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Postpartum Weight Retention In First Time Mothers And Weight Outcomes In Their Offspring

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POSTPARTUM WEIGHT RETENTION IN FIRST TIME MOTHERS AND WEIGHT
OUTCOMES IN THEIR OFFSPRING

by

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A Dissertation

Submitted to the Graduate Faculty

of the

University of North Dakota

In partial fulfillment of the requirements

for the degree of

Doctor of Philosophy

Grand Forks, North Dakota

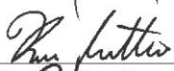
May
2017

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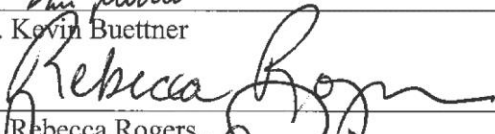
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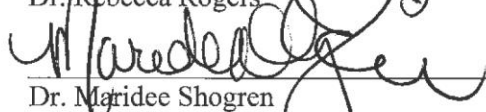
Dr. Jody Ralph



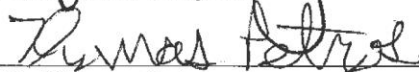
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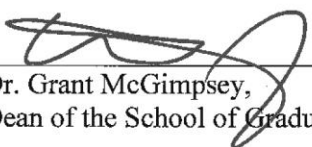


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Dr. Grant McGimpsey,
Dean of the School of Graduate Studies



Date

PERMISSION

Title Postpartum Weight Retention in First Time Mothers and Weight
 Outcomes in Their Offspring

Department Nursing

Degree Doctor of Philosophy

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Kelly Gallagher
May 4, 2017

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ABSTRACT

Background and Purpose: Overweight and obesity are common problems in the United States contributing to significant morbidity. Women may have increased risk for overweight and obesity over their lifetimes if they retain weight postpartum and never lose it. Increasingly, children are diagnosed as overweight or obese. Identification of overweight and obesity in young children coupled with the increased obesity rates in the adult population suggests that maternal factors may be associated with offspring obesity. Body mass index (BMI) and gestational weight gain are two factors that have been associated with increased weights postpartum in women, but these studies have mainly utilized participants who have had more than one baby in their lifetimes. There is little information on postpartum weight and offspring outcomes for women having their first baby. The purpose of this study was to investigate the importance of BMI and excessive gestational weight gain on postpartum weight retention and offspring weight out to 2 years in women having their first baby.

Study Design and Theoretical Framework: This is a retrospective secondary analysis of a prospective longitudinal study of women who were followed during their first pregnancy and up to two years postpartum. Postpartum weight retention and offspring weights were examined by maternal body mass index and ability to gain within the pregnancy guidelines set by the Institute of Medicine (IOM). The developmental model for origins of disease (Barker Hypothesis) is the theory used to frame this study. This theory hypothesizes that a critical event during gestation alters gene expression resulting in potential long-term consequences on human development. **Specific Aims:** 1) To determine if overweight or obese first time mothers retain

more weight gained in pregnancy than first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years postpartum; 2) To determine if first time mothers who gain in excess of IOM guidelines during pregnancy retain more weight than women who gain within the IOM guidelines at 6 weeks, 6 months, 1 year and 2 years postpartum; 3) To determine if the offspring of overweight or obese first time mothers have higher weight for length percentiles than the offspring of first time mothers of normal weight mothers at 6 weeks, 6 months, 1 year and 2 years of life; and, 4) To determine if the offspring of first time mothers who gain in excess of IOM guidelines during pregnancy have higher weight for length percentiles than the offspring of first time mothers who gain within the guidelines at 6 weeks, 6 months, 1 year and 2 years postpartum.

Sample: Data from 652 mother/infant dyads were available for analysis. The women who provided the data were eligible for midwifery care in a low risk obstetrical setting. Underweight women at the initiation of pregnancy care were excluded from analysis.

Methods: A series of one-way analysis of variance (ANOVA) were used to compare normal, overweight and obese participants on demographic variables, postpartum weight retention (PPWR) and offspring weight for length percentiles. A 3x2 between subjects ANOVA was used to compare postpartum weight retention and offspring weight for length percentiles by adherence to weight gain guidelines. Follow-up non-parametric tests were then run because the Shapiro-Wilk test for normality of data was significant and the Levene's test of homogeneity of variances was significant ($p < .01$). Kruskal-Wallis and Mann Whitney tests to determine significant differences between groups were completed.

Results: In the analysis of the demographic data, three observations were made: 1) normal weight women had significantly more years of education than obese women ($p = .01$), 2)

obese women gained significantly less weight during pregnancy than normal weight women ($p < .05$), and 3) offspring of obese women were statistically significantly heavier at birth compared to normal weight women ($p < .01$), but the amount by which they were heavier is unlikely to be clinically significant.

Specific Aim 1: Obese women retained significantly less weight than normal and overweight women at 6 weeks ($p < .05$). Normal weight women retained significantly less weight than overweight women at the 6-month time point ($p < .05$). Normal weight women retained significantly less weight than overweight women at the 1 year time point ($p < .05$).

Specific Aim 2: In an analysis between groups, significant differences for weight gain in excess of the IOM guidelines were seen at the 6-week time period only ($p < .01$). Subsequent Mann-Whitney tests for weight gain in excess of IOM guidelines revealed that normal weight women who gained in excess of their guideline retained significantly more weight than obese women who gained outside of their guideline ($p < .01$) and overweight women who retained in excess of their guideline retained significantly more than obese women who gained in excess of their guideline. No other pairwise comparisons were significant.

In an analysis within groups, normal weight women who gained within their IOM guideline retained significantly less weight than normal weight women who gained in excess of the IOM guidelines at 6 weeks, 6 months, and 1 year time point ($p < .01$). No difference was seen for normal weight women who gained within their guidelines and those who did not at 2 years. Overweight women who gained within the IOM guidelines retained significantly less weight than overweight women who gained in excess of the IOM guideline at 6 weeks, 6 months and 1 year ($p < .01$). No difference was seen for overweight women who gained within their guideline and those who did not at 2 years. Obese women who gained within their IOM guideline retained

significantly less weight at 6 weeks only ($p < .05$). No significant differences were seen for postpartum weight retention for obese women who gained within their guidelines and those who gained in excess of their guideline at any other time point.

Specific Aim 3: No significant differences were detected for offspring weight for length percentiles at any time point for any maternal BMI category.

Specific Aim 4: Offspring of normal weight women who gained within the IOM guidelines had significantly lower weight for length percentiles at the 1-year time point only ($p = .05$). For all other women in all BMI groups there were no differences at any time point.

Conclusions: Obese women had better outcomes than expected with less overall weight gain and less weight retention at 6 weeks. In general, while women who gained in excess of the guidelines tended to retain more weight, this was only seen at the 6-week time period for obese women and compared to normal and overweight women obese women who gained in excess of guidelines retained less weight postpartum. In this study of first time mothers with relatively uncomplicated pregnancies the offspring outcomes were not influenced by maternal BMI. Offspring of normal weight women who gained within their IOM guideline had significantly lighter babies at 1 year compared to normal weight women who over-gained.

CHAPTER I
INTRODUCTION

Background

Obesity is a common public health problem affecting both women of childbearing age and children; 54% of women begin pregnancy overweight or obese; 17% of children age 2-19 and nearly 14% of 2-5 year olds meet the established criteria for overweight or obesity (Gilmore, Klempel-Donchenko, & Redman, 2015; Olson, Strawderman, & Dennison, 2009). Nearly one-half of all pregnant women gain more than is advised (Gilmore et al., 2015).

The Health and Medical Division (HMD) of Sciences, Engineering, and Medicine (the National Academies) makes weight gain guidelines during pregnancy. For clarification, prior to March of 2016 HMD was known as the Institute of Medicine (IOM) and historical reports, publications, and guidelines published prior to the name change retain the previous name (i.e. IOM). While all women are expected to gain weight in pregnancy, excessive weight gain might be a risk factor for long-term weight increase.

Obesity is a particular problem for childbearing women because it is thought to increase the risk of pregnancy complications and contribute to postpartum weight retention. Postpartum weight retention is weight that is gained during pregnancy and not lost after pregnancy. It is of concern because it is thought to be a potential pathway to obesity in young women (Gunderson, 2009). Overweight and obesity outside of pregnancy are associated with multiple chronic diseases including type II diabetes, hypertension and cancer (Siega-Riz et al., 2009). Overweight and obesity during pregnancy are associated with gestational diabetes mellitus, hypertensive

disorders, macrosomia (birth weight of > 4000 g), infection and cesarean section (Gunderson, 2009; Lee, Hwang, Liou, & Chien, 2011).

Obesity in childhood is associated with hyperlipidemia, hypertension and type II diabetes (Olson et al., 2009). Overweight and obesity during childhood is also a risk factor for overweight/obesity during adulthood with all of its associated co-morbidities (Ehrental et al., 2013).

Overweight and obesity have been steadily increasing in the United States for the past 30 years in the adult population (Flegal, Carroll, Kit, & Ogden, 2012). Until recently, high weight/infant obesity was thought to be rare and Kaar et al. (2014) suggest that the fact that obesity is now being identified in infants suggests that maternal factors such as maternal obesity may be associated with offspring obesity even at an early age.

Overweight and obesity are costly problems both in terms of associated healthcare problems such as diabetes and heart disease but also in health care costs. The total estimated healthcare costs because of overweight and obesity status in adults in 2008 dollars was 113.9 billion or 4.8 percent of all healthcare spending (Tsai, Williamson, & Glick, 2011). Most concerning for children, obesity is predicted to contribute to a shorter life expectancy than what is expected for their parents (Ehrental et al., 2013).

The first IOM guideline was issued in 1990 and used the MetLife Insurance cutoffs for weight to establish parameters for underweight, normal weight, overweight and obese body mass index (BMI) categorizations and to make recommendations for weight gain in pregnancy (Siega-Riz, Deierlein, & Stuebe, 2010). In 2009 these recommendations were revised to use the International Obesity Task Force values for BMI. This change led to a marginal increase in numbers of women being classified as overweight (Siega-Riz et al., 2010). The recommended

weight gain using these guidelines was unchanged for underweight, normal and overweight women at 28-40 pounds, 25-35 pounds and 15-25 pounds, respectively. The weight gain guideline did change for obese women from a recommendation to gain at least 15 pounds to a recommendation to gain 11-20 pounds (Siega-Riz et al., 2010).

Table 1. Recommended Weight Gain Based on BMI Category

Pre-pregnant BMI Category	1990 IOM BMI Cutoff	Recommended Weight Gain	2009 IOM BMI Cutoff	Recommended Weight Gain
Underweight	<19.8 kg/m ²	28-40 lb	<18.5 kg/m ²	28-40 lb
Normal Weight	19.8-25.9 kg/m ²	25-35 lb	18.5-24.9 kg/m ²	25-35 lb
Overweight	26.0-29.0 kg/m ²	15-25 lb	25.0-29.9 kg/m ²	15-25 lb
Obese	>29.0 kg/m ²	Minimum 15 lb	≥30 kg/m ²	11-20 lb

Ideally, caloric intake in pregnancy creates a balance between pre-existing maternal stores and maternal intake to supply optimal maternal nutrition and support healthy fetal growth. The approximate weight breakdown of weight gain in pregnancy is: baby, seven to eight pounds; placenta, one to two pounds; amniotic fluid approximately two pounds; breast tissue approximately two pounds; blood volume increase approximately four pounds; fluid in maternal tissue approximately four pounds; and maternal fat approximately seven pounds (Institute of Medicine, 2009).

Problem Statement

Based on previous studies, pre-pregnant obesity and excessive gestational weight gain are thought to contribute to postpartum weight retention and obesity rates in women. Current weight gain guidelines in pregnancy are based on this research. However, almost all of these studies include primiparous (first time mothers) and multiparous women (women who had given birth more than once) and rely on self-reported weights. Combining primiparous and multiparous women may conflate the issue of postpartum weight retention as multiparous women are

generally older and heavier at onset of pregnancy. Data are needed about weight gain and retention among first time mothers to elucidate the utility of the IOM guidelines in this population and to clarify the impact of BMI and weight gain in pregnancy on offspring outcomes.

Purpose Statement

Pregnancy may be an important entree to long-term maternal and offspring overweight and obesity. The primipara experience with gestational weight gain and postpartum weight retention is not well described in the literature. *The purpose of this study was to investigate the importance of BMI and excessive gestational weight gain on postpartum weight retention and offspring weight out to 2 years in women having their first baby.* To achieve this goal, a secondary analysis of data was completed with 652 mother/infant dyads with calculated BMIs and measured weights throughout pregnancy at 6 weeks, 6 months, 1 and 2 years following birth.

Variables of Interest

The primary outcomes of interest were postpartum weight retention and offspring weight for length percentiles. Postpartum weight retention was calculated by subtracting maternal pre-pregnant weight from postpartum weights. The primary outcome of interest in offspring was age specific weight for length percentiles using Centers for Disease Control and Prevention (CDC) charts. Pre-pregnant BMI is calculated using the formula weight in kilograms/height in meters². The National Academies, formerly known as the Institute of Medicine, recommends weight gain ranges in pregnancy for underweight, normal weight, overweight and obese women. Weight gain above the recommended IOM guidelines is termed excessive weight gain.

Specific Aims

Specific Aim 1: To determine if overweight or obese first time mothers retain more weight gained in pregnancy than first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years postpartum. *Hypothesis:* Overweight or obese women will retain more of the weight gained during pregnancy at each time point compared to women of normal weight.

Specific Aim 2: To determine if first time mothers who gain in excess of IOM guidelines during pregnancy retain more weight than women who gain within the IOM guidelines at 6 weeks, 6 months, 1 year and 2 years postpartum. *Hypothesis:* First time mothers who gain in excess of the IOM guidelines will retain more weight at each time point compared to women who gain within the guidelines.

Specific Aim 3: To determine if the offspring of overweight or obese first time mothers have higher weight for length percentiles than the offspring of first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years of life. *Hypothesis:* The offspring of overweight or obese first time mothers will have higher weight for length percentiles at each time point compared to the offspring of first time mothers of normal weight.

Specific Aim 4: To determine if the offspring of first time mothers who gain in excess of IOM guidelines during pregnancy have higher weight for length percentiles than the offspring first time mothers who gain within the guidelines at 6 weeks, 6 months, 1 year and 2 years of life. *Hypothesis:* The offspring of first time mothers who gain in excess of the IOM guidelines will have higher weight for length percentiles at each time point compared to the children of first time mothers who gain within the guidelines.

Theoretical Framework

The developmental model for origins of disease, also called the Barker Hypothesis, was utilized for the study to help guide thought about the impact of over-nutrition, through high BMI or excessive gestational weight gain, on fetal development. This model proposes that maternal nutritional status has a major role in the long-term health of babies and that variations in the supply of nutrients affect fetal programming, which is a permanent alteration in gene expression (Barker, 1997; Barker & Thornburg, 2013). Another important concept is developmental plasticity, which refers to the ability to respond to environmental influences during critical developmental periods (Barker & Thornburg, 2013).

In the 1980s researchers in England made an observation that regions of the country that had the highest infant mortality rate and lowest birth-weights also had the highest mortality rate for heart disease decades later (de Boo & Harding, 2006). This observation led to a hypothesis, called the Barker hypothesis, after the lead researcher also called the developmental origins of adult disease hypothesis (de Boo & Harding, 2006). This observation and hypothesis that low birth weight was linked to heart disease was tested and confirmed, and then replicated in other studies around the world. Many adult diseases have been tested using the origins of adult disease hypothesis. Diseases associated with low birth weight that have been tested and replicated include: hypertension, coronary artery disease, type II diabetes, stroke, dyslipidemia, elevated clotting factors and impaired neurodevelopment (de Boo & Harding, 2006).

While this hypothesis began with links between low birth weight and untoward health effects, the developmental origins of adult disease hypothesis has also been tested for high birth weight outcomes and links to diseases such as polycystic ovary disease, breast, prostate and testicular cancer as well as childhood leukemia (de Boo & Harding, 2006). The mechanism is as

of yet unclear, but it is hypothesized that an insult during a critical time has developmental consequences that are long term.

It is possible to have over-nutrition but with inadequate nutrients to the fetus concurrently. This may be due to the quality of nutrients or the inability to receive the nutrients due to suboptimal functioning of maternal metabolism (Barker & Thornburg, 2013). Maternal obesity increases the risk of developing insulin resistance in pregnancy and is linked with gestational weight, adiposity and diabetes in offspring (Ojha, Saroha, Symonds, & Budge, 2013). This early life exposure of excess nutrient supply to offspring while in utero may cause persistent changes in metabolism and endocrine function and lead to life-long increased risk for obesity, diabetes and other diseases (Ojha et al., 2013). The developmental model for origins of disease informs this study on postpartum weight retention and offspring outcomes through the understanding that health outcomes are related to experiences during development that are in turn, related to lifetime maternal nutritional stores (Barker & Thornburg, 2013). Pre-pregnancy BMI and the ability to gain within the IOM guidelines during pregnancy are maternal factors that influence nutritional stores, which could affect offspring development and weight outcomes.

Significance of the Study

This research examined the risk of obesity and excessive gestational weight gain on postpartum weight retention in women and offspring obesity at multiple time points from birth to 2 years. This study provided valuable information about weight gain and retention among healthy first time mothers, serving to elucidate the utility of the IOM guidelines in this population. A large sample of mother/infant dyads and measured rather than self-reported weights enhanced this study. Since the obesity epidemic is unlikely to cede anytime soon it is important to understand and delineate the long term consequences of overweight status and

excessive gestational weight gain (GWG) in women and their infants in order to develop interventions to address these public health problems.

Delimitations

- This study is a secondary analysis of a large prospective cohort study.
- Study took place at University of New Mexico from 2006-2013.
- Study participants included healthy women eligible for nurse-midwifery care.

Assumptions

- Pre-pregnancy BMI was calculated by the nurse-midwife with the participant at the first prenatal visit using maternal report of pre-pregnant weight, which was compared to weight at entry into care for plausibility. It is assumed that this value is accurate.
- All women received similar nutrition and activity education during prenatal care from their nurse-midwife.
- Clinic scales, which are all of the same type and calibrated on the same schedule, are accurate and similar to one another.
- Women who receive their care at University of New Mexico Hospital (UNMH) will also bring their children to UNMH for their care.

Definitions of Terms

The following terms are used throughout this document:

- Primigravida - a woman pregnant for the first time.
- Primiparous – a woman who has birthed one baby.
- Multigravida – a woman who has been pregnant more than once.
- Multiparous- a woman who has birthed more than one baby.

- Gestational Weight Gain (GWG) = the weight gained by a woman during pregnancy = weight at delivery – pre-pregnant weight.
- Body mass index (BMI) = weight in kilograms/height in meters squared (kg/m^2).
- Overweight/Obese: as defined by the current Health and Medical Division of the National Academies guidelines. Overweight is defined as $\text{BMI} \geq 25 \text{ kg}/\text{m}^2$, obese $\geq 30 \text{ kg}/\text{m}^2$.
- Normal weight: as defined by the current Health and Medical Division of the National Academies guidelines normal weight is $\text{BMI} \geq 18.5 \text{ kg}/\text{m}^2 - < 25 \text{ kg}/\text{m}^2$.
- Postpartum weight retention (PPWR) = postpartum weight – pre-pregnant weight.
- Data Collection Time Points
 - Initiation to care: when women first made contact with a certified nurse-midwife, usually late first or early second trimester
 - 6 weeks postpartum = 6 weeks after delivery (+/- 1 week)
 - 6 months postpartum = 6th month after delivery
 - 1 year postpartum = 1 year after delivery
 - 2 years postpartum = 2 years after delivery
- First trimester = up to 13 weeks 6 days gestation
- Second trimester = 14 weeks - 27 weeks 6 days gestation
- Third trimester = 28 weeks to delivery

Summary of Key Points

1. Gestational weight gain and pre-pregnant BMI are important factors in postpartum weight retention in women.

2. The importance of gestational weight gain and BMI on postpartum weight retention is poorly described in the literature in primiparous women.
3. Combining primiparous and multiparous women in research studies to evaluate the effects of gestational weight and BMI on postpartum weight retention is problematic as multiparous women are generally heavier and older than primiparous women.
4. Obesity in young women and offspring is a problem with potential for increased morbidity and mortality.

Organization of the Study

The following four chapters include a review of the relevant literature, the methodology employed for the study, results and analysis of data, and the discussion. References and appendices follow the final chapter.

CHAPTER II

LITERATURE REVIEW

Introduction

Body mass index and gestational weight gain may be important factors in long-term weight changes for women. The purpose of this study was to investigate the importance of BMI and excessive gestational weight gain on postpartum weight retention and offspring weight in women having their first baby. While there are many studies examining maternal weight issues on the outcomes of postpartum weight retention and offspring weights, primiparous and multiparous women are often studied together. This may be problematic as primiparous women may have different weight gain and postpartum retention from multiparous women and there is inadequate research on postpartum weight retention for primiparous women (Gunderson, 2009). In all of the studies reviewed in this section, the sample populations included both primiparous and multiparous women, except where noted. Furthermore, in the following review of literature, most of the data on weights were self-reported rather than measured. Self-reported weights are known to be underestimated especially in those with higher weights (Connor Gorber, Tremblay, Moher, & Gorber, 2007). Postpartum weight retention is thought to contribute to obesity rates in women, but there is an important need to differentiate between PPWR and postpartum weight gain, which serial measurements could help determine. Weight gain in pregnancy is a modifiable factor for offspring outcomes and could be key in curbing the obesity epidemic.

Organization of Review of Literature

Weight gain pregnancy guidelines and how they have changed in recent times is outlined first.

Then, the literature concerning postpartum weight retention is examined, specifically the literature on the impact of pre-pregnancy body mass index on the likelihood of postpartum weight retention. The literature on the role of gestational weight gain on postpartum weight retention is examined next. Attention will then be turned to offspring weights, again first examining the literature on the impact of maternal body mass index and the relationship to offspring weights and then the relationship of gestational weight gain and offspring weights.

Weights in the existing literature are sometimes reported in kilograms and sometimes in pounds. Throughout this dissertation weights will be reported first in the unit of measurement reported in the original study and then in the alternative measurement in parenthesis following for ease of comparison for the reader.

Pregnancy Weight Guidelines

All women are expected to gain weight during pregnancy, but how much they should gain has shifted depending on the public health concerns at the time. In 1970 out of concerns for United States (U.S.) neonatal and infant mortality rates, the Committee on Maternal Nutrition recommended a change from the then current recommendation of a 10 to 14 pound weight gain in pregnancy to an average weight gain of 24 pounds during pregnancy (IOM, 2009).

In 1990 the guidelines were changed out of concerns for low birth weight infants and included specific recommendations for weight gain based on pre-pregnant BMI but also for certain populations of women including adolescents, women of short stature, women pregnant with twins, and women of certain racial/ethnic groups. Since 1990 the prevalence of obesity in the U.S. population prompted yet another change in the guidelines (IOM, 2009).

In 2009 the then IOM instituted these changed guidelines. The recommendations for weight gain during pregnancy using these guidelines remain today at 28-40 pounds for underweight women, 25-35 pounds for normal weight women, 15-25 pounds for overweight women and 11-20 pounds for obese women (Siega-Riz et al., 2010).

How Literature Review was Conducted

A literature search using the PubMed, SCOPUS and CINAHL databases was performed. The search strategy included using the key terms in the following way: (“body mass index” and “postpartum weight retention”); (“gestational weight gain” and “postpartum weight retention”); (“body mass index” and “offspring weight”); (“gestational weight gain and “offspring weight”). Additional searches were done on PubMed using the following MeSH terms: “(postpartum period [MeSH] AND “body weight changes [MeSH] AND retention) AND “parity” [MeSH]; and (birthweight [MeSH Terms]) AND body weight changes [MeSH Terms] AND parity [MeSH Terms] AND body mass index [MeSH Terms]. Additional limits included “human” and “English language.” For the offspring outcome search, a literature search using the PubMed and SCOPUS databases was performed. The search strategy included using the key terms in the following way: (“body mass index” and “offspring weight”); (“gestational weight gain and “offspring weight”). Additional searches were done on PubMed using the following MeSH terms: (birth weight [MeSH Terms]) AND body weight changes [MeSH Terms] AND parity [MeSH Terms] AND body mass index [MeSH Terms]. Additional limits included “human” and “English language.” The time limit set for the search was 10 years.

Pre-Pregnancy Body Mass Index and Postpartum Weight Retention

Whether pre-pregnancy BMI is consistently linked to postpartum weight retention is unclear. Of the studies included in this literature review three studies unequivocally reported

associations between pre-pregnant BMI and PPWR, one did not find an association and the other five supported the idea that BMI index is linked to weight retention but only in certain pre-pregnant body mass index groups.

The studies that reported clear associations between pre-pregnancy BMI and PPWR included studies by Begum et al. (2012) Joseph et al. (2008) and Kac, D'Aquino Benicio, Valente, and Velasquez-Melendez (2003). Begum et al. (2012) studied PPWR in Canada using the Canadian 2010 Gestational Weight Gain Guidelines. In their analysis of 600 women, overweight and obese women were more likely to over gain during pregnancy and more likely to experience PPWR at 3 months postpartum. Joseph et al. (2008) examined the relationship between adolescent's pre-pregnant BMI and gestational weight gain and weight retained at 1 year. In this study, pre-pregnant BMI and gestational weight gain were predictors of postpartum weight retention at 1 year. Each increase in BMI resulted in 1.23 pounds (0.55 kg) retained at 1 year and those who exceeded the recommended weight gain retained significantly more weight at 1 year than those who gained within the guidelines.

This study is important because it is one of the few studies with a majority of primiparous women, however, a limitation is that the participants were all adolescents aged 15-21 years and therefore the results are not generalizable to all primiparous populations. Kac et al. (2003) also reported an association between body fat percentage measured by a bioimpedance technique and PPWR. A value of $\geq 30\%$ was defined as obese and PPWR was associated with this measurement. This study of Brazilian women provides less information on the specific weight categories that are associated with PPWR because it used a proxy for body mass index. Women were followed to 9 months postpartum and the study had a large attrition rate (66.9%). While the pre-pregnant weight was self-reported, a strength of this study includes the measurements of

the postpartum weights. This study also highlights the importance of studying the primiparous population and lends support to the idea that the weight gains and losses of primiparous women might be fundamentally different from multiparous women. In this study, primiparous women had a decrease in PPWR when compared to multiparous women (2.7 kg [5.9 lb] reduction in PPWR for primiparous women compared to 1.1 kg [2.4 lb] reduction in PPWR for multiparous women).

Martin, Hure, Macdonald-Wicks, Smith, and Collins (2014) published the one longitudinal study with follow-up at 12 months postpartum that did not find an association between pre-pregnant BMI and PPWR. In this study of 152 Australian women 68% retained weight at 12 months. However, gestational weight gain and not pre-pregnant BMI was associated with PPWR.

The other studies included in this review that examine the relationship between pre-pregnant BMI and PPWR show associations between these two variables with certain exceptions. Gunderson, Abrams, and Selvin (2000) reported no association between pre-pregnancy BMI and early (6 week) PPWR rates but did find lower PPWR rates for underweight and normal weight women at a median of 2 years postpartum as compared to overweight and obese women. This study relied on self-reported pre-pregnant weight and height. The researchers in this study tested a small sample of women for whom there were measured values to validate the self-reported values and the measured weights were on average 1.5 +/- 2.9 kg (3.3 +/- 6.4 lb) for primiparous women and 1.5 +/- 3.3 kg (3.3 +/- 7.3 lb) in women having their second baby. Furthermore, the dates of this study were 1980-1990, a time period when obesity rates were overall lower and increases in weight may have generally been more stable in the population as compared to present time.

Two studies included in the literature review for pre-pregnant BMI and PPWR demonstrated that, in general, pre-pregnant BMI is associated with PPWR except at the level of BMI of 27 kg/m² or higher for one study (Rode, Kjærgaard, Ottesen, Damm, & Hegaard, 2012) and at level of obesity (BMI \geq 30 kg/m²) in another (Huang, Wang, & Dai, 2010). Overweight and obese women are generally thought to be more vulnerable to postpartum weight retention than their normal weight counterparts but this may not be true. Rode, Kjærgaard, Ottesen, Damm, and Hegaard, (2012) investigated the link between gestational weight gain by BMI and postpartum weight retention. This secondary analysis of data based on a study of women in Denmark found that gestational weight gain and postpartum weight retention were linked and consistent until a BMI of 27 kg/m². Women with a BMI greater than 27 kg/m² tended to gain less and retain less postpartum, but for those women who did over-gain, they were more likely to retain weight at 1 year postpartum. Overweight women at the beginning of pregnancy were also more likely to over-gain. The mean postpartum weight retention for women in this study with a BMI below 27 kg/m² was just 1 kg (2.2 pounds) and for those women with a BMI above 27 the mean values were negative – that is, they lost weight by 1 year. This study did have a major limitation in that the weights were self-reported. This study points to the role of gestational weight gain, rather than initial BMI as an important factor in postpartum weight retention and that initial BMI may be a significant factor in the risk of weight gain in pregnancy. Huang et al. (2010) studied postpartum weight retention by initial BMI in 602 women in Taiwan. The average pre-pregnant BMI was 21.5 kg/m² and the average postpartum BMI was just 22.48 kg/m². The overall rates of overweight and obesity combined did go up from 18.27% pre-pregnancy to 27.57% at 6 months postpartum. Interestingly, when weight retention was categorized by BMI, obese women did not retain weight and in fact decreased their weight by an

average of 0.29 kg (0.64 lb) and normal weight and overweight women retained 2.57 kg (5.65 lb) and 1.67 kg (3.67 lb), respectively. While it is generally accepted that increased gestational weight gain leads to increased postpartum weight retention there are conflicting results about which populations are most likely to experience postpartum weight retention based on initial BMI. The overweight and obese women may also be more vulnerable to excessive weight gain generally, both gestational and otherwise, and this may be the risk factor for postpartum weight retention.

Nohr et al. (2008) in a large (N=60,892) cohort study in Denmark also examined pre-pregnancy BMI and gestational weight gain on pregnancy outcomes and found that high pre-pregnancy BMI was associated with postpartum weight retention at 6 and 18 months after delivery only in the setting of excessive gestational weight gain. In this study, pregnancies with complications that could impact weight outcomes such as gestational diabetes were excluded and other factors such as breastfeeding status, which is known to influence postpartum weight was controlled for. Ma et al. (2015) also sought to examine the relationship between pre-pregnancy BMI, GWG and PPWR and found that weight gain above the recommended IOM guidelines increased the risk of PPWR in all weight groups, pointing to the relative importance of GWG over pre-pregnant maternal BMI. A strength of this study was the large sample size (N=1643). This study's limitations included the use of a stratified random sample, which means that it is not the same group of women whose weights are being measured at each time period. This study also relied on self-reported weights. Finally, this study, like many of the studies in this field of research, was conducted outside of the United States where obesity rates are likely lower. In conclusion, the importance of pre-pregnancy BMI on PPWR rates given the available literature is unclear and excessive gestational weight gain may be an important factor influencing PPWR.

Table 2. Summary of Research on BMI and PPWR

Author/Year	Study Details	Findings
Rode, et al., 2012	Secondary analysis. 1, 840 women. 1,030 Primips, 807 multips. Self-reported weights. Denmark	BMI up to 27 kg/m ² associated with PPWR
Huang, et al., 2010	Comparative descriptive study. 602 Primips and Multips, not specified. Pre-pregnant weight from record, pp weights self-reported. Taiwan	Overall overweight and obesity rates increased by 6 months. But, obese women did not retain weight and decreased by 0.29 kg at 6 months.
Nohr, et al., 2008	Survey. 60,892 pregnancies (57,700 women, 27, 995 primips and 32, 897 multips) Phone interviews, self-reported weights. Danish	High BMI + High GWG a/w increased PPWR at 6 and 18 mo.
Begum, et al., 2012	Prospective Cohort Study. 600 women. Measured weights. Primips and multips. Canada	Pre-pregnancy BMI predictor of excessive GWG. Increased GWG associated with increased PPWR for all BMI groups
Kac, et al., 2003	f/u of cohort study 709 Primips and Multips but numbers not reported. Pre-pregnancy weight self-reported, all others measured. f/u to 9 months. Brazil	Highest weight retention in those over 30 and with highest body fat. Primiparous women retained less.
Joseph, 2008	Chart review. 102 adolescents age 15-21. 100 primips, 2 multips. Measured weights. 1 year f/u. US/urban setting.	Pre-pregnancy BMI associated with PPWR at 1 year. GWG in excess of IOM guideline also associated with PPWR.
Martin, et al., 2012	Longitudinal. 152 women. Primips and multips but numbers not reported. Pre-pregnancy weight self-reported. All others measured. f/u 1 year. Australia	68% retained weight at 1 year. BMI not associated with PPWR, GWG was associated with PPWR.
Ma, et al., 2014	1643 Primips. Stratified random sample. No obese in study. Pre-pregnancy weight self-reported, PP weights measured. 11 mo f/u China	BMI negatively associated with PPWR. Weight gain above IOM guidelines increased PPWR.
Gunderson, 2001	Prospective cohort study. 985 mixed primips and multips. Pre-pregnancy weight self-reported. Weight 6 week pp measured. 1980-1990. UCSF	No association between pre-pregnancy BMI and 6 week PPWR.

Gestational Weight Gain and Postpartum Weight Retention

The role of gestational weight gain and its impact on postpartum weight has been studied previously but the issue has taken on more urgency over the last decade as obesity has become more prevalent. Many of the studies of gestational weight gain on postpartum weight retention were conducted in countries with leaner populations and therefore may not be applicable to U.S. mothers. Furthermore, many previous studies on gestational weight gain on postpartum weight retention did not examine the impact of maternal BMI on gestational weight gain, were conducted prior to the IOM recommendations, included primiparous and multiparous women, and were retrospective in nature.

Multiple studies indicate that excess weight gained in pregnancy leads to postpartum weight retention (Amorim, Rossner, Neovius, Lourenco, & Linne, 2007; Ashley-Martin & Woolcott, 2014; Kac, Benicio, Velasquez-Melendez, Valente, & Struchiner, 2004; Martin et al., 2014; Siega-Riz et al., 2009).

Lee et al. (2011) sought to characterize weight changes beginning in pre-pregnancy to 6 months postpartum. The study subjects were 120 Taiwanese women. At 6 months postpartum, the average amount of weight retained was 3.29 kg (7.2 pounds) with the largest amount of weight lost in the first 2-3 weeks postpartum. Overall, 20% of study participants had returned to their pre-pregnant weight by 6 months.

Some research on postpartum weight retention has sought to test the association of gestational weight gain on postpartum weight retention categorized by gaining within or outside of IOM guidelines. Kac, Benicio, Velasquez-Melendez, Valente, et al. (2004) studied 405 women in Brazil over 9 months. Women with gestational weight gain outside of the guidelines retained more than women who gained either within or below the guidelines. Women with the

highest weight gain and highest BMI were most likely to become obese, but interestingly, the women with higher initial BMI experienced less postpartum weight retention, suggesting that gestational weight gain was a more important factor for postpartum weight retention than initial BMI.

Amorim, Rossner, et al. (2007) studied women in Stockholm, Sweden to test the IOM guidelines with respect to long-term BMI changes. BMI was followed for women 15 years postpartum. For those who gained within the IOM guidelines, 6.7 kg (14.7 lb) was retained at 15 years postpartum. For those who gained outside of the IOM guidelines, 10.0 kg (22 lb) was retained at 15 years postpartum. Those women with excessive weight gain weighed more at each time point in the study, but this might be an indicator that women who are vulnerable to weight gain throughout their life remain so during pregnancy and postpartum. Similarly, Widen et al. (2015) examined postpartum weight retention in African American and Dominican mothers and found that weight gain above the IOM guidelines was associated with higher postpartum weight retention in those mothers with a lower pre-pregnant BMI. This study highlights the possibility that gaining within the IOM guidelines may be more important for certain groups of women based on characteristics such as pre-pregnant weight classification or ethnic background, and by extension, the importance of the guidelines depending on parity. In a large retrospective study in Nova Scotia, Ashley-Martin and Woolcott (2014) analyzed data from 12,875 women in a perinatal database from 1993-2010. Weights of both primiparous and multiparous women were analyzed and primiparous women who gained outside of the IOM guidelines retained more weight postpartum. Fifty-eight percent of the total population sample, including primiparous and multiparous women, gained outside of the IOM guidelines.

Nehring, Schmoll, Beyerlein, Hauner, and von Kries (2011) and Mannan, Doi, and Mamun (2013) conducted meta-analyses to study the short and long term effects of weight gain using the IOM guidelines on postpartum weight retention. Postpartum weight retention increased in both studies with time; 3 kg (6.6 lb) at 3 years and 4.72 kg (10.38 lb) at 15 years in the Nehring et al. (2011) study and 3.15 kg (6.9 lb) by 21 years in the Mannan et al. (2013) study. However, Mannan et al. (2013) noted that postpartum weights declined in the early postpartum and then increased later in the follow up period.

Research that examines postpartum weight retention by such long periods obviously attempts to assess the risk of excessive weight gain during pregnancy on long-term BMI changes. This is a difficult task due to the confounding issues of aging and weight gain, lifestyle changes associated with parenting and weight gain, and the influence of parity on weight gain. Somebody who has multiple increases in weight over 2 decades during the course of childbearing is likely to be at greater risk for overall weight gain than a primiparous woman with just one baby. Additionally, Americans average a 2.0 pound (0.9 kg) per year weight gain normally (Strong, Parks, Anderson, Winett, & Davy, 2008) so it seems difficult to say that long term weight gain is attributable to weight gained in pregnancy and not our environment.

Table 3. Summary of Gestational Weight Gain ad Postpartum Weight Retention

Author/Year	Study Details	Findings
Amorim, et al., 2007	Retrospective for weight during pregnancy, then prospectively monitored 1 and 15 years later. 483 participants. Self-reported pp weights. Sweden	Those who gained outside guidelines gained more at every time point. Gain in guidelines = 6.7 kg at 15 yr. outside guidelines 10 kg at 15 years.
Ashley-Martin, 2014	Chart review. 16, 264 women. Primips – 11, 113, Multips 5,156 Measured weights. Nova Scotia	Primips who gained outside of guidelines retained more pp. GWG associated with PPWR in all BMI categories.
Martin, et al. 2012	Longitudinal. 152 women. Primips and multips but numbers not reported. Pre-pregnant weight self reported.	GWG associated with PPWR.

	All others measured. f/u 1 year. Australia	
Kac, et al., 2004	405 women. Primip and multip but numbers not reported. Measured weights. Brazil	High GWG + High BMI led to obesity. Those with high BMI alone retained the least.
Lee, et al., 2011	120 women. 64 prim. 56 multips. Measured weights. Taiwan	20% at pre-pregnancy weight by 6 mo. Avg 6 mo PPWR = 3.29 kg (7.2 pounds).
Widen, et al., 2015	Chart review for weights and some measured weights. 302 US (African American and Dominican) Primips and multips, but no numbers of groups.	Gaining outside IOM guidelines associated with higher PPWR in those with lower BMI.
Nehring, et al., 2011	Meta-analysis. 9 studies with primips and multips. Self-reported and measured weights	Weight gain outside of IOM guidelines associated with PPWR.
Mannan, et al., 2013	Meta-analysis. 68,000 women. 12 studies. Primips and multips. f/u out to 21 years. Some self-reported weights.	GWG outside IOM guidelines associated with PPWR.
Siega-Riz, et al., 2009	Meta-analysis. 35 studies. Primips and multips included.	Excessive GWG a/w higher birth weight and PPWR.

Pre-pregnancy BMI and Offspring Weights

Based on previous literature offspring of overweight and obese women seem to have higher weights than offspring of normal weight women. Birth weight appears to be associated with pre-pregnant maternal BMI with birth weight increased in overweight and obese mothers (Li et al., 2013; Stamnes Koepp et al., 2012). Interestingly while high maternal BMI was associated with high birth weight in the Li et al. (2013) study, offspring weight at 12 months was associated with maternal gestational weight gain but not pre-pregnant maternal BMI. This study of Chinese mothers and offspring may not be generalizable to the U.S. population. While pre-pregnant BMI seems to be associated with offspring birth weight, it seems less clear the impact of pre-pregnant BMI on offspring weights beyond birth. Olson et al. (2009) set out to study the impact of gestational weight gain on offspring weights. They found that children whose mothers were either overweight or obese in early pregnancy, regardless of gestational weight gain, were

more likely to be overweight as defined by 85% for height/weight at 3 years than those whose mother's BMI was either low or normal. In this same study, overweight and obese women who also over-gained by IOM guidelines did not have an increased risk of having an overweight child at 3 years when compared to women who gained the appropriate amount and were overweight and obese, suggesting that pre-pregnancy BMI is more important than gestational weight gain for the outcome of offspring weight.

Pre-pregnant BMI seems to be a factor in birth weight and may be a factor in weight beyond birth, although the role of gestational weight gains, as demonstrated by Li et al. (2013) and Olson et al. (2009), must be considered. Another factor considered in multiple studies is the role of paternal BMI on offspring weights with conflicting results. Durmus et al. (2013) assessed risk of overweight in children up to 4 years by examining both maternal and paternal BMI and found that pre-pregnant maternal and paternal BMI were associated with childhood BMI. The influence of maternal BMI was stronger than paternal BMI and gestational weight gain was also related to risk of overweight in children of normal weight mothers. It is likely that there are multiple factors in both the perinatal and postnatal period that influence the risk of elevated BMI in children, however the influence of maternal BMI and gestational weight gain is likely to be a significant influence. Svensson et al. (2014) also studied maternal and paternal BMI in relation to childhood weights at 3, 6 and 12 months. Interestingly, in this study neither maternal nor paternal BMI was associated with childhood weights but low parental education defined as less than 12 years of education for both parents was associated with excessive childhood weights, suggesting socioeconomic factors as a possible important risk factor for childhood obesity. Additionally, a large Finnish study (Kivimaki et al., 2007) examined 2,980 parent/offspring trios and also found that maternal BMI was not associated any more than paternal BMI with offspring

weight in childhood, adolescence or adulthood. This suggests that genetics is at least as important a factor in offspring weight as fetal environmental conditions.

Table 4. Summary of BMI and Offspring Weight

Li, et al., 2013	Chart review. 38,539 mother child pairs. Unclear primips and multips, states number of prev pregnancies/infants collected but number not reported. Measured weights. China	Pre-pregnancy BMI and GWG a/w increased offspring weight in early infancy.
Stamnes Koepp, 2012	58, 383 Primips and multips. Numbers not reported. Maternal height and weight, BMI and GWG self-reported. Birth weights measured. Norway	Offspring birth weight associated with increasing BMI and GWG.
Olson, et al., 2009	Chart review. 208 participants. 80 primips, 128 multips. US	Maternal early pregnancy BMI a/w offspring overweight at 3 years.
Durmus, et al., 2013	5674 Maternal/paternal/child triads. Measured kids outcomes, all others self-report. Netherlands	Maternal > Paternal BMI a/w childhood BMI. Increased GWG in normal BMI women associated with overweight kids. (only group for this outcome)
Svensson, et al., 2014	197 maternal/paternal/child triads. Primips and multips but numbers not reported. Measured weights unless pregnant during study, then weight reported.	Offspring weight at 3,6, 12 months not associated with parental adiposity. Education associated with offspring weights.
Kivimaki, et al., 2007	2980 maternal/paternal/offspring triads. Maternal and paternal birth weights self-reported. Offspring weights 3-39 years measured.	Maternal BMI a/w birth weight more than paternal, but not associated with weights from 3-39 years.

Gestational Weight Gain and Offspring Weight

Multiple studies have demonstrated an association between increased gestational weight gain and increased infant birth weight. Additionally, there appears to be a link between increased gestational weight gain and offspring weight beyond birth (Oken, Rifas-Shiman, Field, Frazier, & Gillman, 2008; Oken, Taveras, Kleinman, Rich-Edwards, & Gillman, 2007;

Wrotniak, Shults, Butts, & Stettler, 2008). Deierlein, Siega-Riz, Herring, Adair, and Daniels (2012) sought to determine the relationship between gestational weight gain, according to the IOM guidelines, and offspring weights. Increased early infancy and child weights out to 3 years were associated with maternal excessive gestational weight gain. Kaar et al. (2014) in a study on the impact of maternal overweight or obese status on childhood obesity rates found that appropriate weight gain in pregnancy may decrease the impact of pre-pregnant BMI on childhood weight outcomes. This study is limited by oversampling in the diabetic population, and is not generalizable to low risk populations. Laitinen et al. (2012) conducted a prospective cohort study that highlighted the importance of appropriate weight gain, with women who over-gained in the first half of pregnancy having increased risk of overweight/obese offspring at 16 years of age. A high pre-pregnant BMI was also a risk for offspring obesity at 16 years of age. Gillman et al. (2008) studied mothers and children and tried to determine the probability of childhood overweight at three years based on four modifiable maternal factors: smoking status, breastfeeding duration, infant sleep patterns, and gestational weight gain. In this study, gestational weight gain alone produced a probability of overweight at three years of just 0.06, whereas a pregnancy with all four risk factors produced a probability of overweight at three years of 0.29. Likewise Bammann et al. (2014) studied multiple risk factors and used regression analysis to examine multiple influences on childhood weights and found that gestational weight gain and BMI were statistically significant factors, however the odds ratios were low, 1.04, 95% CI 1.01-1.07 and 1.16, 95% CI 1.11-1.20, respectively. These studies highlight the small impact of gestational weight gain and BMI alone on childhood weights.

Table 5. Summary of Gestational Weight Gain and Offspring Weight

Oken, et al., 2008	11,994 dyads. Self-reported (maternal pre-pregnant weights,	Gestational weight gain associated with adolescent
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	gwg, child height and weight)	adiposity.
Oken, et al., 2007	1044 dyad Primips 505, Multips, 539. Pre-pregnant weights reported, others measured. US	Increased GWG a/w increased child BMI to 3years.
Wrotniak, et al., 2008	10, 226 participants. Questionnaire. Primips and multips but numbers of each not reported. Weights measured at delivery and extracted from medical record. Measured child weights at 7 years. Self-reported weights for questionnaire. Study time period 1959-1972	Odds of overweight 48 % higher for kids when mother gained in excess of IOM guidelines.
Deierlein, et al., 2012	476 dyads. Primips -232 and multips -244 measured weights (at least 1 in 3 years)	Gestational weight gain associated with increased offspring weights up to 3 years postpartum.
Kaar, et al., 2014	313 mother/child dyads. Measured weights abstracted from EMR. Weights at 10 years measured.	Pre-pregnant BMI a/w higher BMI in kids at 10 years.
Laitinen, et al., 2012	Chart review and questionnaire. 6637 maternal/child dyads. Primips- 2173 and multips 4328. Measured weights for kids. Pre-preg weights self-reported. Pregnancy data measured.	High weight gain in first 20 weeks a/w overweight/obesity in offspring. Maternal pregravid obesity a/w offspring obesity
Gillman, et al., 2008	Chart review. 1, 110 dyads. Primips 425, multips 685. Pre-preg weights self-reported, all other weights measured.	Risk of overweight at 3 years 6% with normal gwg and no other risk factors. 29% risk of OW at 3 years with excessive gwg
Bammann, et al., 2014	Maternal information by survey. Kids weights measured. 1024 kids from 8 European countries. Primips and multips but numbers of each not reported.	Weight gain in pregnancy associated with obesity. Maternal and paternal BMI strongest risk factors for obesity.

Summary

Postpartum weight retention is a concern in its potential relationship to overweight and obesity in women. In a society that is heavier than ever it is easy to see why the normal life event of growing a baby with its concomitant weight gain could cause concern for women, their

care providers and those interested in public health. Furthermore, overweight and obesity are no longer confined to adults and investigating the maternal links to childhood obesity is important for the future health of society.

Pre-pregnant BMI and gestational weight gain are potentially causative variables that have been previously explored in many populations of women, but not in a group of healthy, young, primiparous women. This study builds on the existing literature by studying this demographic utilizing measured rather than self-reported weights, and includes important weight data on the offspring out to 2 years.

Chapter III details the methods of this study to explore BMI and GWG on PPWR and offspring outcomes in first time mothers.

CHAPTER III

METHOD

Introduction

The purpose of this study was to investigate the importance of pre-pregnancy body mass index and excessive gestational weight gain on postpartum weight retention and offspring weight out to 2 years postpartum. While the impact of postpartum weight retention and maternal weight status on offspring weights has been investigated in the past, previous studies utilized a mixed population of primiparous and multiparous subjects. This research seeks to fill a key gap in the literature by delineating the impact of body mass index and excessive gestational weight gain on primiparous women and their offspring. The methodology for this study including the specific aims and hypotheses, description of study variables, research design, sample and setting, data collection and analysis, protection of human subjects and limitations are described in this chapter.

Specific Aims and Hypotheses

The objectives of this study were to investigate the importance of pre-pregnancy body mass index and excessive gestational weight gain on postpartum weight retention in primiparous women and to investigate the relationship between maternal BMI and excessive gestational weight gain in primiparous women on offspring weight out to 2 years. This research is expected to clarify the risk of excessive gestational weight gain in pregnancy on obesity in women having their first baby and the risk of obesity and excessive gestational weight gain on offspring obesity.

Specific Aim 1: To determine if overweight or obese first time mothers retain more weight gained in pregnancy than first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years postpartum. *Hypothesis:* Overweight or obese women retain more of the weight gained during pregnancy at each time point compared to women of normal weight.

Specific Aim 2: To determine if first time mothers who gain in excess of IOM guidelines during pregnancy retain more weight than women who gain within the IOM guidelines at 6 weeks, 6 months, 1 year and 2 years postpartum. *Hypothesis:* First time mothers who gain in excess of the IOM guidelines will retain more weight at each time point compared to women who gain within the guidelines.

Specific Aim 3: To determine if the offspring of overweight or obese first time mothers have higher weight for length percentiles than the offspring of first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years of life. *Hypothesis:* The offspring of overweight or obese first time mothers will have higher weight for length percentiles at each time point compared to the offspring of first time mothers of normal weight.

Specific Aim 4: To determine if the offspring of first time mothers who gain in excess of IOM guidelines during pregnancy have higher weight for length percentiles than the offspring of first time mothers who gain within the guidelines at 6 weeks, 6 months, 1 year and 2 years of life. *Hypothesis:* The offspring of first time mothers who gain in excess of the IOM guidelines will have higher weight for length percentiles at each time point compared to the children of first time mothers who gain within the guidelines.

Description of Study Variables

For specific aims 1 and 2, the Institute of Medicine guidelines categorization of normal weight (BMI 18.5- <25 kg/m²), overweight (BMI ≥ 25 kg/m²), and obesity (BMI ≥30 kg/m²)

were used. Body mass index is a calculation of body mass for height and is calculated by dividing weight in kilograms by height in meters squared. Women were grouped by their self-reported pre-pregnant weight at their first prenatal visit. These groupings—pre-pregnancy normal weight, overweight or obese women—were compared to one another for postpartum weight retention and for offspring weight to length percentiles. Underweight women were excluded from the analysis.

Postpartum weight retention is an outcome variable in both specific aims 1 and 2. Postpartum weight retention is defined as: [postpartum weight – pre-pregnant weight]. Postpartum weight retention is essentially the weight gained during pregnancy that is not lost postpartum.

Excessive gestational weight gain is a study variable for both specific aims 2 and 4. The Institute of Medicine (IOM) issues guidelines for healthy weight gain in pregnancy. The recommended weight gain using these guidelines for underweight women is 28-40 pounds, 25-35 pounds for normal weight women, 15-25 pounds for overweight women, and 11-20 pounds for obese women. Excessive gestational weight gain for this study was defined by weight gain in excess of the IOM guidelines, and therefore greater than 35 pounds for normal weight women, greater than 25 pounds for overweight women and greater than 20 pounds for obese women. Weight gain within or below IOM guidelines were considered together.

Offspring weight for length percentile is a ratio of the child's weight for length and is used in pediatric populations up to age 2 as a proxy for BMI.

Research Design

This study is a retrospective secondary analysis of a large, prospective longitudinal study of women during and following their first pregnancy. The parent study, called Alterations in

Pelvic Floor with Pregnancy, Labor and the Ensuing Years (APPLE), was a NIH funded study conducted at the University of New Mexico (UNM) from 2006-2013. The primary purpose of the APPLE study was to determine the prevalence of pelvic floor dysfunction and to describe pelvic floor anatomy changes after childbirth in a low risk, primiparous population. First time mothers were recruited during pregnancy and followed through pregnancy, birth and to 2 years postpartum. As part of the parent study, pre-pregnancy BMI was calculated and weights of women were measured throughout pregnancy and at 6 weeks, 6 months, 1 and 2 years following birth. Newborn weights and lengths were also measured. These maternal and offspring weight data were used for the current secondary analysis to achieve specific aims 1 and 2. For specific aims 3 and 4, a chart review was performed for the offspring of the women in the primary study to collect recorded weights and lengths of children at 6-8 weeks, 6 months 1 year and 2 years. Pediatric visits are often timed at the 8-week time point, so weights were collected for the offspring at this time point anywhere between 6-8 weeks.

Sample and Setting

This research was a secondary analysis of data. All weight data collected from women recruited for the parent study, called APPLE, were used for this secondary analysis. The parent study took place in a specialty nurse-midwifery service at UNM, an academic, tertiary care setting. The nurse-midwives care for medically uncomplicated women and women who enter care or develop medical or pregnancy complications are referred to physician colleagues. Nurse-midwives care for insured and uninsured women and the majority of women in this practice received Medicaid. New Mexico is a majority minority state and this practice reflects the state demographics, with a large percentage of Hispanic patients.

Inclusion criteria for the APPLE study and current secondary analysis were nulliparous women with a pregnancy less than 36 completed weeks at entry into study and eligible for midwifery care at the time of admission to labor and delivery. The University of New Mexico midwifery service takes care of women with low risk pregnancy without medical complications. All participants delivered at term, as women with preterm or complicated medical and pregnancy histories are not cared for by the midwives. There are some complications in pregnancy or comorbidities that occur in low frequencies that the midwives do manage. For example, women with well controlled hyperemesis or hypothyroid disorder may have been included in the study, but the number of women with this disorder would have likely been small and these data were not collected as part of APPLE.

The exclusion criteria for the parent study and the present secondary analysis included diabetes (all types, including gestational diabetes), any hypertensive disorders, including pre-existing and pregnancy induced hypertensive disorders, or other major medical problems. Women with active substance abuse problems are referred to a specialty clinic and are not cared for by midwives at the University of New Mexico (UNM). Likewise women with active eating disorders (anorexia or bulimia) are referred to a physician provider. Women who were underweight by IOM guidelines were excluded from the analysis.

Data Collection and Procedures

The primary purpose of the APPLE study was to determine the prevalence of pelvic floor dysfunction and to describe pelvic floor anatomy changes following childbirth in a low risk, healthy primiparous population. In the APPLE study, nulliparous women who received care from the UNM midwifery service in five different clinical sites were invited to participate in the study. Written, informed consent was obtained at usually the second or third visit, after the

patient was able to take home and read study invitation materials. Antenatally women provided information about perineal pain, sexual function, urinary and anal incontinence, and underwent exams to determine anatomical support of the vagina. Women had usual certified nurse-midwifery (CNM) care for labor and birth. During labor, some women were transferred to physician care for operative or instrumental delivery and these women remained in the study. Following birth genital tract trauma was documented by a CNM and verified by a second physician colleague. Postpartum pain was assessed in the hospital before discharge. Women returned to clinic at 6 weeks, 6 months, 1 year, and 2 years for repeat pelvic exams and completion of validated questionnaires for bladder, bowel, pain and sexual function.

As part of the APPLE study weights and heights at initiation to care, 6 weeks, 6 months, 1 year, and 2 years postpartum were measured. Pre-pregnant weight was reported by women and assessed by CNM for likelihood of accuracy and documented. From this information, pre-pregnant BMI was calculated. Immediately after birth, offspring weight and length were measured. Additionally demographic data, smoking status, breastfeeding and birth control data in the postpartum period were collected. In the parent study, 71% of women supplied data at 6 months and 70% followed up at one and/or 2 years postpartum.

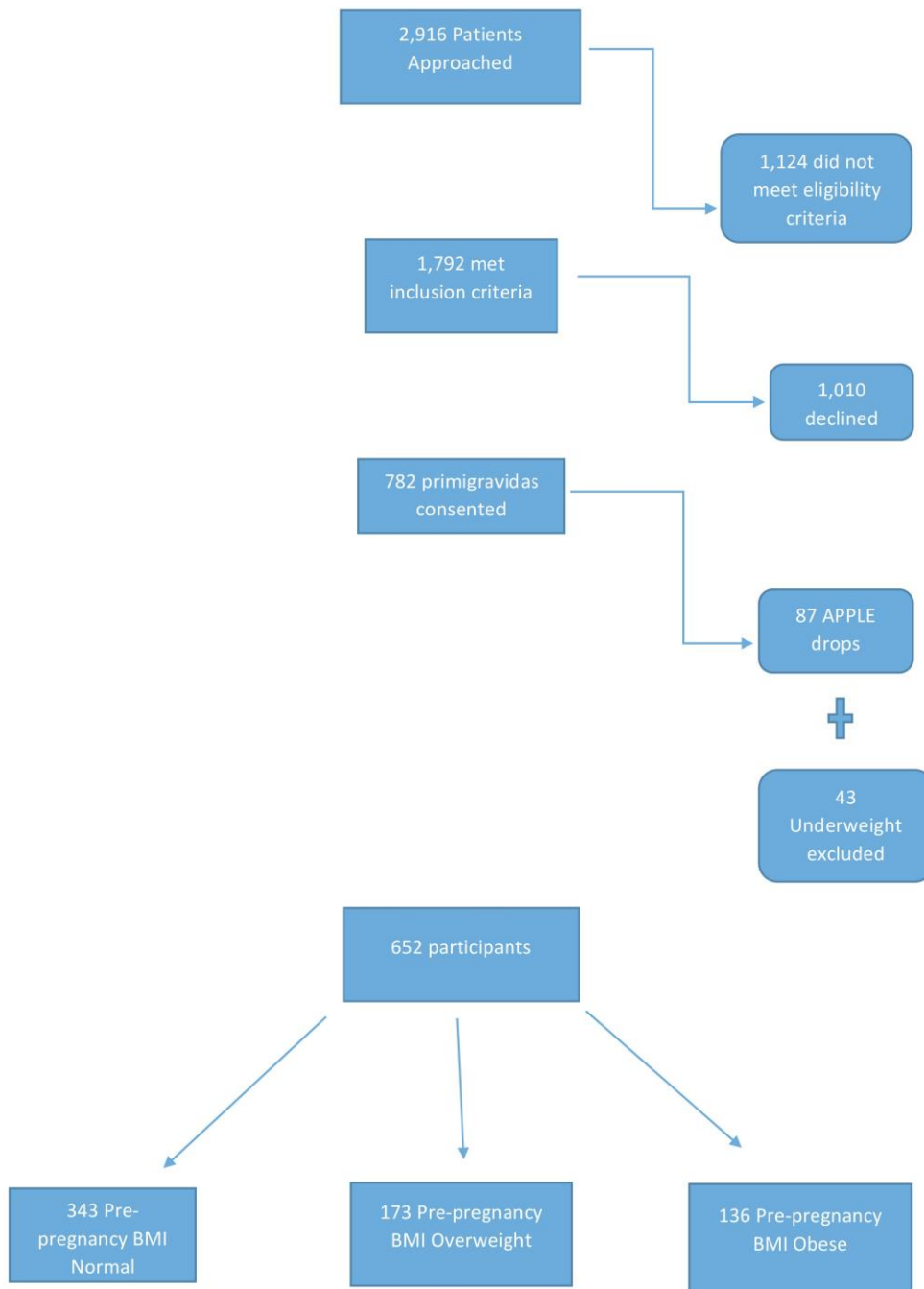


Figure 1. Participant Recruitment and Study

The present study analyzed the impact of BMI and gestational weight gain on maternal postpartum weight retention at 6 weeks, 6 months, 1 year and 2 years postpartum. For specific aim 1 women were divided into three groups based on their pre-pregnant BMI: normal, overweight or obese. Women who were underweight were excluded from these analyses. Baseline characteristics including age, ethnicity, tobacco use, and education level were compared between the groups. Birth control use in the postpartum period was intended to be analyzed but was not because of the way the data were collected in the main database, which was not by specific method but by long acting versus non-long acting methods. There are both hormonal and non-hormonal long acting methods and since weight issues are thought to be related to hormone use, the way the data were categorized was not useful for analyzing the weight data by hormone containing versus non-hormone containing methods. The primary outcome for the comparison in aim 1 was maternal weight retention measured in kilograms at 6 weeks, 6 months, 1 year and 2 years postpartum. Postpartum weight retention was calculated by subtracting maternal pre-pregnant weight from postpartum weight. BMI at entry to care was calculated using the formula, kg/m^2 .

For specific aim 2, an analysis was completed that divided the same groups of women—pre-pregnant normal weight, overweight and obese women—into those who gained within the IOM recommended amount of weight to those women who gained more than the recommended amount. Again, the primary outcome was postpartum weight retention as described above.

For specific aim 3, offspring weights and lengths, other than the birth weight and length already recorded in the database, were collected through chart review. APPLE study investigators have a list of identifiers that link mothers to their offspring, and have gained IRB approval to review the offspring charts (described in Human Subjects section more thoroughly

below). Offspring have multiple well child visits in the first 2 years of life, and at all of these visits weight and length are recorded in the medical record. It was expected that many offspring of study participants would receive care at UNMH. For analyses, weight to length percentiles using the CDC growth charts was retrieved from the medical record. The mean offspring weight to length percentiles was compared between the pre-pregnancy BMI groups—normal, overweight and obese women—for specific aim 3. These weight and length percentiles were retrieved and recorded in Research Electronic Data Capture (REDCap), which was then merged with the parent data set and a Statistical Package for the Social Science (SPSS) file of the variables of interest was created. This database underwent data cleaning to correct outliers and check for accuracy of the values. For analyses, weight to length percentiles was retrieved from the medical record. The mean offspring weight to length percentiles was compared between the pre-pregnancy BMI groups—normal, overweight and obese women—for specific aim 3.

For specific aim 4, an analysis was done that divides the same group of women—pre-pregnant normal BMI, overweight and obese—into those who gained at or below the IOM recommended amount of weight to those women who gained more than the recommended amount to determine if offspring weight for length percentiles was greater in women who gained in excess of IOM guidelines.

Data Analysis Plan

Outcome variables were postpartum weight retention and offspring mean weight for length percentiles. Women were grouped by pre-pregnant weight BMI (normal, overweight or obese), and adhered to IOM pregnancy weight gain guideline (yes or no).

Descriptive statistics were used to describe the cohort of women with means, standard deviations and ranges between groups. For comparisons between normal weight, overweight and

obese groups for continuous variables including age, weight gain, weight retention, years of education and infant weight length percentiles, one-way ANOVA was used. Significance for all tests set at $p \leq 0.05$.

For specific aim 1 a one-way analysis of variance (ANOVA) was done to determine if significant differences in PPWR exist between normal weight, overweight and obese women at 6 weeks, 6 months, 1 year and 2 years. Subsequent Tukey tests were done if there were any significant differences to determine which groups are different from one another.

For specific aim 2 a 3 (normal weight, overweight, obese) x 2 (met IOM weight gain guidelines yes or no) between subjects ANOVA was conducted to see if significant differences exist for postpartum weight retention between the groups at 6 weeks, 6 months, 1 year, and 2 years. Subsequent Tukey tests or Tukey-Kramer tests were done in the event of disparate cell sizes to determine which groups differed from one another.

Specific aim 3 was analyzed exactly as aim 1. A one-way ANOVA was completed to determine if significant differences in offspring mean weight for length percentiles exist between normal weight, overweight and obese women at 6 weeks, 6 months, 1 year and 2 years. Subsequent Tukey tests were done if there were any significant differences to determine which groups were different from one another.

Specific aim 4 was analyzed the same as aim 2. A 3 (normal weight, overweight, obese) x 2 (met IOM weight gain guidelines yes or no) between subjects ANOVA was conducted to see if significant differences existed for offspring mean weight for length percentiles between the groups at 6 weeks, 6 months, 1 year, and 2 years. Subsequent Tukey tests or Tukey-Kramer tests were done if there were any significant differences between the groups.

Power Analysis was done using the program GPower version 3.1.9.2. Using the variability observed in preliminary data (Gallagher, Migliaccio, Rogers, Leeman, Hervey, & Qualls, 2014) for weight gain of 13.1 pounds and 16.4 pounds in normal weight and obese primiparous women a sample size of 138 women per group is adequate to detect a 5 pound difference in weight retention at 1 year with 80% power and alpha at .05. Thus a sample size of approximately 475 (the number of women in the parent study known to have followed up at 1 or 2 years) will be more than adequate. Using the variability observed in our preliminary data (Gallagher et al., 2014) for newborn weights of 430 grams for normal weight mothers and 391 grams for obese mothers, at 1 year a sample size of 138 per group is adequate to detect a difference in the offspring's weight as low as 139 grams or 0.3 pounds with 80% power and alpha at .05.

Protection of Human Subjects

As part of the APPLE study, all women signed consent forms to be in the study that detailed the nature of the study, the procedures involved in the study, the risks, benefits and alternatives of participating in the study, the voluntary nature of the study and the potential for use of the data for other research, including collection of data regarding their offspring (Appendix A). The midwives responsible for obtaining consent reviewed the study and consent form with women at introduction of the study and again after women had time to consider participation. All data were de-identified with links between data and identifiers contained in a separate file that is only accessible to study investigators. The APPLE study is still an open study and in May 2014 an addendum to the APPLE study to collect specific offspring variables without re-consent of participants was submitted to the UNM Institutional Review Board (IRB) (Appendix B). The UNM IRB approved this addendum in August 2014. Once all data analyses

are complete a plan for destruction of study materials and identifiers will be implemented as detailed in the APPLE IRB application. University of North Dakota IRB approval was obtained before the secondary analysis of data was completed (Appendix C). All data are protected, de-identified and only presented in aggregate form. No individual participant will ever be able to be identified in presentations or publications.

CHAPTER IV

RESULTS

The purpose of this study was to investigate the importance of body mass index and excessive gestational weight gain on postpartum weight retention and offspring weight out to 2 years in women having their first baby. The specific aims of this study were:

1) To determine if overweight/obese first time mothers retain more weight gained in pregnancy than first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years postpartum.

2) To determine if first time mothers who gain in excess of IOM guidelines during pregnancy retain more weight than women who gain within the IOM guidelines at 6 weeks, 6 months, 1 year and 2 years postpartum.

3) To determine if the offspring of overweight/obese first time mothers have higher weight for length percentiles than the offspring of first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years of life.

4) To determine if the offspring of first time mothers who gain in excess of IOM guidelines during pregnancy have higher weight for length percentiles than the offspring first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years of life.

This chapter presents the findings of this study including: demographic information on the study sample; descriptive statistics; and analysis of variance for each aim and significant findings. Statistical Package for the Social Science (SPSS Version 20, 2011) was used for statistical analysis.

Description of Sample

Demographic data are shown in Table 6. How women identified in terms of race and ethnicity is shown in Table 7 and tobacco use by women is shown in Table 8. Sample characteristics are reported as mean (+/- SD). Data were available for 652 women having their first baby. Sample characteristics were analyzed for the entire sample for the characteristics of age, educational level in years, weight gain in pregnancy, race, and tobacco use. Birth characteristics such as newborn birth weight and 5 min Apgar were also analyzed. A series of one way Analysis of Variance (ANOVA) was used to compare normal, overweight and obese participants.

Table 6. Demographic Information of Sample Used for Secondary Analysis

	Normal Pre-pregnant BMI	Overweight Pre-pregnant BMI	Obese pre-pregnant BMI	Overall Sample
Age	25.0 (5.47) N =343	25.28 (5.66) N=172	25.04 (5.32) N=136	25.08 (5.49) N=651
Education*	14.16 (3.04) N = 333	13.8 (2.77) N = 168	13.29 (2.16) N = 131	13.89 (2.83) N=632
Weight gain in preg (lb)*	36.42 (13.70) N = 343	35.22 (14.93) N=172	32.56 (15.83) N = 135	35.30 (14.55) N=60
Weeks started care	11.39 (5.99) N = 334	11.51 (6.12) N = 173	11.44 (5.51) N = 132	11.43 (5.91) N=639
Number of prenatal visits	10.88 (2.90) N = 328	10.98 (2.64) N =167	10.63 (2.66) N = 132	10.85 (2.78) N=627
Offspring birth weight g*	3185.39 (440.18) N = 343	3230.26 (479.25) N = 173	3332.64 (476.38) N = 136	3228.01 (461.28) N=652
5 min Apgar	8.87 (.73) N = 343	8.93 (.41) N =173	8.88 (.53) N = 136	8.89 (.62) N=652

Mean (SD) and N for each group. Statistically significant values are denoted with a * symbol.

Table 7. Race/Ethnicity of Participants

Race (N)

	Normal Pre-pregnant	Overweight Pre-pregnant	Obese pre-pregnant BMI	Overall Sample
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	BMI	BMI		
Non-Hispanic White	148	70	45	263
Hispanic	137	82	74	293
Asian Pacific Islander	15	1	0	16
African American	21	3	3	27
American Indian	21	16	14	51

Table 8. Tobacco Use (Y)

	Normal Pre-pregnant BMI	Overweight Pre-pregnant BMI	Obese Pre-pregnant BMI	Overall Sample
Yes	19	10	12	41

Significant differences were seen between the groups for years of education, $F(2,629) = 4.63, p = .01$; weight gain in pregnancy $F(2,647) = 3.44, p = .033$; and birth weight of the baby, $F(2,649) = 5.03, p < .01$. Subsequent Tukey tests for years of education revealed normal weight women had significantly more years of education (M 14.16) than obese women (M 13.29) and no other pairwise comparisons were significant. Subsequent Tukey tests for weight gain in pregnancy revealed that obese women gained significantly less weight (32.56 pounds) during pregnancy than normal weight women (36.42 pounds) and no other pairwise comparisons were significant. Subsequent Tukey tests for birth weight of the baby revealed that offspring of obese women were significantly heavier at birth, mean weight 3332.64 g compared to 3185.39 in normal weight women.

Specific Aims

Specific Aim 1

Aim 1. To determine if overweight or obese first time mothers retain more weight gained in pregnancy than first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years postpartum.

Analysis of variance was used to compare postpartum weight retention, defined as pre-pregnant weight – weight at specific time point (6 week, 6 month, 1 year or 2 year). Non-parametric tests were then run because the Levene’s test of homogeneity of variances was significant ($p < .01$). Kruskal-Wallis and Mann Whitney tests to determine significant differences between groups were completed. Means, SD and N for each group at each time point are presented in Table 9.

Table 9. Results of Specific Aim 1, Postpartum Weight Retention

Group at 6 week	PPWR in Normal Weight Group	PPWR in Overweight Group	PPWR in Obese Group	PPWR Overall Sample
Mean	6.56 kg	5.85 kg	2.59 kg	5.68 kg
SD	6.90	7.76	11.12	8.12
N	236	110	73	419
Group at 6 month	Normal weight	Overweight	Obese	Overall
Mean	4.78 kg	6.37 kg	5.27 kg	5.28 kg
SD	6.78	9.57	10.42	8.34
N	243	114	83	440
Group at 1 year	Normal weight	Overweight	Obese	Overall
Mean	2.92 kg	6.95 kg	3.46 kg	3.99 kg
SD	6.96	14.34	11.49	10.29
N	137	60	56	253
Group at 2 year	Normal weight	Overweight	Obese	Overall
Mean	5.03 kg	4.88 kg	1.01 kg	4.13
SD	8.91	9.62	12.26	9.94
N	83	33	32	148

In this study using a one-way ANOVA, significant differences were found between the groups for postpartum weight retention at the 6 week, $F(2, 416) = 6.87, p = .001$, and 1 year time periods, $F(2, 250) = 3.37, p = .04$. Subsequent Tukey tests for postpartum weight retention at 6 weeks revealed that obese women retained significantly less weight (mean 2.6 kg) than both normal weight women (mean 6.56 kg) and overweight women (mean 5.85). No significant difference for postpartum retention at 6 weeks was seen between normal and overweight women. Tukey tests for postpartum weight retention at 1 year revealed that overweight women retained more weight (mean 6.96 kg) at 1 year compared to normal weight women (mean 2.92 kg) and no other pairwise comparisons were significant. There were no significant differences seen between any of the groups at 6 months or 2 years.

Follow-up non-parametric testing using Kruskal-Wallis test revealed significant differences for postpartum weight retention at the 6 week, Chi square 8.421 (2), $p < .05$; 6 month time period, Chi square 7.328 (2), $p < .05$; and 1 year time period, Chi-Square 7.999 (2), $p < .05$. Subsequent Mann-Whitney tests for postpartum weight retention at 6 weeks revealed that obese women retained significantly less weight than both normal weight and overweight women. No significant difference was seen between normal and overweight women. Mann-Whitney tests at 6 months revealed that normal weight women retained significantly less than overweight women and no other significant differences were seen between groups at this time period. Mann-Whitney tests at the 1 year time point revealed that overweight women retained more weight (mean 6.96 kg) at 1 year compared to normal weight women (mean 2.92 kg) and no other pairwise comparisons were significant. There were no significant differences seen between any of the groups at 2 years.

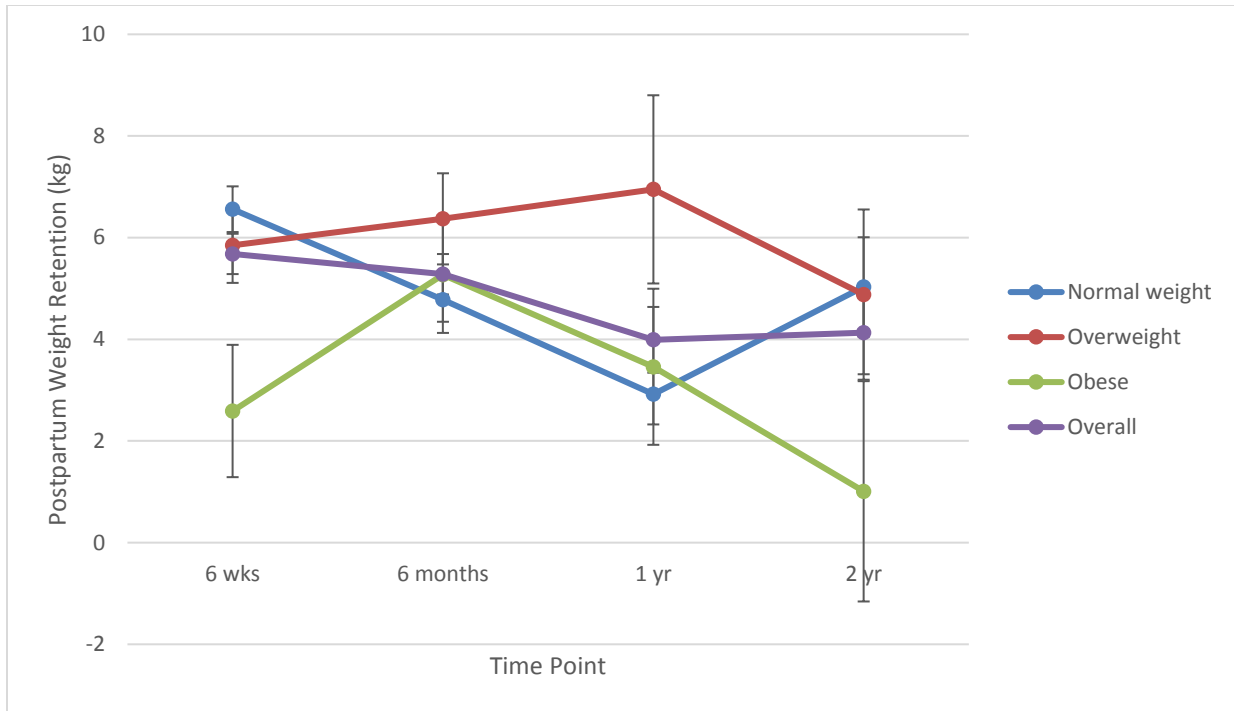


Figure 2. Postpartum Weight Retention at Four Time Points

Errors bars represent SEM (standard error of the mean).

Specific Aim 2

Aim 2. To determine if first time mothers who gain in excess of IOM guidelines during pregnancy retain more weight than women who gain within the IOM guidelines at 6 weeks, 6 months, 1 year and 2 years postpartum.

A 3 (pre-pregnancy BMI) x 2 (IOM guidelines) between subjects analysis of variance was conducted on the mothers weight retention separately at 6 weeks, 6 months, 1 year and 2 years. The means, SD and group size are presented in Table 10 for each of the analyses.

Table 10. Results for Specific Aim 2, Postpartum Weight Retention by Adherence to IOM Guidelines

Group at 6 week	PPWR in Normal Weight Group	PPWR in Overweight Group	PPWR in Obese Group
Gained within IOM guidelines, mean, (SD), N	4.42 kg (3.88) N = 98	0.20 kg (3.95) N = 29	-1.61 kg (3.23) N = 9

Gained in excess of IOM guidelines mean, (SD), N	10.27 kg (7.96) N=105	8.66 kg (7.5) N = 75	4.23 kg (11.94) N= 57
Group at 6 month	Normal Weight	Overweight	Obese
Gained within IOM guidelines mean, (SD), N	2.88 kg (5.55) N=96	1.41 kg (5.60) N =26	5.84 kg (6.59) N = 14
Gained in excess of IOM guidelines mean,)	8.70 kg (6.68) N = 103	8.28 kg (10.06) N=81	5.54 kg (11.43) N = 62
Group at 1 year	Normal Weight	Overweight	Obese
Gained within IOM guidelines mean, (SD) N	1.69 kg (6.08) N = 54	-0.14 kg (7.62) N = 16	3.07 kg (9.15) N = 10
Gained in excess of IOM guidelines mean, (SD) N	5.19 kg (8.16) N = 59	9.93 kg (15.63) N = 42	3.68 kg (12.38) N = 42
Group at 2 year	Normal Weight	Overweight	Obese
Gained within IOM guidelines mean, (SD) N	4.06 kg (6.45) N=34	3.21 kg (9.71) N = 9	-7.76 kg (17.31) N=2
Gained in excess of IOM guidelines mean, (SD) N	7.39 kg (10.94) N = 36	5.32 kg (10.13) N = 22	1.81 kg (12.90) N = 25

A significant main effect of pre-pregnant BMI, $F(2, 367) = 11.14, p < .01$, on postpartum weight retention was seen at six weeks. A subsequent Tukey analysis of this effect showed that women with a normal BMI retained significantly more weight than obese women (7.35 kg compared to 1.3 kg) and that overweight women retained significantly more weight than obese women (4.4 kg compared to 1.3 kg). No other pairwise comparisons were significant. A significant main effect of adherence to IOM weight gain guidelines on postpartum weight retention was also seen at 6 weeks, $F(1, 367) = 36.66, p < .01$. This effect indicated that women who gained within their IOM guidelines retained significantly less weight at 6 weeks (1 kg compared to 7.7 kg). At the 6-week time point there was an absence of interaction between pre-

pregnant BMI and weight gain within IOM guidelines, $F(2, 367) = .928, p = .39$. This absence of interaction indicates that the impact of pre-pregnancy BMI on postpartum weight retention was the same regardless of whether women gained within the IOM guidelines or not.

At the 6-month time point, a significant main effect was not seen for pre-pregnant BMI on postpartum weight retention, $F(2, 376) = .387, p = .68$. A significant main effect was seen for adherence to IOM guidelines and postpartum weight retention at 6 months, $F(1, 376) = 3.17, p < .05$. This effect indicated that women who gained within their IOM guideline retained significantly less weight at 6 months (mean 3.38 kg) compared to women who gained more than their guidelines (mean 7.5 kg). A significant interaction between pre-pregnancy BMI and adherence to IOM weight gain guidelines on postpartum weight retention at the 6 month time period was detected, $F(2, 376) = 3.17, p < .05$. The results of this Tukey-Kramer post hoc analysis indicate that pre-pregnant normal and overweight women who gained outside of their guidelines retained significantly more weight postpartum than normal and overweight women who gained within their guidelines. However, there was no significant difference in weight retention for obese women who gained outside of their guidelines compared to those obese women who gained within their guidelines. A further Tukey Kramer analysis of the simple effect of pre-pregnancy BMI at each level of adherence to IOM weight gain guidelines revealed no significant pairwise comparisons.

Analysis at the 1-year time point revealed no significant main effect for pre-pregnant BMI on postpartum weight retention, $F(2, 217) = .35, p = .71$. A significant main effect was seen for adherence to IOM guidelines and postpartum weight retention at 1 year, $F(1, 217) = 7.49, p < .01$. This effect indicated that women who gained within their IOM guideline retained significantly less weight at 1 year compared to those who gained in excess of their guideline (1.5

kg compared to 6.3 kg). At the 1-year time point there was an absence of interaction between pre-pregnant BMI and adherence to weight gain guidelines on postpartum weight retention, $F(2, 217) = 2.32, p = .10$.

Analysis at the 2-year time point revealed no significant main effect for pre-pregnant BMI on postpartum weight retention, $F(2, 122) = 2.46, p = .09$. No significant main effect was seen for adherence to IOM guidelines and postpartum weight retention at 2 years either, $F(1, 122) = 2.86, p = .09$. There was also an absence of interaction for pre-pregnancy BMI and adherence to IOM weight gain guidelines at the 2-year time point, $F(2, 122) = .387, p = .68$.

Non-parametric tests were then run because the Levene's test of homogeneity of variances was significant ($p < .01$). Kruskal-Wallis and Mann Whitney tests to determine significant differences between groups were completed. In an analysis between groups, follow-up non parametric testing revealed significant differences for weight gain in excess of the IOM guidelines at the 6 week time period only, Chi square 17.98 (2), $p < .01$. Subsequent Mann-Whitney tests for weight gain in excess of IOM guidelines revealed that normal weight women who gained in excess of their guideline retained significantly more weight than obese women who gained outside of their guideline; and overweight women who retained in excess of their guideline retained significantly more than obese women who gained in excess of their guideline. No other pairwise comparisons were significant.

In an analysis within groups, normal weight women who gained within their IOM guideline retained significantly less weight than normal weight women who gained in excess of the IOM guidelines at 6 weeks, $Z -8.561, p < .01$; 6 months, $Z -6.72, p < .01$ and 1 year time point, $Z -3.776, p < .01$. No difference was seen for normal weight women who gained within their guidelines and those who did not at 2 years. Overweight women who gained within the IOM

guidelines retained significantly less weight than overweight women who gained in excess of the IOM guideline at 6 weeks, $Z -6.316$, $p < .01$; 6 months, $Z -4.167$, $p < .01$; and 1 year time point, $Z -3.236$, $p < .01$. No difference was seen for overweight women who gained within their guideline and those who did not at 2 years. Obese women who gained within their IOM guideline retained significantly less weight at 6 weeks only, $Z -2.683$, $P < .05$. No significant differences were seen for postpartum weight retention for obese women who gained within their guidelines and those who did not at any other time point.

Specific Aim 3

Aim 3. To determine if the offspring of overweight/obese first time mothers have higher weight for length percentiles than the offspring of first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years of life.

Analysis of Variance was used to compare the means of offspring height/weight percentile at 6 weeks, 6 months, 1 year and 2 years for women with a normal BMI, overweight BMI and Obese BMI at the start of their pregnancy. Means, SD and N for each group at each time point are presented in Table 11.

Table 11. Offspring weight for length percentiles

Group at 6 weeks	Normal weight	Overweight	Obese
Mean (%)	33.12	30.78	37.64
SD	29.16	27.63	30.49
N	174	70	63
Group at 6 mo	Normal Weight	Overweight	Obese
Mean (%)	40.51	42.09	43.53
SD	31.64	30.56	31.58
N	170	66	58
Group at 1 year	Normal Weight	Overweight	Obese
Mean (%)	43.92	48.89	53.53
SD	31.24	33.38	28.59
N	157	63	56

Group at 2 year	Normal Weight	Overweight	Obese
Mean (%)	53.54	55.41	59.60
SD	33.81	33.43	32.20
N	142	54	48

The results of these analyses revealed no significant differences in the mean values for the groups at any time point: 6 week, $F(2, 304) = .96, p = .39$; 6 month, $F(2, 291) = .22, p = .81$; 1 year, $F(2, 273) = 2.10, p = .12$; 2 year, $F(2, 241) = .59, p = .55$. Non-parametric tests were also completed and also revealed no significant differences in the mean values for the groups at any time point: 6 week, chi-square 1.339 (2), $p = .51$; 6 month, chi-square .598 (2), $p = .74$; 1 year, chi-square 4.427 (2), $p = .11$; 2 year, chi square 1.365 (2), $p = .51$.

Specific Aim 4

Aim 4. To determine if the offspring of first time mothers who gain in excess of IOM guidelines during pregnancy have higher weight for length percentiles than the offspring first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years of life.

A 3 (pre-pregnancy BMI) x 2 (IOM Guidelines) 2-way between subjects ANOVA was conducted on offspring weight for length percentiles separately at 6 weeks, 6 months, 1 year and 2 years. The means, SD and group size are presented for each of the analyses in Table 12.

Table 12. Offspring weight for length percentiles by Adherence to IOM Guidelines

Group at 6 week	Normal Weight	Overweight	Obese
Gained within IOM guidelines, mean, (SD) N	33.59% (29.87) N = 64	35.59% (25.04) N = 14	30.54% (26.15) N = 12
Gained in excess of IOM guidelines mean, (SD), N	30.39% (28.29) N=83	30.69% (28.86) N = 48	39.13% (32.71) N= 44
Group at 6 month	Normal Weight	Overweight	Obese
Gained within IOM guidelines mean,	38.71% (30.49)	39.21% (27.08)	52.70% (35.45)

(SD) N	N=60	N =16	N = 9
Gained in excess of IOM guidelines mean, (SD) N	43.25% (33.31) N = 86	42.47% (30.22) N=45	44.51 (30.44) N = 43
Group at 1 year	Normal Weight	Overweight	Obese
Gained within IOM guidelines mean, (SD) N	39.42% (30.16) N = 59	39.88% (30.95) N = 16	56.03 kg (26.87) N = 10
Gained in excess of IOM guidelines mean, (SD) N	50.26% (31.80) N = 76	52.43% (34.15) N = 46	53.37% (29.03) N = 41
Group at 2 year	Normal Weight	Overweight	Obese
Gained within IOM guidelines mean, (SD) N	53.52% (28.76) N=56	50.48% (33.16) N = 16	42.19% (31.48) N=8
Gained in excess of IOM guidelines mean, (SD) N	54.01% (37.31) N = 65	58.69% (33.38) N = 37	63.05% (32.05) N = 36

Analysis at the 6 week time point revealed no significant main effect for pre-pregnant BMI on offspring weight for length percentiles, $F(2, 259) = .146, p = .86$. No significant main effect was seen for adherence to IOM guidelines and offspring weight for length percentiles either, $F(1, 259) = .001, p = .97$. There was also an absence of interaction for pre-pregnancy BMI and adherence to IOM weight gain guidelines on offspring weight for length percentiles at the 6-week time point, $F(2, 259) = .693, p = .50$.

Analysis at the 6-month time point revealed no significant main effect for pre-pregnant BMI on offspring weight for length percentiles, $F(2, 253) = .766, p = .46$. No significant main effect was seen for adherence to IOM guidelines and offspring weight for length percentiles either, $F(1, 253) = .001, p = .98$. There was also an absence of interaction for pre-pregnancy BMI and adherence to IOM weight gain guidelines on offspring weight for length percentiles at the 6-month time point, $F(2, 253) = .509, p = .60$.

At the 1-year time point, analysis of the data revealed no significant main effect for pre-pregnant BMI on offspring weight for length percentiles, $F(2, 242) = 1.29, p = .28$. No significant main effect was seen for adherence to IOM guidelines and offspring weight for length percentiles either, $F(1, 242) = .185, p = .18$. There was also an absence of interaction for pre-pregnancy BMI and adherence to IOM weight gain guidelines on offspring weight for length percentiles at the 1-year time point, $F(2, 242) = .694, p = .50$.

Analysis at the 2-year time point revealed no significant main effect for pre-pregnant BMI on offspring weight for length percentiles, $F(2, 212) = .029, p = .97$. No significant main effect was seen for adherence to IOM guidelines and offspring weight for length percentiles $F(1, 212) = 2.87, p = .09$. There was also an absence of interaction for pre-pregnancy BMI and adherence to IOM weight gain guidelines on offspring weight for length percentiles at the 2-year time point, $F(2, 212) = 1.08, p = .34$.

Non-parametric tests were also completed and also revealed no significant differences in the mean values between the BMI groups based on weight gain within guidelines or not for offspring weight for length percentiles at any time point: 6 week, chi-square 1.917 (2), $p = .38$; 6 month, chi-square .186, $p = .91$; 1 year, chi-square .341 (2), $p = .84$; 2 year, chi-square 1.65 (2), $p = .44$.

Analysis was also completed within each BMI group to test if offspring weight for length percentile was different based on weight gain within IOM Guidelines. A significant value was found for normal weight women only, and only at the 1-year time point ($Z 1.956, p = .05$). For all other women in all BMI groups there were no differences at any time point.

Summary

The normal weight, overweight and obese groups of women were similar for age, the weeks that they started prenatal care, the number of pre-natal visits that they received and by their offspring Apgar scores. Normal weight women had significantly more education than obese women. Obese women gained significantly less weight than normal weight women during pregnancy but had heavier offspring at birth.

For the question of overall postpartum weight retention differences between the groups were seen at 6 weeks, 6 months and 1 year. At 6 weeks obese women retained less weight than normal and overweight women. At 6 months normal weight women retained less than overweight women. At 1 year, overweight women retained more than normal weight women.

In analysis of the groups and their adherence to the IOM weight gain guidelines, at the 6 week, 6 month and 1 year time point normal weight and overweight women who gained within their IOM guideline retained less weight than those who did not. For obese women this was only seen at 6 weeks. At two years there were no differences in postpartum weight retention between those who gained within their guidelines and those who did not. In comparisons between those who over-gained among all BMI groups obese women retained significantly less than both normal and overweight women at 6 weeks and this was the only time point with a significant finding.

In this study, there were no significant differences in offspring weight for length percentile between the BMI groups at any time point. At 1 year only, normal weight women who gained within their guideline had offspring with significantly lower weight for length percentiles.

Further discussion of these results and their importance can be found in Chapter V.

CHAPTER V

DISCUSSION

The purpose of this study was to investigate the importance of body mass index and excessive gestational weight gain on postpartum weight retention and offspring weight out to 2 years in women having their first baby. The specific aims for this study were: 1) To determine if overweight or obese first time mothers retain more weight gained in pregnancy than first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years postpartum; 2) To determine if first time mothers who gain in excess of IOM guidelines during pregnancy retain more weight than women who gain within the IOM guidelines at 6 weeks, 6 months, 1 year and 2 years postpartum; 3) To determine if the offspring of overweight or obese first time mothers have higher weight for length percentiles than the offspring of first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years of life; and, 4) To determine if the offspring of first time mothers who gain in excess of IOM guidelines during pregnancy have higher weight for length percentiles than the offspring first time mothers who gain within the guidelines at 6 weeks, 6 months, 1 year and 2 years of life.

What follows are the specific findings for this study, a description of how these findings are similar and different than previous findings from other studies, a discussion of the limitations of this study and directions for future practice, education and research.

Specific Findings

In this study 652 women provided data. The mean age of participants was 25 years old, which compares to 26.3 years for the mean age of first time mothers in the U.S. (U.S.

Department of Health and Human Services, 2016). The mean level of education for participants in this study was 13.9 years overall. This is comparable to data available for the U.S. from 2013, which showed a mean of 13 years of education for women 25 years and older (United Nations Development Program, 2015). The mean pre-pregnant weight in pounds for participants overall was 150 pounds, which is somewhat less than the mean weight of women age 20-29 in the U.S. at 161.9 pounds (Fryar et al., 2012). The mean weight gain in this study was 35 pounds, which means that many women gained in excess of their guidelines. This is consistent with the existing literature (Gilmore et al., 2015). The mean birth weight for the offspring was 3228g, which is 7.1 pounds compared to 7.6 pounds for the average boy and girl combined birth weight in the U.S. (CDC, 2009).

Specific Aim 1

Specific Aim 1: To determine if overweight or obese first time mothers retain more weight gained in pregnancy than first time mothers of normal weight at 6 weeks, 6 months, 1 year and 2 years postpartum. Overweight women retained significantly more weight than normal weight women at the 6-month and 1-year time points. Overweight women retained significantly more weight than obese women at the 6-week time point. At 2 years there were no significant differences in postpartum retention for overweight women compared to normal weight or obese women. Obese women did not retain more weight postpartum compared to normal or overweight mothers at any time point. In fact, at the 6-week time point obese women retained significantly less weight than both normal and overweight women.

Specific Aim 2

Specific Aim 2: To determine if first time mothers who gain in excess of IOM guidelines during pregnancy retain more weight than women who gain within the IOM guidelines at 6 weeks, 6 months, 1 year and 2 years postpartum.

Women who gained within the IOM guidelines retained significantly less weight at 6 weeks, 6 months and 1 year postpartum within most BMI groups compared to those who gained in excess of the IOM guidelines. When the particular pre-pregnant BMI groups were considered individually, normal and overweight women who gained in excess of the guidelines retained significantly more weight than those in the same groups who gained within the guidelines. The obese group of women did not have significant differences in PPWR based on whether or not they gained within the IOM guidelines except at the 6-week time point. At the 2-year time point there was no difference between any of the groups whether women gained within the IOM guidelines or not.

Specific Aim 3

Specific Aim 3. To determine if the offspring of overweight or obese first time mothers have higher weight for length percentiles than the offspring of first time mothers of normal weight mothers at 6 weeks, 6 months, 1 year and 2 years of life.

There were not significant differences in weight for length percentiles between offspring of normal, overweight or obese women at any time point.

Specific Aim 4

Specific Aim 4. To determine if the offspring of first time mothers who gain in excess of IOM guidelines during pregnancy have higher weight for length percentiles than the offspring of

first time mothers who gain within the guidelines at 6 weeks, 6 months, 1 year and 2 years of life.

The offspring weight for length percentiles of normal weight women who gained in excess of the IOM guidelines were significantly more than for those offspring of normal weight women who gained within their IOM guideline at 1 year only. For all other offspring in all other maternal BMI groups there were no differences at any time point.

How these Specific Finding Compare to Previous Published Findings

BMI and Postpartum Weight Retention

Overall, this study demonstrated different findings with regards to pre-pregnant BMI and postpartum weight retention at every time point compared to previous studies. This study demonstrated significantly less postpartum weight retention for obese women at the 6-week time point compared to normal and overweight women. Gunderson et al. (2000) studied PPWR at this time point and showed no association between pre-pregnant BMI and PPWR in any weight categories. Kac et al. (2003) studied PPWR at 2 weeks and 2 months and found less retention overall in primiparous women but women with the highest body fat did have higher weight retention which is in direct contrast to the present study where obese women had significantly less postpartum weight retention at 6 weeks.

At 6 months lower PPWR for normal weight women compared to overweight women was demonstrated in this study. Huang et al. (2010) demonstrated very modest postpartum weight retention at this time point for normal weight women at 2.57 kg (5.7 lb) and overweight women 1.67 kg (3.7 lb) while obese women lost weight by this time point by 0.29 kg (0.64 lb). Nohr et al. (2008) also found that high BMI was related to increased PPWR at 6 months and 18 months but only in the setting of increased gestational weight gain.

In this study, only overweight women, not obese women, retained more weight than normal weight women at the 1-year time point. Many previous studies look at the 9-month to 1-year time point and the results are varied. Kac, Benicio, Velasquez-Melendez, and Valente (2004) in the study of PPWR in Brazil demonstrated that obese women had more PPWR at 9 months. Joseph et al. (2008) in a study with predominantly primiparous women found that pre-pregnant BMI was associated with PPWR at 1 year—as BMI increased so did PPWR. In the present study results were mixed. Women with BMIs categorized as normal or obese did not have significantly more postpartum weight retention, but overweight women did have significantly more postpartum weight retention compared to normal weight women only. One study demonstrated better outcomes for women with a BMI greater than 27 kg/m² (Rode, Kjaergaard, Ottesen, Damm, & Hegaard, 2012), which encompasses many women in the overweight BMI category and obese women. In the present study, obese women gained significantly less than the normal weight women, which is similar to the Rode et al. (2012) finding. They also retained significantly less weight at 6 weeks postpartum compared to both the normal and overweight women. Overweight women (BMI of 25-29.9 kg/m²) retained more than normal weight women at 1 year and this is dissimilar from the Rode study where women with a BMI of 27 kg/m² and greater retained less weight postpartum. Martin et al. (2014) found that while most women retained weight postpartum, there was no association between pre-pregnant BMI and PPWR. Ma et al. (2015) studied both the influence of BMI and gestational weight gain on PPWR at 11 months postpartum and found that BMI was negatively associated with postpartum weight retention.

This study found no differences between the different pre-pregnant BMI groups and PPWR at 2 years. This finding is in contrast to Nohr et al. (2008) who found that high BMI in setting of high gestational weight gain was associated with PPWR at 18 months.

As previously stated, overall the present study demonstrated different findings with regards to pre-pregnant BMI and postpartum weight retention. Obese women retained less weight at 6 weeks compared to normal and overweight women. In this study, obese women had statistically lower education levels than normal weight women ($p = .01$) but the mean number of years of education was 13.29 for obese women which may be better than obese women in other studies. One previous study that dealt primarily with primigravidas (Joseph et al., 2008) was a study focused on adolescents. The mean age in the present study was 25 years old and it's possible that adolescence may be a particularly difficult time for weight issues in general and for weight gain in pregnancy in particular. Lastly, only 148 women provided data at the 2-year time point and it is possible that this study is not powered enough to see differences in PPWR at this time point, or that because of loss to follow up, we missed important weight changes.

Gestational Weight Gain and Postpartum Weight Retention

Overall, this study demonstrated similar findings with regards to gestational weight gain and postpartum weight retention out to 1 year compared to previous studies in that those who gained outside of the guidelines tended to retain more postpartum. Lee et al. (2011) examined weight gain in pregnancy and following pregnancy at several time points: 2-3 weeks postpartum, 4-5 weeks postpartum, 11-12 weeks postpartum, and 24-25 weeks postpartum. The mean postpartum weight retention was 5.92 kg (± 3.35) (13 lb ± 7.4) at 5 weeks postpartum. This is similar to the overall mean postpartum weight retention at 6 weeks in the current study of 5.68 kg (± 8.12) (12.5 lb ± 17.9).

Amorim, Rossner, et al. (2007), Lee et al. (2011) and Haugen et al. (2014) all examined gestational weight gain and postpartum weight retention at 6 months postpartum. The mean PPWR at this time point was 1.3 kg, (+/-3.5) (2.9 lb +/- 7.7) (Amorin, et al) and 3.31 kg, (+/- 3.01) (7.3 lb +/-6.6) (Lee et al, 2011). Haugen et al. (2014) studied Norwegian women from 1999 – 2008 and differentiated between primiparous and multiparous women. Primiparous women had a mean PPWR at 6 months of 0 kg (+/- 3.7) (0 lb +/- 8.1). In the present study, the mean PPWR at the 6-month time period was higher than in previous studies. The mean overall postpartum weight retention at 6 months was 5.3 kg (+/- 8.34) (11.66 lb +/- 18.3) with the lowest mean for normal weight women at 4.8 kg (+/- 6.78) (10.6 lb +/- 15) and the highest retention for overweight weight women at 6.4 kg (+/-9.57) (14 lb +/- 21). Normal and overweight women who gained in excess of the IOM guidelines retained significantly more weight at this time period than those who gained within the guidelines.

Previous studies demonstrated that those who gained in excess of the IOM guidelines also retained more weight postpartum. Most of these examined long-term weight changes except one study that examined weights closer to 1 year (Kac, Benicio, Velasquez-Melendez, Valente, et al., 2004). These studies also categorized excessive weight gain by weight gain outside of IOM guidelines, similar to the present study. The present study demonstrated an overall PPWR of 3.9 kg (+/- 10.29) (8.6 lb +/- 22.6) at the 1-year time point with the mean for normal weight women at 2.9 kg (+/- 6.96) (6.4 lb +/- 15.3 lb), mean for overweight women at 6.9 kg (+/- 14.34) (15 lb +/- 31.5) and the mean for obese women at 3.5 kg (+/-11.49) (7.7 lb +/- 25.3). Those women who gained within the IOM guidelines retained significantly less weight at the 1-year postpartum time point.

Previous studies that looked at gestational weight gain and postpartum weight retention tend to focus on longer postpartum time periods, even out to 21 years. Of those that examined the intermediate time period, Haugen et al. (2014) showed that increased gestational weight gain increased the risk of PPWR by just 2 kg in all weight classes at 18 months postpartum. None of the previous studies examined 2 years postpartum specifically, and, as previously mentioned, at this time point the present study showed no significant difference in PPWR based on weight gain within the IOM guidelines or not. Of the previous studies examined that looked beyond 2 years postpartum, the range of time examined was 3 to 21 years. In the Amorim, Linne, and Lourenco (2007) study at the 15 year time point women who gained within the guidelines retained a mean of 6.7 kg (14.8 lb) while those who gained outside of the IOM guidelines retained 10 kg (22 lb). In the present study, the postpartum time periods were limited out to 2 years and at the 2-year time point there was no difference between the groups whether women gained within the IOM guidelines or not.

The present study demonstrated similar findings overall with regards to gestational weight gain and postpartum weight retention compared to previous studies. Primiparous women in the Haugen et al. study (2014) had a mean 6 month PPWR of 0 kg (+/- 3.7 kg). In the present study normal weight and overweight women who gained within their guideline retained significantly less weight at 6 months. However, the mean weight retention for those who gained within the guidelines for all BMI groups was still 3.38 kg (+/- 5.91 kg). This may reflect baseline differences in starting weights and weight variability between Norwegian women and women in Albuquerque.

BMI and Offspring Weight for Length Percentiles

In previous studies pre-pregnant maternal BMI has been associated with offspring birth weight with increased birth weight seen in overweight and obese mothers (Li et al., 2013; Stamnes Koepp et al., 2012). This was also seen in the present study but only for the offspring of obese women. Offspring of obese women had a mean weight of 3332.64 grams and offspring of normal weight women had a mean weight of 3185.39 grams and this difference was significant ($p < .01$). No other group comparisons for offspring weight were significant.

In the present study, there was no association between maternal pre-pregnant BMI and offspring weight for length percentiles at any time point measured beyond birth. Olson et al. (2009) in their observational study of 128 multiparous and 80 primiparous mother child pairs found an association between pre-pregnant BMI (overweight and obese combined) and offspring overweight at 3 years as defined by BMI at or above 85%. This study differs from the present study in the time of follow-up of 3 years compared to just 2 years in the present study and this may account for the different results.

Many of the previously examined studies considered variables other than maternal pre-pregnant BMI such as paternal factors and educational level of parents. Svensson et al. (2014) examined maternal and paternal BMI in relation to childhood weights at 3, 6 and 12 months and neither were associated with offspring weight. Parental education defined as less than 12 years of education for both parents was associated with excessive offspring weight. Durmus et al. (2013) assessed risk of overweight in children up to 4 years by examining both maternal and paternal BMI and found that both were associated with offspring BMI with the maternal BMI a stronger predictor of offspring BMI. Kivimaki et al. (2007) also studied maternal and paternal BMI in relation to offspring BMI in childhood through adulthood and found that maternal BMI

had no more influence than paternal BMI on offspring weights. The present study did not collect data on paternal factors. The present study did collect data on educational status and obese women had significantly less education than normal weight women. However there were no differences between offspring weight for length percentiles at any time point between any of the pre-pregnant BMI groups.

Gestational Weight Gain and Offspring Weight for Length Percentiles

In the present study, there was an association between gestational weight gain in normal weight women and offspring weight for length percentiles at 1 year only with women who gained in excess of the guidelines having higher weight for length percentiles in their offspring. No other associations between gestational weight gain and offspring weight for length percentiles was seen at any time point. The present study was limited to 2 years. Several previous studies demonstrate positive associations between maternal gestational weight gain and offspring weight. These studies looked at long time periods, 3-16 years, and also had the ability to examine multiple covariates such as smoking status, sleep habits, breastfeeding and paternal factors which this study did not do.

Li et al. (2013) studied offspring to 1 year and found that offspring overweight or obesity was associated with excessive maternal GWG as in the present study at this time point. This study took place in China and utilized record review for 38,539 women. The results of this study differ from the present study and the population in the Li et al. (2013) study differs significantly in pre-pregnancy BMI from the present study. The majority of women in the Li et al. (2013) study had a BMI of 23.99 or less (22,492 participants). Furthermore the Li et al. (2013) Li et al study utilized BMI categorizations that are not based on the IOM guidelines but rather on the standard Working Group on Obesity in China and the thresholds for overweight and obesity are

lower than IOM thresholds. Nonetheless these authors used the IOM categorization for determining adequate or excessive weight gain. This means that someone could have been categorized as gaining excessively for their BMI but not if IOM standards had been used for the pre-pregnancy BMI instead of the stricter Chinese standards.

Olson et al. (2009) compared women with normal pre-pregnant BMIs to women with BMIs considered overweight and obese (one grouping) and found no significant relationship between GWG offspring overweight. Grouping overweight and obese women together would limit the ability to see differences between these two groups. Olson et al. (2009) also examined offspring weights at 3 years, which is a longer time period than the present study, though both have negative findings with regards to the impact of GWG on offspring weight outcomes.

In contrast to the Olson et al. (2009) study are the Oken et al. (2007) and Deierlein et al. (2012) studies, which also examined GWG and offspring weights to 3 years. Both found that GWG was associated with higher offspring body mass index z-scores and weight for age, length for age and weight for length z-scores respectively.

Gillman et al. (2008) also examined gestational weight gain and offspring risk of overweight at 3 years with other risk factors including smoking in pregnancy, breastfeeding duration and daily sleep duration of the infant. This study examined covariates that were not available in the present study. Gestational weight gain alone accounted for only .08 predicted probability of overweight at 3 years.

Many other studies examine offspring weights well into adolescence (Kaar et al., 2014; Laitinen et al., 2012; Oken et al., 2008; Wrotniak et al., 2008). All of these studies found positive associations with gestational weight gain and offspring weights and in some cases, other offspring outcomes such as high-density lipoprotein cholesterol, visceral adipose tissue and

triglyceride levels (Kaar et al., 2014). All of these studies included women with normal and higher risk pregnancy profiles. The present study only examined weights out to two years and was limited to generally healthy, low risk women.

Limitations

This study was a secondary analysis and therefore while associations can be determined between variables, cause and effect relationships cannot be determined. Furthermore, in a secondary analysis the analysis of biases are limited to the data that were collected during the parent study. There are many potential biases including exercise patterns, patient pre-pregnancy dietary habits, sleeping habits and presence of depression, among other factors that were not collected. Also, in the parent study, not all women gave data at every time point.

One objective of this study is to analyze postpartum weight retention out to 2 years postpartum. Some women became pregnant again during this time and were not followed to 2 years postpartum because of this. The participants in this study were young and generally healthy, without co-morbidities that would exclude them from nurse-midwifery care and the study findings, particularly for overweight and obese women, may not be generalizable to other overweight and obese women with co-morbidities.

This study took place in Albuquerque, New Mexico, a majority minority state. This study had 293 women who identified as Hispanic and 263 women who identified as Non-Hispanic White. All other ethnicities combined only equaled 84 participants. This demographic make-up is particular to this region and the results may not be generalizable to other populations.

Several unknown variables could influence both pre-pregnant weight and postpartum weight retention. Education was used as a proxy for socio-economic status. However this study took place at the flagship university in the state; it is possible that participants had high levels of

education but still had lower incomes and therefore this proxy may not be useful. Low socioeconomic status can impact weight because it impacts the ability to buy high quality food and have access to leisure time. These data were not directly collected and it is therefore unknown if it influenced weights in the study participants. Other study variables that were not collected include information on exercise and nutrition habits among the study participants. Postpartum weights could also be influenced by breastfeeding status and possibly by birth control choices. These data were not consistently collected and therefore not analyzed. The breastfeeding data in the parent study was collected at the 6-month time point and was charted inconsistently at the other time points. The birth control data was available in a way that did not differentiate between hormonal and non-hormonal methods, which would be most useful in thinking about weight gain.

Although it is standard of care to educate women on appropriate weight gain during pregnancy based on pre-pregnant BMI, it is unknown to what degree this was done by individual providers in the current study.

Offspring weights for lengths after birth were not collected for the parent study, and it was assumed that adequate numbers of offspring would have data in the medical record. This was not the case. A low of 244 total offspring weights at 2 years and a high of 307 total offspring weights were available at 6 weeks. This left fewer than 75 offspring data points available for analysis in the overweight and obese groups and this may have affected overall study power.

This study includes subjects who were free of medical complications and the findings are limited to low risk healthy women giving birth. While these data are not applicable to high risk

populations, the majority of women who give birth in the U.S. are low risk and this study fills an important gap in the literature.

Implications

Future Practice

Based on the findings of this study, women having their first baby could be informed that their ability to limit weight gain to within the IOM guidelines may help them to decrease the amount of weight they retain in the postpartum period. For obese women, differences in mean PPWR were only impacted by gaining within their IOM guideline at 6 weeks. There were no difference between mean PPWR at any other time point in this group of women whether they gained inside of their guideline or not. That being said, there are many reasons other than weight retention or offspring weights to strive for a healthy lifestyle and women should receive information on ideal weight gain during pregnancy. Providers should continue to teach healthy weight gain guidelines, good eating habits and sleep hygiene and appropriate exercise for women during pregnancy. Some women may need help creating appropriate goals and education and support to achieve their goals.

Nursing Education

In this study, obese women having their first baby had lower weight gain in pregnancy and PPWR at 6 weeks than their normal and overweight counterparts. These findings are encouraging but they do not negate the overall health risks of overweight and obesity. Nursing education should continue to focus on health promotion and evidenced based practice.

Nursing Research

It is unclear how much control women have over weight gain during pregnancy. The SDs observed in this study suggests that weight gain in pregnancy was highly variable. It is

unknown if the variability observed was because there was little effort to gain within the guidelines—that is, guideline adherence was seen as relatively unimportant—or if women were trying to stay in the guidelines and really were inconsistent in their ability to do so. Some women may be unaware of the guidelines and without any effort they gain appropriately, whereas other women may be very aware of the guidelines and are seemingly helpless to control either weight gain or loss. It is unknown if education on guidelines alone translates into an ability to gain appropriately. More information is needed on which groups of women might benefit most with dietary and activity counseling. Additionally, more research on optimal prenatal delivery of weight gain guidelines education and support for weight issues in pregnancy is needed.

This study focused on the primipara's experience of postpartum weight retention and offspring outcomes. Previous research has often combined primiparous and multiparous participants. In the future it might be beneficial to examine just multiparous women and their experience with PPWR and offspring weight outcomes.

Much of the previous research on weight gain in pregnancy focuses on pregnancy as a pathway to obesity. This study demonstrated mean PPWR at 1 year of 3.99 kg (8.8 pounds) overall, 2.92 kg (6.4 pounds) for normal weight women, 6.95 kg (15.3 pounds) for overweight women and 3.46 kg (7.6 pounds) for obese women. These weight changes in the case of normal and obese women are quite modest, and it might be reasonable to question whether a return to pre-pregnancy weight is critical for good health.

At the one-year mark in this study, overweight women had a mean PPWR of 15.3 pounds. How this might impact hypertension rates and glucose control in this group would be worth exploring. Furthermore, this is often a time when families are considering expanding

again. Research into pregnancy timing and rates of overweight and obesity in women who return to postpartum weight before the second pregnancy would be beneficial for women and their providers.

Recently an online calculator has been introduced where rather than a range of weight gain, a specific calorie goal recommendation is made for each trimester based on the input values for height and pre-pregnant weight guidelines (Gilmore et al., 2015). Many people use online tools and applications to help manage weight outside of pregnancy. Research on these types of tools during pregnancy is emerging and is needed to see if they can help women gain appropriately.

In this study, there was no association between maternal BMI and offspring weight for length percentiles. There was a difference seen in offspring outcomes based on mother's ability to gain within the guidelines for normal weight women only and at 1 year only. The mean weight for length percentile for normal weight women who gained within their guideline was 39.42% (N 59) and for those who gained in excess of the guidelines it was 50.26% (N 76). This finding was not seen at any other time point or for any other BMI group. This finding could be error as significance was at exactly $p = .05$. This outcome may be a function of a comparatively healthy cohort of mothers or it could be that the timeframe of study was not long enough to see offspring outcomes. It is also noted that the study may have been underpowered to look at differences between the BMI groups. The developmental model for origins of disease posits that a critical event during development may have long term consequences for the offspring, but the magnitude or timing or mediating factors necessary in these events are not yet known. More research on the genesis of offspring overweight and obesity is needed.

Summary

Overweight and obesity remain significant and costly public health problems generally but their impact on postpartum weight retention and on development of longer term obesity in young healthy women having their first baby may be modest. This study demonstrated that for young, healthy women having their first baby obese women retained significantly less weight at 6 weeks compared to normal and overweight women. At 6 months normal weight women retained less than overweight women. At 1 year normal weight women retained significantly less than overweight women. At 2 years the amount of weight retained was modest for all groups and there were no significant differences in postpartum weight retention between the groups.

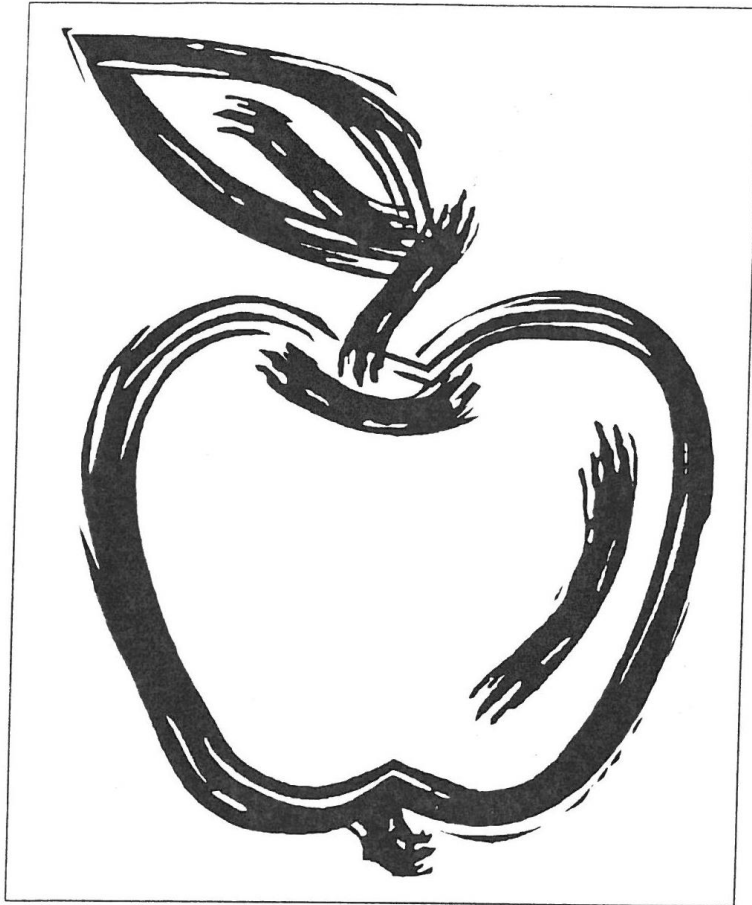
Women who gained within the weight gain guidelines tended to retain less weight than those who did not. However, for obese women at all time points except at 6 weeks postpartum there were no significant differences in PPWR observed within the BMI groupings for those who gained within the guidelines and those who gained in excess of the guidelines.

There was no difference observed in offspring outcomes beyond birth based on pre-pregnant BMI. Offspring weight for length percentile was lower for offspring of normal weight women who gained in their guidelines. Offspring of obese women were heavier at birth but the difference was minimal and likely inconsequential.

Pregnancy is a time when women have multiple interactions with health care providers and discussions about health promotion can occur. The long-term risks of overweight and obesity are associated with many chronic health problems outside of pregnancy including type II diabetes, cardiovascular disease, musculoskeletal problems and cancer. Healthy weights and lifestyle are worthwhile goals to pursue in all times of life to mitigate these risks. Pregnancy and

the postpartum period are especially important times to intervene and improve on healthy weight and lifestyle choices because as caregivers women can set the standards in their families for healthy behaviors.

APPENDICES
APPLE Consent



PLEASE DO NOT REMOVE

Appendix B
UNM IRB Approval

The University of New Mexico Health Sciences Center
Consent to Participate in Research

UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER
CONSENT TO PARTICIPATE IN RESEARCH
APPLE: ALTERATIONS IN THE PELVIC FLOOR IN PREGNANCY, LABOR
AND THE ENSUING YEARS

Introduction

You are being asked to participate in a research study that is being done by Rebecca Rogers, MD, who is the Principal Investigator and her associates, from the Departments of Obstetrics and Gynecology and Family and Community Medicine, and the Nurse-Midwifery Division. This research is studying the potential effects of childbirth on pelvic floor anatomy and function after childbirth. Childbirth may result in temporary or permanent changes in a woman's sexual activity, bladder and bowel control (incontinence). Perineal (the area between the vagina and rectum) pain and vaginal anatomy will also be assessed. This study is being done because we have limited information about the potential effect of childbirth on these functions and changes in anatomy. The National Institutes of Health is supporting this research.

You are being asked to participate in this study because you are pregnant and will be having your baby at UNM hospital with the midwives. 765 women will take part in this study.

This form will explain the research study, and will also explain the possible risks as well as the possible benefits to you. We encourage you to ask questions and talk with your family and friends before you decide to take part in this research study. If you have any immediate questions, please ask one of the study investigators.

What will happen if I decide to participate?

If you agree to participate, the following things will happen:

At your prenatal visit you will be asked to complete this consent form. You will be given a consent form for your own records. During your physical exam for your pregnancy, you will be asked to perform a pelvic floor exercise (a vaginal muscle strengthening exercise) and your midwife will take measurements of the vagina and perform a rectal exam. You will be given a questionnaire to complete regarding your bladder, bowel and sexual function and vaginal symptoms as well as perineal pain. Questions like "Do you leak urine" and "How have your activities been affected by urinary leakage?" will be asked. You will be asked to complete questions one more time late in the pregnancy (after 34 weeks). The questionnaires will take less than 20 minutes to complete.

____ Initials

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OFFICIAL USE ONLY

EXPIRES: 7/5/09

The University of New Mexico Human Research Review Committee

After delivery, your midwife will inspect the vagina and surrounding area for any tears. These will be recorded as well as information about your delivery. Your medical record will be reviewed and your age, race, and information about your care and pregnancy will be recorded. During the pushing phase of labor, your midwife will take some measurements of your perineum and changes that occur with fetal descent. Your baby's head circumference and length is recorded at birth in the medical record. The study will obtain this data. In the first few days after your birth, you will be asked two questions regarding pain in or around your perineum that will take less than 5 minutes to complete.

At your routine six-week postpartum visit your midwife will ask you to perform a pelvic floor exercise (a vaginal muscle strengthening exercise) and take measurements of the vagina and perform a rectal exam. You will be given a questionnaire to complete regarding your bladder function, bowel function and postpartum pain. Questions like "How have your activities been affected by urinary leakage?" will be asked again. The questionnaires will take less than 20 minutes to complete.

Three to five months after your delivery you will be called by a research nurse to schedule an appointment for six months after your delivery. At six months after childbirth you will have an exam with a midwife. At this visit the midwife will ask you to perform a pelvic floor exercise (a vaginal muscle strengthening exercise) and take measurements of the vagina and perform a rectal exam. You will be given a questionnaire to complete regarding your bladder function, bowel function, postpartum pain and sexual function. Questions like "How have your activities been affected by urinary leakage?" and "Since the birth of my baby I derive satisfaction from our sexual activities..." will be asked. The questionnaire will take less than 30 minutes to complete. At this visit you will also have a "paper towel test" where the midwife places a paper towel on your perineum while you cough. You will have an ultrasound examination to evaluate the anal sphincters and muscles of the pelvic floor. The ultrasound transducer is the size and shape of your index finger. To obtain these measurements the transducer is briefly placed near the opening of your vagina (on the outside) and then inside your rectum. The entire visit will take approximately 20 minutes to perform.

At your annual exam one year after your delivery, your midwife will again make vaginal measurements when she performs your pap smear and will ask you to perform a pelvic floor exercise. She will also perform a rectal exam. You will be asked to complete questions regarding your level of pain, level of sexual activity and your bowel and bladder function. These questions will take less than 30 minutes to answer. You may refuse to answer any questions at any time.

At two years after your delivery you will be contacted by telephone to complete questions regarding your level of pain, level of sexual activity and your bowel and bladder function. These questions will take less than 30 minutes to answer. You may refuse to answer any questions at any time.

If you are unable to come to any of the visits, a research assistant will call you to complete the questionnaires by telephone or to see if you would prefer to do this by mail. These questions will take less than 30 minutes to answer. You may refuse to answer any questions at any time.

Questionnaires and information collected as part of this study will be stored in a locked file cabinet in the Department of Obstetrics and Gynecology until it is entered into a computer database. Only Dr. Rogers and her immediate research team will have access to this information. Data will be stored for a period of 5 (five) years after completion of the study and then destroyed.

____ Initials

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HRR#: 04-344

Version: 3/17/08

OFFICIAL USE ONLY

APPROVED: 06/06/08

EXPIRES: 7/5/09

The University of New Mexico Human Research Review Committee

How long will I be in this study?

Participation in this study will take a total of approximately four hours over a period of 2 years.

What are the risks or side effects of being in this study?

- There is the risk of discomfort with the pelvic or rectal exam. You may have some mild discomfort with the ultrasound examination.
- There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality.

For more information about risks and side effects, ask your midwife.

What are the benefits to being in this study?

There may or may not be benefit to you from participating in this study. However, it is hoped that the information gained from this study will help in the treatment of future patients. Benefits include the opportunity to talk about potentially embarrassing conditions that may result from childbirth.

What other choices do I have if I do not want to be in this study?

The alternative to participation is to not participate.

How will my information be kept confidential?

We will take measures to protect your privacy and the security of all your personal information, but we cannot guarantee confidentiality of all study data.

Information contained in your study records is used by study staff and, in some cases it will be shared with the sponsor of the study. The University of New Mexico Health Sciences Center Human Research Review Committee (HRRC) that oversees human subject research, and the National Institutes of Health will be permitted to access your records. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

Information collected as part of the study will be labeled with your name and medical record number and kept in a secure locked file. This information will then be entered in a database which will contain only your study number; personal health information (without your name) will be entered into a computer database in the Department of Obstetrics and Gynecology. Rebecca Rogers, MD and her associates will have access to your study information. Data will be stored for 5 (five) years after completion of the study, and then will be destroyed.

____ Initials

Page 3 of 6

HRRC#: 04-344
Version: 3/17/08

OFFICIAL USE ONLY	
APPROVED: 06/06/08	EXPIRES: 7/5/09
The University of New Mexico Human Research Review Committee	

What are the costs of taking part in this study?

You will not be billed for the cost of any procedures directly associated with this study. However, you or your third-party payer (e.g. insurance company) is responsible for all other costs related to your childbirth.

What will happen if I am injured or become sick because I took part in this study?

No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study. If you are injured or become sick as a result of this study, UNMHSC will provide you with emergency treatment, at your cost. It is important for you to tell the study investigators immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the University of New Mexico Health Sciences Center, Albuquerque, New Mexico 87131, (505) 272-1129 for more information.

Will I be paid for taking part in this study?

In return for your time and the inconvenience of participating in this study, you will be paid for your visits, after your baby is born, as follows: \$50 for specific clinic visits (3 visits at \$50 each visit) and an additional \$25 for the ultrasound appointment. The specific clinic visits are at 6-10 weeks after childbirth, 6 months after birth, and 1 year after birth. If you do not complete the study, you will only be paid \$50 for the clinic visit or \$25 for the ultrasound that you complete. The last page of this consent will ask for your full name, social security number, date of birth, ethnicity, mailing address, phone number, and email address. This is for the purpose of contacting you and issuing you a UNM number in order to reimburse you for your participation. It will take approximately eight weeks to receive your check. Your check will be mailed to the mailing address you provide us with. You will also be asked to sign some additional forms at each visit reflecting your participation, the amount that you will be receiving, and what you've been paid to date. The total amount for participation in the entire study is \$175.

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?

Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled.

____ Initials

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HRRC#: 04-344
Version: 3/17/08

APPROVED: 06/06/08

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EXPIRES: 7/5/09

The University of New Mexico Human Research Review Committee

Who can I call with questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, Rebecca Rogers, MD or her associates will be glad to answer them at 505-272-9712 during 8am to 5pm weekdays. If you would like to speak with someone other than the research team, you may call the UNMHSC HRRC at (505) 272-1129.

Who can I call with questions about my rights as a research subject?

If you have questions regarding your rights as a research subject, you may call the UNMHSC HRRC at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human subjects. For more information, you may also access the HRRC website at <http://hsc.unm.edu/som/research/hrrc/>.

Consent

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this consent form, you are not waiving any of your legal rights as a research subject.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate or let my child participate in this study. A copy of this consent form will be provided to you.

Name of Adult Subject (type or print) Signature of Adult Subject / Date

I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

Name of Investigator/
Research Team Member Signature of Investigator/
Research Team Member / Date

____ Initials

APPROVED: 06/06/08 OFFICIAL USE ONLY EXPIRES: 7/5/09
The University of New Mexico Human Research Review Committee

**UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER
HIPAA¹ AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES**

Title of Study: APPLE: ALTERATIONS IN THE PELVIC FLOOR IN PREGNANCY, LABOR AND THE ENSUING YEARS

Principal Investigator: Rebecca Rogers, MD
UNMHSC Department: Obstetrics and Gynecology
Mailing Address: Department of OB-GYN
MSC10 5580
1 University of New Mexico
Albuquerque, NM 87131-0001

Co-Investigators: Leah Albers, Marianne Berwick, Rebecca Hall, Lawrence Leeman, and Regina Manocchio

Sponsor: National Institutes of Health

1. **What is the purpose of this form?** You have been asked to take part in a research study. The consent form for this study describes your participation, and that information still applies. This extra form is required by the federal Health Insurance Portability and Accountability Act (HIPAA). The purpose of this form is to get your permission (authorization) to use health information about you that is created by or used in connection with this research.
2. **What if I don't want my personal health information (PHI) to be used in this research study?** You do not have to give this permission. Your decision not to sign this form will not change your ability to get health care outside of this research study. However, if you do not sign, then you will not be allowed to participate in the study.
3. **What PHI am I allowing to be used for this research?** We will take measures to protect your privacy and the security of all your personal information, but we cannot guarantee confidentiality of all study data. Information contained in your study records will be used by staff and, in some cases it will be shared with the sponsor of the study (NIH) and UNM Health Sciences Center Human Research Review Committee (HRRC). There may be times when we are required by law to share your information; however, your name will not be used in any published reports about this study.

Information collected as part of the study will be labeled with your initials and a study number and information (without your name) will be entered into a computer database and locked in a file cabinet located in the Department of Obstetrics and Gynecology. Data will be stored for 5 years after completion of the study and then will be destroyed.
4. **Where will researchers go to find my PHI?** We may ask to see your personal information in records at hospitals, clinics or doctor's offices where you may have received care in the past, including but not limited to facilities in the UNM health care system.
5. **Who will be allowed to use my information for this research and why?** The researchers named above and their staff will be allowed to see and use your health information for this research study. It may be used to check on your progress during the study, or analyze it along with information from other study participants. Sometimes research information is shared with collaborators or other institutions. Your records may also be reviewed by representatives of the research sponsor or funding agency, the Food and Drug Administration

¹ HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

DEMOGRAPHICS:

NAME (Please Print) _____
(First) *(MI)* *(Last)*

SS# _____ DOB: _____ ETHNICITY (Circle One):

- African American
- Asian
- Hispanic
- Native American
- White (non-Hispanic)

MAILING ADDRESS: _____

CITY: _____ STATE: _____ ZIP: _____

HOMEPHONE# _____ 2ND PHONE: _____ CELL# _____

EMAIL ADDRESS: _____

NOTE: This form will be used to enter your information into our database and for processing and mailing your payment.

This form will be discarded when the study is over.

For official use only:
Date entered into database: _____
By: _____
Date entered into Banner: _____
By: _____

____ Initials

Page 6 of 6

HRRC#: 04-344
Version: 03/17/08

APPROVED: 06/06/08 OFFICIAL USE ONLY EXPIRES: 07/05/09
The University of New Mexico Human Research Review Committee



Human Research Review Committee
Human Research Protections Office

August 7, 2014

Rebecca Rogers
RRogers@salud.unm.edu

Dear Dr. Rogers:

On 8/4/2014, the HRRC reviewed the following submission:

Type of Review: Modification
Title of Study: APPLE: Alterations in the Pelvic Floor in Pregnancy, Labor and the
Ensnuing Years
Investigator: Rebecca Rogers
Study ID: 04-344
Funding: Name: HHS / National Institutes of Health (NIH), Funding Source
ID: HHS / National Institutes of Health (NIH)
Grant ID: None
IND, IDE, or HDE: None

Submission Summary: Modification submitted on 7/9/2014 to revise protocol and add
investigator Kelly Gallagher

Documents Reviewed: • Protocol v07/08/2014
Acknowledgment of
• Conflict of Interest documents and Human Subject Protection
training for added investigator.

Review Category: Expedited: Categories (8)(a) Long-term follow-up and (8)(c) Data
analysis

Determinations/Waivers: Children: Subpart D 45CFR46.404
Pregnant Women: Subpart B 45CFR46.204
Requires a signed consent form
HIPAA Authorization on record; signed HIPAA required
Study is closed to enrollment - no consents approved.

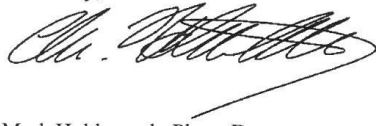
The HRRC approved the study from 8/4/2014 to 7/1/2015 inclusive. Before 7/1/2015 or
within 30 days of study closure, whichever is earlier, you are to submit a continuing review
with required explanations. You can submit a continuing review by navigating to the active
study and clicking Create Modification / CR.

If continuing review approval is not granted before the expiration date of 7/1/2015,
approval of this study expires on that date.

This determination applies only to the activities described in the submission and does not apply should any changes be made to these documents. If changes are being considered and there are questions about whether HRRC review is needed, please submit a study modification to the HRRC for a determination. A change in the research may disqualify this research from the current review category. You can create a modification by clicking Create Modification / CR within the study.

In conducting this study, you are required to follow the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library.

Sincerely,



Mark Holdsworth, PharmD
Executive Chair



Date: Wednesday, April 5, 2017 1:46:24 PM

Print Close

View: SF: Modification Information

Modification Information

1. Study enrollment status:

Study is permanently closed to enrollment

2. Notification of subjects: (check all that apply)

There are no items to display

Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.

3. * Summarize the modifications:

We are modifying our protocol (in track changes) to include collection of weights of mothers and their children in our study. This data will be collected from medical chart reviews, if available. We have already been approved to contact women and collect longer-term follow-up, which includes weight. Our goal is to investigate the impact of maternal weight gain patterns on their children.

We are also adding an investigator, Kelly Gallagher.

Appendix C
UND IRB Approval



UND.edu

Institutional Review Board
Twamley Hall, Room 106
264 Centennial Dr Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.6708
Email: UND.ibr@research.UND.edu

December 1, 2016

Kelly Gallagher
1108 Quincy Street NE
Albuquerque, NM 87110

Dear Ms. Gallagher:

RE: Review of Project Entitled "Postpartum Weight Retention in First Time Mothers and Weight Outcomes in their Offspring" (IRB-201602-272)

In order for Institutional Review Board (IRB) approval of the above-named project to be continued, the project must be reviewed at least annually. Please fill out the enclosed form and submit it to the IRB (Twamley Hall, Room 106, Campus Stop 7134). This form must be completed and returned to the IRB office before December 31, 2016 in order for IRB approval to be continued. A review is required even if the project has been completed.

Please contact Steffanie Brewer, the IRB Administrative Secretary, at (701) 777-4279 if you have any questions.

Sincerely,

Michelle L. Bowles, M.P.A., CIP
Institutional Review Board Coordinator

MLB/sb

Enclosure: Research Project Review and Progress Report Form



Research Project Review and Progress Report
University of North Dakota Institutional Review Board



DATE: 12/1/2016 DEPARTMENT: Nursing
 PRINCIPAL INVESTIGATOR: Gallagher, Kelly
 PROJECT TITLE: Postpartum Weight Retention in First Time Mothers and Weight Outcomes in their Offspring
 PROPOSAL NUMBER: IRB-201602-272
 IF MEDICAL COMPONENT, PLEASE GIVE PHYSICIAN'S NAME: _____

IRB USE ONLY	
<input type="checkbox"/>	FULL BOARD REVIEW REQUIRED, EVEN THOUGH ORIGINAL APPROVAL WAS EXPEDITED
<input checked="" type="checkbox"/>	CONTINUED APPROVAL, "EXPEDITED" CATEGORY <u># 5</u>
<input type="checkbox"/>	NEXT REVIEW REQUIRED BEFORE: <u>JAN 4 2018</u>
<input type="checkbox"/>	CONTINUED APPROVAL, BASED ON FULL BOARD REVIEW
<input type="checkbox"/>	NEXT REVIEW REQUIRED BEFORE: _____
<input type="checkbox"/>	SUSPEND APPROVAL, PENDING INVESTIGATION
<input type="checkbox"/>	APPROVAL TERMINATED
COMMENTS OF REVIEWER: <u>Grant received 4/20/16 (see attached)</u>	
Signature of Chair/Vice Chair or Designee: <u>[Signature]</u>	
cc: Jody Ralph, Ph.D.	Approval Date: <u>1/5/17</u>

1. Is project complete? Yes No
2. Is project ongoing? Yes No
If No, explain below and indicate if continued approval and continuing review is desired.
3. How many subjects have been enrolled in the research project?
_____ since the date of last approval, and _____ since the initial approval
NA -> Secondary analysis of data
4. Is the research permanently closed to the enrollment of new subjects? Yes No
Have all subjects completed all research-related interventions? Yes No
Does the research remain active only for long-term follow-up of subjects? Yes No
5. Is data analysis complete? Yes No

*** If the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, the research does not need to remain active for long-term follow-up of subjects, and all data analysis is complete, please sign here that you would like the IRB to terminate approval for this project, and finish filling out the rest of this form.

Please terminate IRB approval for this research project [Signature] _____ Date _____
 Signature of Principal Investigator enorty

not complete

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