 4 | NS |
| Anemia | 8 | 57 | 5 | 56 | 13 | 57 | 8 | 53 | 3 | 33 | 11 | 46 | 24 | 51 | NS |
| Infections ^b | 0 | 0 | 1 | 11 | 1 | 4 | 0 | 0 | 1 | 11 | 1 | 4 | 2 | 4 | NS |

Note. ^aNS = not significant; ^bInfections = chorioamnionitis, urinary tract infection, herpes.

Table 26

Comparison of Infant Outcomes Between the Experimental and Control Groups

| | Phase 1 n=14 | | | Experimental Phase 2 n=9 | | | Total n=23 | | | Phase 1 n=15 | | | Control Phase 2 n=9 | | | Total n=24 | | | Total N=47 | | | p Value |
|--|-----------------|------------------|---------------|--------------------------------|------------------|---------------|---------------|------------------|---------------|-----------------|------------------|---------------|---------------------------|---------------------|----------------------------|---------------------|--------------------|----------------------------|---------------|--------------------|----------------------------|-----------------|
| | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | \bar{X} | \underline{SD} | Range | |
| Weeks gestation at time of delivery | 39.6 | 2.3 | 36-43 | 37.78 | 6.44 | 21- 42 | 38.9 | 4.4 | 21- 43 | 39.9 | 1.4 | 38- 43 | 37.89 | 4.31 | 27- 42 | 39.1 | 2.9 | 27- 43 | 39.0 | 3.7 | 21- 43 | NS ^a |
| Birthweight in grams | 3283.6 | 436.8 | 2500- 3941 | 3305.3 | 469.0 | 2722- 4000 | 3291.5 | 437.6 | 2500- 4000 | 3268.9 | 300.6 | 2948- 4020 | 3080.0 ^c | 1088.2 ^c | 1050- 4520 ^c | 3208.8 ^c | 637.7 ^c | 1050- 4520 ^c | 3250.1 | 542.1 ^c | 1050- 4520 ^c | NS |

Note. ^aNS = not significant; ^bOf all live births; ^cTwin births excluded.

Significant Correlations Between Variables

Maternal Weight Gain

An increase in weight gain at 20 weeks gestation was significantly correlated with an increase in total maternal weight gain (Table 27).

Infant Birthweight and Placental Weight

An increase in the amount of protein and kilocalories consumed was significantly correlated with an increase in birthweights and placental weights (twin birth and placental weights excluded) (Table 27).

Table 27
Significant Correlations Between Variables

| First Variable | Second Variable | Correlation Coefficient | p Value ^a |
|------------------------|-------------------------------|-------------------------|----------------------|
| 20 week weight gain | Total weight gain | .68707 | .00000 |
| Amount of protein | Birthweight ^b | .33032 | .01751 |
| Amount of kilocalories | Birthweight ^b | .29155 | .02430 |
| Amount of protein | Placental weight ^c | .44674 | .01274 |
| Amount of kilocalories | Placental weight ^c | .49140 | .00164 |

Note. ^aAt two-tailed level; ^bTwin births excluded; ^cTwin placenta excluded.

CHAPTER V

SUMMARY AND RECOMMENDATIONS

The randomized control group design served the study well for the type of data collected and analyzed. The biased coin method was highly effective in assuring randomization between the subjects into experimental and control groups. However, equality among all the cells could not be achieved, even with phases one and two combined, due to inadequate sample size. It is hoped that further phases of this study, when combined with phases one and two, will correct this shortcoming. Especially needed are those subjects who were underweight prior to pregnancy and failed to gain ten pounds by the twentieth week of gestation.

The results of the combined research of phases one and two showed that the majority of women in the experimental group did not meet their nutritional prescriptions (43% met their prescription, 57% did not). It should be noted that this constitutes a difference between phases one and two. If taken separately, phase one results showed a majority of women meeting their prescription, whereas phase two results did not (Figure 4). The reason for this difference is difficult to interpret since interrater reliability was established between all researchers. Whether the difference was due to the interviewing and counseling abilities of the two groups of researchers, or due to the differences in the two populations is

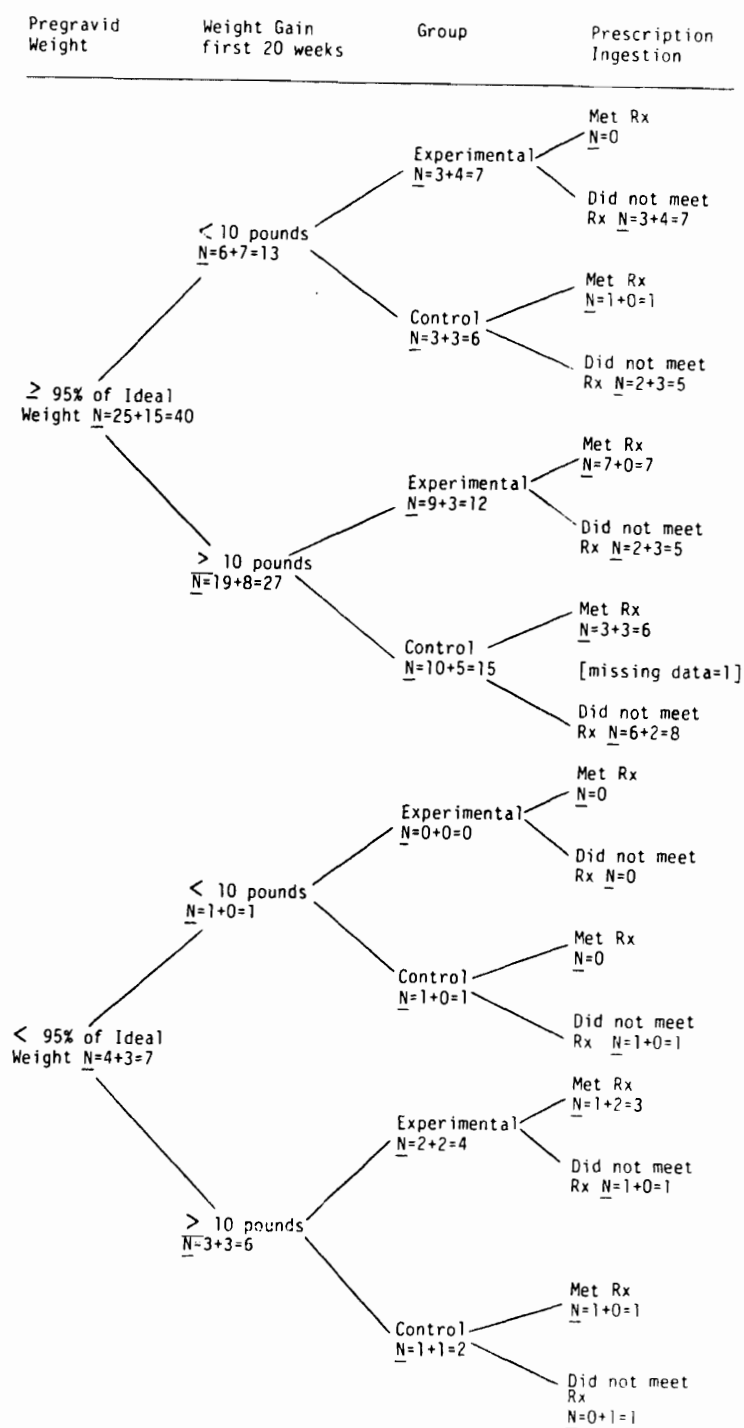


Figure 4. Final sample breakdown. \underline{N} = Phase 1 \underline{n} + Phase 2 \underline{n} = Total \underline{N} .

difficult to determine. It is interesting to note that the subjects in phase two were rated lower in general than the subjects in phase one in compliance and reliability of recall.

The researchers in phase two found that the diet recall and nutritional counseling could occasionally be done in 20-30 minutes using the described methodology, but was more likely to take up to 45 minutes. This was attributed to the environmental conditions of a busy clinic. The interviewing took place in the general waiting area due to lack of more appropriate facilities, and had frequent interruptions. The procedure was done during the subjects' prenatal visits to the clinic, however, without any further inconvenience or imposition to the women.

With the combined results of study subjects in phase one and phase two, findings indicate that those subjects who ate an adequate amount of both protein and kilocalories did not have significantly larger birthweight infants than those who had inadequate nutritional intake ($p=.10$, two-tailed test, twin births excluded). Those women who had an adequate early weight gain in addition to adequate prescription ingestion as compared to those with inadequate early weight gain and inadequate prescription ingestion gained significantly more weight ($p=.00072$, two-tailed test) and showed a trend toward higher birthweight infants ($p=.09$, two-tailed test, twin births excluded).

The researchers recommend this study be replicated to achieve larger sample sizes in order to fill all groups and test all hypotheses. A larger sample size would possibly replace trends with

statistically significant data and substantiate the credibility of the Higgins Method. Twin births, adolescents and various ethnic groups need to be included in future studies.

One further recommendation is that a private area be provided for the nutritional visit. Counseling in an open waiting area presents a serious handicap to nutritional counseling and intervention. An area set apart from the general traffic flow, but not removed from the clinic area, would be especially helpful in counseling those women whose diets are borderline to poor and need extra counseling and encouragement.

APPENDIX A
NUTRITIONAL FORMS

| HCP/CBE TYPICAL MEAL PATTERN | | Form A INITIAL DIETARY INTAKE | | | NAME | DATE | | | |
|------------------------------------|---|----------------------------------|---------|-----------|---------------------------------|----------------------------------|---------|-----------|--|
| FOOD | | UNIT AMOUNT | PROTEIN | KCALORIES | AMOUNTS EARLIER IN PREGNANCY | AVERAGE AMOUNT IN LAST 7 DAYS | PROTEIN | KCALORIES | |
| TIMES: FOODS: | MILK | | | | | | | | |
| | Whole | 1 oz. | 1 | 19 | | | | | |
| Arise | 2% | 1 oz. | 1 | 15 | | | | | |
| | Skim | 1 oz. | 1 | 10 | | | | | |
| | Evaporated | 1/4 oz. | 1 | 19 | | | | | |
| | Yogurt, Plain | 1 oz. | 1 | 10 | | | | | |
| | CITRUS | | | | | | | | |
| | Fruit/Juice | 4 oz. | 1 | 45 | | | | | |
| | FRUITS | 1 serv. | | | | | | | |
| | Other Fruit/Juice | (4 oz.) | 1 | 75 | | | | | |
| | POTATOES | 1 serv. | | | | | | | |
| | Potatoes/Fries/Chips | (6 oz.) | 3 | 105 | | | | | |
| | PASTA/RICE | | | | | | | | |
| | Pasta | 1 oz. dry | 3 | 100 | | | | | |
| | Rice | 1 oz. dry | 2 | 100 | | | | | |
| | VEGETABLES | | | | | | | | |
| | Veg./Salad/Soup/Juice | 1 serv. | 2 | 45 | | | | | |
| | BREADS | | | | | | | | |
| | Breads,Rolls,Muffins, Buns,Crackers,Pancakes | 1 oz. | 2.5 | 80 | | | | | |
| | CEREALS | | | | | | | | |
| | Whole Grain | 1 oz. | 4 | 115 | | | | | |
| | Refined | 1 oz. | 2 | 80 | | | | | |
| | BUTTER,FATS | | | | | | | | |
| | Butter,Margarine,Cream, Cream Cheese,Bacon, Salad Dressing,Mayo | 1 oz. (2 T.) | - | 215 | | | | | |
| | MEAT/FISH/LIVER | 4 oz. | 16-20 | 280-200 | | | | | |
| | PROTEIN SANDWICH FILL | 1.5 oz. | 6 | 115 | | | | | |
| | EGG | 1 | 6 | 70 | | | | | |
| | CHEESE COTTAGE CHEESE | 1 oz. 1/2 c. | 8 16 | 115 120 | | | | | |
| | PEANUT BUTTER/NUTS | 1 oz. | 8 | 160 | | | | | |
| | OTHER PROTEIN | | | | | | | | |
| | Beans,Baked | 5 oz. | 9 | 180 | | | | | |
| | Legumes,Dry | 1.5 oz. | 11 | 155 | | | | | |
| | Pizza | 1/8 14" | 10 | 250 | | | | | |
| | SUGAR | 1 oz.(2 T) | - | 110 | | | | | |
| | OTHER SWEET | 1 oz. | - | 80 | | | | | |
| | PASTRY/CAKE/COOKIE | 1 oz. | 1 | 105 | | | | | |
| | MILK DESSERT | 1/2 c. | 4 | 150 | | | | | |
| | CHOCOLATE BARS | 1 1/2-2 oz. | 3-6 | 230-280 | | | | | |
| | BEVERAGES | 1 oz. | - | 14-70 | | | | | |
| | POPCORN | 1 c. | 1 | 23 | | | | | |
| TOTALS | | | | | | | | | |

Form B

FOOD RECORD FOR _____

DATE STARTED _____

INSTRUCTIONS:

1. START TODAY (Day 1).
2. List all foods you eat each day for 7 days in the designated areas.
3. Indicate type of food (example: whole milk, 2% milk, or skim milk, etc.)
4. Record amounts carefully (example: 4 oz., 8 oz., 12 oz. beverage, 1 slice cheese, 1 cup french fries, 3/4 cup lettuce salad, 1/2 cup corn, etc.).
5. Record butter/mayonnaise/jam etc. by teaspoons (Tsp) or tablespoons (T).

6. Return this sheet as instructed. Thank you.

SAMPLE:

| | |
|---------------------------------|----------|
| Whole Milk | 8 oz. |
| Peanut Butter and Jam Sandwich: | |
| Bread | 2 slices |
| Peanut Butter | 2 T |
| Jam | 2 Tsp |
| Apple | 1 |

| | DAY 1 | DAY 2 | DAY 3 | AMOUNT DAY 4 | DAY 5 | DAY 6 | DAY 7 |
|--|-------|-------|-------|-----------------|-------|-------|-------|
| MILK | | | | | | | |
| Whole | | | | | | | |
| 2 Percent | | | | | | | |
| Skim | | | | | | | |
| Evaporated Milk | | | | | | | |
| Yogurt (Specify Plain or Fruit) | | | | | | | |
| CITRUS (Orange, lemon, grapefruit, lime. NOT "Ades".) | | | | | | | |
| Fruit/Juice | | | | | | | |
| FRUITS | | | | | | | |
| Other Fruits/Juice | | | | | | | |
| POTATOES | | | | | | | |
| Potatoes | | | | | | | |
| Fries/Chips (Incl. corn chips) | | | | | | | |
| PASTA (Cooked amount) | | | | | | | |
| RICE (Cooked amount) | | | | | | | |
| VEGETABLES | | | | | | | |
| Vegetables | | | | | | | |
| Salad | | | | | | | |
| Soup (All types) | | | | | | | |
| Juice | | | | | | | |
| BREADS | | | | | | | |
| Bread | | | | | | | |
| Roll/Muffin/Tortilla | | | | | | | |
| Waffle/Pancake | | | | | | | |
| Soda Cracker/Other Cracker | | | | | | | |
| Hamburger Bun/Hotdog Bun | | | | | | | |

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| FOOD | DAY 1 | DAY 2 | DAY 3 | AMOUNT DAY 4 | DAY 5 | DAY 6 | DAY 7 |
|---|-------|-------|-------|-----------------|-------|-------|-------|
| CEREALS | | | | | | | |
| Whole Grain Cooked/Uncooked Shredded Wheat/Granola | | | | | | | |
| Refined (ALL varieties) | | | | | | | |
| BUTTER/FATS | | | | | | | |
| Bacon | | | | | | | |
| Cream/Whipping Cream | | | | | | | |
| Mayonnaise/Mayonnaise Type | | | | | | | |
| Salad Dressing (Oil type) | | | | | | | |
| Cream Cheese | | | | | | | |
| MEAT/FISH/LIVER/POULTRY | | | | | | | |
| Specify Type & Amount As Purchased | | | | | | | |
| Uncooked | | | | | | | |
| PROTEIN SANDWICH FILL (Specify type) | | | | | | | |
| Tuna Salad, Egg Salad, Wiener, Cold Cuts, Cheese, Etc. | | | | | | | |
| EGG | | | | | | | |
| CHEESE (All kinds) | | | | | | | |
| Cottage Cheese | | | | | | | |
| PEANUT BUTTER/NUTS/SEEDS | | | | | | | |
| OTHER PROTEIN | | | | | | | |
| Beans, Baked | | | | | | | |
| Legumes | | | | | | | |
| Pizza (Portion of inch) | | | | | | | |
| SUGAR/HARD CANDIES | | | | | | | |
| OTHER SWEETS | | | | | | | |
| Jello | | | | | | | |
| Jams/Jellies/Marmalade | | | | | | | |
| Honey/Molasses/Syrup | | | | | | | |
| PASTRY/CAKE/COOKIE/SWEET ROLL/ DONUT/ETC. (Specify) | | | | | | | |
| MILK DESSERT | | | | | | | |
| Ice Cream | | | | | | | |
| Pudding | | | | | | | |
| CHOCOLATE BARS (Specify) | | | | | | | |
| BEVERAGE (Specify) | | | | | | | |
| Soft Drinks, Fruit "Ades", Beer | | | | | | | |
| Wine | | | | | | | |
| Alcohol | | | | | | | |
| POPCORN POPPED | | | | | | | |
| GRAVY | | | | | | | |
| OTHER | | | | | | | |

Form C

Personal Pregnancy Nutrition Prescription

Date Discussed _____
By Whom _____

PERSONAL PREGNANCY NUTRITION PRESCRIPTION* FOR _____

1. Age _____ Due Date _____ Pre-pregnant Weight _____
 Current week of Pregnancy _____ Current Weight _____
 Height _____ Body Frame _____ Ideal Weight _____

2. YOUR NON-PREGNANT REQUIREMENT
 FOR IDEAL WEIGHT:

| | PROTEIN | KCALORIES |
|---|----------|-----------|
| R.D.A., 1980 | OR _____ | _____ |
| R.D.A. (Teenagers, 1958) | OR _____ | _____ |
| Canadian Dietary Standard, 1948 (Montreal Diet Dispensary) | _____ | _____ |

3. YOUR ADDITIONAL REQUIREMENT FOR PREGNANCY:

| | | | |
|---|----|----|-----|
| R.D.A. | OR | 30 | 300 |
| Canadian Dietary Standard after the 20th week (4½ mo.) of pregnancy | | 25 | 500 |

| | | |
|------------------------|-------|-------|
| SUBTOTAL (non-Pg + Pg) | _____ | _____ |
|------------------------|-------|-------|

4. CORRECTIVE ALLOWANCE FOR UNDERWEIGHT:
 Underweight: % _____ lbs. _____

5. CORRECTIVE ALLOWANCE FOR UNDERNUTRITION:
 Protein Deficit _____ grams _____

6. CORRECTIVE ALLOWANCE FOR NUTRITIONAL STRESS:
 Check all that apply: _____

| | |
|---------------------------------------|-------|
| Pernicious Vomiting | _____ |
| Recent Pregnancy | _____ |
| Poor Obstetric Outcome | _____ |
| Failure to gain 10 lbs by 20 weeks | _____ |
| Severe Emotional Stress | _____ |

7. FINAL COMPUTATIONS:

| | | |
|---|-------|-------|
| Total Present Requirements (Subtotal + #4, 5 and 6 if applicable) | _____ | _____ |
| Minus Current Dietary Intake | _____ | _____ |
| Equals Needed Additions to Present Diet | _____ | _____ |

*Based on the formula developed by Agnes Higgins at the Montreal Diet Dispensary

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Form D

Recommended Additions for Pregnancy Nutrition

Date Discussed _____
By Whom _____

| | FOOD VALUES | | RECOMMENDED ADDITIONS | | |
|--|-------------|-----------|-----------------------|---------|-----------|
| | Protein | KCalories | Amount of Food | Protein | KCalories |
| <u>MILK:</u> | | | | | |
| 1 oz. Whole | 1 | 19 | _____ oz. | _____ | _____ |
| 1 oz. 2% | 1 | 15 | _____ oz. | _____ | _____ |
| 1 oz. Skim | 1 | 10 | _____ oz. | _____ | _____ |
| ½ cup powdered skim milk added to 32 oz. quart | 12 | 120 | | _____ | _____ |
| <u>EGGS:</u> | | | | | |
| 1 Unit | 6 | 70 | _____ EGG(s) | _____ | _____ |
| <u>BREAD:</u> | | | | | |
| 1 oz. slice | 2.5 | 80 | _____ SVGS. | _____ | _____ |
| (Equals 1 dinner roll 1 muffin 1 pancake 6 soda crackers | | | | | |
| 1.5 oz. slice = 1 hamburger or hotdog bun) | | | | | |
| <u>BUTTER:</u> | | | | | |
| 1 Tablespoon | -- | 108 | _____ SVGS. | _____ | _____ |
| <u>CITRUS:</u> | | | | | |
| 1 serving (SVG.) (Equals 1 medium orange ½ grapefruit 4 oz. fresh fruit frozen or canned juice) | 1 | 45 | _____ SVGS. | _____ | _____ |
| <u>OTHER SUGGESTED ITEMS:</u> | | | | | |
| 1. | | | _____ SVGS. | _____ | _____ |
| 2. | | | _____ SVGS. | _____ | _____ |
| 3. | | | _____ SVGS. | _____ | _____ |
| TOTAL RECOMMENDED ADDITIONS: _____ | | | | | |
| PLUS CURRENT DIETARY INTAKE _____ | | | | | |
| EQUALS TOTAL RECOMMENDED INTAKE (CURRENT AND ADDITIONS): _____ | | | | | |
| (This should approximate the <u>TOTAL PRESENT REQUIREMENTS</u> on Form C) _____ | | | | | |

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Table 28
Frame Size -- Female

| | Small | Medium | Large |
|---|------------------|---------------------|---------------|
| Wrist Size _____ | | | |
| Wrist Size According to Height (Shoes Off) | | | |
| Under 5' 3" | Under 5 1/2" | 5' - 5 3/4 | Over 5 3/4" |
| 5' 3" to 5' 4" | Under 6" | 6" - 6 1/4" | Over 6 1/4" |
| Over 5' 4" | Under 6" | 6" - 6 1/2" | Over 6 1/2" |
| Glove Size | Under 7 | 7 | Over 7 |
| Shoe Width | Narrow | Medium | Large |
| Blouse Size | Under 34 (12) | 34 - 36 (12, 14) | Over 36 (16+) |

Table 29
Table of Desirable Weights for Women

| Height- no shoes | Weight in lbs. by frame Without Clothes | | | Weight in lbs. by frame Indoor Clothes** | | | | | | | | |
|---------------------|--|------|-------|---|-----|--------|-----|-----|-------|-----|-----|-----|
| | Small | Med. | Large | Small | | Medium | | | Large | | | |
| 4' 8" | | | | 92 | 95 | 98 | 96 | 102 | 107 | 104 | 112 | 119 |
| 4' 9" | | | | 94 | 98 | 101 | 98 | 104 | 110 | 106 | 114 | 122 |
| 4' 10" | 92 | 102 | 119 | 96 | 100 | 104 | 101 | 101 | 113 | 109 | 117 | 125 |
| 4' 11" | | | | 99 | 103 | 107 | 104 | 110 | 116 | 112 | 120 | 128 |
| 5' -- | 96 | 107 | 125 | 102 | 106 | 110 | 107 | 113 | 119 | 115 | 123 | 131 |
| 5' 1" | | | | 105 | 109 | 113 | 110 | 116 | 122 | 118 | 126 | 134 |
| 5' 2" | 102 | 113 | 131 | 108 | 112 | 116 | 113 | 120 | 126 | 121 | 130 | 138 |
| 5' 3" | | | | 111 | 115 | 119 | 116 | 123 | 130 | 125 | 134 | 142 |
| 5' 4" | 108 | 120 | 138 | 114 | 119 | 123 | 120 | 128 | 135 | 129 | 138 | 146 |
| 5' 5" | | | | 118 | 123 | 127 | 124 | 132 | 139 | 133 | 142 | 150 |
| 5' 6" | 114 | 128 | 146 | 122 | 127 | 131 | 128 | 136 | 143 | 137 | 146 | 154 |
| 5' 7" | | | | 126 | 131 | 135 | 132 | 140 | 147 | 141 | 150 | 158 |
| 5' 8" | 122 | 136 | 154 | 130 | 135 | 140 | 136 | 144 | 151 | 145 | 154 | 163 |
| 5' 9" | | | | 134 | 139 | 144 | 140 | 148 | 155 | 149 | 159 | 168 |
| 5' 10" | 130 | 144 | 163 | 138 | 143 | 148 | 144 | 152 | 159 | 153 | 163 | 173 |
| 5' 11" | 142 | 147 | 163 | 138 | 143 | 148 | 144 | 152 | 159 | 153 | 163 | 173 |
| 6' -- | 138 | 152 | 173 | 146 | 151 | 156 | 152 | 160 | 167 | 161 | 171 | 181 |

Note. Adapted from Montreal Diet Dispensary Table (Metropolitan Life Insurance Co., 1962). Women age 25 and over*.

*Subtract 1 lb. for each year under 25.

**Subtract 2-4 lbs. to obtain weight without clothes.

Table 30
Canadian Dietary Standards for Adults, 1948

| Body Wt. Pounds* | Degree of Activity | Kcal. | Pro. | Body Wt. Pounds* | Degree of Activity | Kcal. | Pro. |
|---------------------|-----------------------|-------|------|---------------------|-----------------------|-------|------|
| <u>Female</u> | | | | | | | |
| 80 | Sedentary | 1600 | 40 | 125 | Sedentary | 2150 | 57 |
| | Moderate | 1900 | 40 | | Moderate | 2450 | 57 |
| | Heavy | 2400 | 40 | | Heavy | 2950 | 57 |
| 85 | S | 1650 | 43 | 130 | S | 2200 | 58 |
| | M | 1950 | 43 | | M | 2500 | 58 |
| | H | 2450 | 43 | | H | 3000 | 58 |
| 90 | S | 1700 | 45 | 135 | S | 2250 | 59 |
| | M | 2000 | 45 | | M | 2550 | 59 |
| | H | 2500 | 45 | | H | 3050 | 59 |
| 95 | S | 1750 | 47 | 140 | S | 2300 | 60 |
| | M | 2050 | 47 | | M | 2600 | 60 |
| | H | 2550 | 47 | | H | 3100 | 60 |
| 100 | S | 1800 | 50 | 145 | S | 2350 | 63 |
| | M | 2100 | 50 | | M | 2650 | 63 |
| | H | 2600 | 50 | | H | 3150 | 63 |
| 105 | S | 1875 | 52 | 150 | S | 2400 | 65 |
| | M | 2175 | 52 | | M | 2700 | 65 |
| | H | 2675 | 52 | | H | 3200 | 65 |
| 110 | S | 1950 | 53 | 155 | S | 2450 | 68 |
| | M | 2250 | 53 | | M | 2750 | 68 |
| | H | 2750 | 53 | | H | 3250 | 68 |
| 115 | S | 2025 | 54 | 160 | S | 2500 | 70 |
| | M | 2325 | 54 | | M | 2800 | 70 |
| | H | 2825 | 54 | | H | 3300 | 70 |
| 120 | S | 2100 | 55 | | S | | |
| | M | 2400 | 55 | | M | | |
| | H | 2900 | 55 | | H | | |

*Use your ideal weight.

Instruction 1

Corrective Allowance for Underweight

Underweight is based on a prepregnant weight which is less than 45% of your Ideal Weight.

1. To compute: prepregnant weight (____) - ideal weight (____) = percent of ideal weight (____%).
2. Correction will enable you to gain during pregnancy the number of pounds you were underweight prior to pregnancy.
 - a. For example, if you were 10 lbs. underweight before pregnancy and you are now 20 weeks pregnant, this gain is spread over the remaining weeks of your pregnancy, i.e., 10 lbs. in 20 weeks = 1/2 lb. a week.
 - b. 500 KCalories and 20 grams of protein a day in addition to your other requirements will permit a gain of one pound a week (You would not want to gain more than two lbs. a week to correct underweight, on this formula). In the example above, you would add 250 KCalories and 10 grams of Protein a day to gain the additional 1/2 lb. a week.

Instruction 2

Correction Allowance for Undernutrition

Undernutrition is based on a protein deficit between your normal plus pregnancy protein requirement, and your current protein intake based on your diet history.

- a. Your average daily protein intake will have been previously computed by you from instructions provided, or by your health care provider or childbirth educator from information you have supplied. Use that figure here.
- b. Your normal plus pregnancy requirement (_____ grams) minus your current average daily protein intake (_____ grams) = protein deficit (_____ grams).
- c. Correction equals the amount of your protein deficit, i.e., 15 grams deficit = 15 grams of protein to add as a correction each day. Also add 10 KCalories each day for each gram of protein added, i.e., 150 KCalories in this example.

Instruction 3

Corrective Allowance for Nutritional Stress

Nutritional stress is based on any one of the following maternal conditions. (Check all that apply).

- a. Pernicious vomiting (heavy, persistent) now, or earlier in your pregnancy.
- b. Last pregnancy delivered less than one year before this present pregnancy began.
- c. Poor obstetrical outcome in a previous pregnancy (spontaneous abortions, toxemia, low birthweight, stillbirth, baby ill at birth or with a birth defect, etc).
- d. Failure to gain ten pounds or more in the first 20 weeks (4 1/2 months) of this pregnancy.
- e. Severe emotional stress.

Correction allows for the addition of 20 grams of protein and 200 KCalories for each stress condition, each day, up to a maximum addition of 400 KCalories and 40 grams of protein per day.

Montreal Diet Dispensary Food Values and Equivalents

Chart 1

| | Food Values | | Equivalents |
|------------------------------|--------------------|------------|--|
| | Protein (Grams) | KCalories | |
| <u>Milk Products</u> | | | |
| 1 oz. milk whole (4% fat) | <u>1</u> | <u>19</u> | 1 oz. unit = |
| 1 oz. milk 2% | <u>1</u> | <u>15</u> | ½ oz. condensed milk |
| 1 oz. milk skim (1%) | <u>1</u> | <u>10</u> | 1 oz. plain yogurt |
| 1 qt. milk whole (32 oz.) | <u>32</u> | <u>608</u> | 1 oz. unit + ½ tsp. sugar |
| 1 qt. milk 2% | <u>32</u> | <u>480</u> | 1 oz. flavored yogurt |
| 1 qt. milk skim (1%) | <u>32</u> | <u>320</u> | 1 oz. chocolate milk |
| 1 cup dry powdered skim milk | <u>24</u> | <u>240</u> | *1 oz. hot cocoa mix (+½ tsp. sugar) |
| | | | dry milk powder: 23 cups = 14 - 40 oz. qts. |
| | | | 11.5 cups = 7 - 40 oz. qts. |
| | | | (or see package) |
| 1 oz. Half & Half | <u>1</u> | <u>40</u> | .6 oz. - restaurant cream cup |
| 1 oz. light table cream | <u>1</u> | <u>64</u> | |
| 1 oz. whipping cream | <u>1</u> | <u>90</u> | |
| <u>Citrus</u> | | | |
| 1 serving (4 oz.) | <u>1</u> | <u>45</u> | 1 serving = |
| | | | 1 medium orange |
| | | | ½ grapefruit |
| | | | 4 oz. fresh, frozen or canned juice |
| | | | (6 oz. frozen orange juice concentrate = 24 oz. fluid) |
| <u>Fruits</u> | | | |
| 1 serving | <u>1</u> | <u>75</u> | 1 serving = |
| | | | 1 fresh fruit approx. 4 oz. (size doesn't matter) |
| | | | ½ cup fresh or canned fruits |
| | | | 4 oz. juice (prune, pineapple, etc.) |
| | | | 1 oz. dry fruit - 3 prunes, 4 dates, 2 T raisins |
| | | | (2 lbs. fruit = 7 servings) |
| <u>Potatoes</u> | | | |
| 6 oz. serving | <u>3</u> | <u>105</u> | 1 serving = |
| | | | 1 medium potatoe (2½ lbs. = 7 servings) |
| | | | 1 serving + 1 tablespoon fat = |
| | | | 1 cup french fries (40 pieces ¼" x ½" x 2") |
| | | | 1 oz. potatoe chips |
| | | | (Add Fat from Butter list) |

Food Values and Equivalents (Continued)

| | <u>Food Values</u> | | <u>Equivalents</u> |
|--|---------------------------|--------------------------|---|
| | <u>Protein</u> (Grams) | <u>KCalories</u> | |
| <u>Pasta/Rice</u> 1 oz. dry serving | <u>2</u> <u>3</u> | <u>100</u> <u>100</u> | <u>1 serving =</u> approx. 1/2 cup cooked rice 1 lb. = 3 cups uncooked rice approx. 3/4 cup cooked pasta 1 cup uncooked = 2 3/4 cooked 1 cup dry = 5 oz. |
| <u>Vegetables</u> | <u>2</u> | <u>45</u> | <u>1 serving =</u> 1/2 cup raw or cooked, approx. 4 oz. 3/4-1 cup salad with dressing (1 protein) 1/2 can (10 oz.) soup all varieties 8 oz. vegetable juice (10 oz. frozen veg. = 4 - 1/2 cup portions) |
| <u>Bread</u> 1 oz. slice | <u>2.5</u> | <u>80</u> | <u>1 oz. slice =</u> 1 dinner roll usual loaf bread = 24 oz. 1 muffin 1 slice = 3/4-1 oz. depending 1 pancake on thickness 6 soda crackers <u>1 1/2 oz. slice =</u> 1 hamburger or hot dog bun |
| <u>Cereals</u> whole grain 1 oz. (includes shredded wheat) | <u>4</u> | <u>115</u> | <u>1 serving (1 oz. dry) =</u> 3/4 cup cooked 1/2 cup granola type |
| refined 1 oz. | <u>2</u> | <u>80</u> | 1 cup all varieties (sugar coated add 2 tsp. sugar) |
| <u>Butter, Fats</u> 1 oz. (2 tbsp.) 1 tbsp. | - - | <u>215</u> <u>108</u> | <u>1 oz. serving =</u> 4 sl. bacon (22 sl. = 1 lb.) 4 oz. cream 15% 2 tbsp. mayonnaise 4 tbsp. salad dressing 2 oz. cream cheese 12 tbsp. gravy |

Food Values and Equivalents (Continued)

| | Food Values | | Equivalents | | |
|---------------------------------|--------------------|------------|------------------|---|--|
| | Protein (Grams) | KCalories | 1 oz. = | Protein | KCalories |
| <u>Meat/Fish/Liver</u> | | | | | |
| 4 oz. A.P. | <u>16</u> | <u>280</u> | | <u>4</u> | <u>70</u> |
| 4 oz. A.P. 6:1 | <u>17</u> | <u>260</u> | | 4.3 | 65 |
| 4 oz. A.P. 5:1:1 | <u>18</u> | <u>240</u> | | 4.5 | 60 |
| 4 oz. A.P. lean | <u>20</u> | <u>200</u> | | 5 | 50 |
| | | | | | As purchased with bone and fat |
| | | | | | 6-meat-1 liver/fish/week |
| | | | | | 5-meat-1 liver/fish/week |
| | | | | | Only chicken without skin, liver, fish and meat without fat |
| | | | 1/6 9" meat pie | 15 | |
| <u>Protein Sandwich Filling</u> | | | | | |
| 1 1/2 oz. | <u>6</u> | <u>115</u> | | | average for a variety of filling - egg salad, tuna salad, wiener, cold cuts and cheese |
| <u>Egg</u> | | | | | |
| 1 unit | <u>6</u> | <u>70</u> | | | |
| <u>Cheese</u> | | | | | |
| all varieties 1 oz. | <u>8</u> | <u>115</u> | | | |
| creamed cottage 1/2 cup | <u>16</u> | <u>120</u> | | | |
| <u>Peanut Butter/Nuts</u> | | | | | |
| 1 oz. (2 tbsp.) serving | <u>8</u> | <u>160</u> | 1 oz. = | | |
| | | | | 2 tbsp. or 1 oz. nuts | |
| <u>Other Protein Foods</u> | | | | | |
| canned baked beans 5 fld. oz. | <u>9</u> | <u>180</u> | <u>legumes =</u> | | |
| dry legumes 1 1/2 oz. | <u>11</u> | <u>155</u> | 1/2 cup cooked | | 1 lb. bag beans = 2 1/2 cups uncooked |
| | | | 8 oz. pea soup | | |
| pizza 1/8 of 14" | <u>10</u> | <u>250</u> | | | |
| <u>Sugar</u> | | | | | |
| 1 oz. (2 tbsp.) | - | <u>110</u> | 1 oz. = | | |
| | | | | 6 hard candies | |
| <u>Other Sweets</u> | | | | | |
| | - | <u>80</u> | 1 oz. = | | |
| | | | | 1/2 cup Jello | |
| | | | | 2 tbsp. jam, marmalade, honey, molasses, etc. | |

Food Values and Equivalents (Continued)

| | Food Values | | Equivalents |
|---|--------------------|------------|---|
| | Protein (Grams) | KCalories | |
| <u>Pastry/Cake/Cookies</u> | | | |
| 1 oz. | <u>1</u> | <u>105</u> | cake, plain or iced; 1 piece = 3½ oz. = 16 oz. cake mix (2 env.) = 32 oz. icing - 2 tsp. sugar/1 oz. cake sweet roll, ½ pck. Vachon cake = 1 oz. pie; 6 pieces, 1 piece = 3.3 oz. = 20 oz. donut, tart, poptart = 1½ oz. 6 social tea = 1 oz. 2 all other cookies = 1 oz. *nutbreads, ½" slice = 1½ oz. |
| <u>Milk Dessert</u> | | | |
| 1 serving | <u>4</u> | <u>150</u> | 1 serving = ½ cup pudding ½ cup ice cream |
| <u>Chocolate Bars</u> | | | |
| *chocolate milk type 41 gms. | <u>4</u> | <u>230</u> | i.e., Hershey's Milk Chocolate With Almonds |
| *caramel type with nuts 53 gms. | <u>5</u> | <u>260</u> | i.e., Mars |
| *caramel type with nuts 57 gms. | <u>6</u> | <u>270</u> | i.e., Snickers |
| *caramel type 60 gms. | <u>3</u> | <u>260</u> | i.e., Milky Way |
| *whipped center 64 gms. | <u>2</u> | <u>280</u> | i.e., 3 Musketeers |
| <u>Beverages</u> | | | |
| soft drink/Koolaid/Tang liquid/ beer 1 oz. | - | <u>14</u> | |
| wine 1 oz. | - | <u>20</u> | |
| alcohol 1 oz. | - | <u>70</u> | |
| <u>*Popcorn</u> | | | |
| plain, popped 1 cup | <u>1</u> | <u>23</u> | |
| sugar coated (caramel corn) 1 cup | <u>2</u> | <u>134</u> | |

APPENDIX B

STUDY FORMS

Consent Form I

A study to describe food intake of expectant women during pregnancy, their labor and delivery outcome, and the health status of their babies at birth is currently underway. This study is being conducted by Registered Nurses who are graduate students in the College of Nursing. Their names are Janet Place and Jean Specht.*

This research is classified as a minimal risk study by the Committee for Protection of Human Subjects at the University of Utah. There are no known risks to you or your newborn. There is the possible inconvenience of additional time spent when you come for your prenatal visits. The benefit will be the knowledge gained, which will be helpful in the care of future mothers and babies.

I hereby agree to participate in this study which will involve:

1. 15 minutes today to determine my weight before pregnancy and my ideal weight.
2. 60 minutes after my prenatal visit about the 20th week of pregnancy to:
 - a. Watch a short film,
 - b. Determine my food intake, and
 - c. Be weighed.
3. 20-30 minutes every 3 weeks thereafter until I deliver, after my prenatal visit to:
 - a. Determine my food intake since my last visit, and
 - b. Be weighed.
4. A standard physical and behavior assessment of my newborn baby.
5. Permission to the researchers to review my chart and my baby's chart for medical information.

I understand that information about myself and my baby, collected during this study will be shared with me before I leave the hospital and all of my questions will be answered. I understand that participation in this study can be terminated at any time by withdrawing my consent without prejudice to my future care.

I have read the foregoing and my questions have been answered. I desire to participate in this study. I give permission for information gathered in this study to be released to the researchers listed above.

Signature of Patient

Date

Witness

*Other researchers involved: Helen Smith, Carol Sweeney, Toni LaMalfa, and Bobbi Ryan.

Consent

Upon consideration of the possible benefits and risks of the study as outlined, I approve the participation of my infant(s) in this study.

I give permission for information gathered in this study to be released to the researchers listed above.

Signature

Date

Relationship

Witness

Consent Form II

You have been randomly assigned to the experimental group of this nutrition study. This means that you will be given specific information about the protein and calories you individually require for a healthy pregnancy and outcome. In addition to this information, we will provide you with assistance in determining how to best meet your nutritional needs. If you are willing to receive this additional information and to attempt to eat the amount of foods determined according to your individual requirements, you will need to sign this consent form, which is in addition to Consent I which you signed earlier.

There are no known risks to following an individual food prescription for pregnancy. Several studies have indicated marked benefit to both mother and baby in reduced complications and increased health. There will be no additional time required.

I understand that I will be given specific recommendations for nutrition based on my individual needs, and that I will receive this information during the visits in which I have already agreed to have my food intake assessed. I understand that participation in this study can be terminated at any time by withdrawing my consent without prejudice to my future care.

I have read the foregoing and my questions have been answered. I desire to participate in this study. I give permission for information gathered in this study to be released to the researchers named in Consent I.

Signature of Patient

Date

Witness

Adaptive Randomization by Biased Coin Design

1. If this is the first subject, go to #3.

2a) Fill in numbers of subjects (n) in current table:

| | | PRESCRIPTION DIET | | |
|-------------|----|--------------------|----------------------------|-------|
| | | Less than 10 lb | Greater than or = 10 lb | Total |
| Underweight | n= | | n= | |
| OK weight | n= | | n= | |
| Total | | | | |

| | | CONTROL DIET | | |
|-------------|----|--------------------|----------------------------|-------|
| | | Less than 10 lb | Greater than or = 10 lb | Total |
| Underweight | n= | | n= | |
| OK weight | n= | | n= | |
| Total | | | | |

2b) In each table, circle the weight gain column and ideal weight row identifying the current subject to be randomized. Star (*) the weight gain total, the ideal weight total, and the cell that this subject would fall in, for each table.

2c) For each starred number, fill in t-values from the table below:

| | | | | | | | | | | | | | | | | | | |
|------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| n | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| t(n) | 1 | 4 | 10 | 15 | 20 | 24 | 27 | 30 | 33 | 36 | 38 | 40 | 42 | 44 | 46 | 47 | 48 | 49 |
| n | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | |
| t(n) | 50 | 51 | 52 | 53 | 54 | 55 | 56 | 57 | 58 | 59 | 60 | 61 | 62 | 63 | 64 | 65 | 66 | |

2d) Calculate a score S(PD) for the prescription diet by multiplying together the 3 starred numbers in that table. Calculate a score S(C) for the control diet using the 3 starred numbers in the control table. Write the scores below:

S(PD) = _____

S(C) = _____

Biased Coin Design (Continued)

- 2e) Circle the smaller score and the diet corresponding to it. This is the preferred diet. If there is a tie, write TIE.
- 3a) Use the attached random number table. Close your eyes and point to a digit on the first page. Circle it below.
- 0 or 9 - Get a new digit
 1 or 5 - Stay on p. 1 of the random number table
 2 or 6 - Go to p. 2 of the random number table
 3 or 7 - Go to p. 3 of the random number table
 4 or 8 - Go to p. 4 of the random number table
- 3b) On that page, close your eyes and pick a 2-digit number (a 1-digit number plus the digit to its right). It tells what row the diet assignment will be in.

- 01 or 51 - use row 1
 02 or 52 - use row 2

| Your number | <u>Row</u> |
|----------------|------------|
| _____ | _____ |

- 10 or 60 - use row 10
 20 or 70 - use row 20
 30 or 80 - use row 30
 40 or 90 - use row 40
 50 or 00 - use row 50

- 3c) On the same page, close your eyes and pick another 2-digit number. If it is larger than 70, discard it and pick another. It tells exactly what column the first digit of the 2-digit diet assignment will be in.

| <u>Column</u> |
|---------------|
| |

- 3d) If this is the first subject to be randomized, or if there was a tie for preferred diet, go to 3e. Otherwise, write down the 2-digit number starting in the row and column you found above.
- _____.

Biased Coin Design (Continued)

If the number was 0 - 74 - assign the preferred diet.

If the number was 75 - 99 - assign the other diet. Now go to #4.

- 3e) If this is the first subject, or there was a tie for preferred diet, write down the 2-digit number starting in the row and column you determined in 3b and c. _____.

If even - assign the prescription diet.

If odd - assign the control diet.

4. Call the coinvestigator to inform her of the new assignment. Write the updated assignment table on the randomization form, in the space available for the next subject.

Biased Coin Design (Continued)

1. Old Subjects

| | PRESCRIPTION | | |
|----------|--------------|--------|-------|
| | LT 10 | GTE 10 | Total |
| Underwt. | n= | n= | n= |
| OK wt. | n= | n= | n= |
| Total | n= | n= | n= |

| | CONTROL | | |
|----------|---------|--------|-------|
| | LT 10 | GTE 10 | Total |
| Underwt. | n= | n= | n= |
| OK wt. | n= | n= | n= |
| Total | n= | n= | n= |

2. S(PRESCRIPTION DIET)

$$\underline{\quad} \times \underline{\quad} \times \underline{\quad}$$

$$= \underline{\quad}$$

2. S(CONTROL DIET)

$$\underline{\quad} \times \underline{\quad} \times \underline{\quad}$$

$$= \underline{\quad}$$

3a

0.9

1.5

2.6

3.7

4.8

3b-e

Your #

Row

3c Column

3d/e Number

Diet

4

Call to co-I

Date _____

Time _____

1. Old Subjects

| | PRESCRIPTION | | |
|----------|--------------|--------|-------|
| | LT 10 | GTE 10 | Total |
| Underwt. | n= | n= | n= |
| OK wt. | n= | n= | n= |
| Total | n= | n= | n= |

2. S(PRESCRIPTION DIET)

$$\underline{\quad} \times \underline{\quad} \times \underline{\quad}$$

$$= \underline{\quad}$$

3a

0.9

1.5

2.6

3b-3

Your #

Row

4

Call to co-I

Date _____

Time _____

Pregnancy Flow Sheet

Name _____ Number _____ EDC _____ RX Pro _____ KCal _____

| | <u>Date</u> | <u>Week of Pregnancy</u> | <u>Weight</u> | <u>Current Intake</u> | | <u>Difference from RX</u> | |
|--------------------|-------------|------------------------------|---------------|-----------------------|-----------------|---------------------------|-----------------|
| | | | | <u>Protein</u> | <u>Calories</u> | <u>Protein</u> | <u>Calories</u> |
| Initial Contact | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Initial Assessment | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Return Visit #1 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Visit #2 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Visit #3 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Visit #4 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Visit #5 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Visit #6 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Visit #7 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Visit #8 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Visit #9 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |
| Visit #10 | _____ | _____ | _____ | _____ | _____ | _____ | _____ |

| | <u>Update RX</u> | | <u>Compliance</u> | <u>Significant Medical Conditions</u> |
|-----------|------------------|-----------------|-------------------|---------------------------------------|
| | <u>Protein</u> | <u>Calories</u> | | |
| Visit #1 | _____ | _____ | _____ | _____ |
| Visit #2 | _____ | _____ | _____ | _____ |
| Visit #3 | _____ | _____ | _____ | _____ |
| Visit #4 | _____ | _____ | _____ | _____ |
| Visit #5 | _____ | _____ | _____ | _____ |
| Visit #6 | _____ | _____ | _____ | _____ |
| Visit #7 | _____ | _____ | _____ | _____ |
| Visit #8 | _____ | _____ | _____ | _____ |
| Visit #9 | _____ | _____ | _____ | _____ |
| Visit #10 | _____ | _____ | _____ | _____ |

Demographic Data Sheet

Name _____ Number _____ Phone _____

EDC _____ Parity _____ Taking Prenatal Vitamins and FE _____

Weeks gestation at onset of prenatal care _____

Weeks gestation at initial contact for Study _____

Race/Ethnic Background:

Caucasian
 Black
 Asian
 Hispanic
 Polynesian
 Other (please specify)

Marital Status:

Single
 Married
 Divorced
 Widow
 Separated

Highest Level of Education:

Elementary: 1 2 3 4 5 6
 Junior High School/High School:
 7 8 9 10 11 12
 College: 13 14 15 16
 Post Graduate: 17 18 19 20

Occupation:

Student in high school, trade school
 Laborer, farm worker
 Other service worker
 Domestic worker
 Operator
 Craftsman
 Salesman
 Clerical
 Proprietor, manager, business
 Professional, including college student
 Homemaker
 Other - List: _____

Apx. Total Family Income

From All Sources: _____

How much is spent on food
per week: _____

How many members in the
household: _____

Previous Pregnancies? _____ If so: Year Sex Birth Weight

| | | |
|-------|-------|-------|
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |

Any complications? _____ If so, describe: _____

On WIC program? _____ If so, week gestation that WIC started: _____

Smoking: _____

Drinking: _____

Drugs: _____

Outcome Data Sheet

Name: _____ Number: _____

Prenatal:

Medications (name and amt.): _____

Complications (if present, wks. gest. and date resolved):

Infections: _____

PIH: _____

Miscarriage: _____

Hemorrhage: _____

Anemia: _____

Premature labor: _____

Premature ROM: _____

Other: _____

Labor/Delivery:

Delivery date and time: _____

Weight: Intake room: _____ Total weight gain: _____

Weeks gestation: _____ /Corrected gestation: _____

Complications: _____ Procedures and Indication: _____

Infection: _____ NSVD: _____

PIH: _____ Induction: _____

Premature labor: _____ Augmentation: _____

Premature ROM: _____ Forceps: _____

Prolonged ROM: _____ C/section: _____

Hemorrhage: _____ Hct: _____

Anemia: _____ EBL: _____

Other: _____

Fetal:

Sex: _____ Birth weight: _____ Placental weight: _____

Fetal/placental weight ratio: _____

Placental abnormalities: _____

Gross fetal abnormalities: _____

Postpartum-24 Hours:

Weight: _____ Hct.: _____

Complications: _____

Infection: _____

PIH: _____

Hemorrhage: _____

Anemia: _____

Other: _____

APPENDIX C

NUTRITIONAL ASSESSMENT AND
COUNSELING APPROACHES

The Art of Nutrition Counseling
During Pregnancy

The basis for successful nutrition counseling in pregnancy is an adequate assessment. It is tempting to want to shortcut this process by moving directly into information giving activities with clients, particularly in busy services or with large classes. There are several reasons why we should resist this urge:

1. We are more likely to give correct information relative to the woman's needs.
2. We will achieve a better outcome of pregnancy if her individual needs are met.
3. A woman is more likely to act on information which has been based on her own identified needs.

The section of this guide titled "Suggested approaches for Implementation and follow-up" is designed to assist you in selecting the most time and cost efficient means for obtaining an accurate individual assessment appropriate to your clientele and situation. The logical individualized approach to eliciting an accurate dietary assessment through an interview process is a skill requiring some practice. Once learned, however, it can be done rapidly and effectively in a minimum time period. This is the means used by the Montreal Diet Dispensary, and is more effective with clients who do not have the motivation, time, or ability to complete the assessment process on a "do-it-yourself" basis. The assessment procedure outlined for the client on her own is essentially the same one you would follow if you were eliciting the information through an inter-

view process.

Whatever the means you employ to complete the Personal Pregnancy Nutrition Prescription Form, your next task will be to identify appropriate food sources to make up any deficits in protein and KCalories which may have been identified. The attached form, Recommended Additions for Pregnancy Nutrition (Form D) is designed to assist you to translate grams of protein and KCalories into foods. One of the most important principles is to teach foods, not nutrients. The foods to begin with whenever additions are required, (milk, eggs, bread, citrus) are simple, inexpensive and nutrient dense. Other additions can help provide balance between the four food groups. The decision regarding which foods to add will be facilitated by review of your client's Typical Meal Pattern which is recorded on Form A.

The best results will be obtained if you ADD those items to the present diet. Asking individuals to make major changes in their typical dietary intake seldom leads to compliance. The Montreal Diet Dispensary has had striking success, under the very difficult circumstances of working with a disadvantaged population, in assisting women to make the necessary additions to their diets.

You can prepare Form D, using the information available to you on Form C, prior to your prenatal visit or prenatal class. This will enable you to spend your client encounter time in helping her to apply your suggested recommendations for food additions to her diet.

Motivation

The slide tape production "Building a Healthy Baby: Nutrition for Pregnancy" was designed as a trigger film to be shown in the office or during a prenatal class. This production contains many of the counseling points used at the Montreal Diet Dispensary as well as Higgins' concept of the "Blue Ribbon Baby." It is suggested that this production be shown to the client as an introduction to the assessment process. In this way it can serve as a motivational force for obtaining the Personal Pregnancy Prescription information. You may wish to show it a second time after the counseling session or prenatal class that follows the assessment, for reinforcement.

The following techniques have been found useful in the counseling session or prenatal classes:

1. Help the expectant parents to experience the reality of their baby as an individual human being who needs their help during his development by:
 - a. Show them a picture or model of their baby at his present week of gestation.
 - b. Describe to them what the baby is now able to do.
 - c. Help them to listen to the fetal heart.
2. Give praise for the positive aspects of their current diet quantity and quality.
3. Show the mother what she needs compared to what she is eating.
4. Remind the expectant parents that babies need frequent meals after they are born and their best food is milk.

They will benefit now by the mother eating frequent meals (six small meals rather than 3 large ones), and drinking milk for the baby. Higgins suggests that the mother write a large B on the bottle of milk she is to drink that day, to remind her and the other family members to "feed the baby." Drinking milk for the baby also helps women who otherwise do not like or will not drink milk.

5. Reinforce the principles of the slide/tape production:
 - a. The weight and health of the baby will be positively influenced by what and how much she eats.
 - b. Eating sufficient nutritious food will return her closest to her ideal weight after the pregnancy.
 - c. The process of baby development is a continuous one and the materials need to be constantly available when needed. This means eating well every day.
 - d. You know she can do it.

You need to know whether the woman has sufficient financial resources to provide the necessary diet during pregnancy. If she does not, all possible means should be taken to ensure that they are provided, through whatever sources. The Montreal Diet Dispensary has determined that it currently costs about \$250 to provide needed supplements and pay for the nutritional assessment and counseling, which is carried out every two weeks throughout the pregnancy on an individual basis. Comparison of this sum with the financial and personal costs of even minor maternal or infant complications

quickly brings us to a recognition that this approach is well worth the time, effort and money it may require.

APPENDIX D

COMPARISONS BETWEEN GROUPS WITH
TWIN BIRTHS INCLUDED

Table 31

Group Comparisons with Twin Birthweights Included

| | Pregravid Weights | | <u>p</u> Value |
|-------------------------|---|---|----------------------------|
| | Pregravid Weight < 95% of Ideal Weight <u>n=7</u> | Pregravid Weight ≥ 95% of Ideal Weight <u>n=42</u> | |
| Birthweight in grams | | | |
| \bar{X} | 2968.6 gms | 3210.1 gms | NS ^a |
| SD | 893.6 | 528.3 | |
| Range | 1050-3770 gms | 1700-4520 gms | |
| | Inadequate Early Weight Gain and Adequate Prescription Ingestion <u>n=1</u> | Inadequate Early Weight Gain and Inadequate Prescription Ingestion <u>n=15</u> | |
| \bar{X} | 3480.0 gms | 2919.4 gms | NS |
| SD | NA ^b | 599.1 | |
| Range | - | 1700-4000 gms | |
| | Average Daily Prescrip- tion > 85% <u>n=18</u> | Average Daily Prescrip- tion < 85% <u>n=30</u> | |
| \bar{X} | 3418.3 gms | 3031.6 gms | <u>p=.02</u> ^c |
| SD | 353.7 | 667.3 | |
| Range | 2500-4020 gms | 1050-4520 gms | |
| | Adequate Early Weight Gain and Adequate Pre- scription Ingestion <u>n=17</u> | Inadequate Early Weight Gain and Inadequate Pre- scription Ingestion <u>n=15</u> | |
| \bar{X} | 3413.5 gms | 2919.4 gms | <u>p=.008</u> ^c |
| SD | 363.9 | 599.1 | |
| Range | 2500-4020 gms | 1700-4000 gms | |
| | Experimental <u>n=23</u> | Control <u>n=24</u> | |
| \bar{X} | 3291.5 gms | 3076.3 gms | NS |
| SD | 437.6 | 685.0 | |
| Range | 2500-4000 gms | 1050-4520 gms | |

Note. ^aNS = not significant; ^bNA = not applicable; ^cSignificant at a two-tailed t-test.

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