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Compliance of Prenatal Patients with Dietary Instructions Prior to Blood Glucose Testing and a Comparison of Mixed Meal Screening Tests to Glucose Load Screening Tests

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To the Graduate Council:

I am submitting herewith a thesis written by Rebecca A. Walton entitled "Compliance of Prenatal Patients with Dietary Instructions Prior to Blood Glucose Testing and a Comparison of Mixed Meal Screening Tests to Glucose Load Screening Tests." I have examined the final electronic copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Nutrition.

Frances E. Andrews, Major Professor

We have read this thesis and recommend its acceptance:

Patricia Coulson, John Semmer

Accepted for the Council:

Carolyn R. Hodges

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

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W. Mink
Vice Chancellor
Graduate Studies and Research

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PRIOR TO BLOOD GLUCOSE TESTING AND A COMPARISON
OF MIXED MEAL SCREENING TESTS TO GLUCOSE
LOAD SCREENING TESTS

A Thesis
Presented for the
Master of Science
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Rebecca A. Walton
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This thesis is dedicated to the memory of Dr. Daniel Hubbard, who was a mentor and friend.

ABSTRACT

Three different instruction methods and their influence on selection of a breakfast test meal were studied. Subjects were 139 pregnant, Caucasian females screened for gestational diabetes by two-hour postprandial blood glucose evaluation. Macronutrient components and kilocalories of the self-selected meals were variables analyzed and compared to the nutrient pattern of a standard meal plan. The effect of varying levels of nutrients on blood glucose values was examined.

Subjects were assigned randomly to one of three groups. Subjects in Group I were given no written or verbal instructions about test meal selection but were instructed to eat breakfast. Written instructions in the form of a sample meal pattern card and foods to avoid were given to Group II and Group III subjects. Group III subjects also were given verbal explanation and amplification of the written directions. Fasting blood glucose levels were tested, subjects consumed their test meals, and a second blood sampling was performed two hours after the test meal. Subjects were asked to recall foods and beverages consumed. The entire testing process was repeated for 45 of the subjects at a later date.

Group assignment significantly ($p < .01$) affected kilocalorie and carbohydrate ($p < .0001$) levels in meals selected by subjects during the first testing process. Group I subjects selected meals significantly ($p < .03$) higher in kilocalories and carbohydrate than

Groups II and III. Group II and Group III did not select meals that were significantly different.

When meal selections were compared to nutrient and kilocalorie levels in the standard meal plan, Group I subjects selected meals significantly higher in fat ($p < .0009$), carbohydrate ($p < .0008$), and kilocalories ($p < .0001$) during the first testing process. In the first test meal, Group II subjects selected meals significantly higher in fat ($p < .0001$), protein ($p < .001$), and kilocalories ($p < .005$) than the standard. Group III subjects selected a meal in which no nutrient components were significantly different from the standard. In the second test process, Group II subjects were the only group whose meal selections differed from the standards. Fat ($p < .009$) and kilocalories ($p < .02$) were significantly higher in the Group II meals. Carbohydrate was the only nutrient in both test meals which was positively ($p < .005$) correlated with blood glucose.

Differences between detection of gestational diabetes using a glucose load and one-hour blood glucose levels and/or a mixed meal and two-hour blood glucose levels were investigated. Twelve subjects had both a test meal screening and a one-hour glucose load screening. A total of 30 subjects were screened with 50 gm glucose solution and one-hour blood glucose values. These 30 subjects were compared with 45 subjects who had a second two-hour postprandial screening.

Thirty-seven percent of the 30 subjects tested with a glucose load had one-hour blood glucose values above the upper limits of

normal. Only 4% of the 45 subjects tested with a mixed meal had blood glucose values above the upper limits of normal.

Of the 12 subjects tested by both methods, 50% were considered to have blood glucose levels above the upper limits of normal after a glucose dose. None of the 12 had blood glucose values above the upper limit of normal following a test meal. However, these two different tests were done at different gestational ages in the same individual subject.

In general, carbohydrate and kilocalorie content of self-selected test meals were influenced by instructional method, i.e., group assignment. Group III subjects who received the most instructions in the form of verbal and written guidelines, chose meals closest to a standard meal pattern. In this study, carbohydrate was the only nutrient which positively influenced blood glucose in both test meals. Screening tests using an oral glucose load detected a higher percentage of abnormally elevated blood glucose values than did screening with a mixed meal in this study.

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CHAPTER I

INTRODUCTION

It has been estimated that 1 to 3% of all pregnant women have transitory disturbances of glucose tolerance (1). This transitory glucose intolerance, occurring during pregnancy and abating once pregnancy ends, has been called gestational diabetes. Just as the offspring of overtly diabetic mothers have increased risk of mortality and morbidity, these risks are increased also for the offspring of the gestational diabetic (2). Improved care and surveillance techniques have decreased general perinatal mortality rates in the pregnant diabetic, however, mortality due to congenital anomalies has not declined. Researchers have suggested that an abnormal fuel mixture reaching the fetus leads to derangement of organogenesis or an insulin-induced hypoglycemia may cause congenital malformations (3).

The American Diabetes Association Workshop Conference on Gestational Diabetes (4) identified two areas of research needs: standardization of test procedures for detection and comparison of specificity and sensitivity of different screening tests. Currently, no one test procedure for detection of gestational diabetes is used. In the literature, controversy exists over whether to use a glucose solution or a mixed meal for testing carbohydrate intolerance. Also, there is no agreement on how glucose, if used,

should be administered at the appropriate dosage level. In an informal survey of diabetologists, West (5) found major differences in diagnostic criteria.

This study was designed to examine differences in detection of gestational diabetes using two-hour blood glucose values following a test meal or one-hour blood glucose values and glucose loading. The study was undertaken to determine whether instruction affected breakfast meal selection prior to postprandial blood glucose testing. A final objective was to determine whether varying levels of nutrient components in the test meal affected two-hour postprandial blood glucose values.

Factors selected for evaluation were the self-selected test meal nutrient patterns compared with the nutrient pattern of a standardized test meal used for instruction purposes. One-hour and two-hour blood glucose results were compared graphically since different upper limit norms exist for the two test periods. Statistical correlations between individual nutrients and two-hour blood glucose values were examined.

CHAPTER II

REVIEW OF LITERATURE

I. GESTATIONAL DIABETES

Supporting the growth of a fetus demands maternal metabolic responses to supply continuous fuel for metabolism (6). Storage of adipose tissue and conversion of glucose into adipose tissue fatty acids reach peak levels at mid-gestation. Lipolysis and adipose tissue turnover are enhanced in late gestation (3).

According to Freinkel (1), insulin may be seen as the "arbiter" of the quantity and quality of nutrients that reach the fetus. Basal as well as stimulated insulin levels are elevated during pregnancy. Glucagon levels remain the same as in a nonpregnant state, although the insulin-to-glucagon ratio is increased at all times during pregnancy. Potential for gluconeogenesis is enhanced during pregnancy (3, 6, 7). Fasting in the pregnant state results in a condition of "accelerated starvation" with a rise in plasma free fatty acids and ketone body production to levels two to three times the levels in the fasting nonpregnant individual. The hypoglycemia seen after a fast may be caused by suppression of release of glucogenic amino acids from muscle by elevated ketone body levels or by increased distribution space for glucose (6). The fetal brain is able to use ketone bodies for energy, although the biochemical implications of ketone body use by fetal cells are still unclear (1, 3).

In the fed state during pregnancy, there is an exaggerated insulin response with increasing suppression of glucagon as glucose levels rise (6). Insulin binding by receptors falls progressively because of the increased insulin concentration and the effects of some of the hormones of pregnancy such as progesterone and human chorionic somatomammotropin. Hormones associated with pregnancy also have a direct stimulatory effect on lipolysis. It has been suggested that gestational diabetes may be the result of diminished insulin secretion and an exaggerated reduction in insulin sensitivity (3). Insulin does not cross the placenta, but if an overabundance of nutrients reaches the fetus, extra insulin may be released by the fetus and this in turn may affect fetal beta cells (1). Insulin secretion from the fetal pancreas begins at about twelve weeks gestational age (3). Offspring of gestational diabetic mothers usually are heavier and fatter, with increased islet cell function and hypoglycemic tendencies (1).

Complications of Gestational Diabetes

Complications to the Fetus. Increased perinatal mortality and macrosomia are the most outstanding features in gestational diabetes. Perinatal mortality rate was found to increase with increases in plasma glucose levels above 120 mg/dl two hours after a glucose load (8). O'Sullivan et al. (9) found significantly greater perinatal losses in all gestational diabetics over 25 years of age and slightly more losses if the mother also was overweight.

Perinatal mortality was not increased in the group of gestational diabetics under 25 years of age. This suggests that some factor, other than glucose intolerance, is causing detriment to the pregnancy.

Diabetic macrosomia involves increased body fat and selective organomegaly. Animal studies support the hyperglycemia-hyperinsulinemia theory for disturbances in fetal embryopathy. Insulin is thought to be the major fetal growth-producing hormone (10). There is a correlation between even mild elevations of maternal fasting plasma glucose concentrations and fetal macrosomia in gestational diabetes (11). Increased rates of respiratory distress syndrome are seen also in the offspring of mothers with hyperglycemia and fetal hyperinsulinemia may affect pulmonary maturation (11, 12). Neonatal hypoglycemia may result when the fetus is removed from the maternal source of glucose (11). Evidence of excess congenital anomalies in the offspring of gestational diabetics is lacking (8).

Complications to the Mother. Fetal macrosomia can complicate vaginal delivery due to dystocia (8, 11). In maternal mortality studies in Los Angeles, 24 deaths occurred in pregnant diabetic women from 1957 to 1974. Fifteen of these women were alive at the beginning of labor. Eight of the 15 were delivered by Cesarean section. Four deaths were due to infection and three deaths were due to hemorrhage. The biochemical changes of pregnancy superimposed on a deranged metabolism in the gestational diabetic may increase the chance of sepsis and large blood losses, especially if Cesarean section is

performed (7). Severity of glucose intolerance has been found to be predictive of the rate of toxemia and Cesarean sections (8).

In a group of pregnant Pima Indians screened during the third trimester for gestational diabetes, the rate of development of overt diabetes in the next four to eight years was 45.5% if two-hour plasma glucose levels were between 160 and 179 mg/dl (8). Mestman (13) reported that only four of 51 women with abnormal fasting blood glucose levels during pregnancy had normal glucose tolerance six weeks after delivery. Of 181 pregnant patients with abnormal glucose tolerance tests but normal fasting levels, 23 developed elevated fasting levels and 59 had abnormal glucose tolerance tests up to five years after delivery.

Methods of Detection

For many years, clinicians have attempted to identify that portion of the pregnant population which displays carbohydrate intolerance which appears first during pregnancy and then remits after delivery. Recently, the American Diabetes Association (4) has recommended universal screening for abnormal glucose metabolism during pregnancy. It is important that an easily performed, inexpensive, and acceptable screening method be found. Also, the screening method must be sensitive and specific so true abnormalities are detected.

Clinical Features. In the past, clinicians depended heavily upon the presence of "clinical features" to detect potential

gestational diabetes. These features have included glycosuria, family history of diabetes, previous birth of a large baby (≥ 4000 to 4500 grams), obesity, maternal age, and previous poor pregnancy outcome (14, 15, 17, 19, 20). Lavin et al. (14) screened approximately 1000 patients for gestational diabetes and divided these patients into two groups depending on the presence or absence of any "risk factors." No statistically significant difference was found in the incidence of gestational diabetes between the two groups. Gillmer (18) and colleagues found that features of potential diabetes such as family history and previous large baby used singly or in combination, provided only a 56% detection rate. O'Sullivan (19) also supported the need for universal screening of blood glucose values since 50% of all patients who develop diabetes in pregnancy had no previous history or clinical associations of diabetes. O'Sullivan indicated that women over 25 years of age with gestational diabetes posed special risks. Other researchers (21) found maternal age over 30 to be an important clinical indicator of possible abnormal glucose tolerance. Glycosuria is always an indicator of need for blood glucose screening (16). However, only 15 to 20% of patients with glycosuria during pregnancy have abnormal glucose tolerance (20).

Clinical features which could be indicators of future glucose tolerance problems or symptoms of a currently deranged metabolism always should be noted. These features have not proven reliable enough to form a basis for screening potential gestational diabetics.

Controversy Over Carbohydrate Tolerance Tests. The standard oral glucose tolerance test often has been criticized (22, 25). Much debate has centered around cut-off levels which should be considered abnormal. Some researchers have sought alternatives to the use of pure glucose for testing. Rarely in everyday life does one consume 50 or 100 grams of pure glucose following a fast of several hours.

Charles (26) and associates studied the response of 16 normal patients to a mixed meal as well as response to 100 grams liquid oral glucose. The meal consisted of 550 kilocalories distributed as 48.3% carbohydrate, 26% fat, and 21.7% protein. Plasma glucose levels were consistently higher after oral glucose than after a mixed meal until 150 minutes after dosing. Over the second 150 minutes after dosing, plasma glucose levels fell to significantly lower levels after the oral glucose than after the mixed meal. Total insulin secretion above basal levels was significantly greater after the glucose load than after the mixed meal. Charles et al. (26) also studied 16 patients considered to have idiopathic postabsorptive hypoglycemia. They concluded that gastrointestinal dynamics or hormone responses after a meal produced different glucose levels than after oral glucose loading.

In an extensive review of the literature, Siperstein (25) pointed out that the current definition of abnormal glucose tolerance test values was only a statistical one, based on little published data. The use of the standard glucose tolerance

test may lead to over diagnosis of diabetes. When 152 preselected subjects (average age 39.4 years) with two-hour postprandial glucose values of less than 130 mg/dl were tested, 26% had abnormal glucose tolerance using oral glucose loads and standard diagnostic criteria. Use of glucose tolerance tests and oral glucose loads results in an incidence of diabetes in 30 to 50% of the American population. Population studies place incidence rates between 2% and 6%.

Because the glucose tolerance test amplifies any glucose intolerance, it is regarded by many as only an aid to diagnosis. Owens et al. (24) and other investigators (27) maintain that a standardized meal gives a more clinically relevant representation of metabolic status. The range of values at each time point after a glucose load was greater than after a standardized test meal when samples drawn at 30, 60, 90, and 120 minutes were compared. Subjects studied were 15 young, lean, nondiabetic males. Owens and colleagues (24) also found in other studies that the discrepancy between response to a standardized test meal and a glucose load increased the greater the degree of carbohydrate intolerance in diabetic subjects.

Different criteria and different screening methods can result in very different apparent prevalence rates of gestational diabetes. Some might argue that it is better to overdetect than to underdetect. The label "diabetic" can cause harm to the patient and should not be used without certainty. Many companies will not hire individuals diagnosed as diabetic. Emotional anguish may result

if the patient believes he/she has a disease which may lead to blindness, amputations, and early death. Screening techniques, including oral glucose tolerance tests and use of standardized test meals, should be carefully evaluated. O'Sullivan (28) concluded in 1980 that prevalence rate of gestational diabetes depends on diagnostic criteria selected. This must be considered when evaluating screening procedures.

Modified Oral Glucose Tolerance Test. In 1973, O'Sullivan (19) reported a blood glucose screen consisting of a 50-gram oral glucose load followed by one-hour blood glucose values. A more complete glucose tolerance test was performed if one-hour whole blood values were greater than 130 mg/dl. This one-hour method was found to have a 79% sensitivity and 87% specificity. Beard et al. (22) used the same procedure and an 83% sensitivity was found. Merkatz et al. (29) used 75 grams of glucose and two-hour blood glucose values in a community-wide screening program in Cleveland, Ohio. The researchers theorized that one in four women with positive screens at two hours would be missed by the one-hour screen. The one-hour value also gave a large number of false positive screens. The number of positive screens requiring follow-up in the community-wide program was significantly ($p < .05$) higher after 24 weeks gestational age.

Hohe (30) used a 100-gram oral glucose load and two-hour blood glucose values following a high carbohydrate diet for three days. The high carbohydrate diet consisted of adding three candy

bars and three soft drinks to normal meal patterns. The author indicated that although 2 of 19 patients with abnormal glucose tolerance would have been missed using the single two-hour value, use of a single value would save time, money, and patient discomfort while still providing an adequate screen.

Testing of 1622 male and female Pima Indians (31) indicated that the two-hour venous blood glucose value following 75 grams of glucose was more accurate than the one-hour value. The probability of misclassifying individuals was smaller and the reproducibility greater with the two-hour test than with the one-hour test.

The literature provides numerous examples of differences in protocol based on modified oral glucose tolerance testing. Macafee and Beisher (21) routinely tested their patients at 32 weeks gestation using a 50-gram oral glucose load. These authors used capillary blood whereas other investigators (19, 22) used venous samples. Macafee and Beisher (21) also returned to the practice of blood sampling at each hour for three hours after dosing rather than depending on only a single blood glucose value.

Investigators differ on whether subjects should be in a fasting state when tested and differ on how much glucose to give as a test dose. Guttorm (17) did oral glucose tolerance testing in the last trimester using one gram of glucose per kilogram body weight as the load. Patients were not fasting before the test. Gillmer et al. (18) also tested patients in the nonfasting state. Lavin, Baden, and Miodovnik (14) used fasting subjects given 50 grams of glucose.

This group followed the protocol proposed by O'Sullivan (50 grams glucose, one-hour blood glucose values) because larger doses of glucose are less tolerable to the GI tract and because detection rates with this method are adequate. Valleron et al. (23) reported that a 75-gram glucose load was needed to unmask subtle glucose intolerance.

No one modified oral glucose tolerance test protocol has unanimous support. There is general agreement that a single blood glucose value two hours after glucose loading is an adequate screen.

Postprandial Screening Tests. Due to the generally unphysiological nature of glucose solutions, some researchers used a normal, mixed meal to screen for carbohydrate intolerance. Using 15 male, nondiabetic subjects, Owens et al. (24) compared 50-gram glucose loads with standardized test meals. Subjects consumed at least 200 grams of carbohydrate per day for three days prior to testing and subjects fasted overnight before testing. The standardized test breakfast contained approximately 52 grams carbohydrate, 27 grams fat, and 18 grams protein. Blood samples were drawn immediately prior to the test meal or the glucose load and then at 30, 60, 90, and 120 minutes after, respectively. Plasma glucose levels were significantly ($p < .01$ and $p < .05$) higher at 30 and 60 minutes following the glucose load than following the test meal. At 90 and 120 minutes following the test meal, plasma glucose levels were higher than levels after the glucose load at 90 and 120 minutes. The range

of values at each time point after the glucose load was greater than after the test meal. The discrepancy between responses to a glucose load and to a standardized meal increased the greater the degree of carbohydrate intolerance. A diurnal rhythm of decreasing glucose tolerance throughout the day also was observed by these researchers (24).

Radder and Terpstra (27) suggested that blood glucose values around midday were reflective of the blood glucose level for the whole day. These researchers found the test meal did not have to be standardized as size or composition of the meal did not affect height of response of blood glucose levels. The "lunch tolerance test" was carried out on 81 pregnant women and 10 nonpregnant women with capillary blood glucose values checked at 60 and 90 minutes after the meal. Sensitivity and reproducibility of the test were found to be at least comparable to the oral glucose tolerance test using a 100-gram glucose load after an overnight fast. Standards determined by these authors for lunch tolerance testing were obtained from sampling during the third trimester.

Lind and McDougall (32) devised a system using random venous blood samples to screen for gestational diabetes. At the time of sampling, patients were asked when and what they last ate. Upper limits for normal were set for within two hours of the last meal and for more than two hours after the last meal. Blood glucose values following a normal meal were similar to those seen after a 75-gram oral glucose load but deviations from fasting were smaller.

According to these authors, a disadvantage of using a glucose load is the need for accurate timing as peak values are obtained 45 to 60 minutes after a 50-gram glucose load. Specificity and sensitivity were not determined for the random blood sample method but detection rate resembled the known incidence of gestational diabetes.

Some researchers have used methods other than glucose loading to gauge carbohydrate tolerance. When carbohydrate tolerance testing was based on the use of a mixed meal as a challenge, less dramatic peaks and valleys in blood glucose levels resulted than after glucose solutions. The mixed meal challenge did seem to give a more representative picture of day-to-day glucose tolerance. Numbers of gestational diabetics detected by the various test methods are similar.

Three-Hour Glucose Tolerance Test. The three-hour glucose tolerance test following an overnight fast, with or without previous dietary preparation and usually with a 100-gram glucose load, has been the definitive test for diabetes. Many researchers have indicated problems with this test procedure. Performance of oral glucose tolerance tests during every pregnancy is too expensive and time consuming to be feasible (32). The oral glucose tolerance test, particularly with doses of 100 grams of glucose may be unpleasant for the pregnant woman especially if the test must be repeated or if there is morning sickness (27). Valleron et al. (23) state there is no valid cutoff point for normal versus diabetic at different times during the oral glucose tolerance test. Valleron and his

group analyzed three-hour glucose tolerance results to determine which blood glucose value (fasting, one-hour, two-hour, or three-hour) best discriminated between diabetic and nondiabetic individuals. The best single blood glucose value was found to be the two-hour post-glucose value. A fasting blood glucose and two-hour blood glucose values had the best sensitivity and specificity of any combination of two values. Valleron et al. (23) also tested various currently used criteria for diagnosis of diabetes. It was concluded that only 48% of the subjects would be classified the same way by any of the diagnostic criteria.

In another study reported by Abell et al. (33) 2000 women in the third trimester of pregnancy underwent a three-hour glucose tolerance test. When detection results were compared with and without consideration of the three-hour reading, it was found that two-hour testing detected all cases of gestational diabetes. In addition, two-hour testing was more convenient for patients and for the laboratory personnel.

Summary. There are many problems when comparing literature dealing with detection of gestational diabetes. Some authors (4, 13, 33) state that there are two classes of gestational diabetics: (1) those patients with abnormal fasting plasma glucose, and (2) those patients with normal fasting values but one or more abnormal glucose tolerance test values. Mestman (13) reported that patients with two successive abnormal fasting blood glucose values

should be classified as overt diabetics. The World Health Organization (2) has suggested that criteria for diagnosing diabetes in pregnancy should be the same criteria as are used for nonpregnant individuals.

O'Sullivan's (28) original criteria were devised from data pooled by trimester from over 1000 pregnant women. The data from all three trimesters were averaged and statistically derived criteria, based on the mean plus two standard deviations, were established. In a normally distributed population, if a condition is described as occurring only in persons who are more than two standard deviations above the mean for a particular measurement, then 25 in 1000 (2.5%) would be considered abnormal. Hadden (34) reported that pregnant women whose glucose tolerance is at the upper end of the normal distribution but not beyond three standard deviations above the mean, have only a very minor increase in fetal risk.

When comparing study procedures it should be noted that some researchers required dietary preparation while others did not. Different studies have used different glucose loads and meals with very different compositions. There is still disagreement as to whether there is a diurnal rhythm in glucose tolerance. Two-hour blood samples seem to be favored by the majority of investigators but the one-hour value still has many advocates. Whole blood glucose values are about 14 to 15% lower than plasma glucose values. Venous glucose levels are lower than those of capillary blood and this difference seems to increase after a glucose load (30). Advantages

and disadvantages can be found for all the screening methods proposed. The American Diabetes Association Workshop-Conference on Gestational Diabetes (4) indicated that three different screening tests were acceptable. These recommended tests were: (1) a 50-gram glucose load given at random with a one-hour plasma glucose determination (the cutoff of positivity is equal to or greater than 150 mg/dl); (2) a 75-gram glucose load given at random with a two-hour capillary finger stick determination (the cutoff point for positivity is equal to or greater than 120 mg/dl); and (3) a 100-gram glucose load after fasting with a two-hour plasma glucose determination (the cutoff point for positivity is equal to or greater than 140 mg/dl).

Management

Once a patient has an abnormal screening test, most investigators recommend a three-hour glucose tolerance test. If the three-hour glucose tolerance test is negative, the screening test should be repeated later in pregnancy (4). If the three-hour glucose tolerance test is abnormal, the American Diabetes Association (4) recommends that close surveillance of fasting blood glucose values begin. Rizvi et al. (35) found that basal plasma glucose concentrations reflect control of diabetes in the pregnant state as they do in the nonpregnant state. Urine testing alone is not adequate. Development of conditions associated with gestational diabetes such as hypertension, preeclampsia, infection, and renal disease should be monitored.

Opinion on whether to institute insulin therapy is divided. O'Sullivan et al. (36) found a lower fetal loss rate when insulin therapy was instituted in gestational diabetics over 25 years of age. Gabbe, Mestman and Freedman (37) reported lower perinatal mortality rates if normal fasting glycemia and two-hour postprandial serum glucose levels were maintained. These authors achieved control using 1800 to 2000 kilocalorie diets. Patients with a history of stillbirths or preeclampsia were managed in the same way as overt diabetics. With this type of management, 25% of all of the gestational diabetics had some morbidity.

In discussing the results of intervention in gestational diabetes, Hoet (38) stated that insulin treatment might modify endocrine parameters in the neonate but the abnormal level of blood glucose was not believed to influence the incidence of stillbirth. Hoet suggested that if a diet low in refined carbohydrates and moderate in total calories cannot prevent abnormal blood glucose levels, insulin should be administered.

Oppermann and Camerini-Davis (39) found no protection against macrosomia when insulin was used to treat 90 of 243 gestational diabetics. In a study (40) where insulin was administered on the basis of maximum tolerated dose to gestational diabetics, macrosomia was eliminated virtually. Maximum tolerated dose was defined as the highest quantity of insulin that could be given without causing hypoglycemic disturbances. These patients were hospitalized to stabilize insulin dosage and insulin treatment was continued 40 days

postpartum. Diet was held constant at a calorie level self-selected by the patient. Patients self-selected an "initial menu" after advisement that they must adhere to the caloric content of the menu throughout pregnancy. With this strict control, perinatal mortality and congenital abnormalities decreased significantly ($p < .001$ and $p < .05$, respectively) from previous levels in the multipara.

O'Sullivan and Mahan (41) found no benefit in prevention of subsequent diabetes if insulin treatment was used during pregnancy.

Gabbe (42) used dietary management and frequent checks of fasting blood glucose levels only to treat pregnant patients with normal fasting levels but abnormal glucose tolerance tests. This type treatment resulted in perinatal mortality rates no higher than the general population. Gyves et al. (43) used a more individualized treatment protocol with adequate weight gain a goal but some use of 2200 to 2400 kilocalorie, carbohydrate-controlled diets. Insulin was instituted if two-hour postprandial plasma glucose levels were not controlled by diet alone. Incidence of macrosomia was unchanged with this treatment when compared to previous pregnancies. Perinatal mortality rate was 1.1%.

The American Diabetes Association (4) recommends that dietary intake of concentrated carbohydrates be limited and excessive weight gain be avoided. Weight reduction is not recommended, however.

II. PATIENT COMPLIANCE

The second aspect of this study was an examination of patients' compliance or ability to follow instructions deemed desirable to

standardize blood glucose test procedures. As many as two-thirds of all patients may be partially or completely noncompliant with health care instructions (44). In reviewing current literature related to people's ability or inability to follow a caregiver's instructions, few absolute truths emerge. Most researchers agree that age, gender, race, education, seriousness of illness, and socioeconomic status were of little value as indicators of compliance (45, 47). Persons entering the health care system are not passive recipients of instructions but active evaluators of prescriptions and treatments. According to Stimson (48), patients decide whether or not to follow a caregiver's suggestions.

Communication seems to be a major factor in patient compliance (44). Compliance most often occurs when the patient-caregiver relationship consists of mutual agreement, support, and mutual decision-making about treatment (45, 49, 50). Although fear techniques such as warnings about the dire consequences of noncompliance may be effective, extremely high or low levels of anxiety seem to block ability to retain medical advice (45, 51). There is disagreement over significance of a "formal authority figure" in eliciting compliance (52).

Simplicity of medical advice and regimes that are not disruptive to the usual routines followed by the patient may increase compliance (45, 47, 51, 53). Presentors at the Hamilton Symposium on Improving Patient Compliance (53) stressed that reducing complexity of medical regimes was of primary importance in improving compliance.

Many studies (44, 50, 51) have found that noncompliers perceive themselves as less susceptible to or less threatened by actual or potential illness. Becker and Maiman (44, 47) proposed a value-expectancy model that may prove useful in predicting patient compliance. They base their model on the belief that behavior results from the value of the outcome to an individual and from the individual's expectation that a given action will result in that outcome. Motivation, incentive value of health goals, and patients' estimates of the likelihood of successful outcome all combine to affect patient compliance.

People are believed to learn best when instructed on all relevant facts, information and procedures they need to carry out directives (54). Hecht (55) found that individualized instruction of both a verbal and written nature improved patients' accuracy in taking medication. Physicians are discovering that only by making directions as clear as possible is there hope that these directions will be followed (56).

In summary, levels of compliance cannot be predicted on the basis of factors such as age, education, socioeconomic status, or seriousness of illness. Patients in the health care system should be approached as active participants in their own health care. Health care providers must strive to maintain a high level of communication with patients as this seems to be the best means available for improving compliance.

CHAPTER III

EXPERIMENTAL METHODS

The study which forms the basis of this thesis was originally proposed by Dr. Annell St. Charles in an attempt to standardize instructions given prior to two-hour postprandial blood samplings. Presently in the Knoxville area, little or no instruction is given concerning what the test meal should include. This research was undertaken as a project of the Obstetrics Service at The University of Tennessee Memorial Research Center and Hospital (UTMRCH) because of physician interest in finding the easiest, most reliable screening method for gestational diabetes. It was deemed desirable that all obstetrics patients be screened for this disorder. Physician preference for testing had previously been use of a 50-gram glucose load and one-hour blood glucose value. This project was approved by the Committee on Research Participation at The University of Tennessee campus and by the UTMCH Institutional Review Board.

I. SAMPLE SELECTION

The sample population studied was taken from the private obstetrics service at the UTMCH in Knoxville, Tennessee. The 139 subjects were middle-to-upper class Caucasians from the Knoxville area. Data were collected for the study from November 25, 1981 until February 15, 1983. The 139 subjects (36.8%) were taken from a possible total of 377 patients seen by the obstetrics service

during this time period. The subjects were not randomly selected but were entered into the study by their attending physician as part of routine obstetrical care. The subjects were generally without complicating health factors to their pregnancies. Ages of subjects ranged from 18 to 42 years. Informed written consent was obtained from all subjects (Appendix I, page 60). Subjects were judged literate after each successfully completed a patient information sheet on their initial visit to the obstetrics service (Appendix II, page 62).

II. DESIGN OF THE STUDY

The basic data of the study were obtained from results of three different instruction methods used in two-hour postprandial blood glucose screening. Fasting blood glucose values were measured for all subjects. All subjects were instructed to take nothing but water my mouth after midnight before their morning appointment. Prior to any blood glucose sampling, the subjects were randomly assigned to one of three groups. Generally, subjects were initially screened around 28 weeks gestation. Forty-five of the subjects had postprandial blood glucose screening replicated within the next month. Thirty subjects had either an initial or follow-up screening using a glucose load and one-hour blood glucose value.

Instruction Methods

Group I subjects received instruction based on current test practice, i.e., verbal, nonspecific instructions. They were told

to eat breakfast and return for a second blood sampling two hours after completing this meal. No directions concerning what the test meal should contain or include were given. Group II subjects were given a Dietary Instruction Card (Appendix III, page 64) and no verbal instruction other than to do as the card indicated. The Dietary Instruction Card gave a sample meal pattern that would contain approximately 444 kilocalories, 49 grams of carbohydrate, 18 grams of protein, and 19 grams of fat (44% carbohydrate, 16% protein, and 39% fat). The Dietary Instruction Card also advised subjects to avoid coffee, tea, chocolate, sugar, jam or jelly, soft drinks, and cigarettes. Group II subjects who had questions were told to consult the Dietary Instruction Card. Group III subjects also were given the Dietary Instruction Card and were asked to read it while the clinician observed. Verbal amplification of the instructions was made. Any questions these subjects had about the test meal were answered fully.

All subjects were told to return to the office two hours after completion of their test meal for the drawing of a second blood sample. When the subjects returned, they were asked to recall the type and amount of foods and beverages consumed. Intake of caffeine-containing beverages and use of cigarettes were noted particularly. Carbohydrate, protein, fat, and kilocaloric content plus percent carbohydrate, protein, and fat in the breakfast were calculated using a standard food composition table (57). Foods deemed high in "simple carbohydrate" during the test meal were noted.

Patient Information Sheet

A Patient Information Sheet (Appendix IV, page 66) specifically designed for this study was completed for each subject. Information requested included present weight, family history of diabetes, previous pregnancies, and gestational age. Subjects' weights in pounds were measured using a single balance beam.¹ Subjects were instructed to remove their shoes but not other clothing. Height in inches was measured without shoes on the same instrument using a vertical cross bar lowered to the top of the head. Prepregnancy percentage ideal body weight was calculated using reference values (58). Content of breakfast meal selected, fasting blood glucose and two-hour postprandial blood glucose values were recorded on the Patient Information Sheet. This sheet became part of the subject's medical record.

Glucola and One Hour Blood Glucose

Thirty tests for abnormal glucose tolerance were performed using glucose and a one-hour blood glucose value. For 12 of these subjects, the glucose load screening followed an initial two-hour postprandial test done earlier in pregnancy. Subjects came to the test fasting, blood samples were taken and 240 ml of glucose solution providing 50 grams of carbohydrate was administered. A second blood sample was taken one hour after the glucose solution was consumed.

¹Detecto-Medic Brand, Brooklyn, New York.

Blood Glucose Measurement

An Ames Eyetone Reflectance Colorimeter (Dextrometer)² was used to measure whole blood glucose quantitatively in conjunction with the use of Dextrostix Reagent Strips.² The reliability of Dextrostix Reagent Strips used with a Dextrometer has been closely correlated with laboratory measurements of serum glucose concentrations and is generally considered accurate for home or clinical purposes (59, 61).

The Ames Eyetone Reflectance Colorimeter uses an electro-optical system for measuring the degree of color development on the Dextrostix Reagent Strips in response to the glucose concentration in a drop of whole blood obtained by finger prick. Light is reflected from the reacted area on the Dextrostix and measurement of the amount of light is converted to a direct readout of blood glucose concentration on a Meter Scale. The higher the level of blood glucose, the darker the Dextrostix Reagent Strip becomes, and the less light reflected. The Meter Scale indicates whole blood glucose concentrations from 10 to 400 mg/dl. A daily calibration and standardization procedure was performed according to the manufacturer's instructions before use of the Dextrometer for blood glucose measurement.

The testing procedure for blood glucose concentration began with a finger prick and the application of a large drop of

²Ames Division, Miles Laboratories, Elkhart, Indiana.

capillary blood to the reagent area of the Dextrostix Reagent Strip. The reaction was timed for 60 seconds and then the blood was quickly (one to two seconds) washed off the reagent area using a stream of tap water from an Ames bottle. The reagent area was blotted on a paper towel and then inserted into the strip guide on the Dextrometer. The lid was pressed closed and the resulting value was read from the Meter Scale.

III. STATISTICAL ANALYSES

Statistical analyses were performed with the use of the Statistical Analysis System (SAS) developed by Barr et al. (62). Regression analysis using the General Linear Model Procedure (PROC GLM) was employed to test effects of group assignment on nutrient levels in self-selected meals. Least Square Means were calculated for group assignment, nutrient levels, and blood glucose values at 0, 60, and 120 minutes. Pearson's Product Moment Correlation was calculated among two-hour postprandial blood glucose values, nutrient components (carbohydrate, protein, fat), and kilocalories. Student's t-tests were used to test for significant differences between kilocalories, protein, carbohydrate, and fat content of self-selected test meals and these same components in the sample meal plan.

CHAPTER IV

RESULTS AND DISCUSSION

I. DESCRIPTION OF SAMPLE

A general description of the 139 pregnant, Caucasian females included in this study is shown in Table 1. The pregnant females ranged in age from 18 to 41 years with the majority (70%) between 23 and 32 years. Gestational ages ranged between 10 and 37 weeks with the majority (68%) between 21 and 31 weeks gestation.

Slightly over half (51%) of the subjects were between 91 and 110% of their ideal body weight (prepregnancy) based on standards developed by Bistrian et al. (58). Using these criteria, 12 of the subjects would have been classified as grossly obese (>150% of ideal body weight) prior to pregnancy.

None of the subjects had more than four living children and 55 of the subjects were seen during their first pregnancy. The subjects had a total of 230 previous pregnancies but only 136 living children. This difference in para and gravida status can be explained mainly by previous miscarriages and abortions. One physician in the OB/GYN group at UTMCH is a fertility specialist and patients who have failed to carry previous pregnancies to term are often followed by this obstetrics group.

TABLE 1. Characteristics of the 139 Female Subjects

Characteristic	Respondents
	%
Group	
I	25
II	35
II	30
IV	12
Ages in years	
18-22	13
23-27	35
28-32	35
33-37	17
>37	1
Gestational Ages in Weeks	
10-15	6
16-20	5
21-26	36
27-31	32
32-36	21
>36	1
% Ideal Body Weight (Prepregnancy)	
70-80	3
81-90	10
91-100	23
101-110	28
111-120	9
121-130	10
131-140	6
141-150	2
151-160	3
>160	4
>190	1
Living Children	
0	40
1	36
2	15
3	6
4	4
Family History of Diabetes	
Yes	45
No	55

II. INCIDENCE OF ABNORMAL GLUCOSE TOLERANCE

Twenty-four of the 139 subjects had abnormal blood glucose responses when screened by either glucose loading or a mixed meal. This represents a possible 17.3% incidence of abnormal glucose tolerance. Sixteen (67%) of the abnormal screens followed a 50-gram glucose load and eight (33%) of the abnormal screens followed mixed meals.

Three "risk factors" or indicators of potential risk for development of gestational diabetes were assessed in this study. These were: a positive family history of diabetes, maternal obesity (> 120% of ideal body weight, prepregnancy), and maternal age. Only one subject (4%) who had abnormal screening results had none of these three risk factors. Twelve of the 24 subjects with abnormal screens also had a positive family history of diabetes. Eight of these 24 subjects were between 25 and 29 years of age. Ten of the 24 subjects were 30 years of age or older. Eight of the 24 subjects weighed more than 120% of their ideal body weight prepregnancy.

III. EFFECT OF GROUP ASSIGNMENT

Meal I

Data were analyzed for the effect of group assignment and subsequent mode of instruction on kilocalorie, carbohydrate, fat, and protein content of a self-selected test meal. Group IV was deleted from the analysis since subjects drank a glucose containing

solution, Glucola³, containing a measured amount of carbohydrate rather than selecting a meal. The kilocalorie intakes of Group I subjects ranged from 255 to 1137, whereas for Group II and III the ranges were 183 to 968 and 289 to 1062, respectively. There was a significant ($p < .01$) effect of group assignment on kilocalorie intake the first time a subject selected a test meal. Group assignment also significantly ($p < .0001$) affected intake of total grams of carbohydrate in the first test meal. Amounts of protein and fat selected in the first test meal were not affected by group assignment.

The mean kilocaloric content of the first test meal selected by Group I was significantly ($p < .03$) higher than that selected by both Group II and Group III ($p < .003$) (Table 2). Kilocaloric content of the first test meals selected by Groups II and III was not significantly different. Group I subjects selected the highest ($p < .003$) number of kilocalories (628.7 ± 29.4) and Group III the lowest (506.9 ± 27.2).

The mean carbohydrate content of the first test meals selected by Group I was significantly higher ($p < .0003$) than the carbohydrate content of the first test meals selected by Group II and Group III ($p < .0001$). Subjects in Groups II and III did not select meals significantly different in total carbohydrate content for the first test meal. Mean carbohydrate values for the first test meal were

³Ames Company, Elkhart, Indiana.

TABLE 2. Mean Nutrient and Kilocalorie Content of Test Meal I^{1,2,3}

Group	Meal I			
	Energy	Carbohydrate	Protein	Fat
	Kcal	gm	gm	gm
I (N = 35)	628.7 ± 29.4 ^a (255-1137)	65.3 ± 3.2 ^a (14-127)	22.2 ± 1.2 ^a (7-34)	30.8 ± 2.1 ^a (3-68)
II (N = 46)	544.3 ± 25.6 ^b (183-986)	49.5 ± 2.8 ^b (18-88)	23.6 ± 1.0 ^a (9-44)	27.8 ± 1.8 ^a (6-53)
III (N = 41)	506.9 ± 27.2 ^b (183-1062)	48.2 ± 2.9 ^b (31-76)	20.9 ± 1.1 ^a (9-50)	25.3 ± 1.9 ^a (11-70)

¹Mean ± SEM.

²()range of values reported.

³Figures within the same column followed by different superscripts are significantly different (p<.05).

65.3 \pm 3.2 grams for Group I, 49.5 \pm 2.8 grams for Group II, and 48.2 \pm 2.9 grams for Group III. The highest carbohydrate content (127 grams) and the lowest carbohydrate content (14 grams) of the first meal were selected by subjects in Group I.

These data seem to indicate that lack of instruction, verbal or otherwise resulted in test meal selection different from the test meal selected by those subjects who received some sort of direction or instruction. However, since Groups II and III did not select significantly different amounts of kilocalories or carbohydrate it would seem that the addition of verbal instructions to written instructions may not further influence kilocalorie or carbohydrate composition of meals selected.

Subjects asked frequently about the carbohydrate content of their test meal, particularly how much carbohydrate to include. Without instruction, Group I subjects may have attempted to ensure carbohydrate was adequate for test purposes. Some subjects would name all the carbohydrate containing foods they ate and ask whether this amount was enough. Other subjects listed one or more concentrated carbohydrate items and said these were "too hard to resist." The difference in carbohydrate content of Group I test meals was reflected in the difference in kilocalorie content.

Meal II

Forty-five of the subjects returned for a second two-hour post-prandial blood glucose evaluation. These subjects were reassigned

to their original test group. Data from the second test meal were analyzed in the same manner as data from the first test meal. No significant differences were found for any nutrient component or kilocalorie content in the second test meal consumed by the three groups of subjects (Table 3).

These results might be explained since subjects were more familiar with test procedures the second testing. Also, individuals may have discussed the procedures with subjects in other groups and altered their food selection on this basis. Due to the nature of the study, subjects were allowed to interact freely with each other. Many subjects were professional women, often health professionals. Also, some subjects were married to health professionals. These subjects may have attempted to learn what they should eat before the second test meal. All of these factors may have contributed to a more standardized meal selection during the second testing.

IV. MEAL SELECTION COMPARED TO SAMPLE MEAL PLAN

The standard sample meal plan listed on the instruction card provided to the subjects in Groups II and III containing 444 kilocalories, 49 grams carbohydrate, 18 grams protein, and 19 grams fat. This test meal was used previously by Owens et al. (24) to compare metabolic responses to glucose loads and a standardized test meal.

TABLE 3. Mean Nutrient and Kilocalorie Content of Test Meal II^{1,2,3}

Group	Meal II			
	Energy	Carbohydrate	Protein	Fat
	Kcal	gm	gm	gm
I (N = 15)	537.1 ± 46.9 ^a (347-1079)	57.7 ± 3.7 ^a (26-120)	17.3 ± 2.5 ^a (11-46)	26.4 ± 3.4 ^a (14-60)
II (N = 14)	563.0 ± 61.0 ^a (337-756)	52.5 ± 4.8 ^a (26-65)	23.5 ± 3.2 ^a (20-28)	28.7 ± 4.4 ^a (13-44)
III (N = 16)	409.9 ± 46.9 ^a (222-906)	49.4 ± 3.7 ^a (24-62)	16.1 ± 2.5 ^a (11-49)	16.8 ± 3.4 ^b (7-54)

¹Mean ± SEM.

²() range of values reported.

³Figures within the same column followed by different superscripts are significantly different (p<.05).

Using t-tests, kilocalories, protein, carbohydrate, and fat content of each subject's test meals were compared to the level of these components in the sample meal plan given for instruction purposes. These analysis results are shown in Table 4.

The first test meal selected by Group I subjects was significantly higher in fat ($p < .0009$), carbohydrate ($p < .0008$), and kilocalories ($p < .0001$) than the standard meal. When these subjects selected their second test meal, the nutrient compositions and kilocalorie content were not different from the standard. These findings may be explained by the same factors thought to affect the nutrient composition results discussed on page 34.

Fat ($p < .001$), protein ($p < .001$), and kilocalorie ($p < .005$) contents of the first test meal selected by subjects in Group II also were significantly higher than the standard meal. This same trend occurred with selection of the second test meal. These results differ from those of Group I. Provision of written instructions with a sample meal pattern did not result in selection of a meal similar to the sample.

In Group III, none of the nutrient components or kilocalories were significantly different from the standard in either the first or second test meals. Verbal and written instructions together were a positive influence on test meal choices by Group III subjects. Group I and II subjects had either no instructions or only written

TABLE 4. Nutrient and Kilocalorie Content of Meals Selected by Subjects Compared with Sample Meal Plan¹

Source of Variation	Significance			
	Std KCALS	Std CHO	Std PRO	Std FAT
<u>Group I (Test Meal No. I)</u>				
FAT				***
CHO		***		
KCALs	***			
PRO			NS	
<u>Group I (Test Meal No. II)</u>				
FAT				NS
CHO		NS		
KCALs	NS			
PRO			NS	
<u>Group II (Test Meal No. I)</u>				
FAT				***
CHO		NS		
KCALs	***			
PRO			***	
<u>Group II (Test Meal No. II)</u>				
FAT				**
CHO		NS		
KCALs	**			
PRO			***	
<u>Group III (Test Meal No. I)</u>				
FAT				NS
CHO		NS		
KCALs	NS			
PRO			NS	
<u>Group III (Test Meal No. II)</u>				
FAT				NS
CHO		NS		
KCALs	NS			
PRO			NS	

¹Statistical significance is indicated by **($p < .05$), and *** ($p < .01$). Statements not statistically significant are indicated by NS ($p > 0.10$).

instructions. These methods did not appear to be sufficient to result in appropriate meal pattern selection. In both the first and second testing, Group II subjects did select meals in which carbohydrate was not significantly different from standard meal levels. Group III subjects, who received verbal instructions in addition to the written instructions given to Group II, ate meals with nutrient patterns very similar to the standard meal pattern. This reinforces that handing out written instructions and/or patterns does not result in all of the desired meal component selections. The addition of verbal explanation to this method produced the desired results.

V. GLUCOSE LOADING VERSUS A STANDARDIZED MEAL

The 12 individuals who had a two-hour postprandial blood glucose test followed by a one-hour post-glucose test at a later date were compared (Figure 1). None of these individuals had blood glucose values higher than 125 mg/dl when tested initially using the postprandial screen. When tested a second time, later in pregnancy, six of the subjects (50%) had blood glucose values greater than 160 mg/dl post-glucose load. Five of the six remaining subjects (42%) had blood glucose values greater than 140 mg/dl after Glucola.

O'Sullivan (28) stated that the only substantive changes in mean glucose levels by trimester was 3 to 8 mg higher post-glucose values in the third trimester than in the previous two trimesters.

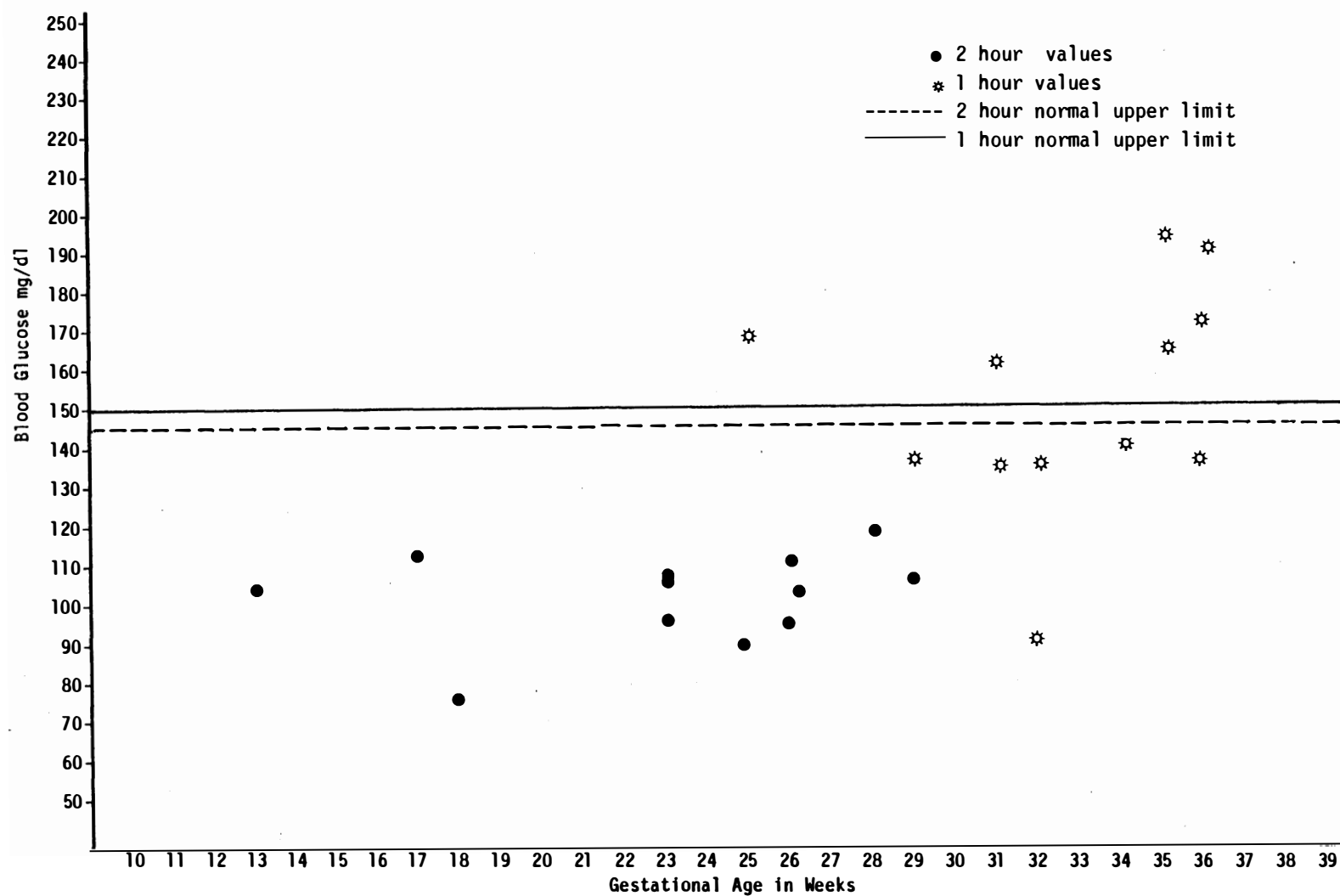


FIGURE 1. Two-hour postprandial blood glucose test values followed by one-hour post-glucola values in the same subject.

All but one of the 12 subjects were tested the second time with Glucola during the third trimester. However, blood glucose values obtained were higher with more abnormal values found post-glucose than after a mixed meal even considering lateness in pregnancy (Figure 1). The blood glucose value of only one subject did not increase by 20 or more mg/dl from the first or second trimester to the third trimester when mixed meal tolerance was compared with glucose load tolerance.

It is possible that 11 of the 12 randomly selected subjects had abnormal glucose tolerance with increases in blood glucose responses of 20 or more mg/dl from the first to second testing. Another possible explanation is that the glucose load produced a much higher blood glucose response than the mixed meal. Owens et al. (24) found that the plasma glucose increase following a glucose load was greater than observed with a standardized meal up to one hour after dosing; thereafter, the reverse was true. Fifty percent abnormal blood glucose values after glucose for a group of 12 subjects is a very high percentage. Other researchers (14, 18, 20, 22, 28, 32, 33) have reported incidences of abnormal screens following a glucose dose ranging from 1.4% to 15%, with the most common level being 7 to 8%.

All one-hour post-Glucola blood glucose results were compared to all two-hour blood glucose results (after a second test meal). Two-hour postprandial values obtained the second testing were chosen for comparison because the second testing tended to be later in pregnancy. Most post-glucose values were obtained late in pregnancy,

also. Since these two test methods measure glucose response at different time periods, blood glucose values were not compared directly but numbers of abnormal screens detected by each method were compared.

Of the 30 one-hour post-glucose values obtained, 11 values (37%) were greater than 150 mg/dl (Figure 2). Nine of the remaining 16 post-glucose values (30%) were greater than 140 mg/dl. At the UTMRHC, 150 mg/dl is the upper limit of normal for one-hour post-glucose values used by the OB/GYN Service. For two-hour postprandial values, 145 mg/dl is considered the upper limit of normal.

Forty-five subjects had a two-hour postprandial screen performed a second time during their pregnancy. Only two of the 45 subjects (4%) had postprandial blood glucose values greater than 145 mg/dl (Figure 3). Four of the remaining 43 subjects (9%) had postprandial blood glucose values greater than 130 mg/dl but less than 145 mg/dl.

If use of glucose loads as a challenge is overdetecting possible gestational diabetes as these data suggest, then many women are unnecessarily facing the expense and discomfort of three-hour glucose tolerance testing to confirm a diagnosis. Sending two of 45 subjects for follow-up testing would seem more reasonable if the incidence of gestational diabetes is accepted as 1 to 3% of all pregnancies (1).

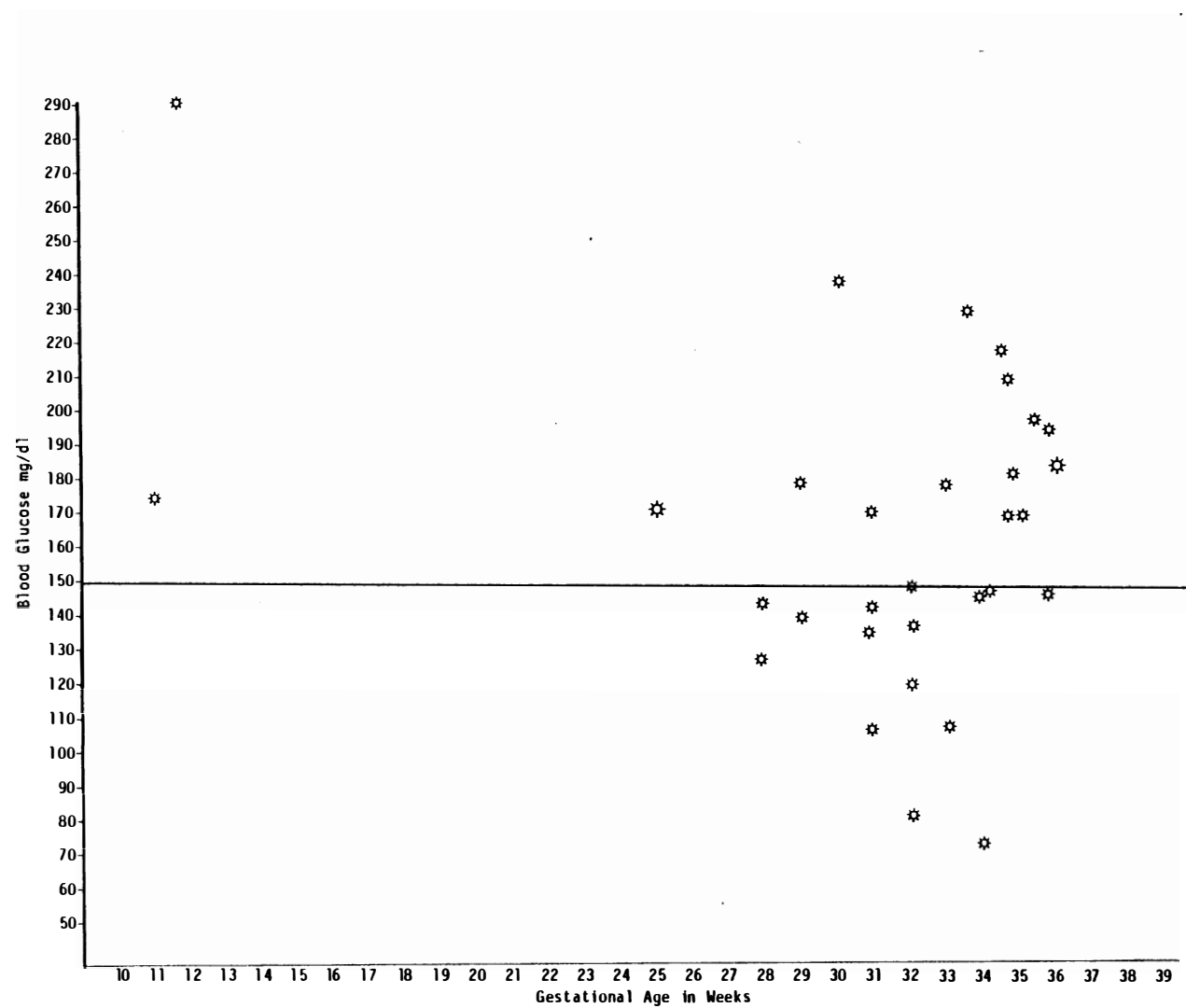


FIGURE 2. One-hour blood glucose values of all subjects who consumed Glucola.

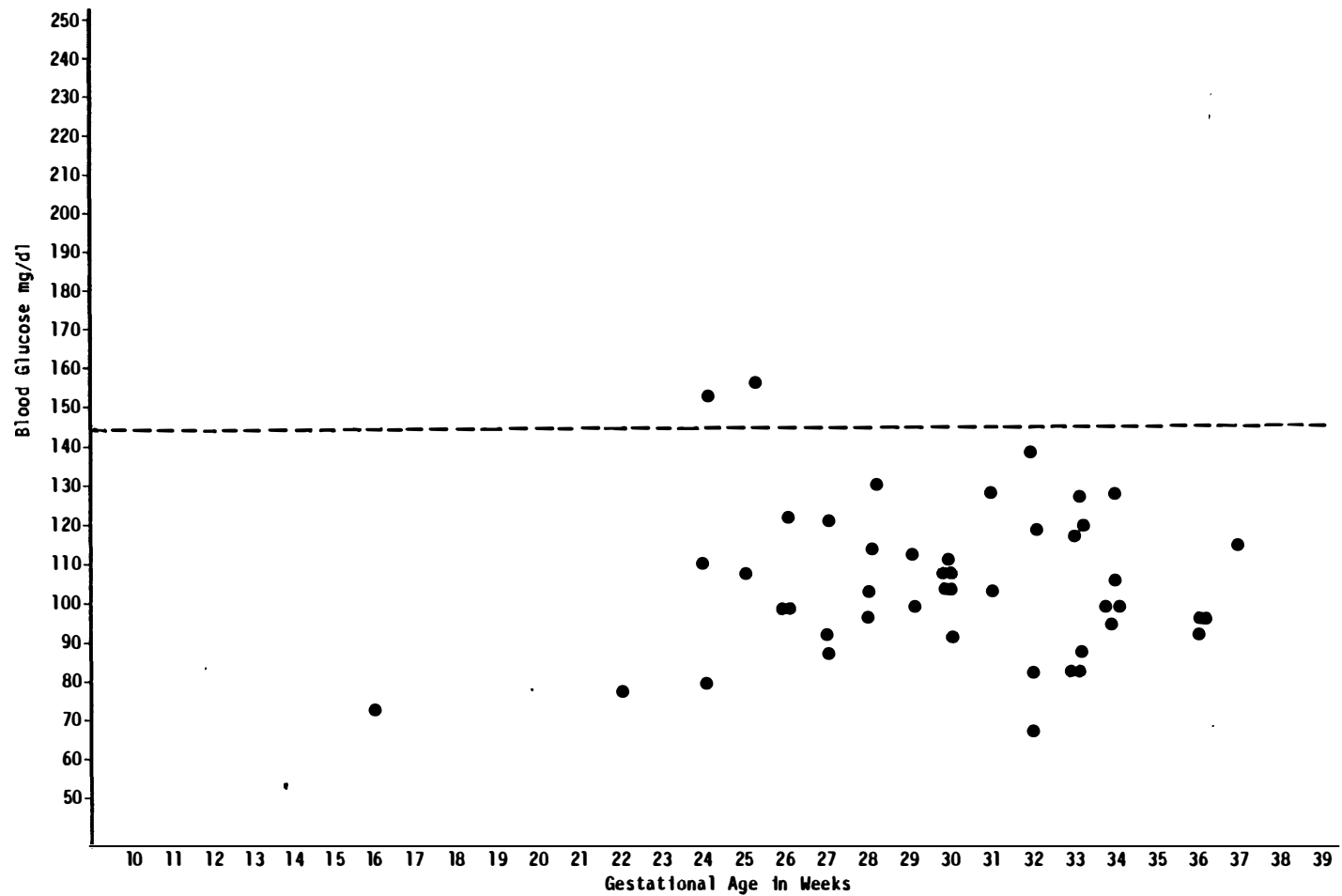


FIGURE 3. Two-hour postprandial blood glucose values following second test meal compared with the upper limit of normal values accepted by the Obstetrics/Gynecology Service at UTMCH.

VI. EFFECT OF NUTRIENT LEVELS ON BLOOD GLUCOSE LEVELS

Correlation coefficients were calculated among the two-hour blood glucose values after the test meals and kilocalories, carbohydrate, protein, and fat contents of the meals. During the first testing, only carbohydrate content of the meal was positively correlated ($p < .005$) with blood glucose values. In the second test meal, kilocalories, carbohydrate, and protein ($p < .05$ for all) were positively correlated with two-hour blood glucose values. These results contradict findings by Radder and Terpstra (27) who stated that composition of a test meal did not affect height of blood glucose response. Knopp et al. (3) stated that higher loads of glucose resulted in hyperglycemia whereas a smaller load did not. Differences in the two postprandial tests could explain correlations which occurred only in the second test meal. The second test meal was chosen by subjects later in pregnancy. The group of subjects who had a repeated or second postprandial test was smaller (45 subjects) than the group having an initial postprandial test only (64 subjects). The time lapse between the two tests varied for different individuals. Subjects were familiar with the test procedures when they chose their second test meal.

Correlation coefficients were calculated also for age, ideal body weight, gestational age, individual nutrient components, and kilocalories. In both the first and second test meals, kilocalories were positively ($p < .05$) correlated with increasing gestational age.

The American College of Obstetricians and Gynecologists (63) stated that caloric needs are greater in the third trimester than in the first.

Carbohydrate in the first test meal but not the second test meal was positively correlated ($p < .05$) with ideal body weight. Protein in the second test meal was negatively correlated ($p < .05$) with age and positively correlated ($p < .05$) with gestational age. Since these correlations did not occur in both the first and second test meals, differences between the two meals may account for the inconsistencies. These factors, discussed previously, include the second test occurring later in pregnancy, a smaller sample size for the second testing, familiarity with test procedures by the second test, and varying time lapses between first and second tests.

CHAPTER V

SUMMARY, LIMITATIONS, AND IMPLICATIONS

I. SUMMARY

The effects of three different instruction methods on selection of a breakfast test meal were studied. Subjects were 139 pregnant, Caucasian women screened for gestational diabetes by two-hour postprandial blood glucose evaluation. Nutrient contents (protein, fat, carbohydrate) and kilocalories of the self-selected breakfast meals were variables analyzed and compared to the nutrient pattern of the sample meal plan. The effect of varying levels of nutrients on blood glucose values was examined, also.

The subjects were assigned randomly to one of three groups. Group I subjects were given no written or verbal instructions about test meal selection but were instructed to eat breakfast. Group II subjects were given written instructions in the form of a sample meal pattern and foods to avoid. Group III subjects were given these same written instructions plus verbal explanation and amplification. Fasting blood glucose levels were tested, subjects consumed their test meals, and returned to the office after two hours for a second blood sampling. Subjects were asked to recall foods and beverages consumed. The entire testing process was repeated for 45 of the subjects at a later date.

Group assignment significantly affected kilocalorie ($p < .01$) and carbohydrate ($p < .0001$) content of test meals selected by subjects in the first testing process. For the first test meal, Group I subjects selected meals significantly higher ($p < .03$) in kilocalories and carbohydrate than Groups II and III. Group II and Group III did not select test meals that were significantly different. No significant differences were found for any nutrient component when a second test meal was consumed by 45 subjects.

In the first test meal, Group I subjects selected a meal containing significantly higher levels of fat ($p < .0009$), carbohydrate ($p < .0008$), and kilocalories ($p < .0001$) than the standard. Group II subjects selected a meal significantly higher in fat ($p < .0001$), protein ($p < .001$), and kilocalories ($p < .005$) than the standard. Group III subjects selected a meal in which no nutrient components were significantly different from the standard.

For the second test meal, Group II subjects were the only group whose meal selection differed from the standard. In this second meal, fat ($p < .009$) and kilocalories ($p < .02$) were significantly higher than the standards of 19 grams fat and 444 kilocalories.

For the first test meal, only carbohydrate content of the test meal was positively correlated ($p < .005$) with blood glucose values. In the second test meal, kilocalories, carbohydrate, and protein were positively correlated ($p < .05$ for all) to two-hour blood glucose values.

Method of instruction seemed to influence nutrient patterns of self-selected test meals. Group III subjects, who received instructions in the form of verbal and written directions, selected meals whose nutrient components and kilocalories were closest to the nutrient components of the sample meal patterns. Group II subjects, who received written instructions only, were able to select only carbohydrate levels close to the sample meal pattern in both test meals. Carbohydrate was the nutrient component which was a consistent positive influence on two-hour blood glucose levels. Group I subjects had no instructions concerning what foods to choose. However, these subjects may have discussed with other subjects or persons outside the study what a test meal should include. If these subjects did seek outside information on what foods to choose, the information could have contributed to the resulting selection of a second test meal not significantly different from the standard.

Differences between detection of gestational diabetes using a glucose load and one-hour blood glucose levels and/or a mixed meal and two-hour blood glucose levels were investigated also. Twelve subjects had both a test meal screening and a one-hour glucose load screening. The blood glucose results from these subjects were examined and compared.

Thirty subjects were tested with a 50-gram glucose load administered in a 240 ml solution. Blood glucose values were measured one hour later. Forty-five subjects who were tested with a self-selected mixed meal were used for comparison. Two hours

after the test meal was consumed, blood glucose values were measured. The 12 subjects who had both tests were screened with a test meal first and later in pregnancy were given a glucose load test.

Thirty-seven percent of the 30 subjects tested with a glucose load had blood glucose values which would be considered above the upper limit of normal (≥ 150 mg/dl one hour after dosing). Only 4% of the 45 subjects tested with a mixed meal for the second time had blood glucose values which were above the upper limits of normal (≥ 145 mg/dl two hours after the test meal).

Of the 12 subjects tested by both methods, 50% were considered to have blood glucose levels above the upper limits of normal using a glucose load. None of the 12 had blood glucose values above the upper limits of normal following a test meal.

Glucose loading produced a higher blood glucose response than the response produced by a mixed meal. The percentages of abnormal screens (37%) following a glucose load were much higher than common detection rates found in the gestational diabetes screening literature. The use of glucose alone as a challenge will result in many more patients than necessary undergoing further diagnostic testing for gestational diabetes.

II. LIMITATIONS OF THE STUDY

Subjects studied were all Caucasian, middle-to-upper class individuals so that instructional method results might be different

if applied to different races or socioeconomic groups. Interaction and discussion between members of different groups were not controlled. Occasionally a subject who received no instructions was observed leaving for breakfast with a subject who received written and verbal instructions. Subjects were studied while pregnant and pregnancy is often a time when health concerns are foremost and instructions from health professionals are most likely to be followed. Instructional method results might have been different if the same subjects were studied when they were not pregnant.

In comparing screening methods, the sample size of subjects who had a glucose load screening test was approximately half the size of the sample of subjects tested with a mixed meal. Only a small number of subjects had both tests. It is not completely reasonable to compare one-hour blood glucose values to two-hour blood glucose values so this was not attempted statistically. Follow-up glucose tolerance test results need to be obtained to determine the actual sensitivity and specificity rates of the two tests.

In this particular study, Glucola use resulted in higher percentages of elevated blood glucose levels than percentages reported in the literature. The reasons for this are not easily determined. Physicians may have requested testing with Glucola for particular subjects because of the presence of clinical features not identified by this study. This would partially account for the high percentage of elevated post-Glucola values obtained.

III. IMPLICATIONS

This particular study reinforces the concept that both written and verbal instructions are needed to produce standardized breakfast test meal choices. Standardization of test meals would seem to be desirable since carbohydrate levels were positively correlated with blood glucose values. Results of follow-up three-hour glucose tolerance tests performed after abnormal Glucola or mixed meal screens would have to be analyzed to determine whether these screens were over-detecting abnormal glucose tolerance in the sample population.

The results of this study could be further explored and validated. Regression analysis could be used to determine the relationship between the variety of carbohydrate levels chosen by Group I subjects and their blood glucose values. A subject for further research might be a study of the incidence of overt diabetes in the sample population five years after this original study.

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LITERATURE CITED

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APPENDICES

APPENDIX I

Consent Form for Participation in a Research Project Entitled,
"Compliance of Prenatal Patients with Dietary Instructions Prior to
Blood Sugar Testing"

Explanation:

Routine screening for pregnancy induced glucose intolerance has become a standard obstetrical procedure. Dr. John Semmer and Dr. Thomas Traylor request that their private patients have a minimum of two blood sugar screening tests during the prenatal period. A research project has been designed to check the reliability and comparability of different dietary instructions prior to post prandial blood sugar testing of private patients.

The investigators request permission to use the results of your tests in their study. The information will be kept strictly confidential. Although the procedures may not directly benefit you or your baby, the results of the study may help to improve overall health care for pregnant women and possibly reduce health care costs.

Certification:

I, the undersigned, certify that I have been informed to my satisfaction of the nature of the research project and voluntarily consent to participate. I understand that I have the right to ask questions at any time during the study of the investigators or from my physician. I understand that my name will not be used in connection with publication of the results of the study. I further understand that I may voluntarily withdraw from participation in the study at any time without affecting my obstetrical care.

Signed:

Date: _____	Participant: _____
Date: _____	Investigator: _____
Date: _____	Physician: _____

APPENDIX II

PATIENT INFORMATION

Person responsible for bill (don't give insurance company)

- | | |
|----------------------|--------------------------------------|
| 1. NAME: _____ | 4. HOME TELE. # _____ |
| 2. ADDRESS: _____ | 5. BUSINESS TELE. # _____ |
| _____ | 6. DOCTOR: _____ |
| _____ zip _____ | OFFICE USE ONLY: 7.GR # _____ |
| 3. SOC. SEC. # _____ | 8.PR # _____ |
| | 9. B. CYCLE _____ 11.CODES: #1 _____ |
| | 10. P. PLAN _____ #2 _____ |

INSURANCE COVERAGE

- | | |
|------------------------------------|-------------------------------------|
| 12. INS. COMPANY _____ | 12A. INS. COMPANY _____ |
| 13. CLAIM # _____ | 13A. CLAIM # _____ |
| 14. SUBSCRIBER _____ | 14A. SUBSCRIBER _____ |
| 15. EMPLOYER (if group plan) _____ | 15A. EMPLOYER (if group plan) _____ |
| 16. GROUP # _____ | 16A. GROUP # _____ |
| | 12B. INS. COMPANY _____ |
| | 13B. CLAIM # _____ |
| | 14B. SUBSCRIBER _____ |
| | 15B. EMPLOYER (if group plan) _____ |
| | 16B. GROUP # _____ |

PATIENT INFORMATION

- | | |
|--------------------------|--------------------------------|
| 17. NAME: _____ | 20. SOC. SEC. # _____ |
| 18. DATE OF BIRTH: _____ | 21. MARITAL STATUS _____ |
| 19. SEX: _____ | 22. STUDENT: (YES OR NO) _____ |
| | 23. REFERRAL DOCTOR: _____ |

REASON FOR VISIT: _____

PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE: I AUTHORIZE THE RELEASE OF ANY MEDICAL INFORMATION NECESSARY TO PROCESS THIS CLAIM AND REQUEST PAYMENT OF MEDICARE/CHAMPUS BENEFITS EITHER TO MYSELF OR PARTY WHO ACCEPTS ASSIGNMENT BELOW.

13. I AUTHORIZE PAYMENT OF MEDICAL BENEFITS TO THE UNDERSIGNED PHYSICIAN OR SUPPLIER FOR SERVICE DESCRIBED BELOW.

SIGNED _____ DATE _____

SIGNED _____

APPENDIX III

PATIENT INFORMATION CARD

PART A

NAME: _____ AGE: _____ GROUP: _____

ADDRESS: _____ EDC: _____ GA: _____

_____ GRAVIDA: _____ PARA: _____

Pre-Pregnancy Weight: _____ Height: _____ Ft. _____ In. _____

Pre-Pregnancy Weight Status: Overweight: _____ Underwt.: _____ Average: _____

Present Weight: _____ Total Weight Gain: _____

History of Diabetes: _____

Family History of Diabetes: Yes _____ No _____

Mother _____ Father _____ Sister _____ Brother _____

Other Family Members: (list) _____

Insulin Dependent: _____

Oral Agents: _____

PART B

Test Results: FBS: _____ Date: _____ Other (Explain): _____

PP: _____ Date: _____

Pre-Test Meal: _____ Analysis: Pro: _____

(Type and Amount) _____ CHO: _____

_____ FAT: _____

_____ KCALS: _____

Signature

Date

APPENDIX IV

DIET INSTRUCTIONS

It is now important for you to go and eat a good, balanced meal. A sample of an appropriate meal would include the following:

- 1/2 cup unsweetened cereal
- 1/2 pint whole milk (part to use on cereal)
- 1/2 cup fruit juice
- 1 slice toast with 1 tsp. margarine
- 1 large or 2 small eggs

Avoid the following:

coffee	chocolate	cigarettes
tea	jam/jelly	
soft drinks	sugar	

Note the time you finish the meal and return to clinic 2 hours later. Tell the receptionist you have returned to give a 2 hour blood sample.

VITA

Rebecca A. Walton was born in New Haven, Connecticut on December 6, 1956. In the next few months her family moved to Georgia. She attended school in Savannah, Georgia and graduated from Herschel V. Jenkins High School in June of 1975. The following September she entered Georgia Southern College in Statesboro, Georgia. In 1976, she transferred to the University of Georgia and in August of 1978 received a Bachelor of Science degree in Home Economics with a major in Dietetics. In September of 1978, she began a twelve-month dietetic internship at the Massachusetts General Hospital in Boston.

In September 1979, she was employed as a clinical dietitian at Baptist Medical Center in Jacksonville, Florida. She accepted a graduate assistantship at The University of Tennessee, Knoxville in September 1981 and began work on a Master of Science degree with a major in Nutrition and a collateral area in Exercise Physiology.